



A retrospective review of 345 patients with lumbar TDR in two years follow-up over 10 years of practice in one Belgian clinical center : Results

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Low back pain is one of the most common symptom with high cost for the public health. When conservative treatment fails, patients are heading to surgical treatment. Instead of lumbar arthrodesis, we can offer an alternative that will keep the intervertebral mobility : Total disc replacement (TDR) by prosthesis. Many studies have published good results rate over 80%, since first implantation in 1984. Believing in keeping the mobility, we promote TDR since 2002. This retrospective study review 345 patients with two years follow-up. The outcomes show 81% of good and really good results, according to gain of improvement on VAS and ODI scores. We report 6.88% of complications for the abdominal approach and 4.57% for the device, without harmful complication. Same results are obtained in case of postdiscectomy syndrome.

Keywords : low back pain ; total disc replacement ; lumbar disc prosthesis.

INTRODUCTION

Low back pain is one of the most common symptoms in the general population, one symptom which has a cost for public health because of the impact on the personal, social and professional life. The incidence of the low back pain has been increasing over the year (13).

In the past years, the surgical treatment for this pathology when the conservative treatment failed

was to replace the disc by either a fusion or prosthesis (motion).

The fusion has been the gold standard treatment for a long time and still is the popular option but in the past years the TDR has been winning on popularity. Yet, the subject is controversial in the spine surgery.

Several studies have shown the higher efficiency of cages and prosthesis over the PLIF which cause more stiffness and stress on the adjacent level.

Some meta-analyses comparing fusion to TDR concluded on the safety and the efficiency of the TDR (19). Those have shown that TDR has slightly better results than fusion (8,14).

For our clinic center, after the performance of the first results, we promoted the TDR for those patients with chronic lumbosciatic symptoms instead of the traditional body fusion.

We would choose the TDR rather than the arthrodesis (ALIF) because we believe in keeping the mobility of the degenerated level like for other de-

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generative osteoarticular pathologies (ex : Hip -> Total Hip Replacement, Knee -> Total Knee Replacement).

But the economical aspect is interfering with the selection of the best treatment. Indeed, in our country the cage is less expensive than the prosthesis. Patients are reimbursed for one prosthesis under certain condition (proof by discography for instance).

In this article, we'll review 345 files of patients who were operated by TDR (2 types of prosthesis, one surgeon) for Degenerative disc disease (DDD), postdiscectomy, since January 2002 until December 2012.

History

The concept of discal prosthesis has been described for the first time in 1966 by Fernström (4).

The German surgeon K. Buttner-Janzen designed the first SB Charité prosthesis which was implanted for the first time in September 1984 (3). In France, The Prodisc prosthesis was developed by Thierry Marnay in 1987.

Since 2000 and over the years, those prostheses have shown a great success in Europe and in the USA.

Today, we have more than 13 years of practice and good experiences with the Prodisc-L device in our clinic center with 500 patients and more to come.

Physiopathology

We know from our anatomy knowledge that, in healthy lumbar disc, only the outer third of the disc is innervated. However, discs taken out from low back pain patient were analyzed and the inner third was innervated as well suggesting the role of ingrowth nerve in the disc could be the origin of the chronic low back pain (6). It would be the inflammatory reaction from the conflict between the nucleus and the annulus fibrosus which would stimulate the Nerve Growth factor (NGF) and initiate the nerve ingrowth into the disc. This new innervation would be the cause of chronic low back pain as the NGF

stimulate the nerve growth, the nerve has a hypersensitivity to NGF which cause hyperalgesia due to an inflammatory reaction (feedback positive effect by the NGF), studied on mice (9).

As we remove the disc, we take out the origin of the pain replacing the disc by an arthrodesis's cage or a prosthesis depending on the philosophy we believe in. We decided to believe in motion to keep the mobility of the lumbar segment and to preserve the adjacent level and the sagittal balance as well.

METHOD AND MATERIALS

The Total Disc Replacement (TDR) is one of the surgical treatment we use for low back pain caused by DDD, post-discectomy, disc-arthrosis in our clinic center.

We reviewed all the patient files since January 2002 to December 2012.

The objective of the review is to acknowledge that TDR is an efficient and safe procedure in a cohort of 345 patients.

Those patients had low back pain for at least 6 months and tried different conservatory treatments as physiotherapy, kinesiotherapy, infiltration but without improvement of the pain. Most of them have quit their job because the pain was not bearable. It is an economic factor that should not be neglected.

Before the surgery, an X-Ray and an MRI of the lumbar segment have been asked. For those who have one degenerative disc, we would perform a discography to confirm the pain is discogenic.

For those patients with several degenerated disc in the MRI, we would as well perform a discography to confirm the level of the painful disc. As already known, a radiographic degenerated disc could most of the time be asymptomatic (12).

For those women of a certain age, we would ask for an osteodensitometry to eliminate the possibility of osteoporosis which is a contraindication for the TDR.

It should be known that in Belgium a discography is mandatory to be reimbursed for a prosthesis which is one of the reasons why this controversial procedure is being done.

The data of the review are a preoperative Oswestry Disability Index (ODI) Questionnaires and VAS and a postoperative ODI and VAS 3 months, 6 months and 2 years after the surgery. We measure the efficiency of the TDR by those data.

A regular lumbar X-Ray is taken at D-1 post-op, 3 months, 6 months. At 1 year post-op a dynamic X-Ray

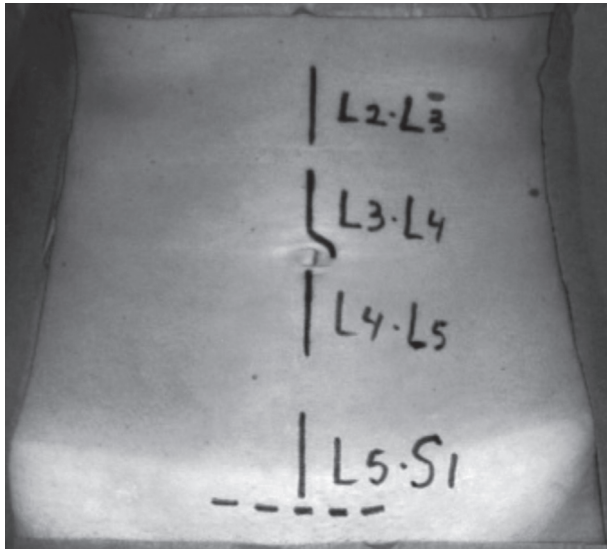


Fig. 1

(extension/ flexion) is taken to measure the angle of the remaining mobility of the operated level. The angle is measured from the upper endplate of the lower lumbar vertebrae and the lower endplate of the upper lumbar vertebrae. We made the inventory of all the patients who had post-operative complication either due to the anterior approach or the prosthesis itself.

As the review is retrospective since 2002 we didn't get all the data on 345 patients. We took out from the review the files which did not have at least one ODI (N = 22) and VAS (N = 16) value in pre-op and post-op for the pain evaluation. We kept all 345 for the other data as complications, indications, mean of age, mean of gender, levels study, etc.

Surgical technique :

All the procedures were performed by retroperitoneal anterior approach in French position by the same orthopedic surgeon. For the L5-S1 level, the incision would be on the median line under the umbilicus leading by the fluoroscopy. For the L4-L5, the incision would be on the median line around the umbilicus and under leading by the fluoroscopy (Fig. 1).

Most of the time, the L5-S1 level is approach by the RIGHT side of the white abdominal line and because of the arterial iliac bifurcation the L4-L5 level or above would be approached by the LEFT side of the white ab-

dominal line. For the L4-L5 level, we would carefully ask for an angioscanner to visualize the iliac vessels bifurcation before surgery. It is usually not necessary for the L5-S1 level.

This retroperitoneal anterior approach is a non-invasive way to approach the spine as the tissues are not cut but separated by surgical tampons in the sliding layer. ("plan de glissement"). When we finally got to the spine itself, small veins and small artery usually are right on the disc in the median line on L5-S1. Iliac collateral veins sometimes need to be ligated because the left iliac vein is going to be isolated to have a good access to the disc on L4-L5. It provides the careless rip of the left iliac vein which could be a source of a major blood loss (one case in our study without consequences). The presence of a vascular surgeon in the clinic is requested, and needs to be close by in case something goes wrong.

We slowly access the spine on the painful disc. A control of the lumbar level by fluoroscopy is performed and then we can proceed on the discectomy with care and put the prosthesis in place. A fluoroscopic control of the prosthesis in AP view and lateral view is performed during the operation to assure that the implant is not too posterior or to avoid a lateral misalignment which could result in a neurological complication by compression.

The material we work with is Prodisc-L (Synthes) (N = 335) and M6 (SpinalKinetics) (N = 10).

RESULTS

The age range of our reviewed population ranges from 21 to 64 years old. The mean is 44 years old.

The patients distribution is 204 women (59%) and 141 men (41%).

All patients had low back pain for at least 6 months with or without pseudosciatica. They received a conservative treatment which was not sufficient before heading to surgery.

In the choice of indication, we identified several etiologies as disc-arthrosis/DDD (72%), post-discectomy (24%), disc herniation (2%), adjacent segment failure (ASF) (2%).

80% of the patients were operated on one level, 18% on two levels and 2% on 3 levels.

Most of the time the concerned disc is L5-S1 (60%) then L4-L5 (16%), L3-L4 (3%), L2-L3 (1%).

In the study, knowing it is a retrospective analyze of 345 patients, only 323 of them filled up the ODI

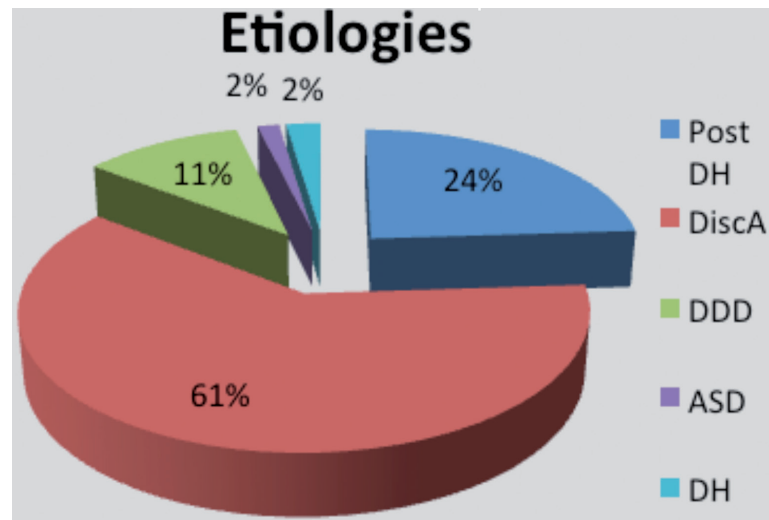


Fig. 2

form (2 years post-op) and 329 of them evaluated their pain on the VAS (unfortunately it is a global ODI and VAS, we didn't ask one for the back pain and one for the leg pain).

In preoperative time, the distribution of the ODI data is centered at 50% and the mean of VAS distribution is 75%.

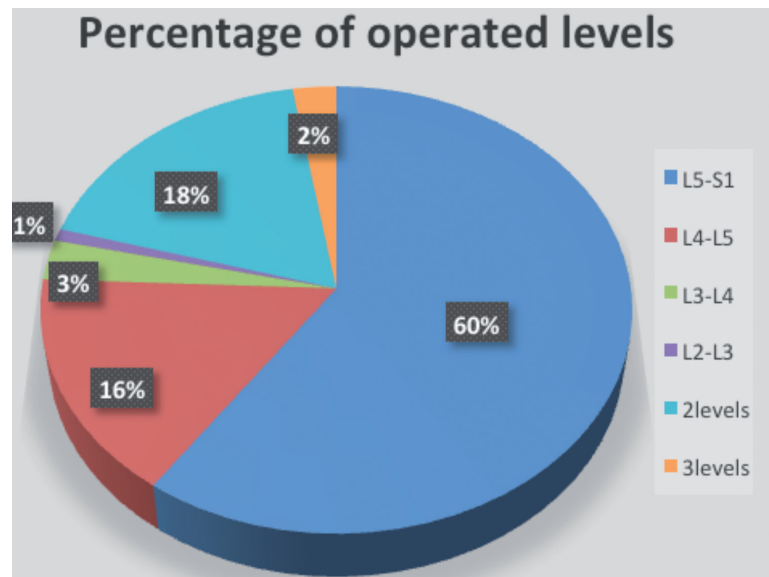


Fig. 3

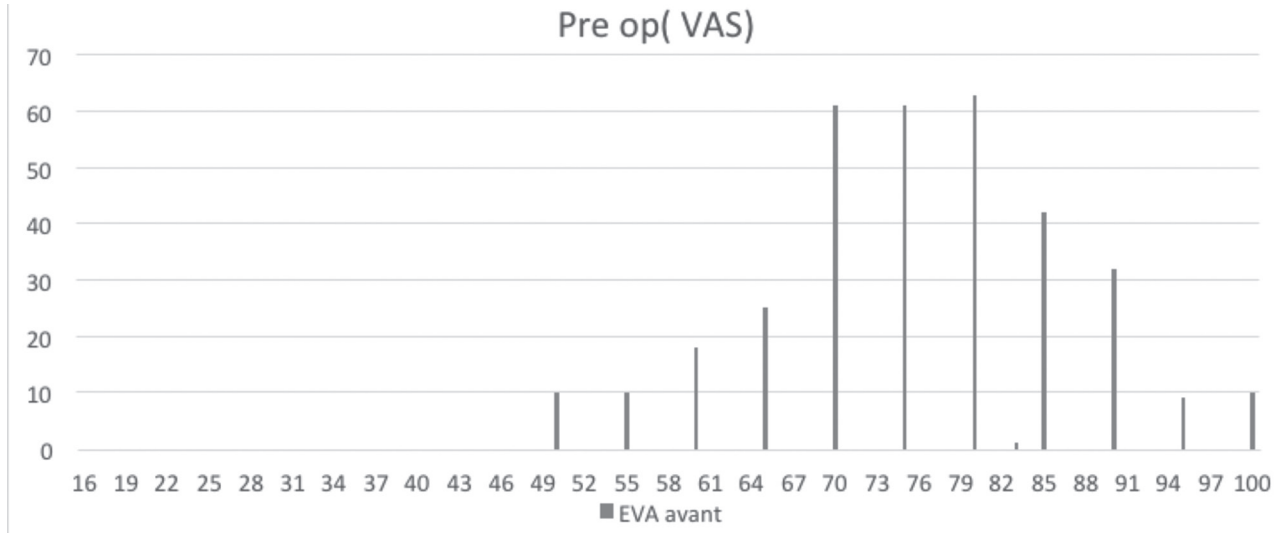


Fig. 4

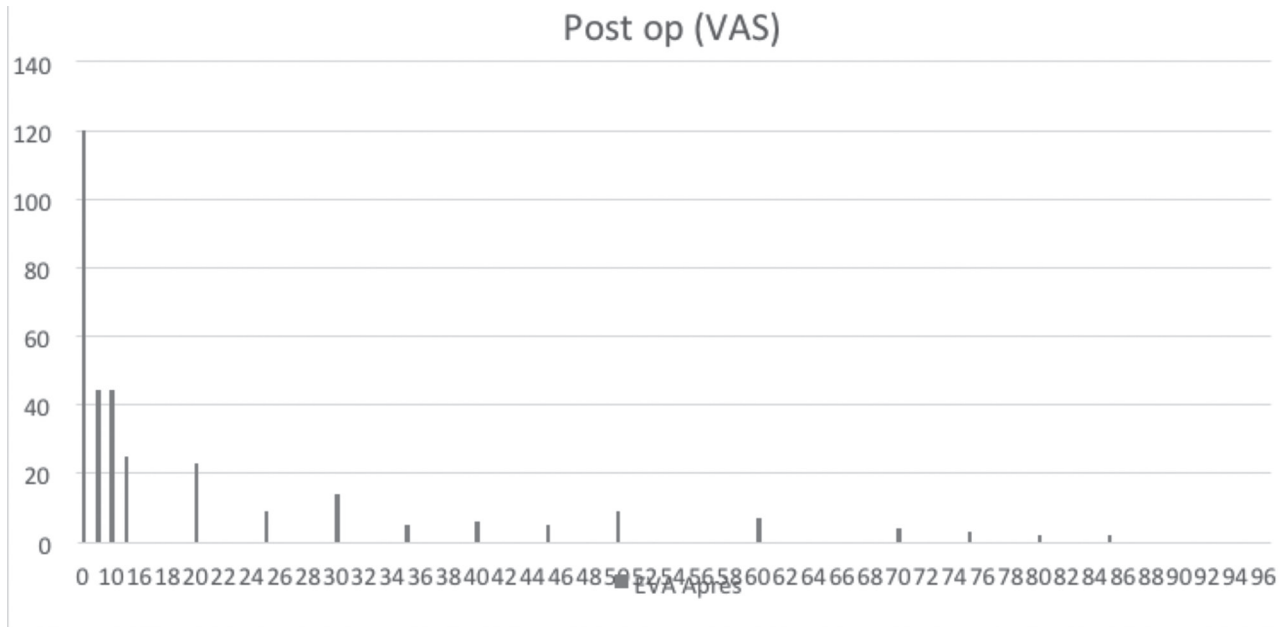


Fig. 5

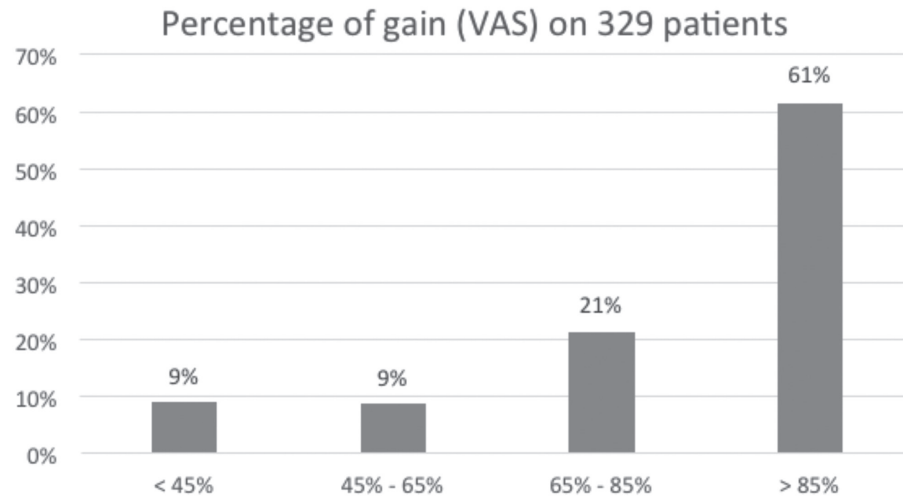


Fig. 6

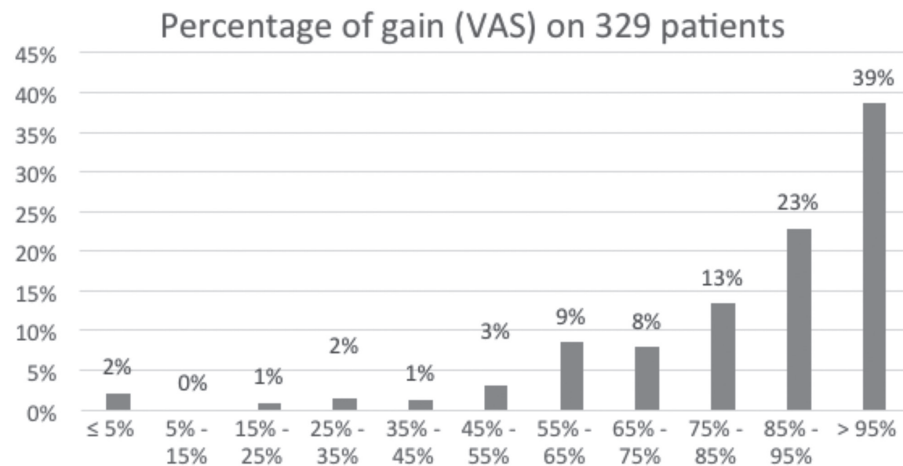


Fig. 7

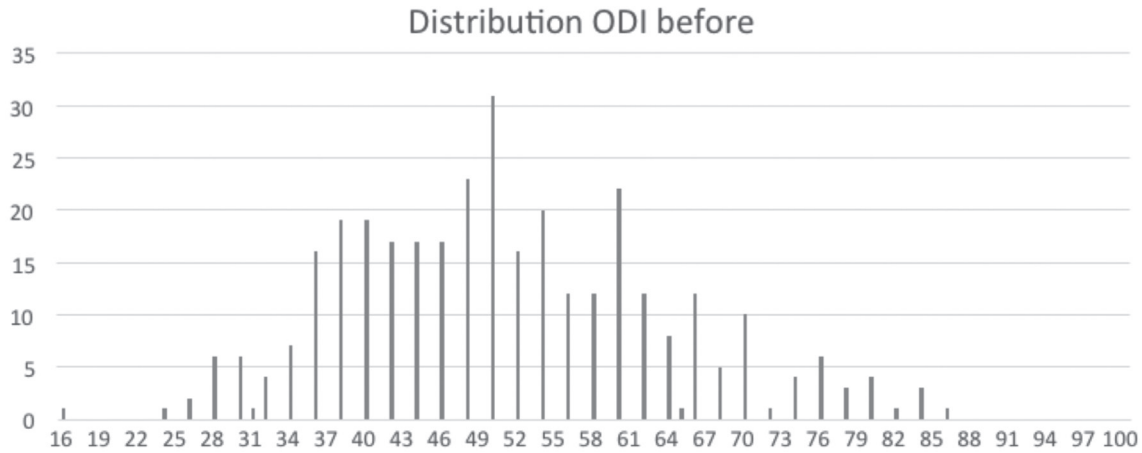
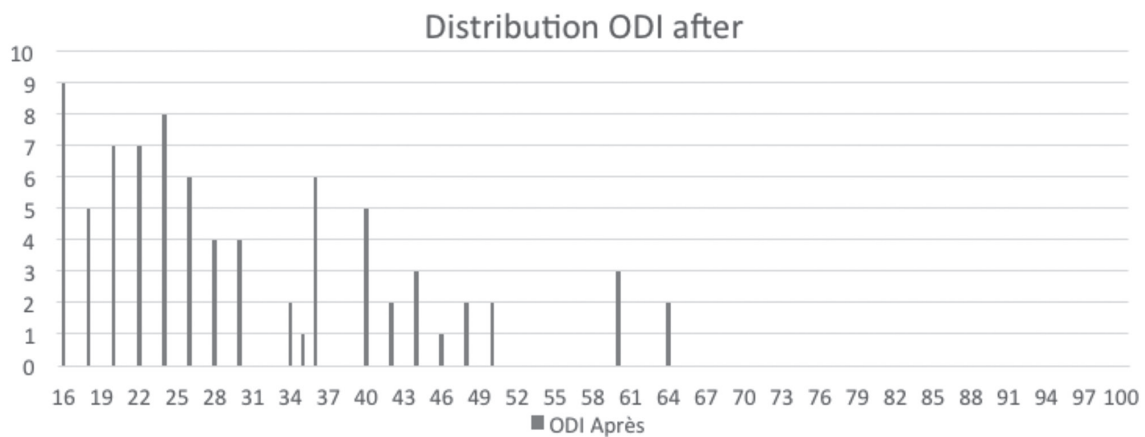
Both of the ODI and VASgraphs have similarity on the distribution, most of the patient are close to the mean, with a normal distribution.

Then, in postoperative time (2 years after surgery), the majority is moving to the left side of the graph on both data which illustrate well the efficiency of the procedure.

Visually, we can acknowledge the strong tendency of a good improvement of the pain reduction and the quality of life as well (ODI) in general.

But we wanted to know what was the impact and the gain of improvement for each patient. For every patient, we calculated the gain between before and after surgery. We put all those data on a graph which we divided in 4 groups : improvement of 0-45% (Bad results), improvement of 45-65% (mixed results), improvement of 65%-85% (good results), improvement over 85% (really good results).

As we can observe on the graph below, if we focus on the ODI score data, 81% of the patients

*Fig. 8**Fig. 9*

have good and really good results. This is similar to the VAS results (82%) (Fig. 6).

10% have bad results.

If we split the results in more categories (Fig. 10, Fig. 11), we have a better idea of the distribution of the results.

For those patients who have more than 85% gain on quality of life which is 53% of the patients they went back to work, stopped taking painkiller pills, and some of them who were doing sport before started doing sport again. They are having a low back painless life at a two-year follow-up.

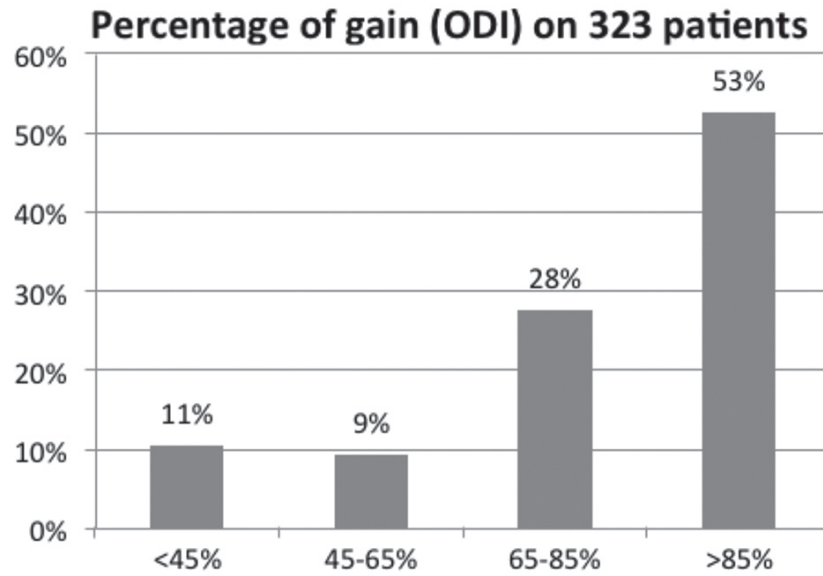


Fig. 10

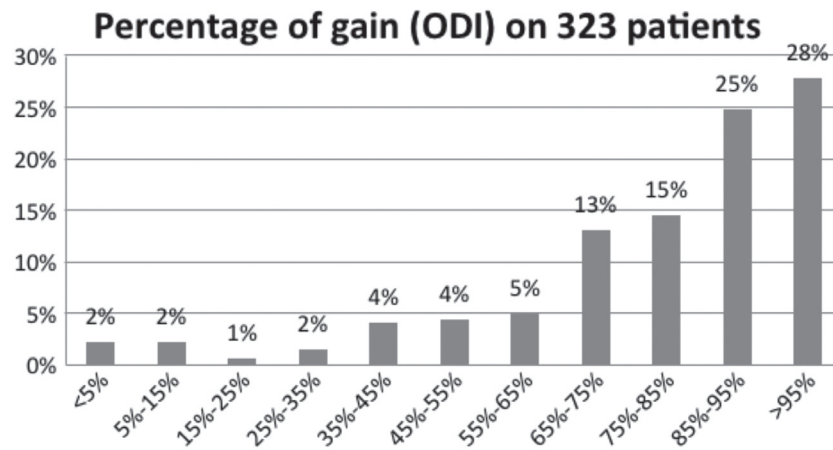


Fig. 11

Clinical examples

1. A 36 years old woman operated on January 2002 with a Prodisc L5-S1 obtained very good results after 12 years (pain free, prosthesis mobility : 14°, no wear debris) (Figs. 12, 13).
2. A 43 years old man operated on 3 discs with Prodisc-L obtained very good results after 7 years (pain free, practicing sport, 3 prostheses mobility : 37°) (Fig. 14-Fig. 18).

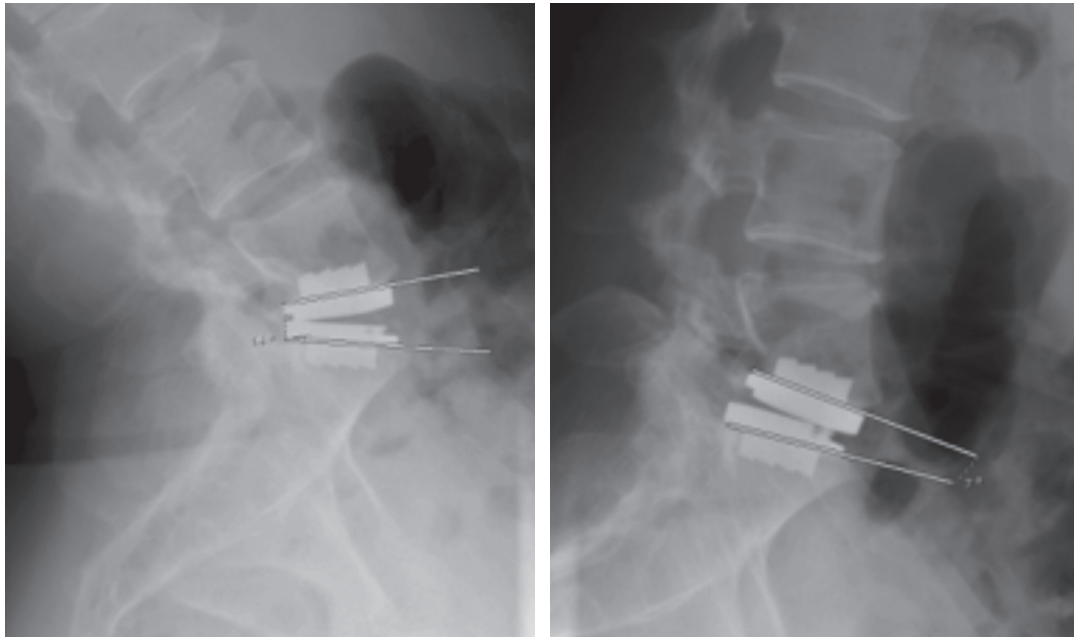


Fig. 12-13

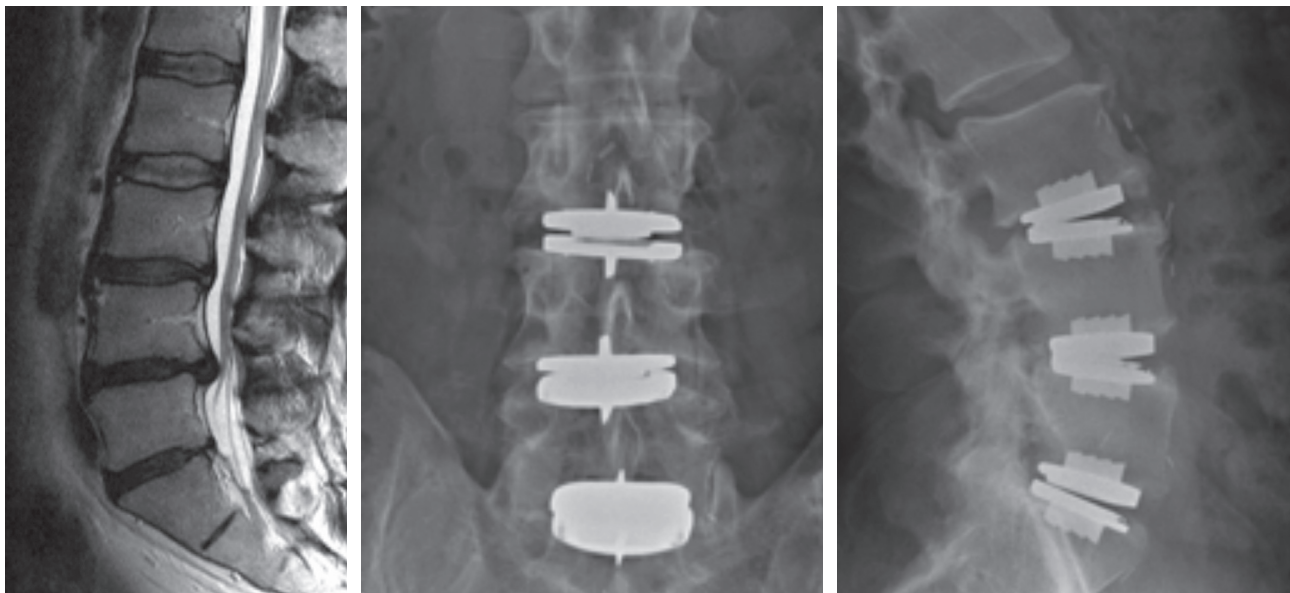


Fig. 14, 15, 16

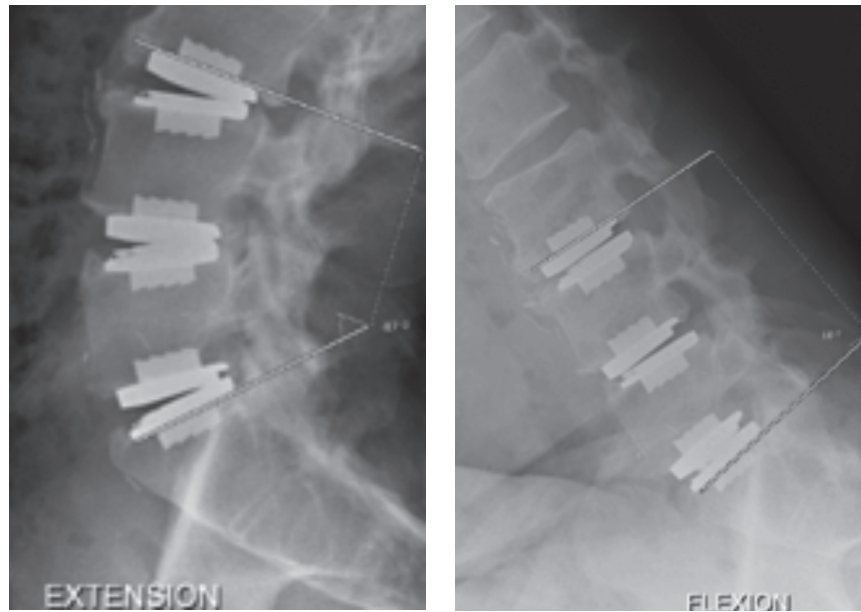


Fig. 17, 18

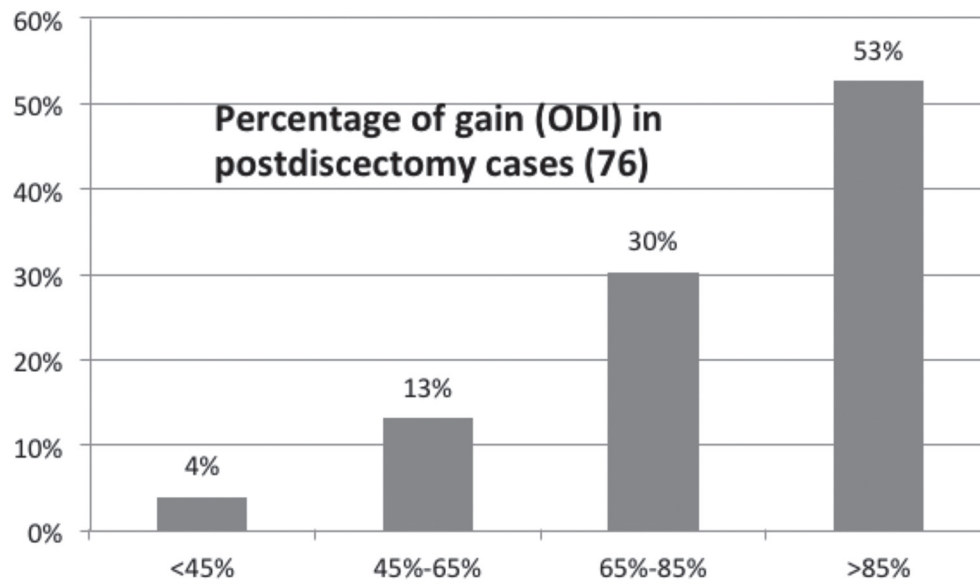


Fig. 19

Preop ODI in 76 postdiscectomy patients

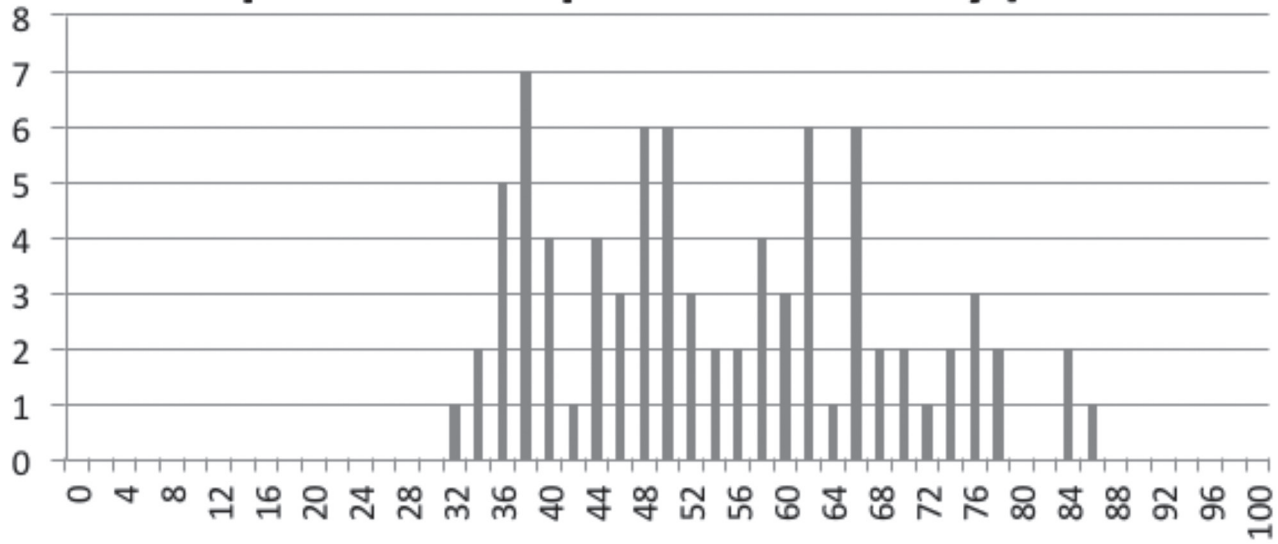


Fig. 20

Post op ODI in 76 postdiscectomy patients

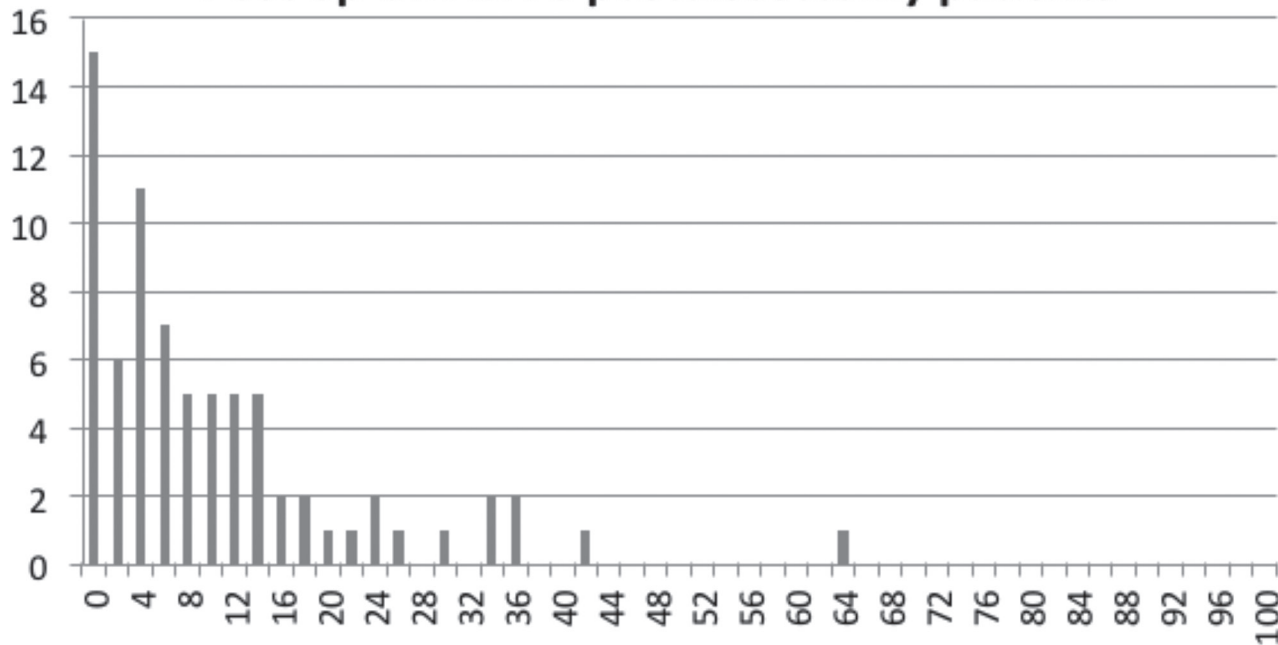


Fig. 21

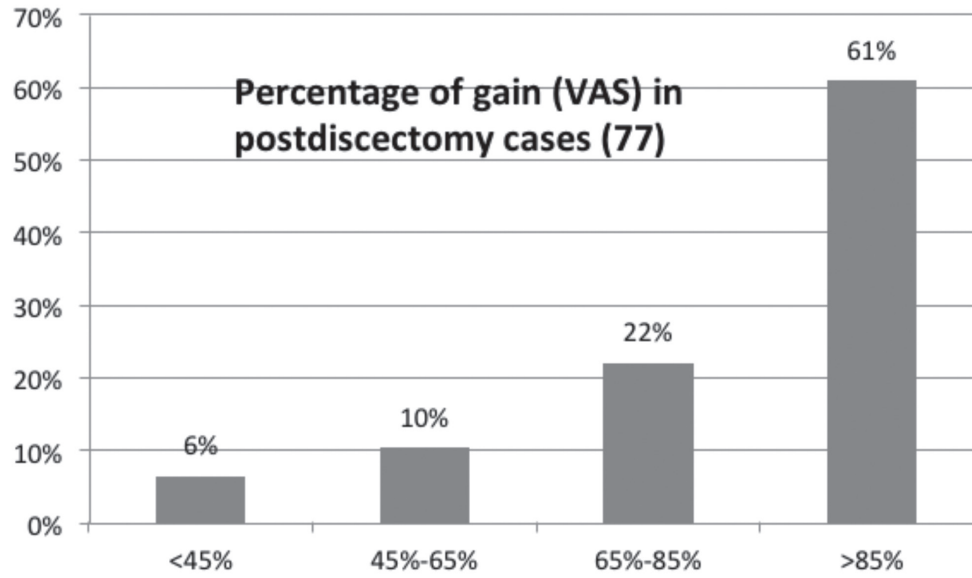


Fig. 22

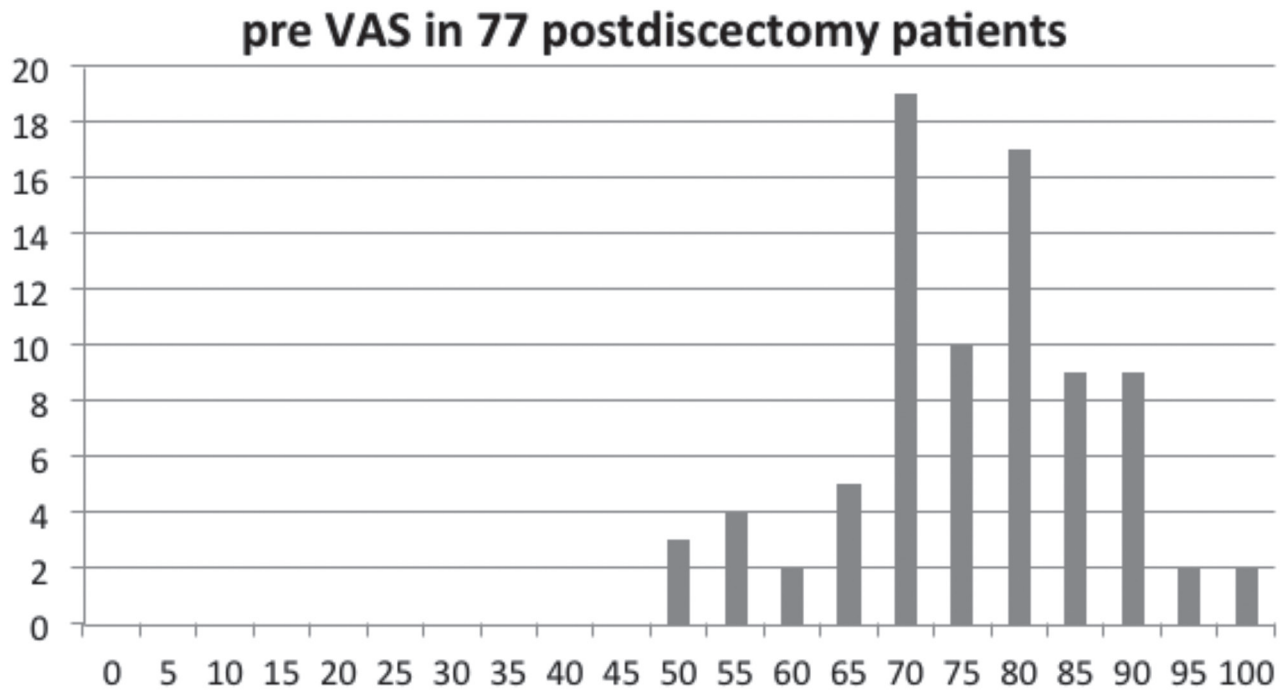


Fig. 23

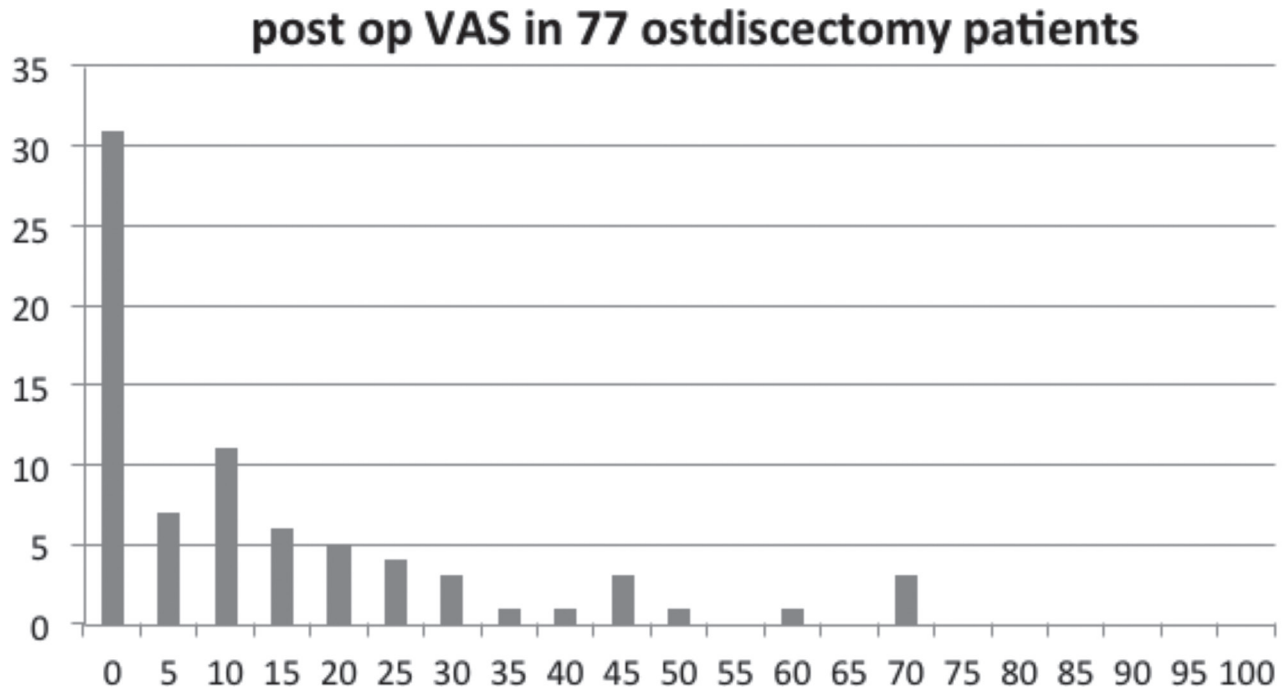


Fig. 24

Postdiscectomy cases

In the 345 files, 81 patients underwent discectomy surgery before TDR. We proceeded the same way to analyze the ODI and VAS results.

The percentage of gain on post-discectomy is 83% for ODI and 83% for VAS which is slightly comparable to the overall result of the 345 patients (which includes post-discectomy cases).

Based on the results we have, we don't think the post-discectomy is a contraindication to a prosthesis and we could say that it is as safe and effective as for other indications.

Complications :

In our review, one procedure has been stopped because of a hemorrhage following an iliac vein wound, and another procedure as well because of the tissue fibrosis.

2 retrograde ejaculations were reversible after 3 months due to an irritation of the superior hypogastric plexus. 6 retroperitoneal hematomas, 2

abdominal wall hematomas and 10 retroperitoneal lymphatic seroma required reoperation for drainage. We recall 1 urethral stenosis and 1 case of diastasis recti.

Regarding the device, we have identified 3 mobilizations of implant (less than 2 mm) 4 mobilizations of PE (less than 4 mm), 6 impactions of the implant in the bone (identified on the X-ray, all were asymptomatic), 3 cases of sciatica because of a postero-lateral bone fragment due to the plugging of the device, 2 cases of vertebrae fissure without consequences in the course of a 2 levels operation only.

In total, we have for the abdominal approach 6.88% of complications but only 2 cases were permanent. And for the device we have 4.57% of complications with 5 surgical revisions without consequences afterwards : 3 surgical revisions were performed because of a sciatic pain in the leg caused by a bone fragment expelled in the canal which was taken out in one case by anterior approach and in two cases by posterior approach. One surgical revision was performed because of a sciatic pain in the

leg caused by a misalignment of the prosthesis. And one last surgical revision was due to an acute lumbar pain in post-operative recovery (18 months after surgery) caused by a dislocation of the polyethylene, in this case we decided to replace the prosthesis by an arthrodesis by cage by an anterior approach which did not cause problems.

Please note that metallosis has been described in a case report regarding the Maverick disc prosthesis (5). It needed to be removed for persistent pain caused by motion between the endplate and the prosthesis. During the surgery they found metallosis around this metal-metal device which would be dramatic if it would reach the canal.

In our study, the devices used are not a metal-metal prosthesis but a metal-PE-metal (Prodisc, M6). As far as we were able to follow our patients we don't recall having any problem of the sort which is comforting.

In our knowledge, no infection cases or neurological cases has been identified. But 2 cases of *unexplained neuropathy of the inferior limbs* (0.5%) with *negative EMG* were non-reversible. There was no improvement of the symptoms even years later.

We acknowledge during the recovery a short period of time during which some patients present what we call a *redistracton syndrome*. It expresses a pseudosciatic symptom likely as an aspecific stretching painful sensation in the posterior surface of the buttock and thigh uni- or bilaterally, symptom which disappears after a month, and without consequences.

DISCUSSION

In the past years, the surgical treatment for the low back pain regarding the indications when the conservative treatment failed is to replace the disc by either a cage (fusion) or prosthesis (motion) even though the PLIF stays an option as well.

The fusion has been the gold standard treatment for a long time and still is the popular option but in the past years the TDR seems to win on popularity. Yet, the subject still remains controversial in the spine surgery today. Some questions remain unanswered and make surgeons uncertain of the safety and efficiency of the TDR procedure.

Different studies (2,7,11,15,17) have published good results rate over 80%. Other studies, comparing prosthesis versus arthrodesis, have shown that the prosthesis is slightly better than the fusion (1,16,18,20).

The major indication of the TDR is DDD which is as the name says correctly a degenerative disease of the disc. That implies an evolution of the disease through the years, one disc after another perhaps the spine can be damage from cervical to lumbar. So, the pain can come back in another disc if the disease is progressing.

In our review, the L5-S1 is the most painful disc. We had cases of 2 or 3 levels surgery which have good outcomes.

The prosthesis will it be without risk at all ? How many years before starting to significant complications ? When researching the literature for TDR complication, we didn't find so many articles. One case report was interesting regarding a reoperation of a Maverick device with metallosis, they removed it and did an interbody fusion. No complication (5).

In some meta-analyses we find different data regarding complications in TDR, but it is not well described. The complication rate published in a meta-analysis is 5.8% (8).

In our review, we can say that we have a reasonable percentage of complication of 6.88% for the abdominal approach and 4.57% regarding the device with only 5 patients who underwent surgery again (over 345 patients).

In case of facet arthropathy and adjacent level disease, is the TDR doing any good ? Few patients of ours had an infiltration in the facet joint years later after TDR but we didn't recall the exact number as it was not a criteria of analysis in the review.

In case of previous discectomy, in our experience, there is no difference either for the abdominal approach or the implant procedure. The quality of life and the pain level are improving as well. This is supported by Leahy *et al* (10). They compare two groups of patient, one with previous discectomy and the other which didn't have this surgery. The results have shown that the outcome of TDR in a post-discectomised patient is not compromised.

So having a previous surgery in the diseased disc doesn't influence the outcome.

CONCLUSION

Even though this study is retrospective, after 10 years of practice in the TDR field, we are confident to assess it is a safe and efficient procedure with high level of recovery, as long as the surgeon is careful during the retroperitoneal approach and choosing the right material. Even so, no one is sheltered of any complication during the anterior approach either to place a cage or prosthesis. The choice of preserving the ROM is a question of philosophy even though meta-analyses comparing interbody fusion and TDR described TDR as the first choice. In case of failure in TDR, they recommend then to perform an interbody fusion (8).

We have 81% of good results on two-years follow-up in more than 10 years of practice. We have good results as well on postdiscectomy patients. None of the complications were threatening life as far as we were able to follow our patient. No cases of wear debris were reported to us until today in our patients. We didn't identified so far some alteration of the implant or the adjacent bone on the few patients operated in the early '00. Those could be treated on a long-term follow-up review in a further study.

Weakness of the article : Retrospective study ; the co-writer is the surgeon himself.

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