Intervertebral Differential Dynamics (IDD) Therapy vs. Exercise Based Physical Therapy – Results from a Randomized Controlled Trial

Intervertebral Differenzial Dynamics (IDD) Therapie im Vergleich zur trainingsorientierten Physiotherapie – Ergebnisse einer randomisierten Studie

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Key words
- low back pain
- exercise therapy
- conservative therapy

Schlüsselwörter
- Rückenschmerzen
- Physiotherapie
- konservative Behandlung

Abstract

Study Design: Prospective, randomized controlled trial.

Objective: To compare the effectiveness of Intervertebral Disc Dynamics (IDD) therapy with an exercise-based physical therapy program in patients with chronic low back pain caused by degenerative disc disease.

Background: IDD therapy is commonly used in clinical practice, but has not been studied extensively in a controlled trials.

Methods: 48 patients with chronic low back pain >3 months secondary to mild to moderate degenerative disc disease were included. Patients were randomized in a 2:1 ratio to IDD therapy or a physical therapy program based on lumbar stabilization exercises (PT). Patients in both groups had to complete a minimum of 6 treatments over a 6-week period.

Results: In the IDD group, the mean Visual Analog Scale (VAS) score improved from 43.1 to 27.4 (95% CI 2.3-29.1, average 36.4% decrease, $p<0.05$) after completion of treatment to 22.1 after 1 year (95% CI 7.8-34.1, av. 48.6% decrease, $p<0.01$). In the PT group the mean VAS score improved from 58.5 to 36.9 (95% CI 0-43.3, av. 37.0% decrease, $p=0.05$) after completion of treatment to 26.0 (95% CI 13.1–51.9, av. 55.6% decrease, $p<0.01$) after 1 year. There were no significant differences in mean pain scores between groups at any follow-up interval. The mean Oswestry Disability Index (ODI) improved significantly in both groups only at the 1 year follow-up. There were no significant differences in mean ODI scores between the groups at any follow-up interval.

Conclusions: Patients in both groups experienced a mild to moderate improvement in pain symptoms after completion of treatment, with further improvement at 1 year. There was significant improvement in back-related function only at 1 year. However, there were no signifi-

Zusammenfassung

Studien Design: Prospective, randomisierte klinische Studie.

Ziel: Die Effektivität der Intervertebral Differenzial Dynamics (IDD) Therapie wurde mit einer trainingsorientierten Krankengymnastik an Patienten mit chronischen, bandscheibenbedingten Rückenschmerzen verglichen.

Hintergrund: Die IDD Therapie ist eine weit verbreitete physikalisch-medizinische Behandlungsmethode, die bisher nur in wenigen klinischen Studien kritisch untersucht wurde.

Methoden: 48 Patienten mit chronischen, mehr als 3 Monaten bestehenden spezifischen Rückenschmerzen, bedingt durch leichte bis mittelschwere degenerativen Bandscheibenveränderungen, wurden in die Studie aufgenommen. Die Patienten wurden in einem 2:1 Verhältnis IDD Therapie zu stabilisierender Krankengymnastik randomisiert. Die Patienten in beiden Gruppen mussten an mindestens 6 Behandlungen über einen Zeitraum von 6 Wochen teilnehmen.

Ergebnisse: In der IDD Gruppe verbesserte sich der durchschnittliche Schmerzscore (VAS) von 43,1 auf 27,4 nach Behandlungsabschluss (95% Vertrauensintervall 2,3–29,1, durchschnittliche Verbesserung 36,4%, $p<0,05$) und auf 22,1 nach einem Jahr (95% Vertrauensintervall 7,8–34,1, durchschnittliche Verbesserung 48,6%, $p<0,01$). In der KG Gruppe verbesserte sich der durchschnittliche Schmerzscore von 58,5 auf 36,9 nach Behandlungsabschluss (95% Vertrauensintervall 0–43,3, durchschnittliche Verbesserung 37,0%, $p=0,05$) und auf 26,0 nach einem Jahr (95% Vertrauensintervall 13,1–51,9, durchschnittliche Verbesserung 55,6%, $p<0,01$). Zu keinem Zeitpunkt gab es signifikanten Unterschiede in den Schmerzscores zwischen den Gruppen. In der IDD Gruppe verbessert sich der durchschnittliche Oswestry Score (ODI) von 26,8% auf 20,4% nach Behandlungsabschluss (95% Vertrauensintervall −1,0–13,8, durchschnittliche Verbesse-

received: 14.06.2010
accepted: 26.10.2010

Bibliography
DOI http://dx.doi.org/10.1055/s-0030-1268469
Phys Med Rehab Kuror 2011; 21: 34–40

ISSN 0940-6689

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cant differences in outcomes between the groups. IDD therapy offers similar clinical improvement compared to exercise-based physical therapy in patients with symptomatic lumbar degenerative disc disease.

rung 24,1%, n.s.) und auf 13,8% nach einem Jahr (95% Vertrauensintervall 4,8–21,2, durchschnittliche Verbesserung 48,5%, p<0,05). In der KG Gruppe verbesserte sich der durchschnittliche ODI von 33,0% auf 29,1% nach Behandlungsabschluss (95% Vertrauensintervall −15,1–22,8, durchschnittliche Verbesserung 11,7%, n.s.) und auf 17,6% nach einem Jahr (95% Vertrauensintervall −1,9–32,7, durchschnittliche Verbesserung 46,8%, p<0,05). Zu keinem Zeitpunkt gab es signifikanten Unterschiede in den ODI scores zwischen den Gruppen.

Zusammenfassung: In beiden Gruppen wurden signifikante Verbesserungen in den Schmerzscores nach Therapieabschluss festgestellt, die sich ein Jahr nach Therapieabschluss noch weiter verbesserten. Die funktionellen Scores verbesserten sich nur nach einem Jahr, aber nicht unmittelbar nach dem Therapieabschluss. Es gab keine signifikanten Unterschiede in den Ergebnissen im Gruppenvergleich. Diese Studie zeigte keine Unterschiede in den Behandlungsergebnissen zwischen IDD Therapie und stabilisierender Krankengymnastik.

Introduction

Degeneration of the intervertebral discs is one of the most common structural causes of chronic low back pain. The pain is generated by degenerative changes within the disc (e.g., annular fissures), but degenerative changes in other collateral structures of the spine, such as the zygapohysial joints, also can contribute to the pain syndrome [1–5].

Multiple non-surgical treatment options represent the first line of therapy for pain sufferers including relative rest, activity modification, medication such as anti-inflammatories and muscle relaxants, physical therapy modalities (e.g., heat, ice electrical stimulation, ultrasound, TENS units, traction), chiropractic care, and spinal injections.

One of these commonly used treatments for back pain is lumbar traction, which has a long history of use. It is frequently used in modern spine medicine, but the scientific evidence for its use in low back pain remains inconclusive. While one study has shown that traction had a positive, although moderate treatment effect for patients with sciatica [6], other studies investigating the efficacy of traction to treat chronic low back pain have been of poor methodologic quality [7]. The only high quality randomized trial of traction for patients with chronic low back pain showed no statistically significant difference in improvement between traction with 35–50% body weight (65% improvement in Visual Analog Scale (VAS) scores) and traction with sham therapy with 25% body weight (59% improvement in VAS scores) [8]. There are no clear indications, however, that traction is an ineffective therapy for back pain [9]. Since many studies lack methodologic rigor, the prevailing opinion is that further clinical trials are needed before any firm conclusions and recommendations can be made about the therapeutic effects of traction [7].

Recently, several advanced therapeutic modalities based on the principle of traction have been developed for the treatment of painful spinal conditions. These treatments are widely available, but are controversial because of the limited scientific evidence to support their claimed benefits, which are widely promoted.

One of these treatments is Intervertebral Differential Dynamics (IDD) therapy. Through a motorized cable/harness system (1), the system applies a computer controlled distraction force to the lumbar spine. The specific biomechanical effects of IDD therapy on the lumbar spinal segments are unclear and have not been studied. In theory, the distraction of the intervertebral segments may cause a decompressive effect on the intervertebral discs. Previous studies using lumbar traction have demonstrated that forces in excess of 26% body weight have a distraction effect on the lumbar spine [10]. 60–80 pounds of weight result in an average vertebral distraction of 0.5 mm per lumbar spinal segment [11] and can result in negative intradiscal pressures [12]. It may also decrease the pressure on nociceptors in the discs, zygapophysial joint capsules, ligaments and muscle tissues and potentially can mobilize “hypomobile” segments, through angulation of the treatment force delivery system [13]. While these proposed mechanisms suggest short-term rather than long-term effects or benefits, the IDD treatment protocol recommends additional physical rehabilitation with a course of stretching and strengthening exercises to improve the neuromuscular control of the spinal column.

Claimed improvements of the IDD treatment over conventional traction devices include: A free floating bed to minimize effects of gravity; treatment angles directing the primary force varying from 0 to 30 degrees; computer monitored sensors to assure accurate and repeatable dosing of the therapeutic force; stabilization harnesses to provide comfort and support during treatment; and multiple treatment wave forms to deliver varying forces and the ability to generate secondary oscillation waveforms designed to target surrounding musculature. In one small controlled study this type of therapy was compared with conventional traction for lumbosacral pain. Of 49 patients with symptoms for less than 1 year, 86% of patients with a herniated disc achieved “good” (50–89% improvement) to “excellent” (90–100% improvement) results with IDD therapy. In the conventional traction group, only 55% of patients achieved “good” improvement with traction, and none “excellent”. In patients with facet arthrosis, 75% obtained “good” to excellent” results with IDD therapy and only 50% of these patients achieved “good” to “excellent” results with traction. The study did not employ standardized outcome measures and failed to provide statistical comparisons between treatment groups [14].

A more recent randomized trial compared IDD therapy with sham traction of 4.45 kg. It showed no difference in pain and functional outcome measures between the treatments [15].

However, no previous study has compared IDD therapy with a standardized exercise program. The primary objective of the

current randomized controlled trial was to compare the changes in pain, function, quality of life scores using a battery of standardized outcome instruments in patients with chronic low back pain secondary to mild to moderate degenerative disc disease, treated with either IDD or exercise-based physical therapy (PT). We chose an exercise based PT program based on the principles of lumbar stabilization as control group [16]. These exercises are the most accepted PT program for painful lumbar degenerative disease, and have been shown to provide clinical symptom relief in the mild to moderate range [17].

Our hypothesis was that IDD therapy would result in better pain reduction and function compared to exercise based PT for chronic low back pain secondary to mild to moderate degenerative disc disease. We targeted patients who had not exhausted non-surgical treatments and for whom surgery would be considered too aggressive.

Methods

Patients

Approval for this study was obtained from the institutional review board of the University. Inclusion Criteria included: Chronic axial low back pain without radicular pain >3 months secondary to mild to moderate disc degeneration and lumbar spondylosis, based on a spine physiatrist's history and physical and at least anterior-posterior and lateral x-rays of the lumbar spine; age >18 years. The patients' history and physical demonstrated symptoms and signs typically associated with lumbar discogenic pain: Pain worse with sitting, relieved by rest and reproduction of pain with lumbar flexion as well as localized tenderness over the affected lumbar segment. Exclusion criteria included: infection, lower extremities neurological deficits, systemic disease that would affect treatment outcome; malignancies undergoing treatment or any malignancies with involvement of the musculoskeletal system; evidence of severe neural compression on advanced imaging studies (if available), spondylolisthesis; uncontrolled mood disorders, such as depression, anxiety; history of drug or substance abuse; lumbar spine pathology requiring surgical intervention; previous spine surgery of the lumbar spine, except discectomies >12 months; chronic pain syndrome; chronic opioid therapy; physical therapy, traction or traction related therapies in the last 3 months; active litigation; workers compensation; and pregnancy.

Patients were recruited from our practice in 2005 and 2006, a large multidisciplinary academic spine center. The patients were informed about the trial by their physician, fliers and through the clinical trials office at the University.

Sample size and randomization procedures

The study was designed as a pilot trial to determine if a larger trial would be needed to prove the hypothesis of the study. The available literature was insufficient for a power analysis to determine the appropriate sample size for this trial. Therefore, the initial study size was arbitrarily set at 48 patients with a 2:1 randomization in favor of the IDD group. We chose this randomization ratio to increase the number of patients in the IDD group, a technique that has been previously used for another randomized trial for a novel spine treatment [18]. Randomly-allocated treatment assignments were computer generated. Both the patient and physician were blinded to assignments prior to enrollment.

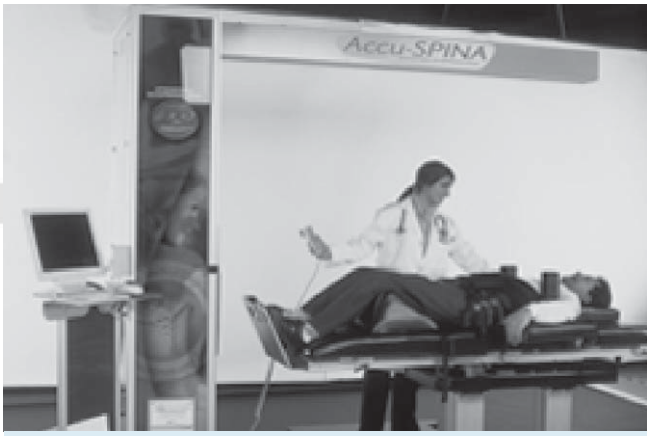

Fig. 1 IDD equipment.

Interventions

In the IDD group, patients were treated with the Accu-Spina device for a minimum of 6, and up to a total of 20 treatments over a 6-week period. For the treatment, the patient was positioned in a stabilization harness in the upright position. The patient was then positioned with the back facing the bed cushions and lowered into the supine position, with the lumbar spine in a neutral position (**Fig. 1**). A calibrated strap was attached to the pelvic stabilization harness which was connected to the equipment's tower electronics. Depending on the pathology, affected vertebral level and patient tolerance, the therapeutic parameters were entered by the physical therapist. The treatment force was gradually increased to approximately 50% of the patient's body weight to ensure mobilization and distraction of the affected intervertebral segment, but was allowed to be increased or decreased depending on the patient's tolerance. The treatment force was constantly monitored by computer sensors and allowed a gradual build-up over a 2-minute period to the desired therapeutic force. The force was maintained for 1 min, and then the pressure was reduced to half the therapeutic force (or 45 lbs, whichever was less) for 30–60 s before the process repeated itself. Anecdotally, this temporary force release appears to decrease the occurrence of reflectory muscle spasms during and after treatment. The total treatment time was approximately 25 min. The patients were treated with heat and ice before and after each treatment session, but other modalities and other types of physical therapy and exercise therapy were not allowed. The patients did not receive any other treatment after completion of the IDD therapy and during the 1-year follow-up. They were told to remain active, but without instructions for a specifice home exercise program to avoid introduction of a bias by adding another type of treatment.

In the PT group, patients were treated with a course of physical therapy with a minimum of 6 and up to 18 sessions. The focus of physical therapy sessions was on the implementation of an active exercise program consisting of stretching, strengthening and lumbar stabilization exercises as well as instruction in a home exercise program [17, 19, 20]. They were encouraged to stay active and not to restrict their activities. Modalities such as ice and heat were used at the discretion of the treating physical therapist, but other passive treatment modalities (such as TENS, electrical stimulation, and ultrasound) and manipulation/mobilization were not allowed. All patients were treated by the same physical therapists in the same location. They were encour-

aged to continue with the home exercise program during the 1-year follow-up.

Both groups were treated during a 6-week time period. Anti-inflammatories and muscle relaxants were prescribed at the discretion of the treating physician; the prescription of opioids and spinal injections were not allowed. The patients were reevaluated at 6 weeks, 3 months, 6 months and 12 months after treatment initiation. Physician visits were scheduled after completion of treatment and per physician's discretion thereafter.

Outcomes

Patient reported outcomes were measured prior to treatment as well as at 6 weeks, 3, 6 and 12 months. Back pain severity was evaluated using a standard 100 mm visual analog scale (VAS). Condition-specific functional impairment was evaluated with the Oswestry Disability Index (ODI). Health-related quality of life was evaluated with the SF-36 Health Survey. After the initiation of the randomly-assigned therapy, patients, physicians and therapists were unblinded treatment assignment.

Statistical methods

Background characteristics and clinical results are presented as descriptive statistics or frequency and percentage distributions, as appropriate. Within group changes from baseline in each outcome were evaluated using the paired t-test, 2-tailed, and 95% confidence intervals are provided. The Wilcoxon Signed Rank test was used for between groups comparisons at each follow-up interval.

Results

Of the 48 patients enrolled in the trial and randomized to study-specific treatment, 37 patients (28 IDD, 9 PT) started their assigned treatment. Patients withdrew their consent because of several reasons: dissatisfaction with the assigned treatment (3), cost of treatment because of health plan limitations (5), and travel limitations to treatment site (1) and unspecified reasons (2). 31 of 37 (84%) patients completed the required minimum of 6 treatments in their assigned group (**Fig. 2**). Overall, the average number of treatments in the IDD group was 17.6 and 13.8 in the PT group. The baseline pain scores of the 6 patients who did not complete their treatment did not differ from the patients who completed their treatment. Drop out was proportional in the IDD group (n = 4) as well as the PT group (n = 2). Reasons for drop-out were not specified.

The patient's mean age was 50 ± 14 years in the IDD group and 57 ± 13 years in the PT group. 43% (12 of 28) in the IDD group were female, 22% (2 of 9) in the PT group.

Pain severity

Both groups reported pain scores in the moderate range at the outset of the study. In the IDD group, the mean VAS pain score improved from 43.1 ± 22.4 to 27.4 ± 22.7 (95% CI 2.3–29.1), (−36.4%, $p < 0.05$) after completion of treatment to 22.1 ± 14.2 after 1 year (95% CI 7.8–34.1), (−48.6%, $p < 0.01$). The PT group had a higher average pain score at baseline ($p = 0.09$). The mean pain score in the PT group improved from 58.5 ± 17.9 to 36.9 ± 22.0 (95% CI 0-43.3), (−37.0%, $p = 0.05$) after completion of treatment to 26.0 ± 16.7 (95% CI 13.1–51.9), (−55.6%, $p < 0.01$) after 1 year. There were no significant differences between groups at any follow-up interval (**Fig. 3**, **Table 1**).

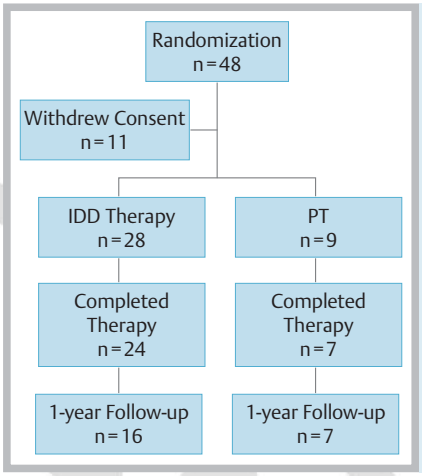

Fig. 2 Randomization table.

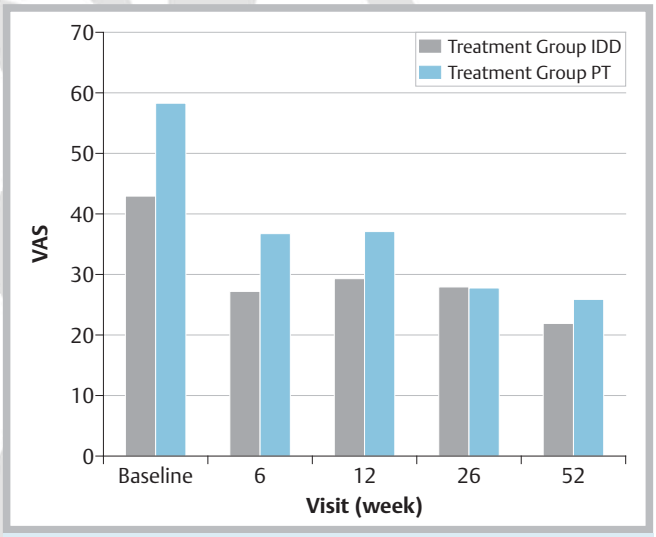

Fig. 3 VAS scores for IDD and PT groups.

Back function

Both groups had low back related disability in the moderate range at the outset of the study. In the IDD group, the mean ODI score improved from 26.8% ± 13.9% to 20.4% ± 11.2% (95% CI −1.0–13.8), (−24.1%, not significant – n.s.) after completion of treatment to 13.8% ± 9.5% after 1 year (95% CI 4.8–21.2), (−48.5%, $p < 0.05$). In the PT group, the mean ODI score improved from 33.0% ± 17.9% to 29.1% ± 18.0% (95% CI −15.1–22.8), (−11.7%, n.s.) after completion of treatment to 17.6% ± 13.6% (95% CI −1.9–32.7), (−46.8%, $p < 0.05$) after 1 year. There were no significant differences between the groups at any follow-up interval (**Fig. 4**, **Table 2**).

Quality of life

Analysis of the 2 subcategories of the SF-36 most relevant for this study population showed that in the IDD group the average Physical Functioning (PF) score improved from 59.8 ± to 70.9 ± (95% CI −3.1–25.1), (+18.5%, n.s.) after completion of treatment to 69.4 ± after 1 year (+16.0%, n.s.). The average Bodily Pain (BP) score improved from 39.3 ± to 52.0 ± (95% CI 4.2–21.4) (+32.6%, $p < 0.01$) after completion of treatment to 73.5 ± (95% CI 22.8–45.7 (+87.3%, $p < 0.001$) after 1 year. In the PT group, the average PF score improved from 42.8 ± to 58.5 ± (95% CI −12.2–43.6), (+36.7%, n.s.) after completion of treatment to

Visit (week)	Treatment Group						P-Value, Wilcoxon Signed Rank Test for Differences (2-Sided)
	IDD			PT			
	N	Mean (VAS)	Standard Deviation	N	Mean (VAS)	Standard Deviation	
baseline	28	43.1	22.4	9	58.5	17.9	0.09
6	24	27.4	22.7	7	36.9	22	0.21
12	16	29.4	22.5	6	37	26.1	0.53
26	15	28.1	21.4	6	27.8	12	0.46
52	16	22.1	14.2	7	26	16.7	0.34

Table 1 Comparision of Visual Analogue Scale (VAS) scores between IDD and PT groups by Visit Date.

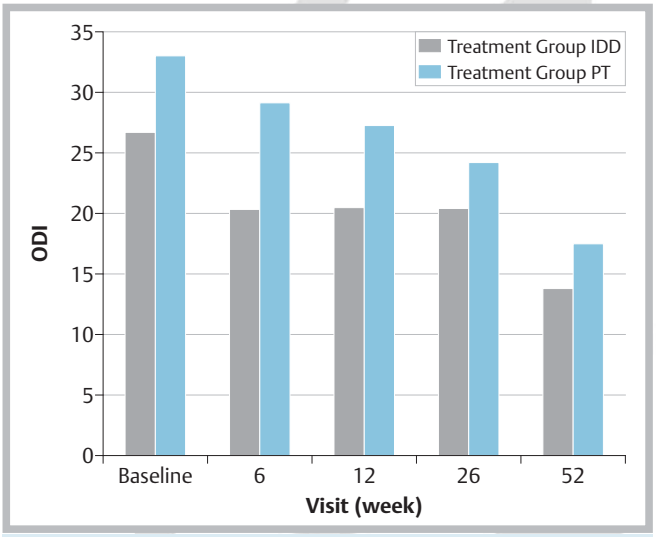

Fig. 4 Oswestry scores for IDD and PT groups.

59.8 ± after 1 year (95 % CI −12.5–46.6) (+39.9 %, n. s.). The average BP score improved from 27.0 ± to 43.6 ± (95 % CI –0.5–33.6) (+61.4 %, p = 0.05) after completion of treatment to 55.0 ± (95 % CI 9.9–46.1), (+103.0 %, p < 0.05) after 1 year.

There were no significant differences between the groups at any time point, except for the BP scores at baseline (p < 0.05).

In addition, there were no statistically significant differences comparing the in-group improvements between the 2 groups for both VAS and ODI scores at any time point (**Table 3**).

No adverse events were observed during the study. A temporary increase in pain immediately after the IDD treatment was occasionally observed, but subsided quickly.

Discussion

Degenerative changes of the intervertebral disc play an important role in the development of low back pain, but it is still unclear which factors transform the physiologic aging process of the spine into a painful condition. A conservative course of treatment is considered appropriate for the majority of patients during the acute phase. Most spine practitioners agree that an active exercise program with return to normal activities should be the primary treatment and standard of care for this condition, before more aggressive treatments, such as spinal injections and surgery, are considered. In general, such exercise-based therapies provide moderate pain relief and functional improvement for most patients with chronic low back pain [21]. Therefore, an exercise program based on the principles of lumbar stabilization was chosen as the most appropriate control treatment for this study.

IDD therapy and other, similar treatment modalities based on the principles of traction have become popular in the last several years and are commonly promoted as highly effective treatments for low back pain. However, claims of therapeutic efficacy are not supported by acceptable scientific studies. Therefore, our goal for this study was to establish a baseline of treatment outcomes for IDD therapy and to determine how the treatment effects compare to the current standard of care.

Our results indicate that IDD therapy provided similar clinical improvement to an exercise-based PT program through 1 year of follow-up. Outcomes were quite similar in both groups, showing a statistically significant, mild to moderate improvement in low back pain. There was no statistically significant difference between groups in low back related disability on the ODI after completion of treatment, but there was statistically significant improvement in both groups after 1 year. On the PF subscale of the SF-36, there was no statistically significant improvement at any time point in either group. As a generic measure of quality of life, this scale is less sensitive to demonstrate back related disability than the ODI. The BP subscale of the SF-36 followed the outcomes of the VAS, with significant improvement of scores after completion of treatment and after 1 year in both groups. However, it is unclear if the observed improvements are true treatment effects or if they represent a placebo effect or a regression to the mean.

Patients in the PT group were instructed to stay active and to continue their home exercise program. On the other hand, the patients in the IDD group were not given any specific instructions about a home exercise program. Interestingly, the treatment effects in the IDD group were mostly maintained, and sometimes continued to improve, at the 1-year follow-up.

IDD therapy may have a treatment effect comparable to PT. Thus, further research with this technology is warranted. In particular, it would be of interest to determine if the combination of PT with IDD therapy would lead to improved outcomes. We decided not to include any other treatment modalities in the IDD group (as recommended in the clinical IDD treatment protocol) to avoid the introduction of potentially confounding interventions. However, in clinical practice, therapists often employ a combination of methods to achieve best results.

The true treatment effect of IDD remains unknown and a number of other questions about the technology were unanswered. The mechanism of action of the device is unclear, and radiographic studies and intradiscal pressure measurements are needed to determine the distraction effect and biomechanics on the lumbar segments [12].

Visit (week)	Treatment Group						P-Value, Wilcoxon Signed Rank Test for Differences (2-Sided)
	IDD			PT			
	N	Mean (ODI)	Standard Deviation	N	Mean (ODI)	Standard Deviation	
baseline	28	26.8	13.9	9	33	17.9	0.38
6	24	20.4	11.2	7	29.1	18	0.18
12	16	20.6	10.4	6	27.2	14.8	0.25
26	15	20.4	12.7	6	24.2	13.2	0.48
52	16	13.8	9.5	7	17.6	13.6	0.36

Table 2 Comparision of Oswestry Disability Index (ODI) scores between IDD and PT groups by Visit Date.

Visit (week)	Wilcoxon Statistic, Standardized (VAS)	P-value, Wilcoxon Test (2-sided)	Wilcoxon Statistic, Standardized (ODI)	P-value, Wilcoxon Test (2-sided)
0–6	1.25	0.21	1.33	0.18
0–12	0.63	0.53	1.14	0.25
0–26	0.74	0.46	0.7	0.48
0–52	0.94	0.34	0.91	0.36

Table 3 Wilcoxon analysis comparing the in-group improvements between the 2 groups for both VAS and ODI scores (n.s. at all time points).

Further studies will need to investigate the optimal set-up and distraction-angle of the device, treatment force, treatment time, and number of treatments. Many IDD practitioners believe that each patient should undergo at least 10–20 treatments to achieve optimal treatment results. We felt that such a high number of treatments would be difficult for patients to complete if no significant symptom improvement was appreciated during the treatment course. We therefore set the minimum required treatment number at 6 to improve compliance. Patients were encouraged to continue with the therapy until at least 6 treatments were completed, regardless of the patient's perceived improvement. They were encouraged to continue with the treatment to 20 treatments if the patients noticed improvement of symptoms. A sub-analysis of treatment outcomes in patients undergoing high-frequency IDD therapy (13–20 treatments) vs. low frequency IDD therapy (6–12 treatments) did not show any significant difference in pain scores between the groups.

Study Limitations

Unfortunately, we had a high drop-out after randomization, before the start of therapy and at 1 year. Reasons for withdrawal were primarily financial, as we were unable to offer treatments free of charge to our patients. Patients received a thorough instruction prior to randomization that the cost of treatment in either group would be charged to their insurance company at standard rates, and that patients would be responsible for any balances. Several patients did not realize the limitations in health insurance coverage for physical therapy services until after the randomization, explaining a portion of the drop-outs. We did not intend to conduct a definite study on IDD therapy. Our goal was to obtain baseline data on this widely used, but scientifically unproven treatment.

Compliance with the assigned treatments was good in both groups: 24 of 28 patients in the IDD group completed the required number of treatments (86%), and 7 of 9 patients in the PT group (78%). 1-year follow-up after completion of treatment was excellent for the PT group (100%), and acceptable in the IDD group (67%). Given the overall small sample size, the loss of any patient to follow-up may have an influence on the outcomes, and needs to be considered when evaluating the results of this study.

We did not require advanced imaging studies such as MRI or advanced diagnostic tests such as discography for a more specific structural diagnosis of symptomatic degenerative disc disease. The role of these diagnostic tools to determine the physiologic cause of low back pain remains unclear. Therefore, we elected not to require these studies in the inclusion criteria, particularly because the studied patient population presented with only moderate pain and functional limitations before entering the study.

We did not keep a medication log, but only muscle relaxants and antiinflammatories were allowed in both study groups. It is unlikely that these medications would have resulted in a significant difference in outcomes between the groups, particularly at the 1-year follow-up.

Conclusion

IDD therapy did not result in better pain or functional outcomes than physical therapy and a home exercise program for symptomatic, chronic low back pain due to degenerative disc disease. Patients in both groups experienced mild to moderate pain relief at all time points and improvement in back related function only after 1 year. There were no significant differences between the groups in any outcome measure during the follow-up period. No significant adverse events were observed. Further investigations should focus on identifying the magnitude of the placebo effect with this treatment, to evaluate the physiological mechanisms of IDD therapy, and to identify the optimal treatment frequency and therapeutic force.

References

1 *van Tulder MW, Koes BW, Bouter LM.* Conservative treatment of acute and chronic nonspecific low back pain. A systematic review of randomized controlled trials of the most common interventions. Spine (Phila Pa 1976) 1997; 22: 2128–2156

2 *Ashton IK, Ashton BA, Gibson SJ et al.* Morphological basis for back pain: the demonstration of nerve fibers and neuropeptides in the lumbar facet joint capsule but not in ligamentum flavum. J Orthop Res 1992; 10: 72–78

3 *Biering-Sorensen F*. A prospective study of low back pain in a general population. I. Occurrence, recurrence and aetiology. Scand J Rehabil Med 1983; 15: 71–79
4 *Bogduk N*. The anatomical basis for spinal pain syndromes. J Manipulative Physiol Ther 1995; 18: 603–605
5 *van Tulder MW*, *Malmivaara A*, *Esmail R et al*. Exercise therapy for low back pain. Cochrane Database Syst Rev 2000, CD000335
6 *Vroomen PC*, *de Krom MC*, *Slofstra PD et al*. Conservative treatment of sciatica: a systematic review. J Spinal Disord 2000; 13: 463–469
7 *Harte AA*, *Baxter GD*, *Gracey JH*. The efficacy of traction for back pain: a systematic review of randomized controlled trials. Arch Phys Med Rehabil 2003; 84: 1542–1553
8 *Beurskens AJ*, *de Vet HC*, *Koke AJ et al*. Efficacy of traction for non-specific low back pain: a randomised clinical trial. Lancet 1995; 346: 1596–1600
9 *van der Heijden GJ*, *Beurskens AJ*, *Koes BW et al*. The efficacy of traction for back and neck pain: a systematic, blinded review of randomized clinical trial methods. Phys Ther 1995; 75: 93–104
10 *Judovich B*, *Nobel GR*. Intermittent traction for herniated discs; a discussion on a new method of traction therapy. Med Times 1952; 80: 31–35
11 *Gupta RC*, *Ramarao SV*. Epidurography in reduction of lumbar disc prolapse by traction. Arch Phys Med Rehabil 1978; 59: 322–327
12 *Ramos G*, *Martin W*. Effects of vertebral axial decompression on intradiscal pressure. J Neurosurg 1994; 81: 350–353
13 *Cyriax J*. Examination of the spinal column. Physiotherapy 1970; 56: 2–6
14 *Shealy CN BV*. Decompression, reduction, and stabilization of the lumbar spine: A cost-effective treatment for lumbosacral pain. American Journal of Pain Management 1997; 7: 63–65
15 *Schimmel JJ*, *de Kleuver M*, *Horsting PP et al*. No effect of traction in patients with low back pain: a single centre, single blind, randomized controlled trial of Intervertebral Differential Dynamics Therapy. Eur Spine J 2009; 18: 1843–1850
16 *Saal JA*. Dynamic muscular stabilization in the nonoperative treatment of lumbar pain syndromes. Orthop Rev 1990; 19: 691–700
17 *Cairns MC*, *Foster NE*, *Wright C*. Randomized controlled trial of specific spinal stabilization exercises and conventional physiotherapy for recurrent low back pain. Spine (Phila Pa 1976); 2006; 31: E670–E681
18 *Pauza KJ*, *Howell S*, *Dreyfuss P et al*. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. Spine J 2004; 4: 27–35
19 *Barr KP*, *Griggs M*, *Cadby T*. Lumbar stabilization: core concepts and current literature, Part 1. Am J Phys Med Rehabil 2005; 84: 473–480
20 *Barr KP*, *Griggs M*, *Cadby T*. Lumbar stabilization: a review of core concepts and current literature, part 2. Am J Phys Med Rehabil 2007; 86: 72–80
21 *Vad VB*, *Bhat AL*, *Tarabichi Y*. The role of the Back Rx exercise program in diskogenic low back pain: a prospective randomized trial. Arch Phys Med Rehabil 2007; 88: 577–582