A CLINICAL OUTCOMES STUDY OF TWO METHODS FOR THE TREATMENT OF PATIENTS WITH PATELLOFEMORAL PAIN

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Grant Information:

This study was made possible through a research grant from:
Inverse Technology Corporation
1000 West O Street, Suite B
Lincoln, Nebraska, 68528

Galley Proofs:

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Acknowledgments:

The author acknowledges the professional and clinical staff of the St. Luke's Hospital Physical Medicine & Rehabilitation Department, Paul Shyposki, PT, Director, for their help in making this research investigation possible.

ABSTRACT

This study compared the clinical outcomes for two different methods of rehabilitation for patients who had patellofemoral pain (PFP): traditional progressive resistance exercises (PRE's) and Protonics exercises. The relative cost effectiveness of each treatment was also examined. A set of 60 subjects with PFP (40 females, 20 males: mean age 20.8+/-4.2 yrs: age range 14-27 yrs) were randomly assigned into the PRE or the Protonics exercise group and were treated under a format of three clinical sessions per week complemented by home program activities. Each subject was measured on the time period needed to achieve a discharge target score on a Functional Index Questionnaire and on the representative cost of treatment. Group two completed treatment an average of 4.53 weeks (mean 3.24+/-0.24) sooner than Group One (mean 7.77+/- 0.49)(t=49.785, df=29, p<. 001) at an average cost saving of $952.15. It was concluded that the Protonics exercise program was more efficient and cost effective for the rehabilitation of subjects with PFP. Key Words: patellofemoral pain, progressive resistive exercise, Protonics exercise

STUDY

The professional literature describes patellofemoral joint pain (PFP) as a common problem which affects many people who are active in competitive or recreational sports (2,7,10,12,13,15,16,18,19). Patients with PFP typically experience peri- or retro-patellar pain, which is dull and achy in nature, that is aggravated by climbing or descending stairs, or through prolonged sitting in a position of knee flexion (the "movie sign")(2,7,13,15,16,18). Other signs and symptoms include patellofemoral crepitation during knee flexion and extension movements relatively minor swelling, as opposed to a true joint effusion; general stiffness of the knee, which decreases during activity; radiographic changes, which often indicate chondromalacia patella; and an increased angle, owing to abnormal biomechanics for patellofemoral tracking (2,5,7,8,10,12,13, 15-19,23). Abnormal patellofemoral tracking may result from an imbalance, or insufficiency, in the strength or coordination between the vastus medialis oblique and the vastus lateralis components of the quadriceps muscle group, or from tightness of the iliotibial band (2,5,7,10,12,13,15,17-19,23). The current thought is that the pain and other symptoms of PFP stem Prom such abnormal muscle and tissue mechanics (2,5,8,12).

Various methods exist for the rehabilitation of patients who have PFP. Most treatment methods involve a one or more forms of progressive resistance exercise (PRE), which is used to increase the strength and coordination of the vastus medialis oblique relative to the vastus lateralis in order to improve the mechanics of patellofemoral tracking (2,5,7,10,11,13,15,16,18,23). Traditional PRE's have included quadriceps setting, straight leg raising, and short-are movements into terminal Knee extension (2,7,10,13,18,23). Currant exercise treatments may also include closed Kinetic/ Kinematic chain activities, eccentric quadriceps contractions, isokinetic exercise, and EMG biofeedback procedures (2,10,15,23). Patellofemoral taping may also be used as a non-exercise means of improving joint biomechanics (12,14). All methods may be complemented by the adjunct treatments of physical agents, such as ultrasound, cryotherapy, phonophoresis, or electrical muscle stimulation, and functional supports or braces (13,18,23). However, there are very few clinical studies which address the efficacy of the various methods for PFP rehabilitation much of the information on patient outcomes is testimonial (10,15,18,19,23).

Recently, a new variation of PRE has been introduced, known as Protonics exercise (9,20,21), as a possible method for PFP rehabilitation. Protonics (Inverse Corporation, Lincoln, Nebraska) has been operationally defined as "variable range of motion preprogrammed velocity independent resistance" (9) and exists as a device that is attached to a functional, hinged knee brace. When coupled with a brace, the Protonics device provides a PRE stimulus to the quadriceps and hamstrings muscle groups, that is independent of the velocity of knee joint movement, during clinical rehabilitation, home exercise, and ambulation activities that incorporate both open and closed kinetic/kinematic chains (9). PRE resistance may be preset throughout a specified range of knee motion, may be adjusted to allow different or independent work levels for the quadriceps and hamstrings, and accommodates to the demands of exercise by stopping (the resistance becomes zero) when a patient stops moving their knee (9). Rehabilitation protocols which include Protonics exercise have demonstrated better levels of clinical efficiency and cost effectiveness when compared to treatment protocols (20,21), but such studies have been limited to the post surgical management of patients following anterior cruciate ligament reconstruction: PFP has not been investigated.

The primary purpose of this study was to compare the clinical outcomes for two methods of PFP rehabilitation: traditional PRE's and Protonics exercise. A secondary purpose was to examine the relative cost effectiveness for the two treatment methods. The null hypotheses under study were that no difference would exist between the two methods of PFP rehabilitation in terms of clinical outcomes and cost effectiveness.

METHODS

Subjects

A set of 60 consecutive patients who were willing to participate in the study as research subjects under the guidelines of informed consent (1) was randomly divided into two experimental groups. Randomization into groups was achieved through odd/even assignment: the first subject was assigned to Group one, the second subject was assigned to Group two, the third subject was assigned to Group one, the fourth subject was assigned to Group two, and so forth through the 59th being assigned to Group one and the 60th subject being assigned to Group two. The demographic information for both groups appears in Table 1. All subjects were referred for possible participation in the study by a total of 19 independent physicians (14 family practitioners, 5 orthopaedic surgeons). All of the subjects had PFP symptoms for a period of 2-6 weeks prior to the start of the study. None of the subjects had a past history of knee surgery or the clinical treatment of a knee injury. All subjects completed the study. The methodology received prior approval from the Institutional Review Board for St. Luke's Hospital of Saginaw, Michigan.

Procedures - Group One

Group one was treated with the set of PRE procedures listed in Table 2. These procedures are consistent with other treatment programs that have been published in the professional literature (2,13,15,23). The subjects were treated clinically in a format of three sessions per week and were also instructed to perform the exercises at home on a daily basis.

Procedures - Group Two

Group Two was treated with the set of Protonics exercise procedures listed in Table 3. To accomplish these exercises, each subject was fitted with a Bledsoe simple hinge postoperative knee brace (Bledsoe,Inc., Houston, Texas) that was fitted with a Protonics device. The Protonics device covered the hinge of the brace and provided a selectable, or rampable, submaximal resistance of 2.7-17.2 N (9,20,21) to the hamstrings muscle group during exercise activities. The resistance setting for each subject was determined through a trial of having the subject climb two flights of stairs (16 steps) while wearing the brace with the Protonics device; hamstrings loading was adjusted, via an increase or decrease in resistance, until a setting of relative exercise comfort was found for each subject. The subjects were treated clinically in a format of three sessions per week and were also instructed to wear the brace with the Protonics device for all ambulatory activities, within the limitations of each subject's comfort and tolerance, between clinical sessions as a home exercise program.

Measurements

The factors for measurement were rehabilitation time period and treatment cost. Rehabilitation time period was operationally defined as the time interval, in weeks, between the initiation of treatment and the achievement of a target score for discharge from clinical treatment on an objective functional outcome scale, the Functional Index Questionnaire (FIQ)(3) (Table 4). The scale has been validated as a measurement tool for the detection of clinical changes in patients with PFP (3), Treatment cost was operationally defined as the representative charge for patient care that would have been billed to third-party payers had the research subjects been actual patients and not involved in a clinical study. The representative charge would have been $69.50 per treatment session for each research group, which reflected the standard for third party reimbursement that was in place during the study.

RESULTS

The subjects of Group Two completed their treatment program an average of 4.53 weeks (mean 3.24 +/- 22 0.24 weeks) sooner as compared to the subjects in Group One (7.77 +/- 0.49 weeks). This difference was statistically significant (t=49.785, df=29, p<.001). The null hypothesis that no difference would exist between the two methods of PFP rehabilitation in terms of clinical outcome was rejected for the subjects of Group Two achieved the discharge target score on the FIQ (3) significantly before the subjects of Group One.

In terms of treatment cost, the subjects of Group Two required a mean of 10.1 +/- 0.84 sessions to achieve the clinical outcome target as compared to a mean of 23.8 +/- 1.52 sessions for the subjects of Group One. This difference is also statistically significant (t=46.880, df=29, t<.001). The corresponding representative costs for these mean treatment session results would have been $701.95 +/- $ 58.38 for each subject of Group Two, which contrasts with $1,654.10 +/- $ 105.64 for each subject of Group One. The average difference of $952.15 ($1,654.10 minus $ 701.95) was determined to be significant from a practical, economical standpoint. Based upon these findings, the null hypothesis that no difference would exist between the two methods of PFP rehabilitation in terms of cost effectiveness was also rejected for Group Two achieved the clinical outcome target at a significantly lower representative treatment cost charge.

DISCUSSION

This study compared the cost effectiveness and the clinical outcome for a program of traditional PRE's and a program of Protonics exercise for the management of groups of subjects that had PFP. It was found that a program of Protonics exercise produced the desired clinical outcome, meeting the FIQ (3) target score, an average of 4.53 weeks, or 13.7 treatment sessions, sooner than the other program of PRE's. These findings reflected a relative average cost saving of $952.15 13 per subject. This result is consistent with previous studies in which rehabilitation programs that included Protonics exercise were found to generate relative treatment cost savings of $ 990.00 - $ 1,080.00 per subject (20,21). However, those studies examined various aspects of rehabilitation following anterior cruciate ligament (ACL) reconstruction and did not assess samples of subjects who had PFP. Also, the result is based upon the third-party reimbursement practices that existed in the State of Michigan at the time of the study; the findings could be different under other paradigms of health care coverage and payment.

The major finding of this study was that the program of Protonics exercise produced the desired clinical outcome, as measured by the FIQ (3), not only in a significantly faster clinical timeframe, but through activities that emphasized hamstrings muscle function instead of the traditional PRE approach, which emphasized quadriceps strengthening. Previous studies of subjects treated for PFP have not addressed this phenomenon (2,4,5,7,8,10,12-19,22,23). Likewise, the previous investigations of rehabilitation techniques that included Protonics exercise have not examined this clinical result (20,21).

Theoretically, the observed effect may stem from one or more possible causes. These possible causes include the production of quadriceps muscle activity via a co-contraction stimulus from the working hamstrings, which has been found to occur in at least two studies of healthy subjects (6,22). Thus, the Protonics exercise procedures would produce an improvement in patellofemoral joint function, via gains in quadriceps muscle performance, even though the primary muscle training effect involved the hamstrings (9). The improvement in quadriceps ability, especially if the vastus medialis oblique were facilitated, might help to improve the biomechanics of patellofemoral tracking, which would lead to a decrease in PFP (9).

Another theoretical explanation for the current finding is a reciprocal inhibition response in the quadriceps muscle group secondary to hamstrings muscle activity (22). The production of hamstrings contractions through the Protonics exercise activities could facilitate a reciprocal inhibition of the vastus lateralis muscle group, which would decrease its magnitude of lateral pull on the patella (9). In turn, this action might compensate for a functional insufficiency of the vastus medialis oblique and help to create a better pattern of patellofemoral tracking. The improvement in tracking would then cause a decrease in patellofemoral compression, which should decrease a subject's symptoms of PFP (9).

A final possible cause of the observed findings is the nature of the subjects' non-clinical treatment program. While Group one was asked to perform the traditional PRE's as a home program, the subjects of Group Two wore their Bledsoe braces, which contained the Protonics exercise devices, while ambulating outside of the clinical setting. Although subject compliance was not assessed for either group, the prospective additional volume of an exercise stimulus during routine activities of daily living may have been responsible for the differences in outcome between Group One and Group Two. A similar rationale has been speculated as the cause for the differences in treatment outcomes in groups of subjects who were rehabilitated following ACL reconstruction (20,21).

Further research is certainly needed to validate the results of this study and to determine the actual cause of such results. Also, this investigation was limited to just two methods of exercise for the treatment of PFP; future studies must examine the influence of other treatments, such as physical agents and patellar taping. Lastly, this study incorporated relatively young subjects whose PFP was essentially acute in nature: further work must examine other PFP patient populations.

CONCLUSION

Based upon the results, but within the context of this study, the following conclusions were reached in the comparison of a traditional pr program with a Protonics exercise program for the treatment o£ subjects with PFP:

1. Both programs were effective for helping the subjects achieve the desired clinical outcome target on the FIQ (3)
2. The Protonics exercise program resulted in a significantly shorter treatment period, and
3. The Protonics exercise program was more cost 13 effective.

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TABLE 1: Subject Demographics

	Group 1: Pre	***Group 2: Protonics***
	(N=30)	(N=30)
Gender		
Females	19 (63%)	21 (70%)
Males	11 (37%)	9 (30%)
Knee		
Left	16 (53%)	20 (67%)
Right	14 (47%)	10 (33%)
Age (Yrs)		
Mean	19.1	22.4
SD	3.4	4.9
Range	14-24	15-27
Occupation		
Student	12 (40%)	10 (33%)
Service	10 (33%)	10 (33%)
Industrial	7 (23%)	8 (27%)
Professional	1 (4%)	2 (7%)
Sports		
Recreational	11 (37%)	13 (43%)
Competitive	8 (27%)	9 (30%)
Occasional	7 (23%)	6 (20%)
None	4 (13%)	2 (7%)
Physician Diagnosis		
“Anterior Knee Pain”	10 (33%)	12 (40%)
“Patellofemoral Pain Syndrome”	10 (33%)	11 (37%)
“Chondromalacia”	8 (27%)	5 (16%)
“Abnormal Tracking”	2 (7%)	2 (7%)

TABLE 2: Group One – Traditional PRE's

Quadriceps Setting:	isometric Contraction; "Rule of 10s" protocol
Straight Leg Raising:	0-45 deg hip flexion using ankle cuff weights; eccentric DAPRE protocol
Terminal Knee Extension:	0-2- deg knee short-arc using exercise machine; eccentric DAPRE protocol
Leg Press:	0-20 deg knee short-arc using exercise machine; eccentric DAPRE protocol
Closed Chain Short-Arc:	0-20 deg knee short-arc using 18 cm step height; eccentric emphasis
Home Program:	Daily performance of the traditional PRE's

ISOMETRIC "Rule of 10s" Protocol (3)

Contraction:	2 sec force build-up
	6 sec maximal hold
	2 sec force release
Relaxation:	10 sec
Repetitions:	30

Eccentric DAPRE Protocol

Set	Work Load	Reps
1	1 / 2	10
2	3 / 4	6
3	1.0	Max
4	Adjusted	Max

Adjustments

Set 3 Reps	Set 4 Work Load	Next Session
0-2	Decrease 2-5 kg	Decrease 2-5 kg
3-4	Decrease 0-2 kg	same load
5-6	Same load	Increase 2-5 kg
7-10	Increase 2-5 kg	Increase 5-7 kg
11 +	Increase 5-7 kg	Increase 7 + kg

Eccentric emphasis: 2 sec concentric phase

4 sec eccentric phase

TABLE 3: Group Two – Protonics Exercises (9)

Stair Stepping Exercise Device	Initial Goal:	5 minutes
	Progress:	1 minute per session
Stationary Cycling	Initial Goal:	10 Minutes
	Progress:	1 minute per session
Seated Hamstring Flexion / Curls	Initial Goal:	3 sets X 10 reps
	Progress:	1 more set per session
Partial Squats	Initial Goal:	3 sets X 10 reps
	Progress:	1 more set per session
Home Program	Ambulation with knee brace and Protonics Exercise device	

TABLE 4: Functional Index Questionnaire (3)

Tasks	Unable to do	Can do with problem	No problem
1. Waling as far as a mile	0	1	2
2. Climbing up 2 flights of stairs (16 steps)	0	1	2
3. Squatting	0	1	2
4. Kneeling	0	1	2
5. Sitting for prolonged periods with knees bent in one position	0	1	2
6. Climbing up 4 flights of stairs (32 steps)	0	1	2
7. Running a short distance (100 meters)	0	1	2
8. Walking a short distance (1 city block)	0	1	2

Discharge Target Score = 16