Cohort Study

A PILOT COHORT STUDY TO DETERMINE THE EFFECTIVENESS OF FOCAL PULSED STIMULATION ON PAIN AND FUNCTION IN PATIENTS WITH SPONDYLOLISTHESIS

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ABSTRACT

In this retrospective medical records pilot study, a cohort of patients (5F/2M), who were diagnosed with degenerative spondylolisthesis underwent a novel sound-based focal pulsed stimulation over a period of three months. Clinical outcomes included pain intensity and functional disability due to back pain improved from pre- to post-treatment. Clinical outcomes such as shoulder/pelvic tilt, leg length difference, and range of motion are discussed.

KEYWORDS: *vibration, vibroacoustic, spondylolisthesis, spine, rehabilitation.*

INTRODUCTION

Spondylolisthesis (SDL) is characterized by a displacement of the vertebral body in reference to the bordering vertebral bodies and can be associated with pain and spinal dysfunction (1). Degenerative lumbar SDL involves slippage of the vertebrae (usually L4 and L5) due to disc degeneration and zygapophyseal joint arthropathy, often in combination with spinal stenosis (2, 3). Although spine-related degeneration can be asymptomatic (4), sometimes these patients report low back pain radiating pain, and present with neurological deficits. For symptomatic patients, the decision of whether surgery or conservative treatment is the best course of action is still an open question, as is the choice of which type of surgery (2, 5, 6). Conservative treatments include medication, physiotherapy, weight loss, external orthosis, injections, etc.

Although SDL is a common diagnosis in aging individuals, there is little empiric evidence to support many of the common conservative treatments for symptomatic individuals, nor is there conclusive evidence to suggest that one is superior to the other (2). For surgical treatments, a systematic review has found that surgery consistently produced better results in pain relief and functional improvement of SDL over a 2 year period (7), but the well-documented complications associated with spondylolisthesis surgery make it undesirable for many patients (8). Therefore, newer non-surgical treatments that may help improve SDL-related disability and pain would be a helpful addition to the multi-faceted approach to the treatment and management of spine-related pain and dysfunction.

Focal pulsed stimulation involves treatment with sound waves transduced into a mechanical vibrotactile sensation. In chronic pain research, sound-based pulsed treatments most commonly use pulsations in the range of 1-200Hz

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(9). Research evidence has led to the American Food and Drug Administration's (FDA) approval of general vibration therapy for 3 main claims – reduced pain, increased circulation, and increased mobility (10). A recent review underlines the mechanism behind improvements in neurological, hemodynamic, and musculoskeletal symptoms after vibratory stimuli (9). Therefore, the literature on the effects of sound-based pulsed stimulation on decreasing perceived pain and pain-related dysfunction is growing.

In clinical orthopedic practice, pulsed stimulation has also demonstrated benefits on muscle function, physical performance, patient mobility and balancing, and improving bone mineral density (11). For spine related pain and dysfunction, a growing number of studies have demonstrated that focally applied pulsed stimulus to the spine can improve spinal alignment and reduce pain (12). Focally applied mechanical stimulation generated via vibrations can stimulate genetic expression of anabolic proteins such as aggrecan and collagen, helping to regenerate health in the intervertebral discs (13). Mechanical stimulation of the bony structures also stimulates pro-osteogenic factors that stimulate the growth and repair of bone tissue (9). Therefore, the use of focal pulsation applied to the spine may be a promising option for improving SDL related disability and pain.

It must be noted that SDL is not always directly associated with pain and in a clinical context SDL may be an incidental finding. In this pilot study patients were specifically selected who presented with low back pain assessed with palpation among other tests. If a specific segment was tender to touch, and then upon palpatory examination the patient reported greater pain, the prognosis was narrowed. The clinician in those cases then conducted a physical orthopedic examination. If SDL is strongly indicated multiple factors including facet or disc issues are considered and that these conditions could be resulting from SDL. Pain can then be assumed to be originating from these related issues and may be indirectly coming from SDL. If this is the diagnostic direction, we assume the pain mechanisms are complex, but that SDL is a major contributing factor. When treatment based on this diagnosis results in improvement, there is a positive sign that the biomechanical changes indicate that the spondylolisthesis effects are being managed. Causative biomechanical changes of chronic low back pain implicated in SDL include sub-failure spinal injury or micro-trauma just under the major injury threshold originating from ligament or muscle strain, degenerating joints, or degeneration of intervertebral discs causing spinal stenosis and sacroiliac joint, discogenic, and facet joint pain (14).

It must further be noted that pain associated with SDL is frequently a chronic long-standing pain which may result in the recruitment of neurological factors and so become partially neurogenic in origin (9). Research clearly shows changes in brain metabolites and grey matter from chronic low back pain (14). It is, therefore, important to note that pulsed stimulation has been associated with neurological oscillatory reset and circuit function (9). The acoustically derived focal pulsed stimulation used in this pilot study may be contributing to a neurological effect (14).

In this retrospective pilot study, 7 patients with degenerative SDL were given acoustically derived focal pulsed stimuli applied to the spine through a device known as the Khan Kinetic Treatment (KKT) and now also known as SONIK treatment. The actual stimulus of the SONIK treatment can be described as delivering accelerated audible low-frequency kinetically directed impulses (ALKINDI) meaning: “accelerated” – a rapidly increasing frequency curve, “audible low frequency” – at the lowest level of human audibility in the 16 – 100 Hz range, “kinetically directed” – very specifically angled and directed at vertebrae targets, and “impulses” – sound-initiated percussion waves.

In this pilot cohort study the objective was to determine whether ALKINDI applied to the participants’ spine would have an effect of pain and stability-related pain and function outcome measures and if these measures produced a tangible change in medication intake over time. Some published reports have demonstrated improvements in back pain from spinal complications such as disc bulges or atlanto-axial subluxation using this type of stimulation (15, 16). However, to our knowledge, no other type of stimulation with this frequency profile or focused application is clinically available. Therefore, this ALKINDI treatment constitutes a highly novel form of treatment modality.

MATERIALS AND METHODS

Ethics

At the point of intake at the treating clinic, all patients signed consent to allow use of anonymous clinical treatment data for retrospective research purposes.

Cohort selection

Seven patients (5 females and 2 males) with degenerative SDL were included retrospectively from electronic medical records from KKT International orthopedic clinics located in Jeddah, Saudi Arabia, between March 2021 and June 2021. All patients were diagnosed with grade 1 lumbar SDL and presented to the clinic because of pain. Although surgery is usually suggested as a treatment of choice for SDL severity grades 3 and 4, one patient in this study had been

recommended for surgery with grade 1 SDL. All had pursued conservative treatment before coming to the clinic for ALKINDI treatments. The baseline parameters of patients can be found in Table I.

Table I. *Demographic and diagnostic data of the patients.*

Patient	Age	Sex	BMI	# of Tx	Site of Tx	Medical Diagnosis	Medication
1	62	F	31.6	12	C, LS, Abd, Ccx	• Lumbar Spondylolisthesis • Intervertebral disc disorders with radiculopathy, lumbosacral region	n/a
2	74	F	35.7	18	C, LS, Abd	• Lumbar Spondylolisthesis • Cervical, thoracic, and lumbar spondylosis	Insulin 11-100mg
3	69	M	29.4	18	C, LS	• Lumbar Spondylolisthesis • Cervical disc disorder with myelopathy • Lumbosacral intervertebral disc disorder with radiculopathy	n/a
4	44	M	37	18	C, LS	• Lumbar Spondylolisthesis • Intervertebral disc disorder with radiculopathy, lumbar region	Metformin 501-1000mg
5	46	F	24.1	18	C, LS, Ccx	• Lumbar Spondylolisthesis • Intervertebral disc disorder with radiculopathy, lumbosacral region • Spinal stenosis, lumbar region without neurogenic claudication	n/a
6	72	F	38.4	18	C, LS	• Lumbar Spondylolisthesis	n/a
7	46	F	24.1	18	C, L, Ccx	• Lumbar Spondylolisthesis • Intervertebral disc disorder with radiculopathy in lumbosacral region • Lumbar spinal stenosis without neurogenic claudication	n/a

All Lumbar SDL was L5 to S1, grade 1 spondylolisthesis; ***BMI****: body mass index;* ***Tx****: Treatment;* ***C****,* ***LS****,* ***Abd****,* ***Ccx*** *refer to the location of the treatment and are cervical (****C1****), lumbosacral (****L1-S1****), Abdomen, and Coccyx respectively.*

Treatment

Participants came in for up to 18 treatment sessions lasting up to 3 months, during which participants were treated focally at the lumbosacral region (L1-S1) as well as the cervical spine (C1). Some patients were occasionally treated at the abdomen or coccyx regions.

Outcome measures

Outcome measures in this study included routine clinical outcome measures taken within the clinic before and after the completion of the full treatment program, which included the visual analog scale (VAS, 0-10 rating scale for pain intensity), shoulder and pelvic tilt measured using calipers, leg length difference, range of motion, and upper/lower body coordination. Cervical range of motion tests included a measure of the ability to turn the neck from a neutral position to the left or right shoulder. Asymmetry in the movement of capabilities of the neck could suggest underlying ligament damage. The degree to which the neck rotated to the shoulder was labelled as “normal”, “mild”, “moderate”, or “severe”. The upper/lower limb coordination test involved a clinician to provide a downward pressure to the limb of a patient while asking them to resist upward. Values from 0-5 were given based on how strongly they resisted, with zero being no response to five being full resistance without strain. This method has been adapted from the Oxford method of muscle strength grading (17).

RESULTS

A cohort of 7 patients (5 females and 2 males) with lumbar SDL were selected to be included in this pilot study. The mean age (± standard deviation) was 59.0 ± 13.3 years old, and their mean BMI was 31.47 ± 5.91. All patients were diagnosed with grade 1 lumbar SDL, and 6 out of 7 patients had other conditions. Because SDL is most common with people over 60 years of age, most also typically have other spine-related conditions and so these are described individually. Five participants had intervertebral disc disorder with radiculopathy, two had spinal stenosis, one had

spondylosis, and one had cervical disc disorder with myelopathy. Only two patients were reported to have been taking medication. Six out of seven patients underwent 18 treatment sessions whereas 1 patient had 12 treatment sessions. Each patient in this cohort is described here and individual results for outcome measures are described in Table II:

Patient 1: A 62 year old female diagnosed with lumbar SDL and lumbosacral intervertebral disc disorder with radiculopathy. She complained of knee joint pain, back pain, and neck pain. She is diabetic and has self-reported anxiety and depression. Her doctor had advised her for surgery but she had not undergone any. Instead, she took physical therapy with partial benefit and acupuncture with no benefit. She had one accidental fall in 2018.

Patient 2: A 74 year old female diagnosed with lumbar SDL as well spondylosis along the spine. She is a diabetic patient who complained of low back pain. She had one fall accident, but otherwise no major accidents. She was taking insulin three times daily, and no apparent drug use other than 40 years of tobacco use which she had recently quit and some caffeine use. She did physical therapy with partial benefit and massage therapy which worsened her issues.

Patient 3: A 69 year old male diagnosed with lumbar SDL, cervical disc disorder with myelopathy, and lumbosacral intervertebral disc disorder with radiculopathy. He complained of low back pain which radiated to lower and upper limbs on both sides with numbness. He quit tobacco after 26 years of use and drinks caffeine, but otherwise no other drug use. Anxiety was self-reported. Physical therapy was tried with recurrent benefit and massage therapy made his issues worse.

Patient 4: A 44-year-old diabetic man diagnosed with lumbar SDL and lumbar intervertebral disc disorder with radiculopathy. He complained of lower back pain, which radiated to the lower limb with numbness. He is taking metformin and drinks caffeine, but otherwise, no other medical or recreational drugs. He has found benefits in physical therapy.

Patient 5: A 46-year-old female diagnosed with lumbar SDL, lumbosacral intervertebral disc disorder with radiculopathy, and lumbar spinal stenosis without neurogenic claudication. She complained of low back pain which occurred at times due to awkward swimming movements. She drinks caffeine but otherwise no other drugs.

Patient 6: A 72-year-old female diagnosed with lumbar SDL. She complained of low back pain. She has high blood pressure, diabetic, and has self-reported anxiety. She does not use any recreational drugs.

Patient 7: A 46-year-old female diagnosed with lumbar SDL, lumbosacral intervertebral disc disorder with radiculopathy, and lumbar spinal stenosis without neurogenic claudication. The patient complained of low back pain. Other than caffeine use, she does not use any other drugs.

Each of the seven patients improved in VAS pain severity scores from pre-treatment to post-treatment (see Table II for individual outcome measures).

Table II: *Individual clinical outcomes.*

Patient		Pain	RM	ST (º)	PT (º)	LLD (cm)	ULL	ULR	LLL	LLR	ROML	ROMR
1	Pre	8.23	-	1	1	2.5	4	4	3	3	Normal	Normal
	Post	4.35	-	0	0	0	5	3	2	2	Normal	Normal
2	Pre	5.54	13	3	1	0	2	2	1	1	Mild	Mild
	Post	0.68	2	0	0	0	5	5	3	3	Normal	Normal
3	Pre	4.97	8	3	1.25	0	1	1	2	2	Moderate	Moderate
	Post	0.34	1	0	0	0	5	5	3	3	Normal	Normal
4	Pre	6.61	11	1	1.75	1.5	4	4	2	3	Mild	Mild
	Post	1.48	1	0	3.75	0	4	4	3	3	Normal	Normal
5	Pre	6.45	14	1.75	0.75	1.75	3	3	3	3	Normal	Normal
	Post	0.09	1	0	0	0	4	4	3	3	Normal	Normal
6	Pre	8.32	8	1.25	1.75	1	4	4	1	1	Moderate	Moderate
	Post	0.2	1	0	0	0	5	5	1	1	Normal	Normal
7	Pre	6.45	8	1.75	0.75	1.75	3	3	1	1	Normal	Normal
	Post	2.39	1	0	0	0	4	4	1	3	Normal	Normal

***RM**: Roland Morris disability questionnaire; **ST**: shoulder tilt; **PT**: pelvic tilt; **LLD**: leg length difference; **ULL**: left upper limb strength; **ULR**: right upper limb strength; **LLL**: left lower limb strength; **LLR**: right lower limb strength; **ROML**: cervical range of motion on the left side; **ROMR**: cervical range of motion on the right side. Limb strength was measured using the Oxford method to evaluate muscle strength.*

An analysis of the pre- vs post-treatment group results showed the following: The mean visual analog scale (VAS) score decreased from pre-treatment to post-treatment, indicating that pain relief was successfully achieved (6.65 ± 1.25 pre-treatment vs 1.36 ± 1.55 post-treatment respectively; $p<<0.001$; see Table III for mean outcome values).

Table III: *Analysis of means of patient outcome measures.*

Outcome	Pre (m)	Pre (sd)	Post (m)	Post (sd)	Adjusted p-value	Effect size
Pain	6.65	1.25	1.36	1.55	0.0009	3.55
RM	9.8	2.68	1	0	0.0065	3.28
ST	1.82	0.86	0	0	0.0051	2.11
PT	1.18	0.43	0.54	1.42	0.2580	0.529
LLD	1.21	0.94	0	0	0.0390	1.29
ULL	3.00	1.15	4.57	0.53	0.0545	1.12
ULR	3.00	1.15	4.28	0.76	0.1278	0.75
LLL	2.14	0.90	2.86	1.21	0.3115	0.445
LLR	2.29	0.95	2.86	1.21	0.3863	0.353
ROML	0.86	0.9	0	0	0.0829	0.95
ROMR	0.86	0.9	0	0	0.0711	0.953

***RM**: Roland Morris disability questionnaire; **ST**: shoulder tilt; **PT**: pelvic tilt; **LLD**: leg length difference; **ULL**: left upper limb strength; **ULR**: right upper limb strength; **LLL**, left lower limb strength; **LLR**: right lower limb strength; **ROML**: range of motion on the left side; **ROMR**: range of motion on the right side. Range of motion values of "normal", "mild", "moderate", and "severe" were given scores of 0-3, respectively, for quantitative statistics. Pre and post-values are represented by mean (**m**) and standard deviation (**sd**). Effect size is measured as Cohen's **d**. P-values are adjusted for multiple comparisons using the Benjamini-Hochberg procedure.*

Mean values of pre- vs post-treatments were assessed using t-tests, and p-values were adjusted for multiple comparisons using the Benjamini-Hochberg procedure. The mean Roland Morris (RM) disability score decreased from pre-treatment to post-treatment (9.8 ± 2.68 pre-treatment vs 1.0 ± 0.0 post-treatment, respectively; $p<0.001$). Shoulder and tilt improved for all 7 patients and decreased to zero for all patients (1.82 degrees ± 0.86 pre-treatment vs 0.0 degrees ± 0.0 post-treatment, $p<0.001$; Table III). Pelvic tilt improved for 6 out of 7 patients (1.18 ± 0.43 degrees pre-treatment vs 0.54 ± 1.42 degrees post-treatment). Leg length difference significantly decreased from pre- to post-treatment (1.21 ± 0.94 cm vs 0.0 ± 0.0 cm respectively, $p<0.001$) for all patients. Range of motion improved for all patients that began with non-normal values (n=4), and left upper limb strength improved for 6 out of 7 patients (3.00 ± 1.15 pre-treatment vs 4.57 ± 0.53 post-treatment, $p=0.0545$).

Measures of right upper limb strength and right and left lower limb strength did not see statistically significant improvements.

DISCUSSION

Focally applied pulsed stimulation was successfully able to reduce pain and improve functional disability. Improvements in these measures were the most statistically significant and had large effect sizes, showing promising results for pulsed stimuli as a means of SDL rehabilitation. Other clinical measures in the form of shoulder and pelvic alignment, leg length difference and range of motion also improved. Shoulder and pelvic tilt are measures of postural stability, and its relationship with back pain and functional disability are less clearly defined. Abnormal spinal postures maintained over time may lead to certain types of pain and disability.

For example, a hunched forward posture during computer use can lead to neck or back pain (18, 19). This relationship between pain and postural abnormality may also work in reverse, where pain leads to compensatory changes in one's posture (20, 21). Regardless of the direction of cause, the improvements in spinal and pelvic tilt are suggestive of a positive treatment outcome.

Leg length difference (LLD) also improved significantly for all patients. LLD is also associated with postural instability due to pain (22, 23); however, its association with back pain is inconsistent in the literature (24, 25). This may be due to the fact that LLD is dependent on other factors influencing posture and stability, such as shoulder and pelvic tilt. For example, a pelvic tilt may lead to depression of one leg past the other and can produce an LLD. On the other hand, a pelvic tilt may be compensated by an opposite tilt in the shoulder, nullifying the LLD by curving the spine in the frontal plane while keeping a net zero LLD. Therefore, measures of LLD must be interpreted in the context of other postural measurements. Range of motion improved for all patients with non-normal levels. The limitation of this measurement is that the cervical range of motion is not directly related to SDL; however, the improvement of mobility in another region of the spine suggests positive results from the treatment. Upper and lower limb coordination did not show significant changes.

This paper studies the effect of a novel treatment on a cohort of patients retrospectively selected from an electronic health database to fulfill one of the central purposes of a pilot study: might the treatment be a viable complementary treatment for SDL? The primary strength of this study was to show the effectiveness of a novel complementary treatment that uses non-invasive low-frequency pulsed stimulation despite the presence of other spinal conditions. The lack of homogeneity in the cohort is an important limitation to note since confounding variables may be present. However, the lack of homogeneity in this cohort is the reality among SDL patients and affects all forms of treatment for SDL symptoms. The very nature of a pilot study with a limited number of intentionally selected patients makes generalizability impossible but begs for prospective controlled research.

Given the results of this study, there are two avenues for further inquiry. The first is to complete larger, randomized, controlled trials using focally applied pulsed stimulation using the ALKINDI technology. More research is needed to assess the optimization of pulsation parameters on SDL patients, which should include pulse frequency, amplitude, location of the stimulus, and the number of stimuli. A larger study looking into the use of postural measures for back pain and its treatment will also be helpful. A systematic review of reviews suggested no consensus about the relationship between postural measures preceding first-time low back pain (26).

Postural abnormalities may be what leads to back pain, or back pain may cause postural abnormalities either due to compensatory adjustments to minimize the effect of pain or due to deterioration of tissue. Therefore, exploring postural measures “preceding” first-time low back pain may not yield any relationship. A better measure might be to measure its association with “recurring” low back pain. For example, one systematic review found a relationship between postural measures and recurring lower back pain (3). This detail may be a reason for inconsistent results, and thus, a larger study looking into the change in postural measures and the treatment of pain would be valuable.

Another avenue for further research would be to explore the mechanism behind the positive treatment response. There are currently few reports investigating the mechanism of pulsed or vibratory stimulus on pain relief and improved spine health. Focally applied mechanical stimulation generated via vibrations can stimulate the genetic expression of anabolic proteins such as aggrecan and collagen, helping to regenerate health in the intervertebral discs (13). Mechanical stimulation of the bony structures also stimulates pro-osteogenic factors that stimulate the growth and repair of bone tissue (27, 28). Pre-clinical studies have demonstrated that mechanical stimulation of the bones and discs by vibratory stimuli enhances the genetic expression of pro-osteogenic factors as well as factors promoting disc health (9, 13, 29). The possibility of a neurogenic basis for chronic pain would point to the need for further research into changes in brain structure and function (9, 14). Case reports using MRI imaging have shown reductions of disc bulge or spinal stenosis after focal treatment to the cervical areas. Therefore, a growing number of reports are beginning to emerge indicating the use of focally applied pulses delivered to the spine as a useful solution to degeneration-related pain and spinal dysfunction, which should be explored further in both basic science and clinical research.

CONCLUSIONS

This study demonstrates that ALKINDI delivered to the spine can produce pain relief and functional improvements in a series of SDL patients and shows promise for low-frequency pulsed stimuli as an adjunct therapy for spine-related disorders. Given the complications of surgery, conservative treatment is still preferred up until it fails. ALKINDI treatments may add more options to the range of conservative treatments and may be a promising rehabilitative strategy for spine-related pain and dysfunction.

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