A Randomized Control Trial of Acute Post Operative Care Following Anterior Cruciate Ligament Reconstruction: A Comparison of Two Protocols

by

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A thesis submitted in partial fulfillment of the requirements for the degree of

Master of Science

in

Rehabilitation Science – Physical Therapy

Faulty of Rehabilitation Medicine

University of Alberta

Abstract

Very little research has been conducted in this area, and the specific content of any of the protocols during this postoperative period have not been studied. Perhaps because most patients appear to be at similar functional levels by six to 12 weeks following surgery, the assumption has been made that this period of time does not require evaluation. Since the impact on the patient during this phase of recovery sets the tone for the rest of the rehabilitation, optimal short-term outcomes need to be studied because they ultimately may impact the mid and long range outcomes. The sooner patients regain range of motion (ROM) and muscle control the more safely they can return to their functional everyday activity and thus limit the impact of the surgery.

Acute postoperative knee care can impact the physical and emotional tone for the patient's recovery following surgery. Patients who experience an expedited reduction of pain, decrease in swelling, increase in ROM, increase in function, and improved ambulation may result in a faster integration back into the real world of school, work, social lifestyle, and sports.

The objective of this study was to design and implement a randomized control trial based upon consolidated standards of reporting trials (CONSORT) criteria in order to assess the results of the two postoperative protocols over the first six weeks following anterior cruciate ligament (ACL) reconstructive surgery. Subjects were randomly allocated into two groups following their surgery with each group following one of the two protocols. The effects of the two protocols were evaluated using four outcome measures: The International Knee Documentation Committee Subjective Knee score (IKDC), the numerical rating scale of pain (NRSP), circumferential measures and ROM. The four outcomes were recorded pre-surgery and at intervals of one week, two weeks and six weeks post surgery. In addition the IKDC and the NRSP scores were also

recorded at twenty-four hours post surgery. It was hypothesized that Protocol B which consisted of the existing Protocol A plus the instructional DVD would be statistically superior to the current protocol based upon the four outcome measures.

The results of the study rejected the four hypotheses showing no clinical or statistically significant difference between Protocol A and Protocol B. While it may be intuitive that Protocol B would result in better outcomes it did not. Changes in patient education programs, and changes in the patients care pathways in the course of the study, which the researcher had no control over and patient compliance may have affected the outcomes.

The optimal protocol can then be adopted to provide the best standard of practice for future patients following their ACL reconstructive surgery.

While it was the intent of this study to provide an improved protocol for the care of patients, during acute postoperative care following ACL reconstruction surgery, the study hypotheses were rejected for all four outcomes. This is not to say that improved care and understanding has not occurred. Based on the present study, as described above, the following conclusions can be made:

1. The IKDC subjective evaluation form may not be sensitive enough to measure change when used in the acute post-operative setting. Further research and testing of validity and reliability on the IKDC subjective evaluation form and its wording is required when used in the acute post operative stage following anterior cruciate ligament reconstruction.
2. Both post-surgical protocols provide guidance to the patient. The education of the patient prior to and during the implementation of a protocol, along with the interpretation of the information, may be a key factor in the success of a post-surgical protocol.

Preface

This thesis is an original work by Ian William Hallworth. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board. Project Name, “A randomized control trial of acute post operative care following ACL reconstruction - a comparison of two protocols” , Pro00033700, 11/6/2012.

Dedication

To my family, who have taught me and continue to demonstrate the importance of lifelong learning, determination, and perseverance. I would like to thank them for their love and support.

Acknowledgement

I would like to thank Dr. David Magee for being much more than a supervisor and providing me the opportunity to pursue my Masters Science in Rehabilitative Medicine. His patience and mentorship were essential.

I would also like to thank my committee members, Dr. David Otto and Dr. Lauren Beaupre, for their time, advice, and knowledge. Their support was invaluable.

Thank you to the Rehabilitation Research Centre, Corbett Hall, University of Alberta. Specifically Ziling Qin and Dr. Doug Gross.

Thank you to the administrative staff and physical therapists at the Glen Sather Sports Medicine Clinic for their support and patience while I was working with their patients.

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List of Abbreviations

ACL	Anterior cruciate ligament
CONSORT	Consolidated Standards of Reporting Trials
GSSMC	Glen Sather Sports Medicine Clinic
IKDC	International knee documentation committee subjective form score
MCID	Minimal clinically important difference
NRSP	Numerical rating scale of pain
ROM	Range of motion
RTC	Randomized control trial
SIRAS	Sport Injury Rehabilitation Adherence Scale

Chapter One

Introduction

Problem Statement

If one is involved in sports such as soccer, basketball, volleyball, or football, chances are the individual knows someone who has torn his/her anterior cruciate ligament (ACL). The highest risk group for this injury is the young athlete. In some sports, females are two to six times more likely to tear their ACL, (1-16) compared to men, with 50 percent of those injuries occurring between the ages of 15 and 25 years.

The ACL is one of four major knee ligaments critical for knee stability. At the time of their injury, people often complain of symptoms such as an audible pop, rapid swelling, pain, and their knee "giving-out" from under them. The resulting instability and risk of further injury leads many people who sustain an ACL tear to opt for surgical treatment. On average, 600 ACL surgical reconstructions are performed in Edmonton each year. In the United States, over 100,000 ACL reconstructions are performed each year (3,17-20). The recovery period from the time of injury to return to sport can take years (23-29).

The literature has shown that, without proper care, such knee injuries may lead to further knee damage, activity limitations, and early onset of osteoarthritis. (13,20-39,43-47). While there have been significant advances in the diagnosis (41), reconstruction (1,25-27), and rehabilitation of this injury (1,20,25-45), very little research on best practice guidelines for acute

postoperative care have been conducted to date (43,44). With proper patient education and comprehension of the recovery and rehabilitation process may provide more positive outcomes.

Acute postoperative care sets the physical and emotional tone for the patient's recovery following surgery. Present best practice recommendations encourage immediate weight bearing, pain management, control of swelling and inflammation, while establishing symmetric range of motion (ROM), muscle strength, and control (1,8,43,46,47). While these goals and methods are commonly used and practiced by most physical therapists and understood by orthopedic surgeons, inherent assumptions in practice are made that this information is well understood by the patient. The methods, frequency, duration, and intervals of the postoperative care intervention are not commonly included in the protocol.

It would be intuitive to assume that the more clear and explicit the protocol is, outlining the specific interventions and the quicker these postoperative goals are established, the safer the graft will remain and fewer postoperative complications will result. (21,39,43) One must remember, however, that too much information may lead to the patient not reading it and being less compliant as a result. In addition, the format of the information should also be considered; are written instructions, diagrams, or video information more effective for patient retention and comprehension? Is one format superior to the other? Which format will result in the best postoperative outcome measurements? Patients who experience an expedited reduction of pain, decrease in swelling, increase in ROM, increase in function, and improved ambulation have a faster integration back into the real world of school, work, social lifestyle, and sports (32, 51).

Definition of Terms

Subjects: Randomized volunteers who fulfill the inclusion/exclusion criteria and participate in the study.

Acute postoperative care: Patient care from the time of ACL reconstructive surgery to two weeks after surgery.

Swelling / Effusion: Extra articular and intra articular inflammatory reaction to trauma may include soft tissue swelling and effusion measured by circumferential limb measures as outlined in the methods section of this paper.

Symmetrical range of motion: The ability to perform bilateral active and passive ROM equally.

Active range of motion: The ROM of flexion and extension of the knee performed actively by the patient's voluntary muscle contraction, recognizing this is not a pure movement and involves accessory movements.

Passive range of motion: The ROM of flexion and extension at the knee, performed by the examiner, not involving the patient's voluntary muscle contraction, recognizing this is not a pure movement and involves accessory movements.

Pain: Individual subjective level sensation to noxious stimuli, as measured using a numeric rating scale (NRSP).

Purpose

This project was designed to investigate whether the existing acute postoperative rehabilitation following ACL reconstruction could be improved upon relative to the specific outcomes selected for the study. It compared two home-based patient education rehabilitation

protocols. Both protocols had identical goals using best practice standards. The existing control Protocol A contained general information regarding acute postsurgical care. This package was provided to participants who had undergone ACL reconstruction as a personal reference for their self-directed homecare recovery. This protocol was based on best practice standards. The intervention Protocol B, was identical to Protocol A but also included a DVD. The DVD illustrated a patient performing the appropriate exercises providing a constantly accessible resource base for the patient while stating specific goals and allowing patients to monitor their signs and symptoms through enhanced patient guidelines, outlining specific methods, frequency, duration, and intervals to better assist them in self-directed homecare. It was hypothesized that Protocol B would be statistically more effective than Protocol A.

Hypothesis

1. There would be a significant and greater increase in functional outcome using Protocol B compared to Protocol A, as measured by a modified International Knee Documentation Committee Subjective Knee form (IKDC).
2. There would be a significant and greater decrease in pain using Protocol B compared to Protocol A, as measured by a numerical rating scale for pain (NRSP).
3. There would be a significant and greater decrease in swelling using Protocol B compared to Protocol A, as measured by specific circumferential measurements.
4. There would be a significant and greater increase in symmetrical range of motion using Protocol B compared to Protocol A, as measured by goniometric measurements.

Limitations of the Study

This study was limited:

1. To measuring knee ROM using a goniometer, and heel height measure, recognizing limitations in reliability and validity as outlined in the literature and the linear measurement represented the complex motion of the arthrokinemetics of the knee. The author's pre study reliability was established to be: Flexion m=1.5 degrees S.D, 1.15 Extension m=2 degrees S.D. 1.18. Prone m=0.3cm S.D 0.63 cm in a pre study trial (see Appendix A)
2. To measuring circumference of the knee using a tape measure which represented change in diameter of the knee over time and did not represent any specific change such as muscle atrophy or strength. The author's pre study reliability was established to be: 10 cm above m= 0.71 cm S.D 0.66, 5cm below m=0.43cm S.D. 0.46 in a pre study trial (see Appendix B)
3. Patient compliance.
4. By the consistency of the surgical procedures and patient allocation to the study.
5. To a convenience sample.

Delimitations of the Study

1. The age of the subjects examined was between 16 and 44 years of age.
2. The study had only followed patients during the six weeks following anterior cruciate ligament reconstructive surgery.
3. The study addressed one specific surgical procedure and repair, a four-strand hamstring autograft ACL reconstruction as described by the surgeons performing surgery.

Chapter Two

Review of the Literature

Literature Review

This study was unique in that it examined the acute stage of postoperative rehabilitation following ACL reconstructive surgery. Very little research has been conducted in this area and the specific content of any of the protocols during this period has not been studied. Perhaps because most patients appear to be at similar functional levels by 6 to 12 weeks following surgery, the assumption has been made that this period of time does not need to be studied. Since the impact on the patient during this phase of recovery can sets the tone for the rest of the rehabilitation, optimal short term outcomes need to be studied because they ultimately could impact the mid and long range outcomes. The sooner the patients regain ROM and muscle control, the more safely they can return to their functional every day activity and thus limit the impact of the surgery.

Most of the literature and protocols addressing acute postoperative rehabilitation identify the goals of therapy, but few specifics and little research has been applied to this phase of the rehabilitation (39, 49-51). Postoperative rehabilitation varies greatly within clinical practice and within the literature (1,8,20,21,41-43,44). Patient care may range from weight bearing to non-weight bearing, braced to non-braced (51), and from hospital stays as reported in Shaw's paper on inpatient protocols varying from week-long bed rest to day surgery (43). Presently, the current standard of care in Alberta is day surgery.

In 1994, Schroder (51), using a prospective RCT design, studied the effect of cold and compression following ACL reconstruction. He performed group comparisons over time of: circumference measure ($P<0.035$), pain ($P<0.01$), and ROM ($P<0.05$) taken at 1, 2, 3, 6, 14, and 28 days, and demonstrated statistically significant effects. Schroder (51) identified and used very similar functional score measures as those proposed in the present study. While surgical methods and rehabilitation techniques have changed greatly since that time, the study itself provided a good working model for the current study.

Maddison (50) produced a study of similar design examining the psychosocial impact in post operative ACL reconstruction patients. He used video tapes that demonstrated post operative patients performing their exercises. Seeing patients like themselves performing the exercises helped the viewers limit fear and avoidance while promoting post operative exercises. By doing so, he demonstrated a statistically significant increase in both ROM and IKDC scores when compared to subjects who did not view the videos during the early post operative period. Maddison's study looked at the use of video to prevent patient fear avoidance. While some similar outcome measures were used in his study, the measures were recorded at different times over a longer time period and for a different purpose. The focus of the present study was to identify an effective acute post operative protocol.

The present study compared the presently used best practice protocol which uses written material and diagrams to the new protocol using a video format such as that used by Maddison (50). DVD format has been demonstrated to be a more effective method in upper extremity exercises programs (50). Fear of re-injury and avoidance are factors being cited in the literature as reasons for delay or non return to sport (3,53,54). These fears are also evident in the initial postoperative period and, again, set the tone for the rehabilitation process. The video format and

seeing similar patients performing the same exercises or activity was an added benefit of the video format.

Shaw (43), in his literature review of outcome measures following ACL reconstruction, provided an overview of the outcome measures used in this project. Two other literature reviews on evidence-based rehabilitation following ACL reconstruction by van Grinsven (21) and Risberg (55) also provided a further basis for this study. While the use of literature reviews should not be the sole source of information, they do provide a good starting point for finding references related to this topic.

Present Practice

Present best practice goals encourage immediate weight bearing, pain management, control of swelling and inflammation, while establishing symmetric ROM, muscle strength, and movement control (1,8,20,21,27,38,39,29,41,50). The measurements selected for this study were designed to reflect these goals. To detect meaningful change, an outcome measure needs to be valid, reliable, and responsive. The outcome measures selected have been used in studies related to ACL rehabilitation and are valid, reliable, and responsive while maintaining both time efficiencies and cost effectiveness.

Cryotherapy or a form of ice and compression following surgery is advocated in most, if not all, postoperative care plans following ACL reconstruction. The theory is to decrease the inflammatory response following the impact or trauma of the surgery by decreasing pain and swelling. Cryotherapy has been advocated for acute injuries for years, but what is not clear is what form of cryotherapy should be used. (56-61) The method, duration, and frequency vary greatly and best practice needs to be established. (e.g. Crushed ice or cubed? Peas or cold gel

packs? Ice machines with constant pressure or ice machines with varied pressure?) (56) The options are almost endless. Ease of use and cost are important factors in the implementation of a care plan.(61) Assumptions have been made that the patient understands what "icing" means whereas specific instructions would be easier to understand and evaluate.

Protection with bracing, limited weight bearing status and activity level of the limb following surgery are other factors that vary greatly among various proponents of postoperative care. Care may be very conservative involving significant bed rest, non-weight bearing on crutches and bracing to limit the acute inflammatory response of the surgery and to limit any stress to the repair which may affect the integrity of the reconstruction.(26,62-70)

In a 2006 survey of the immediate postoperative use of a knee immobilizer (unhinged brace) in Canada, Hiemstra et al. found that 47.7 percent of responding surgeons used a knee immobilizer immediately postoperatively. (52) Fifty two percent cited pain reduction as a reason for the brace, 39 percent cited graft site protection as the reason, 19 percent cited their reason was to maintain full extension, and 13 percent cited habit as the reason. The length of immobilization ranged from 5 to 42 days. The authors reported two similar studies that yielded similar results and cited the lack of scientific evidence for the lack of consensus. In the same survey, Hiemstra et al. reported, that most surgeons in Canada allow early weight bearing and range of motion in a controlled environment following reconstruction. (52)

The other end of the spectrum in postoperative care stresses early weight bearing, promoting patient confidence, a preference for no bracing, and minimal to no use of crutches. Early weight bearing and joint movement help promote patient confidence and help to maintain symmetrical range of motion attained at the time of surgery while preventing arthrofibrosis (40, 48). Active ROM promotes use of the muscles to minimize muscle atrophy while both pain-free

active ROM and continual passive ROM can help with pain control and limit muscle and joint adhesions. (26,62-70)

The balance of protection and mobility seems to be to protect the repair and to limit the inflammatory response while trying to encourage early ROM in order to prevent factors that can lead to adhesions, limited range of motion, and muscle atrophy. As with the cryotherapy, the method, duration, frequency used vary greatly.

Full ROM is one of the goals of ACL reconstructions. Full range of motion is hyperextension in 99 percent of females, with 5 degrees being the average, and 95 percent of males with 6 degrees being the average. ROM must reflect this hyperextension and any discussion of ROM should refer to symmetry and hyperextension, not neutral extension, both during surgery and rehabilitation. Biggs et al (33) cited the lack of ROM as being an underlying cause of strength loss and function .

When examining any knee, it should be compared to the opposite knee while noting whether there was any previous injury to the knee. When measuring outcomes for this study, symmetry of the two knees was considered and was an eventual goal. Symmetry is the property of being the same or corresponding to both sides of a central dividing line. In terms of ACL reconstruction, this can apply to many things. Noyes and Barber (71) referred to symmetry of hopping during hop tests used to identify deficiencies following ACL reconstruction at end stage return to sport. Symmetry may also refer to symmetry of weight bearing during early and end stage rehabilitation. Bilateral symmetry may refer to strength, muscle bulk, or movement throughout rehabilitation. Symmetry may well include all of these factors and can be limited as a result of pain, swelling, loss of range of motion, weakness, joint restrictions, proprioception, and/or body awareness, all of which should be a primary focus in early postoperative care.

Symmetry of hyperextension, strength, movement, and function is the ultimate goal of both surgery and rehabilitation.

The goal of ACL reconstruction is to improve the function and functional stability of the knee. Outcome measures are used, in part, to determine a successful return of knee stability and a return to full pre-injury function following ACL reconstruction. The IKDC subjective form is a direct functional outcome measure. As function is the primary goal of ACL reconstruction, the IKDC subjective form was chosen as the primary outcome measure for the present study (21,33,42,50,55,73,74). Maddison's (50) paper on modeling and rehabilitation following ACL reconstruction, provided a basis for IKDC use in a more acute stage of rehabilitation and looked at self-efficacy and functional outcomes. While pain, as measured with the NRSP, and swelling and ROM, as detected by circumferential measure and goniometer measures, are not direct measures of function, these quantifiable outcome measures are representative of components needed for function and were used as secondary measures, in the present study.

The surgeons and therapists can guide, educate, and facilitate, but ultimately, it is the patient who has to do the work. Patient adherence to prescribed rehabilitation, be it at a clinic or home-based, is vital to a good outcome (73). Patient's motivation, level of education at the time of preoperative and postoperative procedure, care, and rehabilitation as well as their exercise experience and ability to work independently help determine success (38).

Grant (38) looked at two retrospective studies and two prospective RCT studies comparing clinic and home-based ACL rehabilitation programs. The studies suggested that these patients were successful using a home-based program. He noted that more power would have been created with a larger sample size. Grant then carried out such a study concluding that

recreational athletes undergoing non-acute ACL reconstruction could successfully reach acceptable rehabilitation goals in the first three months after surgery.

The existing home-based protocols used in Grant's study were successful, as outlined in his paper (38). While the surgeons and patients seem pleased with the existing protocol in the currently proposed study, no study has been performed to assess the effectiveness of the protocol to date.

It was then proposed to evaluate the effectiveness of the two protocols comparing the existing Protocol A to a new Protocol B, which used a video format and clear instructions, outlining the goals of the acute rehabilitation period and of the exercises the patients would perform. Patient progress in both protocol groups was then monitored. The results were measured and evaluated for effectiveness, thus identifying the acute postoperative rehabilitative protocol that provided the best practice standards during this phase of rehabilitation, and would provide a standardized procedure which could then be more systemically evaluated in terms of mid and longer term outcomes in the future.

Compliance

Compliance is an issue with any research. Compliance during this study was monitored by the use of a patient-recording diary. The Sport Injury Rehabilitation Adherence Scale (SIRAS) for monitoring patient adherence to rehabilitation was used by the researcher to observe and record compliance (38,73). SIRAS is a numerical score using three indicators: intensity of participation, frequency of following instruction, and degree of receptivity to changes made to

assess in clinical adherence graded by the physical therapist based upon his/her observations on a scale where '1' was the minimum and '5' was the maximum measure.

Present State of ACL Reconstruction

Presurgical rehabilitation, education (20,53,54,75), the surgical procedure (25-27,32,76) and rehabilitation of this injury (20,21,32,55,,65,79-81) impact acute postoperative rehabilitation. During the presurgical period, the literature supports focusing on optimizing the condition (i.e. strength, endurance, flexibility, cardiovascular fitness) of the individual and the knee (i.e. swelling, range of motion, muscle balance) (42,46,48,55,64,84). Such a presurgical rehabilitation program limits detraining of physiological systems and decreases the risk of surgical complications. (21,38,39,43,55,85)

Pre-Operative Rehabilitation

Just as in acute postoperative rehabilitation, the goals of pre-operative rehabilitation are to minimize pain, swelling, and inflammation while establishing full symmetrical range of motion along with strength and neuromuscular control in order to maximize functional activity. The patient should be actively working on cardiovascular fitness, knee muscle strengthening, flexibility, and body mechanics while limiting the risk of re-injury that could occur with throwing, pivoting, and repetitive lower limb high impact activities (21).

Surgical Reconstruction

The surgical procedure used impacted the acute postoperative rehabilitation. The bone-patellar tendon-bone reconstruction required bone and tissue harvesting and might have impacted quadriceps control more than a hamstring tendon or allograft repair. Some surgical procedures are more invasive resulting in more trauma to the joint and surrounding tissues, inflammation, and impact pain, swelling, range of motion, and muscle strength to a greater degree. Secondary repair of meniscus or micro fracture of the chondral surface may have also increased the trauma of a surgery.

Acute Postoperative Rehabilitation

Acute postoperative rehabilitation refers to the first two weeks following surgery. Anterior cruciate ligament reconstruction in Alberta is day surgery. The patient is discharged home with a self-administered, general home-based therapy program to follow. Patients do not usually see the surgeon or physical therapist until two weeks following their ACL reconstruction. While pre-operative education attempts to prepare patients for what to expect physically as a result of the surgery and prepare them for the rehabilitation, the fact remains that patients have not usually experienced this surgery previously nor the accompanying pain, weakness, swelling, fear, and apprehension. During this crucial period, while the physical and emotional tone for the rehabilitation is being established, it is crucial that the patients understand and follow their rehabilitation program (21,23).

There is consensus in the literature that the goals of acute postoperative rehabilitation should be to decrease pain, swelling, and inflammation, while increasing ROM and strength

(19,30,34,35,49,71). Such a rehabilitation program allows for early functional recovery of gait and activities of daily living. There is also consensus in the literature that the use of continual passive motion machines (CPM) and bracing is not required (2,57). Early weight bearing is encouraged with limited use of crutches (2,6,11,12,43,52,69).

Early weight bearing allows for joint compression and nutrition of the joint (18). In 1998, Tyler showed early weight bearing increased initial vastus medialis obliquus activation and decreased anterior knee pain without compromising knee joint stability (26). Early weight bearing and joint movement helped to promote patient confidence and to maintain symmetrical range of motion attained at the time of surgery while preventing arthrofibrosis (72,73). The caution with early weight bearing and this phase of rehabilitation, in general, is the balance of protection and mobility. It is desirable to protect the repair and limit the inflammatory response while at the same time trying to encourage early ROM in order to prevent factors that could lead to adhesions, limited range, and muscle atrophy. As with the cryotherapy, the method, duration, and frequency of using a brace and limiting weight bearing for protection versus early mobility vary greatly within the literature.

Pain control during this acute stage of care involved the use of medications prescribed by the surgeon as well as over-the-counter medications. Monitoring of medication use in the patient diary helped in determining pain control. Icing is another form of pain control in acute traumatic and surgical situations. Pain, swelling, and inflammation, if not controlled, may result in post surgical complication, loss of range of motion, decreased quadriceps control, altered gait, and prolonged recovery (51,57). Ease of use, patient compliance and cost are important factors in the successful implementation of a successful rehabilitation plan.

Outcome Measures

A tool used to measure outcomes should be easy to administer and be both time and cost effective (43,67). The outcome measures selected for this study were used to detect change between the two differing protocols. To detect meaningful change, outcome measures needed to be valid, reliable, and responsive (67). The outcome measures selected have been used previously in ACL rehabilitation studies. The measures selected were valid, reliable, and responsive. While pain, swelling, and range of motion are not functional, these quantifiable outcome measures are representative of components needed for function and were used as secondary measures. The IKDC subjective form is a direct functional outcome measure. As function is the primary goal, it was the primary outcome measure.

International Knee Documentation Committee (IKDC)

The IKDC is a measure of knee function. It is commonly used in the literature as a subjective measure of the patient's function following ACL reconstruction, rehabilitation, and return to sports. The form is more often used as a long term outcome measure. It consists of ten questions on two pages, divided into three sections: symptoms, sports activities, and function. The IKDC item responses are added and then divided by the total possible number of points and then multiplied by 100 to create the score. The higher the score, the less the disability, as outlined in Appendix C.

The IKDC is commonly used as an outcome measure during all phases of ACL rehabilitation, but more so as a mid or long term outcome measure at three months, six months, twelve months, or longer. Maddison (50) and Chmielewski (49) used the IKDC scores at four

and six week follow-ups. Chmielewski (74) reported an ICC of 0.94 for test-retest reliability, a minimal detectable change of 12.8, and a standard response mean, with the mean change divided by the standard deviation of change scores of 0.94. It has been shown to be both reliable and valid (67) and to demonstrate responsiveness (66).

The Numerical Rating Scale (NRSP) is used to measure pain intensity, with '0' representing no pain and '10' representing the worst pain imaginable. The patient is asked, "If zero represents no pain and ten represents the worst pain imaginable, what is your pain at present?" This method is commonly used clinically as well as within the literature and specifically in the study of ACL rehabilitation (21,43,50,75). Herr et al (80) demonstrated 100 percent inter rater reliability, internal consistency of alpha = 0.89 for ages 25-55 years, a criterion validity of 0.87, and good responsiveness within a healthy population using the NRS. Bijur et al. (81) demonstrated excellent construct validity with an excellent correlation between the NPRS and the Visual Analogue Pain Scale (r = 0.94, 95% CI = 0.93–0.95) and an ICC of 0.74 and 0.76 with a minimal detectable change being 2.5 and 2.1 in patients with shoulder and neck pain respectively (49).

Circumferential measure is a combined measure of soft tissue swelling, the composition of the limb, soft tissue mass (primarily muscle), vessels, nerves, and bone, along with the joint effusion. This measure is often used following knee surgery and specifically ACL reconstruction. Circumference measures have been used to evaluate muscle atrophy, knee joint swelling, and effusion. While a popular clinical tool, the validity of the measure has not been well established. An increase or decrease in circumference measure does not identify the quality of that volume increase, swelling versus effusion, fat versus muscle. Used as a measure comparing the contralateral leg, by measuring pre and post surgical size over a shorter period of

time, the increase and decrease of circumference volume should primarily reflect swelling and edema in the area. Knee circumference measures would appear to be an appropriate indicator of knee swelling. The change in size does not, however, distinguish the content of the increase or decrease in volume. Intra-rater reliability has been established to be high in both normal and anterior cruciate ligament reconstructed knees (43).

As a measure of postoperative swelling, a difference of 1.5 cm compared to the non-surgical leg is considered significant at a 95 percent confidence interval (43,51). The validity of the circumferential measure has not been established presumably as it measures only circumference and does not attempt to identify the tissue within the circumference. The measure has been shown to have an intra-rater reliability 0.82-0.99 ICC as shown in the Table 1.

Table 1: Intra-tester Reliability Studies of Knee Circumference Measurement (From Shaw (43) pg 60)

Authors	Number of Subjects	Subject pathology	Location of measurement	Reliability (statistical test)
Harrelson, Leaver-Dunn, Fincher & Leeper, 1998	21	Normal	Medial joint line	*R*=0.98-0.99 (ICC)
Soderberg et al, 1996	18	ACL and normal knees	Medial joint line	*R*=0.82-0.98 (ICC)
Soderberg et al, 1996	18	ACL and normal knees	5 cm above Medial joint line	*R*=0.93-1 (ICC)
Whitney et al, 1995	29	Normal	Superior and inferior pole of the patella and medial joint line	*R*=0.91-1$^{\partial}$ (ICC)

ICC Intraclass correlation coefficient

∂ Intra-rater reliability was calculated using a mean of three trials and also reported for same day measurement and measurements performed on different days.

Range of Motion (ROM) was measured using a long arm goniometer. A goniometer does not measure the arthrokinematics of true joint motion; rather, it measures an axis, and two long arms create a repeatable angle that represents true joint motion. This is an objective tool which has been shown to be both valid and reliable. Construct validity of (r = 0.97-0.98 and ICC=0.98-0.99) as compared with x-ray measures was demonstrated by Currier, and Gogia et al as demonstrated in table referred to in Shaw (43). Studies have demonstrated intra-rater reliability measures ranging from 0.869 to 0.99 ICC and inter-rater reliability ranging from 0.50 to 0.97 ICC for ROM measurement (10). (Table 2)

Table 2: Goniometry Intra-tester and Inter-tester Reliability (From Shaw (43) pg 59)

Intra-tester reliability		Inter-tester reliability	
Study	**Reliability (statistical test)**	**Study**	**Reliability (statistical test)**
Boone et al, 1978	0.869[∂]	Boone et al, 1978	0.502[∂]
		Gogia et al, 1987	0.98 (PCC)
Mayerson et al, 1984	0.99 - 0.99 (PCC)	Mayerson & Milano, 1984	0.97 (PCC)
		Rheault et al, 1988	0.87 (PCC)
Rothstein et al, 1983	0.91 – 0. 99 (ICC and PCC)	Rothstein et al, 1983	0.57 – 0.93 (ICC and PCC)
Watkins et al, 1991	0.98 - 0.99 (ICC)	Watkins et al, 1991	0.86 - 0.90 (ICC)

PCC, Pearson's product-moment correlation coefficient: ICC, Intraclass correlation coefficient.

a. Specific statistical test not reported.

The physical therapist measured both active and passive joint ROM. Active ROM refers to the amount of motion a patients are able to generate on their own. Passive ROM refers to the range available when the examiner moved the joint through its available ROM. The goniometer measures flexion and extension of the knee motion; these motions are complex and require glides and rotation of the joint. It must be remembered that when measuring flexion and extension, the measurement did not measure the complex combined motion (arthrokinematics) of the joint. A loss of flexion or extension can result in a change in arthrokinematics, a result of neuromuscular pathology, joint limitation such as swelling, loose bodies or capsular adhesions; and, in the case of anterior cruciate ligament reconstruction, improper positioning of the graft, all of which need to be restored for normal symmetrical motion of the joint.

While few previous studies have been reported concerning the acute post operative care following ACL reconstruction, the literature review supports the outcome measures proposed in this CONSORT criteria RTC for comparing the two proposed protocols. If one of the two protocols demonstrate statistically or clinically significant differences superior results relative to the selected outcome measures, that protocol may be used in the future and result in earlier return to function following ACL reconstruction.

Chapter Three

Methods

Project Design

This randomized controlled trial was an experimental two-group pretest – two-group post-test design using CONSORT criteria. Such a design used a sample of patients undergoing ACL reconstruction randomly allocated to one of two postoperative home-based rehabilitation protocols. Group one was the control group and used the existing acute postoperative Protocol A. Group two was the intervention group using the new video format acute postoperative Protocol B. A control group was not used in this study as it would have been unethical to provide no patient care. Participation was limited to patients in proximity to Edmonton to facilitate compliance with three follow-up appointments at one week, two week, and six weeks post-surgery (convenience sample) conducted by the physical therapist. The two groups were compared using a variety of outcome measures.

Subjects

Fifty participants were to be recruited from a preoperative ACL reconstruction clinic conducted by two orthopedic surgeons. The actual number recruited was 41, this representative samples from the ACL clinic reflects the diverse backgrounds, age, and gender common to the ACL reconstruction population in the Edmonton area. Participants met the agreed upon surgeons' preoperative criteria, and were then identified by the surgeons as a surgical patient and

placed on the surgical list. The subjects on the surgical list were then given the opportunity to enter the study provided they fulfilled the selection criteria and were not eliminated by the exclusion criteria. Combined, the surgeons performed approximately 25 ACL reconstructions per month. With the majority of patients residing in the Edmonton area, it was anticipated that 50 percent of the patients from the surgical list would agree to participate in the study. At that rate, it was projected that an adequate sample of patients who meet the inclusion/exclusion criteria would be recruited within four months.

Inclusion Criteria

The following were the inclusion criteria of this study:

1. Participants had an ACL deficient knee as determined by clinical exanimation by the orthopedic surgeon.
2. Participants were male or female between the ages of 16 and 44 years, inclusive, in order to limit factors associated with anatomical growth and degenerative changes of aging.
3. Participants had a surgical reconstruction a minimum of eight weeks and a maximum of 12 months from the time of injury to surgery.

Exclusion Criteria

The following were the exclusion criteria of this study:

1. Any complication that arose during surgery which precluded the ability of the patient to follow the assigned protocol.

2. Any surgery that resulted in increased trauma as a result of an increased invasive surgery such as secondary ligament repair, chondral microfracture, and complications that increased pain or swelling, as deemed by the surgeons.
3. Any neurovascular conditions that could influence pain and circumferential measurements taken during the study.
4. Workers' Compensation clients as they might require special consideration in designing their rehabilitation program.
5. Patients from outside the Edmonton area who were unable to receive follow up measures for the study.

The larger the exclusion criterion, the less external validity exists, thus making it more difficult to apply the study findings to the ACL patient population. This study limited the exclusion criteria allowing the results to be relevant to as many patients undergoing anterior cruciate ligament reconstruction as possible.

Sample Size and Power Relative to the Primary Outcome

Before conducting the study, the sample size had to be justified to ensure there would be enough participants to demonstrate a statistically significant effect, if one did exist. The primary outcome measure was the IKDC subjective knee form. Statistical data for the time period of 24 hours to six weeks postoperative, the time period proposed in the present study, was limited. In his 2011 publication, Chmielewski (49) had sufficient data to allow a treatment study size calculation for the use of the IKDC at 24 hours to four weeks measure. With a standard deviation of 12.3, mean response on therapy of 49.6, and a mean response of standard therapy of 26.5, the resultant sample size was 5.88 per group at a power of 95% and an alpha level of 0.05.

The minimal clinically important difference (MCID) was reported to be 11.5 (66). Power calculations were performed to establish sample size using Chmielewski data and then again using MCID as outlined in (see Appendix D). The MCID power calculation was used for the current study as the objective was to identify and to adopt the protocol with the best clinical results.

While many studies establish sample size based on the primary outcome measure, other outcome measures should be checked for adequate sample size to demonstrate an effect. Data was again used from the Chmielewski (49) study to run a sample size based on a postoperative measure and two week follow-up to allow a treatment study size calculation. Chmielewski (49) had sufficient data to allow a treatment study size calculation for the use of the NRS pain intensity at a 24-hour to two-week measure. With a standard deviation of 1.9, mean response of the comparison therapy of 3.3, and a mean response of standard therapy of 1.1, the resultant sample size was 15.66 per group at a power of 95% and an alpha level of 0.05. The minimal clinically important difference in ACL injury has not been reported. In an acute hospital setting, it is reported to be 1.7. As with the IKDC calculation (MCID) was used in the current study as outlined in (Appendix D).

To allow for possible drop outs or surgical complications, it was decided to expand the sample size to 25 subjects per group for a total of 50 subjects.

Procedure

Potential participants were identified from the population of patients attending a preoperative ACL reconstruction clinic at the University of Alberta Glen Sather Sports Medicine

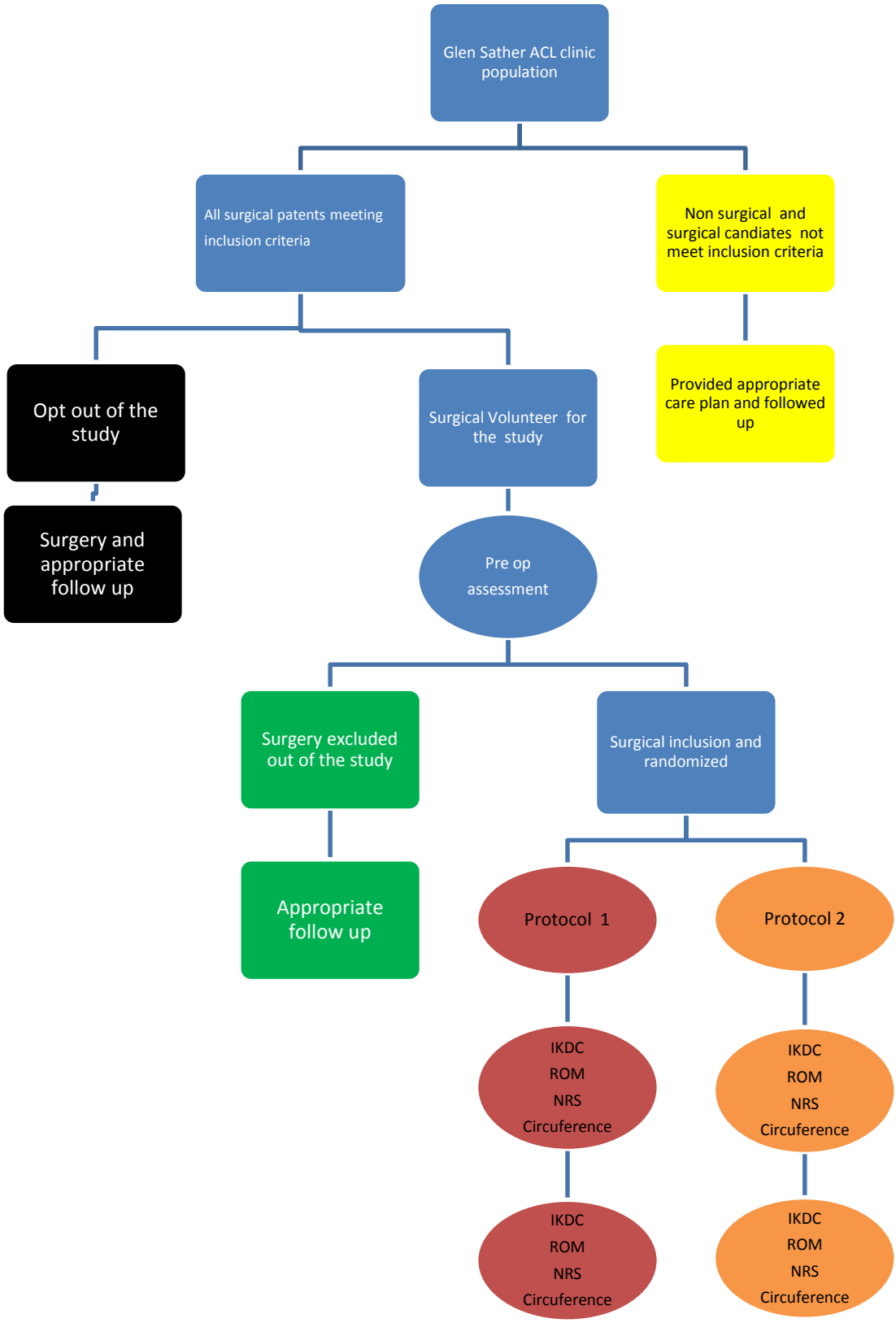
Clinic (GSSMC). All patients with ACL injuries were referred to the orthopedic surgeon from sources throughout northern Alberta. This clinic was conducted by a multidisciplinary team consisting of an orthopedic surgeon, a physical therapist, a nurse, and an administrator. All patients were educated and assessed relative to their individual situation. The surgeon and the patient then determined if ACL reconstructive surgery was required. Surgical patients then received further education on the surgical procedure, its risks, and complications. What could be done to optimize the patient's condition prior to surgery, preparing for the surgery, and what to expect following surgery, the rehabilitation process, and return to activity? This information was also available on the GSSMC website as an additional resource for the patients. The patients identified as surgical candidates by the surgeon and who agreed to participate in the study were informed about the study and signed their consent to participate. They then became potential study participants. Participant information relative to the study: age, gender, height, weight, mechanism of injury (contact or non contact) was collected. Once all paperwork and education was completed, potential participants were given contact information and a physical therapy appointment arranged for one week prior to their surgery.

Potential participants were assessed one week prior to surgery by the sole physical therapist in this study to ensure their compliance with the surgeon's preoperative surgical criteria.

- All participants had minimal or no joint effusion prior to surgery.
- All participants had full symmetrical range of motion (of the non operative knee) prior to surgery.
- All patients had a pain level less than 3/10 on the NRSP.
- All participants demonstrated an absence of quadriceps lag and the presence of quadriceps control prior to surgery.

Patients were assessed preoperatively at the GSSMC using all of the study's outcome measurement tools. These measurements, along with the postoperative baseline measurements, helped determine that the groups were similar. This assessment ensured that educational and administrative steps had been followed and allowed participants to review the ACL reconstruction procedure, postoperative rehabilitation plan, their post-operative exercises, and provided an opportunity for the patients to ask questions. Patients were randomly allocated to Protocol A or B. The protocols were home-based, meaning subjects received instruction on monitoring and follow up; however, the majority of the program was performed on a daily basis at home by the patient. The goals of both protocols were based on present best practice standards. Both protocols included a patient information handbook, a crutch walking information handout, and an exercise sheet. The difference between the protocols was that Protocol B included a DVD in which a patient demonstrated appropriate exercises that clearly showed the goals of the intervention, and how to perform the exercises. Understanding the goals of the exercise allowed patients to monitor their progress and potential problems that may develop. It was hypothesized that the patients in Group B would achieve their postoperative goals quicker. Improved muscle control and improved gait could result in less stress to their grafts and fewer postoperative complications. (21,39) Figure1 outlines the subject flow and their assessment schedule for the project.

Figure 1: Flowchart and Assessment of Subjects for Research Project



All patients from both protocols were assessed onetime pre operatively and a total of four times postoperatively: One at home, a self administered baseline measurement 24 hours following surgery, along with three follow up measurements at the GSSMC at one week, two weeks, and six weeks post-surgery performed by the physical therapist. The outcome measures were performed by the same physical therapist "blinded" to group allocation. Twenty-four hours following surgery, the patient completed the IKDC form and NRSP post-surgical baseline measures. The physical therapist telephoned each subject to confirm the completion of these measures and to ensure subjects had no postoperative concerns. The ROM, circumferential measure, IKDC and NRSP scores were recorded by the physical therapist at the one week, two week, and six week follow-up post surgical assessments at the GSSMC.

- Group A followed the postoperative care Protocol A, as outlined in (Appendix E).
- Group B followed the postoperative care Protocol B, as outlined in (Appendix F).

Both protocol groups received:

1. Pre-operative education outlining what should be done prior to surgery, what to prepare for prior to surgery, what to expect following surgery and the rehabilitation from acute post surgery to return to activity.
2. Early weight bearing as tolerated with no bracing.
3. Pain control using standard prescribed medication.
4. Pain and swelling control using standard cryotherapy practice.
5. Standard ROM exercises to decrease swelling and increase range of motion.
6. Muscle control exercises.

Protocol A differed from Protocol B as follows:

1. Patients in Protocol A received their information in written and diagram format while Protocol B patients received the same information as Protocol A but also in a DVD format.
2. Protocol B had patients demonstrate the exercise along with clearly stated goals, methods and how to monitor the exercises using DVD format.

Day surgeries were performed at the Grey Nuns Hospital in Edmonton using a standardized procedure by the surgeons. The anterior cruciate ligament reconstruction was a four-strand hamstring autograft in a single femoral and tibial bone tunnel (using anteromedial porthole drilling to create the femoral tunnel), with suspensory femoral fixation (CL Endobutton) and interference screw tibial fixation (metal RCI screw).

Patients were then discharged, and reminded of their previously assigned one week and two week follow up appointment times.

Once all patients had completed the study, each group's demographic and preoperative information was compared using the descriptive and inferential statistics appropriate to the outcome measured. Baseline comparisons were made to ensure that both groups were similar prior to surgery. This information ensured that each group had similar demographics; or, if a difference existed, it might have been a confounding variable of the study. If the characteristics were similar, it could then be said that these factors did not interfered with the effect of the postoperative protocol comparison. The data were compared for all measurements. The differential and interferential statistics was compiled in order to compare the two groups, Protocol A and Protocol B. The two group's outcomes were compared relative to pain, range of

motion, circumferential measure, and the IKDC form. Patients who missed more than one of the three follow up outcome measure session were dropped from the study. To account for attrition, additional participants were to be recruited.

Outcome Measures

International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form is a measure of knee function and was the primary measure of this study. It is commonly used in the literature as a subjective measure of patient's function following ACL reconstruction, rehabilitation, and return to activity. The test is more often used as a long term outcome measure.

The numerical rating scale for pain (NRSP) is a measure of pain intensity, with '0' representing no pain and '10' representing the worst pain imaginable. Patients were asked "If zero represents no pain and ten represents the worst pain imaginable, what is your pain at present?" This method is commonly used clinically as well as within the literature and specifically in the study of ACL rehabilitation (21,43,50,75). The NRSP attempts to define the quantity of pain experienced by an individual during an activity or rest at a set point in time. The advantage of this scale is that it is inexpensive and easy to administer. The scale has been demonstrated to be reliable and valid for measurement of acute and chronic pain. (43,80,81) Most subjective tests do not account for cultural differences, nerve injury, or neurological pathology and this must be considered in implementing these tests. The exclusion criteria and comparison of group demographics would limit the impact of these factors.

Circumferential measure when measured by the physical therapist was a combined measure of swelling, effusion, and the composition of the limb soft tissue mass (primarily muscle), vessels, nerves, and bone. This measure is often used following knee surgery and specifically ACL reconstruction. Each patient was measured in a relaxed, supine position with a

plastic tape measure placed 10 cm above the joint line at the joint line and 5 cm below joint line. As a measure of postoperative swelling, a difference of 1.5 cm compared to the non-surgical leg is considered significant at a 95 % confidence interval (43,57). Reliability for the present study was established in a trial study of ten subjects. (See Appendix B and C).

Range of motion (ROM) was measured by the physical therapist with the patients positioned in a relaxed, supine position for both active and passive range measurements. For passive measurements, in extension, the heels were supported by a standardized 10 cm bolster. Knee ROM was measured using a long arm goniometer using the lateral epicondyle as the axis with the middle of the greater trochanter of the femur and lateral mallelous of the fibula as a point of reference for the arms of the goniometer (43). Three measurements were taken with an average of the three measurements calculated to determine the measurement to be used in calculating the results. This is an objective tool which has been shown to be both valid and reliable (57). To help ensure symmetric extension is measure accurately, the patient was also placed in the prone position with their knees resting off the plinth at the base of the patellar and the difference in heel heights was measured to the nearest centimeter using a plastic ruler. Reliability for the present study was determined in a trial study of ten subjects. (See Appendix B)

Compliance

Compliance to the rehabilitation process has been identified as a key component to successful outcomes. This would be especially true with a home-based program. For this study to be successful, compliance would be a key factor. Compliance was monitored through the use of a participant's diary. All participants from both protocols kept a diary and recorded each time they iced or exercised, and recorded their pain level prior to each session. The number of

recordings made was expressed as a percentage of the total possible recordings. See (Appendix G).

The Sport Injury Rehabilitation Adherence Scale (SIRAS) for monitoring patient adherence to rehabilitation was used by the physical therapist to observe and record compliance. The SIRAS was scored by the physical therapist at the one week, two week and six week follow-up sessions. The interval scores were then used to calculate the mean and standard deviation. The difference between the two groups was then calculated. This project was not a study of compliance, rather, the compliance measures were to add support that an intervention had occurred (Appendix H).

Pizzari investigated adherence to rehabilitation after anterior cruciate ligament reconstruction (86). The SIRAS compliance score and IKDC were used, but were scored at the nine and twelve month marks, not in the acutely post operative period as in the present study. The study enrolled 68 patients, 42 males and 26 females, between the ages of 16 and 52 years (86). The average age of 28.8 years is both similar in age range and a mean of 4 years relative to the present study. All three of these studies had similar age ranges, and means, along with a greater proportion of males to females compared to the present study.

In order to minimize bias and maximize accuracy, patients were asked not to rely on memory; but, rather, to record the information at the time of performing the intervention. Patients were informed that this information would add to the value of the study, and they were advised not to randomly or sporadically complete the form. This method has been used in previous studies (29,73). This scale was used as a tool to limit other possible variables.

Data Analysis

International Knee Documentation Committee subjective scores While the scores are an ordinal measure, they are usually treated statistically as an interval measure. The IKDC score was recorded for all participants at 24 hours post surgery and at the one week, two week, and six week follow-up assessments by the physical therapist. The difference between the protocol groups was measured as a mean and standard deviation and compared using a two-way repeated ANOVA.

The Numerical rating scale pain score is an ordinal measure and was recorded for all participants at 24 hours post surgery and at the one week, two week, and six week follow-up assessments by the physical therapist. The difference between the protocol groups was measured as a mean and range, and was compared using a Friedman two-way ANOVA test.

Circumference Measure is an interval measure and was recorded for all participants at the one week, two week, and six week follow-up assessments by the physical therapist. The difference between the protocol groups was measured as a mean and standard deviation and compared using a two-way repeated ANOVA test.

Range of Motion is an interval measure and was recorded for all participants at the one week, two week, and six week follow-up assessments by the physical therapist. The difference between the protocol groups was measured as a mean and standard deviation and compared using a two-way repeated ANOVA test.

Ethical Considerations

Prior to the study, the proposal was submitted to Health Research Ethics Board of the University of Alberta for approval. The Health Panel reviews all non-invasive health research where the researcher would access health information (as defined in the Health Information Act of Alberta).

The surgeons and the literature note that rehabilitation is a key component of a successful ACL reconstruction. The option of no rehabilitation would increase the risk of complication and an unsuccessful outcome. The existing Protocol A has been used effectively for a number of years and is based on present best practice goals. The new Protocol B was believed to be an improved version of Protocol A with additional information and, therefore, would add no increased risk.

All participants were educated in a pre-operative ACL teaching clinic regarding the injury, the surgical procedure, the risks associated with the surgery, the rehabilitation, and postoperative care. All participants were monitored for any potential risks and complications by the physical therapist that called the patients 24 hours following surgery and conducted assessments at one week, two week, and six weeks post-surgery. All participants were also seen by their surgeon at the standard postoperative follow-up appointment two to three weeks post-surgery. Standard practice for patients outside of the study would be to receive only the two week follow-up appointment with their surgeon.

All participants were informed of the study procedure, risks, and precautions. Their participation was voluntary and they could have withdrawn at any time. Their information and data were identified by a code, not a name, and was kept confidential as outlined in Appendix I.

Once the participant had read and understood the information, and their questions had been answered, a signed and dated consent was obtained, as outlined in Appendix J.

Summary Statement

Through the design, procedures and methods described, reliable and relevant data were compiled. It was hoped the analysis of the data would confirm the stated objectives. The information attained, whether supporting or refuting the hypothesis, would help improve and direct the rehabilitation of patients following ACL reconstruction. Patients who experienced an increased reduction of pain and swelling, and an increased ROM and function would experience fewer postoperative complications while having a safer, quicker integration back into the real world of school, work, social lifestyle, and activity.

Chapter 4

Results

Sample Demographics/Characteristics of Subjects

One hundred and twenty nine subjects were identified according to the study criteria from the GSSMC ACL surgical clinics. They were contact by phone to volunteer for the present study, 49 or 38% did not reply to messages left. 41 or 50% of the 80 contacted volunteered for the study. The other 39 or 50% that did not volunteer identified geographic difficulties, wish for the investigating physical therapist do the rehabilitation as primary reasons for not volunteering.

The present study randomized forty one subjects into two groups. Four of the original forty one subjects withdrew from the study prior to the one week follow up. Two were from out of town and two subjects found themselves too busy with work to attend the follow up sessions. Of the remaining thirty seven subjects Group A represented 20 subjects: 12 male and 8 female with a mean age of 26.8 years, with a S.D. of 7.6 years. Fourteen of the 20 subjects sustained non-contact anterior cruciate ligament injuries. This group used the existing anterior cruciate ligament reconstruction protocol following their anterior cruciate ligament reconstruction. Group B represents 17 subjects: eight male and nine female with a mean age of 21.4 years with a S.D. of 5.5 years. Fifteen of the 17 subjects sustained a non-contact anterior cruciate ligament injury. This group used the existing anterior cruciate ligament protocol plus a DVD supplement following surgical reconstruction.

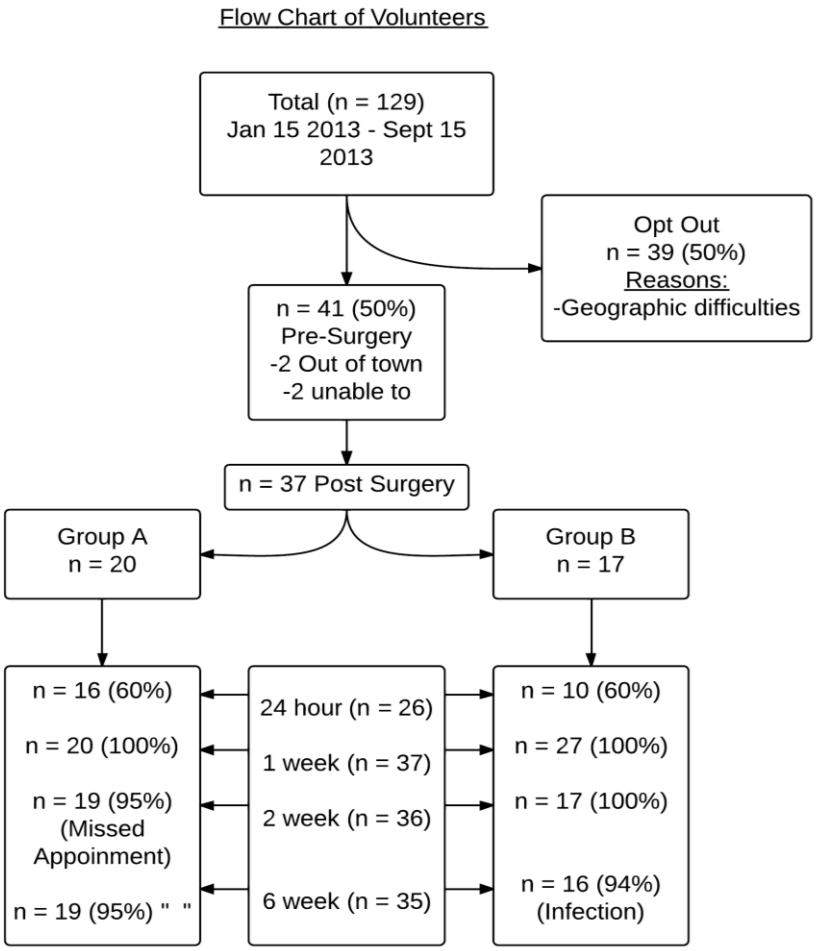
Of the 37 subjects, all had preoperative data collected. Twenty-six of the 37, 70% of the subjects provided 24-hour IKDC results. This data was not complete, as 37 participants, 100% provided one-week follow-up data, 36 or 97 % of participants provided two-week follow-up data due to a misunderstanding of when to do the follow up, and 35 or 95%, provided six-week follow-up data, one dropping out due to an infection.

During the study, one subject's DVD did not operate correctly. The subject had been randomized into Group B. Because the subject did not use the DVD, the subject was switched to the Group A protocol. By doing this, the intention to treat principle was not followed. Appendix M shows the data and graphs for the study if the intention to treat had been followed.

Two infections developed during the study, one in each group. These diagnoses were confirmed through the appropriate laboratory tests. One subject in Group B was progressing very well at four days post-surgery, and then developed a complication that was diagnosed as an infection by the family physician; however, this was not confirmed with laboratory tests. Upon further review, the surgeon did not feel this patient had an infection and the patient improved prior to the post-surgical follow up with the surgeon. One potential deep vein thrombosis developed in Group B (Figure 2). A Doppler test was unable to confirm the diagnosis. One re-injury occurred at two weeks in Group B when the patient twisted the knee when slipping on ice. This resulted in a reported increase in swelling, pain and loss of range of motion. Two subjects in Group B aggravated their hamstrings: one at one week, and the other at two weeks post-surgery. Hamstring irritation following anterior cruciate reconstruction using a hamstring graft is not uncommon and was felt to be a possible complication of this surgery. To provide a typical clinical experience and to allow for maximal external validity, all of these subjects who developed complications were left in the study. While not a group characteristic, these

complications were not consistent between groups and might have had an impact on the outcome results.

Figure 2: Flow chart of Volunteer Subjects



Statistical analysis

Table 3 compares the characteristics of the two groups. When comparing the two groups, randomization contamination had occurred, that is to say that by chance, the randomization of subjects provided two dissimilar groups. The two groups shown to be dissimilar concerning the characteristics for age and weight and analysis showed statistically significant differences between the groups. Gender type of the two groups was also greatly dissimilar but not statistically different. The two groups being significantly different in age and weight may have had some bearing on the final outcomes and the two groups cannot be regarded as the same.

Table 3: Participant Characteristics

	Entire Sample N=37	**Group A n=20**	**Group B n=17**
		Mean (SD) or Percentage	
Age* (years)	24.3 (7.2)	26.8 (7.6)	21.4 (5.5)
Height (cm)	173.1 (8.7)	173.2 (7.6)	173.1 (10.2)
Weight* (kg)	72.7 (16.3)	77.9 (18.1)	66.6 (11.5)
Pain Rating (Out of 10, n=35)	0.4 (0.8)	0.4 (0.8)	0.4 (0.8)
Sex+ (% female)	54.1 n=20	60.0 n=12	47.1 n=8
Meniscus treated (% Yes)	94.6	90.0	100.0
Surgeon 1: 2	18:19	7:13	11:6

** Statistically significant difference observed between groups ($p<0.05$).*
+Large difference but not a statistical significant difference between groups ($p<0.05$).

The study hypothesized that Protocol B would be statistically more effective to Protocol A. This was rejected based upon the study results as demonstrated below.

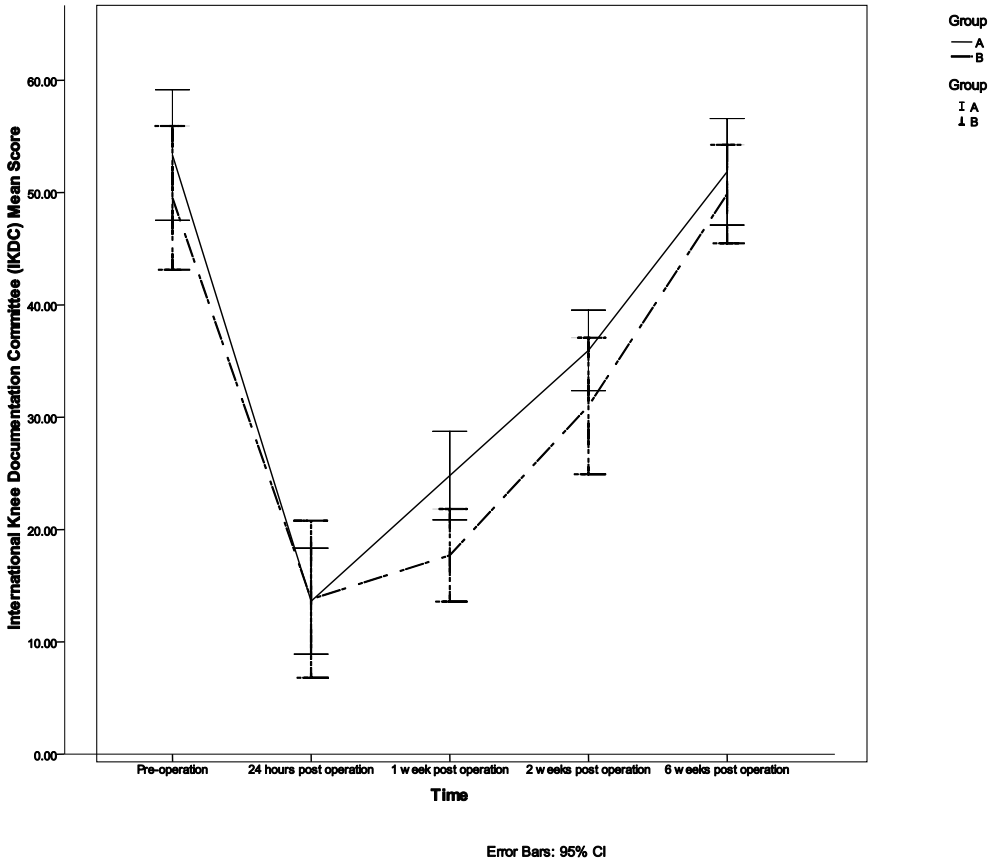
Hypothesis one stated there would be a significant and greater increase in functional outcome using Protocol B compared to Protocol A, as measured by IKDC form. Table 4 demonstrates no statistical significance difference between Groups A and B at specific times during the acute post operative rehabilitation process.

Figure 3 demonstrates Group A beginning and ending the study with greater function than Group B. From Table 4, it can be seen that Group B demonstrated a mean preoperative IKDC score of 49.5 and a six weeks post operative mean score of 49.9, which means these individuals returned to the level of function that was present prior to surgery, outperforming Group A preoperative mean scores of 53.4 and 51.9 at six weeks. Tables 4 and Figure 3 demonstrate no significant difference between Group A and B thus hypothesis one was rejected

Table 4: Participant Pre and Post Operative IKDC Examination Score Between Groups Over Five Intervals

IKDC Clinical Exam Scores	**Entire Sample** *Mean (SD)*	**Group A** *Mean (SD)*	**Group B** *Mean (SD)*
Pre-Operative	51.6 (12.4)	53.4 (12.4)	49.5 (12.5)
24 hours (n=26)	13.7 (9.0)	13.6 (8.9)	13.8 (9.8)
1 week (n=37)	21.5 (8.9)	24.8 (8.4)	17.7 (8.0)
2 weeks (n=35)	33.7 (9.6)	35.9 (7.4)	31.0 (11.4)
6 weeks (n=35)	51.0 (9.2)	51.9 (10.1)	49.9 (7.9)

Figure 3: The Mean of the IKDC Scores Between Groups Over the Five Measurement Intervals



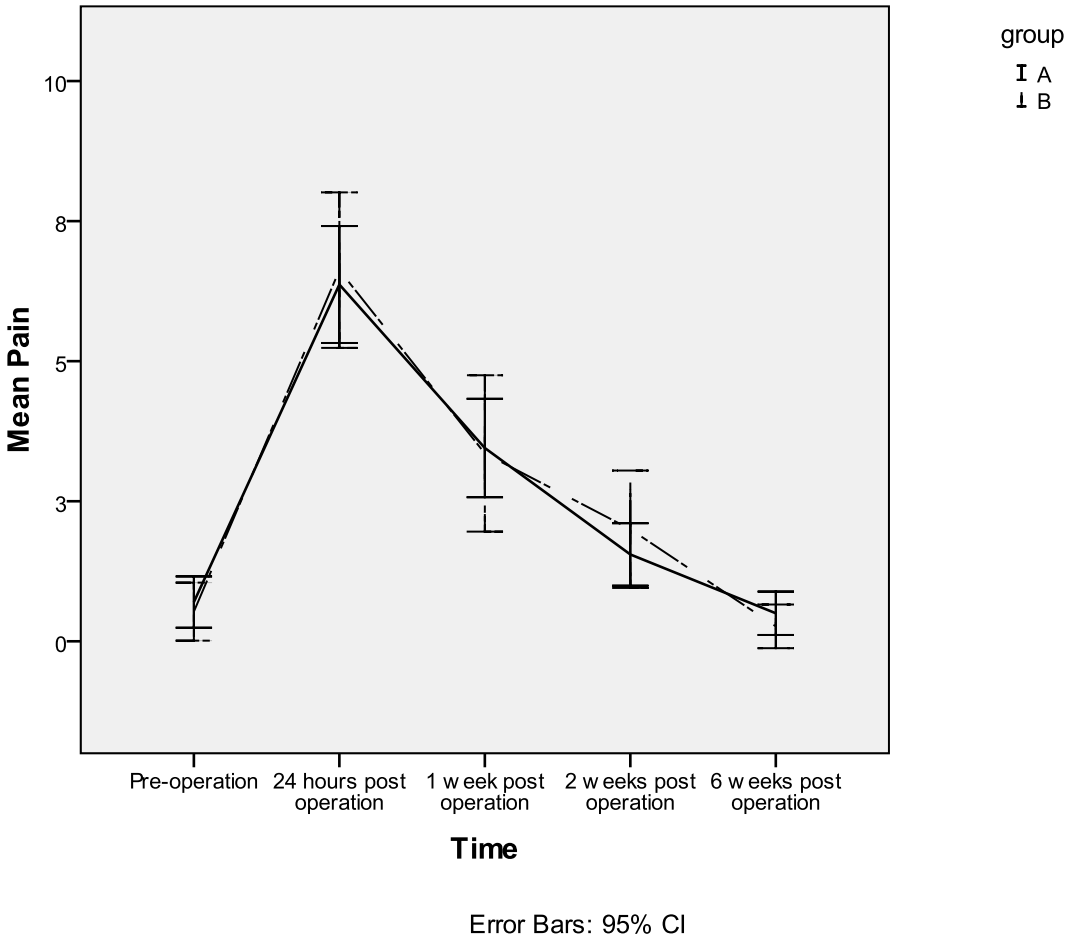
Hypothesis two stated there would be a significant and greater decrease in pain using Protocol B compared to Protocol A, as measured using a numerical rating scale for pain (NRSP). Table 5 and Figure 4 demonstrates no statistical significance difference between Groups A and B. at the four specific measurement times during the acute post operative rehabilitation process. The NRSP measure was selected at the start of the study and was described and identified as the tool of choice for pain measurement. The IKDC subjective score had a pain score which, when analyzed, showed a statistically significant difference between groups and when compared to the NRSP. This will be discussed in Chapter Five. The statistical significance difference between Groups A and B. at one week as measured with the IKDC demonstrated a difference that will be examined in the discussion.

Table 5: Participant Pre and Post Operative Clinical Findings for Pain Comparing NRSP and the IKDC Pain Scale Findings Over Five Intervals

Clinical Exam Measures	**Entire Sample** *Mean (SD)*	**Group A** *Mean (SD)*	**Group B** *Mean (SD)*
Pain			
Pre-Operative (n=37)	0.6 (1.0)	0.7 (1.0)	0.5(1.0)
24hours (n=35)	6.5 (2.3)	6.4 (2.2)	6.6 (2.6)
1 week (n=37)	3.4 (2.3)	3.5 (1.9)	3.4 (2.7)
2 weeks (n=36)	1.8 (1.6)	1.6(1.2)	2.0 (2.0)
6 weeks (n=35)	0.5 (0.8)	0.5 (0.8)	0.3 (0.7)
IKDC Pain			
Pre-Operative	(n=37) 3.1 (2.4)	3.0 (2.4)	3.2 (2.4)
24hours (n=35)	5.9 (2.6)	6.1 (2.3)	5.6 (2.9)
1 week (n=37)*	5.7 (2.0)	5.0 (1.6)	6.5 (2.2)
2 weeks (n=37)	4.2 (2.2)	3.9 (2.1)	4.5 (2.3)
6 weeks (n=35)	2.6 (2.5)	3.2 (2.9)	1.9 (1.9)

** Statistically significant mean difference observed between groups (p<0.05).*
A score of 0 represents no pain 10 represents maximal pain score.

Figure 4: Average Pain Scores on the Numerical Rating Scale for Pain, Between Groups Over the Five Measurement Intervals



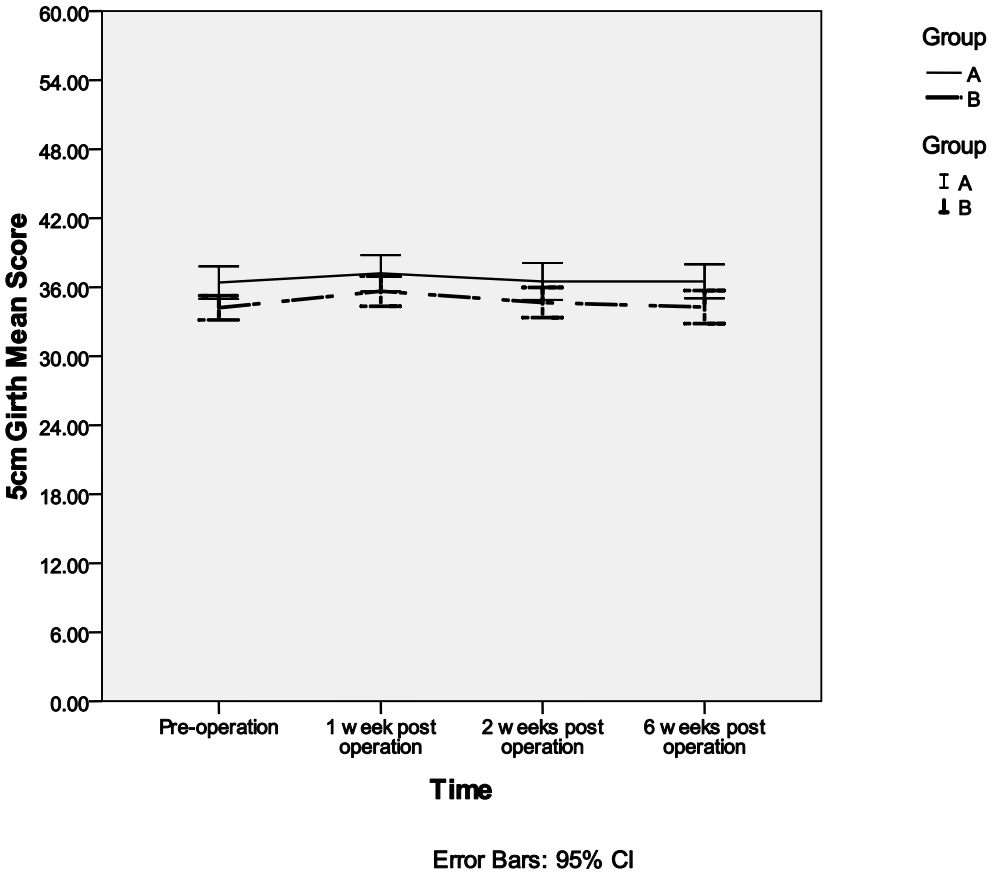
Hypothesis three stated there would be a significant and greater decrease in swelling using Protocol B compared to Protocol A, as measured by circumferential measurements. Table 6 and Figure 5 demonstrate no statistically significant difference between Groups A and B. at specific times during the acute post operative rehabilitation process.

Table 6: Participant Pre and Post Operative Clinical Circumferential Measurements in Centimeters at the Four Measurement Intervals

Circumferential measurements in cm	**Entire Sample** *Mean (SD)*	**Group A** *Mean (SD)*	**Group B** *Mean (SD)*
5cm Circumference			
Pre-Operative	35.4 (2.8)	36.4 (3.0)	34.2 (2.0)
1 week (n=37)	36.5 (3.1)	37.2 (3.4)	35.6 (2.5)
2 weeks (n=36)	35.7 (3.1)	36.5 (3.3)	34.7 (2.5)
6 weeks (n=35)	35.5 (3.1)	36.5 (3.2)	34.3 (2.6)
10cm Circumference			
Pre-Operative	39.7 (3.7)	40.2 (4.4)	38.6 (3.1)
1 week (n=37)	40.6 (3.4)	42.1 (4.2)	39.8 (2.9)
2 weeks (n=36)	41.0 (3.8)	41.0 (4.4)	38.4 (3.3)
6 weeks (n=35)	39.6 (4.1)	41.0 (4.0)	37.7 (3.5)
Joint Line Circumference			
Pre-Operative	34.2 (2.7)	34.9 (3.0)	33.6 (2.3)
1 week (n=37)	36.6 (2.9)	37.4 (3.1)	35.7 (2.3)
2 weeks (n=36)	36.1 (2.8)	36.7 (3.0)	35.4 (2.4)
6 weeks (n=35)	35.7 (2.7)	36.4 (2.8)	34.9 (2.6)

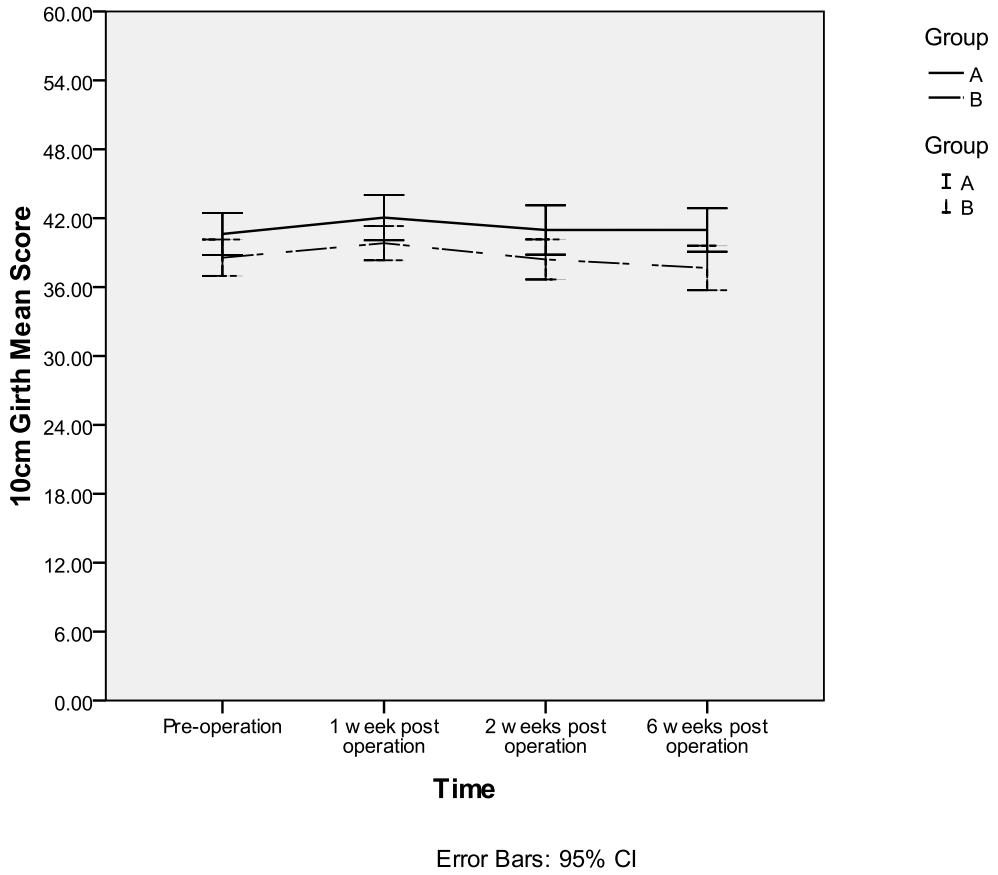
As with the IKDC subject score results, Group B's 5 cm circumferential measurement increased from baseline to one week relative to Group A. The difference was not statistically significant. The circumferential measurements then decreased relative to Group A, but again, the difference was not statistically significant. The measures were recorded in this order as it was the order of measurement during data collection.

Figure 5: Average 5 cm Circumferential Scores in Centimeters Between Groups Over the Four Measurement Intervals



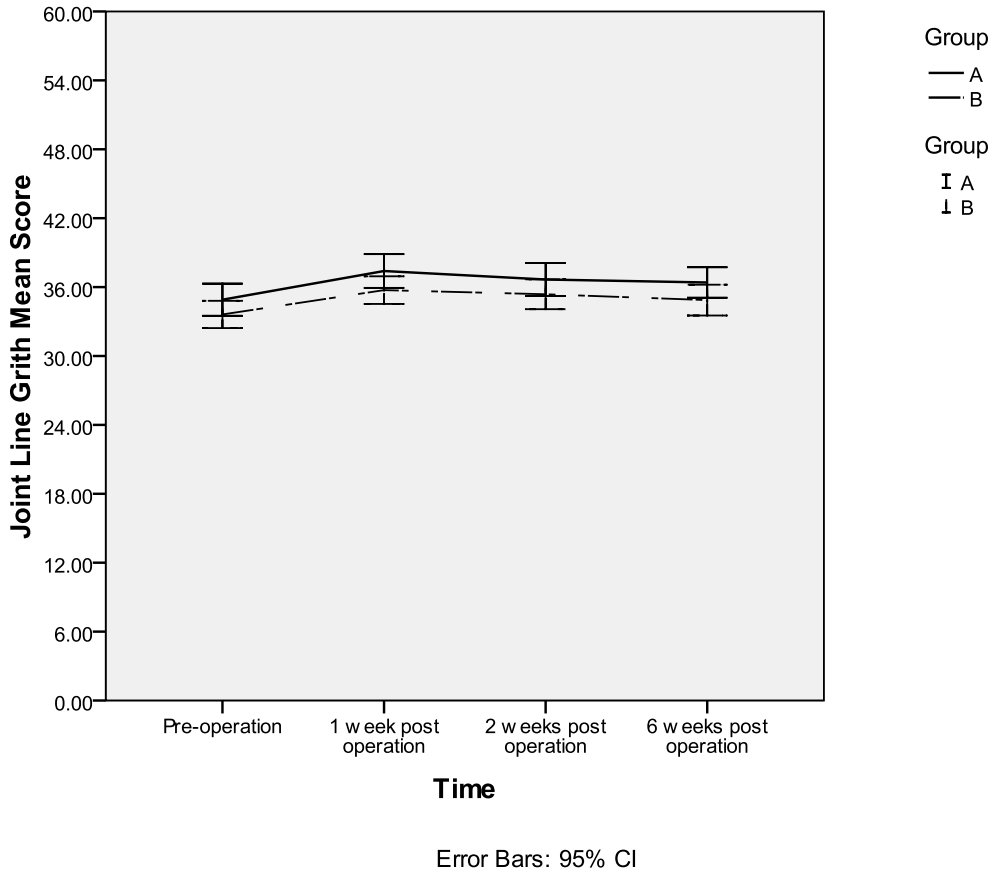
As with the IKDC subjective score and 5 cm circumferential measurements, the 10 cm circumferential results showed Group B measurements increasing at one week as did Group A measurements, the difference was not statistically significant. Group B circumferential mean measurement preoperatively was 38.6 cm and at six weeks 37.7 cm. Group A circumferential mean measurement preoperatively was 40.2 cm and at six weeks it was 41.0 cm. This difference could represent a decreased swelling or atrophy, or a combination of both factors.

Figure 6: Average 10cm Circumferential Scores in Centimeters Between Groups Over the Four Measurement Intervals



Unlike the IKDC subjective scores and other circumferential measurements, the joint line measurements did not increase from baseline at one week for Group B relative to Group A. Joint line circumferential measurements of all the circumferential measurements best represents a joint effusion. If the one week Group B measurements reported for circumferential measurements along with the IKDC subjective scores represent a negative effect as a result of protocol B, it does not appear to be a result of intra articular effusion as measured by joint line circumferential measurements. Table 6 and Figures 4, 5, and 6 demonstrate no significant difference between Group A and Group B circumferential measurements. Therefore hypothesis 3 was rejected.

Figure 7: Average Joint Line Scores in Centimeters Between Groups Over Four Measurement Intervals



Hypothesis four stated there would be a significant and greater increase in symmetrical range of motion using Protocol B compared to Protocol A, as measured by goniometric measurements.

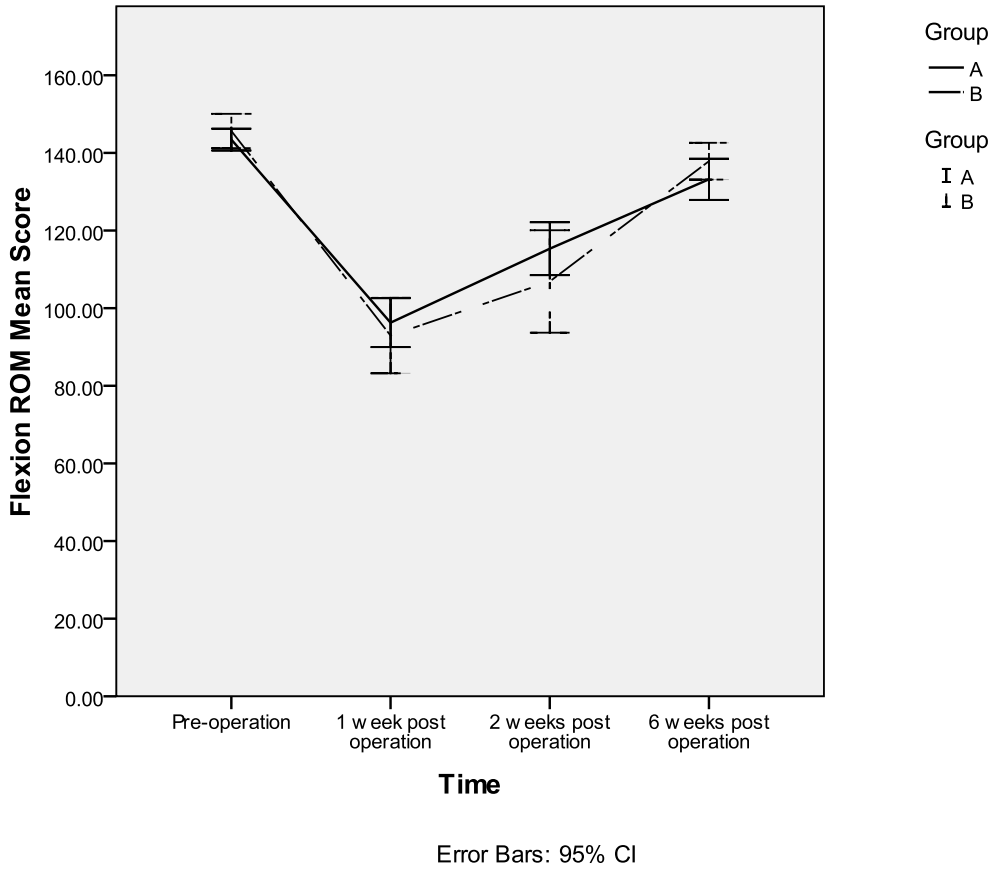
Table 7: Participant Pre and Post Operative Clinical Range of Motion Findings in Degrees Over Four Measurement Intervals

Clinical Exam Measures in degrees	**Entire Sample** *Mean (SD)*	**Group A** *Mean (SD)*	**Group B** *Mean (SD)*
Extension ROM			
Pre-Operative	-4.7 (2.8)	-4.2 (2.8)	-5.4 (2.9)
1 week (n=37)	6.3 (6.1)	6.7 (6.1)	6.7 (6.4)
2 weeks (n=36)	3.2 (5.9)	3.9 (4.8)	2.4 (7.0)
6 weeks (n=35)	-1.9 (3.6)	-1.4 (3.5)	-2.6 (3.6)
Flexion ROM			
Pre-Operative	144.4 (7.3)	143.4 (6.0)	145.6 (8.6)
1 week (n=36)	94.7 (15.9)	96.3 (13.1)	92.9 (18.9)
2 weeks (n=36)	111.5 (19.9)	115.3 (14.1)	106.9 (24.8)
6 weeks (n=35)	135.2 (10.4)	133.2 (11.3)	137.9 (8.6)

Table 7 and Figure 8 provides the range of motion measurement descriptive information between the two groups. The mean values between the two groups were not significantly different for range of motion measurements.

While a range of motion difference between Group A and B exists in flexion, the difference was not statistically significant, but was most evident at two weeks. While function and its effect on swelling and joint effusion may impact range of motion, the results of the IKDC and circumferential measurements difference at 1 week did not reflect this in flexion at 1 week. Group B's two-week score could have been the result of Protocol B's focusing on the importance of getting knee extension and resulted in neglect of knee flexion. Alternatively this two week lack of flexion could have been the result of the greater number of complications that occurred in Group B.

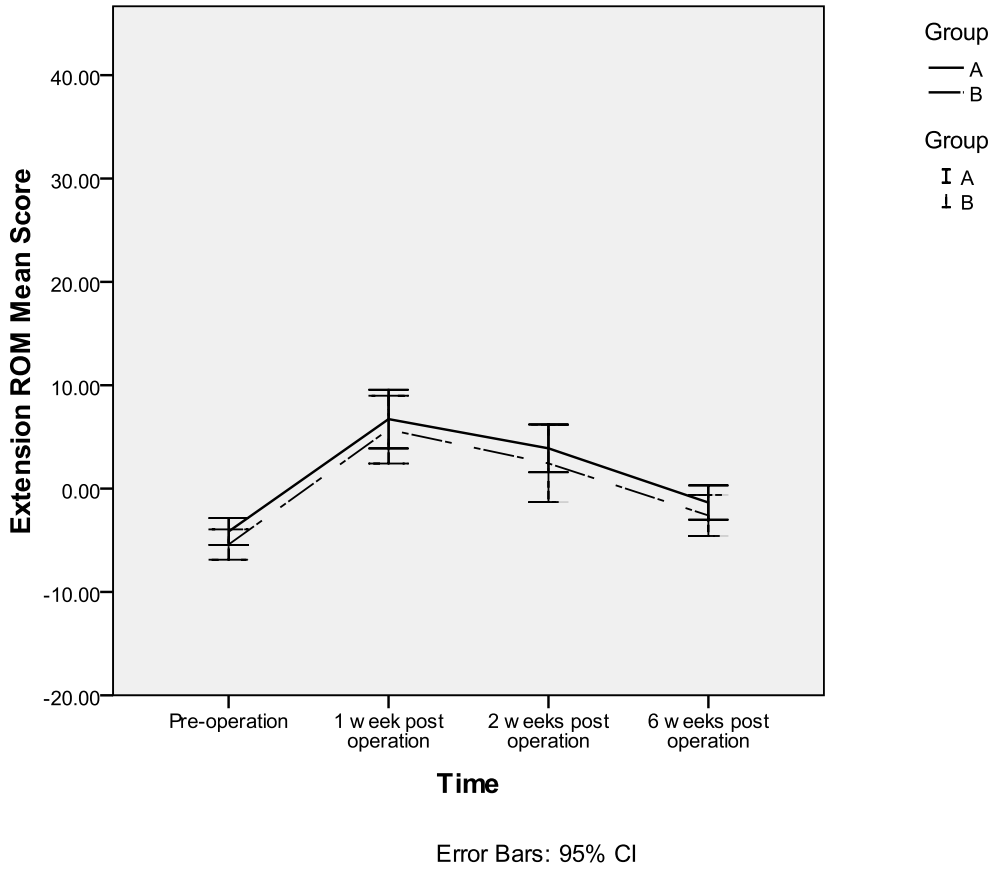
Figure 8: Average Flexion Range of Motion Scores, Measured in Degrees, Between Groups Over the Four Measurement Intervals



Unlike the flexion range of motion at 2 weeks, extension range of motion did not vary between groups A and B. Table 7 and Figures 8 and 9 demonstrate no significant difference between Group A and Group B, thus hypothesis 4 was rejected.

Thus the four hypotheses of the study were rejected by the actual results of the study. Upon reviewing the data, statistical results and considering the study in general, the discussion will discuss some possible explanation for the hypotheses being rejected.

Figure 9: Average Extension Range of Motion Scores, Measured in Degrees, Between Groups Over the Four Measurement Intervals



ANOVA Testing of Intervention Effect

Statistical significance of the between group, between times, and the [group x time] interactions were tested using ANOVA, with the principle test of intervention effect being the interaction (see Table 8). The 'intention to treat' data were also analyzed see (Appendix M). Significant differences ($p<0.05$) were seen between times for the IKDC, joint line girth, knee extension and flexion variables. Significant differences ($p<0.05$) between groups were seen only for the intention to treat data for the 5cm and 10cm girths, knee extension variables. However, no statistically significant differences were observed for any of the [group x time] interaction variables in either of the data sets, indicating there was no significant effect.

Table 8: Tests of Between-Subjects Effects for Original Data

	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	p value
Time	IKDC	26514.0	3	8838.0	88.8	**<0.001**
	5cm	9.8	3	3.2	0.35	0.79
	10cm	20.7	3	6.9	0.44	0.73
	Joint Line	79.8	3	26.6	3.5	**0.02**
	Flexion	48673.7	3	16224.6	80.2	**<0.001**
	Extension	2342.3	3	780.8	37.3	**<0.001**
Group	IKDC	369.8	1	369.8	3.7	0.06
	5cm	5.3	1	5.3	0.56	0.45
	10cm	0.03	1	0.03	0.002	0.96
	Joint Line	0.19	1	0.19	0.03	0.88
	Extension	1.7	1	1.7	0.08	0.77
	Flexion	169.6	1	169.6	0.84	0.36
Time x Group	IKDC	283.2	3	94.4	0.95	0.42
	5cm	5.9	3	2.0	0.21	0.89
	10cm	7.9	3	2.6	0.17	0.92
	Joint Line	5.9	3	2.0	0.25	0.86
	Extension	85.2	3	28.4	1.4	0.26
	Flexion	143.5	3	47.8	0.24	0.87.

Chapter Five

Discussion

In order to accurately compare groups, the groups must be similar. The two groups in the present study were found to have some dissimilar characteristics (age and weight). Additional subject enrolment to increase the number of participants would have increased the power of this study which may or may not have negated the age and weight characteristics between the two groups.

Group Characteristics

The group characteristics were significantly different for both age and weight. Gender distribution was also different but not statistically significant. (See Table 3)

Subjects with greater weight could have impacted their postoperative outcomes. The increased weight could result in greater forces being placed on the knee during functional activity. This could both increase and/or prolong swelling and pain, resulting in a slower recovery. The statistically significant weight difference between the two study groups could have impacted the IKDC scores, range of motion, pain and circumferential measurements.

Controlling weight bearing with the proper use of crutches during the early phase of rehabilitation could have been an important variable and is an area of further study. With Group A having a statistically significant greater weight this may represent a variable within the trial.

During the present study, crutch use was similar between groups. Group A's mean use of crutches was 9.9 days (S.D: 3.8), and Group B's mean was 10.8 days with a (S.D: 4.4).

Weight may also be influenced by both age and gender, as people age and grow, they generally increase in weight and males are generally heavier than females (87,88). The present study showed a statistically significant difference in age between groups but not a statistically significant difference in ages between the two study groups. This difference in gender between the two groups and the difference in age between the two groups could have influenced the difference in the weights between the two groups. While the two groups in this study were statistically different, in age and weight, the population as a whole has similarities and differences relative to previous comparable studies reported within the literature.

The following studies that examine post operative characteristics following anterior cruciate ligament reconstruction have similarities, with patient populations comparable to the present study.

Maddison's study (50), which is the most comparable in design to the present study, having used the IKDC subjective scores as an acute outcome measure, reported a final sample consisting of 58 subjects. Based on the common power calculation of 80% this study was under powered and would have required 76 subjects in order to attain a power calculation of 80%. Subjects ranged in age from 15 to 53 years with no average age reported. The population was 68% male, which is high relative to present study. This may have impacted the average height, weight and other factors that may have impacted the results of the present study. No data on height or weight were included in Maddison's study (50).

Erik Hohmann's study (89) investigated physical therapy guidelines versus home based unsupervised therapy following anterior cruciate ligament reconstruction. This study enrolled

forty subjects over two years, ages 18-35, with an average age of 27.5 years. These numbers and characteristics are comparable to the present study. The combined group mean height in Hohmann's study was 176 cm and the average weight was 77.5 kg.(89). The physical therapy group mean was 75 kg and the home exercise group was 80 kg. This difference was not reported as statistically different. Subjects in the present study had a combined mean weight of 72.7 kg , with Group A being 77.9 kg and Group B 66.6 kg reported as significantly different. Hohmann's study consisted of a total of forty subjects, 30 males and 10 females (89). The physical therapy group had 16 males and 4 females, while the home therapy group consisted of 14 males and 6 females. Similar to the present study, the group with more males had a greater average weight, but this was found to not be statistically different.

Pizzari investigated adherence to rehabilitation after anterior cruciate ligament reconstruction (86). The SIRAS compliance score and IKDC subjective forms were used, but were scored at the nine and twelve month marks, not in the acutely post operative period as in the present study. The study enrolled 68 patients, 42 males and 26 females, between the ages of 16 and 52 years (86). The average age of 28.8 years is both similar in age range and a mean of 4 years relative to the present study. All three of these studies had similar age ranges, and means, along with a greater proportion of males to females compared to the present study.

While similarity exists between previous populations in other studies and the present study, the present study results demonstrated no statistically significant difference between the two protocols used. There was no statistical difference in the study relating to knee function as measured using the IKDC subjective form, range of motion as measured in degrees using a goniometer, circumferential measurements as measured with a tape measure in centimeters. The

present study population was representative of the population seen by two specific surgeons and more specifically at the Glen Sather Sports Medicine Clinic.

The International Knee Documentation Committee Subjective Knee form (IKDC)

The hypotheses one stated there would be a significant and greater increase in functional outcome using Protocol B compared to Protocol A, as measured IKDC Subjective form. This hypothesis was rejected as demonstrated by the study results.

The primary outcome measure for the study, the IKDC subjective score, consistently demonstrated that the mean activity level score of 53.4 for Group A and 49.5 for Group B prior to surgery was followed by a broad and dramatic decrease to a score of 13.6 for Group A and 13.8 of Group B at 24 hours following the surgery. The scores at one week follow surgery were 24.8 for Group A and 17.7 for Group B. This difference, while not statistically significant, showed a decreased function at one week in Group B, which could reflect a potential fault in Protocol B. This difference could also represent a non-statistical difference between groups. Increasing the sample size and thus increasing the power of the study may have answered this. Increasing the sample size increases the power of the study, causing the measurement results to move towards the mean. If this difference is a non statistical difference, the increased power may have decreased the IKDC difference between Group A and B at one week.

During and immediately following surgery, the knee was repetitively, passively brought through a full symmetrical range of motion by the surgeons; therefore, repeating this motion during rehabilitation should not result in complications during early rehabilitation. If the patient does not maintain this range, it is conceivable that adhesions could develop. The adhesions being stressed to achieve symmetrical hyperextension could be over stressed and could have resulted in a microtrauma that was marked by a decrease functional level at the one week mark in Group B.

The emphasis on symmetrical extension in protocol B could also have resulted in increase irritation of the hamstring harvest sight and account for the one week difference in IKDC scores at one week between the two groups.

Function as reported by the IKCD subjective scores at the two-week follow-up increased relative to both the 24-hour and one- week follow-up in both groups. At two weeks the IKDC scores for Group A score was 35.9, and Group B score was 31.0. By six weeks, the functional values as reported by the IKDC subjective score returned the near presurgical levels. At six weeks follow up, Group A were 51.9 and for Group B were 49.9. The presurgical scores were 53.4 for Group A and 49.5 for Group B. While no statistical differences were noted between groups, both groups had recovered to pre-surgical levels by six weeks post surgery.

The IKDC subjective scores in Maddison's study were reported to be approaching a statistically significant difference (50). Their study's combined group scores were 52.91 (S.D: 12.28) pre-operatively and 59.17 (S.D: 8.98) after the six-week follow up, resulting in an IKDC score difference of 6.08. Their study's pre surgical IKDC subjective score for the intervention group scores was 52.25 (S.D: 11.89) and 53.53 (S.D: 12.81) for the control group. The six week follow up IKDC subjective scores for the in study's intervention group were 61.18 (S.D: 8.04), and 57.02 (S.D: 9.58) for the control group. This difference of 4.16 at the six week follow up between the control and intervention group was what they reported as approaching significant difference. Maddison's scores were all higher than the ones recorded in the present study (50). The present study IKDC subjective score group difference at six weeks was 2.16 points The difference between Maddison's score of 4.16 points at six weeks and the present study was 2.0 points (50). The minimal clinically important difference (MCID) for the IKDC subjective score for this study was set prior for the study at 11.5 points, the 2.16 points difference at six weeks

does not represent a difference that is clinically significant. Both of these study's were under powered, could have resulted in similar outcomes. No statistical difference between either study's control or intervention groups was established.

Pizzari investigated adherence to a rehabilitation program after anterior cruciate ligament reconstruction (86). The IKDC subjective forms were used, but were scored at the nine and twelve month periods, not at the acute postoperative period as was done in the present study. Pizzari's study demonstrated the more common time period for the use of the IKDC subjective scoring (86).

The IKDC subjective form (Appendix C) is a well recognized and accepted measure in studies related to ACL reconstruction. The form has had limited use in an acute setting prior to this study. The questionnaire's use in the acute setting may not be as reliable and valid due to the questionnaire's wording and interpretation by the subjects as compared to being used in later stages of rehabilitation. Changes to the questions were proposed prior to the study's implementation, however, were left as is so as not to impact the tool's validity and reliability ratings.

Question two of the IKDC subjective score asked: during the past four weeks, or since the injury, how often have you had pain? Zero represented never, ten represented constant pain. During the present study, the outcome measure was being used to measure change between the presurgical period and the postoperative period and changes from one week to the next. The question asking about the pain level in the past four weeks would not reflect changes between presurgery and postoperative surgery as well as changes over a one week period and, could have lead to misinterpretation by subjects. The misinterpretation was also reflected in the questions asked by the study subjects. The subjects asked the investigator to clarify the question. The

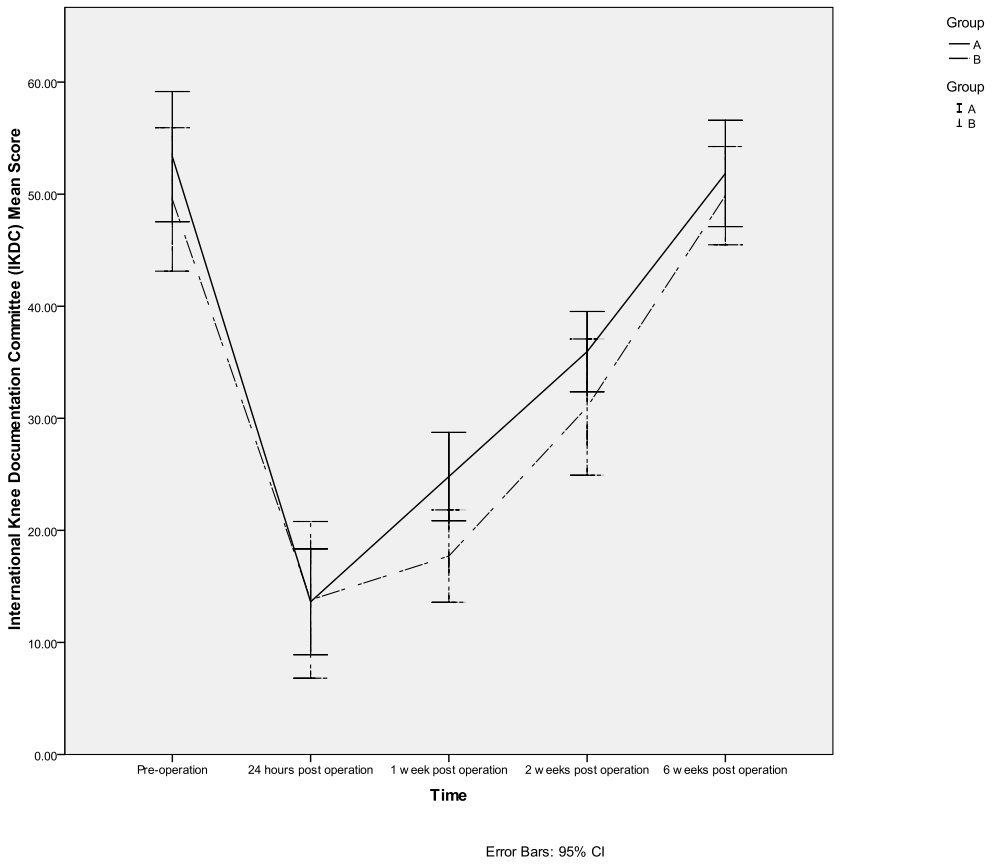
investigator indicated he was unable to offer clarification as this may bias the study, that subjects should respond as best they could based on what made most sense to subjects. Questions four and six were worded in same manner as question two, resulting in the same problems.

Question three asked: "If you have pain, how severe is it?" The question did not indicate if it meant in the past four weeks, one week, to day, or at present? This lack of clarity could leave the question open to interpretation by each subject.

By not evaluating the IKDC subjective scores in the acute setting and not changing the wording for clarification prior to the study, the outcome results could have been impacted. This was reflected in the many questions regarding clarification by the study subjects to the investigator. Review of the IKDC subjective forms by the investigator was also suggestive of a misinterpretation of the questions by the study subjects. Using the IKDC subjective score as the primary outcome measure in the acute setting could represent a key variable in this study. The IKDC subject forms should be modified, clarified and investigated in future for its use in acute knee studies.

Figure 9 demonstrates Group A having greater function at the beginning and end of the study compared to Group B. Group B demonstrated a preoperative IKDC score of 49.5 and 49.9 at six weeks which was equal to the level of function prior to surgery, outperforming Group A's preoperative level of 53.4 and 51.9 at six weeks. Thus Group A did not reaching presurgical levels at six weeks however this difference was not statistically or clinically significant .

Figure 10: Average IKDC Scores Between Groups Over the Five Measurement Intervals



Pain Measures

Hypothesis two stated that there would be a significant and greater decrease in pain using Protocol B compared to Protocol A, as measured by a pain numerical rating scale (NRSP).

Pain is a subjective measure which is difficult to objectively assess. This proved to be the case in this study. The NRSP attempted to define the quantity of pain experienced by an individual during an activity or rest at a set point in time, were 0 represents no pain and 10 represents the maximal level of pain. ACL rehabilitation. (21,43,50,90) The measurement was used for this purpose in this study. The IKDC subjective form scores attempted to define the

quality of pain experienced by an individual over a period of time (the past four weeks). This, along with misinterpretation of the IKDC statements and the IKDC not having been previously tested in the acute setting, might explain the statistically significant difference between the two methods of recording pain. Table 9 and Figure 11 outline the pain scores over the time course of the study.

Table 9: Pain Numerical Rating Scale (NRSP) and IKDC Pain Comparison Between Pre and Post Operative

	(NRSP)Pain	**IKDC Pain**
	Mean (SD)	*Mean (SD)*
Pain Pre-Operative (n=37)*	0.6 (1.0)	3.1(2.4)
24hours (n=35)	6.5 (2.3)	5.9 (2.6)
1 week (n=37)*	3.4 (2.3)	5.7 (2.0)
2 weeks (n=36)*	1.8(1.6)	4.2 (2.2)
6 weeks (n=35)*	0.4 (0.8)	2.6 (2.5)

** Statistically significant mean difference observed between groups ($p<0.05$).*

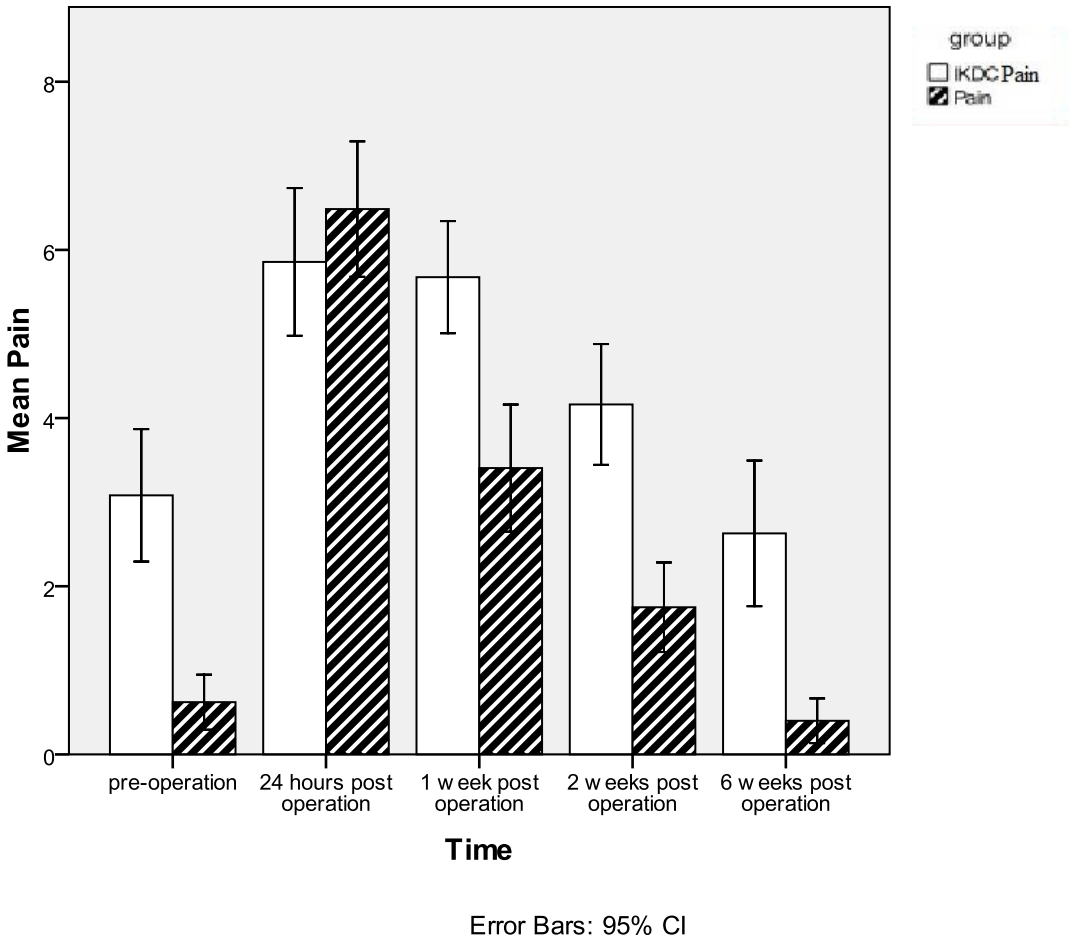
0 represents no pain and 10 represent the maximal level of pain

Circumferential Measures

Hypothesis three stated that there would be a significant and greater decrease in swelling using Protocol B compared to Protocol A, as measured by three circumferential measurements. This hypothesis was rejected as demonstrated by the study results.

All circumferential measurements recorded at the time intervals were greater in Group A than in Group B as stated in hypothesis three, however no statistical difference was found.

Figure 11: Average Pain Scores Between the Two Pain Measures Over Five Measurement Intervals



Group A started the study with larger preoperative circumferential measurements as demonstrated in Figure 5,6 and 7.

The IKDC subjective score was lower at one week in Group B but the trend did not continue at the two and six week periods. This along with the fact that circumferential measurements of protocol B were less than for protocol A, reflecting no increase in swelling or joint effusion. An increase in circumferential measurements could indicate that Protocol B did

not have a negative impact on its subjects, but the week difference was more likely a result of the study being under powered.

Increases in circumferential measurements could impact range of motion measurements, pain scores and function as measured by the IKDC. Increased soft tissue swelling could result in increased pressure on area nerve endings resulting in increased pain. The swelling could also physically limit the ROM. These results could have a negative impact on the IKDC. The fact that the circumferential measurements were not greater in Group B and that no change difference occurred between Group A and Group B at one week is an indication that protocol B did not have a negative impact.

Range of motion

Hypothesis four stated that there would be a significant and greater increase in symmetrical ROM using Protocol B compared to Protocol A, as measured by specific goniometric measurements. This hypothesis was rejected as demonstrated by the study results.

There was no statistical difference in either extension or flexion ROM at any point between Group A and Group B in this study. Extension was very similar between groups throughout all measurement periods. The flexion results were somewhat different but not statistically. Flexion at the one and two weeks periods were lower in Group B. The results at one week show Group B having a mean of 92.9 degrees of flexion versus 96.2 degrees of flexion in Group A not statistically or clinically different. This loss of flexion could have resulted in the lower IKDC at the one week mark. The emphasis in protocol B was on getting extension ROM and getting the muscle to work in extension by emphasizing extension on the video tape. This could have resulted in less focus on the flexion ROM and less flexion gains in Group B. Flexion

is required to perform many of the activities used in the IKDC subjective evaluation such as squatting, sitting and kneeling. Emphasizing one outcome could have resulted in neglect of another. The decrease in flexion in Group B did not continue and at six week, Group B had greater flexion than Group A, but the difference was not statistically or clinically significant difference.

Factors that could have influenced results

Many factors changed during the development and implementation of this study that could have impacted and been reflected in the results of the study leading to dissimilar characteristics between the two study groups.

Factors in the educational program and materials

During the development and implementation of the study, changes occurred to the preoperative teaching and rehabilitation at the Glen Sather Sports Medicine Clinic (GSSMC) . These changes could have influenced the study subjects and resulted in other associated variable impacting the study results. During this time, GSSMC placed more emphasis on symmetrical extension during preoperative rehabilitation, educational sessions, and during early post-operative rehabilitation. Also during this time, the surgical clinic at the GSSMC and preoperative teaching at the Grey Nuns Hospital were changed to place more emphasis on achieving full extension and flexion. This was reinforced by the physical therapists, surgeon's, and the hospital's education programs, with the expectation that the patient would have full extension and flexion at the surgeon's follow-up postoperative examination at two weeks postoperative.

The preoperative hospital education clinic program was also modified to more closely coordinate with the GSSMC practice guidelines. These programs were coordinated and streamlined to reinforce the principles taught within the surgical clinic, physical therapy and education package. In which emphasis was placed on early movement and full symmetrical extension and flexion. Both subject groups received this information prior to entering the study.

Outcome measure interdependence

The interdependency between outcome measures is similar to that described when reviewing the circumferential measurements. The IKDC subjective scores, circumferential measurements, ROM and pain scores could have an impact on each other. A change in any of these outcome measures whether positive or negative could have had potential impact the entire study. It then became difficult to determine what caused any changes. In this "chicken and egg" situation it would have been beneficial to isolate all patients in the study who demonstrated increased swelling into a subgroups to determine if they all consistently experienced increased pain and decreased ROM or not. If so, one could then say swelling caused these consistent problems. If not, one could create a sub group of those who experienced pain with their swelling and those who experienced decreased ROM with their swelling.

Patient contact for rehabilitation

The timing of the first postoperative physical therapy session was changed during the implementation and completion of this study. The change in timing and the emphasis of full

range of motion, emphasizing terminal extension were reinforced by the surgeons, during preoperative teaching, hospital teaching sessions and during postoperative follow up appointments. Prior to this change, postoperative physical therapy started one or two weeks following the two week surgical follow-up examination, making it three or four weeks following surgery before the first physical therapy session occurred. The new procedural change then resulted in the first postoperative physical therapy session starting one week following surgery and was booked prior to surgery to prevent delay. This resulted in patients starting physical therapy two or three weeks sooner than previously, resulting in another variable that could have impacted the study's results.

These changes resulted in improved early postoperative outcomes for all patients prior to and during the study. This then could have limited the intended impact of Protocol B, resulting in no clinical or statistical differences between groups. All of these possible individual variables or combination of the variables may have contributed in the similar outcome measures for the two groups and contributed to the rejected hypotheses.

Group demographics and exposure

The initial intent of the study was to have the study open to all patients meeting the inclusion criteria who were undergoing anterior cruciate ligament reconstructive surgery by either of the two surgeons. It was hoped this would then reflect the impact of the study on ACL knee care throughout the Edmonton system. Due to logistics and convenience only patients receiving physical therapy at the GSSMC were opting into the study. This allowed greater continuity in care and a more standardized rehabilitation for the two groups. This affected

internal validity of the study. However, limiting the study to patients of the GSSMC resulted in decreased external validity.

The narrower subject population also resulted in most patients receiving their preoperative rehabilitation with the Glen Sather Sports Medicine Clinic physical therapy staff, where it is standard practice to emphasize not only symmetric range of motion and quadriceps control, but also to use the exercises presented in the DVD used for Group B.

Patient compliance

Compliance is a key component with any intervention and especially with a home based rehabilitation program (29,90). The SIRAS evaluation tool was to be used in this study to help monitor compliance (appendix I). A pilot study of this tool would have been advisable to avoid it being dropped from the study. When attempting to use the SIRAS scoring with the initial study patients, it became clear that monitoring and evaluating exercises would reveal the group randomization for the investigator and thus it was decided to discontinue the use of the SIRAS to enable the investor to remain blinded. The study could have been modified and the SIRAS could have been administered by the treating therapists. This would have involved educating the treating therapists and pretesting reliability and validity would have been required before implementation of the study. This prevented compliance from being monitored and the evaluation of the outcomes relative to compliance. This added another variable that was not controlled and may have impacted the final outcomes of the study.

Patient randomization

The randomization of the patients resulted in contamination of the demographics. That is through the course of randomization, a statistically significant difference in demographics resulted between the two study groups. The two groups were not the same demographically. The characteristics of age and weight were found to show statistically significant difference between the groups. Gender was also dissimilar but not statistically different. These significantly significant differences could have had some bearing on the final outcomes. While the surgical procedure was similar for the two surgeons, they were not identical. The statistically significant difference between the number of surgeries by each surgeon between the two groups as identified in Table 3 could have been a variable within the study. Future studies might be used to investigate this difference.

Patient complications

The complications of infection and hamstring irritation that resulted in Group B may have added to the end outcome results and all the hypotheses being rejected. By further increasing the numbers and removing the subjects who developed complications, the study's outcomes might have been different. This could further reduced the variables between the two groups, resulting in a statically significant difference in outcomes between the groups.

Chapter 6

Conclusion

Summary

The objectives of this randomized control study was to designed and implement a study, to assess the results of two postoperative protocols over the first six weeks following anterior cruciate ligament reconstructive surgery. Subjects were randomly allocated into two groups follow their surgery with each group followed one of the two protocols. The effects of two protocols were evaluated using four outcome measure: The IKDC subject knee score, the NRSP pain scale, circumferential measurements and range of motion. The outcomes were recorded pre surgery at one week, two weeks and six week intervals. The IKDC and (NRSP) pain scores were also recorded at twenty four hours post surgery. It was hypothesized that the protocol that consisted of the existing protocol and practice and included a DVD would be statistically superior to the present existing protocol based upon the four outcome measures.

Very little research has been conducted regarding protocols in the immediate post surgical period and the specific content of any protocols during this period have not been studied. Since the impact on the patient during this phase of recovery sets the tone for the rest of the rehabilitation process, optimal short term outcomes need to be studied because they ultimately could impact the mid and long range outcomes. The sooner the patient regains range of motion and muscle control, the more safely they can return to their functional every day activity.

Ideally one wants an optimal protocol that would provide the best standard of practice to future patients following their anterior cruciate ligament reconstructive surgery.

While it was the intent of this study to provide an improved protocol for the care of patients, during acute post operative care period following anterior cruciate ligament reconstruction surgery, the study hypotheses were rejected. Based on the present study, the following conclusions can be made:

1. The IKDC subjective evaluation form was not sensitive enough to measure change when used in the acute post operational setting. Further research and testing of validity and reliability on the IKDC Subjective evaluation form and its wording in the acute post operative stage following anterior cruciate ligament reconstruction is needed.
2. Both protocols following surgery provided guidance to the patient. The education of the patient prior to and during the implementation of a protocol along with the interpretation of the information could be a key factor in the success of the protocol.
3. The longer it takes to implement a research project and collect data the greater is the potential for increased variables that could impact the test results.

Impact on Clinical Practice

1. The data collected provided a mean measurement and standard deviation that could be used by clinicians when assessing progress using the clinical outcomes used in this study. At two weeks post surgery, a clinician should expect an IKDC Score of 33.7 (S.D: 9.6). pain level of 1.8 (S.D:1.6) with a range of motion of 3.2 (S.D:5.9) degrees of extension and 111.5 (S.D:19.9) degrees of flexion.
2. Subjects are individuals with differing demographic characteristics and they can interpret information and symptoms differently. Factors such as perception of pain, fear, personality and activity level, along with characteristics such as age and weight should be considered when selecting subjects for studies that compare protocols or rehabilitation plans.
3. Informal qualitative information from this study provided helpful information to the researcher. Subjects who were asked the question "what information would you pass on individuals who are going to have this surgery to make it a better experience" replied, "Do the exercises as directed and, the exercises are difficult and make the knee sore. The exercises allow you to increase your mobility and feel better". It was also suggested that patients be educated on any equipment they might require for their rehabilitation prior to surgery in order for them to become familiar with the equipment and exercises, and to purchase the required equipment.

Impact on future research

1. When performing clinical research, many extraneous factors could impact the results. The longer the period of time taken to do the research, the more factors develop that could impact the results. These factors include changes in technology over time, staff changes resulting in lost participants, and implementation of new programs related to the study. Expectations of the researcher regarding what he or she expects of the subject can also affect outcomes. For example, the time subjects are given to return their data such as their diary and twenty-four hour IKDC evaluation subjective sheets.
2. Piloting evaluation tools prior to the study would decrease unexpected complications such as the inability to use SIRAS in the present study.
3. Plan for and establish a method for dealing with patient medical complications, reinjury, attendance, occupation and other time demands. This will help to achieve and to manage the subject population.
4. Researchers need to consider changes occurring outside of the study that could impact their study. In the present study, changes to patient pre operative education, their pre surgical rehabilitation, web site and pre operative educational material along with changes to the hospital teaching program all impacted the study results.

Despite the rejection of the study hypotheses, patient care following ACL reconstruction has improved since the implementation of the new care pathway, with earlier start to rehabilitation, emphasizing terminal extension, symmetrical range of motion along with supporting educational material.

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Appendix A
Pre Study reliability (Goniometry) Testing

Patient	Flex/ext 1	Flex /ext 2	Flex/Ext	Flex/Ext
1	134/1	132/3.5	2/2.5	0-3/0-4
2	152/3	154/1	2/2	
3	109/3.5	110/5	1/1.5	
4	139/1	140/-1	½	
5	128/0.5	130/0	2/.5	
6	149/-8.5	150/-10	1/1.5	
7	118/12	118/12	0/0	
8	155/2	155/-1	0/3	
9	146/1	143/4	3/3	
10	152/4	149/0	¾	
			1.5/2 cm Sd 1.15/1.18	ss =1.2/1.3

Patient	Ext 1 cm	Ext 2 cm	Ext	ext
1	4cm	4cm	0	0-1.5
2	1cm	1cm	0	
3	-1.5 cm	-3 cm	1.5	
4	4cm	4 cm	0	
5	5cm	5cm	0	
6	8 cm	8 cm	0	
7	-8.5 cm	-10 cm	1.5	
8	Equal	Equal	0	
9	-2.7	-2.7	0	
10	Equal	Equal	0	
			0.3cm Sd 0.63	ss=3.6

cm Centimeters
ss Sum of square

Appendix B

Pre Study reliability (Circumferential measurement) testing

Patient	10 cm /5cm 1	10cm/ 5 cm 2	10cm/5cm	
1	45/33	45/33	0 /0	0-1.8/0-1.5
2	44.5/34	44/34.5	0.5/0.5	
3	46.5/36.7	46.1/36.5	0.5/0.2	
4	48.5/37.5	48.9/37.7	0.4/0.2	
5	53.0/43	54.2/43.4	1.2/0.4	
6	53.4/43.5	54.5/43	1.1/0.5	
7	43.5/34.5	43/34.2	0.5/0.3	
8	43.5/35.5	43/35	0.5/0.5	
9	50.7/37.5	50.1/36	0.6/1.5	
10	42.5/31	40.7/30.2	1.8/1.2	
			cm 0.71/0.43 Sd 0.66/0.46	ss=3.94/1.89

cm centimeters
ss sum of square

Appendix C
International Knee Documentation Committee Subjective Form

2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

Your Full Name_____

Today's Date: _____/_____/_____ (Day / Month / Year) Date of Injury: _____/_____/_____ (Day / Month / Year)

SYMPTOMS*:

*Grade symptoms at the highest activity level at which you think you could function without significant symptoms, even if you are not actually performing activities at this level.

1. What is the highest level of activity that you can perform without significant knee pain?

   ❑Very strenuous activities like jumping or pivoting as in basketball or soccer
   ❑Strenuous activities like heavy physical work, skiing or tennis
   ❑Moderate activities like moderate physical work, running or jogging
   ❑Light activities like walking, housework or yard work
   ❑Unable to perform any of the above activities due to knee pain

2. During the past 4 weeks, or since your injury, how often have you had pain?

	0	1	2	3	4	5	6	7	8	9	10	
Never	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	Constant

3. If you have pain, how severe is it?

	0	1	2	3	4	5	6	7	8	9	10	
No pain	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	Worst pain imaginable

4. During the past 4 weeks, or since your injury, how stiff or swollen was your knee?

   ❑Not at all
   ❑Mildly
   ❑Moderately
   ❑Very
   ❑Extremely

5. What is the highest level of activity you can perform without significant swelling in your knee?

   ❑Very strenuous activities like jumping or pivoting as in basketball or soccer
   ❑Strenuous activities like heavy physical work, skiing or tennis
   ❑Moderate activities like moderate physical work, running or jogging
   ❑Light activities like walking, housework, or yard work
   ❑Unable to perform any of the above activities due to knee swelling

6. During the past 4 weeks, or since your injury, did your knee lock or catch?

   ❑Yes ❑No

7. What is the highest level of activity you can perform without significant giving way in your knee?
   ❑Very strenuous activities like jumping or pivoting as in basketball or soccer
   ❑Strenuous activities like heavy physical work, skiing or tennis
   ❑Moderate activities like moderate physical work, running or jogging
   ❑Light activities like walking, housework or yard work
   ❑Unable to perform any of the above activities due to giving way of the knee

SPORTS ACTIVITIES:

8. What is the highest level of activity you can participate in on a regular basis?

❑Very strenuous activities like jumping or pivoting as in basketball or soccer
❑Strenuous activities like heavy physical work, skiing or tennis
❑Moderate activities like moderate physical work, running or jogging
❑Light activities like walking, housework or yard work
❑Unable to perform any of the above activities due to knee

9. How does your knee affect your ability to:

		Not difficult at all	Minimally difficult	Moderately Difficult	Extremely difficult	Unable to do
a.	Go up stairs	❑	❑	❑	❑	❑
b.	Go down stairs	❑	❑	❑	❑	❑
c.	Kneel on the front of your knee	❑	❑	❑	❑	❑
d.	Squat	❑	❑	❑	❑	❑
e.	Sit with your knee bent	❑	❑	❑	❑	❑
f.	Rise from a chair	❑	❑	❑	❑	❑
g.	Run straight ahead	❑	❑	❑	❑	❑
h.	Jump and land on your involved leg	❑	❑	❑	❑	❑
i.	Stop and start quickly	❑	❑	❑	❑	❑

FUNCTION:

10. How would you rate the function of your knee on a scale of 0 to 10 with 10 being normal, excellent function and 0 being the inability to perform any of your usual daily activities which may include sports?

FUNCTION PRIOR TO YOUR KNEE INJURY:

Cannot perform daily activities	0 ❑	1 ❑	2 ❑	3 ❑	4 ❑	5 ❑	6 ❑	7 ❑	8 ❑	9 ❑	10 ❑	No limitation in daily activities

CURRENT FUNCTION OF YOUR KNEE:

Cannot perform daily activities	0 ❑	1 ❑	2 ❑	3 ❑	4 ❑	5 ❑	6 ❑	7 ❑	8 ❑	9 ❑	10 ❑	No limitation in daily activities

Appendix D

Sample Size Calculation

Sample sizes are computed with significance level (alpha) of 0.05 using a two-sided two independent sample t-test.

				Measurement	
				IKDC	**NRS**
Minimal clinically important difference (MCID)				11.5	1.7
Mean response of standard therapy				26.5	1.1
Mean response of experimental therapy (26.5+MCID)				38.0	2.8
SD				12.3	1.9
Power	=	80%	n per group =	19	21
		90%		26	28
		95%		31	34

				IKDC	**NRS**
Based on Chmielewski (difference (Delta) in two therapy)				23.1	2.2
Mean response of standard therapy				26.5	1.1
Mean response of experimental therapy				49.6	3.3
SD				12.3	1.9
Power	=	80%	n per group =	6	13
		90%		8	17
		95%		9	21

Note: Your data may not show the same differences (i.e. Delta) as shown for Chmielewski paper. Best to say that we used the results from Chmielewski paper and computed sample size based on MCID.

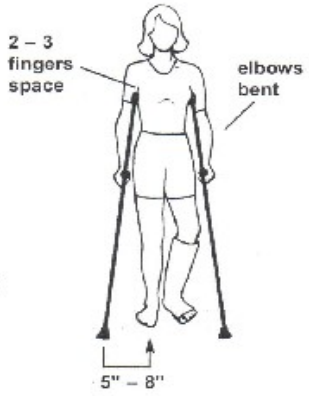
Most of the studies are conducted based on 80% power, you can choose 90% power if you prefer.

Appendix E

Crutch walking

health information

How To Use Crutches



Making Sure the Crutches Fit

Stand up straight with the crutches 5" 8" to the side of your feet.

The crutches are the correct length if there are 2 to 3 finger widths between the top of the crutch pad and your armpit.

The hand grip should be at wrist level when your arm is hanging by your side. Your elbows are slightly bent as you push down on the handgrips.

Walking With Crutches

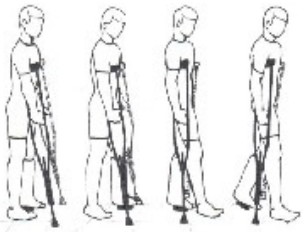
Remember: Support your weight with the hand grips, **not** the crutch pads.

You will be shown one of the methods below:

Non-weightbearing (NWB)	No weight on your injured (sore) leg. This means that you must keep your sore leg off the floor.
Feather-weightbearing (FeWB)	Able to touch your toe down to the floor for balance only.
Partial-weightbearing (PWB)	Able to put up to half of your weight through your sore leg.
Weightbearing as tolerated (WBAT)	Can take most or all your weight through your sore leg.
Full-weightbearing (FWB)	As pain allows.

Alberta Health Services

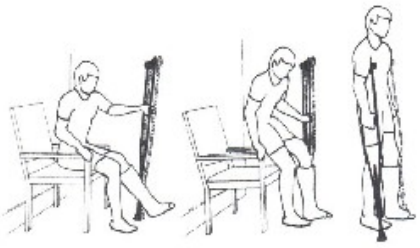
Walking



1. The crutches should be placed ahead and to the sides of your feet for the best balance.
2. Each crutch should be squeezed into your ribs by putting weight through your hands, and keeping your elbows straight.
3. Move both crutches forward at the same time.
4. Move the injured leg forward between the crutches.
5. Move your uninjured (good) leg ahead of the crutches.
6. Repeat these steps to keep walking – crutches, sore leg, good leg.

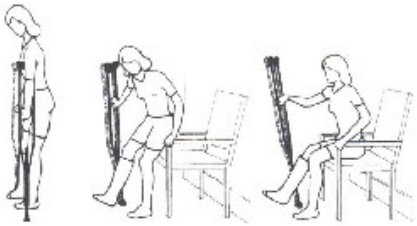
Note: Do not lean on crutch tops.

Standing Up



1. Make sure the chair is steady before you try to stand.
2. Move forward to the edge of the chair so your good foot is flat on the floor.
3. Hold the crutches by the handgrips in one hand. Hold the armrest of the chair (or chair seat) with the other hand.
4. Stand up, taking weight through your good leg. Transfer the crutches under your arms after you gain your balance.

Sitting Down

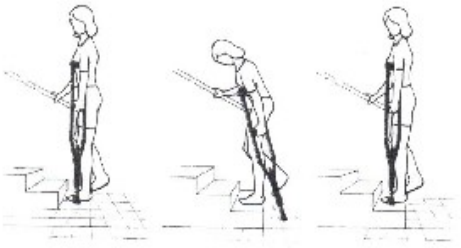


1. Step backwards until the back of your good leg touches the front of the chair.
2. Keeping your weight on the good leg, remove crutches from your arms. Transfer one crutch and hold both crutches by the hand grips in one hand.
3. Hold the armrest of the chair (or chairseat) with the other hand. Slide the foot of your sore leg forward. Lower yourself gently on the chair.
4. Sit down slowly. Keep your crutches next to the chair.

Steps and Stairs

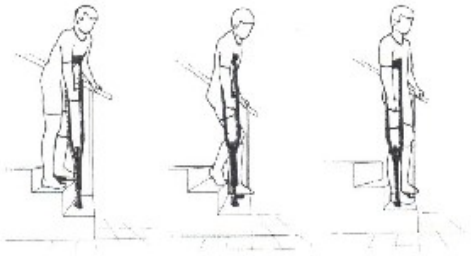
- If there is a handrail on the steps, use it. Put both crutches under the arm away from the railing (or hold as in diagram) and use both crutches as one.
- Hold the railing with your free hand and stand close to the rail.
- On stairs without a railing: follow the instructions for going up and down stairs, except leave one crutch under each arm (as for walking).

Going Up Stairs



1. Stand close to the bottom step.
2. Put your **good** leg up first.
3. Lean forward taking your weight on your good leg.
4. Lift your injured leg and crutches up.
5. Climb one stair at a time.
   If someone is helping you, have them stand behind and to the side of you.

Going Down the Stairs



1. Stand close to the edge of the top step.
2. Move your hand down the railing.
3. Lower your crutches, then your **sore** leg, to the next step.
4. Step down with your good leg.
5. Step down one step at a time.
   If someone is helping you, have them stand in front and to the side of you.

Using One Crutch (Or a Cane)

Use the crutch in the hand **opposite** to the sore leg. This gives you better support and helps you walk with more normal movements.

Using a 4-Point Gait-Style With Crutches

Only use this method if your therapist has told you to do so. You will be instructed in either **partial weightbearing** or **weightbearing as tolerated.**

Follow these steps to walk:

1. Move your right crutch forward.
2. Move your left foot forward so it is even with the right crutch.
3. Move your left crutch forward.
4. Move your right leg forward so it is even with the left crutch.
5. Repeat these steps to keep walking.

Note: If you start with your left crutch, reverse the above order.

Follow the same instructions for crutch walking to:

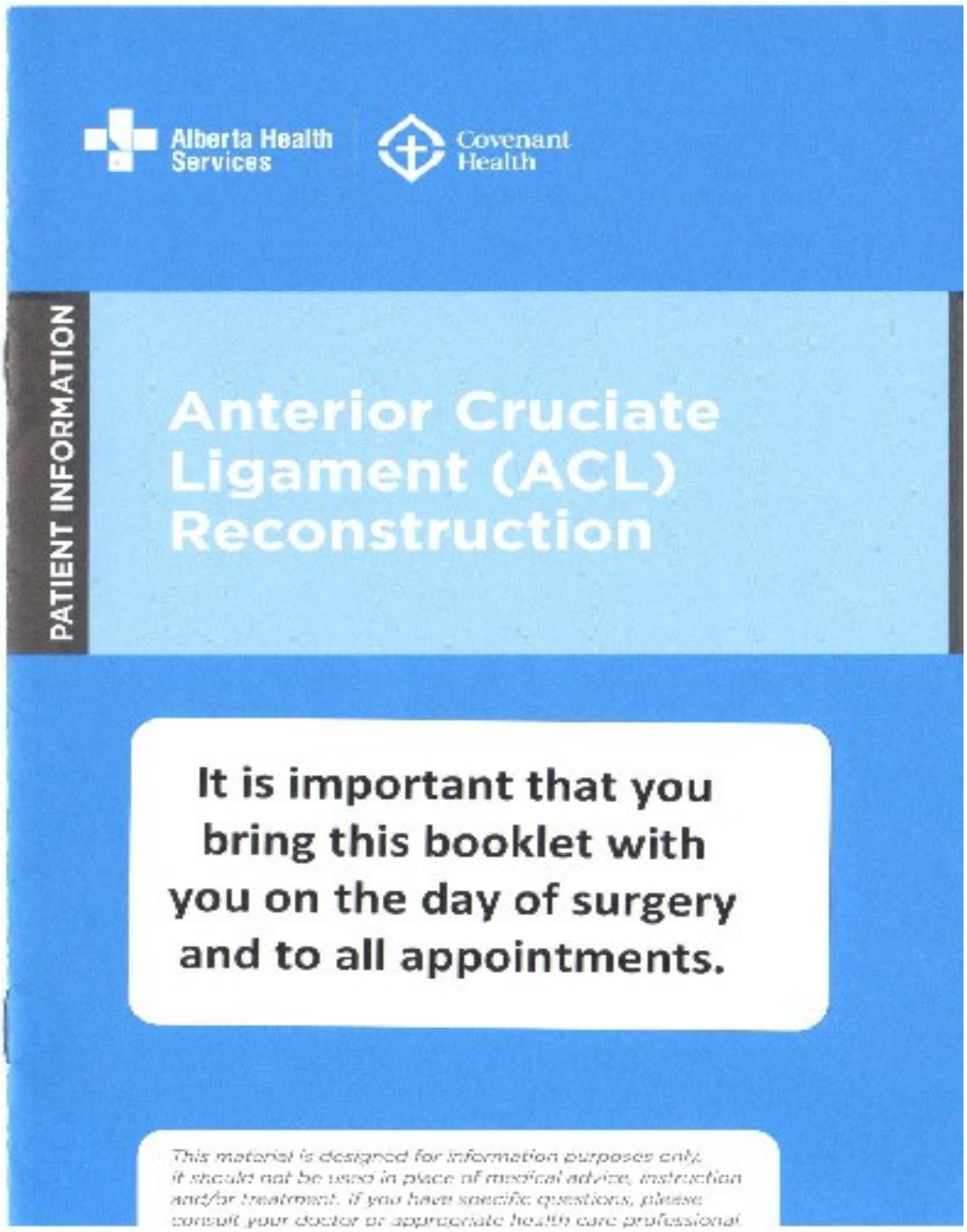
- sit down
- stand up
- go up and down stairs

Safety Tips

- Make sure that your crutches have rubber tips, padded shoulder pieces and hand grips. These should be kept in good condition and replaced as needed.
- It is important to use your crutches correctly. If you feel any numbness or tingling below your armpits or in your upper arms, you are probably using the crutches incorrectly.
- Never stand on your injured (sore) leg unless your doctor says you may.
- Always wear good supportive shoes or bare feet rather than slippers.
- Use a waist pouch as a purse.
- Avoid wet surfaces where possible. Use small steps if you must walk on a wet or slippery surface.
- Scatter rugs or throw mats can be very slippery on a floor. If you have any of these they should be removed.
- Your doctor or physiotherapist will tell you when you can stop using your crutches.

Appendix F

Protocol A



2

Introduction

Many people require surgery following an injury to the anterior cruciate ligament (ACL) of the knee. This booklet will provide you with general information about what to expect before and after surgery and how to take care of yourself at home. Your surgeon may have instructions that are different from this booklet. Please read all the information given to you by your surgeon, nurse or physiotherapist and feel free to ask questions.

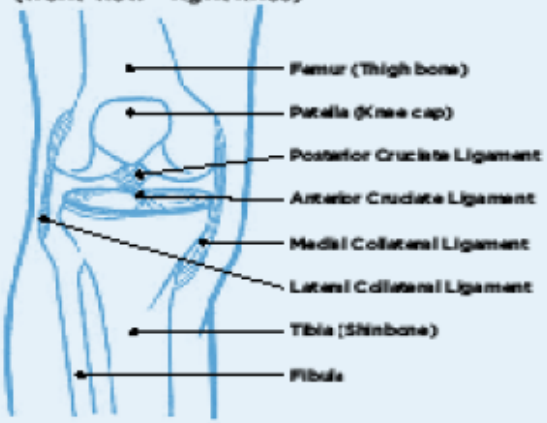
If you receive this book before your surgery, please ensure that you bring it with you on the day of your operation.

What is the Anterior Cruciate Ligament (ACL)?

The anterior cruciate ligament (ACL) is a major ligament which stabilizes the knee. The ACL is in the center of the knee joint and joins the thigh bone (femur) and the shinbone (tibia). A tear in the ACL can occur when the knee has twisted too far, has changed direction too quickly or has received a direct blow. This often happens in sports activities, but can also result from a fall. You may have heard a "pop" and had swelling and pain in your knee. Your knee may now tend to 'give out'.

KNEE LIGAMENTS

(front view - right knee)



What is an ACL reconstruction?

During an ACL reconstruction, the torn ligament is replaced with a graft. The graft is taken from a tendon in the front or side of the knee. It is held in place with small surgical hardware that is made of metal or is dissolvable. This procedure is usually done with the assistance of arthroscopic equipment—inserted through small incisions to allow the surgeon to perform the repair. An additional incision may be required to obtain the graft which will be used.

Preparation for surgery

You may have been advised to bring the following items to the hospital on the day of surgery:

- crutches (If you prefer, you can purchase them at the hospital on the day of surgery.)
- loose-fitting shorts or pants, such as 'tear-aways'

You should not have anything to eat or drink after midnight the day prior to surgery.

Day of surgery

You will be in contact with the hospital prior to your day of surgery, so your admission information will be ready for you.

You will go directly to the day ward when you get to the hospital. All of your admission papers will be waiting there.

Please check with your doctor for instructions about medications that you regularly take.

Discharge instructions

If you live out of town, it is recommended that you stay in the vicinity of your surgical centre overnight.

Arrange to have someone drive you home. A responsible adult must accompany you home either by driving you or going with you in a taxi. Be sure there is room in the vehicle for you to keep your leg straight if you are wearing a knee brace.

Someone must be with you for the first 24 hours after surgery. It may take up to 48 hours for all the effects of anesthetic drugs to wear off.

4

After Surgery Care

You will have some pain and swelling in your knee. This is usually controlled by:

- medications which commonly include analgesics (pain relief pills) or anti-inflammatory pills (for relief of pain and swelling)
- ice
- elevation by keeping the leg you had surgery on raised up on a pillow (see picture on page 5)
- protection of your knee by using crutches when you move around
- relative rest by continuing your daily activities as much as possible, but stopping or avoiding activities that increase pain and/or swelling

Pain

After surgery, you will be given analgesics to control the pain. You are encouraged to take your analgesics as ordered by your surgeon, especially for the first 24–72 hours.

If your knee pain is not managed after using the pain relieving pills, call your surgeon. If you are unable to contact your surgeon or the person covering for him/her, contact your family physician or go to the hospital.

Your surgeon may order anti-inflammatory pills to help with the pain and swelling of the knee. If you experience strong stomach pain from this drug, stop taking it. If the stomach pain continues, contact your family doctor.

INSTRUCTIONS FOR PAIN MANAGEMENT:

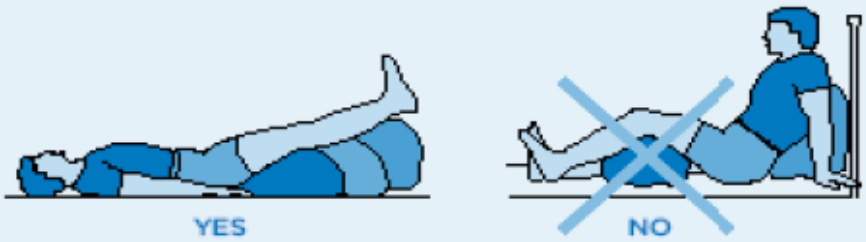
You have been ordered the following medicine for pain:

MEDICINE	HOW TO TAKE	NEXT DOSE

Swelling

Ice is an effective way to treat both pain and swelling. It is more critical in the first 72 hours post-surgery. You will have an ice or a cold pack applied to your knee in the hospital after your surgery. Continue to ice your knee at home, during waking hours for a maximum of 20 minutes per hour as needed.

Elevation of the knee above the heart is an effective way to decrease swelling. When at rest, keep your leg raised by placing pillows under the length of your whole leg.



Nausea

If you feel sick to your stomach or are vomiting, you can take anti nausea medication as suggested by your pharmacist.

You should limit your intake to fluids until your stomach settles. It is important to ensure that your bowel movements are regular.

If you cannot stop vomiting, call Health Link, your family physician or go to the hospital.

For 24-hour general health information or nurse advice, call Health Link Alberta at 780-408-LINK (5465) in the Edmonton area, or 1-866-408-LINK (5465) toll-free.

6

Incision care

Your dressings will be covered with a stretch bandage or tensors. Follow the instructions below for these.

Leave dressing dry and intact until:
❑ post op day _____ ❑ first post op visit

During this time you may rewrap/adjust tensors. Continue to use the tensor as needed after dressing is removed.

Once dressing has been removed, leave steri strips and sutures intact until first post op visit.

May get incision wet in shower on _____

Do not immerse the knee in water or apply creams, lotions, oils or powders until your incisions are well healed (usually 2-3 weeks).

If you have a knee brace, you may remove it to shower.

Activity

Crutches are needed after surgery. A good rule is that if you can't walk normally, you need to use crutches. Advice on when to stop using crutches will come from your surgeon or physical therapist. You will be shown how to use the crutches in hospital.

If you have a knee brace, wear it as instructed.

It is important to move your ankles/toes up and down as if you are pumping on a gas pedal. This will help increase circulation and decreases the risk of a blood clot.

Squeeze your thigh muscle (quadriceps) to help preserve your muscle. Your physiotherapist or surgeon will go over this exercise with you.

Follow the exercise instruction sheet given to you in hospital. It is suggested that you take pain medication one hour before exercise. See your physiotherapist as recommended.

You should not drive until you have discussed this with your surgeon. The decision to drive is based on your safety and ability to control your vehicle, not necessarily on your knee surgery.

You will be advised when you may return to work and play sports.

ACTIVITY INSTRUCTIONS:

Wear your knee brace until _____

Weight bearing instructions:

_____

_____

Problems to report

If you have any of the following problems, call your surgeon. If you are unable to contact your surgeon or the person covering for him/her, contact your family physician or go to the hospital.

- chills or fever
  Persistent temperature above 39°C or 102.2°F. Normal temperature is 36.5 to 37.5°C. It is often normal to have a slight increase in the first 48 hours.
- heavy bleeding
  Blood soaking through the dressing and not stopping for 12 hours
- increased pain or swelling that is not relieved with medication, rest and ice
- severe pain or redness in your calf muscle at the back of your leg that is not relieved with rest or elevation
  It is common to have some pain and discomfort here during the first week. It is often normal to have bruising in the calf and ankle area in the first 2 weeks.
- shortness of breath or chest pain
- incisions that become very red
- drainage from your incisions that is green, yellow or foul smelling

FOLLOW UP:

You will need to see your surgeon for a follow up appointment 2 weeks after surgery.

Please call _____ for your appointment.

Your appointment will be on _____

CONTACT INFORMATION:

If you have questions or concerns after your surgery, please call

_____ at phone # _____

If you are unable to reach your doctor or surgeon, please go to the closest Emergency Department.

For 24-hour general health information or nurse advice, call Health Link Alberta at 780-408-LINK (5465) in the Edmonton area, or 1-866-408-LINK (5465) toll-free.

PHYSIOTHERAPY:

You will need to see your physiotherapist for your first follow up appointment 7 – 14 days after surgery.

Appointment Date _____

Location _____

Rehabilitation

Your physician will tell you when you may see a physical therapist to safely progress your activity. Until then, you can use this guide post-operatively to increase your range of motion.

Early Movement

The exercises you will do during the first two weeks following surgery will help you regain range of motion in your knee. The goal is to establish 90° of flexion, or bend, in your knee by two weeks post-op. You do not need to do any other exercises during this time.

Range of Motion Exercises

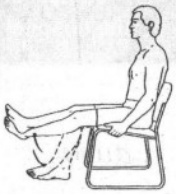
Perform the following exercises three times per day, 10 repetitions each, within pain tolerance.

KNEE - Flexion (Prone)

Using your non-operated leg, gently pull your operated leg towards 90 degrees bend until a light stretch is felt. Hold 5 seconds. Slowly lower leg.

KNEE - Flexion / Extension (Sitting)

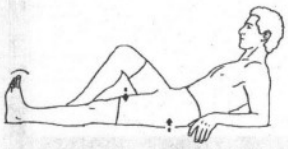
Gently assist operated leg with unoperated leg into extension and then into flexion holding each 5 seconds. Relax as needed.



HIP / KNEE - Heel Slide (Supine)

Slide the heel of the operated heel toward buttocks until a gentle stretch is felt. Hold 5 seconds. Relax.

HIP / KNEE - Isometrics



Pull toes toward operated knee, tense muscles on front of thigh and simultaneously squeeze buttocks. Keep leg and buttock flat on floor. Hold 5 seconds. Relax. Gently extend heel into bed from the hip. Hold 5 seconds. Relax

ANKLE / FOOT - Plantar / Dorsiflexion

With leg relaxed, gently flex and extend ankle. Move through full range of motion. Avoid pain.

Appendix G
Protocol 2 (Video Protocol)

Video 1: http://hdl.handle.net/10402/era.39274

Video 2: http://hdl.handle.net/10402/era.39273

Video 3: http://hdl.handle.net/10402/era.39271

Appendix H
Compliance Diary Participant

No. _____
Group _____

POSTOPERATIVE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION DAILY DIARY

IKDC Subjective Form

For success of the study. Participants will be informed that this information to complete the form daily. This method has been used in previous studies.

24 hours following surgery
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)

Day 2 following surgery	**Day 3 following surgery**
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)

Day 4 following surgery	**Day 5 following surgery**
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)

***** Remember your one week follow-up appointment *****

Day 6 following surgery	**Day 7 following surgery**
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)
Day 8 following surgery	**Day 9 Following surgery**
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)
Day 10 following surgery	**Day 11 following surgery**
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)

***** Remember your two week follow-up appointment *****

Day 12 following surgery	**Day 13 following surgery**
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)
Day 14 following surgery	**Day 15 following surgery**

Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)
Day 16 following surgery	**Day 17 following surgery**
Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)	Pain ___ (0 = no pain 10 = worse imaginable pain) How many exercise sessions completed today? ___ How many icing sessions today? ___ Medication stopped Yes or No (circle one) Crutches stopped Yes or No (circle one)

Appendix I

Sports Injury Rehabilitation Adherence Scale (SIRAS)

Figure 1: Sport Injury Rehabilitation Adherence Scale

SPORT INJURY REHABILITATION ADHERENCE SCALE (SIRAS)

To be completed by the physiotherapist at the end of each of the patient's treatment sessions.
For each of the following circle the number that best indicates the patient's behaviour:

1. The intensity with which the patient completed the rehabilitation exercises during today's appointment						
minimum effort	1	2	3	4	5	maximum effort
2. During today's appointment, how frequently did the patient follow your instructions and advice?						
never	1	2	3	4	5	Always
3. How receptive was this patient to changes in the rehabilitation programme during today's appointment?						
very unreceptive	1	2	3	4	5	very receptive

From: Brewer et al. (1995): A brief measure of adherence during sport injury rehabilitation sessions. *Journal of Applied Sport Psychology* 8(Suppl): S161.

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APPENDIX J
University of Alberta Patient Information Form

A randomized control study of acute post operative care following anterior cruciate ligament reconstruction. A comparison of two protocols.
ACL acute post op care:

Academic Advisor/Investigator: Dr. David Magee, Professor, Faculty of Rehabilitation Medicine, University of Alberta
Co-Investigator: Ian William Hallworth, Physical Therapist, Masters Student, Faculty of Rehabilitation Medicine, University of Alberta

Purpose

Your care during the first two weeks following your surgery will help ensure a full and successful recovery. This will mean less pain and swelling along with better mobility and allow you to return to your daily activities more safely and sooner.

This study will compare two protocols (methods of care) during the first six weeks following your surgery. One week before surgery you will visit the physical therapist for your first assessment, at this time the project administrator will have you select from an envelope a piece of paper that will randomly place you in one of the two protocols. Both protocols are based on best practice standards.

You will be asked to follow one of the two protocols; your effort and adherence to the protocols will result in an optimal recovery for you and provide the best possible results for the study.

You will be assessed the amount on motion in the knee, the swelling around the knee, and the amount of pain you are having and how well you are functioning (getting around and doing their daily activities) will be measured using specific tried outcome measures. The two protocols will then be compared to see which has the best results. We can then improve upon the present program and share this information with other groups in order to benefit all patients having to go through this surgery.

Procedure

You will receive the same care that all of Dr Hui and Otto patients have following this type of surgery. You will follow the same pre operative and post operative plan as described by Dr Hui and Dr Otto. You will be also be assessed by a physical therapist one week before your surgery. This is to ensure that you understand the process of your surgery and the study. Your knee will be assessed at this time and all paper work completed. You will also receive care protocol at this time.

In addition you will be contacted by phone by a physical therapist one day following your surgery. The physical therapist will then checks on your progress and ensure you have completed your first form.

You will then be assessed again by the physical therapist at one week, two and six weeks following your surgery. Your progress will be monitored. Each of these sessions will be approximately 30 minutes in duration. All sessions involve you being asked your pain level at that time, measurement of your knee motion and swelling, and you will complete a knee function form. The evaluations are common to this type of research and standard physical therapy practice and involve no discomfort.

Location

The study will take place at the University of Alberta, Glen Sather Sports Medicine Clinic.
Edmonton Clinic South 11400 University Ave. 2nd level.

Benefits

Patients volunteering for the study will be monitoring by the project physical therapist you will be contacted 24 hours after your surgery and at 1, 2 and 6 week follow up visits. Following the study, the two protocols will then be compared to see if one has better results. We can then improve upon the present program and share this information with other groups in order to benefit all patients having to go through this surgery.

Risks

There is no increased risk in participating in this study.

Privacy/Confidentiality

All data will be kept private, except where codes of ethics or the law requires. The data you give will be kept for at least five years after the study is completed. The data will be kept in a locked filing cabinet. Your name or any other identifying data will not be included in the data generated by your test. Your name will not be used in any presentation or publications related to the study results.

Freedom to Withdraw

Your participation is completely voluntary. If at any time you wish to withdraw you are completely free to do so. Withdrawing will not affect your medical or physical therapy care.

Contact Information

If you have any questions, concerns or complaints regarding the study and procedures, please feel free to contact UofA Research Ethics Office at 780-492-2615.

If you have any questions regarding the study please contact Ian William Hallworth at 780-407-5160 ianh@ualberta.ca or Dr. David Magee at 780-492-5765.

Appendix K

Participant's Consent Form

Name: _____

Participant's Consent Form

Project Title: Evaluation of two acute postoperative rehabilitation protocols following anterior cruciate ligament reconstructive surgery in the study population. Part 1: Researcher Information
Principal Investigator: Dr. David Magee Position: Professor & Associate Dean, Faculty of Rehabilitation Medicine, University of Alberta Contact Information: david.magee@ualberta.ca or (780) 492-5765
Co-Investigator: Ian William Hallworth Position: Physical Therapist, Masters Student, Faculty of Rehabilitation Medicine, University of Alberta Contact Information: ianh@ualberta.ca or (780) 407-5160

Part 2: Consent of Research Participant		
	Yes	**No**

Do you understand you have been asked to participate in a research study?		
Have you received and read a copy of the attached information sheet?		
Do you understand the benefits and risks involved in taking part in this research study?		
Have you had an opportunity to ask questions and discuss the study?		
Do you understand that you are free to refuse to participate or withdraw from the study at any time? (You do not have to give any reason, and it will not affect your care.)		
Has the issue of confidentiality been explained to you?		
Do you understand who will have access to your records/information?		
Do you want the investigators to inform your family doctor that you are participating in this research study? If so, please provide your family doctor's name: Dr. *(Please Print)*_____		

Participant's Consent Form

Part 3: Authorizations
This study was explained to me by : _____ Date (Day/Month/Year): _____
I agree to take part in this study. Name of Research Participant *(Please Print)*:_____ Date (Day/Month/Year): _____

The Research Participant identified above has received an explanation of this study, understands what is involved, and voluntarily agrees to participate.
Name of Researcher *(Please Print)*:_____
Signature of Researcher:
_____
Date (Day/Month/Year): _____

Appendix L

Follow-up Assessment Form

Anterior Cruciate Ligament reconstruction
acute postoperative rehabilitation follow-up testing results.

Week 1 ____or Week 2 ____follow-up (Y)

1. **IKDC subjective score: _____/100**

2. **Pain NRS: _____/ 10**

3. **Range of motion in degrees:**

   Active: Flexion _____/ _____ normal Extension _____/ _____ normal

   Passive: Flexion _____/ _____ normal Extension _____/ _____ normal

4. **Circumferential measure in centimeters:**

Supine: **10 cm above the joint line _____/ _____ normal**

5 cm below the joint line _____/ _____ normal

Seated flexed to 90 degrees: **joint line _____/ _____ normal**

5. **SIRAS Score: _____/15**

6. **Diary outcomes recordings:**

Exercises: _____/_____

Ice: ____/____

Crutches: Yes or No *(Circle)*

Medication being used: Yes or No *(Circle)*

Appendix M: Data Changes Using Intention to Treat

Table A: Participant Characteristics Intention to Treat

	Entire Sample N=37	**Group A n=19**	**Group B n=18**
		Mean (SD) or Percentage	
Age* (years)	24.3 (7.2)	27.4 (7.4)	21.1 (5.5)
Height (cm)	173.1 (8.7)	173.2 (7.8)	173.1 (9.9)
Weight+ (kg)	72.7 (16.3)	77.4 (18.4)	67.8 (12.3)
Graft Size	7.5 (0.5)	7.5 (0.5)	7.5 (0.5)
Pain Rating (Out of 10, n=35)	0.4 (0.8)	0.4 (0.8)	0.4 (0.8)
Sex+ (% female)	54.1	57.9	50.0
Meniscus treated +(% Yes)	94.6	89.5	100.0

** Statistically significant difference observed between groups (p<0.05).*

+ Large difference but not a statistical significant difference between groups (p<0.05)

Table B: Participant Pre- and Post-Operative Clinical Findings IKDC Examination Score Between Groups Over Five Intervals

IKDC Clinical Exam Measures Mean (SD)	**Entire Sample**	**Group A** *Mean (SD)*	**Group B** *Mean (SD)*
Pre-Operative	51.6 (12.4)	53.9 (12.5)	49.1 (12.2)
24hours (n=26)	13.7 (9.0)	13.5 (9.2)	13.9 (9.3)
1 week (n=37)	21.5 (8.9)	24.2 (8.2)	18.7 (8.9)
2 weeks (n=35)	33.7 (9.6)	36.1 (7.6)	31.0 (11.1)
6 weeks (n=35)	51.0 (9.2)	51.2 (9.9)	50.8 (8.5)

Figure A: The Mean of the IKDC Scores Between Groups Over the Five Measurement Intervals Intention to Treat

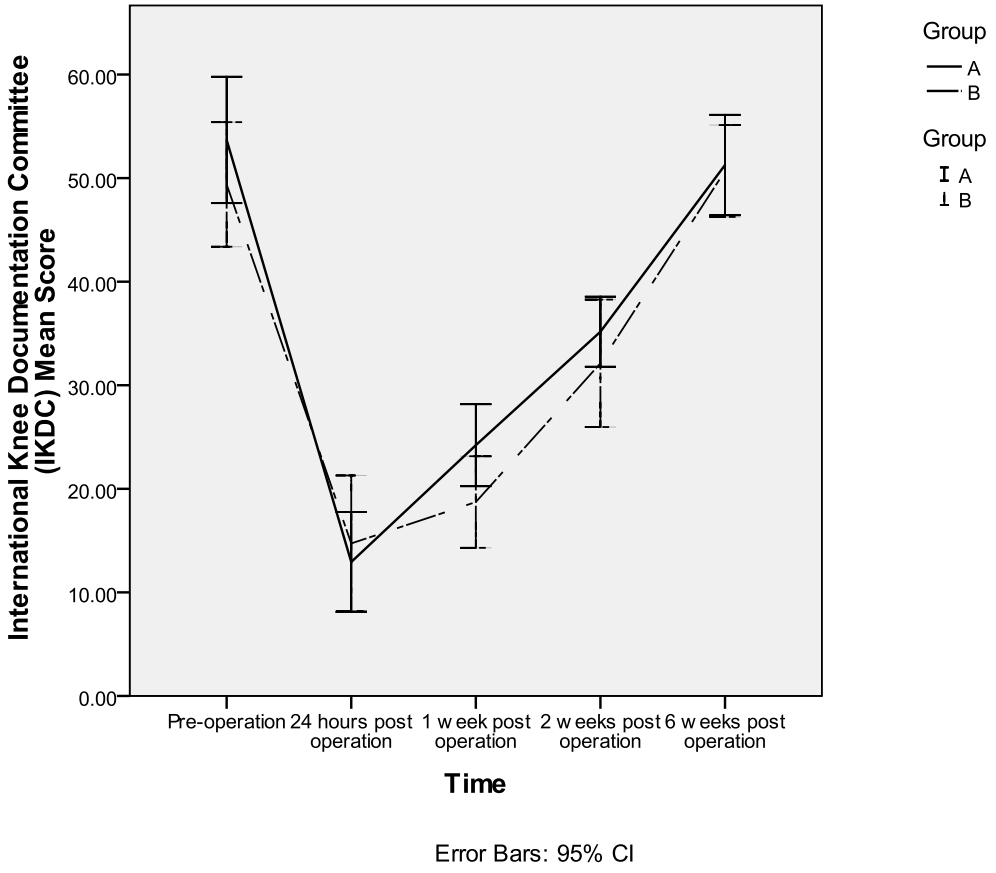

Table C Participant Pre and Post Operative Clinical Findings for Pain Comparing NRSP and the IKDC Pain Scale Findings over Five Intervals Intention to Treat

Clinical Exam Measures	**Entire Sample** *Mean (SD)*	**Group A** *Mean (SD)*	**Group B** *Mean (SD)*
Pain			
Pre-Operative (n=37)	0.6 (1.0)	0.7 (1.0)	0.6(1.0)
24hours (n=35)	6.5 (2.3)	6.3 (2.2)	6.7 (2.5)
1 week (n=37)	3.4 (2.3)	3.4 (1.9)	3.4 (2.7)
2 weeks (n=36)	1.8 (1.6)	1.6(1.2)	1.9 (2.0)
6 weeks (n=35)	0.5 (0.8)	0.5 (0.8)	0.3 (0.7)
IKDC Pain			
Pre-Operative	(n=37) 3.1 (2.4)	3.0 (2.4)	3.3 (2.4)
24hours (n=35)	5.9 (2.6)	6.0 (2.3)	5.7 (2.8)
1 week (n=37)*	5.7 (2.0)	5.0 (1.6)	6.4 (2.1)
2 weeks (n=37)	4.2 (2.2)	3.9 (2.1)	4.4 (2.2)
6 weeks (n=35)	2.6 (2.5)	3.2 (2.9)	2.0 (1.8)

** Statistically significant mean difference observed between groups ($p<0.05$).*
A score of 0 represents no pain 10 represents maximal pain score

Figure B: Average Pain Scores on the Numerical Rating Scale for Pain, Between Groups over the Five Measurement Intervals Intention to Treat

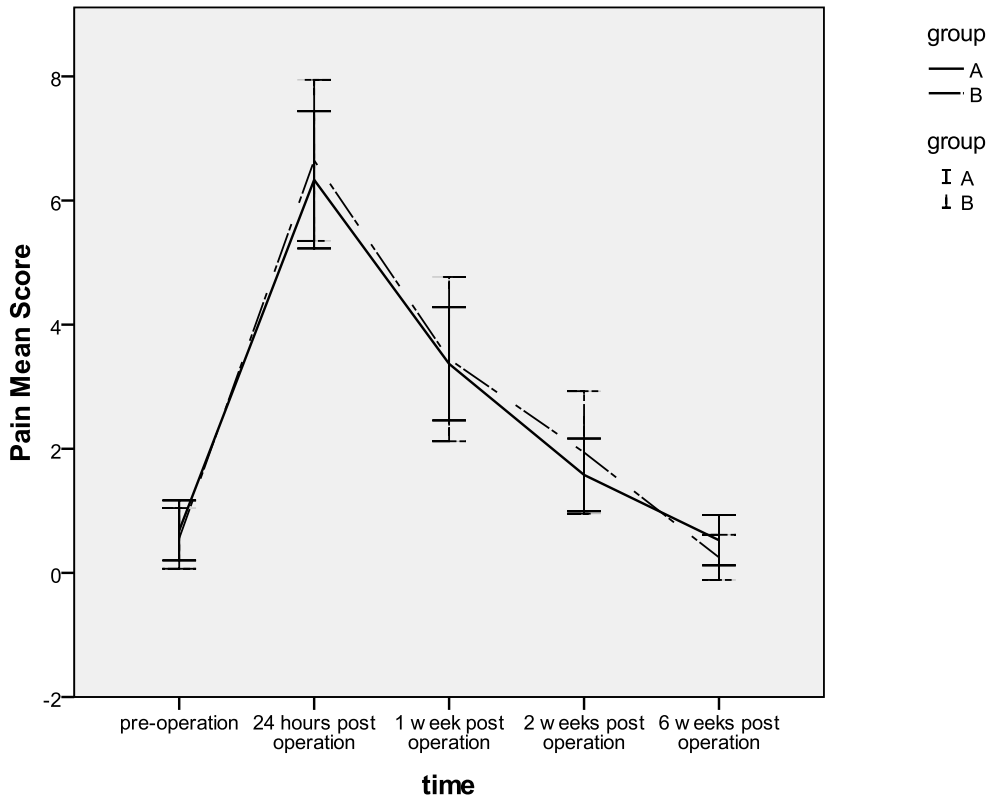

Table D: Participant Pre and Post Operative Clinical Circumferential Measurements in Centimeters at the Four Measurement Intervals Intention to Treat

Circumferential measurements in cm	**Entire Sample** *Mean (SD)*	**Group A** *Mean (SD)*	**Group B** *Mean (SD)*
5cm Girth			
Pre-Operative	35.4 (2.8)	36.3 (3.0)	34.5 (2.3)
1 week (n=37)	36.5 (3.1)	37.2 (3.2)	35.9 (2.4)
2 weeks (n=35)	35.7 (3.1)	36.4 (3.4)	34.8 (2.5)
6 weeks (n=35)	35.5 (3.1)	36.5 (3.2)	34.4 (2.6)
10cm Girth			
Pre-Operative	39.7 (3.7)	40.4 (3.9)	38.9 (3.3)
1 week (n=37)	40.6 (3.4)	42.1 (4.2)	39.8 (2.9)
2 weeks (n=35)	41.0 (3.8)	40.8 (4.5)	38.7 (3.4)
6 weeks (n=35) *	39.6 (4.1)	40.9 (4.1)	37.9 (3.5)
Joint Line Girth			
Pre-Operative	34.2 (2.7)	34.7 (3.0)	33.9 (2.5)
1 week (n=37)	36.6 (2.9)	37.3 (3.2)	35.9 (2.4)
2 weeks (n=35)	36.1 (2.8)	36.5 (3.0)	35.6 (2.5)
6 weeks (n=35)	35.7 (2.7)	36.3 (2.8)	35.1 (2.5)

Figure C: Average 5 cm Circumferential Scores in Centimeters Between Groups Over the Four Measurement Intervals Intention to Treat

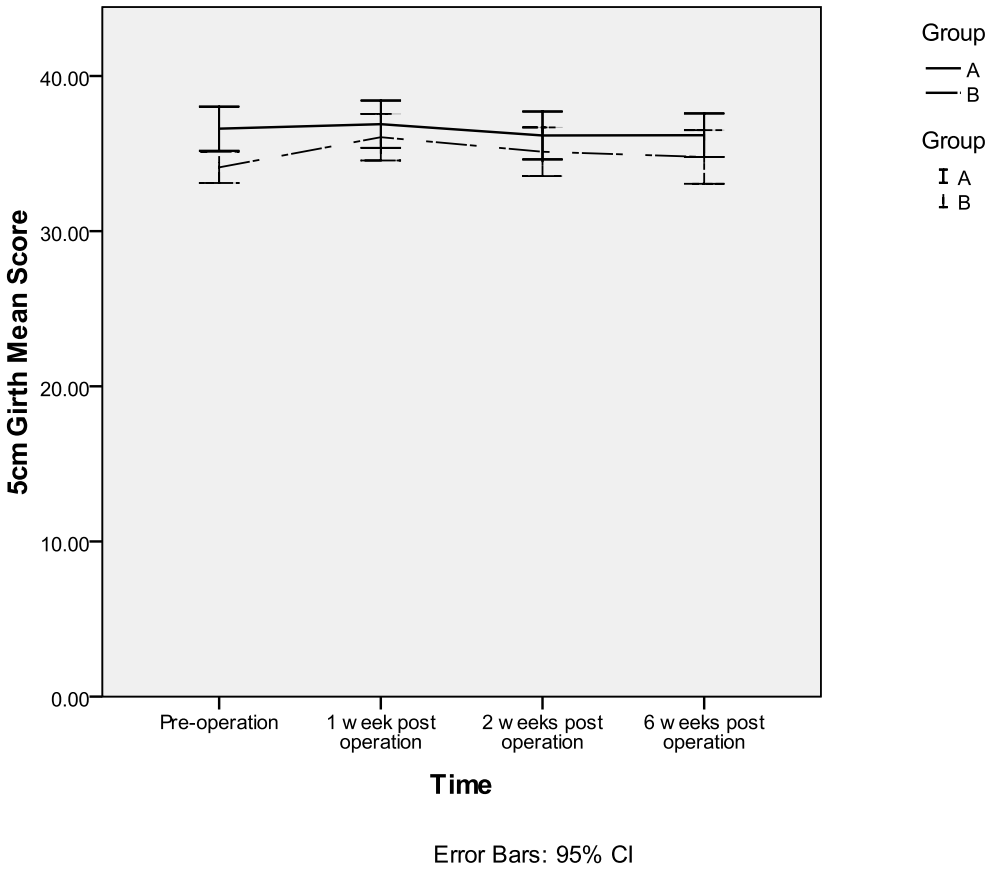

Figure D: Average 10cm Circumferential Scores in Centimeters Between Groups Over the Four Measurement Intervals Intention to Treat

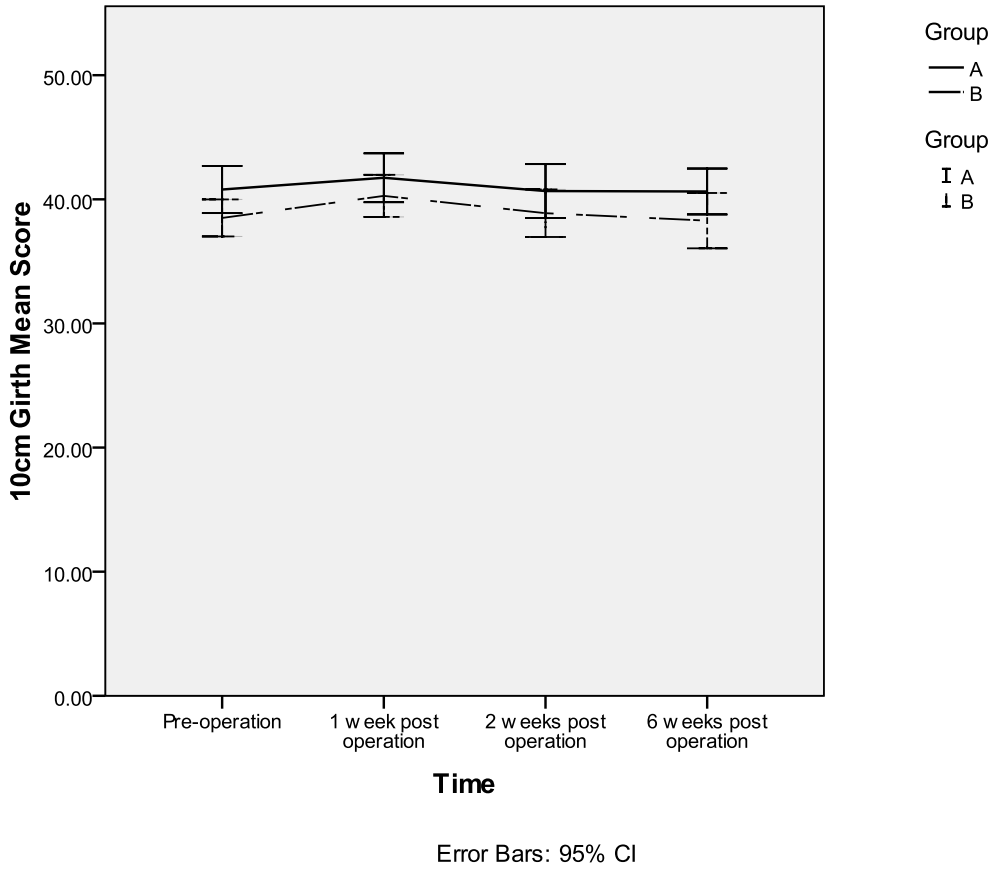

Figure E: Average Joint Line Scores in Centimeters Between Groups Over Four Measurement Intervals Intension to Treat

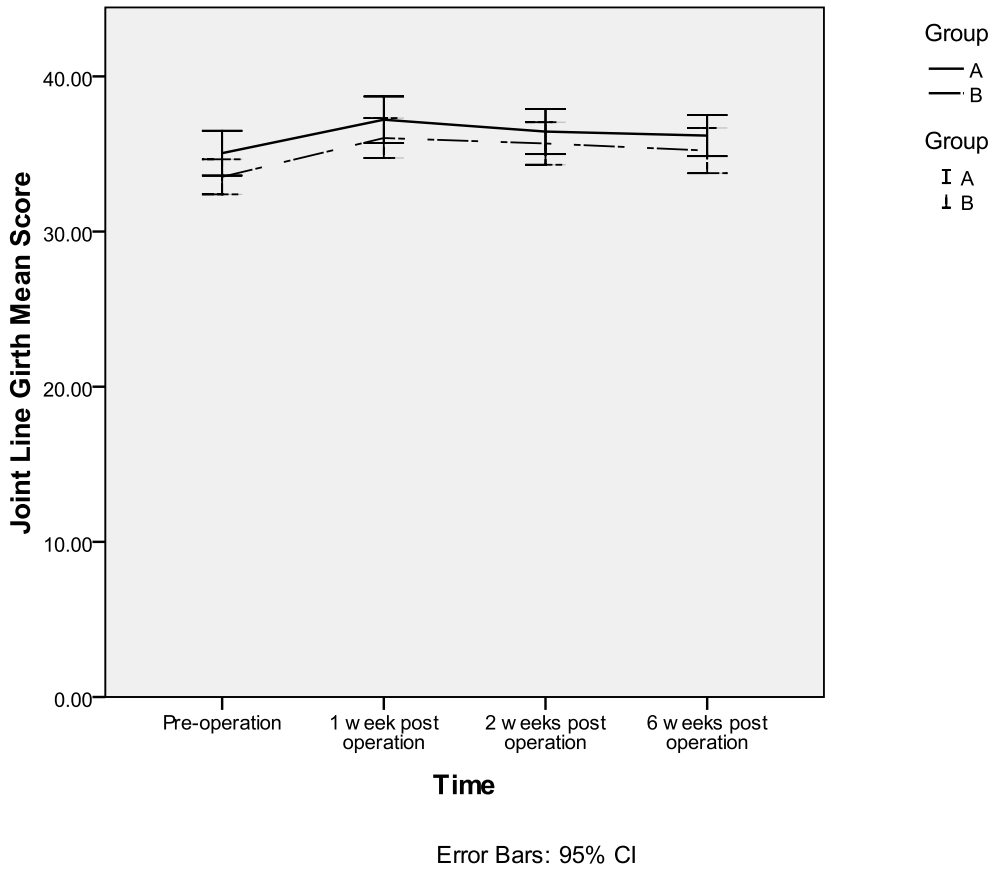

Table E: Participant Pre and Post Operative Clinical Range of Motion Findings in Degrees Over Four Measurement Intervals Intention to Treat

	Entire Sample	**Group A**	**Group B**
Clinical Exam			
Measures in degrees	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*
Extension ROM			
Pre-Operative	-4.7 (2.8)	-4.1 (2.8)	-5.3 (2.8)
1 week (n=37)	6.3 (6.1)	7.2 (5.8)	5.2 (6.5)
2 weeks (n=35)	3.2 (5.9)	4.4 (4.3)	1.9 (7.0)
6 weeks (n=35)	-1.9 (3.6)	-1.0 (3.3)	-2.9 (3.7)
Flexion ROM			
Pre-Operative	144.4 (7.3)	144.0 (5.6)	145.0 (8.9)
1 week (n=36)	94.7 (15.9)	95.7 (13.2)	93.7 (18.6)
2 weeks (n=35)	111.5 (19.9)	115.6 (14.5)	107.1 (24.0)
6 weeks (n=35)	135.2 (10.4)	133.1 (11.6)	137.7 (8.3)

Figure F: Average Flexion Range of Motion Scores, Measured in Degrees, Between Groups Over the Four Measurement Intervals Intention to Treat

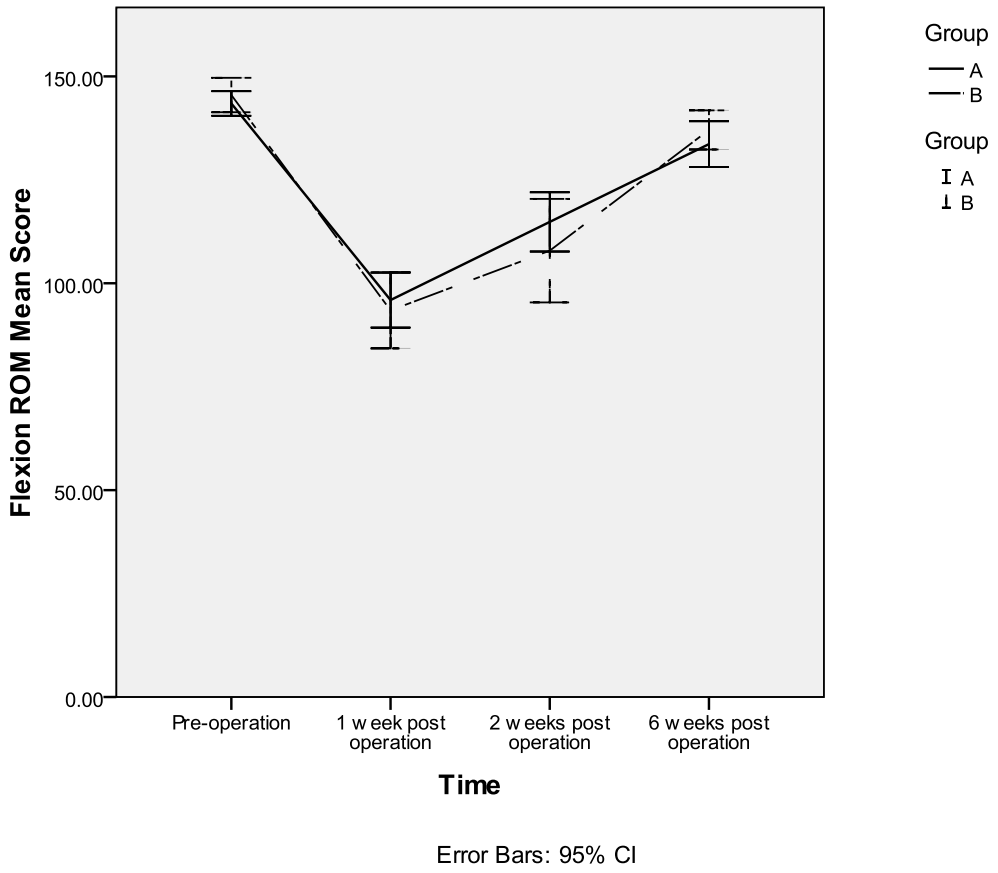

Figure G: Average Extension Range of Motion Scores, Measured in Degrees, Between Groups Over the Four Measurement Intervals Intention to Treat

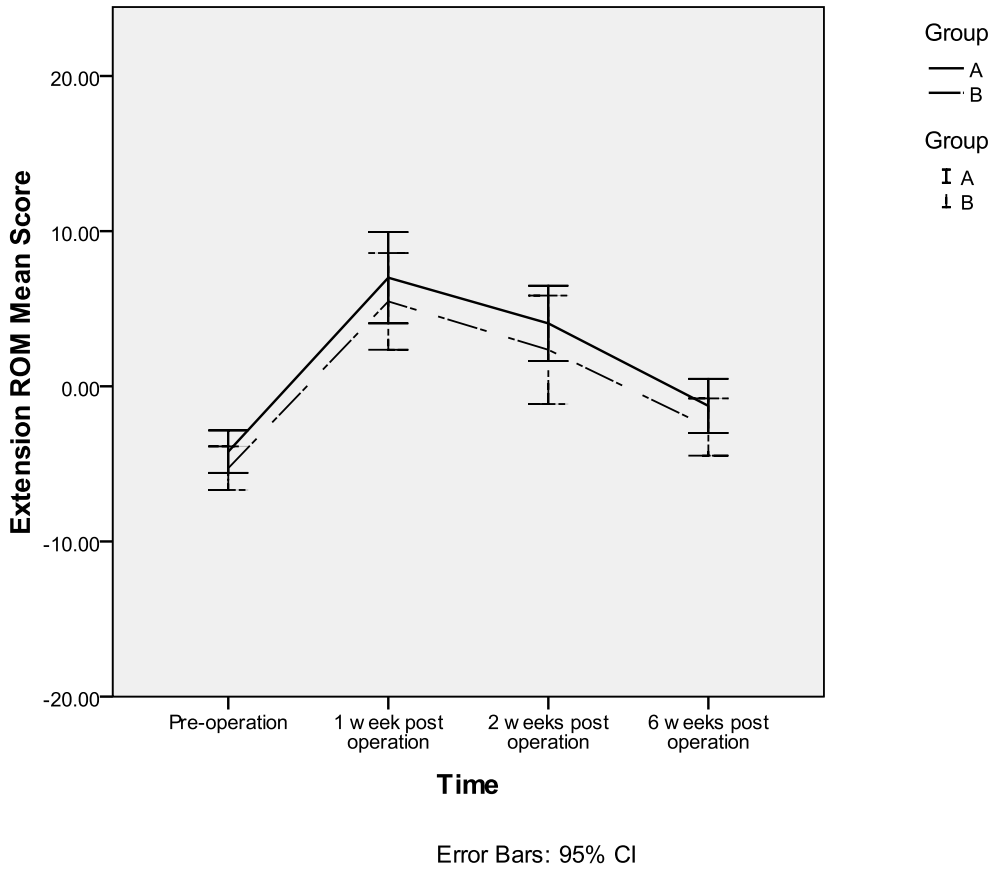

Table F: Pain Numerical Rating Scale (NRSP) and IKDC Pain Comparison Between Pre and Post Operative

	(NRSP)Pain	**IKDC Pain**
	Mean (SD)	*Mean (SD)*
Pain Pre-Operative (n=37)*	0.6 (1.0)	3.1(2.4)
24hours (n=35)	6.5 (2.3)	5.9 (2.6)
1 week (n=37)*	3.4 (2.3)	5.7 (2.0)
2 weeks (n=36)*	1.8(1.6)	4.1 (2.2)
6 weeks (n=35)*	0.4 (0.8)	2.6 (2.5)

** Statistically significant mean difference observed between groups (p<0.05).*

0 represents no pain and 10 represent the maximal level of pain

Figure H: Average Pain Scores Between the Two Pain Measures Over Five Measurement Intervals Intention to Treat

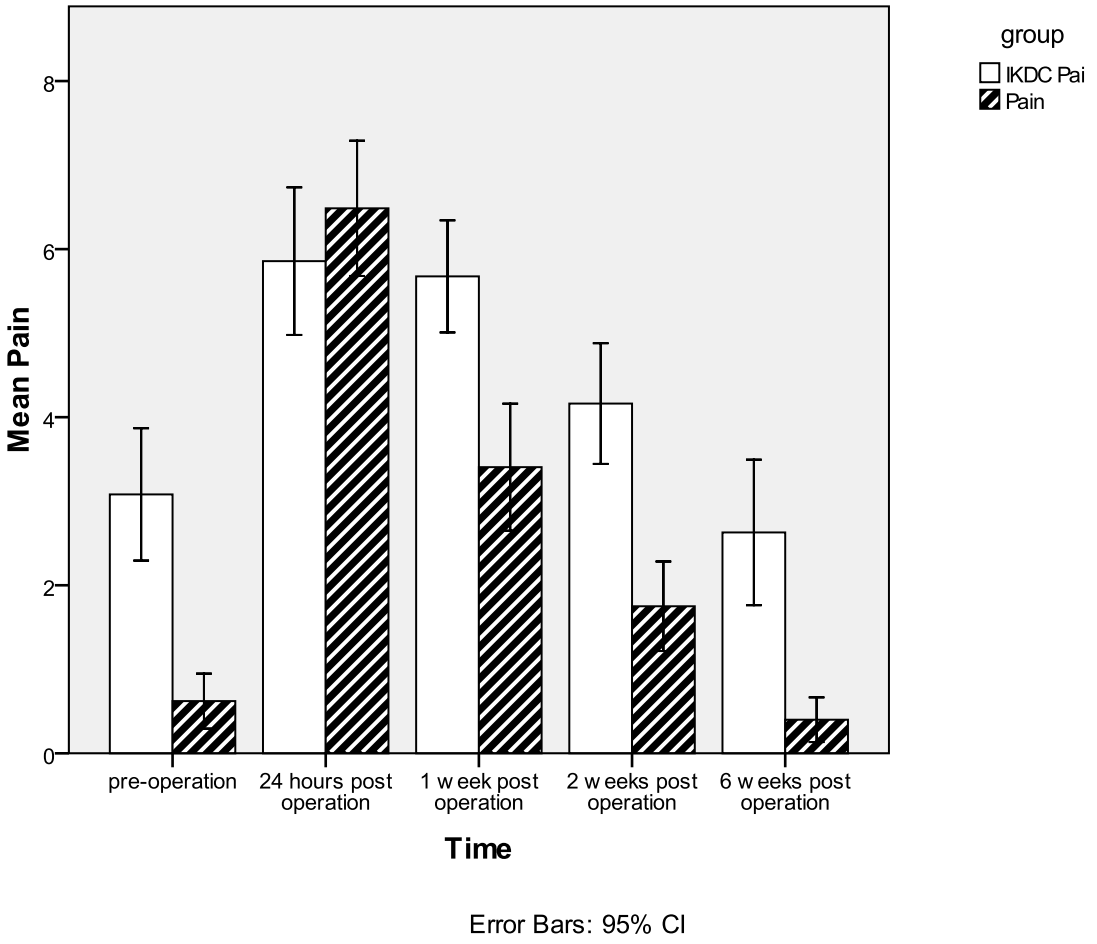

Table G: Tests of Between-Subjects Effects for Intention to Treat Analysis

	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	p value
Time	IKDC	27685.5	3	9228.5	94.1	**<0.001**
	5cm	6.8	3	2.3	0.25	0.86
	10cm	31.1	3	10.4	0.66	0.58
	Joint Line	80.7	3	26.9	3.3	**0.02**
	Extension	2784.8	3	928.3	43.2	**<0.001**
	Flexion	50821.5	3	16940.5	82.9	**<0.001**
Group	IKDC	96.4	1	96.4	0.98	0.32
	5cm	42.9	1	42.9	4.8	**0.03**
	10cm	66.5	1	66.5	4.3	**0.04**
	Joint Line	15.8	1	15.8	1.9	0.17
	Extension	95.0	1	95.0	4.4	**0.04**
	Flexion	49.8	1	49.8	0.24	0.622
Time x Group	IKDC	338.7	3	112.9	1.2	0.33
	5cm	12.0	3	4.0	0.4	0.72
	10cm	7.9	3	2.6	0.17	0.92
	Joint Line	2.3	3	0.77	0.09	0.96
	Extension	16.9	3	5.6	0.26	0.85
	Flexion	561.0	3	187.0	0.92	0.44