Non- surgical Spinal Decompression-ProtecSpine

This quarters medical device review features the ProtecSpine non-surgical spinal decompression (NSSD) system. Manufactured in Japan with corporate distribution offices in Roselle, IL this device has a number of features that we do not cover in this report due to space constraints including a cervical traction component along with a myriad of adjustments that allow the provider to perform manual therapies to both the upper and lower extremities. This report will briefly review the lower spine application (decompression function) and provide some proof of concept data that we hope clinicians will find useful.

Introduction

The Protecspine device achieves inter-spinal segmental distraction through a linear or axial pull force applied strategically to isolate a single or multiple target motion segments. The patient's pelvis is secured using a proprietary pelvic stabilization system ensuring the pelvis is secured in the desired position. The hydraulic seat is positioned to create the actual unweighting/off-loading effect on a patient making this decompression device unique in that it is a non-horizontal device i.e. patient is not supine or prone rather they are sitting up. As the seat is lowered a distraction force is created as the unit separates the target spinal segments and a decompression effect is created. When a distraction event occurs a cascade of physiological events is set into motion leading to pain resolution. With distraction comes the development of negative intra-discal pressure, which counters the compression forces associated with gravity and upright postures. The negative pressure tends to have a vacuum effect on the protruded or extruded nucleus pulposus (disc jelly) drawing this viscous material back into the center of the disc where it provides maximum benefit. While pulling in the disc material might also cause a realigning of the vertebral segments while concomitant soft tissue stretching can elongate shortened and painful muscles that often are in a protective guarding mode. Applying a decompression force to the spine also acts to facilitate the natural disc hydration cycle (imbibing water) that is necessary for disc health. The clinical result of a ProtecSpine treatment can be resolution of pain/spasm, improved spinal alignment, and a restoration of function in many patients.

Product Evaluation

We have tested this device for approximately 2 years and have collected user and clinical data (Patient Reported Outcomes or PRO's) on the device since then. We have found the upright seated position to be more favorable to some patients than the supine position, not to mention, that in this position one can conceivably keep the patient seated and perform other ancillary PT procedures as necessary. The seated position is also advantageous with patients having vertigo or C spine difficulties where they simply prefer not to lay down. An average treatment session is approximately 20-25 minutes with extra time, not necessarily providing extra relief. There seems to be a point beyond which adding more time become unnecessary (diminishing return to scale). Our data consists of patient trials whose conditions have all been confirmed with either a form of imaging or electrodiagnostic testing (EMG).

Patient population/selection

Our patient population were primarily degenerative disc disease, spinal stenosis or nerve root impingement patients with a myriad of secondary diagnosis or co-morbidities. We avoided simply putting non- specific or idiopathic low back pain on this device, rather, only those that responded positively to a few minutes of manual leg traction as a test of irritability. If leg pulls caused discomfort we did not proceed to ProtecSpine.

Data analysis

We used a number of standardized outcome measures including the Oswestry and SF-36 disability scale. We then converted our data into a modified Odds Ratio's (OR) which provides a measure of effect size. When we calculated the OR for the ProtecSpine the results indicated that when we used this device on a patient with some type of spinal compressive or DDD disorder, the odds of achieving the desired outcome (a 3/10 pain score reduction in a single session) was 2.8 (95% CI: 1.07 - 7.42; $p < 0.05$) times greater using Protecspine than not using the device. This was based on a case/control design with a sample of 80 patients 40 of which had standard PT (control group) while the other 40 had standard PT plus NSSD included (experimental group). The ProtecSpine device has demonstrated very good potential for pain relief even in a single session. More information on affordable conservative spinal decompression is available at:

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