

## RESEARCH PAPERS

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# Intrathecal Drug Delivery for Treatment of Chronic Low Back Pain: Report from the National Outcomes Registry for Low Back Pain

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### ABSTRACT

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*Objective.* To obtain data on patient demographics, clinical practices, and long-term outcomes for patients with chronic low back pain treated with implantable drug-delivery systems.

*Design.* The National Outcomes Registry for Low Back Pain collected data at baseline, trialing, implant (or decision not to implant), and at 6- and 12-month follow-ups. Data were collected at all time points, regardless of implant status.

*Outcome Measures.* Numeric pain ratings and Oswestry Low Back Pain Disability scores from implanted patients were compared among baseline and 6- and 12-month follow-ups. Patients were also asked to rate their quality of life and satisfaction with the therapy.

*Results.* Thirty-six physicians enrolled 166 patients to be trialed for drug-delivery systems. The trialing success rate was 93% (154 patients). In all, 136 patients (82%) were implanted. In the implant group, numeric pain ratings dropped by more than 47% for back pain and more than 31% for leg pain at the 12-month follow-up. More than 65% of implanted patients reduced their Oswestry scores by at least one level at their 12-month follow-ups compared with baseline. At 12-month follow-ups, 80% of implanted patients were satisfied with their therapy and 87% said they would undergo the procedure again.

*Conclusions.* Current clinical practices related to trialing of drug-delivery systems resulted in the majority of patients successfully trialed. At 12-month follow-ups, implanted patients experienced reductions in numeric back and leg pain ratings, improved Oswestry scores, and high satisfaction with the therapy.

*Key Words.* Outcomes; Registry; Low Back Pain; Intrathecal Drug Delivery

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### Introduction

Chronic low back pain is a major public health problem in the United States, serving as the second most common cause of hospital admissions [1]. Each year, approximately 25 billion dollars are spent on direct medical costs for low back pain.

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When indirect costs, such as lost productivity and economic hardship, are included, the figure exceeds 100 billion dollars annually [2].

The spectrum of low back pain ranges from lumbar strain, the most common ailment, to failed back surgery syndrome and compression fractures of the lumbar vertebrae. Approximately 300,000 patients in the United States undergo lumbar surgery each year, with failure rates as high as 40% [3]. In patients with osteoporosis, as many as 700,000 patients per year suffer from debilitating compression fractures

[4]. In the acute phase of injury, many patients with lumbar strain respond to conservative therapy such as bed rest and physical therapy, as outlined in federal guidelines [5]. In patients who fail to respond to conservative treatments, more aggressive therapies are often attempted, ranging from oral and transdermal medications to surgical correction and devices such as implantable drug-delivery systems (IDDSs).

The use of IDDSs to administer morphine intrathecally for the treatment of chronic pain was introduced in the early 1980s [6–8]. An IDDS consists of two implantable components: An infusion pump and an intraspinal catheter. The pump is placed abdominally in a subcutaneous pocket, while the catheter is inserted into the intrathecal space of the spine, tunneled under the skin, and connected to the pump. Medication is refilled through a septum in the pump and delivered through the catheter to the intrathecal space.

Despite decades of experience with IDDSs, there is a paucity of information on common clinical practices and long-term patient outcomes in the low back pain population. The National Outcomes Registry for Low Back Pain was created to prospectively collect data (aggregate and center specific) for patients with chronic low back pain who underwent a screening or trial for an IDDS. The data sought to provide insight into patient demographics and clinical practice factors influencing trial success rates and patient outcomes at 6- and 12-month follow-ups.

Among the advantages of medical registries is the opportunity to systematically collect prospective and longitudinal data that can provide insight into current practices and potential correlations between practices and outcomes. Registries can also be used to monitor long-term effectiveness and outcomes of a therapy. In addition, registry data may guide physicians in the formulation of hypotheses for future clinical studies and guidelines for practice improvements [9–12].

Registries are not designed to test hypotheses or to prove cause and effect relationships. Their limitations include a lack of strict control over the quality of the data collected and the possibility of selection bias. Despite these drawbacks, a wealth of knowledge can be obtained from a carefully planned and administered registry.

## Methods

### Registry Design

Centers were invited for participation based on their experience in the implantation of a market-

released IDDS (i.e., the SynchroMed® Infusion System; Medtronic, Inc.; Minneapolis, MN) and spinal cord stimulators (SCSs) for the treatment of chronic low back pain independent of perceived outcomes. The centers were required to have access to adequate staff support for data collection and follow-up. Confirmation and activation of each physician included documentation of an Institutional Review Board (IRB) review of the registry protocol and existence of a patient registration form allowing release of medical records.

Data were prospectively collected at baseline (defined as completion of patient registration) and also at trial (i.e., evaluation of a temporary intraspinal analgesic for adequate pain relief and acceptable side effects), implant (or decision not to implant), and at 6 and 12 months following the trial. Patients were followed regardless of whether their trial was successful and whether or not an implant occurred. Each participating center followed its standard clinical practice for patient selection, trialing methods, criteria for definition of a successful trial, implant methods, and postimplant therapy management. The registry protocol provided guidance regarding registry data requirements and ensured that standardized forms were used among all participating centers to solicit registry data. An independent research organization managed project oversight, communication with registry centers, data procurement, and database development. Centers were not monitored, but electronic error checking parameters were implemented and an error correction process used.

Patients who were enrolled for IDDS trialing had chronic low back pain, with or without leg pain, but with greater back pain than leg pain. Types of pain were grouped into three main categories for analysis: Mechanical, neuropathic, and mixed pain. Underlying causes of mechanical pain included: Osteoporosis/compression fractures, spinal stenosis, degenerative disc disease, and osteoarthritis. Causes for neuropathic pain were: Arachnoiditis, unilateral radicular leg pain, and bilateral radicular leg pain, while failed back syndrome was defined as mixed.

### Data Collection

Data gathered at baseline included information such as patient age and gender, underlying cause of pain and previous pain treatments, work status, trialing site, and trial methodology. Patients provided separate numerical assessments of their back pain and leg pain on a scales of 0–10, with 10 being

the worst pain imaginable. They also completed the Oswestry Low Back Pain Disability Questionnaire [13,14], a scoring system that measures disability status ranging from bedridden (a high score) to minimal disability (a low score).

Additional information was collected concerning patients' previous psychological evaluations and types of medical insurer. At implant, the location where the implant was performed and the type of system used were noted. If a decision was made not to implant, the reasons were recorded.

At the 6- and 12-month follow-ups, data were collected on therapy outcomes, use of concomitant therapies, and patient work status. Patients were again asked to assess their numeric pain levels and functional abilities. Patients who were implanted with an IDDS were asked to rate their overall quality of life, satisfaction with the therapy, and whether or not they would undergo another implant or recommend the therapy to others. Adverse events and their resolutions were described and recorded.

#### *Analytical Methods*

Chi-square tests were used to test for differences between categorical data. Paired *t*-tests were used when comparing baseline with follow-up for continuous data. Repeated measures analysis of variance (ANOVA) was used to test for an association between baseline and screening characteristics and outcome variables over time (i.e., baseline, 6 months, and 12 months) for those patients with an IDDS implant. Significance was determined to be a *P* value  $\leq 0.05$ , while nonsignificant findings did not imply equivalence. Continuous data are presented as the mean  $\pm$  standard deviation unless noted otherwise.

#### **Results**

Data collected during the registry from patients trialed for an IDDS were analyzed according to patient demographics, factors influencing trialing success, and patient outcomes at follow-up.

#### *Patient Demographics*

Patient enrollment was initiated in February 1999 and completed in February 2000, with follow-up ending in February 2001. Of the patients enrolled, 166 were trialed for an IDDS and 136 patients (82%) were implanted. Follow-up data from patients implanted with IDDSs were available from 105 patients at 6 months and 72 patients at 12 months.

The mean age for the 166 patients who underwent a trial for an IDDS was 55.6 years (range:

30–83 years); 54% were female. Patients may have had more than one etiology of pain and all patients had back pain. In addition to back pain, a majority of IDDS patients (66.2%) suffered from failed back syndrome, followed by degenerative disc disease (36.8%), and radicular leg pain (28.7% unilateral and 31.6% bilateral). Patients typically had long histories of pain treatments, including systemic opioids (88.2%), epidural steroids (83.1%), physical therapy (83.1%), and back surgeries (76.3%). On average, patients with previous back surgeries had undergone 2.8 procedures. A number of IDDS patients (75%) had undergone psychological evaluations by the time of enrollment.

Only 3.7% of IDDS patients were working full time, while 62% were not working or were working at a reduced capacity due to pain, 25% were retired, and 9% were not working. Most patients were covered by Medicare (42.3%) or private insurance (37.4%), while Workers' Compensation insured 11.4% of the IDDS patients.

#### *Trialing Results*

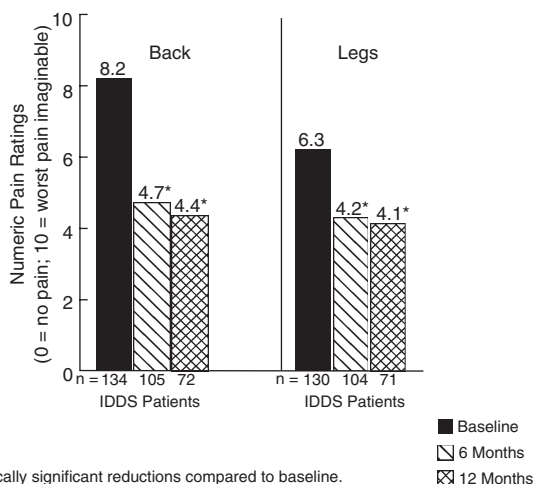
Trialing was performed as an outpatient procedure in a hospital (16%), inpatient procedure in a hospital (72%), or in an ambulatory surgery center (12%). Trialing methodologies were: Continuous epidural infusion (53%), continuous intrathecal infusion (25%), single intrathecal bolus injection (14%), and multiple intrathecal bolus injections (8%). The majority of patients (81.1%) were trialed with morphine only. The mean duration of the trial was  $3.5 \pm 5.4$  days.

A total of 154 of 166 patients (93%) had successful trials for an IDDS. Of these, 136 patients (82%) were implanted with IDDSs. Implants were performed as inpatient procedures in a hospital (75%), outpatient procedures in a hospital (23%), and in ambulatory surgical centers (2%).

Analysis of collected data revealed no statistically significant associations between most factors and IDDS trialing success. Factors not associated with success included: Age and gender; previous pain treatments; use of psychological evaluations; site, methodology, and duration of trialing; and medical insurance. The only category that had a statistically significant association with trial success was type of pain. Patients with neuropathic pain who were trialed with opioids alone had a success rate of 89%, versus a 100% success rate for patients with mechanical or mixed pain.

#### *Pain and Function Scores*

The IDDS group experienced a statistically significant reduction in numeric pain ratings when



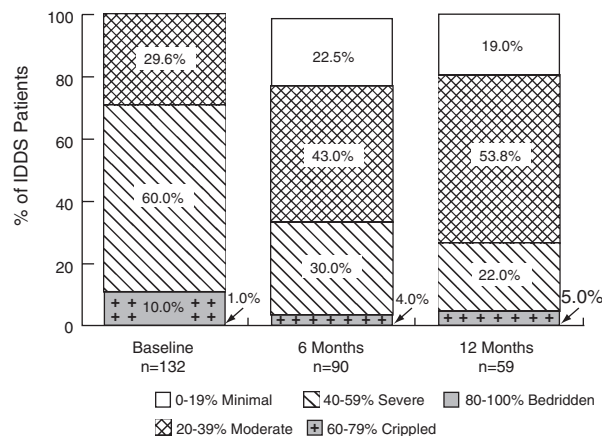
\*Statistically significant reductions compared to baseline.

**Figure 1** Numeric Back and Leg Pain Ratings, IDDS Patients. IDDS: Implantable Drug Delivery Systems.

ratings were compared between baseline and 6 months and between baseline and 12 months ( $P < 0.001$ ). Numeric back pain ratings for these patients declined by more than 48% at 12 months, and leg pain ratings declined by 32% (Figure 1). Additionally, overall pain reduction, as assessed by the patients, was 58% at 6 months and 62% at 12 months. Patient responses to the Oswestry Low Back Pain Disability Questionnaire were analyzed at baseline and at the 6- and 12-month follow-ups. At baseline, almost 30% of the IDDS group scored in the minimal-to-moderate disability range, and 60% had severe disability. By 6 and 12 months, the percentages in the minimal-to-moderate disability range had increased to 65% and 73%, respectively, while the percentages of those with severe disability had decreased to 30% and 22%, respectively (Figure 2).

A successful outcome in functional ability was defined as an Oswestry scores reduction of at least one level. Based on this definition, at the 6-month follow-up, 60% of IDDS patients experienced improvement in their Oswestry scores, and at the 12-month follow-up, 66% had experienced improvement. Overall, improvements in Oswestry scores were maintained at 6 and 12 months by patients implanted with IDDS (Figure 3).

All three Oswestry scores were required for patient inclusion in the following analysis. Patients who were *not* on Workers' Compensation ( $N = 45$ ) had statistically significant improvements in Oswestry scores from baseline to the 12-month follow-up ( $P = 0.01$ ), while patients who *were* on Workers' Compensation had no change in



**Figure 2** Oswestry Disability Scores for IDDS Patients. IDDS: Implantable Drug Delivery Systems.

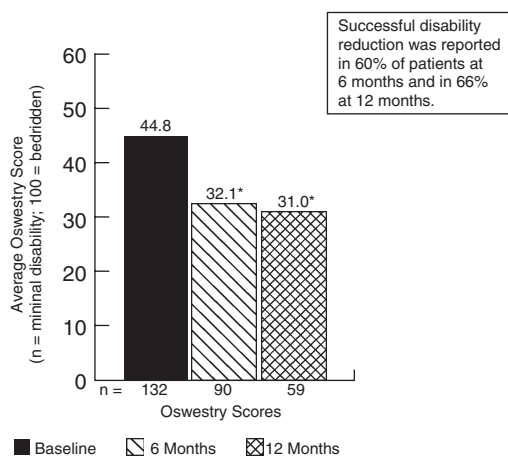
Oswestry scores from baseline to the 12-month follow-up ( $N = 6$ ).

### Use of Systemic Opioids

At the 6-month follow-up, 65% of IDDS patients (total  $N = 108$ ) were able to decrease their use of systemic opioids from the baseline level. At 12 months, 42% of IDDS patients (total  $N = 75$ ) had decreased their usage of systemic opioids compared with the 6-month follow-up (Figure 4).

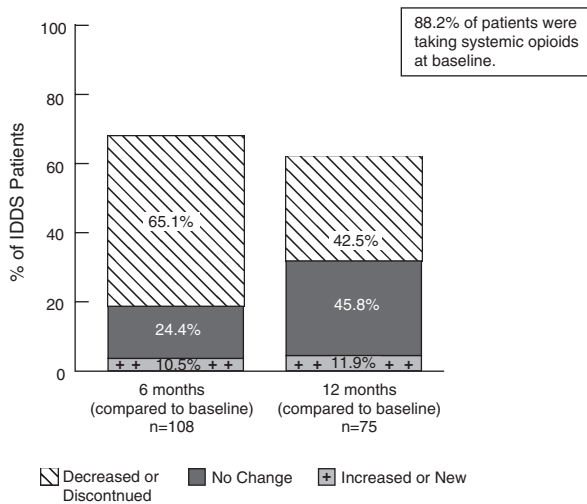
### Return to Work

At Baseline, 54.5% of the IDDS patients (total  $N = 134$ ) had a work status of disabled/not working due to pain, 25.4% were retired, 9% had a status of



\* Statistically significant compared to baseline.

**Figure 3** Oswestry Disability Scores for IDDS Patients.



**Figure 4** Systemic Opioid Therapy at 6 and 12 months.

not working, 7.5% had a status of working at reduced capacity/hours due to pain, and 3.7% were working. Of those patients with baseline statuses of working, working at reduced capacity/hours due to pain, or disabled/not working due to pain who had 6-month follow-ups, 62.3% (total N = 69) remained at the same work status, 24.7% had a lower work status, and 13% had a better work status. Of the patients in those same categories who had 12-month follow-ups, 68.1% (total N = 47) remained at the same work status, 10.6% had a lower work status, and 21.3% had a better work status.

### Patient Satisfaction

Patients were asked to evaluate their satisfaction with the IDDS in terms of overall quality of life, personal satisfaction, whether they would undergo a pump implant again, and whether they would recommend the therapy to others. At the 12-month follow-up, 87% of the IDDS group described their quality of life as fair to excellent. Almost 80% were satisfied with their therapy. When asked if they would repeat the implant procedure, 87% of patients said “yes” and 90% said they would recommend the therapy to a family member or friend.

### Adverse Events

Adverse events were reported in 23 patients receiving an IDDS implant. Of these, 21 required some surgery to correct the problem. Adverse events included: Infection (2.2%), dislodg-

ment/migration (1.5%), and cerebrospinal fluid leak (0.7%). The most common adverse event over 12 months was reaction to medication, which occurred in 5.1% of patients. Other, rarely reported events included catheter kinking in 1.5% and catheter fracture in 0.7% of patients. All adverse events were resolved according to clinically accepted practices and none were unanticipated.

### Nonimplant Patients

In patients who were not implanted with an IDDS, six failed trialing, while 18 had successful trials but were not implanted. Two of the latter (11%) were denied reimbursement, and eight (44%) chose not to undergo an implant. The remaining eight patients (44%) had other reasons for not receiving an IDDS implant, such as respiratory depression, unacceptable medical risks, intractable nausea, decreased pain, use of nerve blocks as an alternative therapy, and death from cancer.

Patients in the nonimplant group were followed through 6 months (N = 14) and to 12 months (N = 13). In these nonimplant patients, the average back pain rating was 7.8 at baseline and remained stable at both 6 and 12 months of follow-up. The average leg pain rating was 6.9 at baseline and also remained stable at both 6 and 12 months of follow-up. These nonimplant patients had an average baseline Oswestry score of 50, which remained stable, without improvement, over the 6 and 12 months of follow-up. The nonimplant group also fared poorly regarding systemic opioid use, with 69% of patients showing no change or increased systemic opioid use at 6 months, and 77% showing no change or an increase at 12 months.

### Discussion

Few studies have analyzed the success of IDDSs for the treatment of patients with chronic low back pain, and none has compared long-term outcomes at 6- and 12-month follow-ups among patients who had successful trials and were implanted with an IDDS. There also is a paucity of information regarding the effect of different factors (e.g., cause of pain and history of previous treatments) on success of trials and long-term outcomes.

Paice and colleagues [15] reported data based on a physician survey and retrospective analysis, which included trialing methods but no associated success rates. They also found no significant dif-

ferences in pain relief outcomes between trialing methods.

In work by Brown et al. [16], the overall success rate using IDDSs to manage low back pain at 3 years was found to be fairly good, but functional improvement among patients was shown to be minimal. However, their data were collected retrospectively, which can limit the implications of these findings and, similarly, those of Paice et al. [15].

Anderson et al. [17] evaluated single intrathecal injections and continuous epidural infusions of morphine to determine the relative efficacy, safety, and costs of each when used in the selection of IDDS patients ( $N = 37$ ). Those authors found no significant differences in long-term outcomes when the two methods of trialing were compared.

The National Outcomes Registry for Low Back Pain was created to collect data from a large number of patients ( $N = 136$ ) trialed for IDDSs for the treatment of chronic low back pain enrolled through a variety of medical centers across the United States. In the patients who had successfully undergone a trial for an IDDS, we noted an absence of any statistically significant correlation between most factors and trialing success. This fact suggests that once standard selection criteria and trial methods are employed, age, gender, method of trialing, history of previous treatments, medical insurer, and psychological evaluations have little impact on the success of a trial. This report reflects the diversity in methods and management of these patients among these centers.

We found type of pain to be the only variable that had a statistically significant impact on trial success. Patients with neuropathic pain had a statistically significantly lower success rate and, correspondingly, in patients receiving opioids alone at the trial, the success rates were statistically significantly lower in patients with neuropathic pain. These data suggest that, in patients with neuropathic or mixed pain, the use of combined drug therapy may improve the chances of trialing success and long-term outcomes. The practice supporting these data was reported by Hassenbusch and Portenoy [18], who noted that the current practice is to use drug combinations in many patients with mixed or neuropathic pain being treated with an implantable intrathecal delivery pump.

Measuring the effect of a therapy on quality of life has historically been elusive. The subjective nature of an individual's perception of pain, disability, and functional status make measurement

difficult and results sometimes questionable. Yet, quality of life is increasingly being viewed as a valuable patient outcome, and health-related quality of life data are being used more frequently in clinical trials and cost-effectiveness studies.

We chose to use a threefold approach to help measure the level of improvement in quality of life among patients being treated with IDDSs. These measures were numerical pain ratings, Oswestry functional scores, and patient satisfaction assessments. Statistically significant improvements were seen when numeric pain ratings and Oswestry functional scores were analyzed for this patient group. Data collected at baseline were compared with data collected at 6- and 12-month follow-ups and showed statistically significant improvements in both scores.

While improvements in numeric pain ratings were impressive (overall pain reduction as assessed by patients was 58% at 6 months and 62% at 12 months), the responses to the Oswestry Low Back Pain Disability Questionnaire were even more dramatic. At baseline, almost 30% of the IDDS group scored in the minimal-to-moderate disability range, and 60% had severe disability. By 6 and 12 months, the percentages in the minimal-to-moderate disability range had increased to 65% and 73%, respectively, while the percentages of patients with severe disability had decreased to 30% and 22%, respectively. This becomes especially compelling when comparing the definitions of these disability categories. Patients in the severe disability category, for example, experience pain as the main problem in their lives, affecting personal care, social life, sexual activity, sleep, and travel. Moving into the moderate disability range, as defined by the Oswestry scale, means the patient may still experience pain and problems with sitting, lifting, and standing, as well as travel and social life, but personal care, sexual activity, and sleeping are not grossly affected. Usually the back condition in patients with moderate disability can be managed with conservative therapies. Advancement into the minimal disability category is even more profound. This group can engage in most living activities, usually without treatment, other than taking care in posture, lifting, and general physical fitness [19]. This finding is reinforced by the maintenance of and improvements in work status noted in a subgroup with 12 month data. These findings, and the reduction of systemic opioid therapy, have implications for easing the patient management burden, both from the physician's and patient's perspective.

In addition to measurable improvements in pain ratings and Oswestry scores, the IDDS patient group experienced significant personal satisfaction with their therapy. At 12 months, the majority of IDDS patients (80%) were satisfied with their therapy and believed that their quality of life had improved (87%). Furthermore, most patients said they would repeat the procedure and recommend the therapy to others (90%). The results are compelling and should prompt pain management physicians to consider more frequent use of IDDSs for patients with chronic low back pain.

Adverse events requiring surgery over 12 months occurred in 21 IDDS patients (13%). The majority of those complications were resolved without further surgery. In separate studies, Anderson and Burchiel [20] and Follett and Naumann [21] summarized common side effects and complications seen with intrathecal therapies. In both papers, the percentage of patients experiencing adverse events or complications appeared consistent with our findings.

In general, this registry study was limited by the lack of a strict protocol for defining disease states, determining trial methods, and specifying drug usage. However, data do reflect actual practice in a cross-section of physicians who use IDDSs regularly. Generalizability of these results may also be limited due to missing data at the 6-month (21% missing) and 12-month (44% missing) follow-up visits. The rate of missing data at 6 and 12 months was within the range reported in the literature. Paice et al. [15] had missing data for 32% of their patients at 6 months and for 50% at 12 months. Anderson and Burchiel [20] had missing data for 17% at 6 months and for 33% at 12 months. The strength of the data interpretation is based on inpatient comparisons (baseline versus trial or long-term follow-up) and several significant findings were reported.

The prospective data from the registry have provided us with valuable insights into what factors influence IDDS trialing success and the kind of outcomes to expect in patients being treated with IDDSs for chronic low back pain. Based on these findings, more work is needed to determine which patients with chronic low back pain are most likely to respond to IDDSs.

## Conclusions

We conclude that IDDSs are successful in managing chronic low back pain in patients who have not found effective relief with other therapies. There

was impressive functional improvement described, with disability reduction seen in the Oswestry scores. Quality of life improvements were significant, with the vast majority of IDDS patients (80%) being satisfied with their therapy and most (87%) believing their quality of life had improved. Additional studies may help to better determine predictors for successful trials and quantify the benefits of IDDS for managing chronic low back pain.

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