THE CLINICAL AND COST EFFECTIVENESS OF TWO DIFFERENT PROGRAMS FOR REHABILITATION FOLLOWING ACL RECONSTRUCTION

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ABSTRACT

This study compared the clinical and cost effectiveness of an established method for anterior cruciate ligament rehabilitation to a program which included Protonics® exercise. Sixty patients (42 males, l8 females mean age 24.7+/-3.9 yrs: age range 19-30 yrs) were randomly assigned into two groups: Group One was the established protocol; Group Two received a Protonics® exercise regiment. Both groups were measured for the time needed for return to unrestricted activity on the basis of objective, functional, and clinical exams: all tests were repeated at a one-year follow-up exam. Group Two completed treatment an average of 3.3 weeks sooner than Group one (mean 19.8+/-0.6 wks vs. 23.1+/-0.3 wks: t=100.77, df=29, p<. 001) at an average lower cost of $990.00 per subject. All subjects had good functional outcomes at the one-year follow-up exam. It was concluded that the Protonics® exercise program was more clinically and cost effective than the other program, although both methods were successful for post surgical anterior cruciate ligament rehabilitation.
Key Words = *Anterior Cruciate Ligament Rehabilitation, Knee Rehabilitation, Protonics® Exercise*

STUDY

The surgical procedures and the rehabilitation techniques for the successful management of a ruptured anterior cruciate ligament (ACL) continue to evolve in terms of expediency. Current processes produce better functional outcomes for patients in a shorter period of time, which also tends to be less expensive, as compared to older models of care. Surgery has changed from the older procedure of direct repair, or

excision, of the torn ACL to the contemporary ACL reconstruction approaches which use vascularized allografts or autografts from the central one-third of the patellar tendon or from the hamstrings tendons (2,4-7,10,12-15,17,18). In parallel, rehabilitation methods have also changed from the older procedures of casting, delayed knee motion and ambulatory activities, and open chain exercise to the newer techniques of CPM, early motion using a functional knee brace, and closed chain exercise (2-7,12-15,17,18). This evolution of ACL surgery and rehabilitation is reflected in patient outcomes: the expectation of return to unrestricted activity by six months, at most, without the need for a knee brace has replaced the old standard of 12-18 months in treatment along with the need to wear a motion-control brace during any type of high-demand physical activity (6,12-15,17,18). As the techniques for effective ACL management continue to evolve, newer methods of treatment have been introduced in an effort to expedite the process of rehabilitation even further. One of these newer methods is known as Protonics® exercise (8,9). Protonics® (Inverse Corporation, Lincoln, Nebraska) has bean operationally defined as, “variable range of motion preprogrammed velocity independent resistance”, (8,9). This concept is applied in the rehabilitation process as a device that is attached to a patient's postoperative ACL knee brace to provide progressive resistance exercise to the quadriceps and hamstrings muscle groups, particularly during ambulation activities (8,9). The Protonics® device allows resistance to be preset throughout a specified range of knee motion, to be adjusted to differing and independent levels of farce during quadriceps and hamstrings exercise procedures, and to accommodate to functional demands on the healing ACL graft through unloading of the exercising muscles (the resistance becomes zero) when joint motion stops (8,9). Protonics® exercise has been used for both open chain and closed chain exercise procedures and has demonstrated better levels of rehabilitation efficiency and clinical cost effectiveness in an initial study when compared to an established ACL protocol (16).

The purpose of this investigation was to compare the clinical outcomes for subjects who were treated under a common rehabilitation program following ACL reconstructive surgery to the clinical outcomes for a newer, previously unstudied rehabilitation protocol. The specific factors for measurement were the rehabilitation time period needed for a patient to return to unrestricted physical activities and a patient's functional status at a follow-up examination one year after discharge from rehabilitation. The null hypotheses under study were that no difference would exist between the two programs in terms of the rehabilitation time period and that no difference would exist between the two programs in terms of patient functional status at one-year follow-up examination. A secondary purpose was to examine the relative cost effectiveness of rehabilitation, on the basis of comparing the relative cost of the two methods of treatment. The null hypothesis for this purpose of the study was that there was no difference in cast between the treatment programs.

METHODS

Subjects

A group of 60 consecutive patients (42 males, 18 Females; mean age 24.7 +/- 3.9 yrs; age range 19-30 yrs) was randomly divided into two experimental groups. The subjects, each of whom had undergone an ACL reconstruction using a vascularized bone-central one-third of the patellar tendon-bone autograft procedure (2,4,7,12,15,18), were referred for possible participation in the study by six different orthopaedic surgeons. All autographs were harvested from the same knee that was being

reconstructed for a ruptured ACL. Each experimental group contained 30 subjects, but had different collections of gender and surgical knee characteristics. Group One had 20 men (11 right and 9 left ACL reconstructions) and 10 women (7 right and 3 left ACL reconstructions) while Group Two consisted of 22 men (13 right and 9 left ACL reconstructions) and 8 women (3 right and 5 left ACL reconstructions. The subjects volunteered for the study under the guidelines of informed consent (1) and of the Institutional Review Board for St. Luke's Hospital of Saginaw, Michigan. All subjects completed the rehabilitation and the one-year follow-up examination components of the study.

Procedures - Group One

Group One was treated using an established ACL rehabilitation protocol which included specific criteria for progression along its sequence of treatment phases (Table 1) (17). This protocol has demonstrated positive success for functional patient outcomes under an expectation of returning a patient to unrestricted activities, including sports, within six months following ACL reconstruction (16,17). At the time that this study was started, the protocol represented a moderate approach to ACL rehabilitation, as compared to other treatment programs that were perceived to be either more aggressive (5,6,14,15) or more conservative (2,4,7,13) by the orthopaedic surgeons who referred the subjects for the study. Bledsoe simple hinge postoperative knee braces (Bledsoe, Inc., Houston, Texas) were used by all subjects during the Immediate Postoperative, Maximum Protection, and Controlled Ambulation Phases of rehabilitation (Table 1) (17).

Procedures – Group Two

Group Two was treated under a protocol which used Protonics® exercises to complement traditional clinical exercise techniques for rehabilitation following ACL reconstruction (Table 2) (8). Bledsoe simple hinge postoperative knee braces were also used during rehabilitation far the subjects of Group Two, but unlike Group One, the braces were fitted with Protonics® devices. The Protonics® devices covered the hinges of the braces and provided a selectable, or rampable, submaximal resistance of from 2.7 up to 17.2 N (9) to the quadriceps and the hamstrings muscle groups during clinical and non-clinical ambulatory activities that involved knee flexion and extension. Thus, the subjects were, theoretically (9), exercising their knee muscle groups with each step that they took while wearing their Bledsoe braces, which they were instructed to do at least though the 14th postoperative week (Table 2). The subjects were instructed to wear their braces as much as possible during ambulation and activities of daily living when outside of the clinic as a complement to their treatment protocol (Table 2). A previous study has demonstrated a positive clinical outcome for an ACL rehabilitation program which included Protonics® (16), but incorporated this protocol used with Group One within its treatment criteria.

Measurement

Both groups were measured for the time period, in weeks, needed to achieve the status of discharge from rehabilitation to normal, unrestricted physical activity. Discharge for both groups was based on the Criteria For Return To Activity that were part of the rehabilitation protocol used for Group one (Table 1) (16). Specifically, a satisfactory isokinetic test was operationally defined as the production of at least 80% peak torque and power values for the quadriceps and hamstrings muscles of the reconstructed knee

as compared to the opposite leg (16). An unchanged KT 2000 test required no increase in measurable tibiofemoral displacement as compared to the test results from the fourth post-surgical week. Functional tests, which also required at least an 80% level of performance as compared to the non-surgical leg, included the one legged vertical jump test, the one legged hop for distance test, and the one legged timed hop test (5). Lower extremity proprioception was measured with the BREG Kinesthetic Action Training System (BREG, Inc., Vista, California) (16). The finding of a "satisfactory clinical exam" for each subject was based on established and standardized subjective and objective procedures for the orthopaedic assessment of the knee (11,16). The exact same measurement procedures were repeated at the one-year follow-up examination of each subject.

Cost effectiveness was measured as based on the following equation: $100.00 X three sessions per week X mean time for completion of the return to activity phase for table 1. This equation reflected the charge system that was used during the period of this study, which reflected the reasonable and customary reimbursement practices of major third party payers in the state of Michigan. The charge of $100.00 represented a set fee per session, regardless of the specific procedures performed on the subjects. However, there were no actual charges generated, since the subjects participated as volunteers for research, even though their treatments were similar to the services provided to routine patients.

Data Analysis

The statistical analysis of collected data were accomplished via *t* tests. An alpha level of p=.05 was adopted *a priori* for the testing of the null hypotheses.

RESULTS

The subjects of Group Two completed their rehabilitation program an average of 3.3 weeks (mean 19.8 +/- 0.6 weeks) sooner as compared to the subjects in Group One (mean 23.1 +/- 0.3 weeks). This difference between Group Two and Group One was statistically significant ($t = 100.77$, $df=29$, $p < .001$). The null hypothesis that no difference existed between the two groups for the time period needed to complete rehabilitation was rejected: Group Two returned to unrestricted activity significantly before Group One. There was no difference between groups for achievement of the criteria for the Return To Activity Phase (Table 1) (16), other than the factor that the subjects of Group Two reached the goals faster than the subjects of Group One. All subjects of both groups demonstrated isokinetic performances of at least 80% of the opposite leg, an unchanged KT 2000 test as compared to the fourth postoperative week, functional jump and hop tests at least 80% of the opposite leg, equal proprioception performance when comparing both legs, and a satisfactory clinical examination. There was also no difference between groups for these functional results at the one-year follow-up examination: each subject of both groups still met all of the criteria. The null hypothesis that no difference would exist between the two programs in terms of the patients' functional status one year after discharge from rehabilitation was not rejected. An additional point of information was that all subjects reported the ability to return to their desired levels of physical activity, including competitive and recreational sports, with only minimal or infrequent knee pain and without disability. Economically, the treatment for Group Two would have cost an average of $990.00 +/- $90.00 less per subject (mean $5,940.00 +/- $180.00) when compared to the treatment

for Group One (mean $6,930.00 +/- $90.00) if the subjects had been charged for rehabilitation services as actual patients, instead of receiving treatment at no cost as subjects in the research study. This difference between Group Two and Group One was both statistically significant ($t = 244.42$, $df = 29$, $p < .001$) and clinically important because of the monetary contrast (mean= $990.00 */- $90.00); Group Two was less expensive than Group One. These factors combined with the previous finding of a significant difference between groups for the time period required for the successful completion of each rehabilitation program and with the finding that no difference existed between groups in terms of achieving the functional discharge criteria, both at the end of treatment and at the follow-up examination, lead to the determination that the protocol used with Group Two was more cost effective than Group One's rehabilitation program. The null hypothesis that there was no difference in cost between the treatment programs was rejected: the Group Two protocol achieved a successful outcome more quickly and at a lower cost.

DISCUSSION

The purposes of this study were to compare the clinical outcomes for rehabilitation success and treatment cost following ACL reconstruction of an existing clinical program (17) with a newer, unstudied program which includes Protonics® exercise. The first finding was that the subjects who were rehabilitated under the newer program reached the goal of return to unrestricted physical activity, as based upon established performance criteria, by a factor of 19.2 - 20.4 weeks after surgery, which was an average of 3.3 weeks sooner than for the subjects of the other group. However, all of the subjects from both groups successfully completed rehabilitation before currently expected milestone of six months (6,12,14,15). The Protonics® exercise component of the Group Two protocol may be responsible for the observed difference in clinical outcomes, especially since the other exercise components of both rehabilitation programs were very similar. Theoretically, the presence of an additional stimulus for the progressive resistance exercise of the knee muscle groups during ambulation activities, which was the major factor that separated the two treatment regimens, could explain the difference in the clinical Findings. The additional muscles work, as compared to the Group One protocol which did not include progressive resistance exercise during non-clinical ambulation activities, might have enhanced the physiological and neuromuscular processes of knee strengthening to promote a quicker recovery of the muscle functions that are known to be compromised as a result of ACL reconstruction (8,9). A previous study of Protonics® exercise supports this idea (16). However, further research is necessary before these ideas can be firmly established and validated. The second finding of this study was that all subjects of both groups successfully satisfied the criteria for discharge from rehabilitation and return to normal activities, even though the subjects of Group Two reached this point in a significantly shorter time. The third finding was similar; all subjects of both groups still satisfied all of the functional criteria at their follow-up examination one year after the end of the rehabilitation programs. These findings indicate that both clinical protocols are effective for the rehabilitation of subjects following ACL reconstruction, at least in the context of a one-year period of follow-up. There was no indication that Group Two's rehabilitation program produced any negative results within the period of study. However, further follow-up study is necessary to ensure that the observed success for both groups can be translated to a longer term perspective of five to ten years after ACL surgery. The final finding was that the newer rehabilitation program was more cost effective than the other program. Group Two's program produced functional outcomes that were equal to those for Group

One, but did so in a shorter period of time and at a projected average cost saving of $990.00 per subject. A previous study found a cost saving of $1,080.00 per subject for a rehabilitation program which incorporated Protonics® exercise. The expense projections were based on the reasonable and customary reimbursement practices of the major third-party payers in the State of Michigan during the period of study and upon the presumption that each subject for each group would be charged the same amount per week of rehabilitation, had they been actual patients instead of research subjects. However, these projections would change in light of the charges that would be incurred for the specific use of Protonics® exercise, if the technology becomes acceptable for third-party reimbursement, and in light of general changes in the environment for the third-party payment for rehabilitation services.

CONCLUSION

Based upon the results, but within the context of this study, the following conclusions were reached in comparison of the two rehabilitation protocols that were used following ACL reconstructive surgery:

1. Both programs were effective for returning the subjects to unrestricted physical activity before six months after surgery.
2. Both programs had positive results for functional outcomes at one-year follow-up.
3. The program which included Protonics® exercise resulted in a significantly earlier return to activity.
4. The program which included Protonics® exercise was more cost-effective.

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TABLE 1

I. IMMEDIATE POSTOPERATIVE PHASE

Postoperative Days 1-7:

Continuous passive motion 0-90 deg
Brace locked at 0 deg for ambulation
Weight bearing as tolerated with crutches and brace
Ankle pumps
Passive knee extension to 0 deg
Intermittent passive ROM 0-90 deg
Patellar mobilization
Straight leg raises (flexion, abd/adduction)
Mini squats and weight shifts
Electrical muscle stimulation 6 hrs daily
Ice and elevation

Criteria for Hospital Discharge:

Quadriceps setting and straight lag raise control
Full passive knee extension
Passive ROM 0-90 deg
Good patellar mobility
Ambulation with crutches

II. MAXIMUM PROTECTION PHASE

Postoperative Weeks 2-6:

Brace locked at 0 deg for ambulation
Brace unlocked for ROM exercises ROM exercises 4-5 times per day
Passive ROM 0-105 deg
Ambulation weight bearing as tolerated
Discontinue crutches 7-10 days
Straight leg raises (flexion/extension, abd/adduction)*
Knee extension from 90-40 deg*
Mini-squats 0-40 deg and weight shifts
Hamstring curls*
Hamstring stretches
Patellar mobilization
KT 200o test: 15 lb test only

Progression; Postoperative Week 3-4:

Passive ROM 0-115 deg
Bicycling to increase ROM
Pool walking
Leg press 0-60 deg*
Stairmaster
Nordic Trak
Proprioception exercise
KT 2000 test at week 4; 20 lb test only

* Exercises start with 1 lb, progress 1 lb per week

III. CONTROLLED AMBULATION PHASE

Postoperative Weeks 6-9:

Full weight bearing with unlocked brace
Passive ROM 0-130 deg
Swimming program
Step-up exercises, starting with 6-inch steps
KT 2000 test: 20 and 30 lb tests

Criteria For Ambulation Without A Brace:

Active ROM o-11B deg
Isometric quadriceps strength 60% of opposite leg
Unchanged KT 2000 test
Minimal effusion

IV. MODERATE PROTECTION PHASE

Postoperative Weeks 9-14:

Continue step-up exercise
Continue mini-squat exercise
Continue leg press exercise*
Continue leg extension 90-40 deg*
Hip abd/adduction*
Continue hamstring curls*
Continue hamstring stretches
Calf raises
Bicycling for endurance
Forward/backward pool running
Walking program
Stairmaster

V. LIGHT ACTIVITY PHASE

Postoperative Months 3-4:

Isokinetic test; Week 12
Begin running program
Begin agility drills
Continue strengthening exercises*
Plyometric program Sport specific drills

Criteria For Running Program:

Satisfactory isokinetic test
Unchanged KT 2000 test
Functional tests 70% of opposite leg
Satisfactory clinical exam

VI. RETURN TO ACTIVITY PHASE

Postoperative Months 5-6:

Continue strengthening exercises*
Continue plyometric program
Continue running program
Continue sport specific drills

Criteria For Return To Activity:

Satisfactory isokinetic test
Unchanged KT 2000 test
Functional tests 80% of opposite leg
Proprioceptive tests 100% of opposite leg
Satisfactory clinical exam

TABLE 2

I. POSTOPERATIVE DAYS 1 - 10

Day 1-4: Hospital Program:
Continuous passive motion 0-120 deg
Weight bearing as tolerated with crutches and brace
Ice and elevation
Straight leg raising
Instructions in Protonics® exercise

Day 4-10: Clinic Program:
Protonics® exercise - mini-squats
Hamstrings resistance to tolerance

Day 4-10: Home Program:
Protonics® exercise - ambulation with brace
Hamstrings resistance 2.7-3.6 N

II. PROGRESSIONS*: POSTOPERATIVE DAYS 10 - 14

Clinic Program:
Protonics® exercise - wall slides
Hamstrings resistance 2.7-3.6 N
- Mini-lunges
Hamstrings resistance to tolerance
- Double leg press
30-120 deg flexion
Hamstrings resistance to tolerance
- NK Table knee flexion
Hamstrings resistance to tolerance

Home Program:
Protonics® exercise - standing hamstrings curls
Hamstrings resistance 3.6-4.5 N
- Sitting hamstrings pulls
Hamstrings resistance 3.6-4.5 N
- Prone hamstrings pull
Hamstrings resistance 2.7-3.6 N
- Ambulation with brace
Hamstrings resistance 3.6-4.5 N

III. PROGRESSIONS: POSTOPERATIVE WEEKS 2 - 3

Clinic Program:
Protonics® exercise - stationary bicycling
Hamstrings resistance 4.5-5.4 N
- Treadmill retro walking
Quadriceps Resistance 3.6-4.5 N
- Single leg press
30-120 deg flexion

Hamstrings resistance to tolerance
- Stair climbing machine
Hamstrings resistance 2.7-4.5 N

Home Program:

Protonics® exercise - closed chain terminal extension
Quadriceps resistance 2.7-4.5 N
- Ambulation with brace
Quadriceps resistance 2.7-3.6 N

IV. PROGRESSIONS: POSTOPERATIVE WEEKS 3 - 4

Clinic Program:

Protonics® exercise - treadmill retro walking
Hamstrings resistance 3.6-4.5 N
- Stair climbing machine
Quadriceps resistance 2.7-4.5 N

KT 2000 test

Home Program:

Protonics® exercise - ambulation with brace
Quadriceps resistance 2.7-3.6 N
Hamstrings resistance 3.6-5.4 N

V. PROGRESSIONS: POSTOPERATIVE WEEKS 4 - 7

Clinic Program:

Protonics® exercise - stationary retro bicycling
Quadriceps resistance 2.7-4.5 N

Home Program:

Protonics® exercise - ambulation with brace
Quadriceps resistance 4.5-5.4 N

VI. PROGRESSIONS: POSTOPERATIVE WEEKS 7 - 8

Clinic Program:

Protonics® exercise - functional plyometrics
Hamstrings resistance to tolerance

Home Program:

Protonics® exercise - ambulation with brace
Quadriceps resistance to tolerance
- Functional activities
Quadriceps resistance to tolerance

VII. PROGRESSIONS: POSTOPERATIVE WEEKS 9+

Continue Clinic Program activities
Continue Home Program activities
Increase hamstrings resistance to tolerance

Increase quadriceps resistance to tolerance

*Note: Once an activity has been listed, it may be considered to be appropriate, if needed, throughout the rehabilitation process.