

# **THE EFFECTS OF PROTONICS® EXERCISE ON KNEE REHABILITATION AFTER ACL RECONSTRUCTION**

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## **ABSTRACT**

The purpose of this study was to examine the effects of Protonics® exercise on the processes and outcomes for knee rehabilitation following ACL reconstruction. A stratified matched sample of 60 patients (30 females, 30 males: mean age 23.6+/-4.7 yrs; age range 18-32 yrs), each of whom had received ACL reconstruction using a patellar tendon graft, was randomly divided into two groups of 30 subjects. Group One was treated under an established, criteria-based ACL rehabilitation protocol while Group Two was treated under the same protocol with the addition of Protonics® exercise. Specifically, Protonics® devices were fitted to the postoperative knee braces of the subjects and provided a submaximal resistance of 5.4 N for both knee flexion and extension during clinical and ambulatory activities in the early stages of treatment. Group Two achieved un-braced ambulation 16 a mean of 2.7 weeks sooner than Group One (week 5.8 versus week 8.5:  $t=44.471$ ,  $df=29$ ;  $p<.001$ ), achieved return to activity a mean of 2.6 weeks sooner than Group One (week 21.4 versus week 23.9;  $t=49.531$ ,  $df=29$ ;  $p<.001$ ), and had a mean lower treatment cost of \$1,010.80. There were no detracting limitations from normal ADL's and competitive or recreational sports for any subjects of either group at a one year follow-up exam. It was concluded that a protocol which includes Protonics® exercise is more efficient and cost effective for functional rehabilitation following ACL reconstruction.

**KEY WORDS** = Knee rehabilitation, Protonics® exercise, Anterior cruciate ligament rehabilitation

The techniques for the surgical management of a compromised anterior cruciate ligament (ACL), and the procedures for knee rehabilitation following ACL surgery, continue to evolve through the production of better functional outcomes for patients in a shorter period of time. In the early 1980's, surgery consisted of the excision or direct repair of the torn ACL fragments which was followed by a period of cast immobilization and then by a rehabilitation program designed to restore normal knee motion and muscle strength (3,4,6,8,12,15,19). The entire process usually required 12-18 months of treatment after surgery, most frequently on a three sessions per week basis, demanded that a patient wear a motion-control knee brace for high-demand activities and sports, but produced only marginal levels of success in terms of a patient's functional outcome (3,4,6,11,12,15,17,18). Patients did not usually regain full, normal levels of tibiofemoral and patellofemoral joint motion and normal levels of quadriceps and hamstrings muscle performance capabilities, which altered the normal biomechanics of the knee and which ultimately lead to failure of the surgical repair, premature degenerative changes within the joint, and significant restriction of desired activities of daily living (ADL's).

In the middle and late 1980's, the processes of both surgery and rehabilitation became more efficient and produced better patient outcomes. ACL surgery evolved from direct repairs to reconstruction procedures which allo- or autografts from the tendons of the hamstrings muscles or from the patellar tendon (2-4,6-11,13,15,17,18,20-29). Medical and biomechanical research guided the refinement of the various surgical techniques to the present "gold standard": reconstruction of the ACL using a vascularized bone-tendon-bone graft from the central third of the patellar tendon fixated within the tibiofemoral joint at a position of isometric placement, where the graft does not elongate by more than 10% with routine movements of the knee (2,7,10,11,17,18,20,24-29). Rehabilitation techniques also advanced by shortening the period of immobilization and introducing continuous passive motion (CPM) procedures immediately after surgery, or replacing the plaster cast with a cast brace which permitted controlled movement through a limited range of knee motion, and by expediting the process of muscle conditioning, through the use of newer electronic muscle stimulation protocols to complement programs of isometric, isotonic, and isokinetic exercise (3,6,7,10,11,17,18,21,24,25,26,28,29). Overall, the treatment process required a time period of 9-12 months, usually under a format of three sessions per week, and produced better functional outcomes (3,6,7,10,11,17,18,25,28,29). Usually, the only modification from a patient's normal lifestyle was the requirement of wearing a motion-control knee brace during athletic activities: routine APL's were largely unaffected.

In the present day, the "gold standard" for ACL surgery is largely unchanged: the majority of current research supports the vascularized bone-patellar tendon-bone graft as the procedure of Choice (10,17,18,25,26,28,29). However, the rehabilitation process has continued to change. CPM is evolving into early active knee motion by the patient right after surgery; the traditional open chain isometric, isotonic, and isokinetic exercises are being replaced by functional closed chain activities: the standard of three treatment sessions per week is giving way to fewer clinical sessions complemented by extensive self-care programs, in order to meet the market demands of third-party payers and the environment of managed health care; and functional bracing during the initial stages of rehabilitation, followed by a return to ADL and athletic activities without a brace has been substituted for motion-control bracing of the knee (5,7,10,11,17,18,24-26,28,29). The current expectation, in terms of a functional outcome, is that a patient will return to

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normal, unrestricted activity by 6 months, at most, following ACL reconstructive surgery (10,18,25,28).

Although the current procedures for ACL surgery and rehabilitation have been successful, the processes of medical research continue toward the goal of producing similar or better patient outcomes over an even shorter period of treatment. This goal is also consistent with the current market forces of health care reform, which are seeking to maximize the effects of successful treatment techniques over a minimal number of treatment sessions in order to curtail health care costs. The current research study was undertaken in order to investigate the effects of a new form of rehabilitation exercise, known as Protonics<sup>®</sup> (14), on both the clinical and the economic processes associated with patient treatment following ACL reconstructive surgery. The specific purposes of this study were to investigate the effects of Protonics<sup>®</sup> during the early stages of rehabilitation following ACL surgery, specifically for the time needed for a patient to achieve ambulation without a knee brace, to track the influence of Protonics<sup>®</sup> on the later stages of treatment, up until a patient's discharge from rehabilitation, to examine patient functional outcomes, in terms of a one year follow-up, and to analyze the cost effectiveness of Protonics<sup>®</sup> as compared to a commonly accepted rehabilitation protocol. The specific null hypotheses under study were that Protonics<sup>®</sup> would have no effect during early rehabilitation, that Protonics<sup>®</sup> would have no influence on the later stages of treatment, that no difference would exist between treatment programs at one year follow-up, and that there would be no difference in cost effectiveness between the rehabilitation programs.

## **METHODS**

### ***Subjects:***

A stratified, matched sample of 60 patients (30 females, 30 males; mean age 21.6 +/- 4.7 yrs; age range 18-32 yrs) was randomly selected from a larger pool of 88 potential subjects, who were referred by seven different orthopaedic surgeons for possible participation in the study. Each subject had undergone knee surgery for ACL reconstruction using a vascularized bone patellar tendon-bone graft procedure (6,9,13,20). The sample was then divided into two groups of 30 patients each (15 females, 15 males). However, the knees that were operated upon were not evenly distributed; Group One contained 21 patients (6 females, 15 males) who needed reconstruction of their right ACL and nine female patients who required surgery for their left ACL while

Group Two included 13 patients (6 females, 7 males) who received reconstruction of the right ACL and 17 patients (9 females, 8 males) who had their left ACL reconstructed. The subjects volunteered to participate in the experiment under the guidelines of informed consent (1) and of the Institutional Review Board for St. Luke's Hospital of Saginaw, Michigan. All subjects successfully completed all phases of the study, including a follow-up analysis one year after the end of their treatment program.

### ***Procedures - Group One***

Group One was treated after surgery under the guidelines of an established ACL rehabilitation protocol, which included specific criteria for patient and treatment progression (Table 1) (28). The protocol was the treatment paradigm of choice by the seven orthopaedic surgeons for the patients whom they referred for participation in the American Journal Sports Medicine, 1995

study. The protocol represented a rehabilitation program that was moderately aggressive, in relative comparison to other treatment regimens that are either more aggressive (10,25,26) or more conservative (11,17,24) for patient management following surgical reconstruction of the ACL, and has demonstrated a good level of success in terms of functional patient outcomes (28).

### ***Procedures - Group Two***

Group Two was treated using the exact same rehabilitation protocol as was used for Group One, but with the addition of Protonics<sup>®</sup> exercise activities. Protonics<sup>®</sup> (Inverse Corporation, Lincoln, Nebraska) has been operationally defined as "variable range of motion preprogrammed velocity independent resistance" (14) and exists as a device which may be fitted to a patient's knee brace to provide an additional form of progressive resistance exercise for the quadriceps and hamstrings muscle groups. A Protonics<sup>®</sup> device allows for the application of resistance to the knee muscles independent of the velocity of joint movement during treatment procedures and while a patient ambulates when wearing a knee brace (14). Resistance can be preset throughout the available knee ROM following surgery, can be adjusted for differing and independent levels quadriceps and hamstrings exercise activities, and accommodates to a patient's rehabilitation demands by stopping when joint motion ceases (14). Protonics<sup>®</sup> can be used for both open and closed chain exercise procedures (14).

Protonics<sup>®</sup> technology was created to provide a means of controlled progressive resistance exercise while a patient is walking with a knee brace during the early stages of rehabilitation following ACL reconstruction surgery (14). This would complement a patient's clinical treatment routine through quadriceps and hamstrings exercise during non-clinical ambulation activities. Theoretically, the additional exercise stimulus would expedite the post surgical conditioning of the knee muscle groups and, therefore, speed up the entire process of ACL rehabilitation (14).

Specifically, Protonics<sup>®</sup> devices were fitted to the knee braces used by the subjects in Group Two for the Immediate Postoperative (week 1), Maximum Protection (Weeks 2-6), and Controlled Ambulation (Weeks 6-9) stages of treatment under the Wilk and Andrews ACL rehabilitation protocol (28). A subjects of both experimental groups used a Bledsoe simple hinge postoperative knee brace (Bledsoe, Inc., Houston, Texas): the braces of Group One were not fitted with Protonics<sup>®</sup> devices. The Protonics<sup>®</sup> devices provided a submaximal resistance of 5.4 N for both knee flexion and extension during both clinical exercise and non-clinical ambulatory activities. The use of Protonics<sup>®</sup> was the only factor, which separated the treatment of the subjects of Group Two from the subjects of Group One.

### ***Measurements***

Both groups were measured for the time needed, in weeks, to achieve the four criteria established within the Wilk and Andrews rehabilitation protocol as necessary for patient ambulation without the use of a brace: Active ROM 0-115 deg, Isometric (22, 23, 24, 25, 26) quadriceps strength 60% of the opposite leg, Unchanged KT 2000 test, and Minimal effusion (Figure 1) (28). Isometric quadriceps strength was measured with a MicroFet hand-held force gauge (Empi, Inc., Minneapolis, Minnesota). Joint effusion was evaluated subjectively, as based on direct observation of each subject's involved and noninvolved knees.

When this milestone was achieved, each subject of both groups then continued under the Wilk and Andrews rehabilitation protocol (28) until the point of discharge from treatment. Treatment was the exact same for each subject of both groups beyond the Controlled Ambulation stage since the use of a knee brace and, therefore, Protonics<sup>®</sup> devices had been discontinued.

Both groups were also measured for the time needed, in weeks, to complete the criteria of the Return To Activity phase of rehabilitation: Satisfactory isokinetic test, Unchanged KT 2000 test, Functional tests 80% of the opposite leg, Proprioception ability 100% of the opposite leg, and Satisfactory clinical exam (Figure 1) (28). For this study, a satisfactory isokinetic test was operationally defined as the generation of quadriceps and hamstrings peak torque and power values at least 80% of the opposite leg. Functional tests included the one legged vertical jump test, the one legged hop for distance test, and the one legged timed hop test (5). Proprioception ability was measured using the BREG Kinesthetic Action Training (K.A.T.) system (BREG, Inc., Vista, California). The clinical exam included established and standardized subjective and objective procedures for the orthopaedic assessment of each subject's knees (16).

The same tests used relative to the criteria of the Return To Activity phase of rehabilitation were also used for a follow-up examination at one year post-surgery. Each subject of both groups completed follow-up isokinetic, KT 2000, functional performance, proprioception, and clinical exam tests at the one year anniversary date, plus or minus one week, of their ACL reconstruction surgery.

## **RESULTS**

The subjects of Group Two completed the Controlled Ambulation phase of rehabilitation an average of 2.7 weeks (mean 5.8 +/- 0.4 weeks) sooner than did the subjects of Group One (mean 8.5 +/- 0.2 weeks). The difference between Group Two and Group One was statistically significant ( $t=44.471$ ,  $df=29$ ,  $p<.001$ ). The null hypothesis that Protonics<sup>®</sup> would have no effect during the early rehabilitation period was rejected.

The subjects of Group Two completed the Return To Activity phase of rehabilitation an average of 2.6 weeks (mean 21.4 +/- 0.7 weeks) sooner than the subjects of Group One (mean 23.9 +/- 1.1 weeks). This difference was also statistically significant ( $t=48.531$ ,  $df=29$ ,  $p<.001$ ). However, the null hypothesis that Protonics<sup>®</sup> would have no effect on the later stages of treatment was not rejected because the difference paralleled the finding for the Controlled Ambulation phase of rehabilitation; Protonics<sup>®</sup> provided no additional benefit to, and did not detract from, the expediency of treatment after the early stages of rehabilitation.

The difference between groups for the Return To Activity phase also reflected a mean lower cost of \$1,010.80 per subject for Group Two, if the subjects had been charged for rehabilitation services as routine patients instead of receiving free services as participants in the research process. Although not formally tested through statistical methods, this difference is significant in terms of economic implications and clinical practicality. This finding caused the rejection of the null hypothesis that there would be no difference in cost effectiveness between the rehabilitation programs.

There was no difference between groups upon their satisfaction of the criteria for the Return To Activity phase. All subjects of both groups had isokinetic muscle torque and power values at least 80% of the opposite leg; an unchanged KT 2000 test; functional one legged vertical jump, one legged hop for distance, and one legged timed hop test scores at least 80% of the opposite leg; proprioception scores equal to the other leg; and a satisfactory clinical examination. There was also no difference between groups for all test results at the one year follow-up examination, with the exceptions that isokinetic and functional performance scores were now at least 90% of the opposite leg. All subjects reported the ability to return to desired ADL's, including competitive or recreational sports, without disability and with only minimal and infrequent knee pain. The null hypothesis that no difference would exist between treatment programs at one year follow-up was not rejected.

## **DISCUSSION**

The purposes of this study were to investigate the effects of a new type of rehabilitation exercise, Protonics<sup>®</sup>, on the processes, outcomes, and cost effectiveness of treatment following ACL reconstruction in a complementary relationship to a common rehabilitation protocol. The first finding was that Protonics<sup>®</sup> exercise facilitated the progression of a subject from a state of protected knee motion to a state of ambulation without the use of a knee brace by a factor of 5.4-6.2 weeks after surgery, which was an average of 2.7 weeks sooner than the comparison group. This result is some one to four weeks sooner than the expected outcomes reported in other studies (7,10,11,17,18,25,26,28) and certainly suggests an enhancement of the efficiency of the rehabilitation process. Theoretically, this enhancement occurred as the product of an additional progressive resistance exercise stimulus to the subjects, knee muscles as they ambulated while wearing their protective braces. The additional muscle work may have expedited the physiological processes of neuromuscular strengthening to promote a faster recovery of the muscle functions that are routinely compromised as a consequence of ACL reconstruction (2,3,5,6,11,14,15,22,29). However, further research is necessary to validate this theory and to explore other possible clinical means for the production of a similar effect.

The second finding was that the gain achieved during the early phases of rehabilitation carried through to the point the subjects, discharge from treatment. The group that received Protonics<sup>®</sup> exercise completed treatment and returned to normal ADL's an average of 2.6 weeks sooner than the comparison group, which is essentially the same interval of time that was gained for the group during Controlled Ambulation. This finding indicates that the training effect from Protonics<sup>®</sup> exercise did not continue beyond the point of their cessation, but that the other forms of exercise treatment were sufficient to maintain the early gains produced through the protocol that included Protonics<sup>®</sup> exercise. However, the finding also indicates that the use of Protonics<sup>®</sup> exercise did not have a negative effect on the healing knee, either through abnormal elongation of the graft, as measured by KT 2000 scores, or through reversal of muscle or functional performance outcomes, which would have detracted from the early gains in rehabilitation efficiency. In addition, Group Two achieved return to activity at a mean of 21 weeks after surgery, as compared to a mean of 24 weeks for Group one, which is about three weeks sooner than both the expected (10,18,25,28) and the observed milestone of six months. This also reflects the factor of the increased efficiency for the rehabilitation of the subjects who were treated with Protonics<sup>®</sup> exercise.

The third finding was that since the subjects of Group Two spent a shorter period of time in treatment, they would have required a lower treatment cost if actual treatment Charges had been generated. The subjects participated as volunteers for research and, therefore, were not charged for their treatments, even though such treatments were in parallel to the services provided to routine clinical patients. Under the standard charge system that was in place during the period of the study, which was based upon reasonable and customary reimbursement from the major third-party payers in the State of Michigan, the rehabilitation protocol which incorporated Protonics<sup>®</sup> exercise would have cost an average of \$1,010.80 less per subject than the comparison protocol. This reflects a theoretical projected savings of about \$30,324.00 (\$1,010.80 x 30 subjects). However, this projection would be tempered by the charges that would be incurred for the use of Protonics<sup>®</sup> exercise, if and when the technology becomes acceptable for third-party reimbursement. Theoretically, a service charge could be constructed for the use of Protonics<sup>®</sup> exercise that would represent both a monetary cost savings, relative to the observed difference between the two treatment groups, and a practical improvement of clinical methods, through the expedited return of a patient to normal ADL's following ACL surgery.

The final finding was that no difference existed between Groups One and Two upon completion of the Return To Activity phase of rehabilitation and at the one year follow-up examination. At both instances and for both groups, all subjects were able to demonstrate functional criteria (5,10,17,18,25,28,29), which supported a positive outcome from their surgery. This was reinforced by the subject reports at one year follow-up that they were participating in desired ADL's and competitive or recreational sports with only minimal, infrequent discomfort and without disability. This is a reasonable and expected outcome at one year following ACL reconstruction and rehabilitation using contemporary procedures. This is also an indication that the efficiency for post-surgical rehabilitation gained through the use of Protonics<sup>®</sup> exercise does not at a later time translate into a structural or functional compromise of the repaired ACL and knee, at least over a one year time frame. However, further research, including a longer term of follow-up, is needed to verify this finding and the other results of this study regarding the effects of Protonics<sup>®</sup> exercise as well as to examine other possibilities for the continued refinement of rehabilitation following ACL reconstruction.

## **CONCLUSION**

Based upon the results, but within the context of this study, the following conclusions were reached in comparison of a rehabilitation protocol which included Protonics<sup>®</sup> exercise to a similar protocol which did not include Protonics<sup>®</sup> exercise for the treatment of Subjects after ACL reconstructive surgery using a vascularized bone-tendon-bone graft from the central third of the patellar tendon:

1. Protonics<sup>®</sup> exercise was more effective for the expedient progression of subjects to the status of ambulation without a knee brace
2. Protonics<sup>®</sup> exercise was more cost effective, and
3. There were no detracting limitations from normal ADL's and competitive or recreational sports present upon a one year follow-up examination.

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## 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 leg 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 2000 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

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#### 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 0-115 deg
- Isometric quadriceps strength 50% 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:

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

Figure 1: Wilk and Andrews ACL Rehabilitation Protocol (28)