

CASE REPORT:

Cost Benefit of the Integrity Spinal Care System (ISCS)

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After attending the University of Hawaii where he earned a Bachelor's of Science Degree, majoring in Biology and Nutrition.

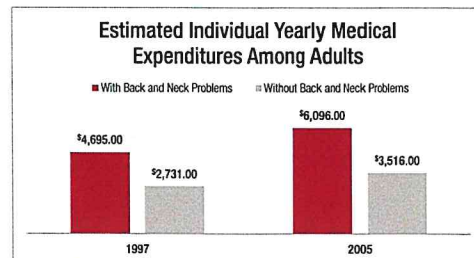
Dr. Munroe continued his education at Life

Chiropractic College in Atlanta, GA where he earned his Doctor of Chiropractic in 1985. Munroe Chiropractic was founded in 1987 by Dr. Munroe and his wife, Ellen. Dr. Munroe contributes to the content of this case report.

Introduction

Chronic back pain has plagued most industrialized countries for years. It is now considered a widespread condition as it is estimated that 70-85% of people in developed countries will experience some type of back pain in their life. Back pain is more common in adults over the age of 45 and slightly more prevalent in women.

These statistics have remained stable over the last 30 years as the cost of treatment for neck and back pain in 2005 was \$86 billion¹ and back pain continues to be responsible for 12-15% of all physician visits.¹ After adjusting for inflation, it is estimated individual yearly medical expenditures among adults with back and neck problems were \$4,695 in 1997 and \$6,096 in 2005, compared with \$2,731 and \$3,516, respectively, for people without back and neck problems.²



The course of back pain can be variable and unpredictable. When evaluating treatment strategies, activity limitation may be a better measure of outcome than the level of pain.¹ While rates of operative intervention have steadily increased over the past 20 years,³ treatment of back pain with radiculopathies remain unpredictable, with success rates in the 50-70% range.^{4,5} Researchers used the Quality Adjusted Life Year (QALY) scale to perform a cost/benefit analysis over a two-year post-surgery period. Spinal fusion surgery is estimated to be \$115,000 per QALY gained. In the United States, \$100,000 is the maximum at which procedures are considered cost effective.⁶ Given the high cost and limited benefit significant risk, surgery should be reserved as a last resort. Non-surgical measures remain the mainstay.

Until recently, the non-surgical management consisted of patient education, medications, physical modalities such as manipulation, traction, transcutaneous electrical nerve stimulation and others.¹ Regarding steroids, the US Food and Drug Administration (FDA) issued a severe warning against the use of epidural corticosteroid injections for pain. The warning cautions, "...that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death."⁷

Non-steroidal medications include analgesics, anti-inflammatories, muscle relaxants and anti-depressants. They are not without adverse effects and may require possible dosage adjustments. The goal of therapy would be to keep the patient on the lowest possible dosage that helps relieve the pain. With anti-depressants, there is an association between pain and mood, especially in chronic disorders. For chronic pain, tricyclics have shown some promise in alleviating the pain associated with Lower Back Pain (LBP) when compared to placebo. Again, the side effect profile may be significant, and there may be a benefit to starting them at night.

Most of the physical modalities have limited value in treating chronic LBP. Patients become noncompliant especially with the physical modalities if they are not getting the expected relief.

Another non-surgical treatment option to be considered early in treatment is the Integrity Spinal Care System (ISCS) by Integrity Life Sciences. Through the US FDA clearance process for medical devices, the ISCS has repeatedly been defined as a non-surgical spinal decompression modality and can be considered as an alternative to surgery in chronic, protocol inclusive candidates.

The propriety protocol for this modality takes place over 6-8 weeks with varying of patient visits. Continuous physician monitoring is necessary to customize the patient's progress. In similar cases, after the successful completion of the protocol, peer reviewed literature reports that patients with chronic LBP experience greater than a 80% reduction in their verbal pain intensity score,^{8,9,10} require fewer pain medications,⁹ and achieve better function.⁹ There have been no significant adverse events reported.^{9,10,11} The cost of this treatment protocol varies from \$2,500 to \$3,500¹² for the entire protocol and it is suggested as a precursor to surgery.

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Case Report

This case report examines the case of a 77 year old female, post trauma, complaining of a 14+ week history of severe post traumatic headaches in the form of cervicgia that appear to be migrainous in phenotype as well as mild short-term memory loss. The patient sought previous consults with a neurologist, chiropractor and neurosurgeon. Traditional chiropractic manipulative techniques as well as non-steroidal anti-inflammatory (NSAIDs) medication provided mild relief. Occipital nerve blocks also provided temporary relief.

While undergoing traditional chiropractic manipulations, MRI images of the spine were obtained. The examination included a MRI of cervical spine, thoracic spine and lumbar spine without contrast. The cervical spine MRI revealed left sided C3-C4 disc herniation impinging on the anterior aspect of the cervical cord, concentric bulging of the disc and minimal posterior osteophytes at C5-C6 and C6-C7 and 3mm retrolisthesis at C3 on C4. Thoracic spine MRI showed disc narrowing, desiccation and concentric bulging at the T7-T8 and T8-T9 levels. Lumbar spine MRI concluded L5-S1, L4-L5 and L1-L2 disc herniations indenting the anterior aspect of the thecal sac (**Fig 1**) as well as disc desiccation, and concentric bulging of the disc at L2-L3 and L3-L4 levels.

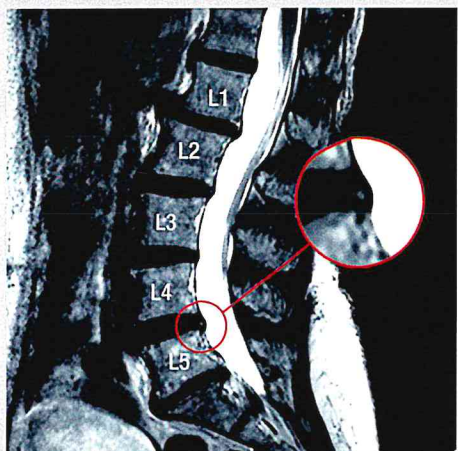


Fig. 1

The patient was assessed three times by neurology. The first was three weeks post trauma, and NSAIDs were prescribed. Three weeks later the patient received a bilateral greater occipital nerve block where post-traumatic migraine symptoms temporarily subsided. Six weeks later the patient returned to the neurologist complaining of similar headache and neck pain. Another bilateral greater occipital nerve block was performed.

Twelve weeks post trauma the patient was evaluated by a neurosurgeon where patient care was coordinated and the patient was counseled on surgical options. It was concluded that the patient was considered to have a surgical indication as MRI imaging showed pathology consisting of a left-sided C3-C4 disc herniation that impinged on the anterior aspect of the cervical cord. Concentric bulging of the C5-C6 and C6-C7 was also shown. The thoracic spine did not show an indication for surgery. Review of the lumbar spine showed concentric bulging of L2-L3, and L3-L4 levels with disc desiccation. The patient's symptoms can be explained by a central L1-2, L4-5, and L5-S1 disc herniation that indented the anterior aspect

of the thecal sac. The worst objective level is L5-S1, where there was the worst disc space narrowing and the worst effacement of the thecal sac, but no significant central stenosis or compression of the conus or caudal equine. A relative indication for low back surgery therefore existed. Epidural injections were not indicated due to the absence of radiating leg pain. The patient was fearful of the risks in surgical options, and therefore declined.

The Integrity Spinal Care System (ISCS)

A thorough workup including an examination, review of systems, past medical history, social history, activities of daily living, review of previous medical records, advanced diagnostics and other pertinent testing to rule out red flags, quantify yellow flags, exclude contraindications and confirm diagnosis was performed at a medical facility that underwent training and certification by ILS in the protocols, and medical intended usage. Patient self described symptoms are constant (75%-100% of the time), performing daily self care was uncomfortable and slow. There was difficulty climbing a flight of stairs, pain limitations to short term standing, walking and sitting, difficulty in manipulating objects in hands, difficulty in kneeling, bending, squatting, disturbance in sleep that occurs 2-3 hours nightly, and complained of pain most of the time.

The ISCS contains the proprietary iECLIPS Technology. The iECLIPS Technology as defined within the records of the US Patent and Trademark Offices is an acronym for "Intelligent Engineering Closed Loop Integrated Programming System". It is further defined as technology that "... constantly monitors the feedback signal from the servomechanism and continually adjusts for deviation from expected behavior to insure the ISCS treatment stays true, delivering true spinal decompression every time, to every patient". When incorporating this technology into the ISCS treatment it allows the physician to change the angle of pull that most benefits the patient's condition and causes a positive pathophysiological change in the disc. The device has two independent feedback modalities: a main loop and nested loop which perform at 13x per second and 400x per second, respectively. This noted iECLIPS technology can specifically target and isolate the logarithmic curve of decompressive forces to the precise location of the diagnosed spinal disease, making it more clinically beneficial than traction.^{13, 14} Per the ISCS protocol, the physician can direct the forces over a targeted discal space to deliver a greater magnitude of pull in the prescribed region. This directed pull makes the ISCS disc-specific, thereby creating a pathophysiologic change to the disc itself, which is the ultimate goal of this modality. The primary disc lesion is impacted the most with forces affecting the level above and the level below. The logarithmic pattern using decompressive forces reduces potential reactive muscle resistance and spasm proprioceptor response.^{9, 13-15} No device-related adverse events have been reported. Overall, more than 80% of patients reported clinically significant pain improvement after noninvasive spinal decompression.^{8-11, 13}

Treatment goals included decreased pain; increased range of motion, function and mobility. Ultimately the goal was to sustain decreased pain long term. Because of the patient's initial diagnosis of lumbar disc displacement without myelopathy and somatic dysfunction of lumbar

region, her prognosis was guarded. The plan was to start the patient on the ISCS L4-L5 reevaluating as prescribed in the proprietary protocol.

The patient was reevaluated throughout the treatment protocol where the same subjective and objective parameters were documented. Pain continued to decrease in severity, disturbance in sleep and range of motion continued to improve (**Table 1**). After the initial protocol, based on continued documented feedback and reevaluation, the patient was prescribed a full ISCS proprietary protocol on each the following consecutively: L1-L2; L2-L3; L3-L4.

Table 1: Lumbar Goniometry Results

	L1-L2		L2-L3		L3-L4		L4-L5	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Restricted flexion	25/60	30/60	37/60	45/60	48/60	53/60	55/60	55/60
Restricted extension	10/25	17/25	20/25	20/25	20/25	22/25	25/25	25/25
Restricted right lateral flexion	15/25	19/25	23/25	25/25	25/25	25/25	25/25	25/25
Restricted left lateral flexion	15/25	20/25	25/25	25/25	25/25	25/25	25/25	25/25
Restricted right rotation	10/25	14/25	16/25	18/25	20/25	25/25	23/25	25/25
Restricted left rotation	13/25	17/25	18/25	20/25	22/25	24/25	24/25	25/25

At the end of the 4th and final protocol, the patient described symptoms as intermittent, rated pain 1/10, symptoms are markedly better since onset and denies neurologic symptoms including numbness, tingling or weakness. Evaluating activities of daily living: self-care was not limited and could be performed easily and normally. The patient indicated no problem with walking and could climb a flight of stairs easily and without pain. Sitting tolerance was not pain limited and there were no standing or walking limitations. Reaching and grasping for things overhead could be done without pain as well as pushing or pulling very heavy loads. Manipulating things was not problematic and was routinely done. There was no difficulty in squatting, kneeling or bending. There was no difficulty with repetitive motion with hands and there was no difficulty sleeping. The patient clearly stated that the ISCS treatments had improved her quality of life without surgery.

Nearly two years after the initial MRI (22 months) the patient's subsequent MRI concluded "Central L4-5 disc herniation indenting the anterior aspect of the thecal sac which has decreased in size from the prior examination." (**Fig 2**) The aforementioned treatment plan for this patient noted that the L5 disc herniation was not treated by the medical team, only lumbar levels L1 through L4. The radiologic report noted central L5-S1 disc herniation indenting the anterior aspect of the thecal sac, unchanged from the prior examination. This unchanged L5 disc herniation, with positive change in the L4 disc, supports the theory behind the ability of the ISCS to isolate the disc pathology and offer a patient specific treatment plan.



Discussion

This patient was in a chronic pain status, in excess of 14 weeks, post automobile accident, with impairment of the lumbar discal region with herniations and other soft-tissue injuries. Prior to being assessed for ISCS treatment; the patient was seen multiple times by a chiropractor for manipulations, three times by neurology she patient was prescribed medications and nerve blocks, once with a follow up scheduled by a neurosurgeon where it was determined the patient was a surgical candidate for the neck and a relative candidate for the low back. If the patient had been willing to have surgery, the cost of these procedures would have been \$26,000 to over \$100,000¹⁶ for either anterior cervical discectomy or low back. Even without surgery, total health care expenditure before actually receiving relief from the ISCS was over \$6,000. This particular patient was medication adverse and was conservative in analgesic use, but typically with patients in chronic pain there would be a titration or change in medication by the 15th week of being in constant pain.

If the ISCS modality had been considered early in the treatment plan, this patient's cost of health care would have been \$2,500-\$3,500/targeted area, thereby eliminating the initial failed costs. This patient was also an exceptional case where several discs were specifically targeted to provide relief. The goal of this paper is to begin the thought process of including the ISCS earlier in the treatment plan, thereby increasing quality of life, decreasing pain, begin to restore the integrity to the spine, as well as providing substantial savings to the healthcare system. More prospective studies are needed to support the conclusion that the ISCS should be considered as standard protocol before surgery in patients that fit the inclusion criteria.

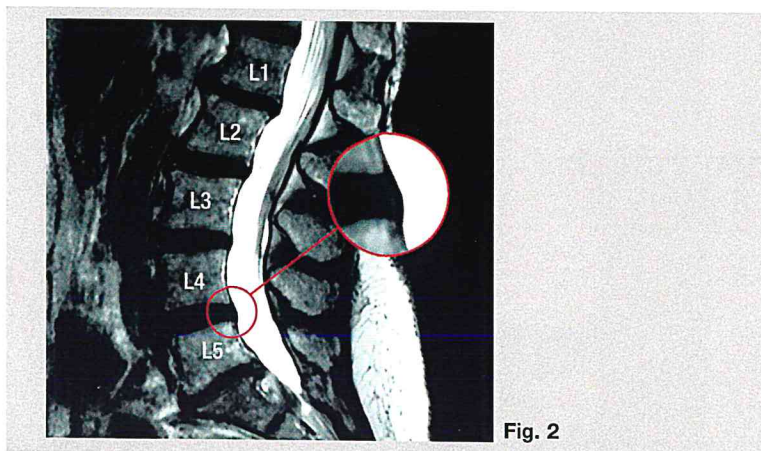


Fig. 2

PEARL CAN DANCE AGAIN



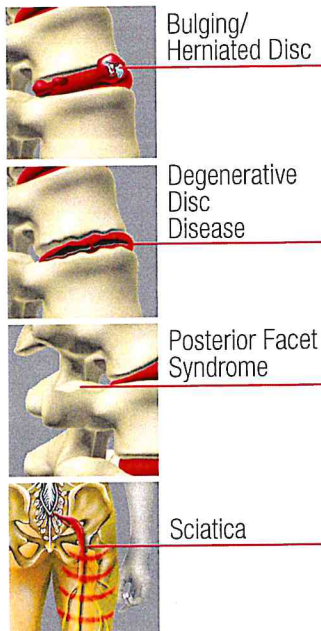
Pearl has been a dancer for as long as she can remember, and at 77 years of age she enjoyed a very full life prior to experiencing her chronic back pain conditions. She enjoyed travel, gardening, and taking walks to the local markets even during the harsh Buffalo winters. She describes her spinal condition and the pain associated with it as not only life changing but causing her life to "slow down", a point Pearl was sure to get across. As Pearl puts it, "I always found myself slowing down, and always afraid to make that first move. Whether it was trying to stand while sitting or awakening in the morning. My first movement was always hindered and tentative and I lived in fear for the next jolt of pain".

She was frustrated with the recommendations of her doctor and the surgeon overseeing her pain management as she was risk adverse to any form of surgery and anesthesia. Eventually she was referred to Dr. Ken Munroe and his team of Integrity Spinal Care System (ISCS) specialists at Munroe Chiropractic to determine if she was a candidate for the ISCS protocol. Upon her successful evaluation she began treatments and said she found a calming presence about her daily life soon thereafter. "One night after I was treated, and I was in the kitchen preparing some dinner, I noticed that there was a calm about me. So I sat down and said to myself with a smile on my face that help is here". Pearl liked the fact that she was finally aware of the treatment parameters and the feedback that both the technician and the machine provided.

Pearl has been adamant about two things since she finished the ISCS protocol. The first she is a proud advocate for the ISCS and has referred many people suffering from back pain and encouraged them to seek help from Dr. Munroe. The other is the advice she has for her insurance carrier after she regained her life back. Pearl explained, "I called them and told them that they owed it to all of their clients to try the ISCS before surgery".

Since Pearl has responded positively to the ISCS treatments, she has resumed her full life of vacationing, dancing, Caribbean cruises, and travel with her family. Pearl recently completed a trip to Africa with her daughter and grandchildren where she had the exhilarating experience of being whisked to the top of a mountain in a chair lift, something she says would have never been possible without the results she experienced with the ISCS.

For Treatment of Lower Back and Neck Pain



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