

Prodisc-L[®]. Retrospective Clinical Study: 7 to 11 Year Follow-up.



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Prodisc-L®

Retrospective Clinical Study: 7 to 11 Year Follow-up

Abstract

In early 1990, Dr. Thierry Marnay, the inventor of Prodisc-L, started implanting a series of Prodisc-L total disc replacements. He and another surgeon completed a 64 patient series in 1993. They then followed the patients 5-10 years in order to evaluate the performance of Prodisc-L. Given the prevailing skepticism about total disc replacements at the time coupled with the poor experience with other total disc replacements, specifically the Charité, Dr. Marnay felt that the only way a total disc replacement implant could be accepted by the mainstream clinical community was to provide data on a well defined small group of patients followed for a long period of time. In order to evaluate and document the long-term clinical safety and preliminary efficacy of the Prodisc-L to justify a U.S. pivotal clinical trial, Spine Solutions conducted a retrospective study of all patients (64) implanted with Prodisc-L. Preoperative, intraoperative, early postoperative and contemporary follow-up information were collected. Information was extracted from medical records and was also obtained during the contemporary follow-up. A case summary was created from this information and signed by the treating surgeon.

Between May and December of 2000, ninety-five percent (95%) (58/61) of the patients who were theoretically available for a contemporary follow-up returned for a visit 7 to 11 years after the original implantation. Patients were clinically, physically and radiographically examined and asked a series of questions pertaining to their medical history, general health and the status of their pain and disability. This included a self-administered assessment of their pain using a Visual Analog Scale (VAS), their disability using the Oswestry Low Back Pain Disability Questionnaire and their general health using the SF-36 Health Survey.

Additionally, using the preoperative, postoperative, intermediate follow-up and final follow-up radiographs, as well as the case summaries, a U.S. orthopedic spine surgeon performed an independent review of the data.

In summary, based on the patients' and surgeons' evaluations as well as the independent U.S. surgeon's review, at a contemporary follow-up for 61 of the 64 Prodisc-L implanted patients at 7 to 11 years post-implantation:

- 95% of the patients returned for follow-up.
- One third (33%) of the patients were 2 level Prodisc-L implantations.
- All implants were intact and functioning.
- There was no evidence of subsidence or migration.
- There were no implant revisions or removals.
- There was a significant reduction ($p < 0.001$) in patient-reported back and leg pain.
- 92.7% of the patients reported they were satisfied or entirely satisfied with the procedure.
- There was no outcome difference between 1 and 2 level Prodisc-L implantations.
- There were no device related safety issues, untoward effects, complications or adverse events.

In conclusion, the Prodisc-L was found to be safe and preliminarily effective in a series of patients followed at 7 to 11 years post-implantation.

Background

Prodisc-L was originally manufactured and distributed by JBS, France. Although commercially available in France in the early 1990's, JBS and Dr. Marnay, Clinique du Parc, Montpellier, the inventor, proceeded cautiously with the product's initial release, limiting its use to two orthopedic surgeons, one in the south and one in the north of France. They were Dr. Marnay and Dr. Louis Villette, Dunkerque, France. Between March 1990 and September 1993 sixty-four (64) patients were implanted with ninety-three (93) Prodisc-L's by the above mentioned surgeons.

Objectives

The primary objectives of the retrospective study were to:

- Verify and validate all implantations of Prodisc-L;
- Collect and document previously recorded medical information concerning these implantations including preoperative, intraoperative and postoperative data;
- Locate and contact all patients and request that they return for a contemporary follow-up visit including examination and imaging;
- Have a physical, neurological and radiographic examination of each patient performed at his/her contemporary follow-up visit;
- Document all previously recorded information and contemporary follow-up information for each patient on standard Clinical Report Forms (CRF);
- Establish an electronic database of all information; and
- Have a U.S. orthopedic spine surgeon perform a qualitative independent clinical and radiographic evaluation of all available radiographic studies and case summaries and document his findings and write a report on his overall impressions.

Methodology

Verification and validation of all implanted cases

To begin the process an intensive and comprehensive effort was made to identify all patients who received a Prodisc-L. First, Drs. Marnay and Villette were asked to review their medical records and provide the names and last known addresses and phone numbers of all the patients in which the Prodisc-L devices were implanted, as well as the date of each surgery and the number of devices which were implanted. They were asked to provide all available clinical and radiographic information for each patient. Because of the privacy laws in France, copies of the medical records were not possible; instead, the data were transcribed onto standard CRFs and case summaries were written for all patients. The clinics were asked to retain the records for easy review should it become necessary. Since radiographs are the property of the patient in France many patients had taken their prior films home. Patients were therefore requested to bring with them all radiographic studies they may have retained when they returned for the contemporary follow-up visit. The dates and quantity of Prodisc-L devices implanted were cross-checked against the original sales and shipping records of JBS that were retained by Aesculap. This was done to validate that all patients have been captured in the retrospective study. After exhaustive review and verification we are confident that the 64 patients that are reported herein were the only patients to receive the Prodisc-L implants.

Locating patients

Every effort was made to contact all recipients of the original Prodisc-L and to have them return for a contemporary follow-up visit. The first attempt to contact the patient was based on their last known address and phone number. If a patient was found to be dead as was the case for three (3) patients (patient numbers 5, 23, 31) every effort was made to document the date and cause of death. When the initial effort to find a patient proved fruitless, a private investigator was hired to find the patient. All attempts made by the private investigator to find a patient were documented. The effort to find the patient continued until the private investigator determined that the chance of finding the patient or any additional information about the patient was negligible.

Preoperative and operative information

Standard CRFs for collecting and documenting preoperative and intra-operative (intention) information were developed and used in the data extraction process. As much information was extracted from each patient's medical record as was available. Further, this information was supplemented when necessary with data acquired during the patient interview conducted at the contemporary follow-up visit. The following preoperative and operative information were recorded when available.

Preoperative information:

- Demographics including gender, weight, height, age (date of birth);
- Type of work and everyday life;
- Level of physical activity;
- Previous spinal diseases, operations and treatments;
- Analgesic use;
- Description of the pain felt including low back and root pain;
- Sensory and muscular deficits and claudication;
- Radiographic findings from MRI, CT scan and/or myelography;
- Degree of arthrosis of the endplate and facet joint and calcification of the annulus; and
- Range of motion (segmental and global) including flexion/extension and lateral bending

Intra-operative (intervention) information:

- Surgical approach;
- Site of implantations including level and position;
- Ease and quality of implantation;
- Prodisc-L information including size, height, lordosis angle;
- Concurrent surgical procedures (associated tasks);
- Operative time and blood loss;
- Intra-operative complications; and
- Early postoperative information including number of days to begin walking, type and duration of first immobilization and length of hospital stay.

Contemporary follow-up visit (7 to 11 years post-operative)

Patients who were located were asked to return for a contemporary follow-up visit. Whenever possible the visit included a physical, neurological and radiographic study of the patient. A general Follow-up Form was completed during this visit. Plain films and flexion/extension films as well as CT scans were taken at this visit whenever possible.

The following information was requested during this follow-up visit:

- Time since surgery;
- Type of work and everyday life;
- Physical activity;
- Analgesic use;
- Current/previous non-surgical treatments;
- Description of the pain felt including low back and root pain;
- Sensory and muscular deficits and claudication;
- Implanted levels;
- Disc height including loss of height;
- Degree of facet joint degeneration;
- Lordotic and kyphotic changes;
- Range of motion (segmental, global, and T12/S1) including flexion/extension and lateral bending;
- Radiographic findings from MRI, CT scan and/or myelography;
- General radiographic findings including but not limited to amount ofolisthesis, new inter-vertebral disc herniations, implant position, implant migration, implant height, appearance of implant wear, bone resorption, the degree of arthrosis of the endplate and facet joint and calcification of the annulus;
- Postoperative complications;
- Re-operations detailed;
- Patient satisfaction;
- Visual Analog Scale (10cm) reading of pain; and
- Patient self-administered assessment using the Oswestry Low Back Disability Questionnaire and the SF-36 Health Questionnaire.

Independent radiographic and clinical review

Dr. Raymond Linovitz, San Dieguito Orthopaedics, Encinitas, CA, a spine surgeon was used as an independent evaluator of the radiographic and clinical information. Copies of preoperative, postoperative, intermediate follow-up and contemporary follow-up visit radiographs were made when available. He examined the radiographic information for each patient and documented his findings on the Radiographic Report Form. Additionally he was also provided the clinical information in the form of a case summary for each patient.

Findings

Device/patient accountability

Verifying and validating the universe of Prodisc-L implantations

A review of the medical records of Dr. Marnay indicated that he implanted 38 patients with one or more Prodisc-L devices; his first surgery was on March 13, 1990 and his last was on February 24, 1993. The records of Dr. Villette indicated that he implanted 26 patients with one or more implants, the first on April 14, 1990 and the last on September 9, 1993. The medical records from the two surgeons further indicate that Dr. Marnay performed 21 one-level, 13 two-level and 4 three-level procedures and Dr. Villette performed 18 one-level and 8 two-level procedures. (All multi-level procedures were performed on adjacent levels.) Therefore, a total of 93 Prodisc-L devices were implanted.

In order to validate that all patients have been captured in this retrospective study, the dates and quantity of Prodisc-L devices implanted by these two orthopedic surgeons were cross-checked against the original sales and shipping records of JBS, now retained by Aesculap. The records confirmed that the 64 patients and 93 implants are all of the clinically used original Prodisc-L devices.

Patient follow-up accounting

The flow chart below summarizes the efforts to locate the 64 patients and to have them return for a contemporary follow-up visit, "Patient Disposition". Of the 64 patients who received Prodisc-L implants between 1990 and 1993, 62 patients were located and 2 patients could not be found, even with the assistance of a private investigator. The effort to locate the remaining 2 patients continues today. Of the 62 patients located, 3 were found to be dead. The remaining 59 patients were asked to return for a follow-up visit. One patient refused to return. Therefore, 58 patients returned for a contemporary follow-up visit. Excluding the 3 deaths, 58 patients represents a 7 to 11 year long-term follow-up of 95% (58/61) of the theoretically available cases.

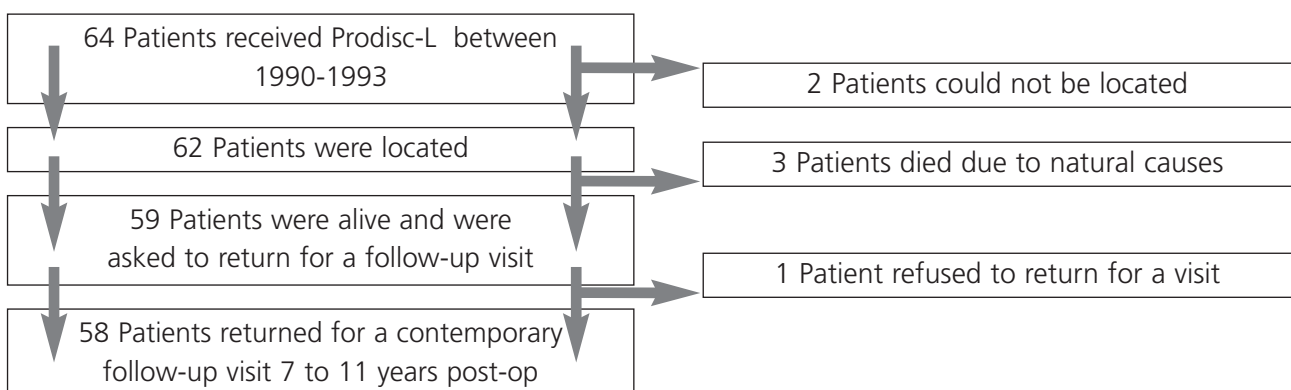


Figure 1: Patient disposition

Preoperative/ baseline data

The preoperative/baseline characteristics of the 64 patients who received one or more Prodisc-L implants were extracted from the clinical records of the patients. The information was recorded on CRFs and transferred to the electronic database. A summary of these characteristics is provided in the table below. This information was further supplemented with information provided by the patient during his/her contemporary follow-up visit. That is, the patient was asked to recall his/her medical history and the status of his/her condition prior to the original implantation, including pain and activity level.

(This information is discussed in detail below in the section entitled "Contemporary follow-up data"). Further, Case Summaries were written based upon the information found in the patient files and the data collected on the case report forms.

All 64 patients were diagnosed with and treated for degenerative disc disease. Of the 64 patients 34 (53.1%) were male and 30 (46.9%) were female. The mean age was 46 years with a range of 25 to 65 years. Many of the patients had had a prior discectomy (34.4%) or other surgical treatment (31.3%) prior to the Prodisc-L implantation.

Characteristic	Categories	No. patients/ value
Diagnosis	DDD	64 cases (100%)
Gender	Male	34 cases (53.1%)
	Female	30 cases (46.9%)
Age, years	Mean	46
	SD	8.25
	Max	65
	Min	25
Weight, kg	Mean	71
	SD	13.1
	Max	102
	Min	44
Prior surgical procedures	Discectomy	24 cases (34.4%)
	Laminectomy	3 cases (3.1%)
	Others	21 cases (31.3%)
Duration of back pain prior to surgery	6 months	4 (7.4%)
	1 yr	11 (20.4%)
	3 yr	16 (29.6%)
	10 yr	8 (14.8%)
	>10 yr	16 (27.8%)
Duration of leg pain prior to surgery	6 months	4 (8.5%)
	1 yr	11 (23.4%)
	3 yr	15 (31.9%)
	10 yr	9 (19.2%)
	>10 yr	8 (17.0%)

Table 1: Preoperative/baseline characteristics of Prodisc-L recipients

The distribution of the intervertebral levels affected by disease and receiving a Prodisc-L implantation is presented in the following table. Thirty-nine one-

level, 21 two-level and 4 three-level cases were performed totaling 93 implants in 64 patients.

Levels diseased	Level	Cases	Discs
One-level (N=39)	L3/L4	3	3
	L4/L5	25	25
	L5/S1	11	11
Two-level (N=21)	L3/L5	2	4
	L4/S1	19	38
Three-level (N=4)	L2/L5	1	3
	L3/S1	3	9
Totals		64	93

Table 2: Distribution of diseased intervertebral disc involvement

Intraoperative data

Both surgeons used both retroperitoneal and transperitoneal approaches. Both implant sizes were used. Intraoperative data is summarized in the table below. There were no "device related" incidences of intraoperative complications associated with Prodisc-L.

There were two general surgical complications both vascular, that resolved uneventfully and are listed as "other".

Characteristics	Categories	No. Patients
Complications	Device related	0 (0.0%)
	General surgical	2 other (3.3%)
Surgical approach	Retroperitoneal	21 (32.8%)
	Transperitoneal	25 (39.1%)
	Unknown	18 (28.1%)
Implant sizes (N=93)	Medium	57 (61.3%)
	Large	32 (34.4%)
	Unknown	4 (4.3%)

Table 3: Intraoperative data

Contemporary follow-up data (7 to 11 years post-operative)

As described in the patient disposition, 58 patients returned for a contemporary follow-up visit, which included a physical, neurological and radiographic examination. Excluding the 3 deaths, these 58 patients represent a 7 to 11 year long-term follow-up of 95 % (58/61) of the theoretically available cases.

General findings from the follow-up are presented in table 4. Findings from self-administered assessments completed by the patients during the follow-up visit are presented in table 5. The self-administered assessments included an evaluation of the patient's pain using a Visual Analog Scale (VAS), their disability using the Oswestry Low Back Pain Disability Questionnaire and their general health using the SF-36 Health Survey.

In order to better understand the benefits and risks of the implant, patients were first requested to recall their pain and activity prior to the Prodisc-L implantation and to quantify their recollections. After answering questions regarding their preoperative medical state, the patients were asked about their current pain and activity. Similar to asking a question pertaining to overall satisfaction, asking the patient to describe their pain and activity before implantation and 7 to 11 years after provides a good indication of the benefits and problems associated with the device.

The mean time from the original implantation to the contemporary follow-up was 104 months (8 years and 8 months) with the range being 85 months (7 years and 1 month) to 128 months (10 years and 8 months). No complications were reported which were related to the device. Complications related to the surgery included 2 sexual dysfunctions (retrograde ejaculations) (3.1 %), 1 hematoma with an infection (1.6 %) and 2 categorized as other (3.1%). After 7 to 11 years 63.6% of the patients (35/55) said they were entirely satisfied with the Prodisc-L implant surgery, 29.1% (16/55)

said they were satisfied and 7.3% (4/55) said they were not satisfied. We believe this is a clinically high rate of satisfaction (i.e., a total of 92.7%) for a treatment of low back pain, particularly after 7 to 11 years follow-up.

A comparison of the preoperative ratings by the patient of both back and leg pain and activity relative to contemporary values, some 7 to 11 years later, clearly indicates patients have less pain and are also more active. For back pain, 57.4% (31/54) of the patients indicated they had either no pain or mild pain at the contemporary follow-up visit versus 5.6% (3/54) preoperatively. The same was true for leg pain, 77.8% (42/54) of the patients said that they had either no pain or mild pain at the follow-up versus only 14.8% (8/54) preoperatively. The improvement in patient activity is as dramatic. Seven plus years after Prodisc-L implantation 81.5% (44/54) of the patients said that their activity was either normal or lightly limited versus 16.7% (9/54) preoperatively. There was no difference between the one and two level patients.

The VAS scores indicate a similar pattern. For back pain, the preoperative VAS was 8.6, as compared to the post-operative VAS of 3.2 on a 10 cm scale. For leg pain, the preoperative VAS was 7.1 and, 7 to 11 years post-operative was 2.1 also on a 10 cm scale. Both of these differences are highly statistically significant in a paired t-test $p < 0.001$. Again, there was no difference between the one- and two-level patients.

Lastly, the mean Oswestry score at the long-term follow-up was 9.2 with a standard deviation of 7.9. This represents patients having minimal disability.

Characteristics	Categories	Contemporary	Preoperative*
Time since surgery, months	Mean	104	
	SD	10.78	
	Max	128	
	Min	85	
Complications postoperative	Device related	0 (0.0)	
	Non device related		
	Sexual	2 (3.1%)	
	Haematoma/Infection	1 (1.6%)	
Satisfaction with Prodisc-L	Other	2 (3.1%)	
	Entirely satisfied	35 (63.6%)	
	Satisfied	16 (29.1%)	
	Not satisfied	4 (7.3%)	
Back pain			
Intensity	None	10 (18.5%)	0 (0.0%)
	Mild	21 (38.9%)	3 (5.6%)
	Moderate	18 (33.3%)	9 (16.7%)
	Severe	5 (9.3%)	42 (77.8%)
Frequency	Episodic	30 (68.2%)	13 (24.1%)
	Continuous	14 (31.8%)	41 (75.9%)
Daytime hours of pain	Day	22 (50.0%)	16 (29.6%)
	Night	2 (4.6%)	0 (0.0%)
	Both	20 (45.5%)	38 (70.4%)
Leg pain			
Intensity	None	31 (57.4%)	7 (13.0%)
	Mild	11 (20.4%)	1 (1.8%)
	Moderate	10 (18.5%)	9 (16.7%)
	Severe	2 (3.7%)	37 (68.5%)
Frequency	Episodic	14 (60.9%)	14 (29.8%)
	Continuous	9 (39.1%)	33 (70.2%)
Daytime hours of pain	NA	31 have no pain	7 had no pain
	Day	15 (65.2%)	13 (27.7%)
	Night	0 (0.0%)	1 (2.1%)
	Both	8 (34.8%)	33 (70.2%)
Root involvement	NA	31 have no pain	7 had no pain
	L3/L4	1 (4.3%)	3 (6.4%)
	L4/L5	22 (95.7%)	38 (80.8%)
	Both	0 (0.0%)	6 (12.8%)
	NA	31 have no pain	7 had no pain

Table 4: General follow-up findings

* Values are based on patient's recollection.

Characteristics	Categories	Contemporary	Preoperative
Side of pain	Right	12 (52.2%)	21 (44.7%)
	Left	7 (30.4%)	13 (27.7%)
	Both	4 (17.4%)	13 (27.6%)
	NA	31 have no pain	7 had no pain
Activity	Normal	25 (46.3%)	3 (5.6%)
	Lightly limited	19 (35.2%)	6 (11.1%)
	Obstructed	8 (14.8%)	32 (59.2%)
	Totally obstructed	2 (3.7%)	13 (24.1%)

Table 4: General follow-up findings (cont.)

Characteristics	Categories	Contemporary	Preoperative
VAS			
Back pain	Mean	3.2	8.6
	SD	2.9	2.1
	Max	10	10
	Min	0	0
Leg pain	Mean	2.1	7.1
	SD	2.7	3.4
	Max	8.9	10
	Min	0	0
SF-36			
Physical functioning (PF)	mean	50	NA
Bodily pain (BP)	mean	44	NA
Role-physical (RP)	mean	47	NA
General health (GH)	mean	50	NA
Vitality (VT)	mean	50	NA
Social functioning (SF)	mean	49	NA
Role-emotional (RE)	mean	52	NA
Mental health (MH)	mean	42	NA
SF-36 Global	mean	385	NA
Oswestry Score	Mean	9.2	NA
	SD	7.9	NA
	Max	33	NA
	Min	1	NA
Satisfaction with Prodisc-L	Entirely satisfied	35 (63.6%)	
	Satisfied	16 (29.1%)	
	Not satisfied	4 (7.3%)	

Table 5: Self-administered assessment findings

Independent radiographic and clinical findings

Dr. Raymond Linovitz, San Dieguito Orthopaedics, Encinitas, CA, a spine surgeon was used as an independent evaluator of the radiographic and clinical information. Copies of preoperative, postoperative, intermediate follow-up and contemporary follow-up visit radiographs were made when available. He examined the radiographic information for each patient and documented his findings on the Radiographic Report Form. Additionally he was also provided the clinical information in the form of a case summary for each patient.

Presented below is a summary of his findings

The radiographic review focused on:

- the vertebral bone response specifically implant loosening, migration or subsidence
- the durability of the implant i.e. was there any mechanical failure or breakage
- was there spontaneous fusion of the implanted motion segment
- were there any signs of tissue response or irritation (chronic inflammation) that could be seen due to wear debris that inevitably would be produced at the polyethylene/metal articulation
- revisions or removal of implants
- additional subsequent surgeries performed

The clinical data review focused on:

- intraoperative complications
- postoperative complications
- patient population that was utilized in this study
- neurological side effects or sequelae
- patients pain and function outcomes
- return to work status
- any additional treatment or surgery required

Radiographic findings

Preoperatively all the cases showed moderate to severe degenerative disc disease. In many cases the DDD was isolated to one level but in many cases the disease was at several levels.

Overall there was a benign vertebral bone response seen from the implants particularly considering the long-term follow-ups. There was no implant migration or subsidence of any significance and all implants appeared stable with no signs of loosening. There were no signs of implant breakage or mechanical compromise. There were no signs of any implant removals or revisions.

There were no signs of tissue response that could be attributed to chronic inflammation.

In several cases there were surgical procedures performed at levels other than the Prodisc-L level, such as fusions and laminectomies. This is not surprising as these were patients with disease that were followed for a long period of time and it is likely that some of them would become symptomatic and require intervention at other levels. The subsequent disease that manifested in these patients after surgery could not be attributed to the implantation of the Prodisc-L.

There were 4 cases (#4,#12,#30,#58) that were subsequently surgically fused from a posterior approach using pedicle screws. In these cases the Prodisc-L was still in place in the intervertebral space and in all cases appeared to be solidly fixed and stable. All 4 cases appeared to be successfully fused. There were 6 cases (#3,#10,#28,#42,#48,#49) with some osteophyte formation. In most of these cases there was a tendency for the patients to form osteophytes that could be seen at other levels in some cases prior to Prodisc-L surgery. The osteophytes at the implanted level in these cases were not extensive and did not affect the motion at these segments. Clinically there was no correlation between the presence of these small osteophytes and a patient's outcome. These patients had outcomes that were typical of the other cases. Patient #35 had a spontaneous fusion with the Prodisc-L in place after 8 years. There was definitely no motion at the implanted segment. In evaluating the immediate postoperative radiographs it does appear that the implant disrupted the anterior vertebral endplate and possibly induced a fusion response. This patient is clinically doing well and is no worse radiographically and clinically than if a fusion had originally been performed.

Clinical outcomes

The patients selected for these implantations all had longstanding DDD and in most cases had symptoms for several years and had failed conservative therapy. They are a typical fusion population.

There were several intraoperative complications that were not implant related and would be expected as a result of performing the anterior approach. There were several postoperative complications (2 sexual dysfunctions, 1 hematoma/infection) which again are not implant related and are anticipated using the anterior approach.

There were no unusual postoperative findings or side effects. A high percentage of patients got early and prolonged pain relief and in some cases out to 10 years.

Summary

In summary, although a relatively small group of patients, the duration of follow-up (10 years) is something that is not commonly seen with new procedures. In fact the duration of follow-up on these cases rivals anything that has been seen in the technologies now used for fusion in the U.S. Radiographically the Prodisc-L is remarkably well accepted in the intervertebral space with no migration, subsidence or loosening of any significant degree. There was a very low percentage of reoperation, only 4 of 61, and these patients did well with an ultimate fusion and were not compromised by their initial treatment with Prodisc-L, and actually got years of pain relief before requiring fusion. Clinically there was a low number of anticipated non-implant related complications. Most patients achieved a significant level of pain relief that was sustained for many years postoperative.

Conclusion

In conclusion, based on the patients' and surgeons' evaluation as well as an independent U.S. spine surgeon's review, at a contemporary follow-up for 61 of the 64 Prodisc-L implanted patients at 7 to 11 years post-implantation:

- 95% of the patients returned for follow-up.
- One third (33%) of the patients were 2 level Prodisc-L implantations.
- All implants were intact and functioning.
- There was no evidence of subsidence or migration.
- There were no implant revisions or removals.
- There was a significant reduction ($p < 0.001$) in patient-reported back and leg pain.
- 92.7% of the patients report they were satisfied or entirely satisfied with the procedure.
- There was no outcome difference between 1 and 2 level Prodisc-L implantations.
- There were no device related safety issues, untoward effects, complications or adverse events.

The benefits of the surgery and implant continued over the 7 to 11 years since the original surgery. A high percentage of patients continued to experience reduced pain and improved function relative to pre-operative levels and was satisfied with the implants. No safety issues, untoward effects, complications or adverse events occurred due to the implant.

Prodisc-L®. Retrospective Clinical Study: 7 to 11 Year Follow-up.



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