

Failed Back Surgery Syndrome: A Physiotherapeutic Approach

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ABSTRACT

Background and Purpose: Improving functional disability and pain level in patients with failed back surgery syndrome (FBSS) is of primary importance. The purpose of this study was to examine whether patients with failed back surgery syndrome, when offered access to the physical therapy care alongside conventional care, gained more long-term relief from pain and disability than those offered conventional care only. **Materials and Methods:** Eight patients were classified randomly into two groups, study group (group 1) received physical therapy program three settings/week for eight weeks. The control group (group 2) received conventional care from their physicians. All patients were diagnosed as having failed back surgery syndrome, of 12-48 weeks' duration of illness with a mean age of 46.8 ± 9.3 years. Outcome measures were the Short Form 36, Bodily Pain dimension and physical function, and the Oswestry Pain Disability Index (ODI). Spinal mobility was measured by Schober's test and finger tip to floor. All measures were assessed at baseline, two, six and 12 months. **Results:** Analysis of results showed that; in both groups there were significant pre-post treatment improvements for all scores. Analysis of data revealed an intervention effect of 6.8 and 9.5 points on both the SF-36 Pain and Physical Function Scores in favor of the group 1 at two months and at six as well as 12 months. For the Oswestry Pain Disability Index, patients showed statistically significant improvements in pain and functional state especially immediately post treatment with statistically significant difference for the group 1, also at six month follow-up, and the effects were still maintained at 12 months. **Conclusions:** Physical therapy program is effective to patients with failed back surgery syndrome in reducing bodily pain and disability than conventional care at 12 months follow-up.

Key words: Failed back surgery syndrome, Physical therapy, Physical disability.

INTRODUCTION

The surgery for herniated disc is the most common operation at the level of the lumbar spine. The failed surgery rates range between 10% and 40%, conforming what is known as FBSS. Return to work after surgery occurs in 70-85% of the cases²⁴. Patients with FBSS have traditionally been classified as "spinal cripples" and are consigned to a life of long-term narcotic treatment with little chance of recovery²³. FBSS is an imprecise term used to categorize a heterogeneous group of causes to residual symptoms after back surgical treatment. It is not a definitive diagnosis and it is considered a syndrome because it has many explanatory etiologies as clinical as surgical¹³.

FBSS is defined as severe persistent or recurrent pain, long-lasting, mainly in the lower back and/or legs, disabling and relatively frequent (5-10%) complication of lumbosacral spine surgery^{16,26}, even after successful spinal surgery¹². The failure has been mostly related to: calcified herniated disk; spinal canal or foraminal stenosis; recurrent herniated disk with epidural fibrosis²²; small descending herniated disk at the level of the lateral recess⁷, painful disc(s), pseudoarthrosis, neuropathic pain, psychological problems²⁹, facet joint pain, sacro-iliac joint pain²⁵, wrong level of surgery, inadequate surgical techniques¹⁵, vertebral instability, and lumbosacral fibrosis¹². As teep increase of the number of performed spinal procedures has also led to an increase in the number of FBSS cases⁶.

Treatment of such patients is difficult; it is not likely to disappear quickly. Over the years, a number of treatments for persistent low back pain following spine surgery, (FBSS) have been developed¹. Conservative therapy and repeated back surgery often unsuccessful

at providing adequate pain relief¹⁸. The results after repeated surgery on recurrent disc herniations are comparable to those after the first intervention, whereas repeated surgery for fibrosis gives only 30-35% success rate, and 15-20% of the patients report worsening of the symptoms⁶. The purpose of this study was to investigate the effectiveness of physical therapy program for patients with FBSS.

SUBJECTS, MATERIALS AND METHODS

Eight patients from both sexes (with a mean age of 46.8 ± 9.3 yr; and mean body mass index 24.65 ± 1.74) were randomized into two equal groups: physical therapy group (group 1) and control group (group 2). The study was conducted in Sharkia Health Insurance Hospital; Physical Therapy Clinic, from Jan 2006 till end of July 2007.

All patients were recruited from neurosurgeons or orthopedic surgeons to the study coordinator in the outpatient physical therapy clinic. Patients were included in the study if they were 45-55 years with FBSS of 12-48 weeks duration of illness but less than one year, with pain radiating to the legs, and there was indication for surgical intervention.

Exclusion Criteria: Subjects were not eligible for the following reasons: compression fractures of the spine, spondylolisthesis, sacroiliac sclerosis, moderate/severe spinal stenosis, moderate/severe hip or knee osteoarthritis, certain medical conditions, e.g., cancer, systemic infection, osteomyelitis, diabetes, rheumatologic disease, reflex sympathetic dystrophy/ complex, myelopathy, endometriosis, operable fibroids, psychiatric disorder, obesity and pregnant woman.

Interventions

Patients were randomized to the physical therapy program (G1) or to receive conventional care (G2). The trial protocol allowed up to eight weeks. All patients in both groups were instructed for their home program which included the recommended sitting and standing neutral postures, body mechanics, and home exercise (lumber flexion, extension, stretching, and stabilization), low back instruction in proper posture, body mechanics,

and lifting techniques. Medications, advices on diets were permitted for both groups.

Treatment Protocol

Physical therapy program included Low level laser treatment, Ultrasound applications (US), and exercise program three times a week for eight weeks.

Laser Application:

Low power laser source, Helium-Neon (He-Ne) Infra Red laser using Space laser unit (Italy) were applied over the most tender points (two min.) in the lumbosacral region. Laser was applied by contact technique at low intensity (660-950 nm, 31.9 j/cm^2 , pulsed at 16000- 73000 Hz).

Ultrasound applications:

The pulsed Ultrasound application was applied three times a week for eight weeks to the same area as laser by a Fysiomed sonic 15 unite (Belgium) at a frequency of 1 MHz and a spatial average temporal average intensity of 1.5 W/cm^2 . Treatment duration was three minutes for each point.

Exercise program:

Exercise program to enhance trunk performance was applied for the G1 through the training of long trunk muscles (erector spinae and rectus abdominis) and included stretching, flexion and extension range of motion exercises and intensive dynamic training.

Conventional care:

For patients in the control group (G2) conventional care entailed including medication by their neurosurgeon or orthopedic surgeons, bed rest, advice on diet, home exercises and self-care education.

Outcome Measures:

Patients were assessed and followed up at baseline immediately before randomizations, at two months, and again at six and 12 months post randomization by the following measures:

- The self-report measures of the Short Form 36 (SF-36), Bodily Pain dimension (range 0-100 points), SF-36 Physical Function. A difference, or change, between 5 and 10 points on SF-36 dimension scores is widely thought to represent a clinically significant benefit²⁷.

- The Oswestry Low Back Pain Disability Questionnaire (ODI) which is a 10-item scale; each item has six ranked detractors, scored from 0 to 5, yielding a maximum score of 50. The first section is a pain-related scale, and the other sections deal with various daily activities that are relevant to low back capability. The ODI score (index) is calculated as: $(\text{point total} / 50 \times 100 = \% \text{ disability})^{19}$.
- Spinal Mobility was measured in standing with two methods, Schober's test and finger tip to floor distance (FFD). The modified Schober's test was performed as follows: with the patient standing erect, a mark on the back at the midpoint on an imaginary line joining the posterior superior iliac spines. Another mark 10 cm. above the first. The patient was asked to bend forward maximally, keeping the knees fully extended. With the spine in fullest flexion, the distance between the two marks was measured with a tape¹⁷.

Statistical Analysis

Data were analyzed using the SPSS computer program, Version 10 for Windows. Data were statistically described in terms of mean \pm standard deviation (\pm SD). t- test was

used to compare between the study and control groups. Dichotomous data were analyzed using chi-square. The relative percentage of improvement was calculated as the difference in the percentage of improvement between both groups.

RESULTS

The overall results of the study revealed no statistical differences between the two groups at the baseline clinical characteristics ($P > 0.05$) (table 1).

Table (1): Characteristics of all subjects of the study.

Characteristics	Mean	SD	Range
Age	46.8	9.3	45-55 Yr.
Weight	78.9	7.6	65-82 Kg
BMI	24.65	1.74	-25.7 kg/m ² 24.6
Sex M/F	36 M,24 F	-	-

BMI: body mass index.

Comparisons of data showed no statistical difference between both groups (G1&G2) before treatment, however, the before and- after comparisons showed favorable effects (table 2), and the effects were still maintained at 12 months follow-up.

Table (2): The pre- and post two month's measurements of the both groups (G1&G2).

Measures	Group 1				P- Value	Group 2				P- Value
	Pre-treatment		Post-treatment			Pre-treatment		Post-treatment		
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
VAS	8.3	2.1	4.1	1.4	0.01**	8.3	2.1	5.6	1.7	0.01*
Schober's	12.5	1.3	15.9	1.1	0.01**	12.5	1.3	13.6	1.4	0.01*
FFD cm	37.5	32	19.2	19.3	0.01**	37.8	32	27.5	34	0.04*
ODI	57.9	14.7	33.4	6.3	0.01**	58.3	14.5	47.6	7.2	0.01*
SF-36 PFS	48.9	29.4	64.3	20.9	0.01**	48.9	29.4	54.8	21.6	0.01*
SF-36 PS	29.9	16.2	62.5	21.3	0.01**	29.4	14.7	55.7	23.4	0.01*

Significance* at $P < 0.05$. SD: standard deviation. VAS: visual analogue scale. FFD=finger floor distance. ODI, Oswestry Pain Disability Index. SF-36 PFS: Short Form 36 physical function score. SF-36 PS: Short Form 36 pain score.

Tables 3–5 give the estimated between-group effects for measurements scores at two, six and 12 months. Comparisons of all measurements between the two groups at two months gave a significant estimated effect on the SF-36 Pain dimension of 6.8 points (95% CI -1.4 to 13.2), also there were an intervention effect of 8.2 points [95% confidence interval (CI 2.9 to 14.7)] at six

months, and 7.9 points (95% CI 1.9 to 14.2) at 12 months in G1. A 15.5 point of intervention effect at 12 month follow up for the SF-36 Physical Function scores (95% CI -0.9 to 14.2) in G1. For the ODI, patients showed a marked functional improvements especially immediately post-treatment with an intervention effect of -14.2 (95% CI -8.8 to 16.7) in G1 (Fig. 1).

Spinal mobility measures showed also a statistically significant difference with an intervention effect for the Schober's test of 3.4 points (95% CI -0.95 to 8.6) at two months follow up in G1 (Fig.2). FFD cm. scores

showed also a statistically significant difference with an intervention effect of -8.3 (95% CI -6.7 to 11.3) at two months follow up in G1 (Fig 3).

Table (3): Effect of intervention on variables scores at two months in both groups (G1&G2).

Measures	Adjusted means of both groups (N= 40)				
	G1 Mean	G2 Mean	Estimated effect	95% CI	P-Value
VAS	4.1	5.6	- 1.5	1..2 to 5. 3	0.02*
Schober's	15.9	12.5	+3.4	3..95 to 8.6	0.03*
FFD cm	19.2	27.5	-8.3	6.7 to 11.3	0.01*
ODI	33.4	47.6.	- 14.2	8.8 to 16.7	0.03*
SF-36 PFS	64.3	54.8	+9.5	1.8 to 13.3	0.04*
SF-36 PS	62.5	55.7	+6.8	1.4 to 13.2	0.03*

Significance* at P<0.05.

Table (4): Effect of intervention on variables scores at six months in both groups (G1&G2).

Measures	Adjusted means of both groups (N= 40)				
	G1 Mean	G2 Mean	Estimated effect	95% CI	P-Value
VAS	4.0	5.3	- 1.3	-1.46 to 3..2	0.02*
Schober's	15.6	13.9	+1.7	5.83 to 9.2	0.03*
FFD cm	15.4	22.9	-7.5	-0.3 to 8.3	0.04*
ODI	29.7	43.8	-14.1	1.5 to 14.6	0.01*
SF-36 PFS	69.1	56.4	+12.7	1.4 to 17.8	0.04*
SF-36 PS	64.6	56.4	+8.2	2..9 to 14.7	0. 03*

Significance* at P<0.05.

Table (5): Effect of intervention on variables scores at 12 months.

Measures	Adjusted means of both groups (N= 40)				
	G1 Mean	G2 Mean	Estimated effect	95% CI	P-Value
VAS	3.7	5.1	- 1.4	1..32 to 4.4	0.04*
Schober's	16.2	14.4	+1.8	1..52 to 6.3	0.04*
FFD cm	13.2	20.6	-7.4	1..51 to 11.3	0.03*
ODI	27.8	39.8	-12	8..5 to 14.7	0.02*
SF-36 PFS	74.2	58.7	+15.5	3.6 to 17.8	0.005*
SF-36 PS	66.1	58.2	+7.9	1..9 to 14.2	0. 01*

Significance* at P<0.05.

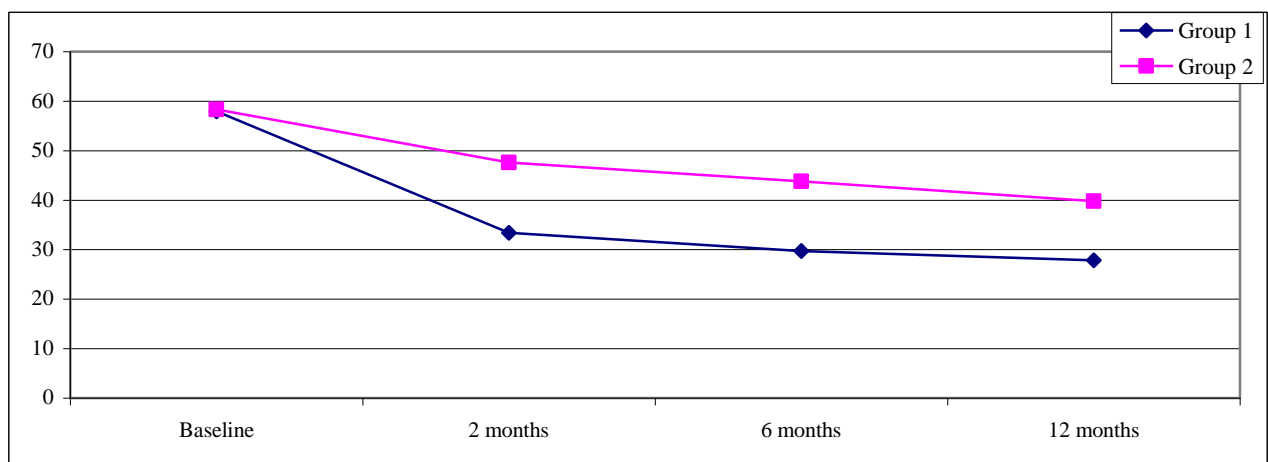


Fig. (1): Mean ODI score for both groups.

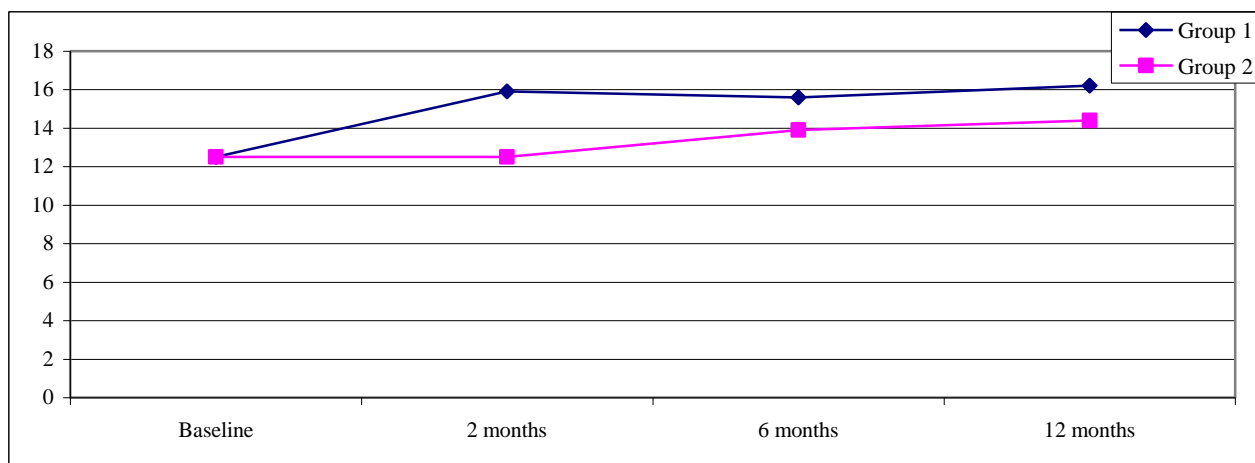


Fig. (2): Mean Schober's test for both groups.

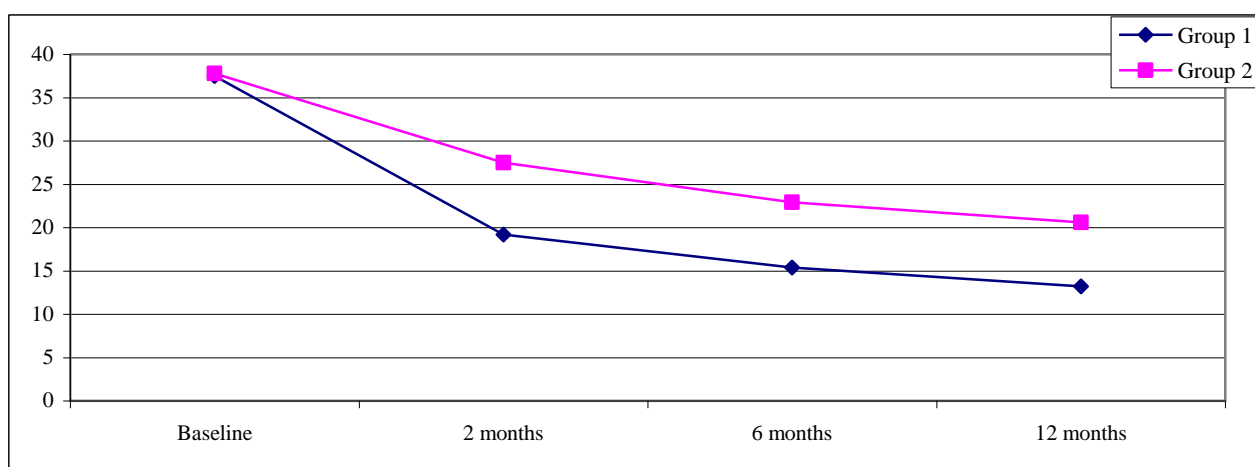


Fig. (3): Mean FFD test for both groups.

DISCUSSION

FBSS has become unfortunately a common challenging clinical entity. It does not have a specific treatment as it does not have one specific cause. Some features are shared with chronic low back pain (CLBP) and some pathological processes are specific. Both pathologies are leading causes of disability²¹ and intractable pain which interferes and limits home activities, often with disastrous emotional and financial consequences to the patient in the industrialized world¹⁹.

Recent advances in surgical reconstruction, rehabilitation, and pain management technique offer hope for patients with this painful and disabling condition²³. Regarding results of the present study, the reduced functional state and spinal mobility of all participants at the start of the present study explained by the results of Kofotolis and Kellis¹⁹ who reported reduced muscle strength

and endurance levels and altered flexibility accompanied by low-intensity pain levels and reduced functional ability people with CLBP.

Kovacs et al.,²⁰ investigated the effects of pain on the physical functions and disability and found that: on day one of the onset of pain, a 10% increase in VAS worsens disability by 3.3% and quality of life by 2.65%. On day 15, a 10% increase in VAS worsens disability by 4.99% and quality of life by 3.80%. The authors added that the influence of pain and disability on quality of life progresses and doubles in 14 days. The researchers concluded also that clinically relevant improvements in pain may lead to almost unnoticeable changes in disability and quality of life in patients with low back pain.

The ODI actually measures pain and its impact on function³⁰ showed marked improvements immediately post-treatment followed by a slowing down of the improvements in average pain in the six

months measurements at the long-term follow-up³⁰. In the present study, significant improvement was observed in the physical therapy group for both measures which sustained at six or 12 months. Most of the improvement occurred during the first eight weeks; thereafter the changes were minor. More patients in the study group reported 12 months pain free compared with those in the control group. The ODI data indicated a significantly severe disability at baseline measurements for both groups, while the results of the study group showed significant improvement (52% vs. 31.4%) at the end of the study.

Walsh et al.,³⁰ reported better function by 10% on the Oswestry scale. Skaf et al.,²⁶ found that an average preoperative ODI mean score of 80.8; could be improved postoperatively to 36.6 at one month and 24.2 at one year and best scores were obtained at three months of follow-up in most cases.

In the present study ODI showed 57.9 pre-treatment, 33.4 immediately post-treatment and 27.8 at 12 month measurements in the study group. This would be consistent with the improved SF-36 PFS, PS at short-term follow-up, and the general improvement in all functional activity at long-term follow-up. The selected SF-36 scores improved significantly at six months and one year of follow-up with a maximum effect on pain and physical function. Patients in physical therapy group have higher significant SF-36 PS compared with the patients in the control group. Physical therapy program improved functional scores by 52.35% compared to 20% for the conventional care.

These results are in parallel to Walters et al.,³¹ who reported that successful cumulative relief, defined as relief greater than 50% with any treatment program. Change in flexion explained most of the improvement in Oswestry scores immediate post-treatment measurement. Extra parameters include, FFD which represents the decrease in the distance between the fingers and the earth with the knees fully extended and the back fully flexed and the improvement in spinal mobility of the Schober's test which is reported to be the most responsive method for measuring spinal mobility⁷.

The results of the present study showed the effectiveness of physical therapy modalities in management of FBSS. The inter comparison showed that the US and laser application with the routine physical therapy had significant effect than routine conventional care alone with significant improvement in ODI, FFD, Schober's test and SF-36 PF scores in both groups in the immediate post-treatment measurements suggesting the positive effects of pain relieve.

These results are in agreement with Bjordal et al.,³ who concluded that low level laser treatment (LLLT) can reduce inflammation and pain. Basford et al.,² found that treatment with low-intensity laser irradiation produced a moderate reduction in pain and improvement in patients with musculoskeletal low back pain. Gur et al.,¹⁴ concluded that LLLT seemed to be an effective method in reducing pain and functional disability in the therapy of CLBP. The reason for the application of laser contact technique to the paraspinal lumbar area was essentially as follow, the maximization of power density/irradiation on the target tissue, reflection is minimized and increase the amount of radiation delivered to the underlying tissue. Carrinho et al.,⁵ demonstrated that LLLT is effective in reducing post-injury inflammatory processes and accelerating soft tissue healing. Moreover, it was suggested that LLLT, at the cellular level, produces increased ATP synthesis, increased mitochondrial respiration, and increased production of molecular oxygen, thus stimulating DNA synthesis and cell proliferation. LLLT can accelerate the healing process of tendinitis after injury by creating new blood vessels, increasing collagen fiber deposition, promoting higher fibroblast cell proliferation in the site of the lesion and increasing the tensile strength of completely severed and surgically repaired rat tendons¹¹.

Previous study⁹ reported the interesting similarities between the physiological effects of laser and US in the following effects: alteration in cell proliferation and motility, phagocytosis, immune response and respiration. US may benefit for tissue trauma through increasing the delivery of oxygen and macrophages to the underlying tissue and

promoting healing. It also stimulates the fibroblasts to secrete collagen which accelerate the process of wound contraction and increases tensile strength of the healing tissue, also the connective tissue will elongate well if heat and stretch are combined.

Contrary to the results of the present study the study of Bouter et al.,⁴ found that LLLT and US have no effects on most musculoskeletal disorders. Also Craig et al.,⁸ concluded that combined LLLT had no effect in alleviating the signs and symptoms of delayed onset muscle soreness over an 11-day period. The reason for that difference may be due to the addition of active exercises beside the main line of treatment during the study and different techniques used in this study.

Early treatment with physical therapy has been shown to be very effective in well selected FBSS patients and should be considered instead of re-operation. The substantial improvements in quality of life and functional status permit many patients to return to work. Thus, physical therapy is the treatment of choice in medically refractory FBSS patients where recurrent neuropathic pain persists after surgery and analgesics are no longer effective or accompanied by intolerable side effects beside it has a great benefits in improving patient functioning²⁸.

Conclusions

Physical therapy program for FBSS patients is safe and effective when compared with conventional care carried out by neurosurgeons or orthopedic surgeons. It can provide significant long-term pain relief with improved quality of life and employment.

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الملخص العربي

متلازمة الجراحة الظهرية الفاشلة : نظرة العلاج الطبيعي

تهدف الدراسة إلى تقييم قيمة تدخل العلاج الطبيعي في مرضى متلازمة الجراحة الخلفية الفاشلة . أجريت الدراسة على ثمانية و أربعين مريضاً من الجنسين أجريت لهم جراحة بالعضروف القطني (بنفس الطبيب الجراح ونفس الطريقة) . تم تقسيم المرضى لمجموعتين متساويتين عددياً، تم علاج المجموعة الأولى ببرنامج علاج طبيعي يتكون من تمارينات علاجية للظهر(شد ومدى حرك ي وليونة) وليزر وموجات فوق صوتية على النقاط المؤلمة بالظهر لمدة ثمان أسابيع بمعدل ثلاث جلسات أسبوعياً . بينما عولجت المجموعة الثانية ببرنامج تقليدي يعتمد على تلقي الأدوية من الطبيب المعالج والراحة بالإضافة إلى نصائح تخص الحركة وحماية لمنع زيادة الوزن . أستخدم مقياس الألم لقياس شدة الألم واستفتاء أوستري لقياس عجز الظهر بالإضافة إلى اختبار شوير لقياس مدى الحركة بالعمود الفقري . وقد أثبتت النتائج تحسن في المجموعتين ولكن هناك فروق ذات دلالة إحصائية عالية بين المجموعتين لصالح المجموعة الأولى ولذلك يتبين أن تدخل العلاج الطبيعي بعد جراحة العضروف القطني ينتج عنه تحسن ملحوظ في شدة الألم وزيادة في المدى الحركي مما يقلل من احتمالية فشل في النتائج المترتبة على الجراحة .