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New approaches to proven technology: Force control posterior thoracolumbar fusion with an innovative pedicle screw system

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A R T I C L E I N F O

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A B S T R A C T

Objective: Despite continuous advancements, posterior thoracolumbar fusion with pedicle screw systems (PSS) has failed to reduce the rate of reoperation over recent decades. Implant failure, including screw pullout or loosening, implant breakage, and disassembly, is the leading cause for hardware-related reoperations. Since mechanical failure is due to overloading, efforts must be made to eliminate avoidable stresses. The study aim is to compare the results of a novel force-controlled PSS with literature.

Methods: This retrospective, consecutive cohort includes 150 patients who received the Neo Pedicle Screw System™ for single- or multilevel thoracolumbar fusion. Fusion rate, VAS back pain, reoperations, screw loosening, and surgical site infections (SSI) were evaluated. A structured literature search was performed specifically on screw loosening. Statistical significance was assumed at $p < 0.05$.

Results: Indications were mainly trauma (62,7%) and degeneration (34,0%), and mean age was 66 years. Overall fusion or fracture healing rate was 93,8% (CI 89,3%-98,3%), mean VAS back pain improvement 6,2 ($p < 0,001$), overall reoperation rate 16,7%, (CI 10,7%–22,7%), including 8,7% (CI 4,2%-13,2%) re-interventions involving the implant system, patient-based screw loosening rate 8,9% (CI 3,9%-13,9%) and screw-based loosening rate 2,3% (CI 1,3%-3,3%), SSI rate 2,7% (CI 0,1%-5,3%). No implant breakages occurred. The literature search revealed screw loosening rates of 15,1% (CI 14,2%-16,0%) patient-based and 3.8 % (CI 3,5%-4,1%) screw-based, which were statistically significantly higher than in the study.

Conclusion: By controlling the forces applied intraoperatively, the surgeon can avoid unintended spinal stresses and better consider the patient's individual anatomical and biomechanical balance. The results suggest that the principle of force-control can be effective.

1. Introduction

Posterior thoracolumbar fusion using pedicle screw systems (PSS) is a standard for the treatment of various spinal disorders requiring internal stabilization. This technique dates to the late 1950 s when Harrington [1,2] developed his rod system with hooks, which was later extended by pedicle screws. The instrumentation was primarily developed to correct severe scoliosis through compression and distraction nevertheless it has increasingly also been used to reduce and stabilize spondylolistheses and fractures. A cohort study in the early 1990 s demonstrated significant improvement in fusion rates with the use of pedicle screws for degenerative spondylolistheses (89,1% vs 70,4%) and fractures (88,5% vs 81,0%). [3] Since then, numerous advancements of PSS have been made and spinal fusions have rapidly increased worldwide. In the United States, the number of lumbar fusions grew by 113 % from 1996 to 2001, while the corresponding number for hip and knee replacements was between 13 % and 15 %. [4] At the same time, the indications for spinal fusion have been considerably expanded to include degenerative spondylosis, disc disorders, back pain, non-deformative spinal stenosis [5], infections and tumors.

However, after decades of further development in spinal instrumentation, systematic literature reviews failed to demonstrate significant improvement after spinal fusion in either the 1990 s [6] or the first 15 years of this century [7]. Since 2000, there has been a trend toward increased use of device-based, more complex and more expensive techniques such as posterior or transforaminal lumbar interbody fusion (PLIF: 20,1%/ TLIF: 12,6%). With these techniques, fusion rates have improved notably (PLIF 94,7%, TLIF 93,3%), but at the same time, complication rates have increased compared with posterolateral fusion (PLF). [7] Today, overall reoperation rates range from 9 % to 13 %

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Table 1
Inclusion and exclusion criteria of the study.

Inclusion criteria	Exclusion criteria
• Age ≥ 18 years • Patient has received NEO as a matter of routine for primary posterior, non-cervical fixation as an adjunct to fusion in accordance with the intended use and indications • Patient signed Informed Consent	• Patient is under the age of 18 or skeletally immature • Any contraindications of NEO including ∘ active infectious process ∘ signs of local inflammation ∘ fever or leukocytosis ∘ morbid obesity ∘ pregnancy ∘ any medical or surgical condition which would preclude the potential benefit of spinal implant surgery ∘ suspected or documented metal allergy or intolerance ∘ any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality ∘ any patient unwilling to follow postoperative instructions ∘ any case not described in the indications

NEO, Neo Pedicle Screw System™.

[8,9,10], reaching as high as 19 % for spondylolisthesis ≥ grade II [11] and 20 % for adult spinal deformity [12] two years after initial fusion surgery, with increasing rates over the long-term [8,9,13,14,15]. Hardware-related reoperations alone have been reported to be in the range of 8 % to 28 % [11,12,16,17], with a higher risk of revision in 2014 than in 2006 [12]. This trend is alarming and requires critical consideration. The main reason for hardware related reoperations is implant failure, including screw pullout or loosening, implant breakage, and disassembly [11,12,18], followed by infection, curve progression, nonunion, neurologic deficit, and others [12].

Any type of mechanical failure is caused by overloading. To reduce mechanical complications and consequently the rate of hardware related reoperations, efforts must be made to avoid mechanical overloading. For this purpose, all stresses on the construct during and after fusion surgery must be reduced to the minimum necessary for an intended correction. At the same time, the instrumentation should be adapted to the expanded indications of recent years. Force control, a relatively new philosophy in surgical technique, follows these principles by consequently aiming to avoid unnecessary intraoperative stress on the implants and thus on the spine. To achieve this, it is mandatory to keep the applied forces under control as much as possible by respecting the following three aspects: 1) Unique physiological screw head position 2) Maintaining screw head mobility, 3) Awareness and control of mechanical loads applied. In this way, the patient's individual anatomical and biomechanical balance can be better considered at the same time. The aim of force control is to reduce the number of implant failures and thus may have the potential to benefit not only patients but also healthcare systems through reduced follow-up costs.

The objective of this study is to evaluate early user clinical and radiological results of patients treated with a novel PSS for thoracolumbar fusion based on the principle of intraoperative force control and to compare them with the results of the relevant literature. The primary endpoint is a comparison of the patient-based screw loosening

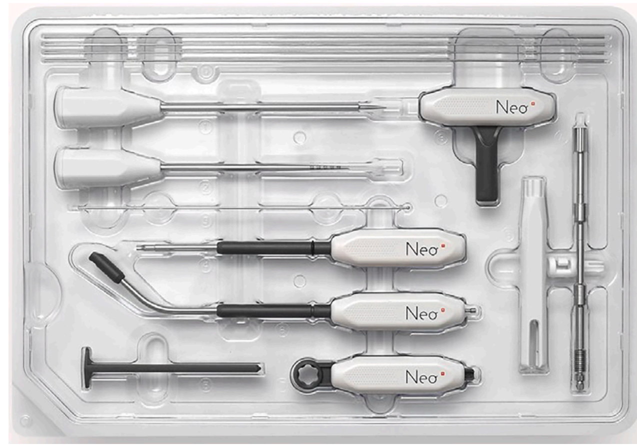

Fig. 2. Sterile single-use instrument kit for posterior fixation: lightweight instruments made of high-performance polymers.

Fig. 3. Common large and heavy pedicle screwdriver instruments and NEO pedicle screwdriver instruments.

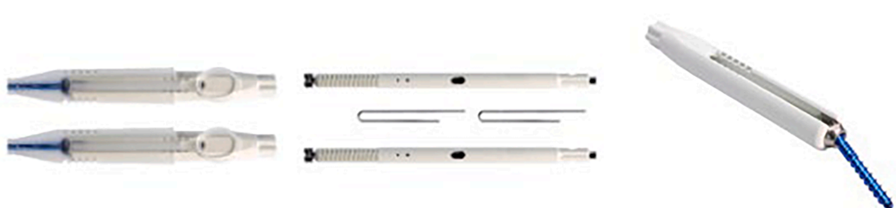

Fig. 1. Sterile pedicle screw set: screws are pre-mounted on screw extenders with tissue dilators.

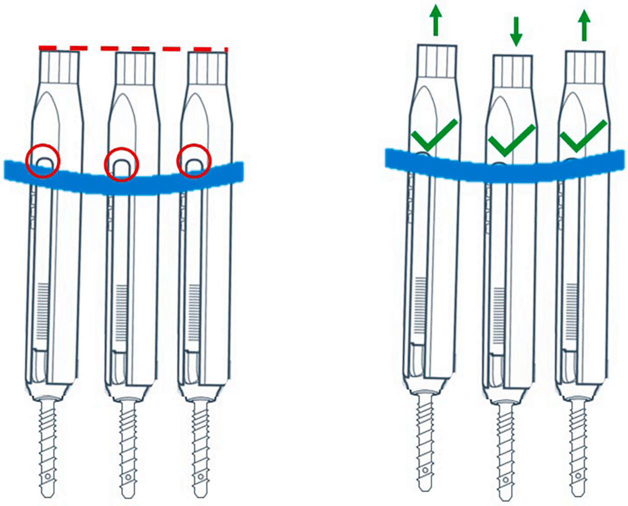

Fig. 4. Slotted screw extensions allow checking the screw depth (=height control of the towers) and visual confirmation of the seating of the rod in the screws (=contact with the dome of the slot).

Table 2
Patient accounting.

	Preop	Intra-op	VAS at final FU (6mo-2y)	X-rays 3mo	X-rays for fusion assessment (1y-2y)
Available	150	150	108	10	112
Deaths (cum.)	–	0	2	1	2
% Follow-up	–	–	73,0	6,7	75,7

FU, follow-up.

Table 3
Patients' demographics.

	Mean (range, SD) /N (%)
Age in years	66 (18–91, 15)
Preoperative VAS pain	8,0 (4–10, 1,1)
Gender	
Male	69 (46%)
Female	81 (54%)
Indication	
Trauma	94 (62,7%)
Degeneration	51 (34,0%)
Neoplasm	2 (1,3%)
Others	3 (2,0%)
Low back pain	127 (84,7%)
Hight back pain	66 (44,0%)
Radiculopathy	62 (41,3%)
Neurological deficit	33 (22,0%)
Claudicatio	36 (24,0%)

rate of the recent study with that of a structured literature search.

2. Methods and materials

This retrospective, observational study was performed at Nordwest-Krankenhaus Sanderbusch, Clinic for Neurosurgery and a certified Spine Center, in Germany. The consecutive cohort of 150 patients enrolled in the study fulfilled the inclusion and exclusion criteria listed in Table 1. Patients underwent single- or multilevel thoracolumbar fusion at the study site and received posterior stabilization with the PSS under investigation between November 14, 2016 and September 5, 2019. All data were collected for internal quality purposes as part of routine clinical practice in a spine-specific data management system (KEOPS, SMAIO, France) and extracted from it for analysis. No additional study-specific X-ray images or computer tomography (CT) scans were acquired. The study was reviewed by the relevant regional ethics committee, and written informed consent was obtained from patients prior to study start.

2.1. Pedicle screw system (PSS)

The PSS under investigation is the Neo Pedicle Screw System™ (NEO, Neo Medical S.A., Villette, Switzerland). It includes common titanium alloy rods and screws in various sizes, all supplied sterile. The screws are provided preassembled on a screw extender with a tissue dilator (Fig. 1). The disposable instruments made of high-performance polymers are consistently streamlined and supplied in a single sterile instrument set for all indications of posterior fixation (Fig. 2). Due to the material all instruments are lightweight. The center of gravity of the instruments is balanced and close to the surgical site to avoid long lever arms (Fig. 3). The PSS is suitable for open, minimally invasive or percutaneous posterior approaches.

2.2. Intraoperative technique and postoperative management

The intraoperative procedure was performed according to the NEO surgical technique via open or mini-open approaches. Special attention was paid to maintain the polyaxiality of the pedicle screws at each surgical step and to achieve an optimal 90° alignment between screw heads and rods. This can be checked with the screw extender, which must not be hindered in its free movement and must align itself at an angle of 90° to the rod. The screw extender also assists to monitor screw depth as well as correct spine and rod profile (Fig. 4). Appropriate rod bending was performed ex-situ. Final locking was done level by level from the most caudal to the most cranial screw once both rods were reduced in the screw heads. Wearing a brace for four to six weeks after surgery was foreseen only in osteoporotic cases.

2.3. Data collected

Besides demographic and intraoperative data, the following postoperative results were evaluated:

- Screw loosening rate, calculated 1) on the number of subjects (patient-based = primary endpoint) and 2) on the number of screws (screw-related) whose 3 months, 1 year or 2 year radiographs, and/or CTs showed one or more screw loosening during the follow-up period after implantation. Screw loosening is defined as a radiolucent zone of greater than 1 mm around the screw [19].
- Fusion rate or, in the case of trauma, fracture consolidation rate based on all available 1 year or 2 year radiographs or CT scans. Successful fusion/fracture consolidation is present, if there is
  - o evidence of bridging trabecular bone between the affected vertebral endplates / fracture consolidation
  - o angular motion < 5°
  - o translational motion < 3 mm [20]

For multi-level involvement, all levels must be fused to be considered a successful fusion.

- Visual Analogue Scale (VAS) on back pain intensity (0–10 cm): preoperatively, at 6 months, at final follow-up and improvement from preoperative baseline to final follow-up
- Reoperation rate, based on the number of subjects who underwent reoperation during the follow-up period. Reoperations include all

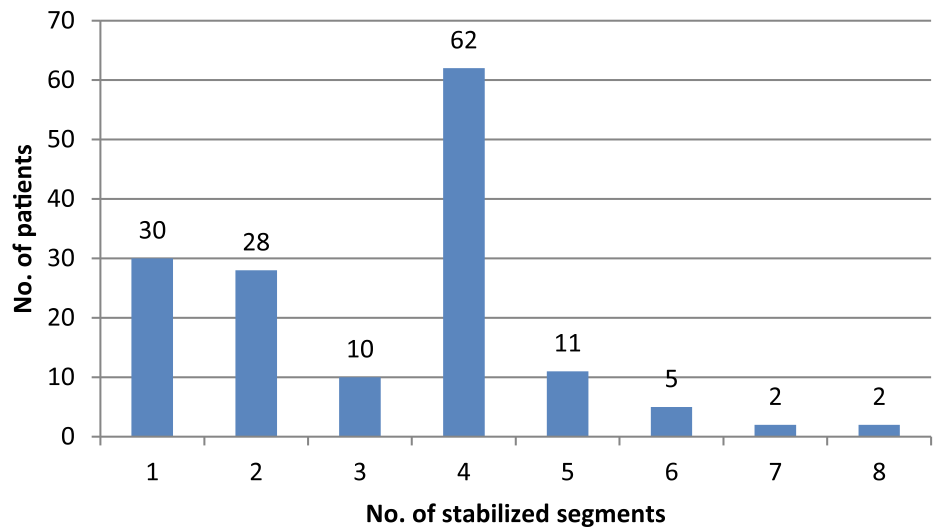

Fig. 5. Distribution of the number of thoracolumbar segments stabilized with Neo Pedicle Screw System™.

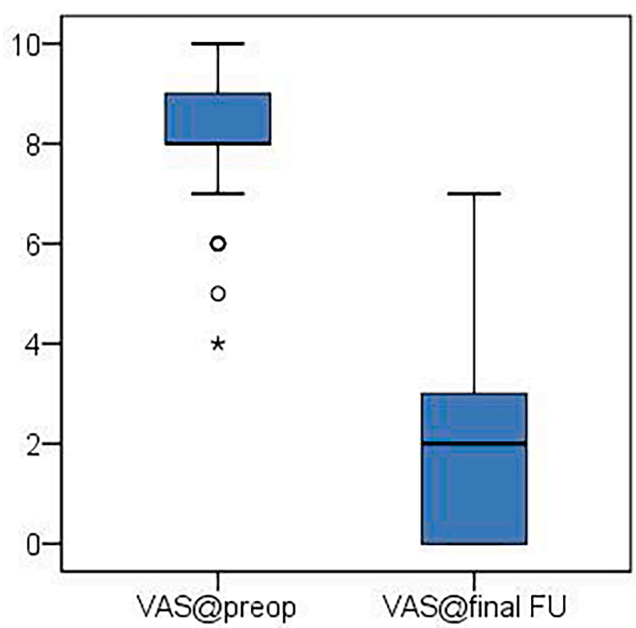

Fig. 6. Visual Analog Scale (VAS) back pain improvement: preoperative vs final follow-up (FU: 6 months – 2 years).

subsequent surgical procedures due to an Adverse Event (AE) with or without removal or replacement of implants. Excluded are elective implant removals, e.g. after successful fracture healing or fusion

- Implant-related reoperation rate (re-interventions) is a sub-group of the overall reoperation rate. It is based on the number of subjects who underwent implant-related reoperation due to an Adverse Device Effect (ADE) during the follow-up period. Implant-related reoperations include all subsequent surgical procedures with removal or replacement of implants. Excluded are elective implant removals, e.g. after successful fracture healing or fusion
- Infection rate, based on the number of subjects who developed a clinically determined superficial or deep wound infection according to the criteria of the Centers for Disease Control and Prevention (CDC) during the follow-up period. For reference, see McClelland et al. [21]
- AEs, grouped by seriousness and device-relation

Table 4
Occurrence of AEs grouped by seriousness and device-relation.

	AE	SAE
Hematoma/Hematoseroma	1	2
Excessive bleeding/Anemia	1	3
Dural leakage	–	3
Wound healing disorder	2	1
SSI	–	4
superficial		(2)
deep		(2)
Anesthesia related	1	5
UTI	11	–
Neurological disorder	7	3
Pain	3	–
Postoperative muscular tension	1	–
Facet joint syndrome	3	–
Secondary fracture	–	6
ASD	–	2
	ADE Count (%)	SADE Count (%)
Screw malpositioning	3	5
with paresis	(-)	(2)
with paresthesia	(-)	(1)
with nerve root syndrome	(1)	(-)
Screw loosening	2	9

AE, Adverse Event.
SAE, Serious Adverse Event.
ADE, Adverse Device Effect.
SADE, Serious Adverse Device Effect.
UTI, Urinary Tract Infection (UTI).
SSI, Surgical Site Infection (SSI).
ASD, Adjacent Segment Degeneration.

2.4. Structured literature search

A structured literature search was performed for screw loosening, the most common reason for implant-related failure. On January 12, 2022, a PubMed search was done for papers published in 2000 or later using the keywords "pedicle screw [MeSH Terms]" and "loosening [all fields]" with the following filters: humans, English, German, full text and abstract. The resulting 182 publications were screened for in-vivo studies with screw loosening rates in more than 50 patients at the thoracic, lumbar and/or lumbosacral spine (N = 37). Studies with loosening rates related only to cement augmented screws were excluded. In the remaining publications, patient-related loosening rates were reported in 28 cases and screw-related loosening rates in 14 cases [22–55]. These

Fig. 7. Female, 68 years old, isolated T12 fracture: preoperative MRI (lateral & transversal) and X-ray 2d postop (lateral & ap).

data were used to calculate pooled loosening rates.

2.5. Statistical analysis

Qualitative parameters are described by frequency, percentage and 95 % confidence intervals (CI), if relevant. For quantitative parameters, mean, standard deviation (SD), minimum, maximum and CI, if relevant, are given. Comparison of dependent means (pre- versus postoperative VAS results) uses a Related-Samples Wilcoxon Signed Rank Test on nonnormally distributed data. Statistical significance is assumed at $p < 0.05$. Statistical analyses are performed using IBM SPSS Statistics (version 21).

3. Results

At the time of analysis, the clinical and radiological data listed in Table 2 were available for the 150 study patients. Mean follow-up time was 1,2 years (range 0,0–2,9, SD 0,7).

3.1. Patients' demographics

The mean age at the time of surgery was 66 years, ranging from 18 to 91 years. For patients' demographics see Table 3.

3.2. Intraoperative data

The total number of stabilized segments was 479. Overall, 1107 pedicle screws and 299 rods were implanted. For more details on the number of stabilized segments, see Fig. 5.

Anteriorly, additional TLIF was performed in 42/150 patients (28 %) and PLIF in 5/150 patients (3,3%). In one case (0,7%) PLIF and TLIF were performed at different levels. Vertebroplasty was done in 15/150 cases (10 %) and kyphoplasty in 4/150 patients (2,7%). Vertebral body replacement was required in 3/150 subjects (2 %), and in another case (0,7%), a vertebral body replacement had been implanted previously. No anterior column treatment was performed in the remaining 79/150 patients (52,7%).

3.3. Postoperative results

Screw loosening was found in 8,9%, CI 3,9%-13,9%, of patients (11/123). It is based on all subjects with available postoperative radiographs plus one additional case with a known revision due to screw loosening without accessible radiographs. In 9 of these patients, a surgical re-intervention was performed. Patients diagnosed with trauma had a loosening rate of 6.3 % (5/79) and those with degeneration of 15 % (6/40). On a screw basis, 2,3%, CI 1,3%-3,3% (22/941 screws) were found to be loosened. No screw or rod breakages occurred.

The overall fusion or fracture healing rate, based on all patients with available 1- or 2-year postoperative radiographs, was 93,8%, CI 89,3%-98,3%, (105/112 patients). In 7/112 patients (6,3%), no fusion or fracture healing was achieved.

The mean VAS back pain improvement from preoperative baseline (8,0, range 4 to 10, SD 1,1) to final FU (2,0, range 0 to 7, SD 2,1, CI 1,6–2,4) was clinically [56] and statistically significant ($p < 0{,}001$) with a reduction of 6,2 (range 0 to 10, SD 2,6). The VAS pain score distribution by time point is shown in Fig. 6.

During the course of the study, 25 of 150 patients required one or more reoperations. Thus, the overall reoperation rate was 16,7%, CI 10,7%–22,7%, including 13 re-interventions (8,7%, CI 4,2%-13,2%) involving the implant system. The following reoperations were performed: 3 revisions of dural tears/leakages, 7 wound revisions, 1 hematoma revision, 1 puncture of hematoseroma, 5 fracture treatments on non-instrumented spinal segments, 9 screw replacements (including 2 with extension of instrumentation), 3 implant removals, and 1 shortening of rods. Elective implant removals after successful fusion or fracture consolidation were reported for 20/150 patients (13,3%).

Surgical site infection (SSI; 2x superficial and 2x deep) was diagnosed in 4/150 patients (2,7%, CI 0,1%-5,3%), each requiring wound revision.

A list of AEs noted during the study, whether or not related to the implant system surgery, is shown in Table 4.

3.4. Case presentation

Fig. 7 shows pre- and postoperative images of a 68-year-old woman with isolated T12 fracture after a fall. She complained of back pain. Neurologically, the patient was alert, attentive, and oriented, and the cranial nerves were intact. There were no sensory or motor deficits, reflexes were 2 + and symmetric. posture and gait were painful. We stabilized with NEO from T10-L2 without additional anterior column support. The patient could be discharged after 16 days without postoperative complications. One year after surgery, the fracture was consolidated and VAS back pain had improved from 8/10 to 1/10.

3.5. Screw loosening rates according to literature

According to data from the literature, the pooled patient-related screw loosening rate was 15,1% (863/5710, CI 14,2%-16,0%, range 0 %-63,4%). The screw-related loosening rate was 3.8 % (585/15333, CI 3,5%-4,1%, range 0 %-20,3%). For further information see Table 5.

Table 5
Summary of articles included in the literature review.

Reference	Study design	Indications	Assessment	N	Screw loosening (patient-based)	Screw loosening (screw-based)
Asamoto S et al. [22]	retrospective study, single centre, ≥ 1Y FU, mean FU 30mo	lumbar spondylosis	X-ray: presence of a translucent zone surrounding the pedicle screw	55	_	10,7%
Bredow J et al. [23]	retrospective, mean FU 4Y	pathological and traumatic fractures, osteochondrosis or spinal stenosis, tumors, spondylodiscitis and spondylolisthesis, misalignments, and iatrogenic instability after laminectomies	postoperative CT scans using the standard radiological @50,8 mo	365	12,3%	3,0%
Chang HK et al. [24]	retrospective study, single-centre, mean FU 43mo	symptomatic spinal stenosis with hypertrophic ligamentum flavum, facet hypertrophy, minimal or less than grade I spondylolisthesis, degenerative disc disease, and recurrence of herniated intervertebral discs	X-ray or CT: double-halo sign (radiolucency around the screw for more than 1 mm wide)	176	20,5%	8,5%
Cho JH et al. [25]	retrospective study, single-centre, ≥ 2Y FU	spinal stenosis (including foraminal stenosis) or spondylolisthesis (degenerative or isthmic)	X-ray @3,6,12,24mo or CT @2Y: 1 mm thickness criterion of radiolucency	86	19,8%	_
Girardo M et al. [26]	prospective study, single-centre	somatic osteoporotic fractures aged over 65 years	X-ray	91	15,4%	_
Guo HZ et al. [27]	retrospective study, single-centre, ≥ 2Y FU	osteoporotic spine with degenerative lumbosacral disease	CT for about 70 % of patients	217	17,1%	_
Herren C et al. [28]	prospective non-randomised single-center study, 4Y FU	lumbar spinal stenosis, previous lumbar fusion procedure, degenerative lumbar disc disease, and/or spondylolisthesis	X-ray	55	52,7%	_
Ishak B et al. [29]	retrospective study, single-centre	degenerative, traumatic, or infectious diseases	X-rays @≥3mo	1054	0,7%	0,2%
Kaliya-Perumal AK et al. [30]	retrospective study, single-centre, 1Y FU	Multisegmental spinal instability (spondylolisthesis ≥ grade 1), multilevel degenerative spondylosis, degenerative scoliosis	X-ray @1Y FU: occurrence of halo sign around the pedicle screws or change in the screw position on dynamic radiographs	62	_	19,0%
Kim DH et al. [31]	retrospective analysis of a multicenter prospective randomized placebo-controlled trial; @ 6 and 12mo	single-level posterior instrumented lumbar fusion surgery for degenerative disease: does postoperative ultrasound-enhanced radiographic fusion?	CT@12mo	151	13,9%	6,2%
Kim JH et al. [32]	retrospective, single-centre, ≥ 2Y FU	fracture, traumatic myelopathy, traumatic kyphosis, traumatic stenosis, stenosis with deformity, other	X-ray: displacement of a screw from the original position or hollowness around a screw	36	50 %	_
Kim KT et al. [33]	systematic review and *meta*-analysis	_	_	72	12,5%	_
Leng J et al. [34]	retrospective study, single-centre, ≥ 1Y FU, mean FU 35mo	degenerative lumbar scoliosis with preoperative cobb angle ≥ 20°; ≥4 fused levels; lower instrumented vertebra (LIV) at L5 or S1	CT at final FU: 1 mm or wider circumferential radiolucent line around the pedicle screw at LIV	137	56,2%	_
Liu L et al. [35]	cohort study	lumbar degenerative disease in patients with osteoporosis at 1 or 2 adjacent vertebral levels	_	70	28.13 % vs 6.5 %	_
Marie-Hardy L et al. [36]	retrospective cohort study	degenerative disease, scoliosis, spondylolisthesis	X-ray @ ≥1Y: radiolucent rim greater than 1 mm	166	40.4 %	
Maruo K et al. [37]	retrospective matched case-control study, ≥1Y FU	degen. spondylolisthesis, degen. scoliosis, form. stenosis, destructive spondyloarthropathy, multiple operated back	CT @1Y	77	18,2%	_
Matsukawa K et al. [38]	retrospective cohort analysis of prospectively collected data, single-centre, ≥ 1Y FU	degenerative spondylolisthesis, degenerative disc disease, lumbar foraminal stenosis	CT @1Y: presence of a radiolucent zone greater than 1 mm around the screw	92	13,0%	4,6%
Mei J et al. [39]	*meta*-analysis of RCTs and other comparative cohort studies: postoperative bisphosphonate vs none	_	@2YFU	2 studies: 64 + 64	31,3% and 9,4%	_
Mo GY et al. [40]	retrospective, single-centre, ≥ 2Y FU	osteoporosis with lumbar spinal stenosis or lumbar spondylolisthesis	CT @2Y: translucent shadow around the screw	28	_	5,1%
Ohba T et al. [41]	retrospective, single-centre, 1Y FU	osteoporotic vertebral fracture, infection, metastasis	CT @1Y	53	_	13,6%

(*continued on next page*)

Table 5 (*continued*)

Reference	Study design	Indications	Assessment	N	Screw loosening (patient-based)	Screw loosening (screw-based)
Prud'homme M et al. [42]	literature review, ≥1Y FU, 46 papers	degenerative disk diseases, spinal stenosis, disk herniation, segmental instability, low-grade spondylolisthesis, revision surgeries	various	1608	10,1%	_
Sakai Y et al. [43]	retrospective, single-centre, 3mo FU	lumbar degenerative disease	CT @3mo: radiolucent area ≥ 1 mm in circumference	52	23 %	11,70 %
Sugawara R et al. [44]	retrospective study, single-centre, ≥2Y FU	adolescent idiopathic scoliosis, congenital scoliosis and kyphosis, syndromic scoliosis	CT @2Y	86	0 %	0 %
Tang YC et al. [45]	prospective study, single-centre, mean FU 35,6mo	osteoporotic lumbar degenerative disease: 3-level & 4-level	halo sign showing a radiolucent line of ≥ 1 mm around the screw in X-ray or CT images on one or both sides	93	_	8 %
Tu CW et al. [46]	retrospective study, single-centre, 2Y FU	osteoporosis with lumbar degenerative spondylolisthesis and spinal stenosis, 1- & 2-level	X-ray @2Y: radiographic lucent zone	64	31,5% (18 % with ZOL, 45 % in control group	_
Uehara M et al. [47]	retrospective study, single-centre	adolescent idiopathic scoliosis (AIS)	CT @6mo, appearance of radiolucency around pedicle screws	120	26,7%	2,6%
Wagner A et al. [48]	retrospective, single center, mean FU 9,8mo	spinal metastasis	CT: surrounding translucent area	51	11,8%	_
Wang W et al. [49]	retrospective study, single-centre, mean FU 38,4mo	adult degenerative scoliosis	X-ray & CT: 1-mm or wider circumferential radiolucent line around the pedicle screw	93	63,4%	_
Weiser L et al. [50]	_	_	intraoperative screw loosening: radiological dislocation of an inserted screw, or clinically significant loosening in the form of a wobbly screw in the vertebral body without relevant insertion torque	524	2,1%	_
Wen Z et al. [51]	retrospective, single-center cohort study, ≥ 3Y FU	severe single osteoporotic thoracolumbar vertebral compression fracture with kyphosis	X-ray	121	2,5%	_
Xu F et al. [52]	retrospective study, single-centre	lumbar degenerative diseases	CT ≥ @1Y	143	_	20,3%
Yagi M et al. [53]	systematic review and *meta*-analysis on single-arm and/or randomized controlled trials	spinal instability such as spondylolisthesis, degenerative disease, trauma, spondylosis, spondylolysis, pseudoarthrosis, injury, fracture, dislocation, scoliosis, kyphosis, spinal tumors, failed previous fusion and spinal injury	various	308	15,3%	_
Zhou Q et al. [54]	retrospective, single-center, comparative study ≥ 1Y FU (mean 2Y)	lumbar degenerative spondylolisthesis	X-ray	88	2,3%	_
Zou D et al. [55]	retrospective study, single-centre, 1Y FU	lumbar degenerative diseases, including degenerative lumbar spinal stenosis, degenerative lumbar spondylolisthesis, lumbar disc herniation, degenerative lumbar scoliosis	X-ray @1Y: radiolucent zones of ≥ 1 mm around any pedicle screw	253	30,6%	_

4. Discussion

In the recent study, a patient-related screw loosening rate of 8,9% (CI 3,9%-13,9%) was demonstrated. On a screw basis, the screw loosening rate was 2,3% (CI 1,3%-3,3%). Thus, both the patient-related and screw-related loosening rates are statistically significantly lower than the pooled rates of the current literature search at 15,1% (CI 14,2%-16,0%) and 3.8 % (CI 3,5%-4,1%), respectively. Since implant-related failures include screw loosening as well as screw fractures, rod fractures, and disassembly of the construct - the latter were each 0 % in the present study - it can be assumed that the number of implant failures must also be considerably lower. With a mean VAS pain score of 2,0 (CI 1,6–2,4) at final follow-up, pain tends to be milder but is generally consistent with that reported in the literature [57]. In general, the postoperative pain reduction in the presented study was clinically [56] and statistically significant.

Regarding fusion rate, the study results (93,8%: CI 89,3%-98,3%) are similar to the pooled fusion rate for PLIF and TLIF reported in the literature (94,2%: CI 93,3%-95,1% [7]), although TLIF and PLIF accounted for only 31,3% of all procedures in the study. Compared with Makanji's [7] pooled fusion rates for PLF, PLIF, and TLIF (89,4%: CI 88,6%-90,2%), the study shows a statistically nonsignificant trend toward increased fusion. The reoperation rate of 16,7% (CI 10,7%–22,7%) reported in this study includes any kind of subsequent surgery with or without implant revision, replacement, or removal, but not elective implant removals. Due to inconsistent definitions, reoperation rates reported in the literature vary considerably between<2 % to 20 % [8–12,58] 1 to 2 years after surgery. The rather high reoperation rate may be due to different definitions or patient populations; however, for the impact of force control on surgical outcome, implant-related reoperations and the number of implant failures are much more indicative. Reoperations associated with the implant (8,7%: CI 4,2%-13,2%) were slightly lower than those reported by Deyo et al. (9,8%: CI 9,2%-10,4%) [16].

The novel concept of force control aims to apply only as much force as is absolutely necessary for an intended correction. Special attention is given to the various aspects of rod insertion and final tightening by using instruments that allow the screws to be inserted in their unique physiological positions, control the alignment thereby achieved, and pre-bend the rod ex-situ so that it can be inserted and fixed in the screw heads without tension. The importance of this intraoperative steps is demonstrated by the results of Obha et al. [59], who found that about 82 % of all loosened screws are already pulled out intraoperatively during rod connection, which negatively affects patient functional outcome and pain intensity. Commonly used heavy screwdrivers with long lever arms lead to unnoticed and unintended multiplication of loads acting on the bone-implant interface and reduce the tactile feel and feedback during insertion. The use of compression and distraction devices attached to the pedicle screws for reduction have the same effect. But also, when screw placement and rod bending are not optimally adapted to the patient and thus the polyaxiality of the screws is blocked or if a rod cannot be aligned without force at a 90° angle in the screw head, avoidable forces act on the construct. Cetin et al. [60] investigated the impact of a deviation of only 15° and found a significant reduction in screw pullout stiffness compared to a perpendicular rod orientation. Ardura et al. [61] studied the effects of a 5° deviation combined with a 7,5Nm preload on the rod and found construct failures after final tightening in cases with standard set screws, which were due to asymmetric alignment of rod and screw or improper tightening of the set-screw. The authors believe that mismatches between the rod and screw are caused by stress overloading, which can and should be avoided as it may lead to pedicle screw loosening, implant breakage, misalignment, pain or adjacent segment degeneration (ASD) [61]. Especially rod persuaders, which are commonly used to overcome gaps between the screw head and the rod, provide high and uncontrolled loads to the screw-bone interface. Numerous studies have evaluated the biomechanical effects of this practice and demonstrated an associated increased risk of screw loosening [62–64]. The present study results support the assumption that a consistent reduction of avoidable loads has a positive effect on screw loosening rates, although the impact on different diagnostic groups needs to be further investigated.

SSI is a burden to the affected patient, but also to hospitals and health care systems [65]. McClelland et al. [21] suggest that SSI rates of 2 %-13 % reported in the literature tend to be underreported, which the authors attribute to the mostly retrospective study design and inconsistent criteria for SSI. The results of their prospective randomized controlled trial on SSI according to the Centers for Disease Control criteria in patients undergoing thoracolumbar spine surgery for deformity or degenerative disease showed an overall incidence of 12,7% (CI 9,0%-16,4%), which is significantly higher than in this study (2,7%, CI 0,1%-5,3%), where sterilely provided and preassembled implants and instruments were used. It is known that the risk for SSI and potentially also the risk of screw loosening [66] increases with the duration of device exposure to the surroundings [66,67], prolonged surgery time [67,68] and the number of reprocessing cycles [67,69–71]. Litrico et al. [67] have demonstrated that single-use instrumentation can contribute to reducing the SSI rate after posterior lumbar fusion to 2 % by providing sterile screw and instrument sets whose packaging is opened only when needed. This is consistent with the finding of the present study. Others have shown that sterile supply and consistently optimized implants, instruments and surgical techniques are able to reduce SSI and its subsequent costs, but also to relieve the hospitals financially through process-oriented improvements [65].

Limitations of the present work include, in particular, the retrospective study design, the heterogeneous patient population, and the relatively high lost-to-follow-up rate. Whether the principles of force control described here actually help to reduce implant-related failures and possibly even improve clinical outcomes requires confirmation by further prospective controlled studies.

5. Conclusion

By controlling the loads applied intraoperatively to the implants, and thus to the spine, the surgeon can avoid unintended spinal stresses and better consider the patient's individual anatomical and biomechanical balance. Lightweight instruments made from high-performance polymers that can, as a side effect, be offered as sterile single-use products could be a way to reduce screw loosening and other implant failures and consequently lower implant-related reoperation rates. At the same time, the expanded indications for spinal fusions in recent years are considered, in which most patients require stabilization rather than correction or reduction.

Authors contributions

YA, SH: The authors contributed equally under the lead of the first author: planned the study design, performed the clinical and radiological data collection, manuscript writing process, and have approved the submitted version.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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