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Hardware complications and patient satisfaction after semi-rigid dorsoventral spondylodesis using PEEK rods combined with a ‘topping-off’ technique

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Nele Balser
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Hardware complications and patient satisfaction after semi-rigid dorsoventral spondylodesis using PEEK rods combined with a “topping-off” technique

von Nele Balser

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1. INTRODUCTION

1.1. Biomechanics of the spine

The spine represents the largest and most important part of the human axial skeleton. It enables upright walking and bears an increasing load from the head to the hips (see Attachment 1 & 2). The smallest functional spinal union is a motion segment. It is defined as two vertebrae, their linking joints and the surrounding soft tissue (Junghanns, 1951).

Each functional spinal union's range of motion (ROM) is minimal, but the total of these small ROMs enables substantial movements in all directions (Aumüller, Aust, & Doll, 2010). Biomechanical studies have shown the lumbar spine to be in a complex equilibrium of loads. The individual weight, muscular and ligamentary stability as well as flexibility keep the body balanced in different degrees of bending (Butler, Trafimow, Andersson, McNeill, & Huckman, 1990). Pressure, torsion, bending and translational forces are absorbed and distributed by each motion segment. The intervertebral discs cushion axial forces and limit rotation and tension. These forces are compensated both by bony, discal and, ligamentary elements and the muscles (Kummer (1991).

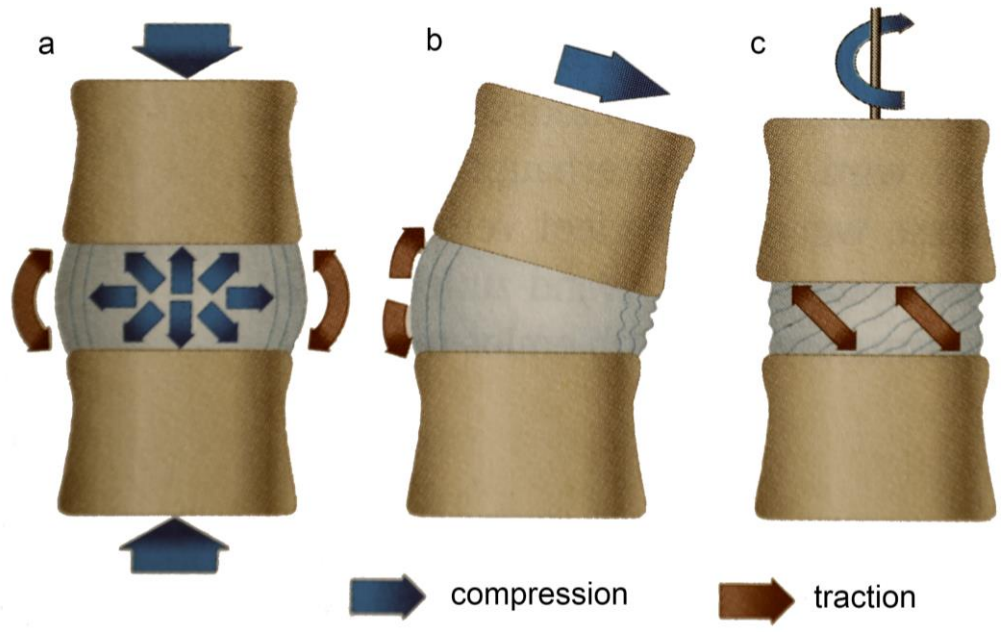

Figure 1: Schematic of a spine segment displaying different forces applying to it; a) axial compression, b) bending, c) rotation; the blue arrows marking compression forces and the red arrows marking tension forces to the intervertebral disc *(Aumüller et al., 2010)*

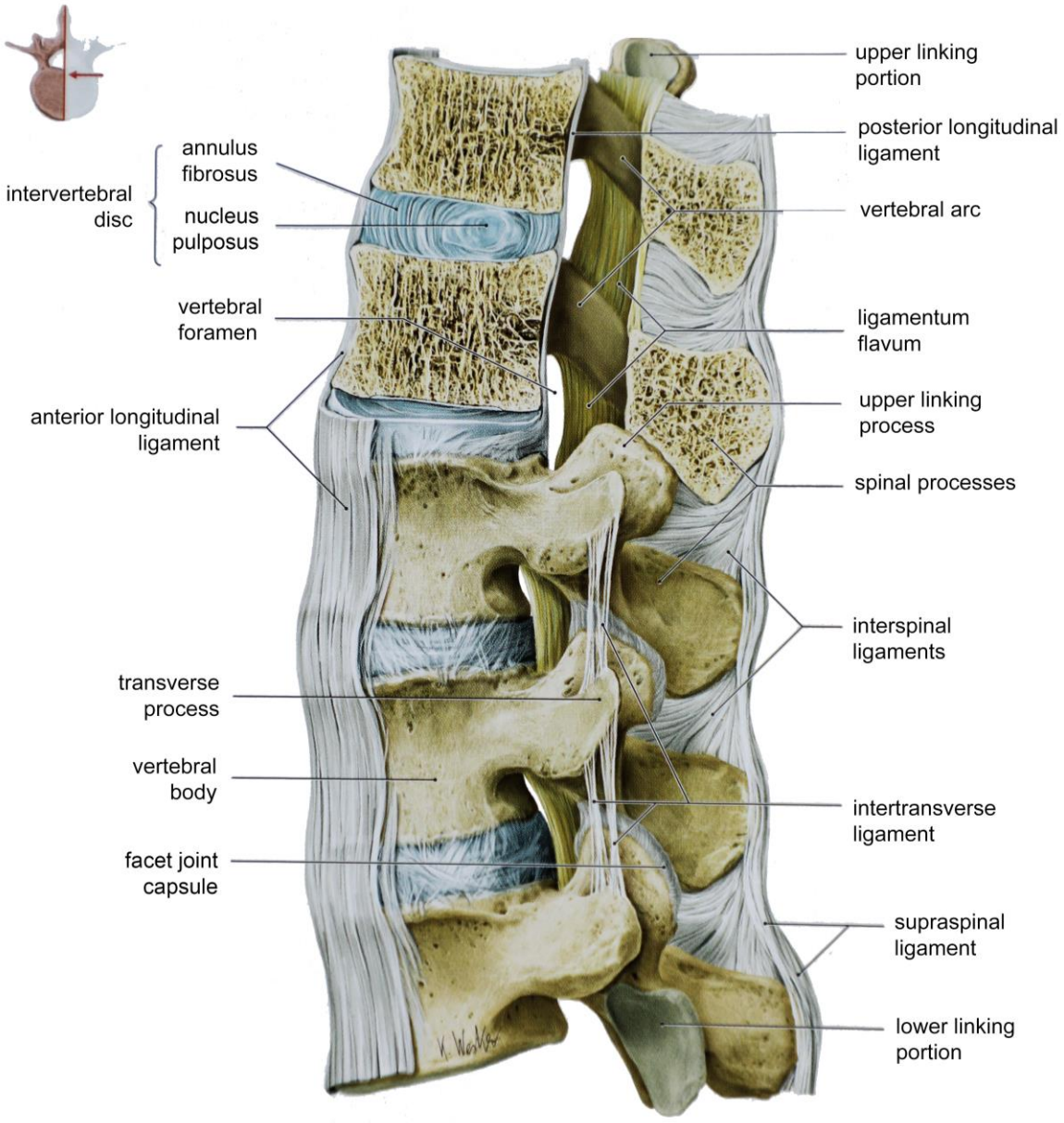

Figure 2: Sagittal view of a thoracic part of the spine, including bones and ligaments, visualising the components of the anterior column on the left side and the posterior column on the right side. (Aumüller, Aust, & Doll, 2017)

Biomechanically, the spine can be divided into an anterior and posterior column. The anterior column consists of the vertebral body and the intervertebral disc. The dorsal column consists of the vertebral arc, the facet joints and the linking ligaments.

Physiologically, the anterior column primarily takes in pressure forces and the posterior column tension forces resulting in the principle of load sharing (Kummer (1991). Hence, the axis of the body's centre of gravity lies anterior to the spine.

During a lifetime, degenerative abrasion and erosion strain this complex balanced system.

1.2. Aetiology of degenerative lumbar spine disease

The pathophysiology of degenerative lumbar spine disease is as various and complex as its treatment. Environmental parameters, such as physical work, obesity, chronic axial compression or degeneration, are influencing factors (Frost, Camarero-Espinosa, & Foster, 2019). Kirkaldy-Willis and Farfan (1982) were among the first to describe the origins of degenerative instability and discogenic pain of the lumbar spine. They assumed that minor changes in segmental balances lead to major malfunctions. The mere ageing of the spine due to the loss of elasticity of the discs and the ligamentary system can lead to disc protrusion and prolapse and then result in a narrowing of adjacent vertebrae (Kirkaldy-Willis & Farfan, 1982; Taher et al., 2012). According to Frymoyer (1985), primary segmental instability develops as a result of degenerative disc disease. Furthermore, Butler et al. (1990) indicated, that facet joint osteoarthritis (spondylosis) occurs after disc degeneration due to biomechanical changes in load sharing.

Regarding changes in bone structure, we find bony growths (spondylophytes), spondylarthrosis and spondylankylosis or spondylolysis. In addition, the ligamenta flava show reactive hypertrophia. All these factors can lead to stenosis of the neuroforamina and then to impingement of the nerves. Finally, degenerative disc disease leads to secondary deformity or instability. Hence, spondylolisthesis and multisegmental degeneration with or without instability are detected in many cases (Kalff, Ewald, Waschke, Gobisch, & Hopf, 2013).

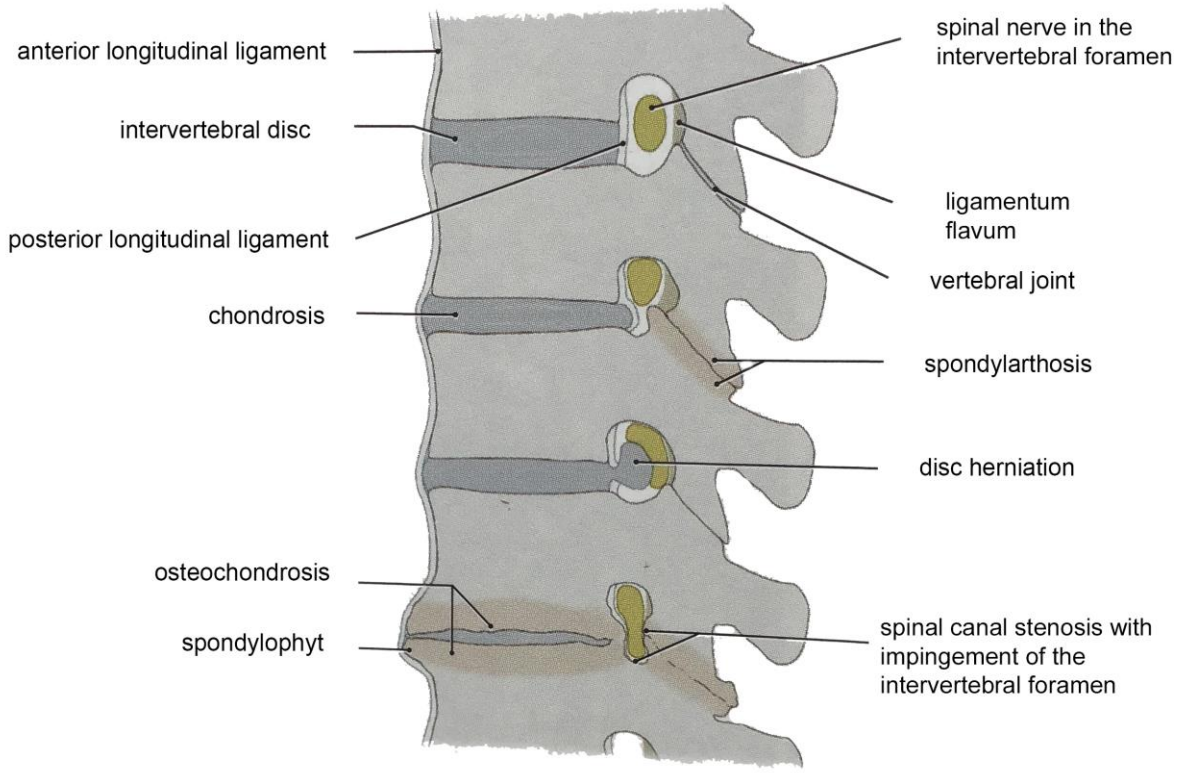

Figure 3: Schematic displaying the various degenerative alterations of the spine that can occur(Aumüller et al., 2010).

Spondylolisthesis can be diagnosed radiographically. It is defined as a misalignment of adjacent vertebrae in the frontal and/or sagittal plane, in one or more segments (Newman, 1955). Various origins exist, and the degenerative form is important because of its frequent appearance. It results from facet arthritis, consecutive joint remodelling and a ligamentary weakness and is seen as a sign of lumbar instability by many surgeons (Försth et al., 2016).

Further, lumbar spinal canal stenosis is a common degenerative change of the spine. It is defined by a narrowing of the lumbar spinal canal due to spondylarthrosis, spondylolisthesis, osteochondrosis (see Figure 4) (Försth et al., 2016). The diagnosis is based on typical symptoms and stenotic segments found on magnetic resonance imaging (MRI).

In addition, lifestyle factors like physical work, for example, lifting of heavy objects or chronic exposure to vibration, affect posture and spinal stability Brinckmann et al. (1994); John W Frymoyer et al. (1980).

Besides, the degeneration of muscular stability affects the complex system of the spine. Obesity promotes the loading on the spine. Increased pressure reduces discal height and then the ability to compensate forces. This might lead to an overloading of

the surrounding structures, for example, the facet joints, spinal ligaments and paraspinal muscles (Ranger, Newell, Grant, Barker, & Pearcy, 2017).

The lumbar spine is primarily affected by these changes since it carries the highest amount of weight and still shows a high degree of flexibility. These degenerative transformations can result in chronic low back pain and neurological deficits (Fairbank et al., 2005; Grifka and Kuster, 2011).

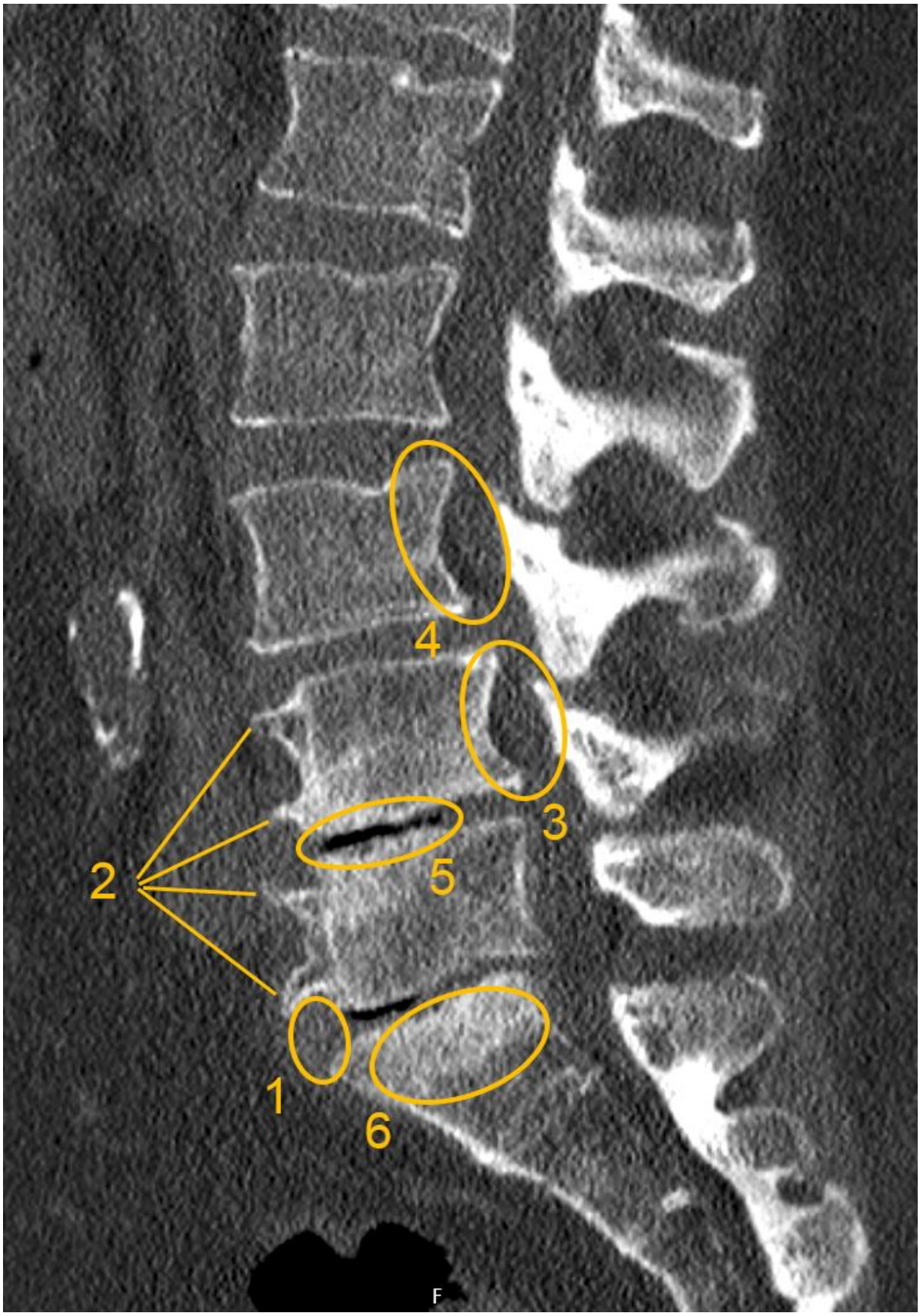

Figure 4: CT sagittal, showing various degenerative changes of a lumbar spine: 1. Retrolisthesis (L5-S1), 2. Spondylophytes, 3. spinal canal stenosis, 4. Corpus deformation of L3, 5. narrowing of L4 to L5 with reduced intradiscal height, 6. Sclerosis of the groundplate. (Source: Radiologie Klinikum rechts der Isar)

1.3. Symptoms

Patients with symptomatic degenerative lumbar spine disease frequently complain of local lumbar and gluteal pain. Radicular pain symptoms, like sciatica or pseudoradicular pain radiation into the legs, are called neurogenic or neuropathic pain. This neurogenic pain arises due to the compression of nerves by prolapsed intervertebral discs, constricting osteophytes or hypertrophic connective tissue.

Symptoms can depend on changes in positioning and movement. The development of symptoms is a slow process as is typical for degenerative diseases (Grifka and Kuster, 2011). The anamnesis of patients reveals long-time pain, eventually accompanied by hypoaesthesia and slow-developing paresis (Kalff et al., 2013). Many patients report years of persisting and worsening symptoms (Cramer and Darby, 2017). Especially in lumbar spinal canal stenosis, dorsal bending and walking worsen the pain, whereas anterior bending alleviates it (Kalff et al., 2013; Thomé, Börm, and Meyer, 2008). In spinal canal stenosis, sitting in an upright position or walking can lead to pain. De-lordosing movements, such as bending over when riding a bicycle, can lead to fewer symptoms (Grifka and Kuster, 2011). In facet joint arthropathy, pain may be accelerated by an extension (Taher et al., 2012). Kalff (2013) remarked that the prevalence of symptoms existing less than a year before starting therapy was associated with a better outcome.

1.4. Epidemiology of degenerative lumbar spine diseases

Degenerative spine disease (DSD) is one of the most important disorders in our population. Sixty per cent of degenerative bony changes are located in the spine. It increases because of demographic changes (Frost et al., 2019; Grifka and Kuster, 2011; Kummer, 1991; Weiss, 2014). DSD gathers various degenerative changes of the bony and ligamentary spine, which can lead to pain, paraesthesia and loss of muscular strength.

Epidemiological studies have shown that 70% of all people suffer from low back pain at least once in their lives (Zdeblick, 1995). Twenty per cent of patients older than 60 years, who suffer from low back pain, are diagnosed with spinal canal stenosis (Boden, Davis, Dina, Patronas, & Wiesel, 1990). DSD has a considerable impact on our healthcare system (Taher et al., 2012). In the United States of America, back

pain, mostly lumbar pain, is the declared diagnosis for 20% of sick leave (Rajaee, Bae, Kanim, & Delamarter, 2012). The number of surgical interventions in that sector is continually rising, resulting in high costs for the healthcare system (Deyo, 2004). Spinal fusions were 3.1% of all operating room procedures in the US in 2011. An epidemiological study of the healthcare cost and utilisation project sponsored by the US Department of Health and Human Services revealed a 70% increase in fusion procedures over ten years. In comparison, the rate of laminectomy remained stable, as shown in Figure 5. Between 1998 and 2008, the increase had been even higher at 137%. In contrast, other surgical procedures associated with degeneration and a higher life expectancy, such as hip replacement, percutaneous coronary angioplasty and laminectomy, increased at more moderate rates, (50%, 39% and 11%, respectively). In addition, the average age for spinal fusion increased, and the in-hospital mortality decreased significantly. The average age for receiving lumbar fusion was 56 years (Weiss, 2014).

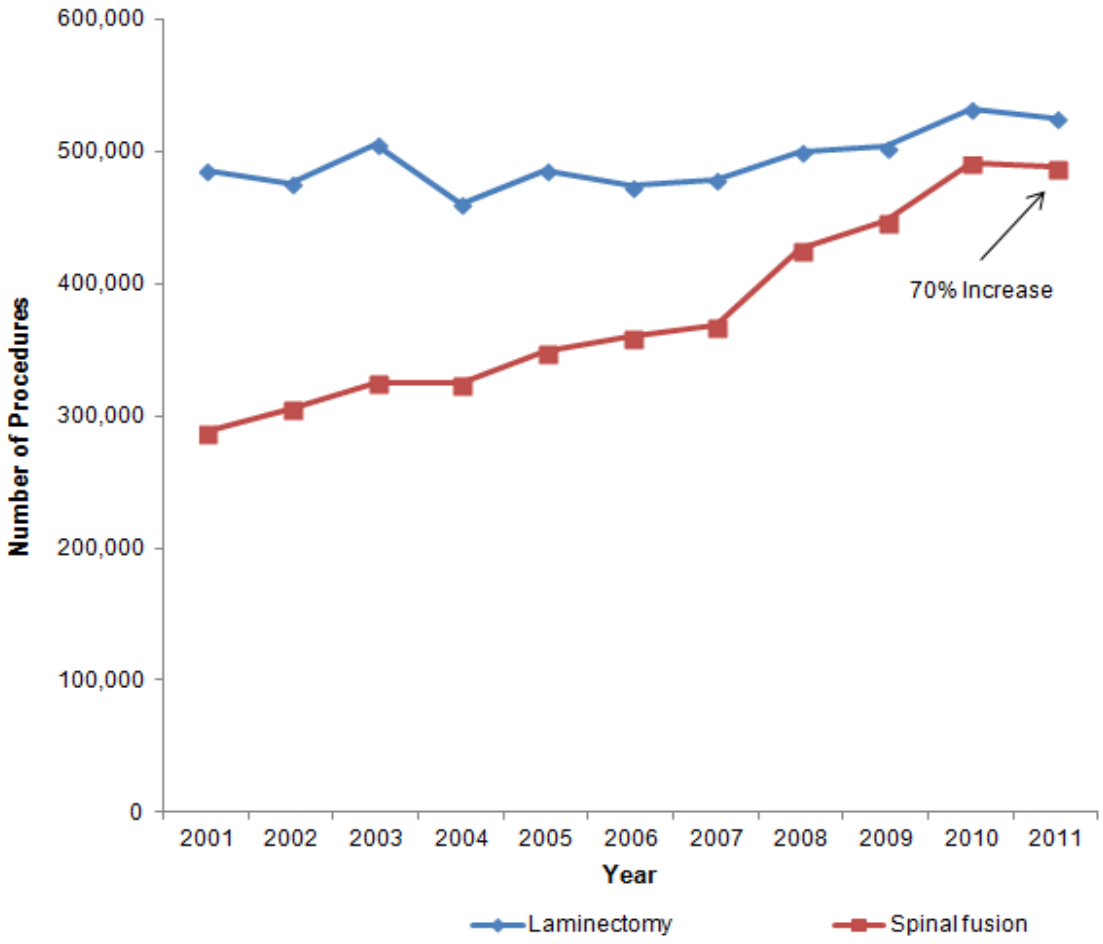

Figure 5: Illustrating the relative increase of spinal fusion operations in the United States of America between 2001 and 2011 (Weiss, 2014).

1.5. Diagnosis and medical imaging

The diagnosis 'degenerative lumbar spine disease' implies various entities:

- degenerative spondylolisthesis,
- osteochondrosis,
- spinal canal stenosis,
- adjacent segment disease (Kapetanakis et al.) and
- segmental instability.

These are the focus of the present study.

Usually, patients present with symptoms as described in Chapter 1.3. Medical imaging is indicated to specify the entity of the presenting symptoms and make a diagnosis.

X-rays taken in the upright position in two planes are the basis of radiographic imaging. Deformities or fractures can be seen in X-rays and computed tomography scans (CT-scans). Often the findings of degeneration indicate the need for further imaging using, for example, CT-scans. CT-scans enable an assessment of the extent, degree and clearer visualisation of degenerative changes, such as disc space narrowing, endplate sclerosis and osteophytes, as shown in Figure 4. The advantage is a thin stratification in which even minor bony alterations can be detected.

Further, functional imaging in flexion and extension may be necessary to detect instability. Thus, pathological micro- or macromotion in the respective segment are signs for segmental instability.

Besides, MRI is more sensitive to reveal soft tissue changes. It provides the best information regarding ligamentous structures, intervertebral discs and the spinal cord. Therefore, it delivers important information about spinal canal stenosis and degenerative disc disease (Caserta et al., 2002; Taher et al., 2012). MRI allows the different stages of activity of degenerative disc disease to be distinguished by enabling the visualisation of oedema, fatty and fibrous changes in the endplates, as shown in Figure 6. These changes can be categorised with the Modic classification and help in the indication setting process (Nguyen, Poiraudeau, & Rannou, 2015). Nevertheless, the critical factor for indication setting is the clinical signs, because MRI can lead to an overestimation of findings (Boden et al., 1990).

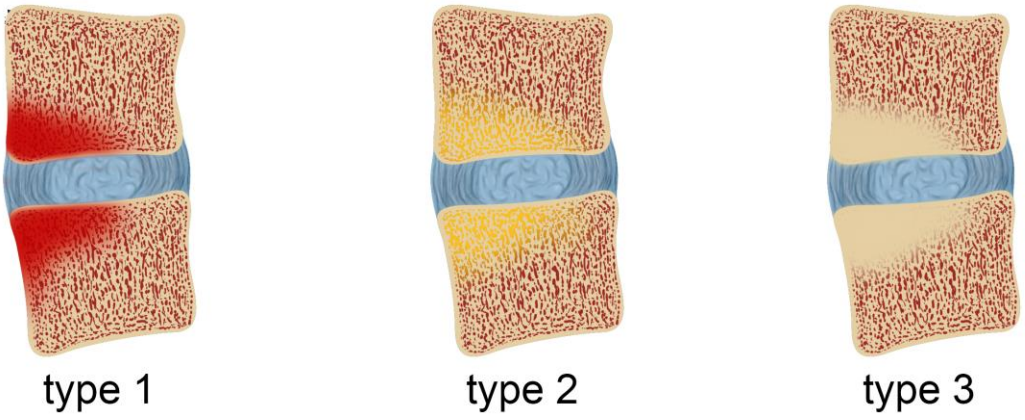

Figure 6: Modic type 1 is bone edema, type 2 is fatty degeneration of the former haemopoetic bone marrow, type 3 is sclerosis of the endplates. (Skalski, 2015, May ninetheenth)

1.6. Therapy

DSD can be treated conservatively or surgically, depending on the specific entity, the severity and the duration of the symptoms. The entities considered in this study are designated in Section 1.5.

1.6.1. Indication setting

However, the decision for conservative or surgical treatment depends on the severity of the clinical symptoms (Frost et al., 2019; Kalff et al., 2013). Kalff (2013) states that important indication parameters for surgical treatment are neurological deficits, such as loss of motor function, sensibility or loss of bladder and bowel control. A compelling instability or a rotative instability joined by spondylolisthesis and facet joint degeneration can be indications for lumbar fusion (Yavin et al., 2017). Furthermore, a high level of pain, measured with the Numeric Rating Scale (see Attachment 3), sciatica or a reduced walking distance are notable indicators for a lumbar spine intervention (Kalff et al., 2013).

As a result, a prospective, randomised study, called SPORT (Spine Patient Outcomes Research Trial) compared surgical versus conservative treatment for various degenerative spine conditions. For example, the study evaluated the outcome of a conservative therapy vice versa a surgical therapy for symptomatic spinal canal stenosis. It demonstrated that the outcome referring to the reduction of pain and improvement of function was significantly better in the surgery group than in

the conservative treatment group at the two- and four-year follow-ups (Weinstein et al., 2010). Also, the SPORT study has shown that surgical therapy was more effective than conservative therapy in patients with symptomatic degenerative spondylolisthesis, at the short-term (two years) and long-term (eight years) follow-ups (Abdu et al., 2018). This conclusion is supported by De Iure (2012). Significant evidence was found by Groff et al. (2014) to perform dorsal fusion for spondylolisthesis combined with lumbar spinal canal stenosis.

Nevertheless, a systematic review using the Cochrane database could not find clear evidence supporting surgery for nonradicular back pain with degenerative changes compared with intensive conservative therapy (R. Chou, Atlas, Stanos, & Rosenquist, 2009).

1.6.2. Conservative therapy

As long as the spine is stable and no severe neurologic deficit is apparent, the first approach is commonly a conservative therapy, including a multimodal regime. In these approaches, analgesics and physical therapy, such as torso muscle reinforcement exercise, motion therapy and massage, as well as thermal treatment, are important. Further, behavioural therapy and multidisciplinary rehabilitation can be successful (Frost et al., 2019; Grifka and Kuster, 2011; Hayden, van Tulder, Malmivaara, and Koes, 2005; Karppinen et al., 2011). In many cases, pain compensation and participation in daily life can be achieved. If not, further conservative treatments can be targeted, such as infiltration with anaesthetics and steroids or transcutaneous nerve stimulation (Kaner, Sasani, Oktenoglu, Cosar, & Ozer, 2009). Supportive orthoses can be relieving for the patient because they level the lumbar lordosis and gain room in intervertebral foramina (Frost et al., 2019). The need for surgery should be prolonged or avoided (Kalff et al., 2013). On the other hand, a longer persistence of symptoms is a negative prognostic factor for surgical treatment. If conservative therapy does not yield benefits after three months, surgical therapy is advisable (Thomé et al., 2008).

1.6.3. Surgical therapy using dorsal stabilisation and fusion

1.6.3.1.History

Early successful intervertebral fusion dates back to Capener (1932) to stabilise spondylolisthesis. He used tricortical bone fragments to replace the intervertebral

disc. In (1953) Watkins described the first posterolateral fusion of two vertebrae. He attached the bone to the area of the facet joints and the interarticular portion of the adjacent vertebrae and subsequently succeeded in merging them. It is a standard fusion procedure used currently (Zdeblick, 1995). After intervertebral fusion, patients were formerly immobilised with bed rest or braces to improve bone healing of the fusion. Instead, complications like thromboembolism or muscular atrophy necessitated internal fixation of the fusion. Various approaches for internal fixation of the fusion had been tested. The first one to use an internal dorsal rod fixation of the spine was Harrington in 1962. He hooked rods onto either side of the centre line and fixed them there. In (1959), Boucher described the first screw insertions into the pedicle. Later in 1970, Roy-Camille combined them with a plate to reach posterior stabilisation. In summary, the fusion of the two vertebrae can be achieved in three ways. Spongiosa can be positioned lateral and in-between the vertebral bodies, a cage can be introduced between two adjacent vertebral bodies with additional spongiosa, or ventral fusion can be accompanied by dorsal stabilisation.

1.6.3.2.Theory

Currently, the most accepted technical standard of surgical treatment of painful and unstable degenerative lumbar spine disease is dorsal stabilisation combined with anterior fusion (Bydon et al., 2017; Caserta et al., 2002; Cheng, Gordon, Cheng, & Welch, 2007; Groff et al., 2014; Kaner et al., 2009).

Here, the ambition is to eliminate abnormal motion and instability at symptomatic degenerated levels to reduce pain and immobilisation (H. Wang, L. Ma, D. Yang, T. Wang, et al., 2017). A satisfactory spondylodesis combines a solid blockage of the affected segments and a physiological alignment of the vertebrae, keeping the risk of adjacent segment disease to a minimum (Desjardins, 2016). Furthermore, after decompression of the spinal segment, a rigid rod system provides segmental stability Moumene, Harms, Geisler, and Vaccaro (2010).

1.6.3.3.Practice

A lumbar spondylodesis comprises the ventral and dorsal fractions. The operation is performed with cuts in the respective region, preparing the subcutaneous tissue and the paravertebral muscles, before introducing screws under radiographic control

through the pedicles and placing them into the body of the vertebra. Adjacent levels of screws are joined with rods transpedicularly.

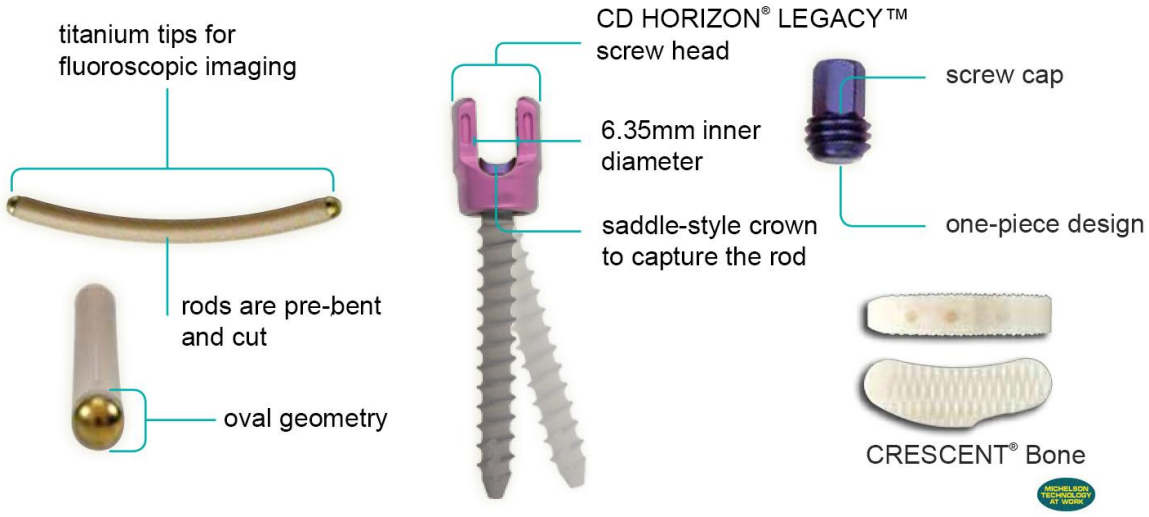

Figure 7: Material used for spinal stabalization and fusion; left to right: metal rod, bone screw with cap, two sizes of cages (M. Gornet, Lanman, & Nockels)

Anterior fixation aims to fuse the bodies of adjacent vertebrae, respectively the anterior column. Different approaches to the ventral column exist: Dorsal approaches are the posterior (PLIF), transforaminal (Zygourakis et al.), extreme lateral (XLIF) or oblique (OLIF) lumbar interbody fusion. Ventral access through the abdomen or thorax is the anterior interbody fusion (ALIF). Both approaches remove the disc of the concerned segment and replace it with a cage, as illustrated in Figure 7. The cage consists of titanium or a different type of polymer and induces a solid fusion of the two neighbouring vertebrae. Harvested spongiosa or bone morphogenetic protein can accelerate this process.

If the approach is from the anterior, two surgeries will be performed: first the dorsal fixation and then the second ventral fusion. The advantage of the ventral approach is that it demonstrates better fusion rates with comparable complication rates.

1.6.3.4. Sequelae of dorsal instrumentation and fusion

One of the main problems in rigid stabilisations is ASD (W. Y. Chou, Hsu, Chang, & Wong, 2002; Gomleksiz, Sasani, Oktenoglu, & Ozer, 2012; Kaner et al., 2009; Kapetanakis et al., 2017). It is a common sequela and leads to prolonged pain, with the frequent need for revision surgery (Putzier et al., 2010). Hilibrand & Robbins

(2004) defined the ASD as a pathologic process associated with disc degeneration leading to clinical symptoms, such as radiculopathy, stenosis and instability after spinal fusion surgery. It needs to be differentiated from adjacent disc degeneration, which is just the radiographic finding without clinical symptoms (Zhang, Berven, Fortin, & Weber, 2016). In a Cochrane review, a pooled prevalence of 29.3% of radiographic ASD and 7.3% of symptomatic ASD were detected. The review included 94 studies with over 34,000 patients having had spine surgery (Xia, Chen, & Cheng, 2013). The symptomatic adjacent segment degeneration rate lies between 2% and 3% per year after lumbar fusion (Radcliff et al., 2013).

It is important to note that a combination of surgery complications and adjacent level disease is responsible for 27.6% of revision surgeries (Carreon, Glassman, & Howard, 2008). Different explanations for the development of ASD exist, such as its occurrence due to increased stiffness of the stabilised segment, further degeneration, screw loosening or non-fusion (Fairbank et al., 2005). The adjacent level disease might result from a hyper-rigidity of the merged segments and an increased ROM in the adjacent segment that eventually leads to overstress after spinal fusion (Putzier et al., 2010).

Lee et al. (2013) found persuasive evidence in the biomechanical and clinical data that the increased rigidity and decreased mobility of the fused segments lead to compensation of these forces in the adjacent segments. Moreover, the increased ROM of segments adjacent to the fused levels is considered crucial for predisposing ASD (Cakir et al., 2009; W. Y. Chou et al., 2002; Strube et al., 2010).

Further, the transition zone between fused segments and non-fused segments is problematic. It is characterised by decreased elasticity and increased stiffness, leading to a concentration of stress with consecutively higher intradiscal pressure (Ruberte, Natarajan, & Andersson, 2009). It can be increased up to 45% on axial compression and anterior flexion compared with a normal disc (Cunningham, Kotani, McNulty, Cappuccino, & McAfee, 1997). In particular, degenerated, but stable discs adjacent to a fusion are vulnerable and can become symptomatic or unstable after a spondylodesis (Anandjiwala, Seo, Ha, Oh, & Shin, 2011; Kim et al., 2015). The ASD can be determined radiographically via X-ray, CT or MRI. Here secondary degenerative disc disease, facet joint arthrosis, spondylolisthesis or spinal canal stenosis can be found.

Another common sequela after lumbar spondylodesis is screw loosening (SL). The bone-screw interface must endure a high impact. SL can lead to insufficient spondylodesis and then to persistent or even a progression of a patient's symptoms. On radiography, the SL manifests in lucent zones surrounding the screws.
Screw dislocations, screw breakage or cage dislocations are fewer common complications after dorsal stabilisation.

1.6.4. Changes in dorsal instrumentation systems

The leading materials for posterior stabilisation are stainless steel or titanium-based rod systems Moumene et al. (2010). Nevertheless, new concepts have been developed to counteract biomechanical stress at adjacent segments and create a transition zone between the fused and mobile segments that distributes the load more homogenously between anterior and posterior spine elements. Ideally, injurious forces shall be avoided, and function that approximates physiological is restored. However, the balance between maintaining motion in the joint and alleviating pain by stabilisation is difficult to achieve (Stoll, Dubois, & Schwarzenbach, 2002; Strube et al., 2010).
Modern approaches seek biomechanical features more adapted to the spine Moumene et al. (2010). Materials to reduce bone-stressing factors are polymer compositional semi-rigid rods and/or flexible systems (Gomleksiz et al., 2012). Dynamic stabilisation (DS), on the one hand, uses bendable screw heads to enable more micromotion at the instrumented levels (Schmoelz et al., 2003). Semi-rigid instrumentation (SRI), on the other hand, promotes bony fusion of the instrumented segments via more equitable load sharing (P. H. Chou et al., 2017; M. F. Gornet et al., 2011). DS or SRI tries to restrict motion of the respective segment without loss of function. They help to relieve intradiscal pressure, unload the facet joints and widen the neuroforamina and the spinal canal (Kalff et al., 2013).

1.6.4.1.Dynamic stabilisation

Posterior DS limits the ROM in all three directions-flexion, extension and lateral bending. Motion in the axial rotation is still possible, but the ROM is higher in flexion/extension. The residual motion is more controlled and shifts the load from the implant to the bridged segment. Thus, the adjacent segment should be better protected, and implant failure should be avoided (Xu et al., 2006).

Kaner et al. (2009) had obtained good clinical results utilising dynamic rods with dynamic transpedicular screws. According to them, the DS systems restrict segmental motion, prevent degeneration and deformation of the lumbar spine.
Supporting the previous point, Lawhorne (2009) proposed that DS of degenerative spondylolisthesis should be performed before the translation of the vertebrae exceeds Meyerding Grade II (see Attachment 4). Thus, patients could undergo surgery at an earlier point in the disease and decompression combined with fusion might not be necessary. Still, no difference in VAS, ODI and complications were found between regular fusion and DS in a comparative review performed by Chou et al. (2011).

1.6.4.2.Semi-rigid instrumentation using PEEK rods

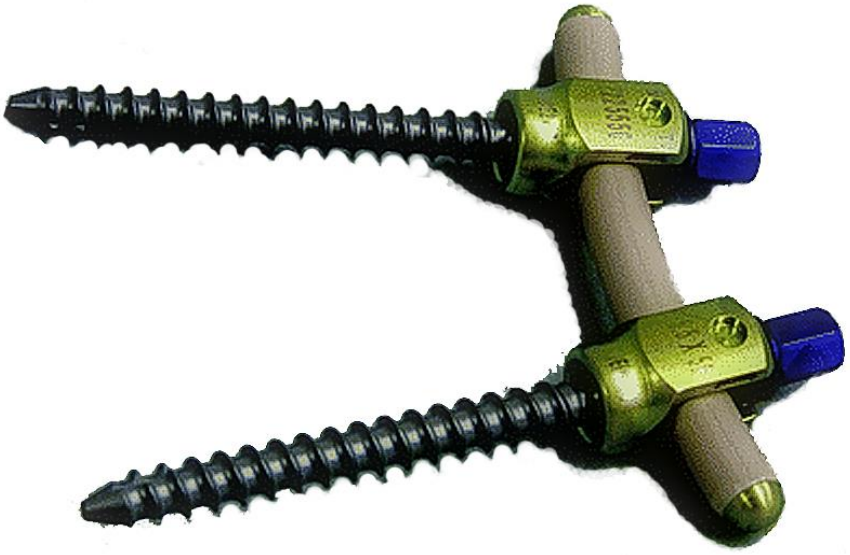

Figure 8: Horizon Legacy PEEK Rods Medtronic® implant Vieweg and Grochulla (2012)

PEEK is the acronym for polyetheretherketone. It is a polymer composition that is less rigid than titanium and has elasticity closely resembling that of bone. PEEK rods allow the blocked spine segments more microflexibility, thereby reducing the difference in stiffness from the stabilised to the non-stabilised segment. On top of that, it facilitates bone fusion by lowering the stress induced by titanium constructs on the bone-screw interface (De Iure et al., 2012). It has been shown in animal models that the risk of ASD, as well as implant failure rates, is lower (W. K. Chou, Chien, & Wang, 2015). Under axial compression, a spine stabilised with PEEK rods and a

ventral cage showed fewer fractures than a spine stabilised with titanium rods and anterior cage instrumentation (Önen et al., 2018).

Biomechanical studies demonstrate that PEEK rods show a contrastable intervertebral load distribution rate compared to titanium rods. The load sharing between the anterior and posterior columns was measured and revealed a distribution of 70% to 30% from the anterior to posterior column for titanium rods. However, PEEK rods showed a distribution of 85% to 15% from the anterior to posterior partition (see Figure 9). Thus, more closely resembling the physiological load distribution.

Furthermore, the load of the screw-bone interface was reduced by 85% and 71% in flexion and extension, respectively, when compared with titanium rods. In accordance with these findings, a better biomechanical balance can be achieved.

Based on this, natural healing processes are supported by increased loads on the anterior column and reduced stress on the bone-screw interface Moumene et al. (2010). These findings were supported by further biomechanical and clinical studies that provided additional proof of the similar stiffness regarding titanium rods and sufficient stabilisation power. Also, PEEK rods demonstrated a larger adjacent segment ROM that protected the spine from ‘overstabilisation’ (C. Li et al., 2018).

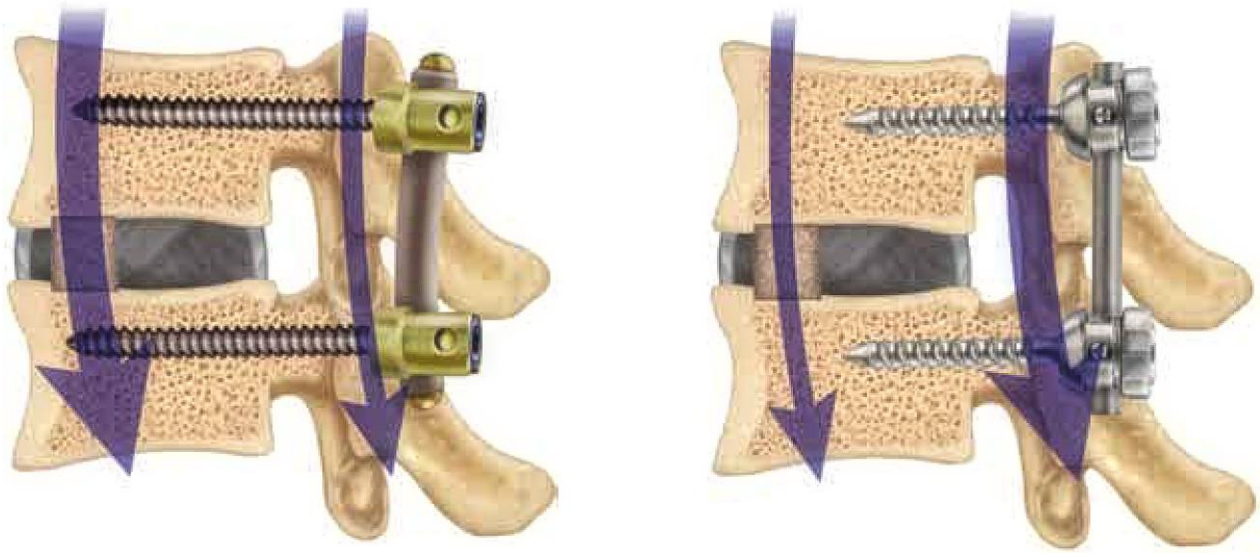

Figure 9: Load distribution of a PEEK rod stabilisation (left) and load distribution of a classic titanium stabilisation (right), the arrows illustrating a higher load distribution on the anterior column with PEEK rod stabilisation, CD HORIZON LEGACY PEEK ® rod system, Medtronic Inc.™ (M. Gornet et al.)

Several clinical studies have shown that the use of PEEK rods is safe, and patients experience a significant clinical improvement compared with the presurgical state (Selim, Mercer, & Tang, 2018). Mavrogenis et al. (2014) found PEEK rods to be compliant with physiological spinal movement. Furthermore, they observed a higher fusion rate, a lower chance for ASD and a low rate of complications.

In a meta-analysis, Selim et al. (2018) found no statistically significant difference in successful fusion rate, function nor pain alleviation between patients that had received a stabilisation with PEEK rods or titanium rods. In conclusion, using PEEK rods showed good stabilisation and a low rate of device-related events. Further, De Iure et al. (2012) examined 30 cases using PEEK rods and concluded that the semi-rigid system was a viable option for treating the degenerative lumbar spine. Their results supported previous findings that PEEK rods increased the load distribution on the anterior column by promoting interbody fusion, reducing stress on the bone-screw interface, showing a lower rate of screw mobilisation, and reducing the incidence of ASD in the long-run. Desjardins (2016) states in his work that the outcomes of 48 patients who were dorsally instrumented with the semi-rigid PEEK rods system, in a time-frame of approximately three years, demonstrated that further research with a bigger cohort and longer follow-up is needed.

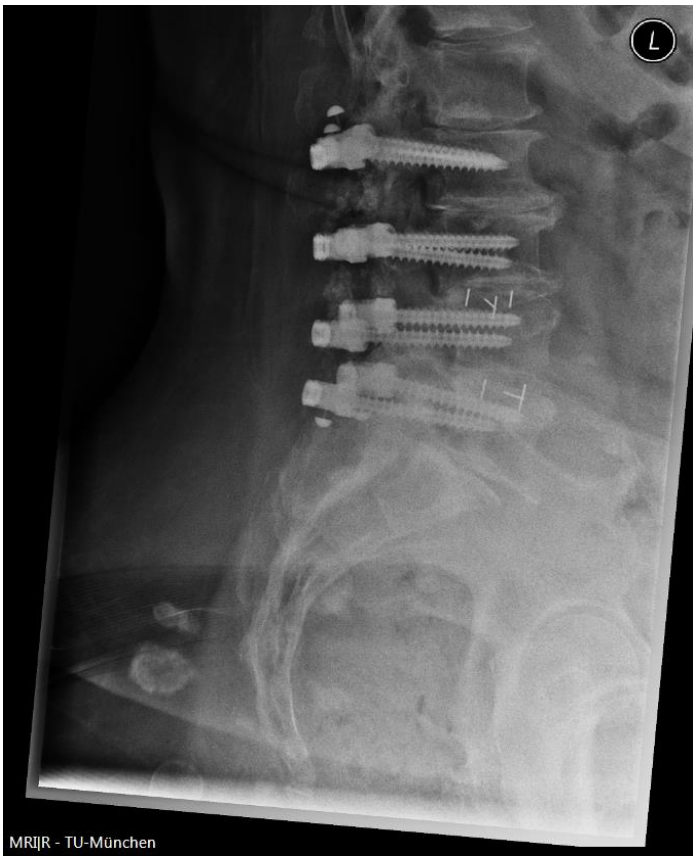

Figure 10: X-ray of a lumbar spine, sagitally, with implanted PEEK rod system L2-L5, anterior fusion of L3-L5, with 'topping-off' L2-L3 . The rods are invisible in the X-ray (Source: Radiologie Klinikum rechts der Isar, 2018)

1.6.4.3.'Topping-off'

Several studies revealed that adjacent level instabilities tend to occur cranial to the stabilisation (H. Wang, Ma, Yang, Yang, & Ding, 2017)

The concept of 'topping-off' is to reduce the stress on the adjacent segment further by allowing the rods to swing more by leaving the most cranial motion segment without anterior fusion (see Figure 10). To reduce ASD by creating a smooth transition from fused to free motion segments, the most cranial stabilised segment was left without an anterior cage (P. H. Chou et al., 2017).

Strube et al. (2010) described that an anterior cage seems to increase the ROM of adjacent segments and consecutively the risk for ASD. The more levels that are fixed, the higher the stiffness of the implant, because with each blocked segment, ROM is lost. Proportionally, hypermobility in the adjacent segment increases, which may be the source or at least the aggravation of ASD. In addition, the intradiscal pressure adjacent to a dorsally instrumented spine with PEEK rods is still higher than the physiological pressure (Abode-Iyamah et al., 2014).

Strube et al. (2010) summoned benefits of a one-level dorsoventral stabilisation and 'topping-off', compared with a two-level dorsoventral stabilisation concerning lateral bending, axial rotation and flexion. They quote the first to be '*protective limitation of ROM',* similar to a two-level stabilisation, but with less adverse effects, like hypermobility or rigidity.

Putzier et al. (2010) proposed that the DS of a degenerative segment adjacent to a stabilised and fused segment may reduce the process of degeneration. Though without the anterior fusion, forces will be distributed only at the bone-screw interface, which might lead to higher forces in the transition zone and then to a higher rate of side effects, such as SL (Chien, Kuo, Lin, Chuang, & Luh, 2014).

Still, using that method, we hoped to find less adjacent level instabilities and SL compared to common rigid stabilisation and sustain a higher level of satisfaction.

1.7. Objective

Degenerative lumbar spine disease affects many patients and is associated with high healthcare system costs. Besides, the established surgical methods show moderate outcomes regarding complication rates and patient satisfaction. Assessing the outcomes of semi-rigid dorsoventrally instrumented patients exist only in a few large cohorts or long-term follow-up surveys. Studies that focus on the principle of 'topping-off' are even rarer. The purpose of the present study was to validate the long-term outcomes in a large group of patients after lumbar stabilisation with the semi-rigid method using PEEK rods combined with the 'topping-off' technique. We analysed and evaluated the rate and type of hardware failures such as ASD and SL and subsequent revision surgery. The aim was to assess potential risk factors for ASD and SL. Age, gender, previous surgery, number of segments involved, anatomic level of surgery and the time elapsed since surgery were the factors evaluated. Furthermore, the patients' reports on personal benefits from the intervention were included in this study.

The hypothesis of this study was that PEEK rods and 'topping-off' support the load-sharing idea, reduce the risk of adjacent level instability and thereby diminish reoperation rates. Therefore, we compared this prospectively collected and post-hoc analysed cohort in the context of the literature on lumbar dynamic and rigid dorsoventral spondylodesis.

2. Materials and Methods

2.1. Ethical Standards

The local ethics committee approved the study (registration number: 159/16S) and it was conducted in accordance with the Declaration of Helsinki. Written patient consent was waived by the local ethics committee due to the retrospective design of the study.

2.2. Inclusion and exclusion criteria

The patients presented with persistent lumbosacral and/or radicular complaints after an unsuccessful conservative therapy and having had the indication for surgical stabilisation.

We included patients diagnosed with degenerative lumbar disorders such as

- spinal canal stenosis with or without claudication
- degenerative lumbar spondylolisthesis
- degenerative lumbar instability
- previous dorsal instrumentation and need for a change of system.

Furthermore, patients that already underwent previous disc or decompression surgery were included.

We excluded non-degenerative disorders such as traumatic or oncologic indications, infection or inflammation, as well as the correction of scoliosis or isthmic spondylolisthesis. Included were the level BWK12 to S1 of the spine. But surgery had to be conducted without the usage of cemented screws. Further modifying factors, such as medication with corticosteroids, non-steroidal anti-inflammatory drugs, osteoporosis, adipositas, abusus of nicotine and alcohol, were not considered.

2.3. Patients characteristics

We report on 322 patients retrospectively enrolled from 2009 to 2015. The follow-up period lasted until March 2017. 164 women and 158 men underwent surgery and were included for investigation.

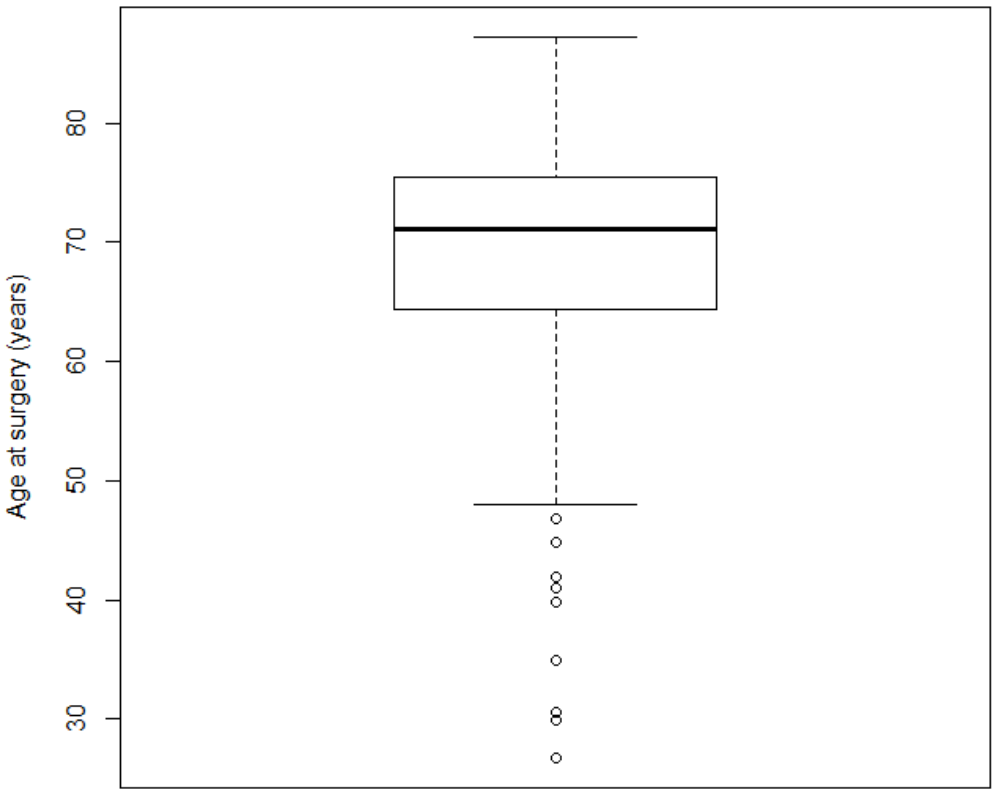

Figure 11: Box plot demonstrating the age distribution of the cohort

The mean age was 69.1 ± 9.9 years; the youngest patient was 26 years old and the oldest was operated at the age of 87 years. Further patient characteristics are displayed in Table 1. All patients underwent pedicle screw based semi-rigid stabilisation and fusion of the lumbar spine with a PEEK rod system (CD HORIZON LEGACY PEEK Rod ©, Medtronic ®, Minneapolis, Minnesota, USA) and the 'topping-off'-approach.

We considered pre- and postop X-ray and/or CT-scans, as well as multiple outcome measures (resurgery rate, numeric analogue scale (NRS) for the measurement of pain, Oswestry Disability Index (ODI), Roland Morris Disability Questionnaire (RMDI)). Clinical follow-up was recorded after 3 months, 12 months, and maximum follow-up examinations after surgery.

Table 1: Patient´s characteristics

Sex (% of patients)	**Female**	50.9
	Male	49.1
Previous lumbar surgery	**Yes** (% of patients)	59.9
	Previous screw implantation (% of patients)	27.3
	Time since previous lumbar surgery (in years; mean ± SD, range)	8.9 ± 5.7 (2.0 – 48.0)
Duration of symptoms prior to surgery (in years; mean ± SD, range)		3.2 ± 6.3 (0.1 – 60.0)
Presurgical pain (% of patients)	**Low back pain**	10.6
	Sciatica	33.2
	Lumboischialgia & spinal claudication	25.5
	Unclear	30.7
Presurgical sacroiliac joint or facet joint syndrome (% of patients)	**Sacroiliac joint syndrome**	1.9
	Facet joint syndrome	7.8
	Unclear	54.6
	None	35.7

The focus was to detect hardware failure and evaluate patient satisfaction. 'Hardware failure' subsumed screw loosening or failure, ASD, cage dislocations, fracture of (adjacent) vertebrae. Concerning the satisfaction level, patients were asked, if they had a benefit after the surgery regarding the reduction of pain, increase of mobility, and alleviated daily routine. The data was imposed through information from personal appointments at the neurosurgical department of *Klinikum rechts der Isar, München* and via phone call interview with standardised questions for the long-term follow-up. Mean follow-up after surgery was 4.3 ± 1.8 years (range: 0.8 – 7.0 years). 121 patients (37.6%) were lost during follow-up after a mean time of 10.2 ± 14.4 months (range: 0.0 – 59.6 months). A total of 171 patients (53.1%) completed the 3-months follow-up by hospital visit and examination.

75% of the cohort showed comorbidities, 25% presenting with multimorbidity (see Figure 12 and Figure 13).

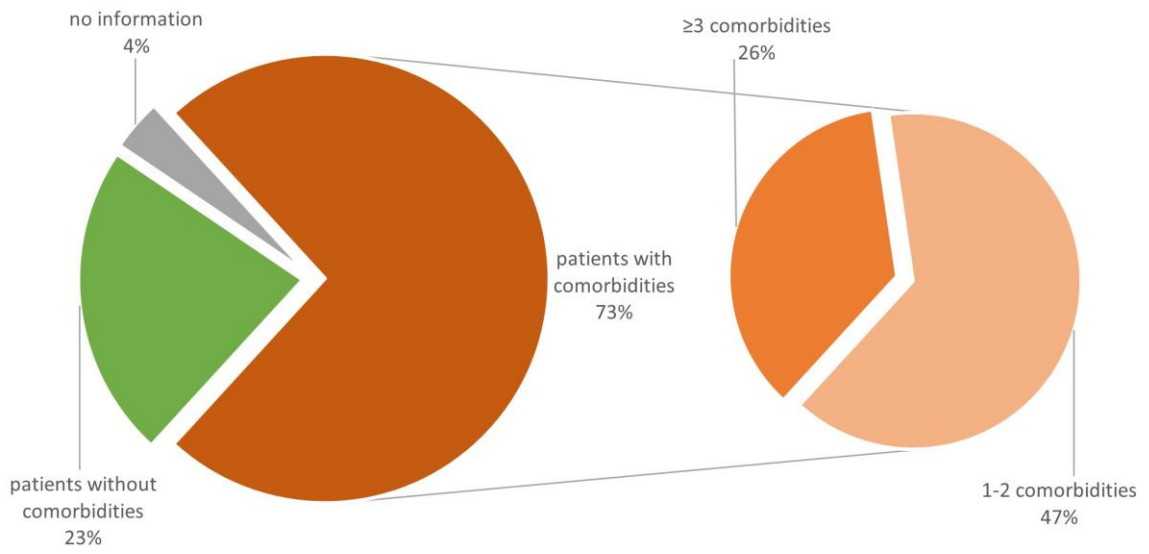

Figure 12: 240 of the patients entered the procedure having pre-existing side-diagnosis, 72 patients had no further issues than back pain and for 10 patients no information on comorbidities is given.

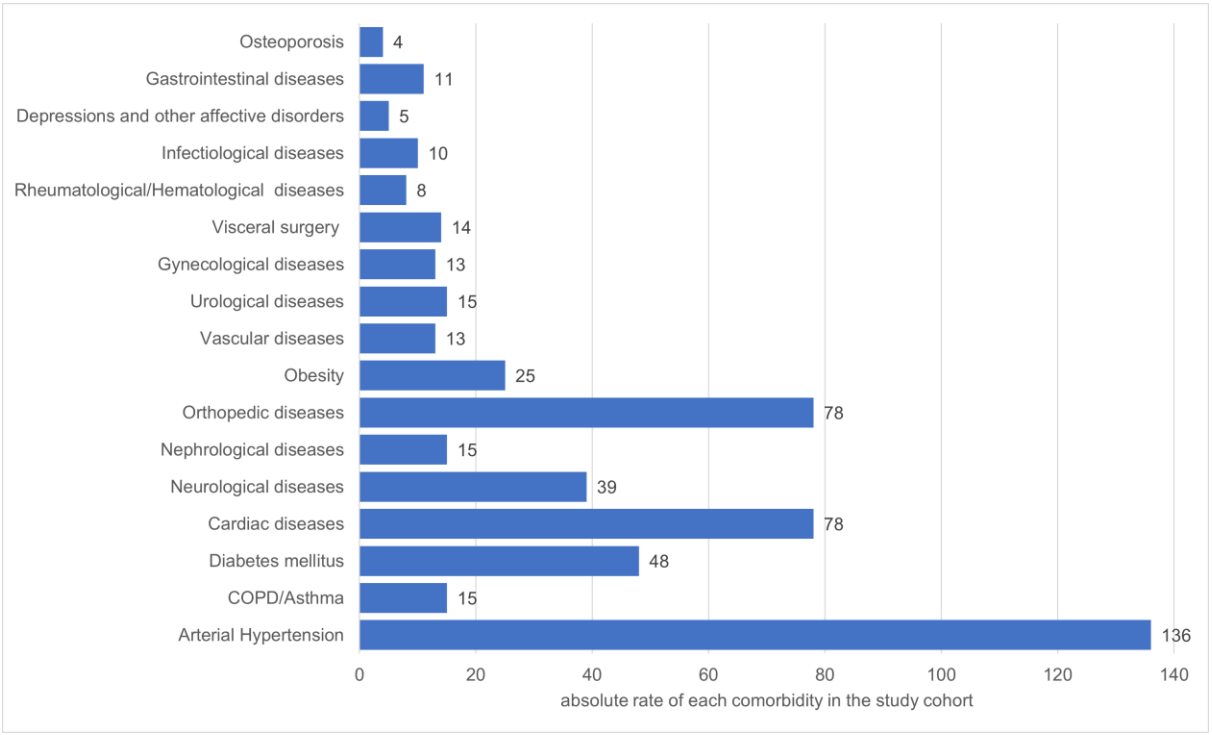

Figure 13: Division of secondary diagnoses

2.4. Indication

All patients presented with symptomatic degenerative lumbar spine disease. We included spinal canal stenosis, degenerative spondylolisthesis, osteochondrosis and degenerative lumbar instability.

Further inclusion criteria were secondary screw loosening or adjacent level instability from a former surgery. We included patients who could not sufficiently be treated with analgetics, physiotherapy or injections for at least three months or had undergone lumbar stabilisation surgery already.

Table 2: Relative distribution of diagnoses the included patients presented

Indication for current surgery (% of patients)	Instability & spinal stenosis	47.2
	ASD	19.3
	Instability without spinal stenosis	14.0
	Instability & spondylolisthesis & spinal stenosis	9.6
	Spondylolisthesis	3.7
	Screw loosening	2.5
	ASD & screw loosening	2.2
	Instability & spinal stenosis & ASD	0.9
	Instability & spinal stenosis & screw loosening	0.6

2.5. Surgery

Surgical strategy included dorsal stabilisation with the PEEK rods Medtronic System® and posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (Zygourakis et al.) , anterior lumbar interbody fusion (ALIF), oblique lumbar interbody fusion (OLIF), extreme lateral interbody fusion (XLIF).

2.5.1. Dorsal stabilisation

Eight different board-certified neurosurgeons implanted the SRI in a standardised way. After general anaesthesia and a prophylactic antibiotic, the patient was placed in a prone position and a posterior midline approach was used to access the affected lumbar levels. Correct positioning of the vertebrae, strictly in neutral zero position without any malrotation, as well as the following steps, took place under radiographic control. A needle was inserted in the physiological course of the pedicle to punction the vertebral body.

The inner stylet of the needle got removed and a guide wire was inserted to lead the following instruments. Dilatators widened the canal and optionally a thread cutter was

used. The pedicle screws were inserted transpedicularly and bilaterally, utilizing a 3D spinal navigation system for positioning and confirmation (Brainlab Vector Vision and Brainlab Curve®, Brainlab Munich, Germany) based on 3D X-ray reconstructions (Arcadis®, Siemens Healthcare, Munich, Germany).

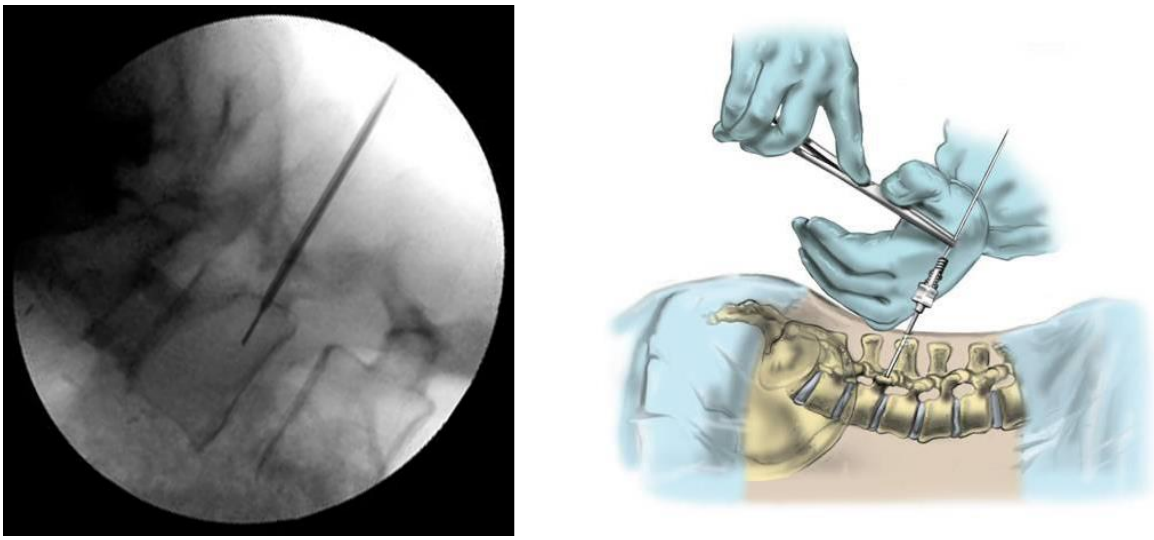

Figure 14: CD HORIZON LEGACY PEEK ® rod system, Medtronic Inc.™ (M. Gornet et al.)

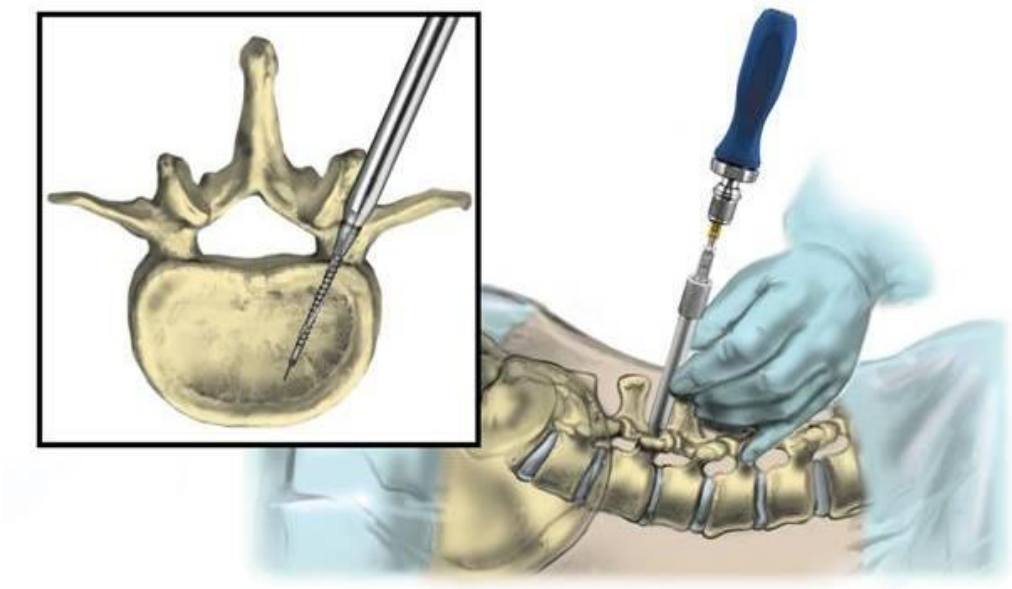

Figure 15: CD HORIZON LEGACY PEEK ® rod system, Medtronic Inc™. (M. Gornet et al.)

The size of the PEEK rods needed could be determined by a bendable plastic measuring rod. Then, equally sized PEEK rods were positioned and connected to the pedicle screws. Correct positioning was controlled via the navigation system. Screw

plugs were inserted with a compressing turnscrew. Wound closure was done with suture of the fascia, subcutaneous and skin suture. At last sterile wound dressing was applied.

On average three motion segments were stabilised (range 1-5 segments). One patient (0.3%) was instrumented in one motion segment, 46 patients (14.3%) in two, 188 patients (58.4%) in three, 83 patients (25.8%) in four and four patients (1.2%) in five motion segments. Therefore, a maximum of six vertebrae were dorsally stabilised, a minimum of two and the median was four instrumented vertebrae.

The majority of the patients received dorsal instrumentation of the segment L3-4 (292p., 90.7%) and L4-5 (310p., 96.3%). The segment L1-2 was instrumented in 25 cases (7.8%), L2-3 in 180 (55.9%) and L5-S1 in 202 cases (62.7%).

2.5.2. Ventral fusion

288 patients (89.4%) underwent ventral fusion in the same surgery. This was done via TLIF in 73.3%, via XLIF in 3.1%, 1.1% by combined TLIF & XLIF. Ventral approaches via the abdomen were performed with a second general anaesthesia a few days later with ALIF in 18.4%; 3.1% were treated by combined TLIF & ALIF, and 0.7% by combined ALIF & XLIF and via OLIF in 0.3% of these cases.

Intervertebral cages were placed in the segments L1/2 in 0.3%, L2/3 in 5.0%, L3/4 in 37.6%, L4/5 in 66.5%, and L5/S1 in 52.5% of patient cases. Fusion was considered to be achieved when a bone bridging through the cages was clearly visible.

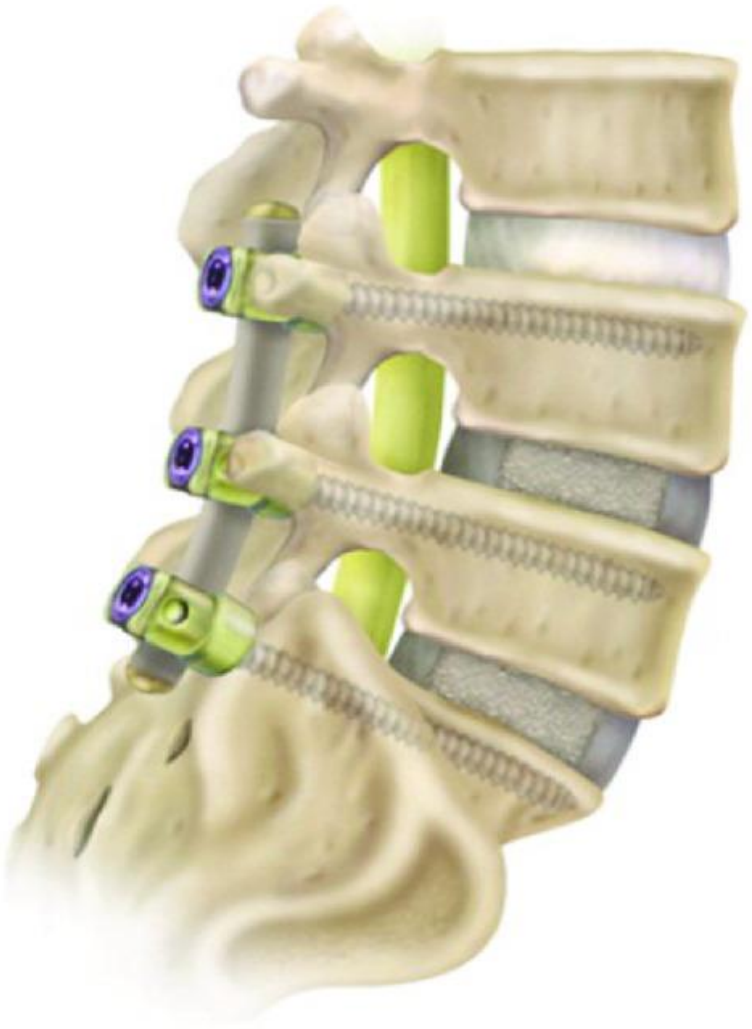

Figure 16: Model of a lumbar spine dorsally stabilised from L4 to S1 with the Medtronic PEEK rods System and anterior fusion of L4-L5 and L5-S1;

2.5.3. Decompression

Laminectomy oder hemilaminectomy were used to decompress the spinal canal. It was performed in patients according to their clinical symptoms.

If necessary, it was completed by discectomy. After adequate decompression, proper-sized alloy rods were inserted, and distraction was accomplished. 83 patients (25.8%) underwent decompression of one segment, 75 (23.3%) of two segments, 85 (26.4%) of three, 32 (9.9%) of four and two (0.6%) of five segments. Another 45 patients (14.0%) did not need a decompressive surgery. A mean of two decompressed segments was evaluated with a range from 0-5 segments.

2.5.4. 'Topping-off'

There was a division in fused segments which included the ones dorsally stabilised and ventrally fused. 98 of 322 patients (30.4%) of the patients had one fused segment, 148 (46.0%) had two, 41 (12.7%) three and one (0.3%) four fused segments. The segments just dorsally stabilised in the technique of 'topping-off' were so called 'free segments'. In 192 of 322 (59.6%) cases there was one 'free segment', in 81 (26.0%) two, in 34 (10.6%) three and in eight cases (2.5%) four 'free segments'.

2.6. Radiographic measurements and Evaluation

Presurgically CT or plain X-ray and/or MRI of the affected spine were available for all patients included in the study. X-rays were done in lying position or in upright position for the functional recording, because frequently malposturing and compression equivalents can only be seen in upright position, reclination or inclination. For many patients X-rays of the whole spine were done. Two plane X-rays were made for every patient- one anterior- posterior and a sagittal view. They were used for indication setting and surgery planning. The assessment was obtained by a conference of neuroradiologists and neurosurgeons of *Klinikum rechts der Isar, Munich*. Intrasurgically the location of screws, rods and cages was controlled using 3D X-ray imaging. In the first days after surgery a CT-scan or plain X-ray were repeated (see: 3.7 Illustrative patient , p.44). Patients underwent X-rays, CT-scans or MRI, if clinical symptoms or findings indicated any kind of potential complication with the instrumentation during follow-up. The clinical symptoms for ASD or SL, such as newly or increased lumbar pain, claudication or radiating symptoms, indicated plain X-rays or CT-scans during follow-up. ASD was defined as the degeneration of vertebrae neighbouring a spinal fusion, which can be seen radiographically (Hilibrand & Robbins, 2004). SL was suspected when a 'halo zone sign' or 'double halo sign' could be seen on the X-ray and was followed by a CT-scan to answer the question, if resurgery was necessary and reasonable.

2.7. Follow-up

The follow-up is divided into a clinical and a phone call follow-up. The clinical follow-up took place during postop appointments, where an anamnesis, an examination and, if necessary, radiological imaging was performed. The phone call follow-up gave us long-term data by anamnesis of many patients, which stopped or had never showed up for a personal appointment.

2.7.1. Clinical follow-up

The patients were followed up in personal appointments in our neurosurgical department at the *Klinikum rechts der Isar.* Pre- and postoply each patient was examined clinically and radiologically. We reviewed clinical notes, surgical narratives and radiology reports. Naturally, in a retrospective study we lost patients during follow-up, because they felt too satisfied to need further examination or too dissatisfied to seek another appointment in our hospital. Some may have switched to other surgeons for further monitoring or revision. To minimize this lack of information, we set up the last follow-up as a phone call inquiry about the patient's functional status and surgical history after our last clinical contact. Some patients had died in the time span between the surgery and this phone call interview. Moreover, some patients could not be reached via phone because they are residents from foreign countries such as Saudi- Arabia, United Emirates or Russia and had not left sufficient contact data. We recorded the mean duration of surgery and hospital stay. Perisurgical complications were ascertained and observed during follow-up. All patients were included up to their individual final follow-up. We registered the numeric rating scale for pain with a scale graduation from 0 to 10 (see Attachment 3), sensoric and motoric or vegetative (bowel/bladder function) deficiencies. Additionally, the patients were asked about their degree of satisfaction after the surgery. 29% of patients had answered the Oswestry low back pain disability questionnaire, so we calculated the Oswestry disability index (ODI). The ODI is a well-established method to evaluate the functional status of patients with low back pain. The questionnaire asks for the intensity of pain during different daily activities in 10 questions. The intensity was measured with numbers 0 to 5, 0 meaning no limitation and 5 big limitations. A high value in the ODI shows a more severe restriction in daily life due to low back pain (see Attachment 5). On top of that, the same amount of patients answered the Roland- Morris Disability Questionnaire, which is calculated into an

index as well, the Roland- Morris Disability Index (RMDI, see Attachment 6). It is similar to the ODI in its questions and statements. Hardware failure was detected by radiography, if indicated, during the hospital-stay, three and twelve months postop (after surgery) and, if possible or necessary, in another long- term follow-up.

2.7.2. Phone Call Follow-up We performed the final follow-up via phone call. We reached 201 patients (62.4%). 27 patients (8.4%) had had a change in therapy for example the implementation of a rigid stabilisation system. We could not follow 94 patients (29.2%), the main reasons were the lack of a valid phone number, patients from foreign countries or the patient had died in the meantime.

2.8. Statistical Analysis

We worked out patient demographics and parameters of surgery and outcome. Therefore, we calculated the descriptive statistics arithmetic mean and standard deviation (SD), median and ranges. Pain intensity according to the presurgically assessed NRS were compared to the NRS assessed during maximum follow-up using Wilcoxon matched pairs signed rank test. We calculated an univariate and a multivariate regression model for potential risk factors for revision surgery and screw loosening. We included 171 patients (53.1%), who had completed the three months follow-up by hospital visits and examination. The univariate calculation was formed to identify potential risk factors as an independent variable with 1) revision surgery due to ASD, 2) revision surgery due to implant failure, 3) revision surgery due to SL, 4) any revision surgery, and 5) SL. A multivariate regression model was calculated to proof which of the primarily found risk factors were independently significant ($p< 0.1$). The model was calculated with mutual adjustments of all risk factors associated with the corresponding outcome ($p< 0.1$). Results were presented as odds ratio (OR) with a 95% confidence interval (95%-CI). A p-value <0- 0.05 was defined as statistically significant. Statistical analyses were performed with the statistical software R (version 3.4.2; https://www.r-project.org/) and Microsoft Excel.

3. RESULTS

3.1. Surgery characteristics

All enrolled patients underwent stabilisation in the department of neurosurgery at *Klinikum rechts der Isar,* Munich. The surgery time ranged between 97.0 to 449.0 minutes, with a mean duration of 239.0 ± 61.2 min. Patient's hospitalization lasted from 3 to 49 days with a mean stay of 10.3. ± 5.7 days. On average, 8.2 ± 1.3 screws were implanted, with a range of 4.0 – 12.0 screws. 4.4% of the patients needed a screw revision in the initial surgery or directly postop. 34 patients (10.6%) did not undergo ventral stabilisation, mostly because they already had undergone surgery and already had inlaying ventral cages. The cages were implemented rather in the lower lumbar segments. 121 cages (37.6%) were placed in L3-4, 214 (66.5%) in L4-5 and 169 (52.5%) in L5- S1. One cage was placed in the segment L1-2 (0.3%) and 16 cages (5.0%) in L2-3.

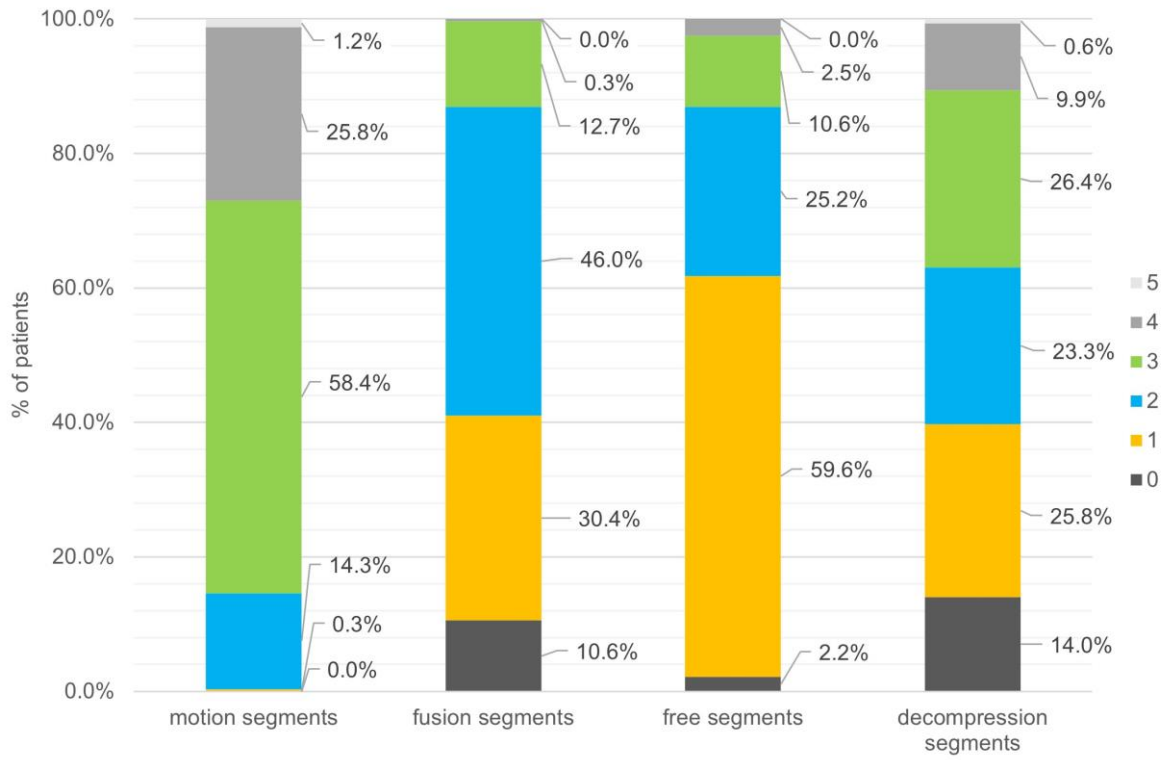

Figure 17: Diagram displaying the instrumented lumbar spine segments

The surgeons performed spinal canal and/or foraminal decompression if indicated. Thus, the range of decompressed segments ranged between 0-5 segments. The median lay at two decompressed segments. The segment L1-2 was decompressed in 6.8% of the cases, in 33.2% L2-3, in 60.3% L3-4, in 67.4% L4-5 and in 31.4% L5-S1.

Figure 17 shows, how many segments were instrumented dorsally, how many fused ventrally and how many left without anterior cage. The number of decompressed segments is illustrated, as well.

3.2. Complications

We distinguished between surgical and perisurgical complications. Surgical complications included hardware failure, for example screw failure or cage dislocation, screw loosening and ASD.

Perisurgical complications counted all incidences prolonging the hospitalization of the patient, for example a lower urinary tract infection, an impairment of wound healing, prolonged postop pain, or heart attack.

3.2.1. Surgical complications

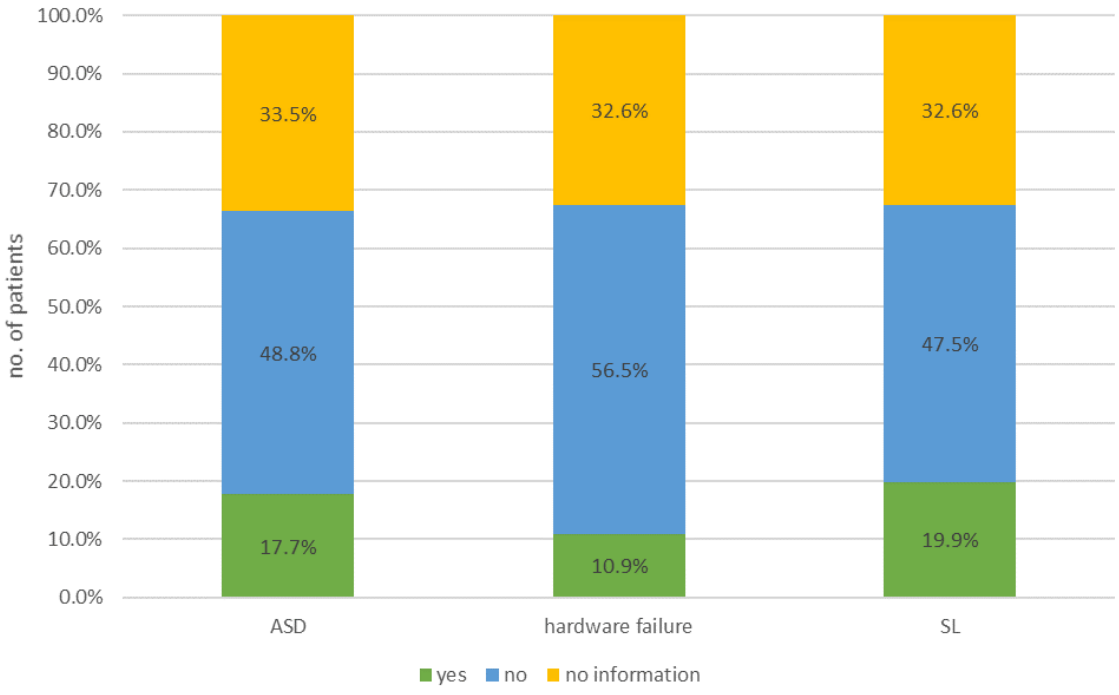

Figure 18: Division of complications. ASD and screw loosening were more common than hardware failure

The rate of ASD during our follow-up was 17.7%. We know, that 48.8% of the patients did not suffer from ASD, still the account for cases without proper information during follow-up is one third of all operated patients. In 19.9% of the patients we could radiographically detect screw loosening and in 10.9% hardware failure such as cage dislocation or screw breakage occured.

Figure 19 shows, how often each vertebra was affected by complications.

Revision surgery was performed in approximately half of the cases. Screw loosening was reoperated in less cases. It can be found radiographically without clinical symptoms. The mere finding of lucent zones is a relative revision indication and many patients without symptoms renounced this option.

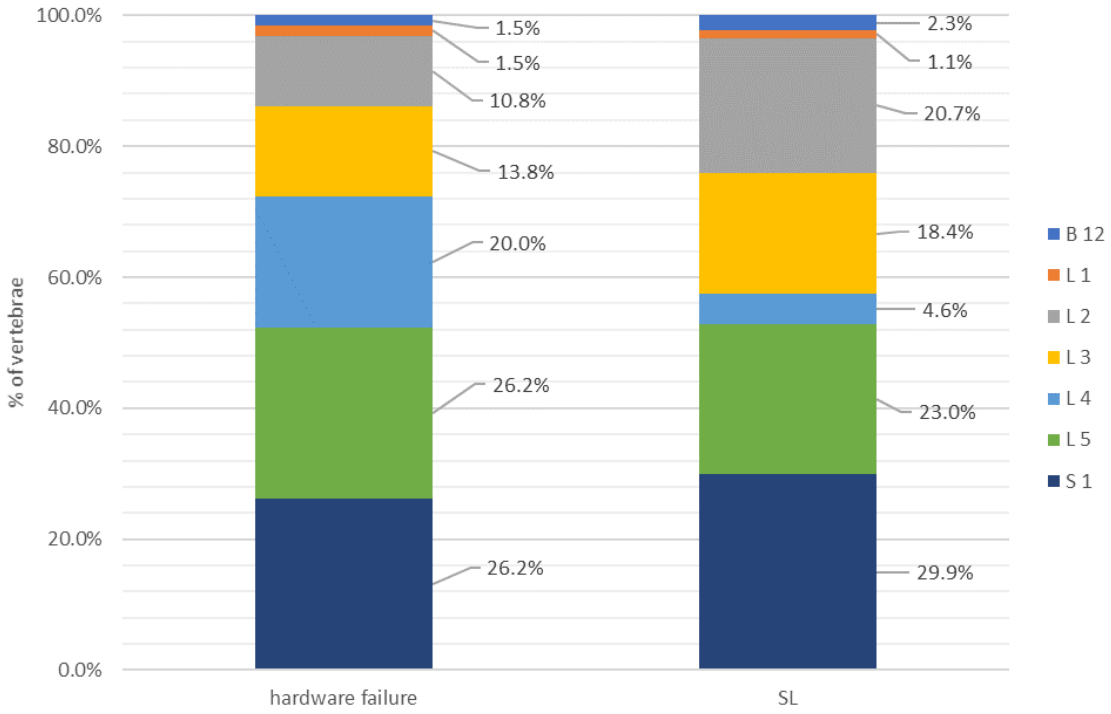

Figure 19: Vertebrae affected by complications

3.2.2. ASD

During the follow-up 56 ASD were reported, which gives a rate of 17.7% They occurred 26.5 ± 17.6 months (range: 1.0 – 70.0 months) after surgery. 142 (46.9%) patients did not show any sign of instabilities, in 105 cases (34.7%) no information could be gathered at all.

The ASD could be found cranial of the stabilisation in 45 (80.7%) of the cases. Seven (12.3%) showed the instability caudal of the fusion and four (7.0%) cranial and

caudal of the instrumentation. Figure 20 demonstrates, where the ASD were located. 29 patients (50.9%) were reoperated.

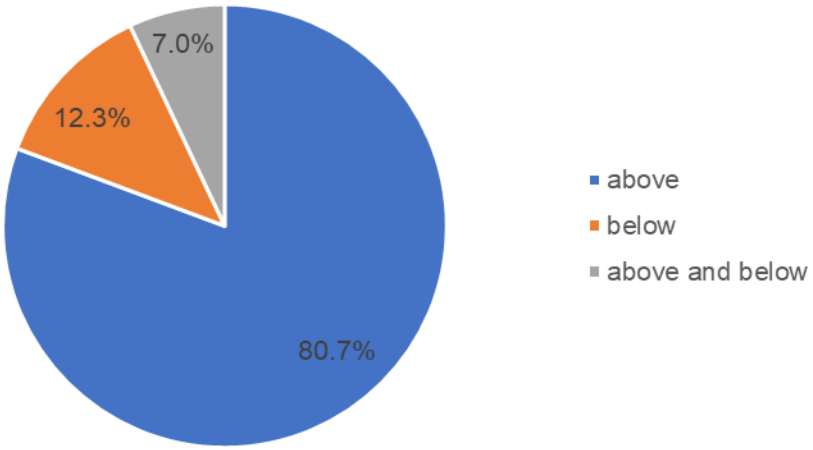

Figure 20: Displaying the location of ASD in relation to the dorsal stabilisation

3.2.3. Screw loosening

Screw loosening was found in 62 radiographies (20.5%) after 14.9 ± 16.0 months (0.5 – 70 months) with respect to surgery. In 55 cases (89.1%) the screw loosening was found on both sides of the pedicle. Four patients (6.3%) just had a left sided screw loosening, three (4.7%) a right- sided one. 29 patients underwent further intervention (45.3%). Screw loosening was found in the segment S1 in 24 cases (40.6%), 19 (31.3%) in L5, four (6.3%) in L4, 16 (25.0%) in L3, 17 (28.1%) in L2, one (1.6%) in L1 (see Figure 19).

3.2.4. Hardware failure

Summed under the headline hardware failure were 35 cases (10.9%) after 12.9 ± 13.6 months (range: 0.1 – 63.0 months), which concluded breaking of screws (twelve cases), seven non-fusions, five cage-dislocations, an epidural infection caused by an infected screw, a screw dislocation, 17 patients (48.6%) were reoperated.

Hardware failure could be found 17 times (48.6%) in L5 and S1 respectively, in 13 cases (37.1%) in L4, in nine (25.7%) in L3, in seven (20.0%) in L2 and in one (2.9%) in L1. The failure concerned both sides of a vertebra in 20 cases (57.1%), seven (20.0%) were only right- sided and eight (22.9%) only left- sided.

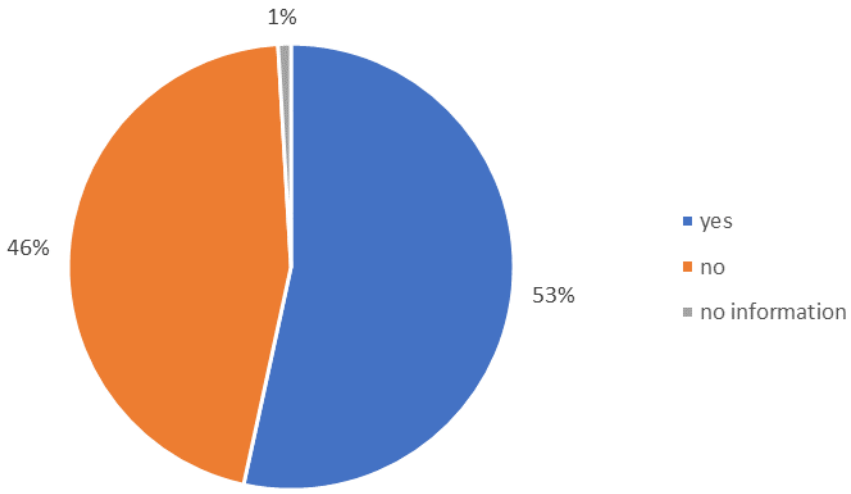

Figure 21: Approximately half of the patients showed complications after surgery, caused by a variety of reasons, partially prolonging the duration of hospitalization

3.2.5. Perisurgical complications

170 patients, slightly more than half of the cases, had perisurgical complications. Perisurgical complications subsume factors such as symptomatic blood loss or urinary infection which are related to the surgical procedure or hospital stay but not primarily a specific surgical complication. In many cases those factors led to a prolonged hospitalization.

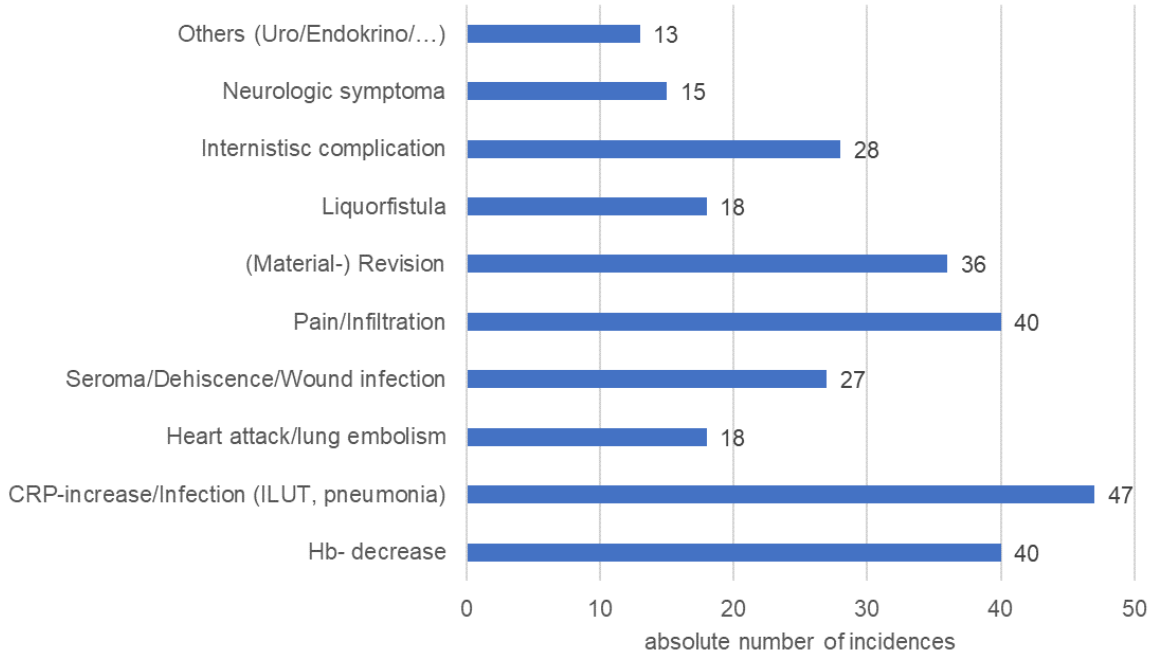

Figure 22: Variety of postop complications

We registered 12% of therapy-indicating Hb- decreases, 15% of postop infections, for example pneumonia or lower urinary tract infections, not including 8.4% wound complications for example seroma or wound infection. Ongoing pain and the need to infiltrate were given in 12.4% of the cases and in 11% of the cases revision surgery during the same stay became necessary.

3.3. Revision surgery

Revision surgery was performed for ASD, hardware failure or symptomatic screw loosening. Non symptomatic screw loosening did not always lead to a new surgery. Figure 23 shows that in half of the cases of ASD revision surgery was performed; the rates for hardware failure and screw loosening (SL) are slightly lower.

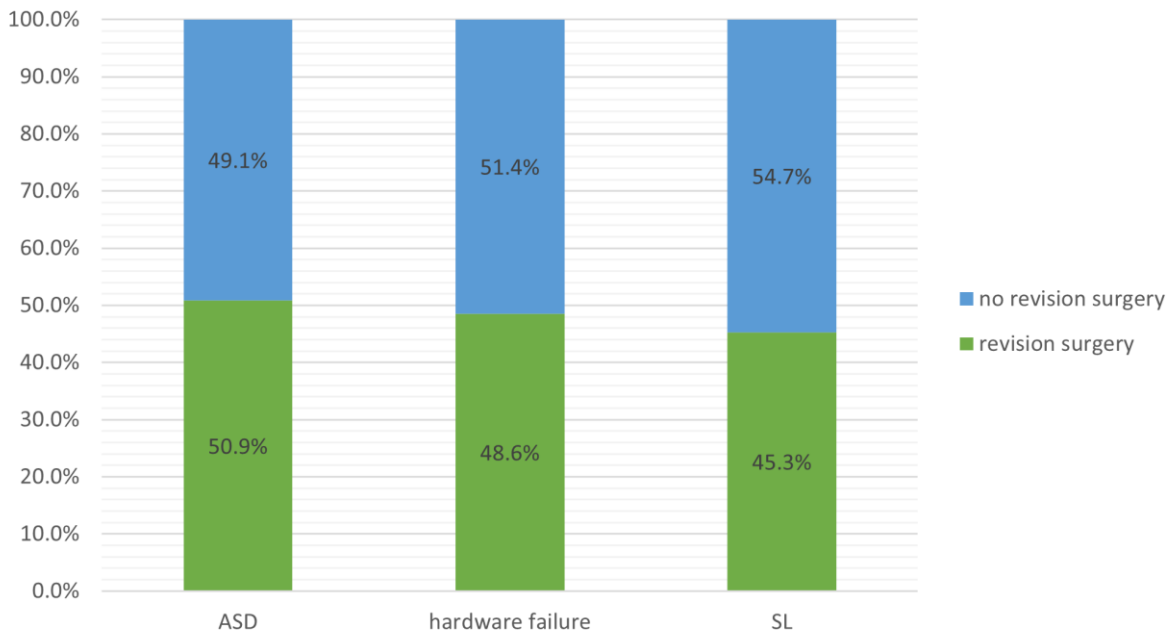

Figure 23: Rate of revision surgery distributed between ASD, hardware failure and SL

The indication setting was a complex consideration weighing individual risks and benefits resulting in different approaches for revision surgery depending on aetiology and surgical potential.

Figure 24 demonstrates the relative distribution of the surgical treatments in revision surgery. In many cases an extension became necessary. In more than half of the cases this was combined with a change of material, frequently with a change from

semi-rigid to rigid systems. The mere changing of screws was performed only in a few cases.

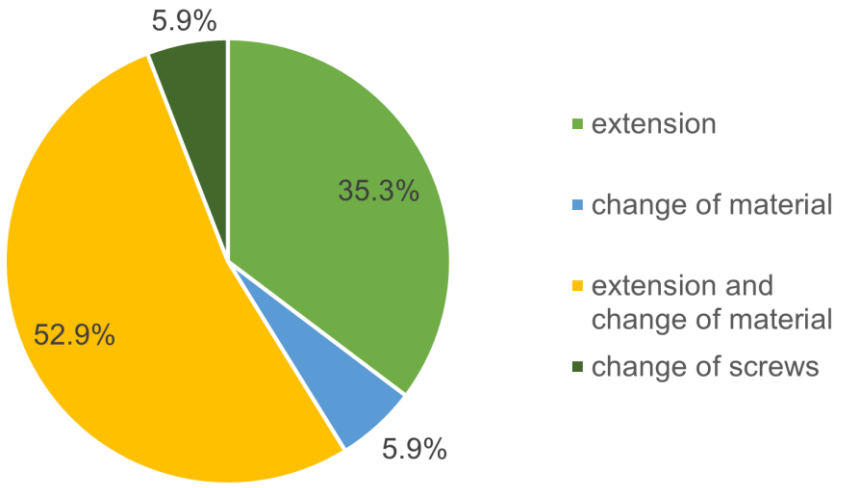

Figure 24: Relative distribution of revision surgery procedures

3.4. Subjective outcome

Subjective outcome describes the changes of pain, neurological deficit and daily abilities compared pre- and postoply and throughout the follow-up.

3.4.1. Pain

After the surgery 165 patients (51.2%) stated, they felt pain relief compared to the status before the surgery. Eleven patients (3.4%) even reported there was no pain left after the intervention, 28 patients (8.7%) did not have a reduction of pain.

In 118 cases (36.7%) no postop status was imposed. The mean value of pain measured by NRS was 4, SD 1.4. The first follow-up was set 3 months later. Here 214 patients (66.5%) stated they still suffered pain, 60 were pain free (18.6%). Of the 214 patients 67 (20.8%) at least felt an alleviation, 75 patients (23.3%) noticed no difference in pain compared to the time before the intervention. After approximately one year the next follow-up included 155 patients. 63.5% of them, equalling 73 patients, felt they had profited from the surgery. The mean value of pain, measured via NRS, was at 1.8 with 1.8 SD. A third follow-up, where the patients were examined by a physician, was designed as a maximum follow-up, with a mean value of 23.1

months (SD: 19.1, range: 0.5 - 73.0 months) post surgery. Here, 184 patients could be asked, if they still suffered from pain. This was the case for 145 patients (78.8%) and negative in 38 cases (20.7%).

Figure 25 shows the relative number of patients stating pain during the follow-up appointments. Presurgically all patients suffered from back pain, after one year the rate could be reduced to 61% patients with back pain. In the long-term follow-up, we can see, that 27% of the patients still lived without pain.

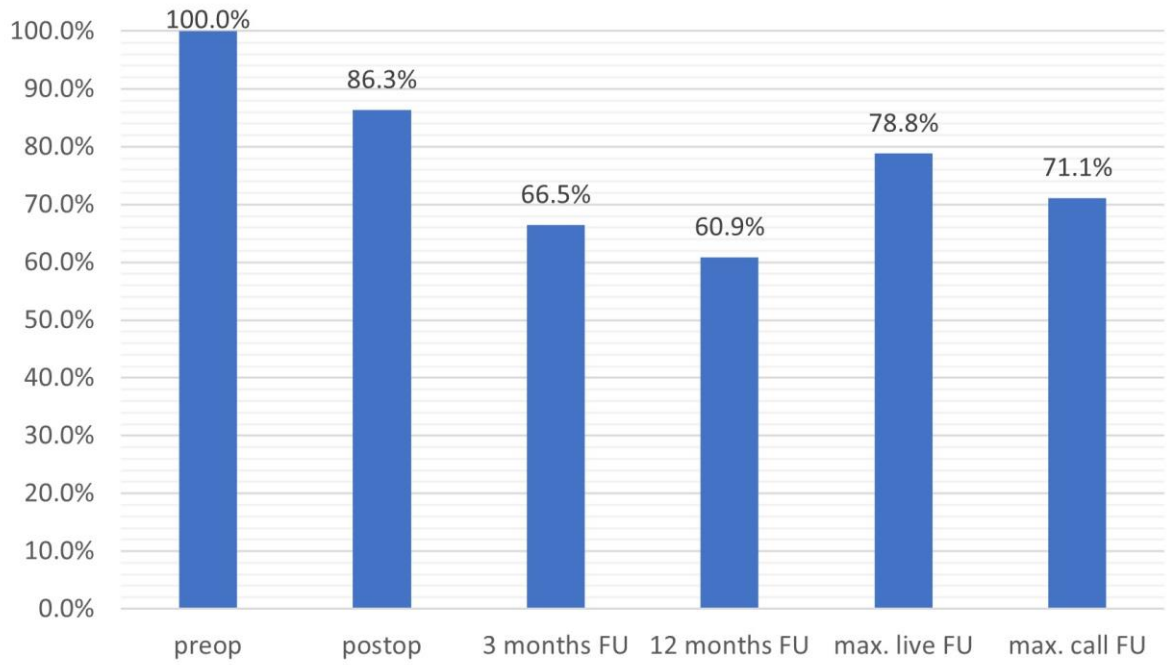

Figure 25: Patients stated to feel pain during the follow-up

Figure 26 visualises the alleviation of pain in the change of NRS score during follow-up. However, at the last follow-up the mean value for pain measured with NRS, lay at 4.0 ± 3.1 (range: 0.0 – 10.0; $p < 0.001$). In comparison to preop (before surgery) 7.9 ± 1.0 (range: 6.0 – 10.0) the NRS had significantly decreased postop.

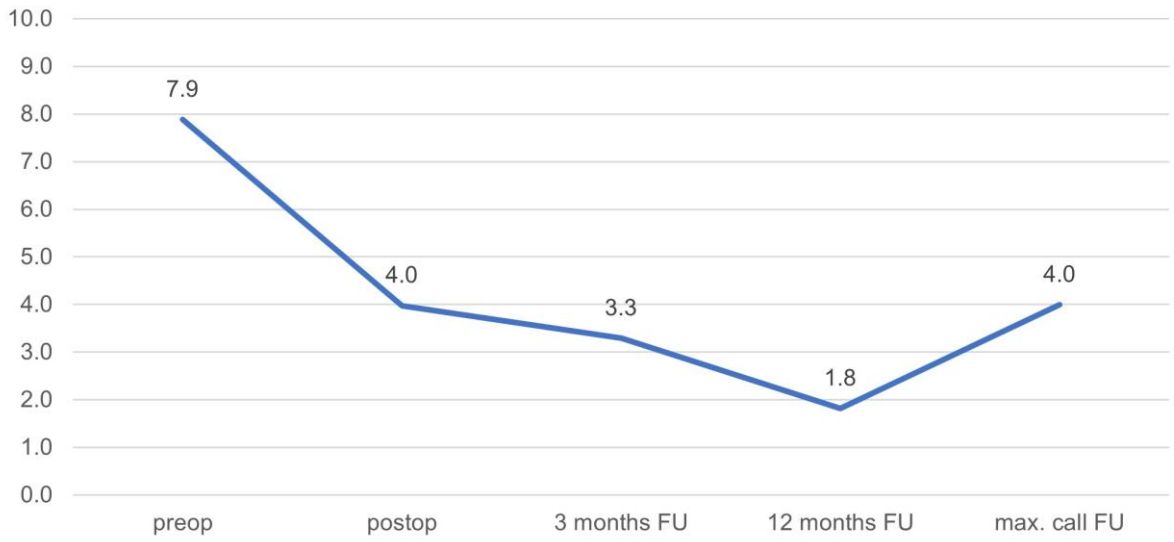

Figure 26: Numeric rating scale during follow-up

The box plot provided in Figure 27 illustrates the distribution of pain during each follow-up appointment. It shows the deviation in pain reduction postoply more detaillied with SD and 25% and 75% distribution of the results.

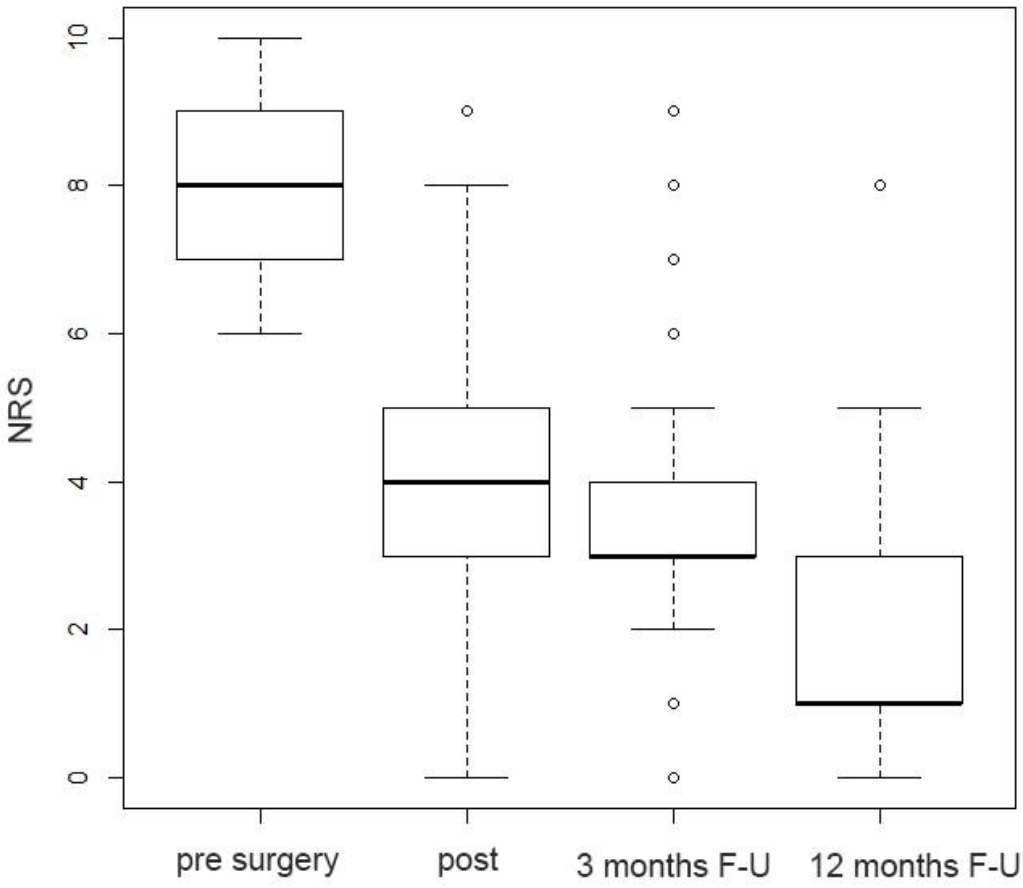

Figure 27: Box plot of NRS change during follow-up

3.4.2. ODI and RMDI

Table 3 shows the change in ODI and RMDI from pre to postop status. Unfortunately, data of only a third of the enrolled patients were imposed. Still, a clear reduction of disability in daily activities was reported by the patients.

Table 3: Mean value and range for pre- and postop ODI/RMDI

Presurgical ODI score (available from 29.2% of patients; mean ± SD, range)	45.8 ± 6.8 (31.0 – 70.0)
Postop ODI score (available from 29.2% of patients; mean ± SD, range)	33.4 ± 8.0 (6.62 – 60.0)
Presurgical RMDI score (available from 29.2% of patients; mean ± SD, range)	15.7 ± 2.8 (11.0 – 21.0)
Postop RMDI score (available from 29.2% of patients; mean ± SD, range)	10.5 ± 2.8 (0.0 – 18.0)

3.4.3. Neurological deficit

The neurological deficit contained the measurements of sensoric, motoric and vegetative deficit. 42% of the patients showed a sensoric deficit before the surgery, which could be reduced to 33% postoply. Motoric deficits did not decrease as much after spondylodesis, from 27% to 21%. Just 7% of the patients complained about bowel and bladder dysfunction before the surgery. The vegetative deficit showed complete extinction postoply. The newly acquired 9% in the maximum follow-up were found as sequelae of thereon newly acquired problems.

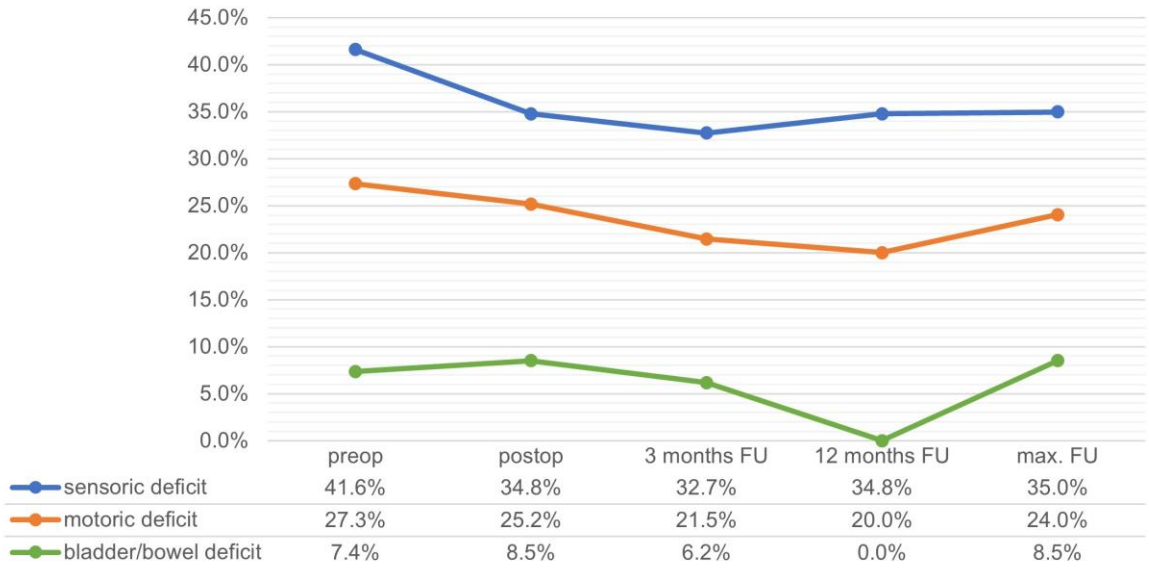

Figure 28: Development of neurological deficits during follow-up

3.5. Subjective satisfaction

Asked at time of discharge 83.2% (268 patients) said, they benefited from the surgery. After one year 63.5% (73 patients) still felt to have profited from the surgery, 39 patients (33.9%) did not. Asked in the phone call follow-up, 113 (56.2%) responded to still be statisfied with the outcome of the surgery. 71 (35.3%) reviewed, they did not subjectively profit from the stabilisation, in 17 cases (8.5%) the patients could not tell, if or if not, they felt any benefit. A common reason was the development of other diseases with intensified symptoms.

Multimorbidity was highly associated with a lower satisfaction rate. Postop multimorbid patients had 10% lower satisfaction rate than patients with no or just one or two comorbidities. Patients with complications during the hospitalization were significantly less satisfied (p< 0.0001) with the surgical outcome at the end of their hospital stay (97.8% satisfaction rate without complications vice versa 83.0% satisfaction rate with complications).

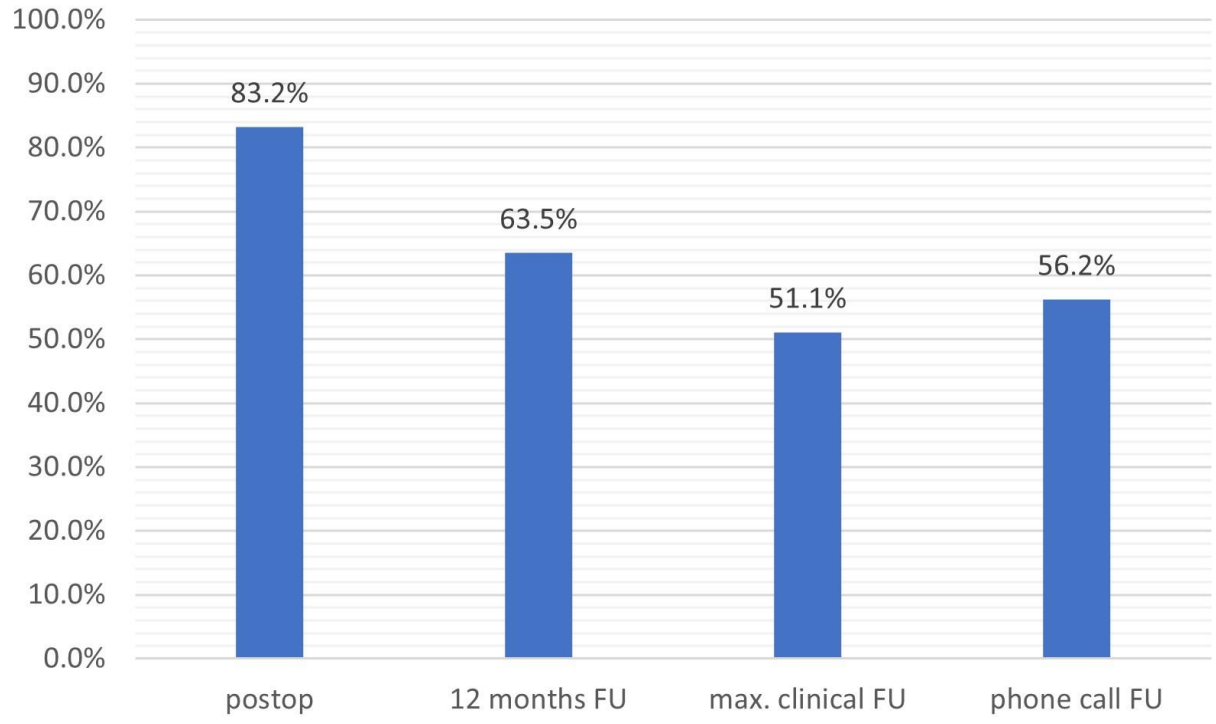

Figure 29: Satisfaction rate during follow-up

3.6. Phone call follow-up

Differing from the other follow-up appointments, we asked the patients about their consumption of pain killers. The patients should give information, if they took more, the same or less pain killers compared to the preop status; 47 patients (23.4%) quoted an increased intake, 92 (45.8%) a decreased intake and 45 (22.4%) the equal amount of medication, 8.5% were unclear. Asked for their ability of participation in daily life 46.8% of the patients answered, they saw an improvement in their daily abilities. 10.0% stated an equal participation, 37.3% less participation and 6.0% of patients were unclear.

3.7. Illustrative patient case

A male patient presented at the age of 76 years with spinal canal stenosis, lumbar instability and osteochondrosis. He stated that he had lumbar and gluteal pain and symptoms of a spinal claudication for more than 10 years. We measured a motoric and a sensory deficit. The motoric deficit was classified as a lesion of the nervous peroneus. Presurgical imaging was performed with X-rays in two layers and CT. Figure 30 and Figure 31 show the presurgical findings a narrowing of the intervertebral space can be seen, and spondylophytes at L3 and L4. The coronary X-ray shows a lateral bending of segments L3-L5 to the right. The segments L3-L5 also show subchondral sclerosis. The CT-scans suggest the diagnosis of degenerative disc disease by illustrating the narrowing of the intervertebral space, the erosion of the endplates and the spondylophytic dragging. Surgical treatment was indicated after the clinical examination in combination with the radiography.

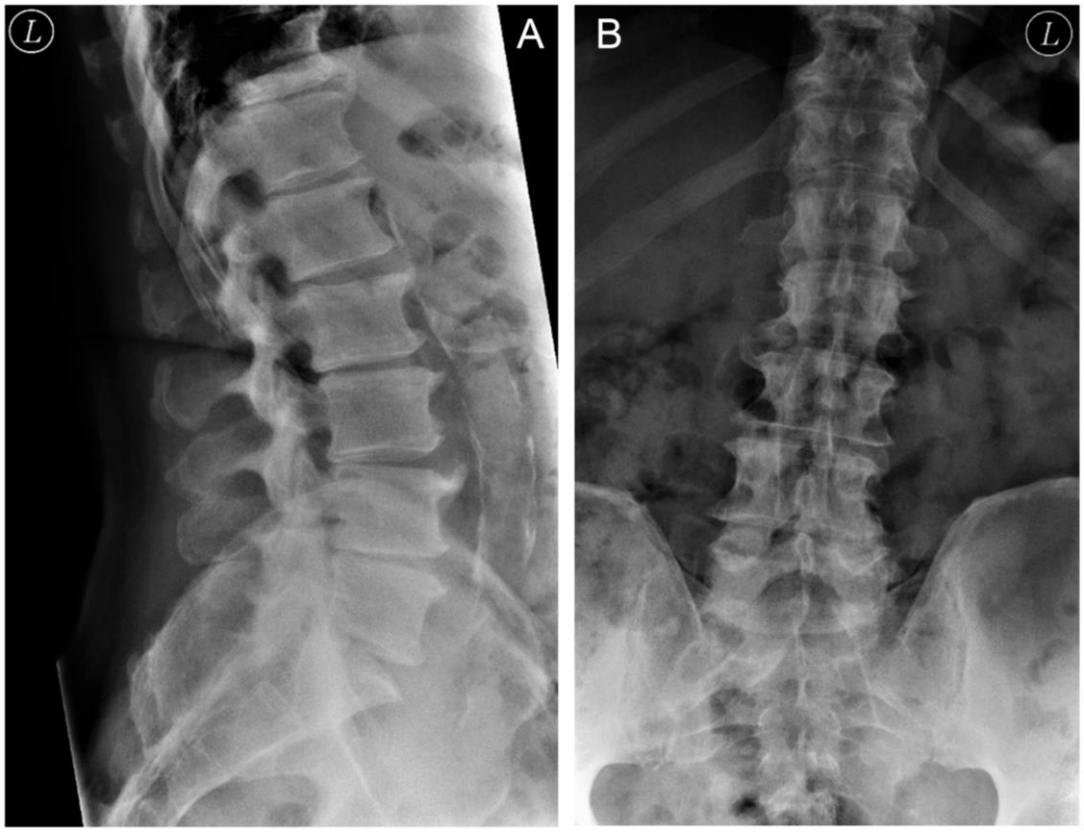

Figure 30: A: X-ray of the lumbar spine sagittal and B: Coronal X-ray of the lumbar spine of the preop patient case profile. (Source: Klinikum rechts der Isar)

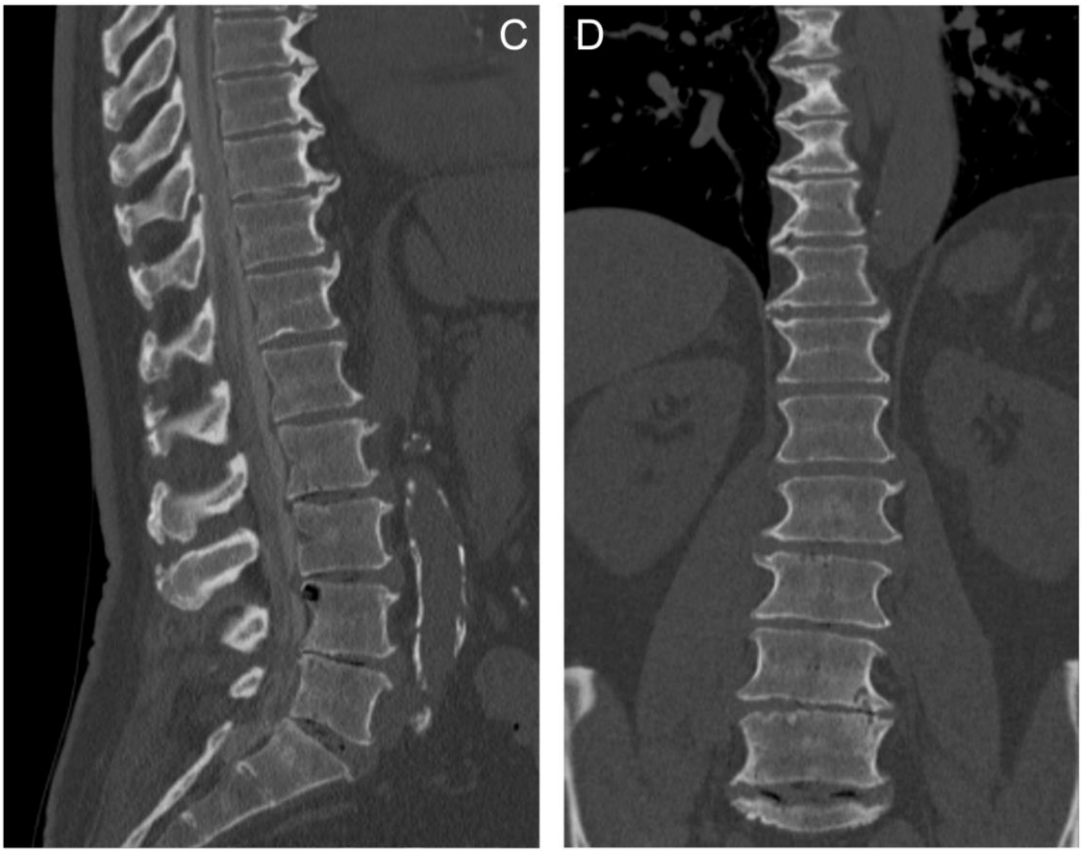

Figure 31: C: Sagittal CT-scan of the lumbar spine and D: Coronal CT-scan of the preop patient case profile. (Source: Klinikum rechts der Isar)

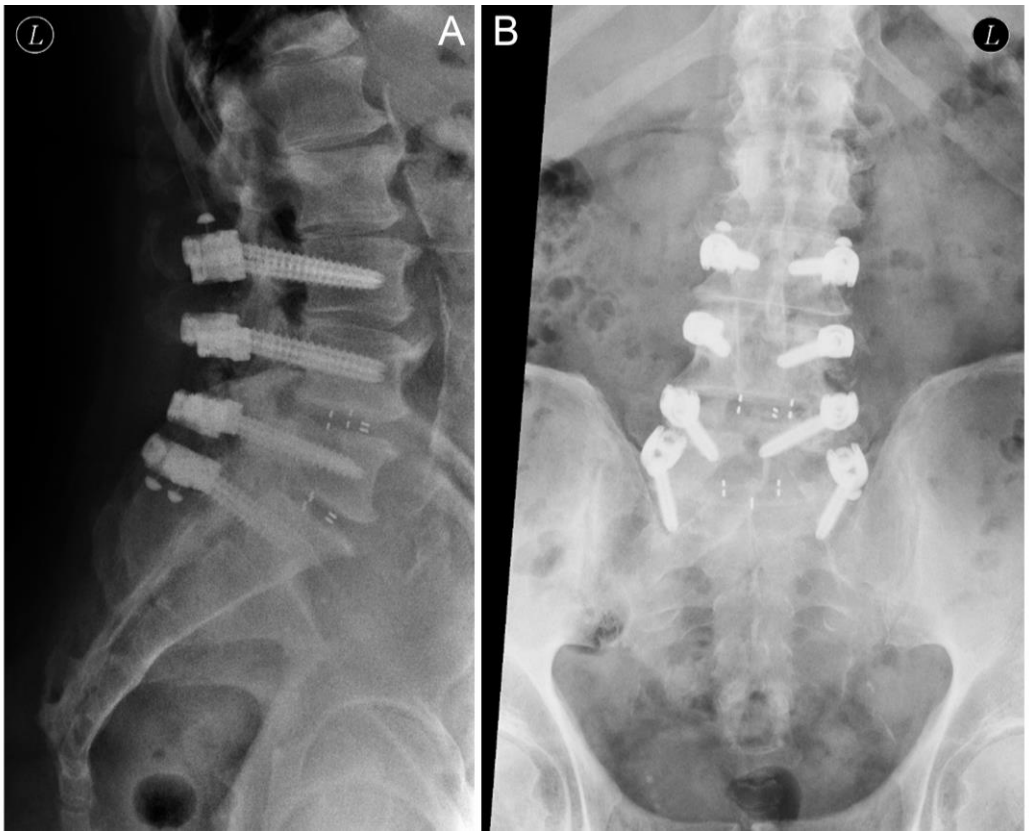

Figure 32: A: X-ray sagittal of the lumbar spine and B: Coronal X-ray of the lumbar spine of the postop patient case profile. (Source: Klinikum rechts der Isar)

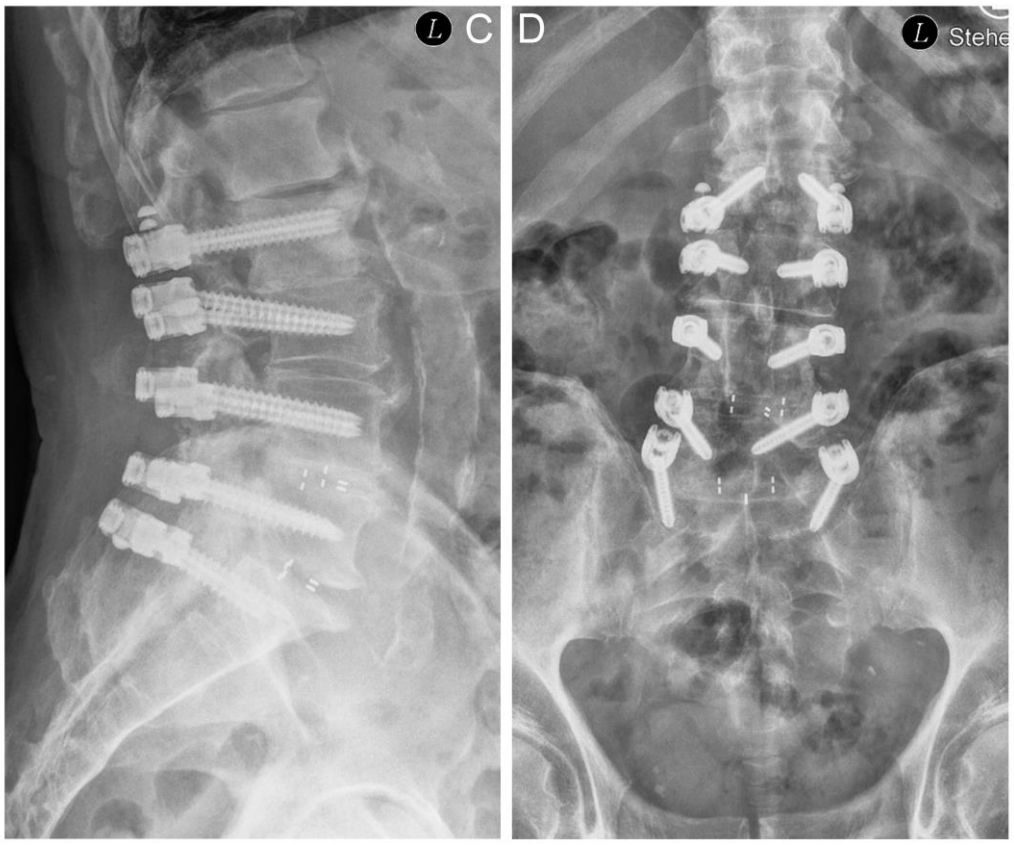

Figure 33: C: Sagittal X-ray and D: coronal X-ray of the lumbar spine post extension*. (Source: Klinikum rechts der Isar)*

The patient underwent pedicle screw-based surgery of L3 to S1 using eight screws, two PEEK rods and two cages introduced via TLIF. Therefore, we fused two segments and left the most upper segment L3-L4 without anterior fusion using the 'topping-off'-technique. Furthermore, in the segment L4-L5, a decompression seemed necessary and was added. Postoply, the patient remained for six days in our hospital and received after-care treatment. He stated to feel less pain. His motoric and sensory deficits remained. Postop radiography was performed and displayed a satisfactory spondylodesis with proper positioning of the TLIF cages, as shown in Figure 32.

When he left the hospital, the patient concluded that he had benefited from the surgery. At the first follow-up, he stated that the pain was equal to the time before the surgery and the sensory and motoric deficits remained. A facet joint-syndrome and an iliosacral-joint-syndrome were treated with infiltration. After 12 months, the patient provided information that he no longer had pain or paraesthesia. The peroneus nerve lesion remained. When asked if he felt that he had profited from the surgery, he approved. The next follow-up dated five and a half years after the surgery. The patient still felt no pain, but new paraesthesia occurred. He continued to have benefited from the first surgery, even though an adjacent level disease at the segment L2-L3 made an extension of the pre-existing spondylodesis necessary, see Figure 33. When we interviewed the patient via phone 6.8 years after the first surgery, he stated that he was still '100% satisfied' with the dorsalventral spondylodesis. He did not feel any pain, nor a sensory or a new motoric deficit. He stated that he could participate easier in daily life and handle tasks of daily work more actively than before the surgery. Also, he no longer needed painkillers.

3.8. Risk factors

3.8.1. Univariate regression analysis

Table 4: Results of the univariate regression model (Krieg et al., 2019)

	Revision surgery		**Revision surgery due to ASD**		**Revision surgery due to implant failure**		**Revision surgery due to screw loosening**	
	OR [95%-CI]	**p-value**	**OR** [95%-CI]	**p-value**	**OR** [95%-CI]	**p-value**	**OR** [95%-CI]	**p-value**
Age (years)	0.99 [0.96 - 1.03]	0.59	1.01 [0.97 - 1.06]	0.71	0.98 [0.94 - 1.04]	0.55	0.97 [0.93 - 1.01]	0.11
Gender (female)	0.49 [0.25 - 0.96]	**0.04**	0.4 [0.17 - 0.92]	**0.03**	0.71 [0.24 - 2.08]	0.53	0.48 [0.21 - 1.09]	**0.08**
Previous surgery	1.79 [0.88 - 3.83]	0.12	1.3 [0.56 - 3.2]	0.56	4.22 [1.11 - 27.58]	**0.06**	1.48 [0.63 - 3.81]	0.39
Number of segments	1.28 [0.75 - 2.2]	0.37	1.93 [1 - 3.81]	**0.05**	1.27 [0.55 - 2.97]	0.58	0.99 [0.52 - 1.9]	0.98
Level L5 / S1	1.92 [0.93 - 4.18]	**0.09**	2.22 [0.9 - 6.35]	0.10	2.3 [0.7 - 10.42]	0.21	1.43 [0.61 - 3.66]	0.43
Time since surgery (month)	1.03 [1.01 - 1.05]	**< 0.001**	1.04 [1.02 - 1.07]	**< 0.001**	1.02 [0.99 - 1.05]	0.10	1.01 [0.99 - 1.03]	0.22

Regression models to identify risk factors for ASD and SL could be calculated with 171 patients (53.1%). We included patients, who had completed at least the 3-month follow-up. The number of segments stabilised (p= 0.05) and the elapsed time since surgery (p< 0.001) appear to increase the risk of ASD. Furthermore, female gender tends to decrease the risk of revision surgery due to ASD. On the other hand, male gender might be associated with revision surgery due to SL (p= 0.08). An association between revision surgery caused by implant failure could be found with previous surgeries (p= 0.06). The factors male gender (p= 0.04), surgery on level L5/S1 (p= 0.09) and time since surgery (p< 0.001) had in common, that they all could be associated to revision surgery.

3.8.2. Multivariate regression analysis

Table 5: Association of revision surgery/screw loosening and potential risk factors in multivariate logistic regression model (Krieg et al., 2019)

	Revision surgery due to ASD		**Revision surgery**	
	OR [95%-CI]	**p-value**	**OR** [95%-CI]	**p-value**
Gender (female)	0.44 [0.17 - 1.07]	0.07	0.53 [0.26 – 1.09]	0.09
Number of segments	2.04 [1.00 - 4.32]	0.06	-	-
Level L5 / S1	-	-	**2.15 [1.00 - 4.93]**	0.06
Time since surgery (month)	**1.04 [1.02 - 1.07]**	**< 0.001**	**1.03 [1.01 - 1.05]**	**< 0.001**

In the univariate analysis we located different risk factors associated to one variable. To identify the risk factors for revision surgery, that were independent and singular, we calculated mutually adjusted models (Table 5). The results display that, in both models association between the different variables was still visible ($p< 0.10$). Indeed, time since surgery appears to be the only significant risk factor (p-value <0.05). Revision surgery due to ASD: OR=1.04, 95%-CI=[1.02 - 1.07], $p< 0.001$; any revision surgery: OR=1.03, 95%-CI=[1.01 - 1.05], $p< 0.001$).

4. DISCUSSION

Low back pain is a common problem in our society. It occurs primarily due to the ageing of the lumbar spine. Degenerative lumbar spine diseases can be treated conservatively or surgically depending on the status of the disease and the patient's pain and disability. The standard surgical treatment is dorsal stabilisation with a screw-rod system combined with the anterior fusion of the vertebral body. Common complications are ASD and SL. Thus, revision surgery becomes necessary. Biomechanical studies concluded that the higher pressure and rigidity on adjacent discs lead to hypermobility of adjacent segments and then to pathologic loading and, finally, degeneration. New hybrid or dynamic systems aim to solve this problem by creating a more physiological load distribution using more bonelike material, such as PEEK for the rods or bendable screws.

In the present study, we compared our results from ventral fusion with a cage, SRI and the additional 'topping-off' technique with those in the literature. The functional results and remaining symptoms were recorded with the NRS, ODI and RMDI. The patients were clinically examined, and complications evaluated with radiographs. The surgical technique used in this study is pedicle screw based with connecting PEEK rods and an anterior fusion of all indicated segments, except the most cranial one. PEEK, as rod material, allows flexion and extension, but restricts rotation and lateral bending better than titanium rods (C. Li et al., 2018). First, this method should lead to a more homogenous loading of the segment, reducing stress on the screws and adding load to the anterior cage.

Second, the risk for ASD should be further reduced by using the 'topping-off' technique for the most cranial segment to create a smoother transition from instrumented to the mobile vertebra (Caserta et al., 2002; P. H. Chou et al., 2017). In a clinical trial, Putzier et al. (2010) randomised and prospectively divided 60 patients into a rigid and hybrid fusion group and comparatively followed-up patients for a six-year period. They found less occurrence of ASD, but a higher rate of implant failure for the hybrid fusion group. Putzier used prophylactic DS of the segment above the affected segment. In contrast to this study, we addressed only affected segments.

4.1. Advantages of this study

This is the largest investigation of longitudinal revision surgery rates for ASD and SL after lumbar SRI. The age (mean: 69.1 ± 9.9 years) of the patients included in our study was older than in many other studies (Bydon et al., 2014; De Iure et al., 2012; Kaner et al., 2009; Putzier et al., 2010; H. Wang, L. Ma, D. Yang, T. Wang, et al., 2017). This age difference might lead to a less convincing outcome because the cohort has more comorbidities and longer patient histories. However, we propose that this leads to a more realistic picture of DSD's prevalence and the typical problems in daily clinics. Three hundred and twenty-two patients form a large cohort to study SRI. Further, in combination with the 'topping-off' technique, there was no similar study. Women and men could be included equally. The mean follow-up was 4.3 ± 1.8 years (range: 0.8–7.0 years). This allowed us to monitor the patient's satisfaction, complications and their further development for a longer time than other studies, which often ended at the two-year follow-up (Desjardins, 2016; Kaner et al., 2009; Ohtonari, Nishihara, Suwa, Ota, & Koyama, 2014; Selim et al., 2018; H. Wang, L. Ma, D. Yang, T. Wang, et al., 2017). This helped to detect complications that occurred at a subsequent status. Certainly, long-term complication rates are higher, and the patient's satisfaction is lower. However, the cases are more realistic and reflect clinical reality. All patients with DSD and the indication for a surgical therapy were included into the study. Older and sick patients were not excluded. Their inclusion in the study may lead to a more realistic picture of the daily situation and postop complications and outcomes. However, the probability of confounders increases during follow-up and with secondary diagnoses. Furthermore, the different diagnoses summed up in DSD form a heterogenous study cohort. The study focussed on lumbar interventions, thus included stabilisation from one to five segments. Other studies were done with one or two stabilised segments. Separate from the long-term evaluation of hardware failure, we registered patients' pain levels and satisfaction rates during the follow-up. Thus, we included a rather subjective, but determining, factor for the procedure. Stabilisations are a frequently chosen therapeutic option when conservative therapy does not alleviate a patient's pain or disability. We found few studies reporting the satisfaction of patients after surgical treatment of degenerative lumbar disorders.

4.2. Limitations of the study

Retrospectively imposed data faces various disadvantages. The information provided in the medical notes from patients' appointments at the hospital was not standardised and incomplete. Hence, it was not possible to collect all data for every patient. Due to this, ODI, RMDI and NRS were not taken for every patient. The times for the three-month and 12-month follow-ups varied for some patients between two and four months.

One main limitation of the study is the limited follow-up rate, with 37.5% of all operated patients being lost during follow-up. Because the aim was to include every patient undergoing the SRI 'topping-off' technique and to follow-up with them to the last contact. The long follow-up period is an advantage on the one hand, but on the other hand, it is a confounder, especially regarding patient satisfaction. Many patients were unable to classify their quality of life compared with preop because they could not remember their subjective status before the surgery. Others had new events such as strokes, heart insufficiency or Morbus Parkinson and, due to these, they were unable to distinguish between the various influences that pain and disability had on their life. This might have lowered patient satisfaction unjustifiably in long term outcomes. Patients' subjective ratings were overshadowed by other illnesses and confound the study results.

As revision surgery was determined as the primary endpoint, very heterogenous follow-up data emerged. Furthermore, the degenerative lumbar spine disease unites various diagnoses in a heterogeneous group. For example, degenerative lumbar spinal canal stenosis, spondylolisthesis or spondylankylosis might naturally develop at different paces or show different outcomes.

Our study focussed on clinically apparent ASD. Thus, new imaging was only indicated for symptomatic patients. As a result, the data cannot provide the important differentiation between mere radiological adjacent segment degeneration and clinical disease. This criterion might lead to an underestimation of the possible influence of radiological adjacent segment degeneration.

A definite correlation between the radiological finding of adjacent segment degeneration and the occurrence of symptomatic ASD has not been proven. For example, in a retrospective radiographic study of 62 patients Han et al. (2016) found

a four-year rate of 29% of radiological ASD after dynamic pedicle screw-based instrumentation in L5/S1, but not in one that required revision surgery.

4.3. Main results of the study compared with the literature

4.3.1. ASD, SL and hardware failure

Detecting ASD, SL and cage dislocation were the main endpoints of this study. Overall, 10.9% of hardware complications were registered and 17.7% of patients developed ASD during follow-up. The time until the occurrence of ASD ranged from 1.0 to 70.0 months after surgery, with a mean value of approximately two years (26.5 ± 17.6 months). In the group that could be followed-up completely, 142 (46.9%) cases did not show any sign of symptomatic instability. However, 105 cases (34.7%) were lost during follow-up. Bydon et al. investigated ASD after posterolateral instrumented lumbar arthrodesis in more than 500 cases between 1990 and 2013. Their cohort was slightly younger than ours with an average age of 60 years. They did not use the 'topping-off' concept, but comorbid patients were included as well as multi-level fusion (average 2 ± 1 fused segment). They found a rate of 15.7% ASD throughout the mean follow-up time of 3.5 years, which is similar to our results (Bydon et al., 2014). In a systematic review, Chou et al. (2017) compared the rates of ASD in classical fusion with hybrid stabilisation devices and interspinous process devices. They found an incidence of 52.6% of radiographic adjacent segment degeneration and 11.6% of ASD in patients receiving a rigid fusion without 'topping-off'. The hybrid stabilisation system showed a rate of 10.5% of radiographic ASD (P. H. Chou et al., 2017). Epidemiological recording for revision surgery for ASD after fusion surgery revealed a mean annual incidence for ASD in the first 10 years of 2.5%, with rising prevalence at five and 10 years after fusion surgery, 13.6% and 22.2%, respectively (Sears et al., 2011). These details confirm the necessity for long-time follow-up as performed in our study to illustrate clearly that revision surgery for ASD is common. In a retrospective study of 237 patients, Wang et al. (2017) investigated incidence and risk for ASD after posterior decompression and instrumented fusion in the degenerative lumbar spine. They found that 6.3% of his patients developed ASD during the two-year follow-up. This rate was much lower than the rate mentioned previously. However, secondary surgerys were excluded

from the study, a maximum of two levels was instrumented and the mean age of patients was 53.2 years. The younger patient age was a result of making disc herniation an inclusion criterion. ASD was only recognised above the fusion. In our study, ASD was 80.0% cranial of the stabilisation; 12.3% below, and 7.0% above and below the operated segment. Other studies found rates of 5.2% to 18.5% for symptomatic ASD after dorso-ventral stabilisation for a five-year timespan (Ghiselli, Wang, Bhatia, Hsu, & Dawson, 2004; Park, Garton, Gala, Hoff, & McGillicuddy, 2004; 2014). The rates of ASD in our study are comparable to the current literature. Frequently, just one or two levels were fused, and a higher count of fused levels was seen as a risk factor for the development of ASD. Lower rates of ASD were more frequent in studies with shorter follow-up periods and smaller cohorts.

SL was detected in 19.9% of patients. This result matches the findings reported by other studies. Kuo et al. (2015) researched SL rates in DSs using the Dynesys system over a follow-up period of four years. They saw a SL rate of 8.2% of all screws inserted and in 20.4% of patients (Kuo et al., 2015). Furthermore, Payer et al. reported a two-year revision rate of 7.0% for symptomatic SL after single-level dynamic stabilisation and decompression with the Dynesys® DS system (Zimmer Biomet Spine Inc., Westminster, CO, USA). The indication was lumbar anterolisthesis and stenosis, excluding previous lumbar surgery and multi-level degeneration (Payer et al., 2014). This outcome appears to be inferior to our series, in which only 8.9% needed revision surgery for loosened screws throughout the whole follow-up. This is particularly relevant, regarding multi-level stabilisation, and especially, since our study had a high rate of secondary surgery and a longer follow-up period.

Not all radiographically SL or adjacent segment degeneration were symptomatic and needed a revision. Approximately half of the patients with a radiographically detected hardware complication underwent another surgery. The overall revision rate was 16.4% after an average maximum follow-up of 4.3 ± 1.8 years. In cases of another surgical procedure, the complications encountered were an extension and a change to rigid material (52.9%) or only an extension (35.3%).

Sato et al. (2015) conducted a long-term, follow-up study on revision rates after decompression alone versus rigid instrumentation plus decompression of 163 patients with degenerative lumbar spondylolisthesis with a minimum follow-up of five

years. An overall revision rate of 6.1% after one and 23.3% five years after surgery was reported (Sato et al., 2015). The overall resurgery rate in this study was at least equal if not superior to that of other series, especially when considering the low rate of first-tier surgeries of this cohort.

Hospitalisation was often prolonged by perisurgical complications that were primarily related to wound infections (15%), therapy indicating Hb decrease (12%) and secondary related to the surgery like heart attacks, kidney failure or bladder dysfunction. These findings might be explained by the advanced average age of our study cohort. Deyo et al. (1992) reviewed around 18,000 hospital registrations over two years, of which 84% had disc herniation or lumbar spinal canal stenosis. They found a complication rate of 18% for patients older than 75 years. They saw significant evidence that the older the patient, the higher the surgical risks. This finding was supported by a more recent study that examined morbidity and mortality in older patients with lumbar fractures. It confirmed that dorsal instrumentation in older patients (>70 years) is associated with higher morbidity (Winkler et al., 2015).

On the other hand, older patients decisively profit from fusion surgery. In a systematic review, Carreon et al. (2008) included 25 studies that had prospectively measured the ODI for a minimum of 12 months postop. Older patients, in particular, presented with symptomatic spondylolisthesis, which is an indication for surgical therapy. They found considerable improvement in ODI for fusion surgery in degenerative disc disease and spondylolisthesis.

As explained previously in the introduction, a rapid increase in surgery, primarily spinal fusion, for spinal canal stenosis has occurred at the end of the twentieth century, especially for patients with comorbidities and older than 65 years. Consequently, perisurgical complications and mortality rose proportionally. Due to this, the risks and benefits of these procedures should be researched further in elderly patients.

Based on this, Yavin et al. (2017) found no clear evidence indicating fusion for lumbar spinal canal stenosis.

Furthermore, a large Swedish prospective, randomised, multi-centre study showed no difference in the reduction of ODI after two and five years in patients receiving just decompression or decompression and fusion, neither for the indication of spinal

canal stenosis nor for spondylolisthesis. Fusion was very expensive, without additional benefits in outcomes. This study included 247 patients between 50 and 80 years, but excluded secondary lumbar spine surgery and spinal instability (Försth et al., 2016).

4.3.2. Subjective outcomes

The Numeric Rating Scale is a subjective factor, but pain is nonetheless the most important issue for patients. Overall, approximately half of the patients felt less pain at discharge from the hospital compared with their preop status. After three months, 39.4% of patients saw an improvement in pain. Before the surgery, all patients suffered from back pain, and after one year, the rate could be reduced to 61% of patients suffering from pain. At the long-term follow-up, 27% of patients still live without pain.

Finally, we saw a significant reduction of NRS from preop to the follow-up phone call. This data is supported by Kaner et al., who conducted a prospective study of a small series with 15 patients and up to one-year follow-up using a DS system. They found a reduction of NRS from 6.9 months preop to 2.5 three months postop. With a mean age of 42 years, the patients were significantly younger compared with our cohort, but still had the primary diagnosis of degenerative disc disease (Kaner et al., 2009).

In (2016) Li et al. did a systematic review on lumbar stabilisations using PEEK rods with or without anterior fusion. They reviewed a series of eight clinical studies with a similar focus as our study. The authors also found statistically improved NRS and ODI in most studies. Athanasakopoulos et el. had a series of 52 patients whom they followed for 18 to 48 months with appointments at 3.6 and 12 months postoply. They compared a preop NRS of 8 of 10 for low back pain and a 9 of 10 for leg pain preop that was reduced to 6 and 5, respectively, immediately postoply and then to 2 during follow-up (Athanasakopoulos, Mavrogenis, Triantafyllopoulos, Koufos, & Pneumaticos, 2013).

A retrospective cohort group comparison was done by Colangeli et al. (2015), who compared the use of PEEK rods to NFlex in 12 cases each over 19 to 36 months. They reached similar results with a preop NRS of 9.4 and a final NRS of 4.0 (Colangeli et al., 2015). When asked about their ability to participate in daily life, 50% of patients answered that they saw an improvement in their daily abilities.

The ODI in our study showed a good reduction 45.8 ± 6.8 (31.0–70.0) to 33.4 ± 8.0 (6.62–60.0). The previously mentioned studies presented similar results, Atharnsakopoulos et al. described a preop ODI from 68 to 24 in their last follow-up, Colangeli et al. (2015) described a preop ODI of 76 and an early postop ODI of 34.8 at six weeks, which is similar to our postop ODI value and its measurement period. Kaner et al. (2009) saw a preop ODI of 65.9 and ODI of 18.3 three months postop. These results are consistent with a review by Chou et al. (2017), including studies from Putzier et al. (2010) and Payer (2014).

The soft parameters we collected in this study appear to validate the data other studies reported previously. Our results showed a significant reduction of pain and gain in daily abilities for patients with degenerative spine diseases after lumbar stabilisation with PEEK rods and in our case, as well with 'topping-off'. We found that at discharge, over 80% of patients felt that they benefited from the surgery. After one year, the rate dropped to approximately 60%, and at the long-term follow-up, approximately 56% felt that they profited from the surgery.

It is important to consider that the follow-up for patients with complications might have been better because they had a subjective reason to attend the follow-up appointments. Patients with a high reduction of pain, no complications and a high satisfaction seemed not to attend further appointments or did not schedule them because there was no need. This is one reason why we set up the last follow-up as a phone interview. We hoped to reach these patients to minimise this follow-up confounder. However, patients with complications may have changed their attending physician and could not be observed further. Due to this, we asked during the phone interview, if further surgerys had been performed at different hospitals.

The long-term follow-up gave us a large amount of information about if and when hardware failure did happen and how satisfied patients are with the results.

After three to five years, many patients could not determine if their condition might have become worse due to the surgery or if it was unrelated to the surgery. Also, patients' secondary diseases might interfere with their well-being, since there was a high rate of patients with secondary diseases (73%) and 26% multimorbid patients with comparatively older age. Furthermore, the indicating diagnoses are degenerative; degeneration cannot be stopped entirely.

4.3.3. Risk factors

Little is known about risk factors determining complications and predispositions for revision surgery after SRI of the lumbar spine. In our study, the univariate regression showed that the number of segments stabilised, gender and previous surgery could be detected as the main risk factors for revision surgery.

The multivariate analysis revealed that only the time since surgery ($p< 0.001$) shows significance as being a risk factor for revision surgery due to ASD. However, it is unclear whether this occurs due to changes in the biomechanical conditions of the fusion as explained by various biomechanical and clinical studies Cheng et al. (2007); Jahng, Kim, and Moon (2013); Moumene et al. (2010)or if it is part of the natural degeneration process that the spine undergoes as Hambly et al.(1998) and Penta et al. (1995) discovered. Penta et al. performed a 10-year post-lumbar interbody fusion and follow-up of 81 patients via MRI. Also, they reasoned that 68% of patients had physiological ASD. They concluded that the development of ASD might be a more individualised process rather than a sequela of fusion surgery. Hambly et al. followed their patients for over 22 years after lumbosacral fusion to monitor the transition zone from the fused to the mobile segment. Their study group was small, with 42 patients who were followed and compared with a standard population cohort. They concluded that degenerative changes in adjacent segments could be seen radiographically in the study group but without any significant difference from the cohort group. Wang et al. (2015) compared fusion patient cohorts separated into ASD and non-ASD groups. They found several risk factors independently associated with ASD, such as a BMI higher than 25, presurgical disc degeneration and superior facet joint violation. These findings were supported by Liang et al. (Liang, Dong, & Zhao, 2014). However, there are clinical studies basing on the assumption that ASD is an element of an ongoing degenerative process rather than altered biomechanical stress on the adjacent disc (P. H. Chou et al., 2017).

It remains unclear whether ASD is a phenomenon of the natural progression of degeneration or a specific complication of surgical intervention. We found a strong correlation ($p= 0.05$) between the number of segments stabilised, and the chance for revision surgery, meaning the more stabilised the segments, the higher the risk for revision surgery. This seems to be conclusive from a biomechanical point of view as more severe degeneration affects more segments that need treatment and elevates the risk of pre-existing predisposed segments or further degeneration. Cheh et al.

(2007) found significant evidence that supported this risk factor in their radiographic study of 188 patients with a follow-up of five years. Furthermore, Strube et al. (2010) found that with an increasing number of fixated levels and increasing stiffness of the fixation, the compensatory hypermobility at the adjacent segment also accelerates.

A gender disparity was observed: female gender was associated with a lower risk of revision surgery due to ASD and male gender with a higher one. On the other hand, Wang et al. (2017) did not find significant differences between the genders.

Implant failure as a reason for revision surgery is often associated with previous lumbar spine surgeries. Moreover, we observed longer surgery times in patients with previous spine surgeries, as well. One factor is that tissue preparation is more difficult for patients with second or third lumbar surgery.

Furthermore, we included many patients that already had a dynamic stabilisation and received a change of system and an extension. Thus, these patients present a more complicated and vulnerable surgery field with difficult healing conditions. Further studies differentiating these risk factors in patients with previous lumbar tier surgeries should clarify this issue.

A retrospective clinical study has been performed by Wang et al. (2004) to research the risk factors for ASD after posterior decompression and lumbar instrumentation. They followed 237 cases for two years. They grouped patients into non-ASD and ASD. As independent risk factors, the body mass index >25 kg/m² and presurgical adjacent segment disc degeneration were found significantly more often in the ASD group, and a higher rate of upper facet joint violation. These factors are supported by a 10-year-retrospective study by Liang et al. (2014). They detected no higher risk for older patients or more levels fused. However, they only included one or two-level stabilisation and their cohort group was young with a median age of 53.2 ± 10.8 years. In contrast, Sears (2011) found a significant association between the number of levels fused and ASD up to 40% after 10 years for three or four levels fused. Their count of revision surgery was considerably higher than that of Liang's cohort. Furthermore, patient's age, L5 fusion and laminectomy of the segment adjacent to a fusion increased the risk for ASD (Sears et al., 2011).

Another study found laminectomy in the segment adjacent to a fusion and residual sagittal imbalance to be apparent risk factors for ASD (Radcliff et al., 2013). In a study with a large cohort of 1069 cases undergoing dorsoventral lumbar and

lumbosacral fusion, the assessed incidence of revision surgery for ASD was 2.6%. Facet degeneration was determined to be a significant risk factor by matching ASD and non-ASD groups. Age could not be identified as a relevant risk factor (C. S. Lee et al., 2009). The study retrospectively covered a time span of 11 years between 1995 and 2006, but the follow-up time was heterogeneous with a minimum one-year follow-up.

4.4. Perspective

Prospective studies with large cohorts are necessary to optimise, standardise and complete the collected information further. It is also necessary to generate lower drop-out rates. Short term studies might not count in the illness' development, but comorbidities would be less confounding. Further studies should focus on significant risk factors for hardware complication and patient dissatisfaction to improve indication setting. We identified multimorbidity as a risk factor for a low patient satisfaction. We propose thoughtful indication setting for this patient group.
The salvation of the ASD problem remains problematic as there are indicators that it might be caused by the natural progression of the illness.

4.5. Conclusion

The use of PEEK rods proves to be a safe and valid alternative to titanium rods. We could validate this through long-term follow-up with multi-level instrumentation for a heterogenous diagnosis-group and a multimorbid cohort. The rates of ASD, SL and hardware failure are comparable to other current clinical studies. Considering the high rate of secondary lumbar back surgerys and comorbidities, our results seem superior to most other series. The 'topping-off' technique does not lead to outcomes that are significantly better regarding the reduction of either ASD or hardware failure compared with the literature. On the other hand, it does not worsen outcomes. Patient satisfaction with PEEK rods and 'topping-off' is solid but is not ground-breaking.

5. Summary/ Zusammenfassung

5.1. English

Dorsoventral stabilisation is a surgical treatment standard for degenerative spine disease. However, negative outcomes such as comparatively high rates of subsequent spine disease in adjacent segments, screw-loosening and overall low patient satisfaction require the development of new advancements of the current stabilisation techniques.

Modern concepts aim at sharing the load between the anterior and dorsal column of the vertebral body, while also reducing the relative hyper-rigidity of the stabilised segment in comparison to the adjacent vertebrae. One approach has been to use connecting rods made of plastic (PEEK- polymerethyletherketone) instead of titan to link the screws implanted in the vertebral bodies. Applying the topping- off technique is a further expansion of this approach, which omits ventral fusion in the most cranial segment, this way enabling a more physiological transition from stabilised to non-stabilised vertebrae.

The present retrospective study examined the outcome of semi-rigid stabilisation with PEEK rods and 'topping-off' technology in a large cohort up to seven years (median 4.3 years). Primary endpoints were the rate of implant failure and patient satisfaction. The data was extracted from the initial surgery protocols as well as ongoing medical reports of the department of neurosurgery of *Klinikum rechts der Isar, München*, in the years 2009 to 2015. In addition, final follow-up interviews were conducted by phone. Specifically, patients had been asked on their level of pain and subjective satisfaction rate before and after the surgery, and had been examined for neurological dysfunction.

Additionally, comorbidities, previous surgery in the respective region and duration of hospital stay were recorded. One primary endpoint depicted implant failure, comprising the development of subsequent adjacent level disease, screw loosening, as well as breakage or dislocation of material. The results revealed a rate of implant failure comparable to other recent studies. In the light of the high number of lumbar preoperated (60%) and multimorbid patients (26%) in the present cohort, this appears to be a positive result. Furthermore, comparing pre- and postop conditions, pain could be reduced significantly.

Finally, regarding patient satisfaction, over half of the cohort (56%) stated to be satisfied with the surgical result in the long run. Thus, stabilisation with PEEK rods and the application of the 'topping-off' technique present a safe and symptomatically satisfying alternative to the classic spondylodesis using titanium rods.

5.2. Deutsch

Dorsoventrale Stabilisierungen sind chirurgischer Standard in der Therapie der degenerativen Wirbelsäulenerkrankungen. Vergleichsweise hohe Raten an Anschlussdegenerationen, Schraubenlockerungen und ähnlichem, sowie eine durchwachsene Patientenzufriedenheit machen eine Weiterentwicklung der Systeme dringend notwendig.

Moderne Konzepte zielen auf eine bessere Ladungsverteilung zwischen vorderer und hinterer Säule des Wirbelkörpers und die Reduktion der Hyperrigidität im stabilisierten Bereich im Vergleich zu angrenzenden Wirbeln. Ein Lösungsansatz hierfür ist die Verwendung von Kunststoffstäben (PEEK) statt Titanstäben zur Verbindung der in die Wirbelkörper inserierten Schrauben. Die Weiterentwicklung im Sinne des 'topping-off', also dem Weglassen der ventralen Fusion im obersten inkludierten Bewegungssegment, soll einen physiologischeren Übergang von stabilisierten zu nicht- stabilisierten Wirbeln ergeben. In dieser Studie wurde das Konzept der semirigiden Stabilisierung mit PEEK- Stäben und 'topping-off'´-Technologie hinsichtlich der Rate an Implantatkomplikationen und Patientenzufriedenheit an einer großen Kohorte über einen langen Zeitraum betrachtet.

Die retrospektive Studie bezieht ihre Daten aus den OP- Protokollen, Arztbriefen und Verlaufs-Ambulanzbriefen der Neurochirurgischen Abteilung des *Klinikums rechts der Isar, München* in den Jahren 2009 bis 2015, sowie aus einem abschließenden Telefoninterview. Die Patienten wurden prä- und postoperativ zu ihren Schmerzen und ihrer persönlichen Zufriedenheit befragt sowie hinsichtlich neurologischer Ausfälle untersucht. Zusätzlich wurden Komorbiditäten, Voroperationen und Länge des Aufenthalts erfasst.

Ein primärer Endpunkt war die Erfassung von Implantatfehlern wie Anschlussdegenerationen, Schraubenbruch oder -fehllagen und Materialdislokationen. Es zeigte sich eine Rate an Fehlern am Implantat, die mit

gängigen Studien vergleichbar ist. Im Hinblick auf die hohe Rate an voroperierten (60%) und multimorbiden Patienten (26%) scheint dies ein positives Ergebnis. Schmerzen konnten im Vergleich von prä- zu postoperativem Zustand signifikant gesenkt werden. Über die Hälfte der Patienten (56%) gab auch im Langzeitverlauf Zufriedenheit mit dem Operationsergebnis an, was nach vier bis fünf Jahren dem Durchschnitt entspricht.

Die Stabilisierung mittels PEEK Stäben und 'topping-off' stellt somit eine sichere und für die Patienten zufriedenstellende Alternative zur klassischen Spondylodese mit Titanstäben dar.

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7. TABLE OF FIGURES

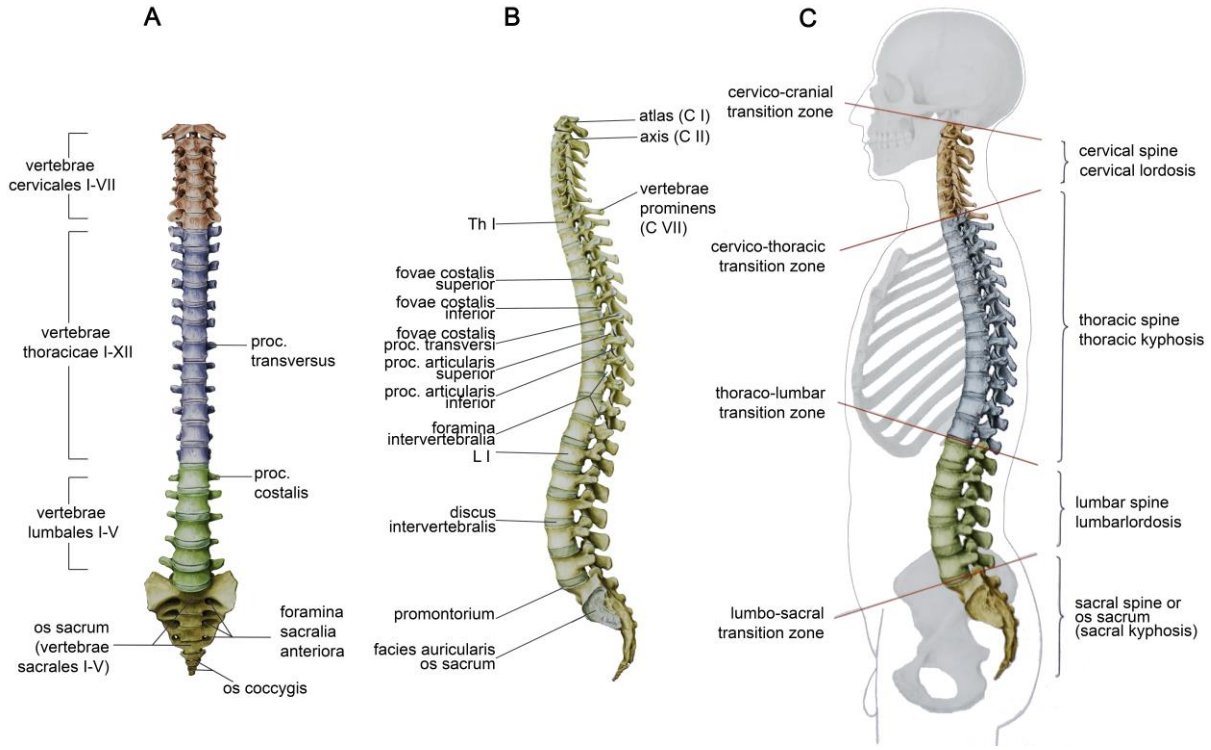
8. TABLE OF TABLES

9. TABLE OF ATTACHMENTS

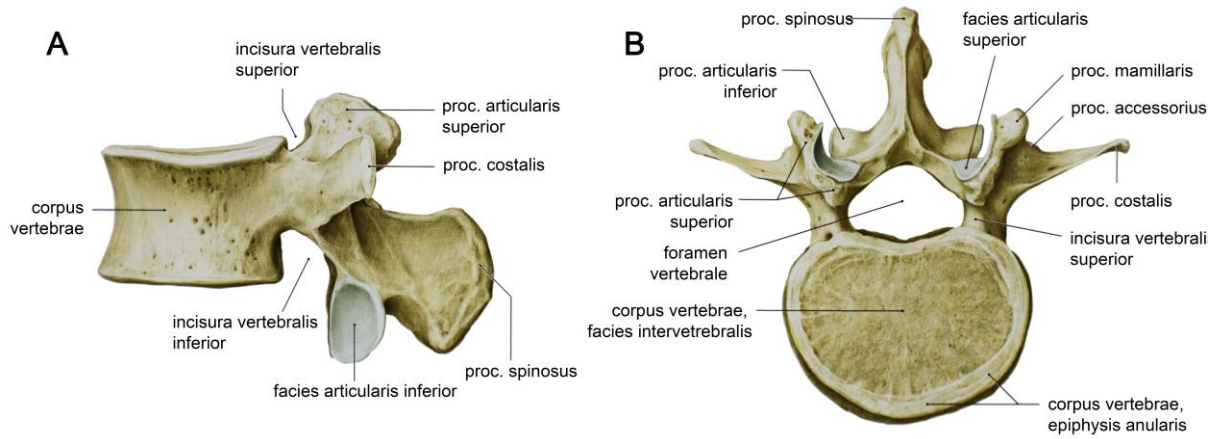
10. ABBREVIATIONS

3D	Three- dimensional
ALIF	Anterior lumbar interbody fusion
ASD	Adjacent level disease
CT	Computed tomography
DS	Dynamic stabilisation
LSS	Lumbar spinal stenosis
MRI	Magnetic resonance imaging
NRS	Numeric rating scale
ODI	Oswestry Disability Index
OLIF	Oblique lumbar interbody fusion
PEEK	Polyether ether ketone
PLIF	Posterior Lateral interbody fusion
Postop	Post operation (post surgery)
Preop	Pre operation (pre surgery)
RMDI	Roland-Morris Disability Index
ROM	Range of motion
SL	Screw loosening
SPORT	Spine Outcomes Research Trial
SRI	Semi- rigid instrumentation
TLIF	Transforaminal lumbar interbody fusion
XLIF	Extreme lateral interbody fusion

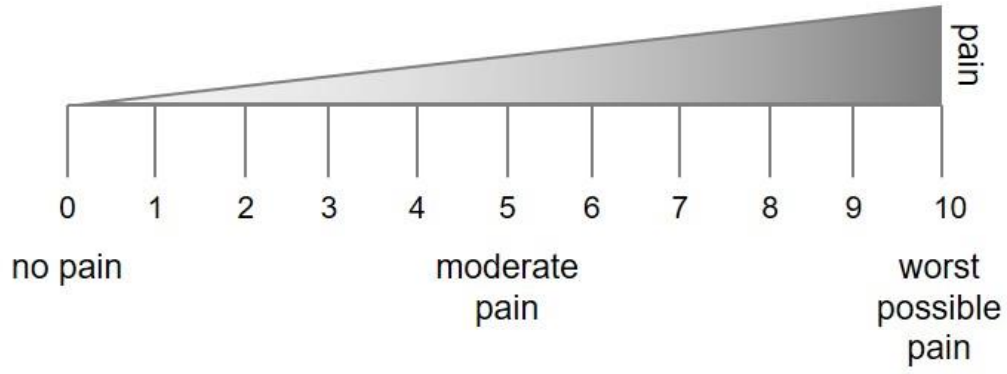
11. ATTACHMENTS



Attachment 1: Human spine anterior-posterior A; sagital view B, demonstrating the double-S-constitution of the spine. (Aumüller, Aust, & Doll, 2017)



Attachment 2: Fourth lumbar vertebra positioned in the spine in sagital view marked red and in axial view. (Aumüller et al., 2017)



Attachment 3: Numeric Rating Scale

Attachment 4: The Meyerding classification describes the percentage of anterior translation of one vertebra to the adjacent vertebra (Lasanianos, Triantafyllopoulos, & Pneumaticos, 2015)

the Meyerding classification of spondylolisthesis	
grade 1	<25%
grade 2	26-50%
grade 3	51-75%
grade 4	>75%

Attachment 5: Oswestry Disability Questionaire (Mannion, Junge, Grob, Dvorak, & Fairbank, 2006)

Schmerzstärke
Ich habe momentan keine Schmerzen
Die Schmerzen sind momentan sehr schwach
Die Schmerzen sind momentan mäßig
Die Schmerzen sind momentan ziemlich stark
Die Schmerzen sind momentan sehr stark
Die Schmerzen sind momentan so schlimm wie nur vorstellbar
Körperpflege (Waschen, Anziehen, etc.)
Ich kann meine Körperpflege normal durchführen, ohne dass die Schmerzen dadurch stärker werden
Ich kann meine Körperpflege normal durchführen, aber es ist schmerzhaft
Meine Körperpflege normal durchzuführen ist schmerzhaft, und ich bin langsam und vorsichtig
Ich brauche bei der Körperpflege etwas Hilfe, bewältige das meiste aber selbst
Ich brauche täglich Hilfe bei den meisten Aspekten der Körperpflege
Ich kann mich nicht selbst anziehen, wasche mich mit Mühe und bleibe im Bett
Heben
Ich kann schwere Gegenstände heben, ohne dass die Schmerzen dadurch stärker werden
Ich kann schwere Gegenstände heben, aber die Schmerzen werden dadurch stärker
Schmerzen hindern mich daran, schwere Gegenstände vom Boden zu heben, aber es geht, wenn sie geeignet stehen (z.B. auf einem Tisch)
Schmerzen hindern mich daran, schwere Gegenstände zu heben, aber ich kann leichte bis mittelschwere Gegenstände heben, wenn sie geeignet stehen
Ich kann nur sehr leichte Gegenstände haben
Ich kann überhaupt nichts heben oder tragen
Gehen
Schmerzen hindern mich nicht daran, so weit zu gehen, wie ich möchte
Schmerzen hindern mich daran, mehr als 1-2 km zu gehen
Schmerzen hindern mich daran, mehr als 0,5 km zu gehen
Schmerzen hindern mich daran, mehr als 100 m zu gehen
Ich kann nur mit einem Stock oder Krücken gehen
Ich bin die meiste Zeit im Bett und muss mich zur Toilette schleppen
Sitzen
Ich kann auf jedem Stuhl so lange sitzen wie ich möchte
Ich kann auf meinem Lieblingsstuhl so lange sitzen wie ich möchte
Schmerzen hindern mich daran, länger als 1 Stunde zu sitzen
Schmerzen hindern mich daran, länger als eine halbe Stunde zu sitzen
Schmerzen hindern mich daran, länger als 10 Minuten zu sitzen
Schmerzen hindern mich daran, überhaupt zu sitzen

Stehen
Ich kann so lange stehen wie ich möchte, ohne dass die Schmerzen dadurch stärker werden
Ich kann so lange stehen wie ich möchte, aber die Schmerzen werden dadurch stärker
Schmerzen hindern mich daran, länger als 1 Stunde zu stehen
Schmerzen hindern mich daran, länger als eine halbe Stunde zu stehen
Schmerzen hindern mich daran, länger als 10 Minuten zu stehen
Schmerzen hindern mich daran, überhaupt zu stehen
Schlafen
Mein Schlaf ist nie durch Schmerzen gestört
Mein Schlaf ist gelegentlich durch Schmerzen gestört
Ich schlafe auf Grund von Schmerzen weniger als 6 Stunden
Ich schlafe auf Grund von Schmerzen weniger als 4 Stunden
Ich schlafe auf Grund von Schmerzen weniger als 2 Stunden
Schmerzen hindern mich daran, überhaupt zu schlafen
Sexualleben
Mein Sexualleben ist normal, und die Schmerzen werden dadurch nicht stärker
Mein Sexualleben ist normal, aber die Schmerzen werden dadurch stärker
Mein Sexualleben ist nahezu normal, aber sehr schmerzhaft
Mein Sexualleben ist durch Schmerzen stark eingeschränkt
Ich habe auf Grund von Schmerzen fast kein Sexualleben
Schmerzen verhindern jegliches Sexualleben
Sozialleben
Mein Sozialleben ist normal, und die Schmerzen werden durch nicht stärker
Mein Sozialleben ist normal, aber die Schmerzen werden dadurch stärker
Schmerzen haben keinen wesentlichen Einfluss auf mein Sozialleben, außer dass sie meine eher aktiven Interessen, z.B. Sport einschränken
Schmerzen schränken mein Sozialleben ein, und ich gehe nicht mehr so oft aus
Schmerzen schränken mein Sozialleben auf mein Zuhause ein
Ich habe auf Grund von Schmerzen kein Sozialleben
Reisen
Ich kann überallhin reisen, und die Schmerzen werden dadurch nicht stärker
Ich kann überallhin reisen, aber die Schmerzen werden dadurch stärker
Trotz starker Schmerzen kann ich länger als 2 Stunden unterwegs sein
Ich kann auf Grund von Schmerzen höchstens 1 Stunde unterwegs sein
Ich kann auf Grund von Schmerzen nur kurze notwendige Fahrten unter 30 Minuten machen
Schmerzen hindern mich daran, Fahrten zu machen, außer zur medizinischen Behandlung

Attachment 6: Roland Morris Disability Questionaire (english)

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly then usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all the time.
14. I find it difficult to turn over in bed because of my back.
15. My appetite is not very good because of my back pain.
16. I have trouble putting on my socks (or stockings) because of the pain in my back.
17. I only walk short distances because of my back.

18.	I sleep less well because of my back.
19.	Because of my back pain, I get dressed with help from someone else.
20.	I sit down for most of the day because of my back.
21.	I avoid heavy jobs around the house because of my back.
22.	Because of my back pain, I am more irritable and bad tempered with people than usual.
23.	Because of my back, I go upstairs more slowly than usual.
24.	I stay in bed most of the time because of my back.

This questionnaire is taken from: Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine 1983; 8: 141-144

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13. PUBLICATIONS

Original papers

Sandro M. Krieg, Nele Balser, Haiko Pape, Nico Sollmann, Lucia Albers, Bernhard Meyer

Topping-off technique for stabilisation of lumbar degenerative instabilities in 322 patients

Journal of Neurosurgery: Spine