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Outcome Study of Physical Therapy Rehabilitation of Patients with Patellar Femoral Dysfunction

Scott Hurd

University of North Dakota

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OUTCOME STUDY OF PHYSICAL THERAPY REHABILITATION OF PATIENTS WITH PATELLAR FEMORAL DYSFUNCTION

by

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An Independent Study
Submitted to the Graduate Faculty of the Department of Physical Therapy School of Medicine University of North Dakota in partial fulfillment of the requirements for the degree of Master of Physical Therapy

Grand Forks, North Dakota
May
2000
This Independent Study, submitted by Scot Hurd in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
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Title         Outcome Study of Physical Therapy Rehabilitation of Patients With Patellar Femoral Dysfunction

Department    Physical Therapy

Degree        Master of Physical Therapy

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ABSTRACT
This study was conducted to assist St. Alexius Medical Center's Institute of Sports Medicine in the analysis of physical therapy outcomes for patients who underwent patellofemoral surgical procedures including lateral retinacular release, vastus medialis oblique advancement, and tibial tubercle transfers. A review of data collected by the physical therapists at St. Alexius was performed and statistically analyzed to determine the efficacy of outcomes both clinically and functionally. This outcome analysis will assist current and future practice patterns by providing a basis for clinical effectiveness. The results of this study will be a useful resource for the facility as a guide to insure quality improvement and as a tool for quantifying treatment to third party payers.

Overall, satisfactory outcomes, as determined by predetermined goals, were obtained by all patients for all areas of rehabilitation. On average, knee range of motion was functional and within protocol goals with no differences noted secondary to surgical procedure or patient's age. Pain was kept to a minimum and was found to have no correlation with the age of the patient or return of strength. Joint effusion was also within the protocol goals and showed no correlation with achieved range of motion. Functional assessment demonstrated satisfactory results, overall, with transfers, ambulation, and activities of daily living.
CHAPTER I
INTRODUCTION AND LITERATURE REVIEW

**Education and change cost money, ignorance and complacency cost more -- Anonymous**

Physical therapists are individuals who have chosen their profession to help the sick and disabled regain their highest level of function possible. Clinicians have seen many changes in recent years including technological advances, new disease treatments, and improved rehabilitative techniques to aid in the care of patients. In contrast, there are fewer employment opportunities, increased workloads, and an increased reluctance towards reimbursement of services by third party payers. ¹ The quote written above clearly states what health-care providers are facing in a new era of patient care. These changes appear to exemplify what is right with our profession along with what is wrong with it.² As we move forward to increase the level of care for our patients, there is a growing concern that we seem to be moving backward in our ability to care for our profession.

As with all areas of the health care community, physical therapists are finding they are forced to compete for the shrinking dollar. Physical therapists are finding themselves engulfed by indirect patient care matters of cost containment, budgeting, and the growing concerns of reimbursement. Rothstein²
believes that these "new issues" with which physical therapists deal daily are the result of a health care industry which has ignored a ticking time bomb. Double-digit health care inflation of the 1980s and early 1990s forced businesses and government to seek a cure to solve the growing problem of seemingly endless healthcare inflation.³ It was these big spending buyers of health care benefits who turned to the systematic approach of managed care.

Managed care is a general term for organizing doctors, hospitals, and other providers into groups to enhance the quality and cost-effectiveness of health care.⁴ Managed care has also been described as a comprehensive approach to health care to include planning, education, and cost control of patient care. Traditional fee-for-service health insurance companies have, in some instances, begun to employ many of the characteristics of the managed care system. The new owner-managed care systems are now in control of decisions once left up to the patient and clinician.³ This transformation of responsibility has raised many questions regarding the quality of care that customers, patients, are receiving.

Supporters of managed care contend that managed care provides higher quality care by coordinating each patient's individual care package, promoting preventative medicine, and continuing to monitor and demand quality. Many believe that clinicians previously billed for unnecessary or lengthy treatments and managed care has limited this practice.³⁵ Meanwhile, critics of managed care contend that managed care is ruining what is considered as "American health care." Critics claim managed care is merely a bureaucracy that eliminates the
freedom patients once controlled.\textsuperscript{6} More seriously, doubters also claim that managed care has forced clinicians to place cost cutting ahead of patient care.

Each of these groups, according to Trueman,\textsuperscript{7} are correct in their observations to a certain degree. One undermining point is that no two managed care plans are alike. Some systems are large corporate industries, most for profit, while others are owned by small community physicians, with care of utmost concern for the consumer. However, regardless of their makeup, managed care systems all have one goal in common, cutting costs.\textsuperscript{8}

Managed care systems cut costs mainly in two ways.\textsuperscript{3,6,7} First, providers are paid a predetermined, limited amount of money for services. This is many times done on a diagnostic, monthly, or daily basis. Payments are also limited by allowing consumers to visit only clinicians who have agreed to accept lower rates for treatments for being included on the provider list. The other method by which managed care systems reduce costs is to limit services. Patients can no longer seek alternative physicians; the systems gatekeeper must refer them, often a physician who decides whom the patient may or may not see.\textsuperscript{4} Services are also limited by not paying providers for specific treatment procedures. After costs have been reduced, the remaining question is “what is the level of patient care as a result?”

Proponents of managed care contend that this system eliminates the waste that payers incurred during the inefficient and unlimited fee-for-service era.\textsuperscript{7} Skeptics charge that necessary and justified treatments for patient's well being is many times compromised for the need to reduce costs. One agreement
that both sides hold is that managed care is now upon us in full array and we must learn as a health community how to survive in this new age. According to the Health Care Financing Administration (HCFA), over 100 million American were enrolled in managed care plans at the beginning of 1999. The most widely used by patients is the Health Maintenance Organization (HMO). According to HCFA, 51 million Americans belong to HMOs as of 1999. HMOs offer prepaid, comprehensive health coverage for both hospital and physician services.

HMOs are given the power to choose where members receive care. More importantly, the HMO is given the ability to provide the discretion for dollars dispersed for patient care fees. This financial decision has left our profession in the middle of a very competitive state. Each clinic is forced to comply with the performance standards of another clinic, which has found a more cost efficient means of treatment. Many believe that this pushes clinics to strive for the best methods of care possible and results in optimal patient benefits, low cost, and high function. However, many factors are not taken into consideration with this assumption. Many unforeseen issues accompany patient care such as complications, infections, treatment compliance, and the fact that each patient and his or her injuries is different. In other words, we cannot separate the effect of our “treatment” from other outside variables occurring at the same time, including natural disease, other treatments, patient’s history, and other professional involvements. These outside factors lead to instances of increased rehabilitation time and costs that may not be compensated by HMOs. Many clinics have also been forced to cut back on staff and services to comply with
decreased payment schedules resulting from competition with other member providers and with denied payments. This may have a negative effect on patient care with decreased time available to patients, overworked clinicians, and decreased visits. These changes and new responsibilities have resulted in many new approaches by the clinical therapist.

Outcomes Research

In order to receive reimbursement for treatment, therapists have been forced to change many of their practice patterns. It is these changes that many clinicians have blamed on the use of managed care organizations. However, Rothstein\(^2\) encourages us to use this opportunity to lay claim to the treatment methods that work and shed those that do not. According to Rothstein, physical therapists have observed, over the last decade, an increasing need for an evidence-based practice. This scientific basis for our treatments would help to provide the necessary evidence for treatment efficacy and, subsequently, reimbursement.

One such method many physical therapists are utilizing is the use of outcomes research to provide proof of treatment effectiveness and the basis for reimbursement. Physical therapy is seen in the medical field as having treatment methods that do not carry with them a high mortality rate. According to Duncan,\(^8\) cardiac surgeons obviously carry more risk of catastrophic outcomes than do physical therapists to a certain degree. However, Duncan points out that using unproven treatments that are not founded in any scientific knowledge is
costly and misleading to the patient and, at times, unethical. This leads us to the shift to evidence-based practice, outcomes research.

Outcomes research is a proactive method of reviewing clinical results of patients with data taken during and following treatments. These results may include objective information obtained by the therapist, patient’s perceptions of care received, and levels of functional status following treatment. Knowledge concerning treatment outcomes does not, however, come without hard work and criticism. The collection of data pools requires many changes of personal beliefs and clinical beliefs including planning, time, money, increased dedication, attention to detail, and a commitment to change which can be big issues to overcome. Clinicians must also accept that becoming more knowledgeable on a particular subject often times does not solve questions; instead, it raises more. However, outcomes research provides evidence to keep the treatments that work, discontinue those that do not, and modify those that simply need adjusting.

Outcomes research also allows clinicians to fight for payment when it is deemed appropriate through supporting data. Issues of reimbursement along with issues relating to the most effective treatment methods seem to be driving the current trends for outcomes research. The fears from reimbursement issues have, however, led us, at times, to show evidence of treatment effectiveness, rather than show examination of treatments for effectiveness. Many clinicians want to show third party payers what we already have learned. We must be careful when using outcomes research to not just approve past techniques, but
to help prove new effective and efficient methods that improve our patient's care. Outcomes research will not succeed or fail solely because data exists, but instead how clinicians use it.

We must be open to change and accept better practice patterns to allow data to become relevant. Duncan⁸ points out four patterns that will result in a new physical therapy paradigm following proper outcomes research. First, clinical practice will place a much lower value on authority. This is not to say that we must ignore what experts have learned and gained through years of experience. It does say, though, that physical therapists whose practice is based on critical appraisal and the understanding of the underlying evidence will provide superior care. Secondly, practice will be guided by clinical practice guidelines based on rigorous methodological review of the available evidence. This will assist the clinician with patient decisions about appropriate care for specific clinical circumstances. Thirdly, physical therapists will better incorporate valid, reliable, and responsive measures of impairments, functional performance, and disability into clinical practice. Development of a standardized database will help to establish predictors of outcomes and better assess prognosis.¹,² This will also help to establish common measures to monitor progress, judge treatment efficacy, and evaluate quality in our programs. Lastly, outcomes research reminds us that our goal is not to cure but return patients to their highest level of function possible. Some patients do not benefit from some treatment options; our job is to find those that work best.
Outcomes research pushes us to be our own critic and hold ourselves accountable for providing cost effective care. We are taking a proactive approach with outcomes to develop our own criteria to drive change and improvements in our practice of physical therapy.

An example of such research could be the investigation of treatment outcomes of patients following patellofemoral surgery. This research could be utilized, as stated above, to provide a facility, and the physical therapy practice in general, with some evidence of treatment effectiveness and what the typical patient profile should be following similar procedures.

The pain involved with the patellofemoral joint accounts for the most prevalent disorder involving the knee. One study demonstrated that 25% of all knees evaluated in a sports injury clinic were diagnosed with patellofemoral pain, while McConnell reports that patellofemoral pain affects 25% of the general population.

The patellofemoral joint is one of the two joints that encompass the knee. However, the stresses, location, and makeup of this joint lend itself to direct and indirect injury. The tremendous forces generated at this joint during functional activities and the repetitious movements accompanying them leave this joint vulnerable. Studies have shown that the patellofemoral reaction forces can reach three times body weight during normal stair ambulation and as much as six times body weight with maximal efforts at knee extensions of 90°. Outside factors that increase the patellofemoral joint to injury are many. Rotation of the hip and leg, anatomy and function of the gluteal and quadriceps
muscles, makeup of the femoral groove (trochlea), alignment of the tibial
tuberosity, and foot alignment all play a role in the biomechanics that may result
in patellofemoral joint pain.13,14,16,17

Anatomy of the Patellofemoral Joint

The patella is the largest sesmoid bone in the human body.16 It is located
at the anterior junction of the femur and tibia and encompassed in the posterior
aspect of the distal quadriceps tendon. The four muscles of the quadriceps
(rectus femoris, vastus medialis, vastus intermedius, and vastus lateralis)
intersect, via the quadriceps tendon, on the dorsal aspect of the patella and
insert at the tibial tuberosity. The patella is flattened, triangular distally, curved
proximally, with predominately anterior and posterior surfaces.16,17 The anterior
surface is convex in all directions. The superior third is rough with the
quadriceps tendon insertion area. The middle third contains vascular
perforations numerous in number. The inferior third is pointed distally due to the
developed pull of the patellar tendon. The posterior patella is comprised of a
non-articulating inferior quarter and an articulating superior three quarters.

The superior portion is covered by the thickest cartilage (hyaline) in the
body.16 It is interesting to note that the patellar cartilage does not follow the
contour of the underlying subchondral bone. The cartilage exhibits multiple
facets that are unique to each individual. A vertical ridge divides these facets
laterally and medially. The lateral facets are much longer and wider than the
medial facets and are concave. The medial facets are slightly flat and convex.
These facets make up the segments of the patella that contact the femur though the degrees of knee motion.\textsuperscript{16,18}

Through knee motion, the patella articulates with the distal aspect of the femur, more specifically, the patellar trochlea. The trochlea is divided into two surfaces, lateral and medial. The lateral surface is larger and extends more proximally and anteriorly that the medial surface.\textsuperscript{16,17} The articular cartilage and material structure of the groove do not match those of the patellar cartilage. The shape of the patella varies from patient to patient. Some patients have a small patella relative to other body structures. This may make some patients more prone to sustaining patellar lesions.\textsuperscript{18}

The synovium of the patella consists of three portions.\textsuperscript{16} The suprapatellar pouch covers the anterior surfaces of the femur and prefemoral fat pad. The quadriceps tendon covers this pouch ventrally. The peripatellar synovium covers the patella medially and laterally blending with the suprapatellar pouch. This medial portion is marked with a plica, synovial pleat, which has inflammatory symptoms similar to the pain associated with articular degeneration and should be considered for a differential diagnosis. Lastly, the infrapatellar synovium extends posteriorly and proximally to conjoin with the peripatellar synovium laterally and medially. This fat pad has been associated with hypertrophy and also has the potential for differential diagnosis of patellar pain.

Both passive and active stabilizers support the patella. The ligamentous structures are considered passive stabilizers. Caudally, the patellar tendon restricts proximal displacement (patella alta) of the patella on the tibia.\textsuperscript{16,17} The
patellar tendon is orientated with the long axis of the lower extremity, though the
tendon extends slightly lateral from proximal to distal which may lend the patella
toward increased lateral pressure and displacement.

Lateral support comes from the peripatellar retinaculum, which derives
itself from two components, the superficial oblique retinaculum and the deep
transverse retinaculum.\textsuperscript{16,17} The superficial oblique retinaculum runs from the
iliotibial band to the patella. The deep transverse retinaculum is itself made up
of three structures: the lateral patellofemoral ligament, deep transverse
retinaculum, and the patellotibial band. These three structures combine and run
from the iliotibial band to the patella with greater density than their superficial
counterpart. The deep transverse retinaculum is considered a more important
restraint to medial displacement of the patella.

Medial support comes from capsular and retinacular tissue as well as the
primary restraint of the medial patellofemoral ligament.\textsuperscript{16} This ligament extends
from the medial femoral epicondyle to the medial patellar surface. The patella is
also supported to a lesser degree by the medial meniscopatellar ligament
inferiorly. The medial patellofemoral ligament, however, is considered the
primary restraint to lateral patellar displacement.

Balance between both medial and lateral restraining structures is critical
allowing for proper alignment of the patella in the femoral groove.\textsuperscript{16-19} When the
knee is flexed, the lateral and medial structures are pulled dorsally causing
increased compression of the patella within the femoral groove. Often times
there tends to be stronger and tighter support on the lateral side than medial.
This is enhanced by the iliotibial band, which contributes to lateral pull during flexion. This imbalance is one factor leading to lateral patellar tracking.

Active stabilizers of the patella include adjoining musculotendinous structures. This primarily involves the quadriceps femoral muscle. The patella is superficially covered by tendinous structures arising from the rectus femoris muscles, which insert into the anterior portion of the superior patella. Uniting midline on the patella are the vastus lateralis oblique (VLO) and medialis oblique (VMO) muscles, which insert into a tough fibrous band at the base of the patella. Insertion of the vastus medialis is more distal than that of the vastus lateralis.

These two muscles must also remain in proper balance to prevent abnormal patellar tracking from increased pull from the lateral or medial side. Other patellar active stabilizers include the hip adductors. Most fibers of the VMO originate from the adductor magnus and longus tendons, aiding in medial support of the patella.

Patellar Biomechanics

The patella serves one major function, to enhance the mechanical advantage of the extensor mechanism. This task of the patella is associated with tremendous compressive and directional forces even with what most would consider light activity, such as walking. Compression is produced as the patella increases the quadriceps muscles distance from the knee axis, thereby improving force production. The patella functions similar to both a pulley and class I lever. Simply put, the patella redirects and magnifies force and displacement of the quadriceps muscle.
When viewed from the frontal plane, the pull of the quadriceps muscle, proximal to the patella, is in a proximal lateral direction. This angle is straightened by the patella through its tracking in the patellar groove, similar to a pulley redirecting forces of a rope. By increasing the effective moment arm, the patella magnifies the force of the quadriceps similar to a class I lever.

While enhancing the quadriceps muscle function, the patella combines the forces of the VLO and VMO to allow for proper patellar tracking. These muscles provide transverse support while also providing compressive support to aid patellar alignment in the femoral groove. This is enhanced by the transverse retinacular structures, which tighten during flexion and loosen during extension. Any imbalance or pull greater in one direction may result in malalignment of the patella.

Patellofemoral Injuries

Patellofemoral pain is the most common disorder involving the knee with multiple symptoms. Clinicians for years have used the term "chondromalacia" to diagnose anterior knee pain. This all-inclusive term fails to describe the injury nor does it lend any plan towards treatment. Pain is generally described as being diffuse arising, however, from the anterior aspects of the knee. Generally, onset is insidious and progression is slow. Pain is usually activity induced and aggravated by compression that occurs during stair ambulation, inclined walking, squatting, or prolonged sitting.

Etiology of patellofemoral pain is still unknown, though many intrinsic and extrinsic factors are suspected predisposing factors to the injuries that cause this
pain. Some of these factors may include patellar compression syndromes, direct trauma, soft tissue lesions, overuse syndromes, osteochondritis dissecans, neurologic disorders, and malalignment, which may or may not result with instability. The latter, malalignment and instability, are often treated with surgical means and will be discussed further with relevance to this study. Malalignment of the patella occurs when the passive or active structures are insufficient to allow normal patellar tracking. This may include abnormal osseous structural alignment of the limb, abnormal static soft tissue restraints, or abnormal dynamic soft tissue restraints. These abnormalities may lend the patella to instability and subluxation. Once a malalignment has been established, the next step is to determine the structures responsible.

Malalignment may be the result of an increased angle between a line drawn through the patella and tibial tubercle, marking the path of the patellar tendon, and a line drawn from the anterior superior iliac spine and the proximal patella, marking the path of the quadriceps tendon. This angle is referred to as the Q angle and indicates the relative medial or lateral insertion of the quadriceps mechanism. Normal ranges are considered for males to be between 8° to 10° and females to be between 10° to 20°. The Q angle is an attempt to measure the forces applied to the patella, which is responsible for proper tracking through the femoral groove. The measurement of the Q angle is not all-inclusive for malalignment, but can be used a tool for evaluation of patellar malalignment.
Another cause for patellar malalignment and pain may be a tight lateral retinaculum.\textsuperscript{16,17} The insertion of the retinaculum on the patella may result in patellar tilt and increased pressure on the lateral patellar facets causing stress to soft tissues and degenerative changes. In contrast, deficiencies of the medial structures often lead to malalignment and pain. Weaknesses in the VMO or static medial structures allow for the patella to tilt laterally leading to adaptive shortening of the lateral structures and lengthening of the medial structures.

Treatment Procedures

Treatment of patients with patellofemoral pain remains a challenge to clinicians. Such options include conservative, non-operative treatments as well as less conservative, surgical treatments. An accurate diagnosis of the underlying pathology remains the biggest determinant for the optimal treatment plan.\textsuperscript{13} Other patient demographics including age, causative factors, condition of the injured and surrounding tissues, and activity level are also items to consider when formulating a treatment approach.

The ideal approach is a conservative treatment of muscle strengthening, stretching, bracing, modalities, or medications and patient education.\textsuperscript{13,21} Once conservative treatment fails, surgical considerations are approached in regard to the type and level of pathology. Operative treatment is usually reserved for the patient who exhibits severe and unimproving pain for greater than six months. Surgery is indicated with recurrent dislocations, pain with malalignment, pain without malalignment but accompanied by other lesions (plica, bone spurs, or degenerative changes).\textsuperscript{13,18}
Surgical procedures may release tight soft tissues, reinforce or relocate medial stabilizing structures, or relocate the tibial tubercle, the insertion of the patellar tendon. The three main surgical options include lateral retinacular release, proximal VMO realignment, and distal realignment of the tibial tubercle. As with any surgical procedure, individual injury, demographics, and condition of the structures involved must be taken into consideration when choosing the appropriate technique.

**Lateral Retinacular Release**

The Lateral Retinacular Release procedure is indicated for patellofemoral pain with lateral tilt, lateral retinacular pain with lateral patellar shift, or excessive lateral pressure syndrome caused by lateral tilt. Contraindications include acute patellofemoral pain without lateral tilt, chronic patellofemoral degeneration (arthritis), hypermobility, normal patellar tracking, and chronic subluxation and dislocation with malalignment. This procedure is performed with an open technique or arthroscopically involving a release of the lateral retinaculum and lateral VLO fibers. The lateral capsule is incised to create a separation of the lateral structures.

A common complication may include extending the release too far into the insertion of the VLO, which may result in medial patellar subluxation. Other complications are typical of any surgical technique and may include hemarthrosis, arthrofibrosis, reflex sympathetic dystrophy, surrounding structure damage, and/or infection. Postoperative rehabilitation emphasizes controlling hemarthrosis to prevent scarring and further complications.
Proximal VMO Realignment

For those patients who do not respond favorably to the Lateral Retinacular Release, Proximal VMO Realignment is necessary when a release procedure fails to restore normal orientation to a maligned extensor mechanism. VMO realignment addresses the needs of patients who experience recurrent subluxations or dislocations and those whose patella fails to centralize after a lateral release. This procedure is performed by relocating the insertion of the VMO to a more central location on the patella. This restores normal patellar alignment by altering the pull of the quadriceps musculature. Malalignment in these individuals is usually caused by incorrect extensor mechanism alignment.

Complications may include overtightening of the medial capsule and/or VMO, which may lead to medial subluxations of the patella or increased patellar tilt resulting in medial patellar compression syndrome. Rehabilitation should center on careful progression of range of motion (ROM) exercises with the precautions of muscular adaptation, soft tissue healing, and unhealed sutures. Also, the clinician should be aware of the chance of reflex sympathetic dystrophy due to entrapment of the saphenous nerve.

Distal Tibial Tubercle Transfer

Distal Tibial Tubercle Transfers involves relocating the patellar tendon insertion to correct patellar instability on patients who demonstrate recurrent lateral patellar dislocations or subluxations with a laterally tracking patella, lateral patellar tilt, or an increased Q angle. Distal realignment has also been shown to benefit patients with patellofemoral arthritis; the transfer will elevate the
tibial tubercle and decompress the patellofemoral joint alleviating painful symptoms. The fundamental concept of this procedure is to transfer the insertion of the patellar tendon medially.

Complications of this procedure may include local hematoma due to the osteotomy, and if the patellar alignment is not properly restored, a proximal VMO realignment may also be necessary. This procedure is performed openly by transferring the tibial tubercle medially and anteriorly by 8 to 10 millimeters. Normal pull of the patellar tendon should be restored so that the line of pull is slightly lateral, resulting in a normal Q angle. Complications of improper alignment and placement of the tibial tubercle may lead to patellofemoral arthritis. Rehabilitation should be centered around the precaution of the osteotomy though the bone is screwed and early ROM exercises are allowed with limited weight bearing. Radiographs are often necessary to confirm proper healing for advancement to 50% weight bearing. Those individuals who receive this procedure are not expected to return to sports; the goal is to return to functional daily activities.

Problem Statement

Physical therapists are facing many new challenges to offer the most effective care while facing challenges from the government and insurance groups for reimbursement. The use of outcome studies, documenting and providing evidence of treatment effectiveness, has provided a means for clinicians to prove the need for treatment and its payment. Such studies have
also given insight to treatment techniques that work and those which need modification.

Seeking the analysis of outcome measurements, St. Alexius Institute of Sports Medicine has initiated cooperation for various studies utilizing data they have documented. One such data set involves patients who have undergone patellofemoral surgery. With the prevalence of patellofemoral pain and a need for surgical intervention once conservative treatment fails, St. Alexius chose to document and research the outcomes of such patients.

Purpose of Study

The purpose of this research study is to assist St. Alexius in the analysis of outcomes for patients who have undergone patellofemoral surgical procedures and subsequent physical therapy. During specific time intervals of rehabilitation, various measurements were recorded. These data will be statistically analyzed and evaluated to determine the clinical effectiveness of treatment procedures utilized for this patient population.
CHAPTER II

METHODS

Study participation included 17 subjects for data analysis following patellofemoral surgery. Subjects volunteered for longitudinal outcome studies during rehabilitation at St. Alexius Medical Center in Bismarck, North Dakota. Participation in this study was dependent upon patients giving signed consent allowing rehabilitation and collection of data by the clinical physical therapists employed at St. Alexius Institute of Sports Medicine. Physical therapists performing the rehabilitation and data collection used a standard form to collect data from December 1995 to January 1999. Authorization for this study was secured through the Institutional Review Board of the University of North Dakota and the St. Alexius Medical Center.

Data Collection

Data were collected from 17 subjects, 19 knees, following surgery at the predetermined intervals of two weeks, three weeks, seven weeks, ten weeks, six months, one year, and two years. Data collected beyond ten weeks were done voluntarily without cost to the patient and performed solely for the purpose of gathering information. Due to the fact that information collected beyond ten weeks of the patient’s rehabilitation was done for clinical use, participation varied resulting in incomplete information for some patients. Allowances were made for
patients with incomplete files; data collected at appropriate time periods were still utilized for inclusion into this study.

Instrumentation and Procedure

Data were collected with various means of both subjective and objective tests and measures. Measurements include knee range of motion, patient's pain rating, quadriceps strength, joint effusion, self reported function, patellar mobility, isokinetic testing, as well as other patient demographics.

Knee Range of Motion

Range of motion measurements of the involved knee were taken during each visit using a standard, double-armed goniometer with full 360° range. Measurement techniques followed standard clinical practice outlined in *Measurements of Joint Motion: A Guide to Goniometry* by Norkin and White. Knee range of motion was measured passively with the patient in a supine position on a firm surface. Active range of motion was also measured using the same principles, however, in an antigravity, seated position.

Functional Range of Motion

Functional range of motion for knee flexion was defined by the researchers as 117° or greater as stated in *Orthopedic Assessment* by Magee. Measurements of 116° or less were considered non-functional.

Pain Rating

Patient subjective pain rating was recorded with each visit. Patients were asked to rate their pain on a scale of 0 to 10 with 0 being no pain and 10 being their worst pain, as outlined by Magee.
Quadriceps Strength Testing

Manual muscle testing of the quadriceps muscle was performed beginning with the seventh week visit. Testing was done using the standard methods outlined by Magee. Measurements were graded by the physical therapist on a scale of 0 (no contraction) to 5 (maximum resistance against gravity through complete range of motion).

Joint Effusion

Joint effusion was measured at the patient's mid patella, with the knee in full extension, using a standard cloth tape. Palpating for superior and inferior borders of the patella and measuring at the midpoint determined measurement landmarks. Knee girth was recorded in centimeters at two weeks post-operatively. Effusion data were analyzed as an edema difference between the involved and uninvolved limb. This difference was calculated by subtracting the measurement of the uninvolved limb from the measurement of the involved limb. An edema ratio was also developed by dividing the involved knee measurement by the uninvolved knee measurement.

Functional Tests

Self-reported functional data were recorded by the physical therapist using a standardized, lower extremity, functional assessment form. This form uses a numerical scale from 1 (non-satisfactory level of function) to 5 (satisfactory level of function). Functional activities on the form included: 1) quality of ambulation on level ground, distance of ambulation, and stair climbing, 2) transfers of toilet, tub, chair, and car, and 3) daily activities of dressing, work, and recreation.
Data were analyzed at the 52-week visit. A total score was calculated with a maximum possible score of 50. A sum of the subjects' scores was tallied and used to calculate a total raw score, which was compared with the maximum of 50.

Patient Demographics

Other information included on the patient's outcome form included age, gender, date of injury, date of surgery, type of surgery, doctor, occupation, and dominant lower extremity. This information is used to draw comparisons between patients of both similar and different demographics and surgical procedures.

Age

Age was recorded as the original number in years. Subjects were then divided into three equal groups, based on age ranges of 25 years, for statistical analysis of functional knee flexion return. The first group was 0-25 years, the second 26-50 years, and the last 51-75 years. This was an attempt to further specify which age groups may or may not display a return to functional range of motion at 10 weeks.

Bilateral Subjects

Various data analyses were performed excluding the bilateral surgery subjects due to the fact that they lacked a control or uninvolved extremity for comparison upon evaluation. Periods of exclusion within the results are noted when appropriate.
Data Collection/Analysis

Data were provided for the researcher through the use of an already established collection sheet as part of St. Alexius outcome study. A data collection sheet included a wide range of material, much of which is listed above and will be analyzed within this study. Data from patient charts were compiled into SPSS on one data file. Statistical procedures were used to describe values and analyze differences and relationships between and among the variables. For all statistical tests, an alpha level of 0.05 was utilized. Data reporting was accomplished using the form established by St. Alexius physical therapists (Appendix A). Chapter III includes the results supported by tables, which contain the statistical and descriptive data.

Reporting of Results

The results of this independent study will be stored with St. Alexius Medical Center Institute of Sports Medicine for further reference.
CHAPTER III
RESULTS

All of the 17 subjects selected for study participation were used for data analysis. Of the 17 subjects, two were bilateral patients giving a total of 19 patellofemoral joints assessed. Selected measurement comparisons were deemed invalid secondary to the bilateral patients failing to have a non-involved limb for reference of pre-injury status. Instances of exclusion of such data will be noted as it is addressed in this section.

Due to possible bilateral involvement, as stated above, the number of subjects varied for each data category analyzed. In addition, the number of subjects varied for each phase of measurement secondary to subject participation.

The patellofemoral surgical procedures were performed by one of four orthopedic surgeons employed by the St. Alexius Medical Center. Each surgeon included patients within this study. Data were grouped according to the type of patellofemoral surgery performed to draw comparisons between each. However, data will also be compared in a combined manner to draw conclusions about patellofemoral surgeries and rehabilitation regardless of surgery performed. Post-surgically, all subjects were treated by St. Alexius physical therapists using the guidelines outlined in the rehabilitation protocol (Appendix B).
Of the 17 subjects, 3 (18%) were male and 14 (82%) were female. The subjects ranged in age from 13 to 70 years with a mean age of 27 (±17.01) years. The sample age range was positively skewed secondary to 59% of the subjects being 19 years of age or younger. Of the three surgeries performed, 11 (58%) were a lateral retinacular release, 3 (16%) a VMO advancement, and 5 (26%) a tibial tubercle transfer. It should be noted that all tibial tubercle transfer procedures were performed with inclusion of a lateral retinacular release.

Research Question #1 – Is there a significant difference in return of functional range of motion based upon surgical procedure at 10 weeks post surgery?

Lateral Retinacular Release (LRR)

Average knee range of motion measurements for lateral retinacular release subjects at 10 weeks post surgery are reported in Table 1. Mean range of motion measurements, active and passive, were shown to be in functional range for both extension and flexion respectively. Passive extension noted an extensor lag upon evaluation of 0.78 degrees. Analysis of Variance (ANOVA) determined no significant difference in ROM between rehabilitation time intervals (weeks 2, 3, 7, and 10) for passive extension [F (3,34) = 1.21, p > 0.05] or active extension [F (3,34) = 0.57, p > 0.05]. There is a significant difference between time intervals for passive and active flexion and the results are reported in Table 1. Overall, Scheffes’ post-hoc testing displayed a significant improvement in ROM between weeks 2 and 10 post surgery. The level of significance is reported within Table 1.
Table 1. Lateral Retinacular Release: ROM in Degrees and ROM Comparisons Between Time Intervals

Range of Motion at 10 Weeks

<table>
<thead>
<tr>
<th></th>
<th>Number of Subjects</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive Extension</td>
<td>9</td>
<td>0.78</td>
<td>1.92</td>
</tr>
<tr>
<td>Active Extension</td>
<td>9</td>
<td>4.22</td>
<td>3.77</td>
</tr>
<tr>
<td>Passive Flexion</td>
<td>9</td>
<td>134.00</td>
<td>6.30</td>
</tr>
<tr>
<td>Active Flexion</td>
<td>9</td>
<td>127.13</td>
<td>8.22</td>
</tr>
</tbody>
</table>

ANOVA for ROM Comparisons Between Time Intervals

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between groups</td>
<td>4800.9</td>
<td>3</td>
<td>1600.3</td>
<td>3.6</td>
<td>0.24</td>
</tr>
<tr>
<td>Within groups</td>
<td>14673.8</td>
<td>33</td>
<td>444.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>19474.7</td>
<td>36</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between groups</td>
<td>2315.8</td>
<td>3</td>
<td>771.9</td>
<td>3.1</td>
<td>0.42</td>
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<tr>
<td>Within groups</td>
<td>6934.1</td>
<td>28</td>
<td>247.6</td>
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<tr>
<td>Total</td>
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Scheffe Post Hoc Results for ROM at Weeks 2 and 10

<table>
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<tr>
<th></th>
<th>ROM</th>
<th>Mean Difference</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive Flexion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>103.00</td>
<td>31.00*</td>
<td>0.036</td>
</tr>
<tr>
<td>Week 10</td>
<td>134.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Flexion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>120.57</td>
<td>24.55*</td>
<td>0.046</td>
</tr>
<tr>
<td>Week 10</td>
<td>127.13</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Mean difference is significant at the 0.05 level.
Vastus Medialis Oblique (VMO)

Average knee range of motion measurements for vastus medialis oblique subjects at 10 weeks post surgery are reported in Table 2. Mean range of motion measurements, active and passive, were shown to be in functional range for both extension and flexion, respectively. An extensor lag of 4.50 degrees was noted upon evaluation at 10 weeks. There was a significant difference with ANOVA testing for range of motion measurements between weeks for passive and active flexion, as recorded in Table 2. However, this was not supported with post-hoc testing for the respective groups as recorded in Table 2. ANOVA testing found no significant difference between groups for passive extension \[F (3,7) = 0.071, p > 0.05\] or active extension \[F (3,4) = 0.131, p > 0.05\].

Tibial Tubercle Transfer (TTT)

Average knee range of motion measurements for tibial tubercle transfer subjects at 10 weeks post surgery are reported in Table 3. Mean range of motion measurements, active and passive, were shown to be in functional range for both extension and flexion, respectively. Upon evaluation, a 2.0 degree extensor lag was noted with passive extension. A significant difference was noted for passive and active flexion between weeks 2 and 7 as well as between weeks 2 and 10 as determined by post-hoc analysis. Table 3 shows there was a significant difference between time periods for active and passive flexion. Table 3 shows the differences at weeks 2 and 7 along with 2 and 10, respectively. ANOVA summary determined there was no significant difference between time
Table 2. Vastus Medialis Oblique: ROM in Degrees and ROM Comparisons Between Time Intervals

Range of Motion at 10 Weeks

<table>
<thead>
<tr>
<th></th>
<th>Number of Subjects</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive Extension</td>
<td>2</td>
<td>-4.50</td>
<td>6.36</td>
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<tr>
<td>Active Extension</td>
<td>2</td>
<td>4.00</td>
<td>5.66</td>
</tr>
<tr>
<td>Passive Flexion</td>
<td>2</td>
<td>151.00</td>
<td>5.66</td>
</tr>
<tr>
<td>Active Flexion</td>
<td>2</td>
<td>144.50</td>
<td>7.78</td>
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ANOVA for ROM Comparisons Between Time Intervals

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between groups</td>
<td>6545.8</td>
<td>3</td>
<td>2181.9</td>
<td>5.6</td>
<td>0.036</td>
</tr>
<tr>
<td>Within groups</td>
<td>2345.8</td>
<td>6</td>
<td>390.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>8891.6</td>
<td>9</td>
<td>390.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between groups</td>
<td>7850.9</td>
<td>3</td>
<td>2616.0</td>
<td>4.5</td>
<td>0.047</td>
</tr>
<tr>
<td>Within groups</td>
<td>4077.8</td>
<td>7</td>
<td>582.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>11928.7</td>
<td>10</td>
<td>582.5</td>
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Scheffe Post Hoc Results for ROM at Weeks 2 and 10

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<th></th>
<th>ROM</th>
<th>Mean Difference</th>
<th>Significance</th>
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<tbody>
<tr>
<td>Passive Flexion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>88.57</td>
<td>62.33</td>
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</tr>
<tr>
<td>Week 10</td>
<td>151.00</td>
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<tr>
<td>Active Flexion</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>76.67</td>
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<td>Week 10</td>
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Table 3. Tibial Tubercle Transfer: ROM in Degrees and ROM Comparisons Between Time Intervals

Range of Motion at 10 Weeks

<table>
<thead>
<tr>
<th></th>
<th>Number of Subjects</th>
<th>Mean</th>
<th>Standard Deviation</th>
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<tbody>
<tr>
<td>Passive Extension</td>
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<td>Active Extension</td>
<td>5</td>
<td>2.00</td>
<td>1.22</td>
</tr>
<tr>
<td>Passive Flexion</td>
<td>5</td>
<td>146.40</td>
<td>5.55</td>
</tr>
<tr>
<td>Active Flexion</td>
<td>5</td>
<td>138.40</td>
<td>6.43</td>
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</table>

ANOVA for ROM Comparisons Between Time Intervals

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<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
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<th>Significance</th>
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<tr>
<td>Passive Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Between groups</td>
<td>14452.0</td>
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<td>4817.4</td>
<td>8.6</td>
<td>0.0001</td>
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<td>Within groups</td>
<td>8441.0</td>
<td>15</td>
<td>562.8</td>
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<td>Total</td>
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<td>18</td>
<td></td>
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<tr>
<td>Active Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between groups</td>
<td>11897.8</td>
<td>3</td>
<td>3965.9</td>
<td>5.6</td>
<td>0.01</td>
</tr>
<tr>
<td>Within groups</td>
<td>9901.2</td>
<td>14</td>
<td>707.2</td>
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<tr>
<td>Total</td>
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Post Hoc Results for ROM at Weeks 2 and 7

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<th>ROM</th>
<th>Mean Difference</th>
<th>Significance</th>
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<tr>
<td>Passive Flexion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>77.00</td>
<td>63.75*</td>
<td>0.01</td>
</tr>
<tr>
<td>Week 7</td>
<td>140.75</td>
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<tr>
<td>Active Flexion</td>
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<td></td>
<td></td>
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<tr>
<td>Week 2</td>
<td>73.00</td>
<td>65.25*</td>
<td>0.03</td>
</tr>
<tr>
<td>Week 7</td>
<td>138.25</td>
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Table 3. Tibial Tubercle Transfer: ROM in Degrees and ROM Comparisons Between Time Intervals (Cont.)

Post Hoc Results for ROM at Weeks 2 and 10

<table>
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<tr>
<th></th>
<th>ROM</th>
<th>Mean Difference</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Passive Flexion</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>77.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 10</td>
<td>146.40</td>
<td>69.40*</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>Active Flexion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>73.00</td>
<td></td>
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<tr>
<td>Week 10</td>
<td>138.40</td>
<td>65.40*</td>
<td>0.02</td>
</tr>
</tbody>
</table>

* Mean difference is significant at the 0.05 level.

periods for passive extension [F (3,15) = 2.04, p > 0.05] or active extension [F (3,13) = 2.16, p > 0.05].

The greatest ROM at 10 weeks was seen with patients who underwent VMO advancement with measurements of 151.0 degrees for passive flexion and 144.5 degrees for active flexion. Descriptive analysis of all three surgical procedure groups demonstrated functional knee flexion at the ten-week visit.

**Research Question #2 – Is there a correlation between pain and return of strength based on utilization of manual muscle testing (MMT)?**

Overall, pain measurements at week 7 involved 17 subjects with a mean pain rating of 0.47. MMT during this time involved 8 subjects with a mean of 4.2 for quadriceps strength. Upon evaluation, there was no significant correlation between pain rating and return of strength with use of patient’s subjective pain description and clinical evaluation of manual muscle testing as shown in Table 4.
Table 4. Correlation Between Pain Rating and Manual Muscle Test Strength at Week 7

<table>
<thead>
<tr>
<th></th>
<th>Number of Subjects</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Pearson Correlation Coefficient</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>17</td>
<td>0.47</td>
<td>1.07</td>
<td>-0.144</td>
<td>.734</td>
</tr>
<tr>
<td>Quadriceps</td>
<td>8</td>
<td>4.13</td>
<td>0.64</td>
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</tr>
</tbody>
</table>

The analysis of pain and strength displayed no correlation with the use of Spearman's rho ($r_s = 0.734, p > 0.05$).

Research Question #3 – Is there a correlation between subjective pain reports and the subject's age?

Upon data analysis, there was no significant correlation between pain and the subject's age reported in Table 5. Data were utilized from 18 subjects with pain reports taken at week 2. The analysis of pain and age displayed no correlation with the use of Spearman's rho ($r_s = 0.86, p > 0.05$).

Table 5. Correlation Between Pain Rating and Age Group

<table>
<thead>
<tr>
<th></th>
<th>Number of Subjects</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Pearson Correlation Coefficient</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>18</td>
<td>2.0</td>
<td>1.75</td>
<td>-0.18</td>
<td>.469</td>
</tr>
<tr>
<td>Age</td>
<td>19</td>
<td>26.5</td>
<td>16.16</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Research Question #4 – Is there a significant correlation between functional range of motion and joint effusion at two weeks?

Upon data analysis, joint effusion did not have a significant correlation with active or passive functional ROM at two weeks post surgery as shown with
the use of Spearman's rho for active ($r_s = 0.053$, $p > 0.05$) and for passive ($r_s = 0.234$, $p > 0.05$) ROM. Data for ROM, active or passive, is recorded in Table 6.

The median edema difference, when the affected limb was compared to the unaffected limb, was 1.65 cm showing that 50% of subjects were below this level. Minimum edema difference found was 0.30 cm with a maximum of 3.00 cm.

Table 6. Correlation Between Edema and Passive Flexion and Edema and Active Flexion

<table>
<thead>
<tr>
<th></th>
<th>Number of Subjects</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>$r_s$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edema Ratio</td>
<td>14</td>
<td>1.01</td>
<td>1.07</td>
<td>1.05</td>
<td>-.02</td>
<td>-.226</td>
<td>.436</td>
</tr>
<tr>
<td>Passive Flexion</td>
<td>14</td>
<td>37.00</td>
<td>130.00</td>
<td>95.29</td>
<td>32.47</td>
<td>-.132</td>
<td>.698</td>
</tr>
<tr>
<td>Edema Ratio</td>
<td>14</td>
<td>1.01</td>
<td>1.07</td>
<td>1.05</td>
<td>-.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Flexion</td>
<td>11</td>
<td>37.00</td>
<td>121.00</td>
<td>92.00</td>
<td>31.63</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Research Question #5 – Is there a correlation between age and return to functional knee flexion?

Fifteen subjects at 10 weeks were analyzed relative to age and functional range of motion for passive and active flexion, as shown in Table 7. The sample of subjects was not large enough to establish a correlation coefficient. Therefore, descriptive analysis was utilized and found no trend between age and return to functional range of motion. Of 15 subjects recorded at 10 weeks, all
Table 7. Number of Patients Achieving Functional Flexion at 10 Weeks by Age Group

<table>
<thead>
<tr>
<th>Age Groups in Years</th>
<th>0-25</th>
<th>26-50</th>
<th>51-75</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Passive Flexion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-functional ROM</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Functional ROM</td>
<td>9</td>
<td>5</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td><strong>Active Flexion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-functional ROM</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Functional ROM</td>
<td>9</td>
<td>5</td>
<td>0</td>
<td>14</td>
</tr>
</tbody>
</table>

achieved the criterion for functional passive knee flexion. Data for functional active flexion indicated that 14 of 15 achieved the criterion. The subject who did not reach the functional measure was in the third age group (51-75 years), displaying a measurement of 115° at 10 weeks.

Research Question #6 – What were the results of the functional assessment performed throughout rehabilitation regardless of the surgical procedure performed?

Descriptive statistics of functional assessment are reported in Table 8 with mean scores for each functional activity. Total scores of 50 points were possible for the functional assessment including 15 points for ambulation, 20 for transfers, and 15 for daily activities. Nine different subjects performed a total of 14 functional assessments throughout the time period of 3 months to 24 months. Score variation, from highest to lowest, was 5.0 points for ambulation, 3.0 points for daily activities, and 1.5 points for transfers. The greatest improvements were seen with ambulation and daily activity means, while the least improvement was
Table 8. Functional Assessment: Component Means and Total Score Means

<table>
<thead>
<tr>
<th>Visit</th>
<th>N</th>
<th>Ambulation Score Mean</th>
<th>Transfer Score Mean</th>
<th>Daily Activities Score Mean</th>
<th>Total Score Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>1</td>
<td>10</td>
<td>19</td>
<td>12</td>
<td>41</td>
</tr>
<tr>
<td>6 months</td>
<td>3</td>
<td>14.1</td>
<td>18.0</td>
<td>14.3</td>
<td>46.4</td>
</tr>
<tr>
<td>12 months</td>
<td>8</td>
<td>13.5</td>
<td>18.6</td>
<td>13.9</td>
<td>46</td>
</tr>
<tr>
<td>24 months</td>
<td>2</td>
<td>15</td>
<td>19.5</td>
<td>15</td>
<td>49.5</td>
</tr>
</tbody>
</table>

seen with transfers. However, it should be noted that for each visit throughout rehabilitation, transfer means were maintained above satisfactory levels. Mean totals displayed satisfactory functional achievement, 40.0 or greater, for each visit.
CHAPTER IV
DISCUSSION AND CONCLUSION

This study was conducted to assist St. Alexius Medical Center's Institute of Sports Medicine in the analysis of physical therapy outcomes for patients who underwent patellofemoral surgery. A retrospective investigation of data compiled by the physical therapists at this facility was performed and analyzed to determine the clinical and functional effectiveness of rehabilitation. Outcomes for knee range of motion, pain, quadriceps strength, joint effusion, and functional tests were the areas of focus for pre-determined intervals of rehabilitation. A discussion and comparison of outcomes for 17 patients who underwent patellofemoral surgery follows.

Knee Range of Motion Outcomes

Knee range of motion data were analyzed to determine if there was an effect on the return of functional range of motion at 10 weeks post-surgery due to the type of surgery performed. Subjects were analyzed at 10 weeks post-surgery secondary to the termination of insurance coverage at this time. Mangine\textsuperscript{18} explains the benefits of range of motion return for post-surgery patients include earlier return to activity and function, decreased pain, increased soft tissue nutrition, decreased swelling, and better functional outcomes. Magee
states active knee extension is approximately $0^\circ$, but may be as great as $-15^\circ$, while active knee flexion is approximately $135^\circ$.

The importance of functional knee range of motion has been well documented. Magee$^{27}$ states that full knee extension, $0^\circ$, is usually preferable for function of everyday activities and approximately $117^\circ$ of knee flexion is necessary for activities of daily living, such as squatting to don shoes. Individuals with decreased range of motion are more susceptible to muscle strains and overstress tendonitis. Subjects analyzed for this study showed no significant difference for return to functional knee range of motion with regard to their respective surgery. Each subject in each surgical group, lateral retinacular release, VMO transfer, and tibial tubercle transfer, achieved functional range of motion at the ten-week visit. A similar study conducted by Henry$^{25}$ showed all subjects had regained functional ROM within 10 weeks post patellofemoral surgery.

A study conducted by Mangine$^{18}$ states patients who have undergone lateral retinacular release should have full ROM by three weeks, patients who have undergone VMO transfers should have full ROM by eight weeks, and patients who have undergone tibial tubercle transfers should have full ROM by nine weeks. Guidelines for return of ROM are under different time periods for each surgical procedure secondary to an increased involvement of structures and a more invasive surgical procedure for VMO advancements and tibial tubercle transfers when compared to lateral retinacular release. Overall, this study concluded that functional ROM was achieved for each subject in
appropriate time frames according to the literature and protocols set by St. Alexius. Regardless of procedure, each patient achieved functional ROM by ten weeks post-surgery.

This observation demonstrates that ROM was not a limiting factor for the subjects included in this study with respect for their return to function. It should be noted, however, that other factors such as weight bearing status and/or strength may instead limit a return to function at 10 weeks post-surgery.

Limitations of this analysis may include incomplete data from each patient file for ROM at various periods secondary to outside factors. Another limitation can be seen with the total number of subjects included for study, 17. This number may not be enough to draw conclusions and comparisons to other studies; however, it does show the descriptive results and comparisons of St. Alexius patients. Another limitation is the observation that there were three VMO advancement subjects and five tibial tubercle transfer patients who were compared to 11 lateral retinacular release patients. This observation does not allow for equal comparison of surgical procedures for the subjects involved.

Range of motion was also compared to the amount of joint effusion at two weeks post-surgery. Effusion reduction allows for reduced pain, increased motion, and proper patellar tracking.25 This study demonstrated no correlation between range of motion and amount of knee joint effusion.

If joint effusion is great enough, joint range of motion can be decreased by capsular tightness, decreased elasticity, and diminished joint space leading to reduced area for translation and gliding of articular structures.18 Powers13 states
knee range of motion can be reduced secondary to synovial joint effusion and
the properties of synovial fluid. Synovial fluid, not unlike other liquids, cannot be
compressed; it requires displacement when put under stress leading to tightened
joint capsules reducing range of motion.

Active range of motion may also be reduced due to decreased contractility
of muscles secondary to pressure on type I and II mechanoreceptors. Finally,
Fulkerson states knee joint effusion must be minimal to allow for proper patellar
tracking in the trochlear groove. If synovial fluid remains in the knee capsule, the
patella will "float" freely without restriction during range of motion activities. This
allows for pre-surgical movements of the patella and leads to return of pre-
surgical symptoms associated with improper tracking.

Limitations of this analysis include failure to record pre-surgical effusion
measurements for post-surgical comparison. This failure forces the clinician to
measure the circumference of the non-involved limb for comparison. Problems
with this procedure include unequal limb size and failure to account for any
pathological problems with this non-involved, control limb. Another limitation for
comparing effusion and range of motion at two weeks may be the knee flexion
restrictions for the patient. This observation may give inaccurate data for the
patient's range of motion potential by holding the patient to the ROM restrictions
of the protocol.

Further analysis compared functional knee range of motion to the
subject's age. This study showed there was no correlation between subject's
age and return to functional knee range of motion. All subjects analyzed at week
10 post-surgery achieved the criterion, 117° for functional passive knee flexion. All subjects but one achieved the same criterion for active flexion.

The subject who failed to achieve 117° for active flexion demonstrated active knee flexion of 115°. This subject was in the third and oldest (51 to 75 years) age group and was post lateral retinacular release. Simpson²⁸ states that advancing age is one factor that contributes to poor range of motion results following lateral retinacular release. Scuderi²⁴ reports that younger patients report better post-surgical results, which he attributes to less severe soft tissue degeneration resulting in quicker return of normal range of motion. It should be noted, however, the subject who failed to achieve the active knee flexion criteria failed to do so by 2°. One explanation of this failure is explained by Norkin and White²⁶ who state intra-tester goniometry error may be up to 3°, while inter-tester goniometry error may be up to 5°. With this in mind, this patient could be considered as having achieved functional range of motion.

Another limiting factor of this analysis may include any secondary complications this patient may have encountered post-surgically or during rehabilitation which are not included in the data file. A further limitation may be the unknown pre-surgical function of this patient. Data files do not reveal pre-surgical information leaving the possibility this patient may actually have attained greater range of motion post-surgically than pre-surgically.

Pain Outcomes

The major ailment for which patients seek medical intervention is pain. For physical therapists, one of the major obstacles to overcome for successful
rehabilitation is the pain symptom. Pain may be idiopathic or the result of acute injury, chronic injury, or surgery. The effects of pain with regard to rehabilitation can include decreased patient comfort and satisfaction, strength, speed, ROM, stability, patient compliance, function, and overall outcome success.

Michel uses the example of how pain produces disturbed afferent information leading to general dysfunction in the motor system and a decrease in muscular strength. Patellofemoral post-operative pain can result in muscle weakness by way of the type IV pain receptor or mechanoreceptor. This neural pathway occurs by way of a simple reflex arc, resulting in decreased motion, muscular shut down, and antagonistic muscle spasm. Pain affecting strength leads to decreased function and safety. The need to increase post-surgical strength is demonstrated with a study by Merchant and Mercer who reported weak quadriceps as the major reason for unsatisfactory results. This leads therapists to decrease patient pain and increase functional strength in the least amount of time possible.

A key factor in pain control may be the progression of the exercise program. Excessive use of aggressive approaches may often lead to an increase in the patient’s pain. If pain is caused by aggressive treatment, the clinician is responsible for appropriate progression or alterations with rehabilitation. This study looked at the effects of pain on the return of strength and the effects of age on pain perception.

Upon analysis of pain and its effects on strength, this study showed no correlation between pain and manual muscle test scores at week seven. Manual
muscle testing exhibited a mean of 4.2 for strength. Magee\textsuperscript{27} states that a manual muscle testing score of 4 is considered good, 75\% of normal, and is exhibited by complete ROM against gravity with moderate resistance. Mean data for pain at this time period were 0.47 on a scale of 0 being no pain and 10 the worst. The mean pain measurement indicated that pain was at a minimum.

This study concluded that pain did not limit a patient’s return to functional strength. Limitations of this analysis might include the possibility that pain was low secondary to the delay in strength analysis. In order to allow for proper soft tissue and osseous healing, it was necessary to wait until the seventh week for strength analysis before placing these altered structures under premature stress. Most subjects reported no pain at seven weeks when the manual muscle test was performed.

A second limitation involves the unknown nature of the patient’s activity when pain ratings were taken. It is unknown if the pain ratings were taken when the patient was at rest or during active movement. This would be an important factor to consider for data collection and analysis secondary to pain affecting strength during active movements. Another limitation may have been the manual muscle testing grade of 4 or higher given to patients who could not yet achieve full ROM. Not all patients exhibited full ROM at week 7. This may have resulted in inaccurate data as full ROM is required for a manual muscle test grade of 4.

Another analysis of this study was a comparison between pain and subject’s age. Mostofsky\textsuperscript{31} states there is no connection between age and pain
perception. Numerous studies have shown no correlation between pain perception and age. Clinicians cannot predict a patient's perception of pain from age.

This study supported the findings of other studies showing no correlation between pain and age. Analysis was conducted at two weeks post-surgery with the observation that all subjects reported pain data at this time. Mean pain data was 2.0 with a mean age of 26.53 years. Age was broken down into three groups, 25 years each, to allow for inclusion of all subjects and to allow for a comparison between three groups.

A limitation of this analysis includes the fact that the majority of surgeries, 11, were lateral retinacular release procedures, which are the least invasive when compared to 3 VMO advancements and 5 tibial tubercle transfers. The latter two procedures involve more disruption of soft tissue and osseous structures, which many times leads to an increase in pain.

Another limitation was the fact that the average patient age was 27 years with ages ranging from 14 to 70 years. This observation failed to represent all ages accordingly, putting emphasis on younger subjects. However, similar studies by Scuderi and Henry observed a mean age of 27.3 and 24.0, respectively, when comparing age and pain. Similar ages of prevalence may be explained by the higher activity levels of younger subjects or from secondary lesions of maturing malaligned tissues. Future analysis might look at the relationship between age and pain within each surgical procedure to draw more accurate conclusions.
Functional Assessment Outcomes

The functional ratings assessment form (Appendix A) was developed by the physical therapists at St. Alexius Institute of Sports Medicine after review of various functional tools in use at other facilities and in conjunction with their own parameters. The form utilizes self reporting of function in daily activities during and following patients’ rehabilitation for patellofemoral surgery.

St. Alexius maintains an established goal of an 80% patient score in the categories of ambulation, transfers, and daily activities, which corresponds to ratings of 4 and 5 on the 0 to 5 functional ratings scale. Data for this study utilized information from 9 different subjects who performed a total of 14 functional assessments throughout the time period of 3 months to 24 months. In each category, satisfactory mean scores were seen for each of the 9 patients reporting for each time period. The highest mean scores over time, ranging from 18 to 19.5 out of 20, were seen with transfers, while the lowest mean scores, ranging from 10 to 15 out of 15, were seen with ambulation. The least change was also seen with transfers, with a mean change over time of 1.5; while the greatest change was seen with ambulation, with a mean change over time of 5. Transfers were reported with high function without any unsatisfactory scores.

Ohmann\textsuperscript{32} states the inclusion of functional testing for patient outcomes is supported by the need to not only include clinically measurable data, but to also determine the ability of patients to function in a satisfactory manner in personal and occupational roles. Limits in function may alter patients’ attitudes leading to decreased compliance and satisfaction of treatment. Functional results also give
the patient and clinician a standard guide to determine the patient's safety for activities of daily living.

Lower functional scores for ambulation may be explained by the observation of increased stresses placed on the surgically altered quadriceps extensor mechanism and the increased compression stress placed on the patella during this closed chain activity. Patients may experience increased pain and discomfort due to this biomechanical force. Another reason why ambulation scores were low may be the restrictions placed on patients to decrease the chance of injuring tissues. The inability to walk normally on painful, weak, and shortened structures may lower patients' perceptions of their level of ambulation. Patients may also be apprehensive to walk normally and place full trust in the surgically repaired knee secondary to fear of injuring repaired structures or fear of pre-surgical pain returning.

One of the activities scored in the ambulation category for this study involved patients' perceptions of their performance ambulating stairs. Ascending and descending stairs is the most common activity during which patients with patellofemoral dysfunction report difficulty and pain. Therefore, patients return to stair ambulation and scoring of this activity may initially result in poorer scores reported. In contrast, one reason patients score transfers better on the functional assessment may be secondary to their exposure to transfers immediately following surgery and throughout rehabilitation. Patients transfer from chairs, the toilet, and from a car very early in their recovery. Transfer activities are for short distances and do not require the use of both legs.
Patients can transfer safely and efficiently using their non-involved knee, thereby reducing pain and complications associated with using the surgically repaired leg. Patients may be more apt to score higher and have greater satisfaction of transfer activities for these reasons.

A limitation of this analysis is that scores were determined from patient's subjective satisfaction and self-analysis of function. Patient opinion may be influenced by many personal factors including fear, pain, apprehension, or desire to appear functional.

Another limitation involves the observation that St. Alexius clinicians developed this functional assessment to meet their needs. This only allows for comparison inside St. Alexius patient groups. The functional information obtained cannot be compared to similar studies outside this clinic or to similar patient protocols. The use of standardized functional testing could allow for comparison to other studies. Limitations may also include the failure to record the patient's level of function before surgery.

Overall Outcomes

Overall, this group of patients achieved satisfactory outcomes as demonstrated by their results and the attainment of goals defined by St. Alexius physical therapists. The results of this study suggest the techniques administered by St. Alexius physical therapists are effective for rehabilitation of patients who have undergone patellofemoral surgery. This study will aid clinicians by determining whether the demographic variables analyzed have an effect on patient outcomes. More importantly, however, the results of this study
help to support the efficacy of the current procedures used by the St. Alexius clinicians.

Significance

Ultimately, this study benefits patients who receive rehabilitation from St. Alexius physical therapists following patellofemoral surgery. Information analyzed in this study offers insight and evidence of treatment procedures that work and provides information regarding patient factors which may influence treatment and outcomes. With potential to maintain and improve patient care comes greater chance of patient satisfaction. It is this satisfaction which influences a patient's return to a facility and word-of-mouth referrals. This quality assurance also aids with insurance reimbursement and is required by accreditation agents to maintain national accreditation. Investigation of outcomes adds to a clinic's credibility and allows for maintenance and acceptance of effective rehabilitation techniques.

Limitations

Many limiting factors existed for the data included in this study. The information gathered and ultimately utilized for data analysis was originally intended for use by St. Alexius clinicians, not as a research study. This original intention allowed for instances of missed data collection and perhaps errors in data collection secondary to the multiple researchers. Instances of failed patient participation were also seen secondary to the voluntary participation.

Limitations for specific areas are stated above for each appropriate analysis; however, other factors limited the reliability of data. One such limitation
is the observation that this study looked at patellofemoral surgery as a general procedure and often times did not take into consideration the differences seen within the three procedures performed. For each procedure, there are many different structures involved which influence healing time, restrictions, goals, and complications.

The size of the data pool, 17 subjects (19 knees), is also a limitation. Of the three surgeries performed, a majority, 11 (58%) were lateral retinacular releases, 3 (16%) were VMO advancements and 5 (26%) were tibial tubercle transfers. This did not allow for an equal representation of all procedures.

Data reporting can also be considered a limitation. Information was missing for each patient at various times. Missing data did not allow for full representation of patients’ status and progress throughout rehabilitation. This led to incompletes analysis of not only individual subjects but also the different surgical procedures. Data variability may also be secondary to data collection by several different physical therapists, introducing the questions of inter/intratester reliability.

Data collection for subject demographics may also be a limitation. Data did not include information regarding the patient's pre-surgical level of function, range of motion, pain, degree of activity, or psychological status. Other medical history, previous therapy for the patellofemoral dysfunction, or patient compliance with previous therapies was also not reported.

Secondary complications, which may alter patient outcomes, may be seen as a limitation. Pre-surgical condition, post-surgery infection, joint hemarthrosis,
systemic disease, bilateral involvement, patient compliance, or other factors uncontrollable by the physical therapist may have altered patient outcomes.

Comparison of this study with others was affected by the increased availability of information on lateral retinacular release procedures when compared to the small amount of literature available for both VMO advancements and tibial tubercle transfers. Information of rehabilitation procedures and outcomes for the latter procedures was not readily available.

Information available, but not analyzed by this study, includes patellar mobility, isokinetic testing, presence of a patellar apprehension sign, position of the patella, balance testing, and a single-leg hop test. This information included both subjective and objective data and was not included secondary to incompleteness of data for each subject and increased length of study.
APPENDIX A
LONGITUDINAL OUTCOME STUDY
SURGICAL/PATELLOFEMORAL JOINT PROTOCOLS

NAME OF PATIENT ________________

Doctor __________________________ Dos / / / D01 / / /

Reoperative Diagnosis: ____________________________________________

Surgical Procedure: ________________________________________________

Surgical Complications: ____________________________________________

Age of Patient _____ Sex _____ Involved Side _____ Dominant Side _____

Occupational Injury Yes _____ No _____

Sport Injury- Yes _____ No _____

Injury from other cause (please state): ________________________________

Position of Patella in Trochlear Groove (Saja/Alta/Tilt)

SPITAL DISCHARGE

Date / / / Protocol Title/Date _________________________________________

Check off if complete:

_____ Pt. was given all protocol instructions prior to discharge.

_____ Pt. achieved all discharge parameters satisfactorily.

Alterations from protocol ___________________________________________

[CASE TWO: (2ND WEEK)

Check one: Clinical Care Home Program

You use: Cane Crutches Walker Nothing required

Protocol Date __________

in Scale

Active Extension_____

Passive Extension_____

Active Flexion_____

Passive Flexion_____

Int Effusion (measured mid patella) ______cm.

Posite Side ______cm.

Tisfactory Quad Function - Yes _____ No _____

Tellar Mobility ________ (include form)

prehension Present Yes _____ No _____

Implications/Comments: ___________________________________________

Lateral Measurements Taken: _____ Yes _____ No

Ta Logged: _____ Yes _____ No

# of Visits: __________
RASE THREE: (3RD WEEK)

Check One: Clinical Care______ Home Program______
you use: Cane______ Crutches______ Walker______ Nothing Required____
te______ Protocol Date______
in Scale______
ssive Extension______
tive Extension______
ssive Flexion______
tive Flexion______
nt Effusion (measured mid patella)______cm.
tisfactory Quad Function - Yes_____ No_____
tellar Mobility______ (include form)
prehension Present______
lance Test______ (include form)
sisted Flexion at Six Weeks (MMT)______
mplications/Comments: ________________________________

ta Logged: _____Yes _____No  # of Visits: ______

RASE FOUR: (7TH WEEK)

Check one: Clinical Care______ Home Program______
you use: Cane______ Crutches______ Walker______ Nothing Required____
te______ Protocol Date______
in Scale______
ssive Extension______
tive Extension______
ssive Flexion______
tive Flexion______
nt Effusion (measured mid patella)______cm.
tisfactory Quad Function - Yes_____ No_____
tellar Mobility______ (include form)
prehension Present - Yes_____ No_____  

ual Muscle Testing (Quadiceps)
____5 Complete range of motion against gravity with maximum resistance
____4 Complete range of motion against gravity with moderate resistance
____3 Complete range of motion with gravity
____2 Complete range of motion with gravity eliminated
____1 Evidence of slight contraction, but no joint motion
____0 No contraction palpated
mplications/Comments: ________________________________

ta Logged: _____Yes _____No  # of Visits: ______
FIVE: (10TH WEEK)

Check one: Clinical Care ___ Home Program ___

Protocol Date ___

Pain Scale ___

Active Extension ___

Active Extension ___

Active Flexion ___

Active Flexion ___

Joint Effusion (measured mid patella) ___ cm.

Satisfactory Quad Function - Yes ___ No ___

Tellar Mobility ___ (include form)

Prehension Present - Yes ___ No ___

Kinetic Test ___ Quadriceps and Hamstrings, (60, 180, & 0) (include short form) USE THESE SPEEDS FOR ALL OTHER TESTS

Functional Tests ___ (include form)

Implications/Comments: ______________________

TA LOGGED: ____ Yes ____ No # of Visits: ______

X MONTHS POST SURGERY

Current Symptoms: (check each one that applies)

Pain Scale ___ Unusual Sounds ___ Joint Going Back In ___

Swelling ___ Joint Locking Up ___ Inability To Move ___

Stiffness ___ Joint Giving Way ___

Active Extension ___

Active Extension ___

Active Flexion ___

Active Flexion ___

Tellar Mobility ___ (include form)

Prehension Present - Yes ___ No ___

Kinetic Test ___ (Quadriceps and Hamstrings) (include short form)

Functional Tests ___ (include form)

Implications/Comments: ______________________

Functional Assessment: ____ Yes ____ No

TA Logged: ____ Yes ____ No

E YEAR POST SURGERY

Current Symptoms: (check each one that applies)

Pain Scale ___ Unusual Sounds ___ Joint Going Back In ___

Swelling ___ Joint Locking Up ___ Inability To Move ___

Stiffness ___ Joint Giving Way ___

Active Extension ___

Active Extension ___

Active Flexion ___

Active Flexion ___
Lateral Mobility  
Prehension Present - Yes  No  
Balance Test (include form)  
Kinetic Test (Quadiceps and Hamstrings) (include short form)  
Functional Tests (include form)  
Implications/Comments: 

Functional Assessment:  Yes  No  
Data Logged:  Yes  No  

0 YEARS POST SURGERY  
Current Symptoms: (check each one that applies)  
Pain Scale  Unusual Sounds  Joint Going Back In  
Swelling  Joint Locking Up  Inability To Move  
Stiffness  Joint Giving Way  
Passive Extension  
Active Extension  
Passive Flexion  
Active Flexion  
Lateral Mobility (include form)  
Prehension Present -  Yes  No  
Kinetic Test (Quadiceps and Hamstrings) (include short form)  
Functional Tests (include form)  
Implications/Comments: 

Functional Assessment:  Yes  No  
Data Logged:  Yes  No
LONGITUDINAL STUDY CONSENT FORM

THE RESULTS OF YOUR REHABILITATION PROCESS ARE BEING GATHERED AS PART OF A LONG TERM STUDY OF SURGICAL AND FUNCTIONAL OUTCOMES OF YOUR PARTICULAR DIAGNOSIS. ONCE YOU HAVE COMPLETED YOUR FORMALIZED PHYSICAL THERAPY TREATMENT AND HAVE BEEN DISCHARGED FROM ST. ALEXIUS MEDICAL CENTER, WE WOULD APPRECIATE THE OPPORTUNITY OF RETESTING YOUR STATUS AT 6 MONTHS, 12 MONTHS, AND 24 MONTHS POST DISCHARGE. THESE LAST THREE VISITS WOULD BE FREE OF CHARGE AND ALL RESULTS WOULD BE MADE READILY AVAILABLE TO YOU.

WHEN UNDERGOING THESE TESTS, THERE ARE CERTAIN INHERENT RISKS WHICH INCLUDE THE POSSIBILITY OF MUSCLE AND LIGAMENTOUS INJURY. YOU SHOULD EXERT YOUR BEST EFFORT THROUGHOUT THE EVALUATION BUT AT NO TIME ARE YOU EXPECTED TO EXPERIENCE ANY INCREASE IN PAIN OR DISCOMFORT BEYOND A LEVEL YOU FEEL YOU CAN COMFORTABLY TOLERATE. AT NO TIME WILL YOU BE FORCED TO PERFORM ANY TESTS WHICH YOU DO NOT WISH TO PERFORM AS YOU ARE IN CONTROL OF THE TESTING AND MAY STOP WHenever YOU FEEL THAT YOU SHOULD NOT PROCEED. IF WE SEE YOU EXERTING EFFORTS, WHICH IN OUR OPINION MAY PLACE YOU IN DANGER, WE WILL STOP YOU.

BASED ON THE ABOVE INFORMATION THAT I HAVE READ AND UNDERSTAND, I AGREE TO PARTICIPATE IN THIS LONGITUDINAL STUDY.

DATE

PARTICIPANT SIGNATURE

900 East Broadway  Box 5510
Bismarck, North Dakota 58502-5510
701-224-7000
FAX 701-224-7284
TDD 701-224-7946
LOWER EXTREMITY RANGE OF MOTION MEASUREMENTS
NON-INVOLVED EXTREMITY

<table>
<thead>
<tr>
<th>EXTREMITY</th>
<th>MEASUREMENTS</th>
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</thead>
<tbody>
<tr>
<td>HIP PATIENTS</td>
<td></td>
</tr>
<tr>
<td>Lower Extremity Total</td>
<td>Non-Involved Extremity</td>
</tr>
<tr>
<td>Active Flexion, Supine</td>
<td>Active Extension, Prone With Knee Flexed</td>
</tr>
<tr>
<td>Active Internal Rotation With Knee and Hip Flexed, Sitting</td>
<td>Active External Rotation With Knee and Hip Flexed, Sitting</td>
</tr>
<tr>
<td></td>
<td>R KNEE PATIENTS</td>
</tr>
<tr>
<td>Flexion of the Knee, Prone</td>
<td>Active Extension of the Knee, Sitting</td>
</tr>
<tr>
<td>R ANKLE PATIENTS</td>
<td></td>
</tr>
<tr>
<td>Plantar Flexion, Knee Extended, Sitting</td>
<td>Plantar Flexion, Knee Flexed, Sitting</td>
</tr>
<tr>
<td>Dorsiflexion, Knee Extended, Sitting</td>
<td>Dorsiflexion, Knee Flexed 90 Degrees, Sitting</td>
</tr>
<tr>
<td>Inversion, Supine, Knee Extended</td>
<td>Eversion, Supine, Knee Extended</td>
</tr>
<tr>
<td>SP</td>
<td>STN DF Knee Flexed/Extended</td>
</tr>
<tr>
<td>SP</td>
<td>STN PF Knee Flexed/Extended</td>
</tr>
<tr>
<td>You Use: Cane</td>
<td>Crutches</td>
</tr>
</tbody>
</table>

REFERENCES:
PATELLAR MOBILITY (Check one)

Medial Glide 50%

Greater than 50%  35% to 50%  Less than 35%

Lateral Glide 40%

Greater than 40%  25% to 40%  Less than 25%

Inferior Glide 40%

Greater than 40%  25% to 40%  Less than 25%

Superior Glide 25%

Greater than 25%  15% to 25%  Less than 15%

Patellar Baja/Alta: Patellar tendon length to patella (1:1 ratio)

Baja (20% less)  Alta (20% greater)

Patellar tilt or rotation (at 20 to 30 degrees of knee flexion)

Yes  No  Direction
Yes  No  Direction
**LOWER EXTREMITY FUNCTIONAL ASSESSMENT FORM**

**ATE:**

### Gait Assessment

<table>
<thead>
<tr>
<th>Activity</th>
<th>Satisfactory</th>
<th>Non-Satisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level Ground</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
<tr>
<td>Stair Climbing - (alternating up/down)</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
<tr>
<td>Distance</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
</tbody>
</table>

### Transfers

<table>
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<tr>
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<th>Non-Satisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toilet</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
<tr>
<td>Tub</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
<tr>
<td>Chair</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
<tr>
<td>Car</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
</tbody>
</table>

### ADL Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Satisfactory</th>
<th>Non-Satisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
<tr>
<td>Work</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
<tr>
<td>Recreation</td>
<td>NA 5 4</td>
<td>3 2 1</td>
</tr>
</tbody>
</table>

### Complete Gait Form

...
LOWER EXTREMITY
FUNCTIONAL TEST FORM

FOUR SQUARE TEST - SINGLE LEG

<table>
<thead>
<tr>
<th></th>
<th>UNINVOLVED</th>
<th></th>
<th>INVOLVED</th>
</tr>
</thead>
<tbody>
<tr>
<td>to 4</td>
<td>20 Seconds</td>
<td>____</td>
<td>____ Reps.</td>
</tr>
<tr>
<td>to 2</td>
<td>20 Seconds</td>
<td>____</td>
<td>____ Reps.</td>
</tr>
<tr>
<td>to 3</td>
<td>20 Seconds</td>
<td>____</td>
<td>____ Reps.</td>
</tr>
</tbody>
</table>

Are you able to:
- ____ Jog less than 7 blocks?
- ____ Run less than 7 blocks?
- ____ Jog greater than 7 blocks?
- ____ Run greater than 7 blocks?
- ____ Jog greater than 14 blocks?
- ____ Run greater than 14 blocks?

Can you cut with these or any activities? Yes____  No____

Do you need bracing support with any activity? Yes____  No____

A/MC/alr
/96
APPENDIX B
LATERAL RETINACULAR RELEASE
VASTUS MEDIALIS OBLIGUUS ADVANCEMENT PROTOCOL

AUGUST 1993

INDICATIONS
Patellofemoral Malalignment
Patellar Subluxations
Patellar Dislocations

PRECAUTIONS
Treatment of the post surgical patient must attend to the underlying cause for surgery and associated findings during arthroscopic examination as well as associated procedures performed.

Be Aware Of:
1. VMO advancement
2. Condition of femoral trochlear surface
3. Condition of retropatellar surface
4. Presence of chondroplasty

PHASE ADVANCEMENT
All exercises should be advanced based on the symptoms of the patient. Pain free exercise is the standard for advancement from one stage to the next. Times given for advancement are minimum times frames for the uncomplicated patient to allow for appropriate soft tissue healing constraints. Attention should be given to the response of the patellofemoral joint during the rehabilitation process and adjustments to be made according to this.
LRR - VMO PROTOCOL
PAGE TWO

PATIENT EDUCATION

1. Review surgical procedure.
2. Caution patient about prevention of stress on the sutures for the first 6 weeks.
3. Caution patient about preventing maximal quadricep contractions until 6 weeks postoperative.

DISCHARGE GOALS

1. Normal ROM.
2. 90% quadricep strength and power with no extensor lag.
3. Return to preinjury/surgical activity level.

I. Phase I - Beginning Postop Day #1

A. Recovery Room
   1. Compression wrap with lateral felt horseshoe
   2. Cold Jobst with E-Stim over VMO

B. Immobilize in extension

C. Toe or foot touch weightbearing with crutches first 3 days progressed to 50% weightbearing by day #7

D. Submaximal quad sets with E-Stim

E. Resisted straight leg raises into hip extension and adduction with brace on

F. Hamstring/gastroc stretching

G. Active and resistive knee flexion to 60 degrees if comfortable

H. Patellar mobilization (superior, inferior, medial)

I. Continued compression wrapping

J. Cryotherapy - cold Jobst b.i.d. if possible or icing
K. CPM as ordered by physician.

II. **Phase II - Week #2**

A. Allow limited motion as comfortable 
B. Weightbearing as tolerated 
C. Continue submax quad sets utilizing biofeedback for proper VMO function 
D. Continue straight leg raise into hip extension and adduction with brace on 
E. Begin multi-hip in adduction, abduction, flexion and extension 
F. Active and resistive knee flexion to 90 degrees 
G. Continue hamstring/gastroc stretching 
H. Continue patellar mobilization 
I. Active knee flexion in standing position 
   1. Do submaximal quad sets when knee is extended 
J. Biking when tolerated for range of motion with minimal resistance 
K. Continue compression wrapping 
L. Cryotherapy 

III. **Phase III - Week #6**

A. Full weightbearing with no external support 
   1. May use knee sleeve for comfort
LRR - VMO PROTOCOL
PAGE FOUR

B. Maximal quad sets with biofeedback over VMO
C. Straight leg raises in all planes
D. Pain free submaximal dynamic resisted knee extension
   1. Speed squats, lateral stepups, BAPS board, wall sits
   2. Submaximal leg press
   3. Versa-Climber and Stair Stepper
E. Maximum resistance dynamic knee flexion exercises through full arc
F. Continue hamstring/gastroc stretching
G. Active range of motion and general stretching (bike)
H. Continue patellar mobilization
I. Continue compressive wrapping
J. Cryotherapy
K. Treadmill gait training forward and backward walking on level ground progressing to 5-10% elevation

IV. Phase IV - Week #8
A. Maximal quad sets with continued VMO training
B. Continue straight leg raises
C. Maximum resistance dynamic quadricep and hamstring strengthening exercises (emphasis on endurance)
D. Light jogging
   1. Plyometrics
      - Begin with light weight (<body weight) on supine leg press
LRR - YMO PROTOCOL
PAGE FIVE

- Progress to level ground plyometrics when at 70-80% strength compared to uninvolved side

- Progress to box jumps and resistance with sports cord for lateral stepups, lunges and single leg squats as function and strength improve

2. Continued BAPS, speed squats, and lateral stepups for proprioception

D. Continue hamstring/gastroc stretching

E. Active range of motion and vigorous stretching to regain normal range of motion

F. Functional training
   - Begin a retro-walking program with progression to incline retro-running
   - Increase retro-walking to 2% grade with progression to incline retro-running
   - Lateral shuffles, carioca's and rope jumping

G. Continue compressive wrapping

H. Cryotherapy

V. Phase V - Maintenance Program

A. Continued plyometric progression

B. Continued retro-walking/running program

C. Sports specific training

D. Continue strengthening program for six months after strength returns to discharge parameters.
BIBLIOGRAPHY


Henry, J.H.; Craven, P.R., Surgical Treatment of Patellar Instability: Indications and Results, American Journal of Sports Medicine, Vol. 9 No. 2, March/April 1984. p. 82.

Mangine, Robert; Conference: The Knee, A Clinical Approach, November 5-6, 1988, Grand Forks, North Dakota.


LATERAL RETINACULAR RELEASE PROTOCOL
JUNE 1996

INDICATIONS
Patellofemoral Malalignment
Patellar Subluxations
Patellar Dislocations

PRECAUTIONS
Treatment of the post surgical patient must attend to the underlying cause for surgery and associated findings during arthroscopic examination as well as associated procedures performed.

Be Aware Of:

VMO advancement (separate protocol)
Condition of the femoral trochlear surface
Condition of the retropatellar surface
Presence of chondroplasty

All exercises should be advanced based on the symptoms of the patient. Pain free exercise is standard for advancement from one stage to the next. Times given for advancement are minimum time frames for the uncomplicated patient.

GOALS
1. Full knee flexibility
2. Good and symmetrical lower extremity balance/proprioception
LRR PROTOCOL
PAGE 2

3. Quadriceps/hamstring strength and endurance 80-90%+ involved to uninvolved.

4. Progressive return to full ADLs without associated patellofemoral pain and/or instability

I. Phase I - Acute Postoperative Phase (0-10 Days)

A. Weightbearing as tolerated with crutches
   1. Be aware of specific physician recommendations depending upon surgical technique.

B. AROM in pain free arc

C. Passive patellar mobility (superior, inferior, medial)

D. Thigh strengthening as per isometric setting exercises to quadriceps, hamstrings, and adductors (E-Stim utilized for enhanced VMO training as indicated)

E. Hamstring/gastroc stretching

F. Compressive wrapping, icing, and cold Jobst as indicated for effusion reduction.

II. Phase II - Semi-Acute Phase (7-21 Days)

A. Continue weightbear progression as tolerated

B. Continue range of motion activities with initiation of gentle stretching as indicated

C. Continue passive patellar mobilization

D. Continue open chain strengthening program as per isometric setting versus advancement to multi-hip SLR/Sportcord program as indicated

E. Initiation of functional closed chain strengthening
   - Leg press
   - Wall/quarter squats
   - Step training (lateral, forward, retro, etc.)
LRR PROTOCOL
PAGE 3

F. Initiation dynamic open chain hamstring strengthening

G. Continue hamstring and gastroc/soleus stretching

H. Continue compression and cryotherapy techniques for effusion reduction as indicated

III. Phase III - Non-Acute Phase (4-12 Weeks)

A. Continued knee flexibility program

B. Continued knee strengthening program with orientation towards functional sports specific training as indicated including:

1. Step training
2. Forward lunges
3. Leg press advancing from double to single leg
4. Treadmill retrograde walking
   - 10 to 20° angle for enhanced VMO training if possible

C. Endurance training activities as per biking, swimming, Stair-Stepper, walking, etc.

    1. Emphasize "sports specificity"

D. Quadriceps isotonics/isokinetics

    1. Avoid painful arc
    2. Submaximal loading to minimize patellofemoral stresses

E. Plyometrics/proptrioceptive training

    1. Progressive advancement from static to dynamic training (BAPS versus single leg stance versus leg press routine versus floor jumping drills, etc.)
    2. Emphasize "sports specificity"
    3. Recommend 70-80% return of quad/hamstring strength and endurance before initiation of advanced plyometrics (i.e. box jumping, etc.)
SPECIAL CONSIDERATIONS:

A. McConnell taping
B. Patellar supports
C. Foot orthotics

MEDICAL DIRECTOR

MEDICAL REVIEWER

CLINICAL DIRECTOR

CLINICAL REVIEWER
BIBLIOGRAPHY

LATERAL RETINACULAR RELEASE


TIBIAL TUBERCLE TRANSFER PROTOCOL

INDICATIONS

A. Recurrent patellar subluxation or dislocation
B. Patellofemoral malalignment
C. Acute patellar dislocation

PRECAUTIONS

A. Allow 4-6 weeks bony healing of tibial tubercle
B. Aggressive rehab to patellofemoral joint should be avoided
C. Patellar baja is a frequent complication in Hauser procedure. Not in medial tibial tubercle transfer.

GOALS

A. Painless knee
B. Full active range of motion
C. 80-100% quad to quad ratio at discharge

CRITERIA FOR PHASE ADVANCEMENT

A. Time constraints for bony healing must be met prior to phase advancement.
B. Pain free exercise
PATIENT EDUCATION

A. Clinical
   1. Anatomy
   2. Existing pathology
   3. Planned rehab

B. Pre-Op Instructions
   1. Anatomy
   2. Existing pathology
   3. Planned surgical technique:
      Open lateral retinacular release - tibial tubercle
      wedge osteotomy transfer medially and screw
   4. Post-op precautions
   5. Crutch gait
   6. Teach active resisted flexion and return to extension
      passively.

REHABILITATION SCHEDULE

Phase I - Beginning Post-Op Day #1 Through Week #2
   1. Toe/foot - touch weight bearing
TIBIAL TUBERCLE TRANSFER PROTOCOL
PAGE THREE

2. Hamstring/gastroc stretching
3. Passive knee extension
4. Submaximal resisted knee flexion 0-60 degrees
5. Gentle quad setting/standing knee extension (E-Stim to VMO if necessary beginning Week #2)
6. Modalities as needed for pain
7. Compression wrap
8. Cryotherapy

Phase II - Week #3

1. Partial weight bearing to one half body weight
2. Continue hamstring/gastroc stretching
3. Active knee extension to available range without resistance
4. Continued resisted knee flexion, increasing flexion as tolerated.
   a. Begin isometric hip adduction when flexion is at 90 degrees actively.
5. Continue quad setting/standing knee extension (E-Stim over VMO)
6. Begin straight leg raises (emphasis on flexion and adduction: E-Stim over VMO)
TIBIAL TUBERCLE TRANSFER PROTOCOL
PAGE FOUR

8. Biking as tolerated for range of motion and patellofemoral joint rehab.

9. Modalities as needed for pain

10. Compression wrap

11. Cryotherapy

Phase III - Week #4

1. Progressive weight bearing to full

2. Continue hamstring/gastroc stretching

3. Continue active range of motion until full

4. Continue straight leg raises

5. Begin with lateral stepups start with 2 inch steps

6. Bilateral leg press

7. Retrograde walking 0-10% elevation

8. Continue cryotherapy

9. Versa Climber 4-6 inch steps beginning Week #5

Phase IV - Week #6 Until Discharge

1. Full weight bearing should be achieved.

2. Continue hamstring/gastroc stretching

3. Emphasis on endurance training
   a. Isokinetics at high speed
   b. Isotonic - May begin full arc quad exercises dictated by response of patellofemoral joint.
4. Functional training (Advance plyometrics, BAPS board, etc.)

5. Sportscord resisted lateral stepdown lunge, single leg squats, single leg pushes add resistance as tolerated with Sportscord. Retrograde walking 10-30% elevation. Plyometrics beginning on level surfaces. Single leg on Stairstepper. Add back pedal at 8 weeks utilizing higher elevations.

6. Swimming

E. Phase V - Maintenance

1. Lower extremity flexibility program

2. Lower extremity program with particular emphasis on quad musculature.

---

Reviewed 9/1991
Revised 7/30/93
Revised 8/24/93
BIBLIOGRAPHY

Hanson, J.; Gruby, R.S., Tibial Tubercle Transfer, I.S.M. Library, St. Alexius Medical Center, Bismarck, North Dakota, September 1991.


MANGINE, Robert; Conference: The Knee, A Clinical Approach, November 5-6, 1988 Grand Forks, North Dakota.


MD/air
Reviewed 9/91
Revised 7/30/93
Revised 8/24/93
UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM
FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED
PROJECTS INVOLVING HUMAN SUBJECTS

TITLOR: Dr. Renee Mabey, Scott Hurd, and Tom Henke
TELEPHONE: 701-777-2831
DATE: February 10, 1999

ESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT:
501 North Columbia Road
PO Box 9037
Grand Forks, ND 58202-9037

PROPOSED: 3/1/99-9/1/00

COLLEGE: School of Medicine
DEPARTMENT: Physical Therapy

ECT TITLE: Outcome Study of Physical Therapy Rehabilitation of Patients with Patellar Femoral Dysfunction

ING AGENCIES (IF APPLICABLE): N/A

OF PROJECT (Check ALL that apply):

NEW PROJECT __ CONTINUATION __ RENEWAL __ THESIS RESEARCH X STUDENT RESEARCH PROJECT

HANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT:

ATION/THESIS ADVISER, OR STUDENT ADVISER: Dr. Renee Mabey

CLOSED PROJECT: ____ INVOLVES NEW DRUGS (IND) ____ USE OF DRUG X INVOLVES A

OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE CLASSIFICATION(S):

MINORS (<18 YEARS) ___ PREGNANT WOMEN ___ MENTALLY DISABLED ___ FETUSES ___ MENTALLY RETARDED
PRISONERS ___ ABORTUSES ___ UND STUDENTS (>18 YEARS)

UR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL
RIAL, OR PLACENTAL MATERIALS, CHECK HERE

UR PROJECT HAS BEEN WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE LIST NAME OF
RD(S):
Status: ___ Submitted; Date __ Approved; Date ___ Pending

RACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.

With the rise in health care costs, medical professionals have moved from a fee-for-service to a highly competitive, cost-conscious environment. Physical therapists as members of the medical community are certainly not exempt, being held accountable for treatment efficacy as well as the achievement of functional outcomes. It is these outcomes which will be used to determine treatment effectiveness while providing a basis for third party reimbursement.

This research study is being performed to assist not only St. Alexius Hospital Center of Bismarck, ND, but to assist all health care providers with the information as to effective post-surgical treatment of patellar-femoral pain. Specific procedures examined will include patients who have undergone lateral retinacular release, tibial tubercle transfer, or vastus lialis muscle advancement. As part of the standard rehabilitation
process, St. Alexius physical therapists examined patients at specific predetermined intervals, recording various measurements. This study is intended to examine the recorded data to determine treatment effectiveness well as patient's functional outcomes. Results of this study will be useful to clinician as well as third party reimbursement agencies.

**SE NOTE:** Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Additional appropriate attach sections from your proposal (if seeking outside funding).

**OTOCOL:** (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

This outcome study is being performed as a chart review to determine effectiveness of physical therapy treatments with the following surgical procedures: lateral retinacular release, tibial tubercle transfer, vastus medialis muscle advancement. A copy of the data collection set has been included (Addendum 1). At predetermined intervals, a variety of standard clinical measurements were collected by St. Alexius physical therapists, to help determine patients' rehabilitation status at weeks, three weeks, seven weeks, ten weeks, six months, one year and years post surgery. Questions which we will attempt to answer include are not limited to the following:

1. At predetermined intervals, is there a significant difference in strength between patients who received differing surgical procedures?
2. Is there a significant difference noted when comparing range of motion measurements of open vs. laser procedures for the lateral retinacular release?
3. Is there a significant difference in the number of visits necessary for each procedure to demonstrate a return of functional range of motion?
4. Concerning age, is there a significant difference in results for range of motion and function attained after surgery?
5. Are patients of each procedure able to attain satisfactory functional results as pre-described in the outcome study form upon completion of therapy?
6. Are patients able to demonstrate 90% quadriceps strength and power when comparing the uninvolved versus involved knee upon discharge?
7. Are patients of each procedure studied able to demonstrate pain free, functional range of motion at discharge? Is one more significant than the other(s)?

Patient participation in this study was based upon selection of St. Alexius as the exclusive provider of surgical and rehabilitation care. Patient cooperation for data collection was done on a voluntary basis following agreement of the attached consent form (Addendum 2). Minor sent for participation in this study will also be covered by St. Alexius Medical Center through their signing of a consent form upon beginning therapy.

Traditional statistical analysis will be used to describe and analyze results of information utilized by this study.

**BENEFITS:** (Describe the benefits to the individual or society.)
Patients in this study will knowingly not benefit directly from its results. However, results will provide the clinician with the tools necessary to improve treatments and have sound resources for treatment and training, improving all future patient care. These improvements will not only result in greater cost-efficiency for patients with patellar femoral function, but will provide physical therapists with a rationale for third party reimbursement. It will be of a great deal of benefit to the 1m of professional physical therapists, allowing them to modify treatments if necessary or provide them with justification that what they are doing is effective for patient treatment.

SKS: (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical harm includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the integrity of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

Collection of data by St. Alexius physical therapists was performed on a voluntary basis during standard patient rehabilitation. Confidentiality will be reserved by inserting patient data with the use of arbitrary codes assigned to each patient with no known relevance to the patient. Results will not be individually reported, but rather they will be derived from piled data.

CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement of the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

Consent forms for participants, including adults as well as minors, gathered by staff at St Alexius Medical Center and will be kept within the facility (Addendum 3). No additional consent forms will be utilized for this study. A letter of agreement from St. Alexius Medical Center for inclusion of this study and the use of patient data is also attached (Addendum 4).

FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On-campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of human subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior approval as prescribed by the University's policies and procedures governing the use of human subjects.
DENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal
Panel) the University of North Dakota IRB is unable to approve your project unless the
"Student Consent to Release of Educational Record" is signed and included with
"Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD¹

In accordance with the Family Educational Rights and Privacy Act of 1974, I hereby consent to the
Institutional Review Board's access to those portions of my educational record which involve
research that I wish to conduct under the Board's auspices. I understand that the Board
may need to review my study data based on a question from a participant or under an
audit. The study to which this release pertains is Outcome Study of Physical
Therapy Rehabilitation of Patients with Patellar Femoral Dysfunction.

I understand that such information concerning my educational record will not be released
except on the condition that the Institutional Review Board will not permit any other party to
access to such information without my written consent. I also understand that this
process will be explained to those persons requesting any educational information and that
release will be kept with the study documentation.

________________________
Signature of Student Researcher

¹ Consent required by 20 U.S.C. 1232g.
APPENDIX D
LONGITUDINAL OUTCOME STUDIES

A longitudinal outcome study was set up for a variety of diagnoses, specifically surgical procedures September 1, 1995 by St. Alexius Medical Center and the Institute of Sports Medicine. Outcomes, specific to physical therapy, have been set up to be followed up for two years post surgery. The studies monitored will include those individuals who have undergone the following surgical procedures: Achilles tendon repair, ACL reconstruction, Bankart repair, biceps tendon repair, Brostrom reconstruction, capsular shift, patellofemoral joint surgery, as well as rotator cuff repair. All subjects are notified of the study and will have a consent form filled out specifically when they go beyond the normal insurance reimbursable time table. Please note that under no circumstances, subjects will be exposed to any procedure or test which is beyond the normal protocol.

Data compiled with the outcome studies will be kept within the Institute of Sports Medicine as well as original copies of specific tests during the normal rehab kept within the medical records department at St. Alexius Medical Center. The Bone & Joint Center will also be offering assistance in terms of the actual surgical procedures.

This letter is to notify those institutions which will be assisting in helping to compile this outcome data that individuals are fully aware of their participation in the study, and again, will be put at no risk other than the normal rehab procedures during the compiling of this data. If any questions, please call Kevin Axtman at 1-800-222-7858, assistant director at the Human Performance Center, also Doug Bradford, director of Rehab Services at St. Alexius Medical Center at 1-701-224-7189, or Myron Cullen, assistant director at the Human Performance Center at 1-800-222-7858.

Kevin Axtman, PT/LATC
Doug Bradford, PT
Director of Rehab Services

Richard A. Yschen, FACHE/CEO
St. Alexius Medical Center

"Let all be received as Christ."
APPENDIX E
REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

DATE: March 1, 1999  PROJECT NUMBER: IRB-9903-181
Dr. Renee Mabey, Scott Hurd,  DEPARTMENT/COLLEGE: Physical Therapy
AME: Tom Henke

PROJECT TITLE: Outcome Study of Physical Therapy Rehabilitation of Patients with Patellar Femoral Dysfunction

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on March 16, 1999 and the following action was taken:

☐ Project approved. EXPEDITED REVIEW NO. __________________________
☐ Next scheduled review is on __________________________
☐ Project approved. EXEMPT CATEGORY NO. ________
☐ No periodic review scheduled unless so stated in the Remarks Section.

☐ Project approved PENDING receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. This study may not be started until final IRB approval has been received. (See Remarks Section for further information.)

☐ Project approval deferred. This study may not be started until final IRB approval has been received. (See Remarks Section for further information.)

☐ Project denied. (See Remarks Section for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

LEASE NOTE: Requested revisions for student proposals MUST include adviser's signature.

Renee Mabey, Adviser 3
Dean, Medical School  Signature of Designated IRB Member
UND's Institutional Review Board

Date  3-16-99

f the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.
APPENDIX F
LONGITUDINAL STUDY CONSENT FORM

THE RESULTS OF YOUR REHABILITATION PROCESS ARE BEING GATHERED AS PART OF A LONG TERM STUDY OF SURGICAL AND FUNCTIONAL OUTCOMES OF YOUR PARTICULAR DIAGNOSIS. ONCE YOU HAVE COMPLETED YOUR FORMALIZED PHYSICAL THERAPY TREATMENT AND HAVE BEEN DISCHARGED FROM ST. ALEXIUS MEDICAL CENTER, WE WOULD APPRECIATE THE OPPORTUNITY OF RETESTING YOUR STATUS AT 6 MONTHS, 12 MONTHS, AND 24 MONTHS POST DISCHARGE. THESE LAST THREE VISITS WOULD BE FREE OF CHARGE AND ALL RESULTS WOULD BE MADE READILY AVAILABLE TO YOU.

WHEN UNDERGOING THESE TESTS, THERE ARE CERTAIN INHERENT RISKS WHICH INCLUDE THE POSSIBILITY OF MUSCLE AND LIGAMENTOUS INJURY. YOU SHOULD EXERT YOUR BEST EFFORT THROUGHOUT THE EVALUATION BUT AT NO TIME ARE YOU EXPECTED TO EXPERIENCE ANY INCREASE IN PAIN OR DISCOMFORT BEYOND A LEVEL YOU FEEL YOU CAN COMFORTABLY TOLERATE. AT NO TIME WILL YOU BE FORCED TO PERFORM ANY TESTS WHICH YOU DO NOT WISH TO PERFORM AS YOU ARE IN CONTROL OF THE TESTING AND MAY STOP WHENEVER YOU FEEL THAT YOU SHOULD NOT PROCEED. IF WE SEE YOU EXERTING EFFORTS, WHICH IN OUR OPINION MAY PLACE YOU IN DANGER, WE WILL STOP YOU.

BASED ON THE ABOVE INFORMATION THAT I HAVE READ AND UNDERSTAND, I AGREE TO PARTICIPATE IN THIS LONGITUDINAL STUDY.

________________________________________
DATE

________________________________________
PARTICIPANT SIGNATURE
REFERENCES


