

Intervertebral Disc Biacuplasty for the Treatment of Lumbar Discogenic Pain: Results of a Six-Month Follow-Up

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ABSTRACT

Objective. Intradiscal biacuplasty (IDB) is a novel bipolar cooled radiofrequency system for the treatment of degenerative disk disease. We present the results of a pilot trial with 6-month follow-up.

Design, Setting, Patients, and Interventions. Fifteen patients, 22–55 years old, underwent one- or two-level IDB treatment of their painful lumbar discs. All had chronic low back pain >6 months, back pain exceeding leg pain, concordant pain on provocative discography, disc height >50% of control, and evidence of single- or two-level degenerative disc disease without evidence of additional changes on magnetic resonance imaging. IDB was performed under fluoroscopy using two radiofrequency probes positioned bilaterally in the intervertebral disc. Thirteen patients completed follow-up questionnaires at 1, 3, and 6 months. Pain disability was evaluated with Oswestry and Short Form (SF)-36 questionnaires.

Results. Median visual analog scale pain scores were reduced from 7 (95% confidence interval [CI] 6, 8) to 4 (2, 5) cm at 1 month, and remained at 3 (2, 5) cm at 6 months. The Oswestry improved from 23.3 (SD 7.0) to 16.5 (6.8) points at 1 month and remained similar after 6 months. The SF-36 Physical Functioning scores improved from 51 (18) to 70 (16) points after 6 months, while the SF-36 Bodily Pain score improved from 38 (15) to 54 (23) points. Daily opioid use did not change significantly from baseline: from 40 (95% CI 40, 120) before IDB to 5 (0, 40) mg of morphine sulfate equivalent 6 months after IDB. No procedure-related complications were detected.

Conclusions. Patients showed improvements in several pain assessment measures after undergoing IDB for discogenic pain. A randomized controlled study is warranted and needed to address the efficacy of the procedure.

Key Words. Radiofrequency Annuloplasty; Intervertebral Disc; Degenerative Disc Disease; Internal Disc Disruption; Discogenic Pain; Transdiscal; Intradiscal Biacuplasty; IDET

Introduction

Intervertebral discogenic pain is a major source of lower back pain [1] and remains difficult to treat. Conservative management has not been associated with therapeutic successes and other treatment modalities such as spinal fusion and disc

replacement procedures remain controversial [2,3]. The use of intervertebral disc heating procedures such as intradiscal electrothermal therapy (IDET) has been shown to benefit a small group of properly selected patients [4,5,6]. Patients not likely to benefit from IDET include those with multilevel degenerative disc disease [5], overweight patients [7], and patients receiving Workers Compensation benefits [6,8]. Other reasons for poor outcome following the use of the IDET heating technique to treat discogenic pain can be attributed to the difficulty in navigating the

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catheter reproducibly and the lack of reproducible uniform thermal lesion. Bogduk et al. have argued, for example, that temperatures produced by the SpineCath catheter (Smith and Nephew plc, London, UK) used in IDET procedures may be insufficient to generate effective lesions [9].

Intradiscal biacuplasty (IDB) using the Trans-Discal system (Baylis Medical Inc., Montreal, Canada) is approved for clinical use by the FDA. The system uses bipolar radiofrequency electrodes placed obliquely on the posterolateral aspects of the intervertebral annulus. This system appears to produce precise thermal profiles within the posterior annulus [10]. IDB differs from the IDET annuloplasty in that a long, flexible heating coil catheter is unnecessary and potential difficulty in navigating a flexible device against or in between the lamellae of the posterior annular wall is negated. The TransDiscal electrodes are placed without the need for steering. Presumably, this reduces placement difficulties and leads to reproducible uniform lesions. We thus conducted a pilot study on 15 patients suffering from chronic lumbar discogenic pain to evaluate their pain relief and functional capacity improvement.

Methods

After approval from the Cleveland Clinic Institutional Review Board, written informed consent was obtained from 15 patients who were previously denied minimally invasive intradiscal annuloplasty (IDET) by their health insurance companies. All had received magnetic resonance imaging (MRI) and provocative discography of the lumbar spine in the previous year.

Inclusion criteria adopted for these studies were as follows: history of chronic low back pain unresponsive to nonoperative care for a period longer than 6 months, back pain greater than the leg pain that is commonly exacerbated by sitting, concordant pain reproduced on provocative discography in degenerated, but not in control discs, disc height of at least 50% of the adjacent control disc [4,11,12], single-level degenerative disc disease or two-level disease without evidence of additional degenerative changes in other disc spaces on MRI.

The exclusion criteria were: evidence of compressive radiculopathy, nucleus pulposus herniation on the MRI, disc bulges exceeding 5 mm,

prior surgery at the symptomatic level, symptoms or signs of lumbar canal stenosis, pending Workers Compensation claim or litigation [6,8], psychological issues by examination or history, score >16 on Beck Depression Inventory, tumor, systemic infection or localized infection at the anticipated entry needle sites, traumatic spinal fracture, history of coagulopathy, unexplained bleeding, progressive neurological deficits, history of opioid abuse or current use of long-acting opioids, presence of free disc fragments on MRI, manual labor, smoking, body mass index >30, and age >55 years [4,6].

Intradiscal biacuplasty was performed on an outpatient basis with fluoroscopic guidance. Intravenous access was obtained and five-lead electrocardiogram, continuous pulse oximetry, and noninvasive blood pressure monitors were placed. Prophylactic intravenous antibiotics were administered 15–40 minutes prior to beginning the procedure. Patients were positioned prone and given 1–4 mg of intravenous midazolam and 0–100 µg of intravenous fentanyl before and during the procedure, as necessary. Two TransDiscal probes (Baylis Medical Inc.) were positioned in the posterolateral aspect of the annulus of the relevant disc using an oblique approach (Figure 1). To facilitate accurate placement, two electrically insulated 17 g TransDiscal introducers were used to gain access to the intervertebral disc space. TransDiscal radiofrequency probes were then be positioned within each of the introducers bilaterally to create a bipolar treatment configuration. Probe placement within the disc annulus was confirmed using oblique, lateral, and anterior-posterior fluoroscopy (Figures 2–4).

Tissue heating was initiated through a programmed gradual temperature ramp to 55°C over 11 minutes. This temperature was then maintained for an additional 4 minutes to complete the treatment program. Throughout, patients were awake and able to communicate. When the procedure was complete, patients were transferred to a recovery area and monitored for 45 minutes prior to discharge with postprocedural instructions and a stabilizing brace to be worn only when awake around the abdomen. Patients were also prescribed a physical therapy regimen previously established for patients undergoing treatment for similar procedures [4–6].

Baseline values were obtained before procedure and patients were subsequently monitored for outcomes at follow-up visits scheduled at 1, 3, and 6 months after the procedure. On each occasion,

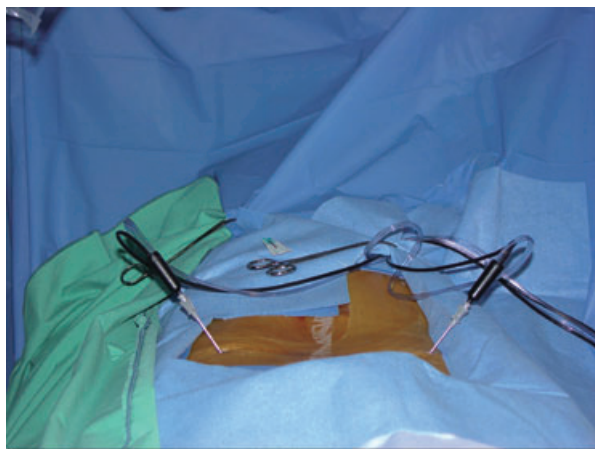


Figure 1 Bipolar electrodes in place during intradiscal biacuplasty of the L4–L5 intervertebral disc. The patient is in the prone position and the back of the patient is prepared and draped.

pain disability data were collected using Oswestry (50 points scale) and Short Form (SF)-36 questionnaires, visual analog scale (VAS) pain scores, and opioid use. Opioids were converted to morphine sulfate equivalents. To assess for possible

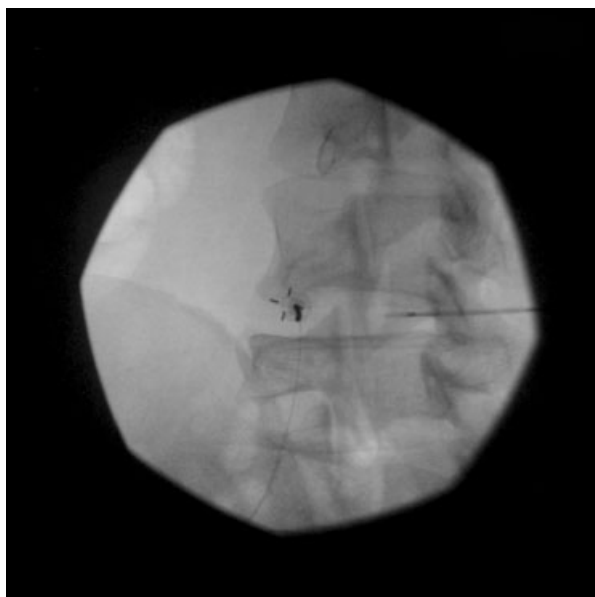


Figure 2 Positioning of bipolar electrodes inside the posterior annulus. An oblique view is used to approach intervertebral disc with the introducer. The radiofrequency electrodes are then inserted through the introducers into the posterior annulus. The first (right) electrode is already positioned inside the annulus. Left electrode is advanced in oblique view to enter posterolateral annulus. Note that the end plates are aligned for precise horizontal electrode placement.

complications follow-up visits were conducted after each periodic questionnaire completion.

Statistical Analysis

For the Oswestry score, SF-36 Physical Functionality (PF) score, and the SF-36 Bodily Pain (BP) score, which were normally distributed at each time point, we used a repeated measures analysis of variance that adjusts the standard errors of the means at each time point based on the within-patient correlation. The overall time effect was tested using an F-test, while pair-wise comparisons of means were made using Tukey's honest significant difference adjustment for controlling experiment-wide error rate.

For the non-normally distributed endpoints (VAS pain score and opioid use) we used the Wilcoxon signed rank test of location difference between time points and Friedman's chi-square test for ranks for the overall test. A Bonferroni adjustment to the significance criterion was used for multiple comparisons.

The experiment-wide error rate for all tests was controlled at a significance level of 5%. Results are presented as mean (SD), median [quartiles] or mean (confidence interval [CI]). SAS version 9.1 software (SAS Institute, Cary, NC, USA) and R version 2.3.1 software (The R Foundation for Statistical Computing) were used for all statistical analysis and graphics.

Results

Patients enrolled in the study ranged from 22 to 55 years old; there were eight women and seven men. Demographic characteristics and details about the patients' back pain are shown in Table 1. Body mass index ranged from 18.3 to 30.3 kg/m², with mean (SD) of 26.7 (5.9). All but two were employed: one woman was a homemaker and one man was retired. Only one patient was previously employed as a light manual laborer. One had a recent history of smoking but quit approximately 1 year previously. Beck Depression Inventory scores ranged from 1 to 13. Among the 15 patients enrolled, 13 remained in follow-up at 6 months; one other withdrew voluntarily and one was removed because she failed to disclose ongoing litigation directly related to her back pain.

Visual analog scale, SF-36, and opioid use are summarized in Table 2 (actual values), Table 3 (changes among time points), and Table 4 (*P* values for changes). VAS pain score decreased from baseline to the first follow-up visit at 30 days

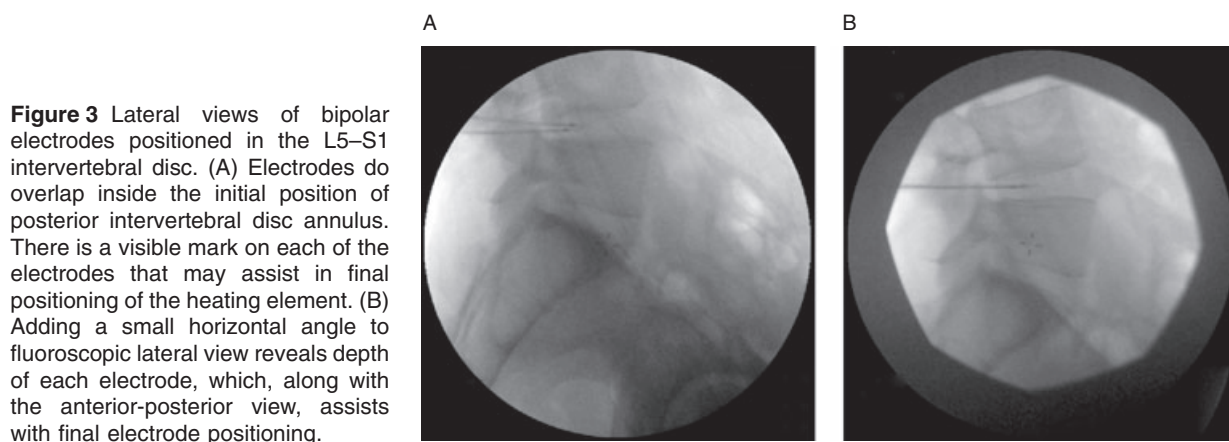


Figure 3 Lateral views of bipolar electrodes positioned in the L5–S1 intervertebral disc. (A) Electrodes do overlap inside the initial position of posterior intervertebral disc annulus. There is a visible mark on each of the electrodes that may assist in final positioning of the heating element. (B) Adding a small horizontal angle to fluoroscopic lateral view reveals depth of each electrode, which, along with the anterior-posterior view, assists with final electrode positioning.

a median (95% CI) change of 3 cm (2, 7). Additionally, at first follow-up visit, Oswestry scores were significantly reduced by an average (95% CI) of 6.8 points (3.1, 10.6). For these two variables, statistically significant differences from baseline were also observed at 3 and 6 months.

Short Form-36 PF scores, SF-36 BP scores, and opioid use did not change significantly from baseline to 1 month. Changes from baseline were statistically significant at 3 months and thereafter, however, for SF-36 PF and SF-36 BP scores. At 3 months, SF-36 PF scores improved an average

(95% CI) of 14.9 points (6.3, 23.5) and SF-36 BP scores improved by 13.7 points (3.6, 23.8). Opioid use did not significantly change through the course of the study. Neither was there any statistically significant difference among the follow-up times themselves (between 1, 3, and 6 months) for any of the outcomes. Seven out of 13 patients followed over 6 months had more than 50% improvements in their pain scores. There were no patients with worse pain scores 6 months after procedure. One patient is considering spine fusion surgery.



Figure 4 Final position of the electrodes from anterior-posterior view. Both electrodes are horizontal and parallel to the end plates. The distance between the electrodes appears to be satisfactory.

Discussion

Pain scores and functional capacity improved in most of our patients, and the results are somewhat better [4] or similar [5] to the outcomes previously reported with IDET in similar patient groups (Tables 2–4). Based on improved functional capacity, decreased pain scores, and reduced opioid use, our results suggest that IDB using the TransDiscal system may be an effective minimally invasive procedure for the treatment of chronic discogenic back pain in properly selected patients (Figure 5 and Table 2).

An advantage of the TransDiscal system over previously available procedures is the ease by which bipolar electrodes can be positioned directly in posterior annulus (Figure 1). This eliminates the difficulties inherent in threading a long, flexible heating coil catheter, over the region of the posterolateral disc where radial fissures are frequently present.

We have previously described histopathological evaluation of the posterior annulus in cadaver tissues subject to IDB using the TransDiscal

Table 1 Demographic, operative, and follow-up data for 15 patients undergoing intervertebral disc biacuplasty

	Patient ID														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Sex	F	M	M	M	M	F	M	F	F	M	F	M	F	F	F
Age (years)	22	41	44	55	28	55	46	33	35	31	49	48	26	23	52
Years of back pain	6	3	10	20	6	7	1	1	6	3	11	5	2	3	4
Degenerated lumbar discs on MRI (number)	2	2	1	2	2	2	1	1	2	1	2	2	2	2	2
Discography positive lumbar discs (number)	2	2	1	2	1	1	1	1	2	1	2	1	2	1	2
Oswestry															
Baseline	—	17	30	29	17	—	12	23	32	13	28	19	25	26	32
1 months	—	15	10	23	12	—	18	9	24	11	9	19	20	13	31
3 months	—	19	25	24	13	—	17	16	22	7	5	16	12	14	30
6 months	—	22	24	24	20	—	13	3	25	6	9	18	13	15	30
VAS pain															
Baseline	—	7	10	7	8	—	6	4	9	5	10	7	7	5	8
1 months	—	0	3	5	3	—	4	0	6	2	1	5	6	4	4
3 months	—	5	7	4	3	—	3	1	6	2	1	5	5	3	5
6 months	—	4	6	5	2	—	1	1	3	1	2	5	5	3	6
SF-36 PF															
Baseline	—	45	25	55	55	—	65	55	40	60	20	85	60	60	35
1 months	—	75	50	45	55	—	65	80	55	67	40	80	50	55	55
3 months	—	44	50	45	75	—	75	70	75	80	60	85	65	80	50
6 months	—	55	50	44	70	—	90	90	70	90	75	80	65	80	50
SF-36 BP															
Baseline	—	45	10	35	58	—	43	35	33	68	35	35	23	45	23
1 months	—	68	33	45	78	—	33	78	58	55	65	45	23	45	20
3 months	—	45	33	35	55	—	45	45	45	78	78	58	68	58	23
6 months	—	33	23	45	68	—	45	90	55	78	78	58	58	58	10
Opioid use															
Baseline	—	40	70	180	40	—	160	40	160	40	20	120	40	5	40
1 months	—	0	70	180	0	—	160	40	80	0	0	120	40	5	40
3 months	—	20	40	180	0	—	0	40	60	0	0	160	40	5	40
6 months	—	20	0	180	0	—	0	0	60	0	0	160	40	5	40

F = female; M = male; MRI = magnetic resonance imaging; VAS = visual analog scale; SF-36 = Short Form-36; PF = Physical Functioning; BP = Bodily Pain.

system, which indicated the absence of nerve root or surrounding tissue damage [10]. As might thus be expected, none of our patients demonstrated an increase in pain, new-onset pain, or neurological deficit. These positive results may be attributable to the radiofrequency electrode cooling technology used by the TransDiscal system, which allows a large volume of tissue to be heated while avoiding excessive heating close to the electrodes.

The selection of patients for enrollment in this study was similar to that used in previous large studies evaluating IDET systems [4,5,11,12]. Selection was stringent and included only a small fraction of the population typically presenting at a spine or interventional pain management clinic with discogenic pain. But these patients seem especially likely to benefit from avoiding far more invasive surgical solutions such as lumbar fusion surgery or disc arthroplasty. IDB might thus benefit their quality of life, at very least because recovery duration is shorter after a minimally invasive, percutaneous outpatient procedure.

Previous clinical experience of posterior annulus thermal treatment for discogenic pain using IDET has suggested that improvements recorded at 6 months post treatment are maintained throughout the first and second year after annuloplasty [4,5,11,12]. It remains unknown, though, whether the improvements we observed at 6 months will be maintained.

The major limitations of our study are that only 15 patients were evaluated, that a contemporaneous control group was not included, and that neither patients nor the investigators conducting follow-up assessments were blinded to treatment. Therefore, the observed changes cannot be attributed solely to the intervention. Our results should thus be considered preliminary rather than definitive. They do suggest, though, that an adequately powered, randomized, and blinded trial would be worth conducting.

In summary, patients having IDB using the TransDiscal system demonstrated substantial and statistically significant improvements in pain

Table 2 Principal results

Response Variable	Time (months)	Mean	SD	Quantiles		
				25th	Median	75th
Oswestry score	Baseline	23.3	7.0	17	25	29
	1	16.5	6.8	11	15	20
	3	16.9	7.1	13	16	22
	6	17.1	8.1	13	18	24
SF-36 PF score	Baseline	50.8	17.5	40	55	60
	1	59.4	13.0	50	55	67
	3	65.7	14.4	50	70	75
	6	69.9	16.2	55	70	80
SF-36 BP score	Baseline	37.5	15.0	33	35	45
	1	49.7	19.3	33	45	65
	3	51.2	16.8	45	45	58
	6	53.8	22.7	45	58	68
VAS pain score	Baseline	7.2	1.9	6	7	8
	1	3.3	2.1	2	4	5
	3	3.8	1.9	3	4	5
	6	3.4	1.9	2	3	5
Opioid use	Baseline	73.5	59.7	40	40	120
	1	56.5	62.6	0	40	80
	3	45.0	59.2	0	40	40
	6	38.8	61.6	0	5	40

Opioid use expressed in morphine sulfate equivalent dose.

SF-36 = Short Form-36; PF = Physical Functioning; BP = Bodily Pain; VAS = visual analog scale.

scores and functional capacity (Figure 5 and Table 2–4). Improvement was apparent at the first follow-up visit at 1 month, and persisted throughout 6 months of observation. The observed

decrease in opioid use was not statistically significant. IDB might be an effective minimally invasive procedure for the treatment of intervertebral discogenic pain.

Table 3 Estimated changes in outcomes across time

Response Variable	Estimated Difference (95% Confidence Interval)					
	Baseline–1 month	Baseline–3 months	Baseline–6 months	1–3 months	1–6 months	3–6 months
Oswestry [†]	6.8 (3.1, 10.6)*	6.4 (2.7, 10.1)*	6.2 (2.5, 10.0)*	–0.5 (–4.2, 3.3)	–0.6 (–4.3, 3.1)	–0.2 (–3.9, 3.6)
SF-36 PF [†]	–8.6 (–17.4, 0.1)	–14.9 (–23.5, –6.3)*	–19.2 (–29.7, –8.6)*	–6.3 (–15.7, 3.1)	–10.5 (–19.7, –1.4)	–4.2 (–9.5, 1.0)
SF-36 BP [†]	–12.2 (–22.3, –2.0)	–13.7 (–23.8, –3.6)*	–16.2 (–26.4, –6.1)*	–1.5 (–11.7, 8.6)	–4.1 (–14.2, 6.1)	–2.5 (–12.7, 7.6)
VAS pain [‡]	3 (2, 7) [#]	3 (2, 3) [#]	3 (2, 6) [#]	0 (–1, 1)	0 (–2, 1)	0 (–1, 1)
Opioid use [‡]	0 (0, 40)	20 (0, 40)	20 (0, 70)	0 (0, 20)	0 (0, 40)	0 (0, 0)

* Statistically significant difference based on Tukey's honest significant difference adjustment for multiple comparisons.

[#] Statistically significant difference based on Bonferroni adjustment for multiple comparisons.

[†] Estimated pair-wise differences in means based on a repeated measures mixed model.

[‡] Estimated median differences based on pair-wise Wilcoxon signed rank tests.

SF-36 = Short Form-36; PF = Physical Functioning; BP = Bodily Pain; VAS = visual analog scale.

Table 4 P values for pair-wise tests of no difference between time points

Response Variable	P Value					
	Baseline–1 month	Baseline–3 months	Baseline–6 months	1–3 months	1–6 months	3–6 months
Oswestry [†]	0.001*	0.001*	0.002*	0.803	0.740	0.934
SF-36 PF [†]	0.053	0.003*	0.002*	0.170	0.028	0.106
SF-36 BP [†]	0.020	0.010*	0.003*	0.760	0.420	0.614
VAS pain [‡]	0.000 [#]	0.000 [#]	0.000 [#]	0.672	0.982	0.285
Opioid use [‡]	0.063	0.078	0.031	0.688	0.344	0.500

* Statistically significant P values based on Tukey's honest significant difference adjustment for multiple comparisons.

[#] Statistically significant P values based on Bonferroni's adjustment for multiple comparisons.

[†] Estimated pair-wise differences in means based on a repeated measures mixed model.

[‡] Estimated median differences based on pair-wise Wilcoxon signed rank tests.

SF-36 = Short Form-36; PF = Physical Functioning; BP = Bodily Pain; VAS = visual analog scale.

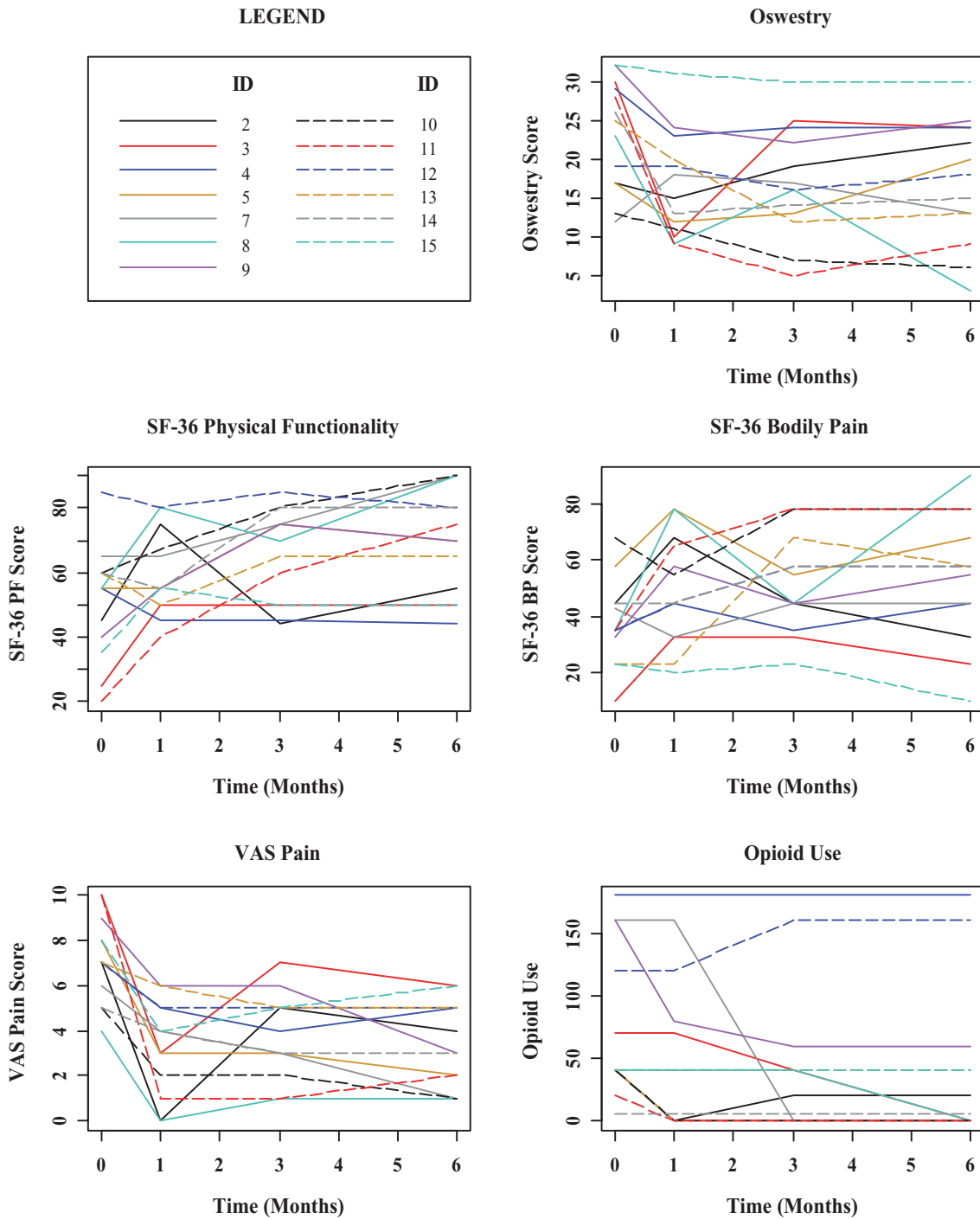


Figure 5 Raw data for each of the patient followed over 6 months. Oswestry (N = 13), Short Form (SF)-36 Physical Function (N = 13), SF-36 Bodily Pain (N = 13), visual analog scale (VAS) pain scores (N = 13), and opioid use (N = 9).

Acknowledgment

This study was supported in part by the grant from Baylis Medical Inc., Montreal, Canada.

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