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ACL Reconstruction Rehabilitation: A Systematic Review Part I

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Introduction

Anterior cruciate ligament (ACL) reconstruction is a common procedure to allow patients to return to their former active lifestyle. Rehabilitation of the reconstructed knee is critical for the successful return to risky cutting and jumping activities. While many of the individual aspects of ACL rehabilitation have been evaluated using randomized trials few reviews have used an evidence based approach to create an overall protocol for ACL rehabilitation. Previous systematic reviews were not inclusive of all possible aspects of rehabilitation i.e. bracing and were old enough to exclude many recently published studies.[1, 2] The goal of this systematic review is to assemble the available randomized controlled trials (RCTs) in ACL rehabilitation to facilitate the development of evidence based rehabilitation protocols. This represents Part I of a 2 part series systematically reviewing the Level 1 and 2 evidence regarding ACL reconstruction rehabilitation.

Methods

Pubmed 1966 to 2005, Embase 1980 to 2005 and the Cochrane Controlled Trials Register were searched for papers appropriate to this study. Bibliographies of identified studies were also searched and a hand review of the last six months of appropriate journals was performed. For the database search terms included anterior cruciate ligament, ACL, rehabilitation, randomized trials, and clinical trials. This search identified 82 potential studies for inclusion. Inclusion criteria included English-language randomized clinical trials involving ACL reconstruction rehabilitation. Exclusion criteria included non-English language, no true randomization, and subject matter not pertaining to ACL reconstruction rehabilitation. This resulted in 54 studies included in this systematic review. Studies

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underwent worksheet appraisal for methodological quality with emphasis on identifying biases present in each study. All studies were level 1 or 2 evidence. Topics included by this review are continuous passive motion, rehabilitative bracing, neuromuscular electrical stimulation, early weight-bearing, home versus supervised physical therapy, open versus closed chain kinetic exercise programs, accelerated rehabilitation and a variety of miscellaneous topics assessed by only one randomized trial.

Continuous Passive Motion

Six randomized controlled trials have been performed assessing the efficacy of continuous passive motion (CPM) in the rehabilitation of ACL reconstructions. Richmond et al [3] in a 1991 study compared short versus longer term CPM use. Twenty patients were randomized to one of two groups. Group 1 used the CPM six hours a day four days while hospitalized. Group two used the CPM six hours a day for the first 14 days postoperatively. Both groups underwent additional rehabilitative activities.

The study was prospective but randomization method was not discussed. Some selection bias was present by exclusion of patients whose insurance would not pay for a CPM machine. Otherwise the two groups were similar. Reconstruction methods were identical for both groups.

Swelling, atrophy, range of motion and instrumented laxity were assessed postoperatively. Swelling, atrophy, and range of motion were assessed at two, seven, 14, 28 and 42 days. No significant difference was noted in any of these values at these time points. A statistically significant difference was noted at KT 1000 89N testing at 42 days. The 14 day CPM group was noted to have statistically significant less anterior translation as compared to the four day CPM group (0.4 mm vs. 2.4 mm, p=0.04). The authors concluded that longer term CPM use given its higher cost was not beneficial and also did not increase the risk of laxity in the knee.

Rosen et al [4] in a 1992 study compared early active motion versus CPM in patients undergoing autograft patellar tendon reconstruction. Seventy-five patients were randomized to three groups: Group A, early active motion while hospitalized followed by outpatient physical therapy (PT) three times a week, Group B, used a CPM machine 20 hours a day while hospitalized (average 2.9 days) followed by six hours a day CPM use for four weeks and outpatient PT three times a week, Group C did early active motion while hospitalized and followed the CPM protocol of Group B, but did not participate in outpatient physical therapy for the first month.The study was prospective and randomization was performed by a lottery. In general there was minimal selection bias with the groups equivalent except for gender. Group B had 42% females versus 24% and 20% in Group A and C. Exclusion criteria included extra capsular procedures and meniscal repairs.

Range of motion and instrumented knee laxity was the most important determinants of outcome for the study. Range of motion was determined at hospital discharge, one week and monthly for the first six months. No statistically significant differences were noted in any of the groups at any time. KT 1000 data was obtained at completion of the surgical procedure and at two and six months postoperatively. No difference in stability was noted between any group at any time point. In addition no difference was noted in analgesic use, hemovac drainage, or length of hospital stay. The authors concluded the use of CPM in the first 30 days after ACL reconstruction resulted in similar results as early active motion. The CPM added an additional cost to treatment.

Yates et al in a 1992 study evaluated the effects of two weeks of CPM use following patellar tendon autograft ACL reconstruction.[5] Thirty patients were randomized using random

sampling to CPM 16 hours a day for the first three postoperative days followed by six hours a day for a total of 14 days use versus identical rehabilitation protocol without CPM. The authors concluded there was decreased hemarthrosis, decreased narcotic use, and decreased swelling in the CPM group. Active and passive flexion was noted to be improved at day three and seven in the CPM group.

McCarthy et al in a 1993 study assessed the effects of CPM use on anterior laxity following ACL reconstruction.[6] Twenty patients following patellar tendon autograft ACL reconstruction were randomized to CPM 16 hours a day for the first three days followed by six hours a day until postoperative day 14 versus an identical rehabilitation protocol without CPM. KT 1000 testing at 12 months postoperatively demonstrated an identical 0.4 mm average side to side difference in both groups and all patients had ≤ 3 mm side to side difference. The authors concluded CPM use did not result in increased anterior laxity.

McCarthy et al [7] in a 1993 study compared three days of CPM use versus no CPM use on pain and narcotic requirements. Thirty patients were randomized to two groups. Group one underwent bone tendon bone ACL reconstruction and began physical therapy on postoperative day one. Group two began use of a CPM machine immediately postoperatively and continued its use for 16 hours a day for three days in addition to routine physical therapy similar to group one.

The randomization methods were not discussed. Patient controlled analgesia (PCA) use during the first 24 hours postoperatively, oral narcotic use on postoperative day two and three, and graphic pain scales were used to assess results. The two groups were similar but no narcotic dose correction for patient body weight was performed to standardize results. Total narcotic dose and the number of times the PCA button was pushed were statistically significantly increased in the non-CPM group ($p < 0.05$). Oral narcotic use on postoperative day two and three was statistically significantly increased in the non-CPM group. Graphic pain scales were similar in all groups at all time periods. The authors concluded that CPM is beneficial following an autogenous bone patellar tendon bone ACL reconstruction to decrease narcotic use.

Engström et al [8] in a 1995 study compared CPM versus active motion in the early postoperative period. Thirty-four patients were randomized to two groups. Group 1 started active motion on postoperative day one following ACL reconstruction and Group 2 started CPM six hours a day for six days in addition to active motion beginning on postoperative day one. The method of randomization was not discussed. Parameters evaluated including swelling, range of motion, and atrophy at six weeks postoperative. Selection bias was present in the fact that the active motion group had more acute ACL (9 vs. 3) and these patients had a much larger extension lag of 7.8° versus 0.8° in the CPM group. Otherwise the groups were similar.

There was no statistically significant difference at six weeks in range of motion or atrophy between the two groups. Mid patellar and base of patella circumference was increased in the active motion group at six weeks ($p < 0.05$). The authors attributed this difference to the fact that the active motion group contained more acute ACL reconstructions and had increased swelling properatively. The authors concluded they could find no benefits of CPM after ACL reconstruction.

All six of these studies have small numbers of patients. Every paper has at least one parameter that was determined not to be statistically significantly different between groups. Selection bias by randomization method potentially exists in all, but the Rosen study. Blinding of examiners was not addressed in any study. Drop-outs and compliance were not addressed in any study. None of the studies presented power calculations to determine the

size of group that would have been necessary to potentially demonstrate a difference if it did exist. Thus, these potentially suffer from a Type II error. Based on this review there is no substantial advantage for using CPM use except for a possible decrease in pain. Thus, its usage cannot be justified with its additional insurance and patient costs.

Early Weight-bearing and Motion

One randomized trial has been performed evaluating the efficacy of immediate weight-bearing versus delayed weight-bearing following ACL reconstruction. Tyler et al [9] in a 1998 study compared immediate weight-bearing as tolerated versus a delay of two weeks. Forty-nine patients were prospectively randomized following endoscopic autograft BTB reconstructions. Randomization technique was not discussed. Independent examiners assessed results, but blinding was not discussed. Group 1 was instructed to discard their crutches as soon as possible and to bear as much weight as possible. Compliance with weight bearing was not determined. Group 2 was instructed to be non-weight-bearing for the first two weeks following reconstruction. They were instructed to not wear a shoe to improve compliance. Two patients in each group were lost to follow-up.

Parameters evaluated included ROM, stability, VMO EMG, Lysholm, Tegner, and anterior knee pain. KT 1000 demonstrated no difference at final follow-up which ranged from six to 14 months. ROM showed no statistical difference at two weeks or final follow-up of six to 14 months (avg. 7.3 mos). VMO activity was statistically significantly increased in the weight-bearing group at two weeks $p = 0.002$. At final follow-up VMO activity was equal in both groups. At final follow-up a statistically significant difference in anterior knee pain was noted. Seven of 20 (35%) non-weight-bearing patients and 2 of 25 weight-bearing patients reported pain $p = 0.03$. Anterior knee pain was evaluated using questions from the Lysholm Scale that described pain with routine exertion, stair climbing or squatting. Lysholm scores demonstrated a significantly greater improvement from preoperatively in the weight-bearing group $p = 0.03$.

The authors concluded there were no deleterious effects of early weight-bearing on stability or function and that anterior knee pain may be decreased by earlier recruitment of the VMO when weight-bearing. A trend had been noted in their study that patients that reported anterior knee pain at final follow-up had decreased VMO activity at two weeks. Potential selection or observer bias exists, but early weight bearing following reconstruction is probably justified. Any future studies need to document compliance with weightbearing in the assigned groups.

Noyes et al. in a 1987 study evaluated the effect of early motion following open and arthroscopic ACL reconstruction.[10] Eighteen patients were randomized following ACL reconstruction or ACL repair with graft augmentation to one of two groups. Group 1 began CPM motion on postoperative day two while group two remained in a hinged brace at 10° of flexion for the first postoperative week and on day seven began CPM use. Randomization method and blinding were not addressed. The authors noted a weak trend towards earlier extension and flexion gains between postoperative day 14 and 21 in the early motion group, but these were not statistically significantly different $p = 0.20$. There was no difference in the two groups with respect to knee laxity as measured by KT 1000 testing. Currently, most ACL rehabilitation protocols institute early motion within the first postoperative week supporting the trend noted in this study.

Post-operative Bracing

One of the authors (RWW) of this current study recently published a systematic review of postoperative rehabilitative bracing.[11] These braces are designed to limit range of motion to

predetermined settings and protect the knee against excessive varus and valgus stresses. Eleven articles[12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22] evaluating results of ACL reconstruction rehabilitation using these braces were included in the systematic review. (Table 1)

Outcomes evaluated included ease and speed of obtaining range of motion especially extension, swelling control, wound drainage, knee laxity, pain and protection from injury. All of the included studies contained biases that attracted from their conclusions. Only one study[20] determined the power to detect a statistically significant difference thus, many studies were potentially underpowered. Independent examiners were only used in three studies.[12, 16, 22] Blinding was only described by three studies.[16, 18, 20] Several studies had potential selection bias due to lack of description of randomization techniques. The only study that demonstrated a potentially clinically significant finding was Melegati et al[17] who found improved extension following locking the brace in full extension in the first postoperative week.

No study demonstrated a potentially worse outcome when a brace was not used. Importantly, no increase in postoperative injuries, increased pain, decreased range of motion or increased knee laxity was found in the control groups that were on braced following surgery. Based on the studies included in the systematic review the authors determined that postoperative bracing was not necessary following ACL reconstruction.

Home-based Rehabilitation

Four RCTs have been performed to evaluate standard clinic based physical therapy rehabilitation versus minimally supervised home-based rehabilitation following ACL reconstruction.(Table 2) Schenck et al [23] in a 1997 study randomized 37 patients by lottery following two incision autograft BTB ACL reconstruction to home-based or clinic based physical therapy. Exclusion criteria included age less than 18 years. Patients were followed by an independent observer. Blinding of the independent observer was not discussed.

Twenty-two patients in the home rehabilitation program used an average of 2.85 (range 0 to 6) visits with a physical therapist in the clinic to supervise a home-based program. Fifteen patients in the clinic based group used an average of 14.2 (range 6 – 40) visits in the physical therapy clinic. There was a significant difference between the groups in the number of visits required $p < 0.05$. The prescribed exercises were the same for both groups with the only difference the amount of clinic supervised therapy.

Parameters assessed to determine outcome included range of motion, Lysholm score, pain VAS, one legged hop, KT 1000, and the sickness impact profile. These were measured preoperatively and at three months and 12 months postoperatively. There was no difference in any measured evaluation between the two groups at any point in the study. No patient in either group required additional surgery. The authors concluded that minimal supervision for rehabilitation could result in equivalent outcome following ACL reconstruction. The authors excluded patients below the age of 18 because they believe these patients are too immature to control their own rehabilitation.

Beard and Dodd [24] in a 1998 study assessed a home versus group exercise program following four to six weeks of standardized supervised physical therapy after ACL reconstruction. Thirty-one patients were randomized and five were lost to follow-up. Randomization was by a computer program. An independent examiner was blinded to patient allocation.

Both groups performed supervised physical therapy two times a week for the first two weeks and once a week for the next two to four weeks following surgery. At that point the 13

patients in the home-based group continued their rehabilitation without supervision. The 13 patients in the supervised group then continued twice a week attendance to a group knee exercise class with the goal of 12 weeks of continued supervision. An attempt to determine compliance of the home group was made but the home-based patients were noncompliant with filling out the compliance forms. In the supervised group the median number of sessions attended was 16 (range 10-22). The maximum number of sessions that could be attended was 32 (16 weeks).

Outcome was assessed by Lysholm, Tegner, IKDC, VAS for sports and activities of daily living, instrumented laxity, and isokinetic testing. These were all assessed preoperatively and at three and six months postoperatively. There was no difference noted in any assessment at any time point. The authors concluded that a home-based regimen of rehabilitation following a short course of supervised therapy is equivalent to further supervised therapy.

Fischer et al [25] in a 1998 study evaluated a group of patients prospectively randomized to a home-based or clinic based physical therapy program following autograft or allograft BTB ACL reconstruction. Fifty-four patients were randomized to the two groups. One patient in the clinic based group was lost to follow-up due to subsequent foot surgery. Randomization technique, blinding and independent assessment was not discussed. Compliance was assessed in the home group using a training log. Exclusion criteria included patients below the age of 15. The patients in the home-based group were prescribed six physical therapy visits over the first six months postoperatively. The clinic based group was prescribed 24 visits over the first six months. The home-based group averaged five visits with a range of three to seven visits. The clinic based patients averaged 19.9 visits with a range of 10 to 28.

Parameters assessed included range of motion, thigh atrophy, anterior drawer compliance, hopping test, Lysholm scores and a subjective health status score. At no time point was there noted to be a significant difference between the two groups for any assessment. The authors concluded that a home-based program is understandable, convenient and reliable and can be used for many of the patients undergoing ACL reconstruction.

Grant et al in a 2005 study randomized 145 patients to a minimally supervised home-based rehabilitation program versus traditional physical therapy supervised protocol.[26] Assessment was blinded and randomization was performed using a stratified blocked procedure. Home-based patients attended four physical therapy sessions within the first three postoperative months. Physical therapy based patients attended two sessions a week for weeks two through seven and once a week for weeks eight through 12 for a total of 17 sessions within the first three postoperative months. Compliance was assessed by therapy attendance. Patients were assessed three times: preoperatively for baseline measurements and at six and 12 weeks postoperatively. ROM, instrumented laxity and strength were assessed at these time points. Three patients dropped out post randomization and 129 patients were assessed at the 12 weeks final follow-up.

Results were determined as acceptable outcomes. A significant difference was noted in flexion and extension ROM. The home-based group had an acceptable rate of 96.8% for extension versus 83.3% for the physical therapy based group ($p = 0.02$). The home-based group had a flexion acceptable rate of 66.7% versus 47.0% for the physical therapy based group ($p = 0.03$). Knee laxity and strength demonstrated no significant differences. A potential performance bias existed because all home-based patients saw the same physical therapist at the sports medicine center while the physical therapy based group was allowed to choose any physical therapist.

These studies each potentially suffer from some form of bias. Each study except that by Grant et al lacked either a discussion of randomization methods, blinding, independent observation or measure of compliance in the manuscript.[26] Despite these potential shortcomings it is reasonable to conclude that a minimally supervised physical therapy program can result in successful ACL rehabilitation.

Conclusions

As can be seen in this systematic review many issues regarding ACL reconstruction rehabilitation have been evaluated using randomized controlled trials. The methodological quality of the studies reviewed is mixed. Most of the studies suffer from some form of potential bias. This is especially true of the studies published prior to 2000 when many of the study quality issues were not yet recognized. Despite this some reasonable conclusion can be made from the studies and used in developing an ACL reconstruction rehabilitation protocol.

Early weight-bearing appears beneficial and may decrease patellofemoral pain. Early motion is safe and may help avoid problems with later arthrofibrosis. CPM usage is not warranted to improve rehabilitation outcome in patients and can avoid the increased costs associated with CPM. Minimally supervised physical therapy in selected motivated patients appears safe without significant risk of complications. Postoperative rehabilitative bracing either in extension or with the hinges opened for ROM does not offer significant advantages over no bracing.

In Part II of this systematic review the evidence available for additional issues surrounding ACL reconstruction rehabilitation will be explored including the areas of open versus closed chain exercises, neuromuscular electrical stimulation, accelerated rehabilitation protocols, and ten RCTs involving a variety of miscellaneous issues regarding ACL reconstruction rehabilitation.

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Table 1

Postoperative Bracing

Author	Feller	Harilainen	Kartus	Timm	Risberg	Moller	Brandsson	Melegati	Henriksson	Muellner	Haggmark
Journal	KSSTA	KSSTA	KSSTA	JOSPT	AJSM	KSSTA	SJMSS	KSSTA	SJMSS	KSSTA	AJSM
Patients/Gps	40/2	60/2	78/39	60/2	60/2	62/2	50/2	36/2	50/2	40/2	16/2
Gp diff	Hinged passive extension brace vs. no brace	Brace 12 wks vs. no brace	Brace 4 wks (range 3-6)	Protonics brace vs. Brace	Rehab brace 2wks, functional 10 wks vs. no brace	Brace 6 wks vs. no brace	Brace 3 wks vs. no brace	Brace at 0° × 7days then 0°-120° vs. brace 0°- 120°× 2 wks	Plaster vs. brace	Hinged brace 0°,↑ progressively vs. Neoprene sleeve- 6wks	Cylinder cast vs. cast brace
Randomization	?	Birth Year	Consecutive not random	?	Block	?	?	Alternating Gps	?	?	?
Parameters assessed	ROM, KT 1000, Isokinetic,	Lysholm, Tegner, Laxity, Isokinetic	Lysholm, Tegner, Laxity, IKDC 1991, 1 leg hop	Isokinetic, Laxity, 1 leg hop	ROM, Cincinnati, CT thigh, Isok, VAS, Laxity, 3 Functional tests	Lysholm, Tegner, Laxity, Isokinetic, 1 leg hop, ROM, swelling, VAS	Lysholm, Tegner, Laxity, Isokinetic, 1 leg hop, ROM, Early complications	Heel ht. difference, laxity	ROM, Isokinetic, laxity, Lysholm, Tegner	Tegner, OAK, ROM, Cybex, KT 1000, 1 legged hop	Thigh atrophy, ROM, muscle biopsy
Significant Findings	No differences at 4 mos	No differences at 1 and 2 yrs	No differences at 2 yrs	80% strength achieved 3.3 wks earlier in Protonics	Brace ↑ Cincinnati and ↑ thigh atrophy 3 mos.	No brace ↑ Tegner 6 mos and ↓swelling 2 wks	No diff at 2 yr F/U Early complications? increased no brace	Brace In ext. better at 4 and 8 wks	Brace decreased strength by Biodex at 24 mos	6 and 12 wks ROM, 24 wk 1 legged hop improved in sleeve gp,	? No data
Recon Method	BTB	BTB	BTB	BTB	BTB	BTB	BTB	BTB	BTB	BTB	Jones PT
Bias	Exclusion, ?Selection	? Selection	? Selection	?Selection	Exclusion	?Selection	?Selection	?Selection	?Selection	?Selection	?Selection

Table 2

Home-Based Rehabilitation

Author	Schenck	Beard	Fischer	Grant
Journal	Arthroscopy	JOSPT	CORR	AJSM
Patients/Gps	37/2 22/15	31/2	54/2	145/2
Gp diff	Home vs. clinic 2.85 vs. 14.2	Gp. exercise class after 6 wks supervised	6 visits vs. 24	4 vs. 17
Randomization	Lottery	Computer	?	Stratified block
Parameters assessed	ROM, Lysholm, VAS, 1 leg hop, Instrumented laxity, Sickness profile	Lysholm, Tegner, IKDC, VAS, 1 leg hop, Instrumented laxity, Isokinetic	Lysholm, 1 leg hop, ROM, Instrumented laxity, Thigh atrophy, subjective health	ROM, instrumented laxity, strength
Significant Findings	None	None	None	ROM improved in home gp
Recon Method	BTB	BTB	Allo or auto BTB	BTB
Bias	?Selection	No obvious	?Selection	?Performance