



Michael Stoffel

15.1 Introduction

Degeneration of the functional spinal unit (FSU) can lead to various pathologies like disc herniation, spinal stenosis, segmental instability, or intradiscal pain, respectively. This can result in back pain and – in case of nerve root irritation – sciatica.

Since pain educed by a degenerated joint is linked to its mobility, suppression of the latter should induce pain relief. Hence, spinal fusion became the golden standard treatment for disc arthrosis, degenerative segmental instability, and spondylolisthesis, respectively.

Nowadays, various fusion techniques exist with acceptable results. However, disadvantages arise from the high surgical effort associated with these techniques – where incidence and severity of complications rise with increased surgical complexity -, the risk of pseudarthrosis, and the increased incidence of adjacent level degeneration, resulting from the transfer of mechanical stress to adjacent segments [1, 2].

Since fusion rate and clinically successful pain relieve are not strictly interrelated in patients after spondylodesis, the complete immobilization of the FSU might not be an absolute prerequisite for pain relief in these patients.

These considerations led to the development of non-fusion techniques (AKA: dynamic techniques) in spine surgery with the following goals:

- relief pain caused by the degenerated FSU,
- maintenance or regain of stability,
- maintenance of mobility and function of the spine,
- reduction of stress transfer to adjacent FSUs as a longterm goal.

Non-fusion techniques can be divided into (a) joint replacement techniques (AKA: arthroplasty, prosthetics), where the nucleus pulposus (nucleus replacement), the whole disc (total disc replacement = TDR), or the facet joints (facet replacement), respectively, are removed and replaced, or (b) dynamic stabilization techniques, where posteriorly placed implants limit the range of motion in a FSU thereby leading to a redistribution of mechanical stress between the disc, the facet joint, and the implant (load sharing). In this group, pedicle-screw based dynamic systems (PDS) and interspinous process devices (IPD) exist.

Aim of the presented cases is to point out,

- in which clinical scenario the most popular non-fusion techniques (IPD, TDR, pedicle-screw based systems) might be used,

M. Stoffel (✉)
Department of Neurosurgery, Helios Klinikum
Krefeld, Krefeld, Germany
e-mail: Michael.stoffel@helios-gesundheit.de

- which pros and cons exist for their use in comparison to traditional fusion techniques,
- which level of evidence exists for clinical decision-making.

15.2 Case Description

15.2.1 Case 1

A 79 y/o male patient presents to our outpatient clinic with a 1 year history of progressive bilateral neurogenic claudication with a maximal walking distance of 200 meters, paravertebral and radiating pain (VAS 8) with right-sided predominance. The physical examination reveals no neurological deficit. His complaints are not responsive to pain killers or physiotherapy. He is a hobby volcanologist and significantly impaired in his activities of daily life. Due to a coronary heart disease and status post coronary stent (drug-eluting) implantation 1.5 years ago, he is on clopidogrel 75 mg (Fig. 15.1).

He is sent to his cardiologist for check-up prior to surgery, who agrees to the transient removal of clopidogrel perioperatively.

Monosegmental decompression via a right-sided approach (interlaminar fenestration) and bilateral decompression in undercutting technique is proposed as first tier therapeutic option. Implantation of a interspinous process device

(IPD) is mentioned as alternative. Clopidogrel was paused 7 days prior to surgery, surgery was uneventful, and the patient left the hospital on post-op day 5. Clopidogrel was restarted on post-op day 7. Three months later he presented again in our outpatient clinic on a routine basis with completely resolved claudication.

15.2.2 Case 2

A 42 y/o male patient suffered from low back pain for app. 7 years with increasing severity exacerbating during sitting and trunk rotation with intermittent pseudoradicular bilateral sciatica. Visual Analogue Scale (VAS) back 6–7 and leg 4, Oswestry Disability Index (ODI) 37. Conservative treatment via the local pain clinics and inpatient rehabilitation remained without lasting benefit. Axial spondyloarthritis was ruled out by a rheumatologist. The patient's quality of life was significantly impaired and he was on sick leave (Fig. 15.2).

Diagnostic bilateral facet joint infiltrations L4/5 and sacroiliac joint infiltrations didn't lead to pain relief. Accordingly, the following therapeutic options were mentioned: total disc replacement (TDR), fusion, spinal cord stimulation, and continuation of conservative measures. TDR was recommended, the patient consented to the procedure, was operated via a left retroperitoneal approach, and a prosthesis was implanted.

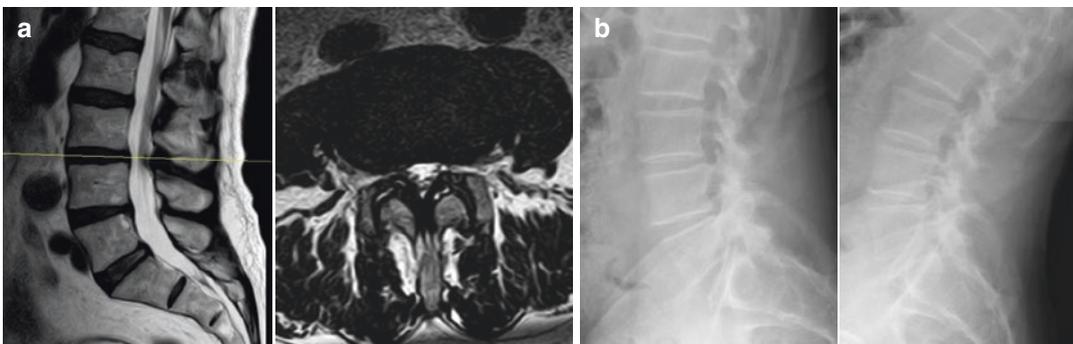


Fig. 15.1 (a) T2-weighted lumbar MRI exhibits bilateral facet joint hypertrophy causing narrowing of the recesses with right-sided predominance. In addition, a small facet

joint cyst is detected on the right side. (b) Lumbar flexion-extension films rule out significant segmental hypermobility



Fig. 15.2 (a) T2-weighted lumbar MRI exhibits a mono-segmental degenerated disc L4/5 with reduced disc height, hypointense signal, a dorsal high intensity zone in the vicinity of the dorsal annulus and a disc protrusion. (b) Lumbar flexion/extension radiographs rule out segmental

hypermobility. (c + d) a.p. and lateral radiographs and flexion-extension films on post-op day 2 confirm the adequate position of the implant and the mobility of the segment

Surgery was uneventful and the patient was discharged on post-op day 4. Post-operative physiotherapy was recommended. He came for routine follow-up 3 months post-op in our outpatient clinic. He was completely weaned from the pain killers, VAS back 2, VAS leg 0, ODI 18, and has resumed his work.

15.2.3 Case 3

A 48 y/o female presented to our outpatient clinic with a 9 months' history of left-sided sciatica predominantly in the L5-dermatome (VAS 7), a L5-dysesthesia, and back pain of similar intensity. Two years ago, she had surgery for disc herniation in L4/5 and L5/S1 on the right side due to a foot drop. After surgery, she had good symptom relief for app. 15 months. The patient was on opioids and non-steroidals for at least 3 months. On physical examination, she was significantly obese

(BMI 30), had diabetes, L5-hypesthesia, and a slight weakness of the left knee extension. The mobility of the lumbar spine was significantly reduced and she reported exacerbation of the back pain on spinal process pressure in the lower lumbar region (Fig. 15.3).

Bilateral medial nerve blocks for L4/5 und L5/S1 led to app. 80% reduction of back pain for 24 h. Surgery was offered including dynamic stabilization of L4/5 and L5/S1, decompression of the spinal recess and the foramina in both segments on the left side. Spondylodesis was mentioned as alternative.

Postoperatively, the sciatica disappeared completely, local back pain along the wound remained, and the patient was discharged on post-op day 8. Inpatient rehab was organized. Three months later, the patient exhibited no motor deficit anymore, denied sciatica or dysesthesia and a reported a VAS (back) 2 without pain medication.



Fig. 15.3 (a, b) T2-weighted lumbar MRIs reveal disc degeneration and protrusion in L4/5 and L5/S1, status post interlaminar fenestrations in L4/5 and L5/S1, facet joint hypertrophy leading to recess stenosis in both segments and left-sided foraminal stenosis. The exact dimension of space occupation in the spinal canal is not

unequivocally assessable due to scarce tissue. (c) Myelography shows significant left-sided space occupation at L4/5 compressing the L4 and L5 root, disc space narrowing in L4/5 and L5/S1, and osteochondrosis. (d) Lumbar radiographs reveal proper implant placement L4, L5, and S1

15.3 Discussion of the Cases

15.3.1 Case 1

A. Why were things done this way

Spinal decompression via a microsurgical approach sparing the midline structures is currently the standard surgical option in patients with neurogenic claudication significantly impaired by their symptoms. Surgery is simple and the clinical benefit foreseeable and durable. Segment instability was ruled out. Platelet aggregation inhibition could be stopped prior to surgery. Therefore, no potentially increased risk of bleeding had to be expected. IPD-implantation appears a valid alternative in this case, however,

much less durable and associated with a much higher reoperation rate.

B. Were they in accordance with the literature guidelines

According to the observational cohort of the SPORT-trial, patients with symptomatic spinal stenosis have a significantly better outcome compared to conservatively treated patients. The benefits of surgery are stable up to 8 years after surgery [3]. Concerning the technical realization of the decompression, laminotomy (uni- or bilateral) sparing the midline structures seems to be the current standard in Europe. Facet sparing laminectomy is still an alternative. A Cochrane Review summarizes 4 high-quality and 6 low-quality RCTs that compare laminotomy

with laminectomy. Thereby, laminotomy and conventional laminectomy show similar effects on functional disability and leg pain. However, perceived recovery at final follow-up was better after bilateral laminotomy. Furthermore, the risk of iatrogenic instability and the severity of postoperative low back pain was less after uni- or bilateral laminotomy [4].

The effectiveness of IPDs in patients with neurogenic claudication was proven in a meta-analysis of two RCTs and eight prospective cohorts. All studies showed improvement in validated outcome scores after 6 weeks and 1 year. Pooled data based on the Zurich Claudication Questionnaire of the RCTs were more in favor of IPD compared to conservative treatment [5]. Compared to surgical decompression, IPDs showed no significant differences for low back pain, leg pain, ODI, and Roland Disability Questionnaire (RDQ) 12–24 months after the procedure, but a significantly higher risk of reoperation (odds ratio 3.34) [6]. This was confirmed in a recent RCT [7].

In patients dependent on platelet aggregation inhibitors, open surgery might be more prone to clinically significant rebleeding – a situation that might represent a niche for the use of percutaneous IPD placement.

As yet, the use of IPDs in the treatment of neurogenic claudication is not covered in a guideline.

C. How strong is the level of evidence available to date

Surgical decompression and the implantation of interspinous process devices improve clinical outcome in neurogenic claudication compared to nonoperative treatment (Level-I Evidence). The direct comparison of both procedures shows - at least in short-term – similar results in relieving symptoms of claudication, however, IPD proved to be much less durable than surgical decompression (Level-I Evidence).

15.3.2 Case 2

A. Why were things done this way

The patient suffered mainly from severe chronic low back pain with significant impact on his activities of daily life including work, refractory to conservative treatment. The MRI exhibited monosegmental degenerative disc disease (DDD) in L4/5. A significant contribution of the facet joints L4/5 and the sacroiliac joints to the generation of pain was ruled out by diagnostic infiltrations. Accordingly, the degenerated disc itself was the supposed pain generator and TDR or fusion would have been the first tier therapeutic options. TDR was our recommendation due to the potential advantages over fusion, i.e. maintenance of mobility and function of the spine and reduction of stress transfer to adjacent FSUs as mentioned above.

B. Were they in accordance with the literature guidelines

Due to results of the Norwegian Spine Study Group, patients with a history of low back pain for at least 1 year, an ODI of at least 30, and degenerative changes in one or two lower lumbar spine levels exhibit significantly better ODI-reduction after TDR than after rehabilitation [8]. Above that, low back pain, patients' satisfaction, SF-36 physical component, self efficacy for pain, and Prolo scale showed significant differences in favour of surgery in this study. Adjacent level disease was observed at similar frequencies at the 2-year follow-up in the surgical and the rehab group [9].

Six randomized controlled trials (RCTs) comparing TDR with spinal fusion for chronic back pain were summarized in a Cochrane Review [10]. Thereby, patients who underwent TDR had slightly better outcomes in terms of back pain and function 24 months after surgery than those who had fusion surgery, although the differences did not appear clinically significant.

Finally, there is growing evidence that the clinical outcome after lumbar TDR is durable over up to 10 years [11, 12].

C. How strong is the level of evidence available to date

The levels of evidence supporting TDR-surgery in this case are as follows:

- TDR superior to conservative treatment (Level-I Evidence)
- TDR at least not inferior to fusion surgery (Level-I Evidence)
- durable clinical outcome after TDR up to 10 years (Level-III Evidence)

As yet, no clear cut guideline for the indication of TDR is existing.

15.3.3 Case 3

A. Why were things done this way

The patient suffered from back pain and radiculopathy. Reason for the radiculopathy was compression of the nerve roots L4 and L5 on the left side, main reason for the back pain was disc degeneration in L4/5 and L5/S1 leading to disc height reduction and facet joint irritation in both segments, responsive to facet joint infiltration. Accordingly, a procedure including nerve root decompression and bisegmental stabilization seems the obvious causal therapy and only the method of stabilization seems questionable. In our experience, mono- or bisegmental dynamic stabilization in the degenerated spine achieves similar results to spondylodesis, however, with less surgical effort. Therefore, dynamic stabilization is our first choice when stabilization is indicated in degenerative disease other than spondylolysis or high-grade spondylolisthesis.

B. Were they in accordance with the literature guidelines

Reoperation for recurrent disc herniation leading to conservatively refractory pain is well established and – as known from a subgroup analysis of the SPORT-trial – patients will likely improve significantly following surgery, but possibly not as much as with primary discectomy [13]. The use of medial nerve blocks for short-term relief of facet-mediated chronic low back pain is suggested in the “Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine” [14]. Unfortunately, outcome prediction for subsequent lumbar fusion

is not possible from the current literature [14]. The same guidelines consider lumbar fusion an option when disc herniation is associated with evidence of instability, chronic low-back pain, and/or severe degenerative changes [15]. The replacement of spondylodesis by a dynamic pedicle-screw based system seems a valid option in the degenerative spine. Thereby, the surgical step that provides the basis for solid fusion – e.g. discectomy and intervertebral cage implantation – can be spared, rendering the surgical procedure less invasive. Thereby, one of the potential advantages is that less complex procedures are also less prone to complications, a fact that could be proven in a RCT comparing different techniques for spondylodesis [2]. Various dynamic pedicle-screw based systems are on the market with different biomechanical ideas behind them. As yet, the most frequently studied systems are the Dynesys (Fa. Zimmer) and the Cosmic (Fa. Ulrich) system. Both systems have been investigated in numerous cohort studies and their efficacy to reduce pre-operative back pain resulting from degenerative disease could be proven – at least on a short term basis (e.g. [16, 17]). However, no high-quality data comparing spondylodesis with dynamic stabilization are available. The data of an RCT on that topic are still pending.

C. How strong is the level of evidence available to date

The levels of evidence for reoperation for recurrent disc herniation is derived from subgroup analysis of an RCT and an observational cohort (Level-II Evidence). The decision for dynamic pedicle-screw based stabilization is based on cohort studies (Level-III Evidence).

15.4 Conclusions and Take Home Message

Interspinous process devices exhibit similar short-term relief of symptoms from neurogenic claudication than open decompression, but with a much higher reoperation rate. Accordingly, their use is reserved for niche indications – at maximum.

Patients with significant chronic low back pain refractory to conservative treatment, who reveal radiological signs of mono- or bisegmental disc degeneration, are potential candidates for lumbar TDR. Segment hypermobility and predominant facet joint syndrome should be ruled out.

Dynamic pedicle-screw based stabilization might be an alternative for spondylodesis in mono- or bisegmental degenerative disease, although sound data comparing these methods are not available so far.

Pearls

- IPDs don't seem to provide durable results and serve – at maximum – for niche indications
- Lumbar TDR is a valid option in selected cases of DDD – probably even with satisfying long-term results
- solid scientific results supporting the use of dynamic pedicle-screw based systems, although widely used and promising, are still pending

Editorial Comment

We strongly recommend to read this excellent chapter on a topic, that has produced considerable controversy in the last 20 years. A “hype” has been provoked initially for these new technologies leading to a massive overuse in unproven indications, which has then triggered an overreaction against them. So on most of them the majority of the spine community has closed the book already. This chapter now provides a very thorough and sober evaluation of the existing high-level evidence in this field. Overall it shows for IPDs (that is the stand-alone variant replacing decompression) and lumbar TDR to have a place in highly selected patients. However, acceptance within the community is questionable these days and the industry is probably not interested in the production of devices, which do not sell in high numbers. As it

evolves, and evidenced by the preliminary data of a RCT comparing fusion with dynamic stabilization (unpublished data) pedicle-screw-based systems may have a place in low grade degenerative instabilities of the lumbar spine.

References

IPD

1. Ghiselli G, Wang JC, Bhatia NN, et al. Adjacent segment degeneration in the lumbar spine. *J Bone Joint Surg Am.* 2004 Jul;86-A(7):1497–503.
2. Fritzell P, Hägg O, Nordwall A, Swedish Lumbar Spine Study Group. Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish lumbar spine study group. *Eur Spine J.* 2003;12(2):178–89.
3. Lurie JD, Tosteson TD, Tosteson A, Abdu WA, Zhao W, Morgan TS, Weinstein JN. Long-term outcomes of lumbar spinal stenosis: eight-year results of the spine patient outcomes research trial (SPORT). *Spine (Phila Pa 1976).* 2015;40(2):63–76.
4. Overvest GM, Jacobs W, Vleggeert-Lankamp C, Thomé C, Gunzburg R, Peul W. Effectiveness of posterior decompression techniques compared with conventional laminectomy for lumbar stenosis. *Cochrane Database Syst Rev.* 2015;(3).
5. Moojen WA, Arts MP, Bartels RH, Jacobs WC, Peul WC. Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: a systematic review and meta-analysis. *Eur Spine J.* 2011;20(10):1596–606.
6. Wu AM, Zhou Y, Li QL, Wu XL, Jin YL, Luo P, Chi YL, Wang XY. Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: a systematic review and meta-analysis. *PLoS One.* 2014;9(5):e97142.
7. Meyer B, Baranto A, Schils F, Collignon F, Zoega B, Tan L, LeHuec JC; NICE Trial Study Group. Percutaneous Interspinous Spacer vs Decompression in Patients with Neurogenic Claudication: An Alternative in Selected Patients?. *Neurosurgery.* 2017.

TDR

8. Hellum C, Johnsen LG, Storheim K, Nygaard OP, Brox JI, Rossvoll I, et al. Surgery with disc prosthesis versus rehabilitation in patients with low back pain and degenerative disc: two year follow-up of randomised study. *BMJ.* 2011;342:d2786.

9. Hellum C, Berg L, Gjertsen Ø, Johnsen LG, Neckelmann G, Storheim K, et al. Adjacent level degeneration and facet arthropathy after disc prosthesis surgery or rehabilitation in patients with chronic low back pain and degenerative disc: second report of a randomized study. *Spine (Phila Pa 1976)*. 2012;37(25):2063–73.
10. Jacobs W, Van der Gaag NA, Tuschel A, de Kleuver M, Peul W, Verbout AJ, Oner FC. Total disc replacement for chronic back pain in the presence of disc degeneration. *Cochrane Database Syst Rev*. 2012.
11. Siepe CJ, Heider F, Wiechert K, Hitzl W, Ishak B, Mayer MH. Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up. *Spine J*. 2014;14(8):1417–31.
12. Plais N, Thevenot X, Cogniet A, Rigal J, Le Huec JC. Maverick total disc arthroplasty performs well at 10 years follow-up: a prospective study with HRQL and balance analysis. *Eur Spine J*. 2017.
13. Abdu RW, Abdu WA, Pearson AM, Zhao W, Lurie JD, Weinstein JN. Reoperation for recurrent intervertebral disc herniation in the spine patient outcomes research trial: analysis of rate, risk factors, and outcome. *Spine (Phila Pa 1976)*. 2017;42(14):1106–14.
14. Watters WC 3rd, Resnick DK, Eck JC, Ghogawala Z, Mummaneni PV, Dailey AT, Choudhri TF, Sharan A, Groff MW, Wang JC, Dhall SS, Kaiser MG. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: injection therapies, low-back pain, and lumbar fusion. *J Neurosurg Spine*. 2014;21(1):79–90.
15. Wang JC, Dailey AT, Mummaneni PV, Ghogawala Z, Resnick DK, Watters WC 3rd, Groff MW, Choudhri TF, Eck JC, Sharan A, Dhall SS, Kaiser MG. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 8: lumbar fusion for disc herniation and radiculopathy. *J Neurosurg Spine*. 2014;21(1):48–53.
16. Stoll TM, Dubois G, Schwarzenbach O. The dynamic neutralization system for the spine: a multi-center study of a novel non-fusion system. *Eur Spine J*. 2002;11(Suppl 2):S170–8. Epub 2002 Sep 10
17. Maleci A, Sambale RD, Schiavone M, Lamp F, Özer F, von Stempel A. Nonfusion stabilization of the degenerative lumbar spine. *J Neurosurg Spine*. 2011;15(2):151–8. <https://doi.org/10.3171/2011.3.SPINE0969>. Epub 2011 May 13.

Pedicle-screw based systems