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Safety and performance of a novel articulating cage for transforaminal lumbar interbody fusion in the setting of intraoperative spinal navigation

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ABSTRACT

Objective: Transforaminal lumbar interbody fusion (TLIF) has been described as safe and effective procedure for the treatment of low back pain. However, only a few retrospective articles describing articulating cages exist in literature. The aim of this study was to assess the clinical and radiological results, as well as patient safety and complications by using a novel articulating TLIF cage.

Patients and Methods: Out of 50 patients, 49 were included in this prospective study. Under computer tomography (CT) guided spinal navigation the TLIF procedure was performed. Clinical outcome scores visual analog scale (VAS), Oswestry disability index (ODI) and short form-36 health survey questionnaire (SF-36) were obtained preoperatively, 6 and 12 months after surgery. Radiological data were acquired preoperatively, after 6 weeks, as well as 6 and 12 postoperatively and included measurements for disc height (anterior/posterior), foraminal height, segmental and global lumbar lordosis.

Results: 71% of the included patients have undergone previous lumbar surgery. In total, 80 SYNCHRO® cages have been implanted. The clinical results revealed a highly significant improvement of VAS, ODI and SF-36 after 6 and 12 months, compared to baseline levels ($p < 0.05$). Radiological analysis revealed a significant increase in anterior and posterior disc height, foraminal height, segmental and global lumbar lordosis postoperatively ($p < 0.05$). 47 out 49 patients (96%) showed evidence for fusion at the 12 months follow-up. Cage dislocation was found in 1 of 80 implanted cages (1%), which required revision surgery. Two dural tears occurred intraoperatively, which have been fixed. Another two patients needed surgical revision due to infection. The overall complication rate was 10% (n = 5/49).

Conclusions: The current study delineates satisfactory clinical and radiological results by using a novel articulating TLIF-cage. The implant-related complication rate was acceptable with low revision rate.

1. Introduction

Until today, chronic low back pain is one of the most resource demanding conditions in the Western World [1–3] and the second leading cause of disability [4]. Even though surgical treatment of this condition involving the fusion of segments was introduced almost a century ago, indications as well as operative techniques and outcomes of this procedure are still widely debated [5–8]. Various surgical techniques and implants have been described for treating lower spinal instability and achieving effective stabilization and decompression, thus relieving pain. The two most established surgical procedures to address this condition are posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF), with the latter having the advantage of requiring less thecal sac retraction during cage implantation due to a more lateral approach to the vertebral canal [9,10].

The intervertebral fusion cage was pioneered in the 1970s and has since revealed good fusion rates and clinical outcomes [11–13]. Over the past decade, various cage designs have emerged. However, there are current product limitations like cage footprint, insufficient anterior contact in the intervertebral space, and non-lordotic shape of the implant. To eliminate most of these problems, articulating expandable cages have recently been introduced [14]. These expandable cages have shown to have endplate violations in up to 36% and the contralateral neuroforamen cannot be well addressed [14].

The purpose of this study is to evaluate the safety, feasibility, clinical performance and radiological outcome of a novel articulating cage (SYNCHRO®, Arcamedica Neuenburg, Germany) within the scope of TLIF procedures. This TLIF cage, made of poly-ether-ether-ketone (PEEK), consists of an anterior and posterior element linked by a joint. The mobility of both elements is supposed to ensure optimal implant

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insertion into the disc space. Cages with an articulating joint between the anterior and posterior cage element have not been addressed in the current literature until today.

2. Patients and methods

This is a prospective, monocentric, observational study conducted from 2016 to 2017 and has been approved by the Ethics Committee (No S-058/2015). Surgery was performed by one senior spine surgeon. The main objectives of this study were to evaluate patient safety, feasibility and complication rate of SYNCHRO® cages used in TLIF procedures. Written informed consent was obtained from all participants. All procedures were in accordance with the ethical standards of the institutional research committee and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

2.1. Patient demographics and surgical information

49 consecutive patients [31 women and 18 men, mean age 63.6 y] suffering from low back pain (LBP) and/or refractory radicular pain that were diagnosed with degenerative spondylolisthesis I°/II° or lumbar degenerative disc disease (DDD), and not responding to a trial of intensive conservative treatments, were prospectively included in this study (Table 1).

All patients were set to receive a one- to four-level fusion including at least one SYNCHRO® cage as interbody fusion. The preoperative diagnosis was made on the basis of preexisting x-rays in anterior-posterior and lateral view and CT or MRI-scans of the lumbar spine.

Exclusion criteria were local or systemic infection, high ESR, CRP and PCT levels, BMI > 45 kg/m^2, pregnancy, allergy against polyether-ether-ketone (PEEK), high-grade osteoporosis and any other medical conditions that would likely prevent a successful operation.

2.2. Study documentation, clinical and radiological outcome

Clinical and radiological postoperative follow-ups were conducted postoperatively, after 6 weeks, as well as 6 and 12 months after surgery. Part of these follow-ups featured a neurological examination followed by standardized clinical measurements based on the Visual Analog Scale (VAS), Oswestry Disability Index (ODI) and the short form-36 health survey questionnaire (SF-36) preoperatively, after 6 and 12 months. Radiological follow-ups included x-rays in AP and lateral view, to assess screw and cage position, and possible screw loosening. Radiographic measurements were independently performed by 2 authors who did not perform the surgery on lateral lumbar x-ray preoperatively, postoperatively and at 12 months follow-up. These measurements obtained included anterior disc height (ADH), posterior disc height (PDH), foraminal height (FH) and segmental lordosis (SL) for all 80 levels in which the SYNCHRO® cage was inserted. Lumbar lordosis (LL) was obtained in 49 patients. ADH and PDH were measured as the minimum distance [mm] between the anterior and posterior edges of the adjacent vertebral endplates [15]. FH was determined as the maximum distance (mm) between the superior margin of the adjacent lower pedicle and inferior margin of the adjacent superior pedicle [15]. SL and LL (L1-S1) were determined using standard Cobb measurements [16].

Signs of fusion, which was defined as the presence of trabecular bony bridging seen in x-rays after 12 months, was evaluated by two independent radiologists.

Table 1
Demographics and Surgical Information.

Variable		Numbers
Age [y]		
	Mean ± SD	63.6 ± 12.3
	Range	22-83
Sex		
	Female	31 (63%)
	Male	18 (37%)
BMI [kg/m^2]		
	Mean ± SD	28.9 ± 4.8
	Range	22-39
BMI group		
	< 25	12 (24%)
	25 to < 30	17 (35%)
	≥30	20 (41%)
ASA score		
	ASA I	3 (6%)
	ASA II	29 (59%)
	ASA III	17 (35%)
Previous Lumbar Spine Surgeries		
	Yes	35 (71%)
	No	14 (29%)
	disc surgery	23 (66%)
	decompression	12 (34%)

ASA = American Society of Anesthesiologist; **BMI** = body mass index.

2.3. Implants used in the study

The SYNCHRO® cage (Arcamedica, Neuenburg, Germany) is made of PEEK and consists of an anterior and posterior element linked by a joint. Angles between both elements may vary from 45 to 90 degrees and the resulting mobility of both elements is supposed to ensure optimal implant insertion into the disc space. The larger footprint of the implant ensures better anterior contact in the disc space and a decreased risk of postoperative dislocation. It also has a large central perforation to allow bony ingrowth for stable fusion (Fig. 1).

For the posterior instrumentation, a polyaxial titanium alloy screw system (Expedium®, Mountaineer®, Depuy Synthes Company, Raynham, Massachusetts, USA) was used, varying in length and diameter according to each patient's anatomy.

2.4. Surgical procedure and spinal navigation

After general anesthesia was induced and a single shot of cefazolin was given as perioperative antibiotic, each patient was set in a prone position with appropriate bolsters. A standard midline posterior approach was used with subperiosteal exposure of the entry points in the standard fashion. After midline incision and exposure of bony structures 4–5 marker screws (Biomet® 4 mm self-drilling screws, ZimmerBiomet®, USA) were inserted into the laminae and the spinous process for CT-based point-to-point navigation, which has been introduced in 2017 [17,18]. After that, a CT-scan (Siemens, CT Emotion®, Sliding Gantry, Erlangen, Germany) is performed under sterile conditions and the acquired dataset is transferred to the planning workstation to define the inserted marker screws as reference points and to virtually determine screw position, trajectory, length, and diameter. After attaching the reference clamp the marker screws were merged with the navigation system. The instruments for screw placement were tracked and become visible to the navigation system to provide real-time multiplanar virtual visualization of the bony anatomy and thus gives the surgeon intraoperative guidance while placing screws. Microsurgical decompression or re-decompression via laminectomy and foraminotomy was achieved. Partial facetectomy was performed on one side to get better access to the disc space and to facilitate cage placement. The SYNCHRO® cage was filled with autologous bone and inserted into the previously prepared intervertebral disc under spinal navigation, which is a helpful tool, especially in patients who underwent previous lumbar surgery. The optimal position of the cage is achieved when the anterior part of the disc space is covered. Additional pieces of bone were positioned anteriorly and laterally to the cage. A final postoperative fluoroscopic image was taken to document the correct position of the implants.

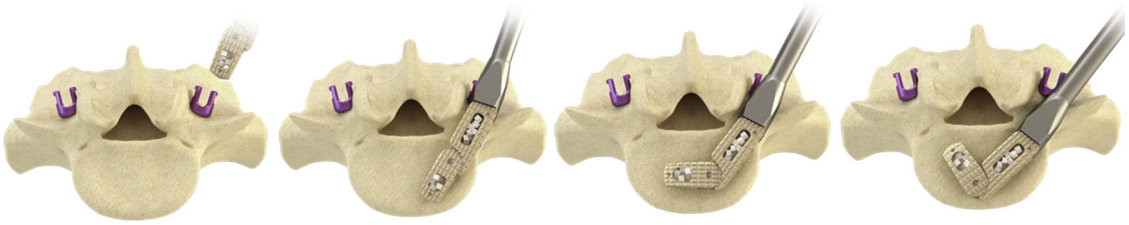

Fig. 1. Step-by-step movement of the cage as it is placed from posterior.

2.5. Statistical analysis

Data were carefully reviewed for consistency, outliners and normality. Descriptive data were expressed as means and standard deviations. The Wilcoxon test for two related samples was used to determine a statistical difference across the time in the same group for VAS, ODI and SF-36. Comparison between radiographic parameters were performed using paired t-test. A p value of less than 5% was accepted as indicating a statistically significant difference. SPSS 22 was used for all statistical analysis.

3. Results

3.1. Patients demographics

49 out of 50 patients were included in this prospective study. One patient withdraw consent shortly after surgery. Mean age was 63.6 years (range 22–83 years). There were 31 females (63%) and 18 males (37%); 71% of patients have undergone previous lumbar spine surgeries and 41% had a BMI ≥ 30 (Table 1).

34 patients (69%) were diagnosed with spondylolisthesis I/II° and a total of 80 SYNCHRO® cages were implanted. In 8 of the 49 patients (16%) who had multilevel fusion, not all addressed levels did receive a SYNCHRO® cage due to insufficient intervertebral space height of 5 mm and below. Therefore, an additional non-articulating TLIF cage was inserted.

3.2. Clinical outcome

Analysis of the clinical outcome scores from the entire cohort showed a significant and maintained improvement of both VAS and ODI scores at all follow-up stages ($p < 0.05$).

Preoperative VAS: mean 7.4, SD 2.2; 6-month VAS: mean 3.1, SD 2.1; 12-month VAS: mean 2.1, SD 1.4 ($p > 0.05$) (Fig. 2). Preoperative ODI: median 0.48, SD 0.15 (severe disability); 6-month ODI: median 0.21, SD 0.16 (moderate disability, $p < 0.05$); 12-month ODI: median 0.13, SD 0.10 (minimal disability), ($p > 0.05$) (Fig. 3).

An improvement of VAS ≥ 50% was achieved in 83% of all patients when compared to baseline levels. In ODI, improvement ≥ 50% was achieved in 69% of all patients when compared to baseline levels.

The SF-36 score improved significantly in all 8 domains 6 months after surgery ($p < 0.001$) (Table 2). Seven SF-36 domains, named Physical Functioning (PF), Bodily Pain (BP), General Health (GH), Physical Role (PR), Emotional Well-Being (EWB), Vitality (VT), and Social Function (SF) continued significantly increasing at the 12-months follow-up, compared to the 6-months results ($p < 0.05$). Emotional Role (ER) did not significantly improve after 12 months, compared to the 6-months results ($p = 0.109$) (Table 2).

3.3. Complications and reoperations

Postoperative complications included one posterior dislocated cage (n = 1/80) within a 12-month period, which required revision surgery in one patient (2%). Two dural tears (4%), which have been successfully fixed intraoperatively and two wound revisions (4%) within the

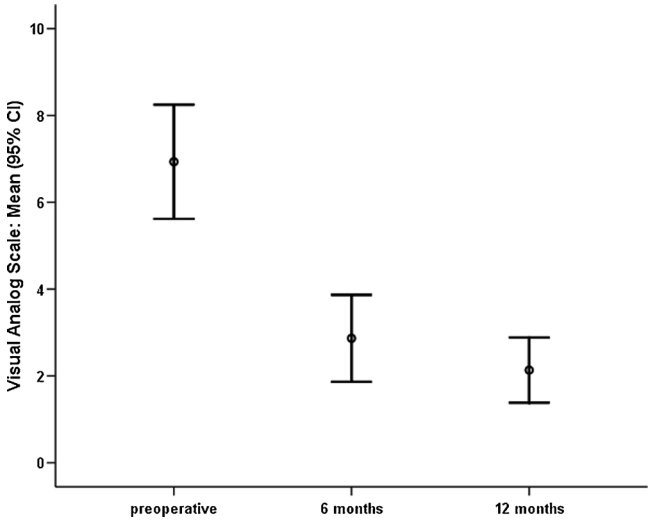

Fig. 2. Mean and Standard Deviation for Visual Analog Scale (VAS) are given for each time. VAS values demonstrated a significant and maintained improvement in comparison to baseline levels ($p < 0.05$). A minor improvement after 12 months in comparison to the 6-month results was seen, but without significant difference ($p > 0.05$).

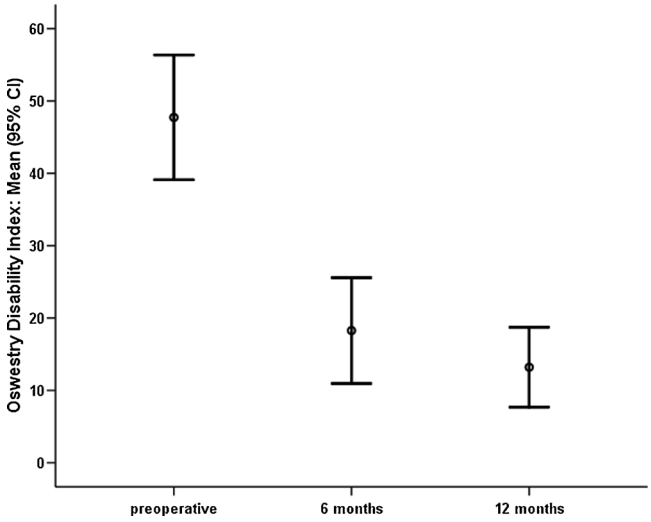

Fig. 3. Mean and Standard Deviation for Oswestry Disability Index (ODI) are given for each time. ODI values demonstrated a significant and maintained improvement in comparison to baseline levels ($p < 0.05$). A minor improvement after 12 months in comparison to the 6-month results was seen, but without significant difference ($p > 0.05$).

Table 2
SF-36 scores preoperative, 6 months and 12 months after surgery.

	Preoperative	6 months	12 months
PF	25.7 ± 20.6	65.5 ± 26.1 *	82.3 ± 14.5 #
BP	18.8 ± 15.8	60.7 ± 27.2 *	80.2 ± 14.7 #
GH	46.3 ± 16.1	65.9 ± 18.9 *	82.3 ± 11.8 #
PR	47.3 ± 21.1	54.3 ± 36.6 *	71.7 ± 22.9 #
EWB	55.2 ± 21.0	75.0 ± 17.8 *	84.2 ± 18.7 #
ER	36.2 ± 45.5	78.9 ± 23.2 *	86.2 ± 30.2
VT	33.4 ± 18.8	50.5 ± 16.7 *	62.0 ± 15.4 #
SF	41.4 ± 32.5	79.3 ± 25.3 *	91.7 ± 11.2 #

Abbreviations: PF Physical Functioning; BP Bodily Pain; GH General Health; PR Physical Role; EWR Emotional Well-Being; ER Emotional Role; VT Vitality; SF Social Function.
* significant difference between preoperative and 6 months.
# significant difference between 6 months and 12 months.

Table 3
Complications.

Variable	Numbers
Cage Dislocation	1 (1%) of 80 cages 1 (2%) of 49 patients
Wound Revisions	2 (4%) of 49 patients
CSF leak	2 (4%) of 49 patients

CSF = cerebrospinal fluid.

first week after surgery occurred. The overall complication rate was 10%. Complications are depicted in Table 3.

3.4. Radiological assessment

X-Rays in AP and lateral view were performed on standing patients postoperatively, after 6 weeks, 6 and 12 months to detect implant failure and determine fusion. One cage dislocation was detected after 12 months, which was not seen at the 6-month follow-up (Fig. 4). Evidence for fusion was seen in 96% (47/49) patients at the 12 months follow-up (Fig. 5). Cage subsidence did not occur.

The overall results from the radiographic measurements are depicted in Table 4. A statistically significant increase in ADH and PDH was noted from mean 8.2 mm (± 3.3 mm) and 3.5 mm (± 1.3 mm) preoperatively to 14.7 mm (± 3.6 mm) and 6.9 mm (± 1.3 mm) postoperatively ($p < 0.05$). Similarly, FH increased significantly from 15.1 mm (± 4.1 mm) preoperatively to 17.3 mm (± 3.8 mm) postoperatively ($p < 0.05$).

SL and LL increased significantly from mean 9.7° (± 5.4°) and 38.8° (± 5.4°) preoperatively to 12.6° (± 2°) and 47.7° (± 4.4°) postoperatively ($p < 0.05$).

All radiographic measurements showed a slight decrease at 12 months follow-up, but without a statistically significant difference compared to the postoperative results ($p > 0.05$) (Table 4).

4. Discussion

Transforaminal lumbar interbody fusion (TLIF) was first introduced by Harms and Rolinger in 1982 and has proved to be a safe and effective procedure for treatment of degenerative disc diseases [19]. In comparison to posterior lumbar interbody fusion (PLIF), TLIF procedures rely on three considerable advantages: circumferential fusion by using a unilateral approach, less retraction of neural structures, and lower incidence of neural injury [19–22]. The number of lumbar fusion surgeries using a TLIF cage has increased over the past years, especially in patients in whom previous decompressive procedures have failed [23,24]. Many indications for fusion in a revision setting exist and include patients who developed disc degeneration, disc collapse or secondary instability after lumber decompression or patients with adjacent level degeneration after previous lumbar fusion [23]. Revision surgeries are always challenging due to epidural fibrosis, adherent neural structures and lost anatomical landmarks. These factors can lead to dural tears and neural complications [20].

In an attempt to reduce complications associated with preparation of the corridor for cage insertion, TLIF has gained widespread popularity [19,21,22,25,26]. However, TLIF still remains a complex surgical procedure with serious complications in revision surgery and multilevel cases [19]. In a 2012 published series of 531 patients who underwent TLIF, a dural tear occurred in 14.3% of patients. An overall complication rate of 25.4% has been evaluated in their large series, additionally including infection, screw misplacement and cage migration; 46% of these patients have undergone previous lumbar surgery. The incidence of complications was significantly higher in those patients who had undergone previous surgery [19].

The fact that our department is a spine referral center for complicated surgeries and reoperations, including older patients with vulnerable dura, we often see patients with advanced degenerative disc disease, who also had previous surgery. This often makes dural preparation more difficult and can easily lead to dural injury.

In this prospective study we show favorable clinical and radiological results of a novel articulating TLIF cage in lumbar interbody fusion procedures for at least 12 months postoperatively. The complication rate, especially the rate for dural tears was low, in spite of the fact that more than two-thirds of the patients have had previous lumbar surgeries. The cage design with a joint connecting the anterior and posterior part is unique and has not been published before.

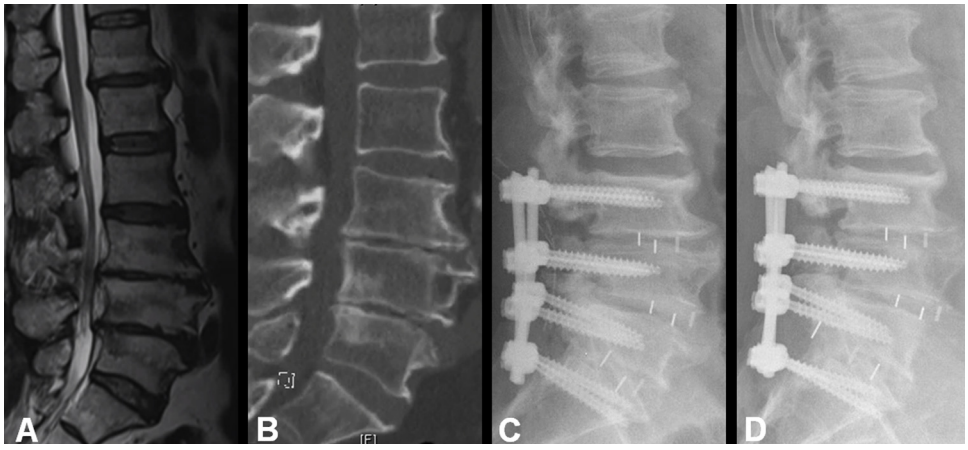

Fig. 4. Preoperative T2-weighted sagittal MRI (A) and sagittal CT scan (B) of a 59-year old male patient with degenerative disc disease L3/4 and L4/5, and neuroforaminal stenosis L5/S1. Proper screw and cage placement L3 to S1 was seen at 6-months follow-up (C). However posterior cage migration in L5/S1, requiring surgical revision occurred 12 months postoperatively (D).

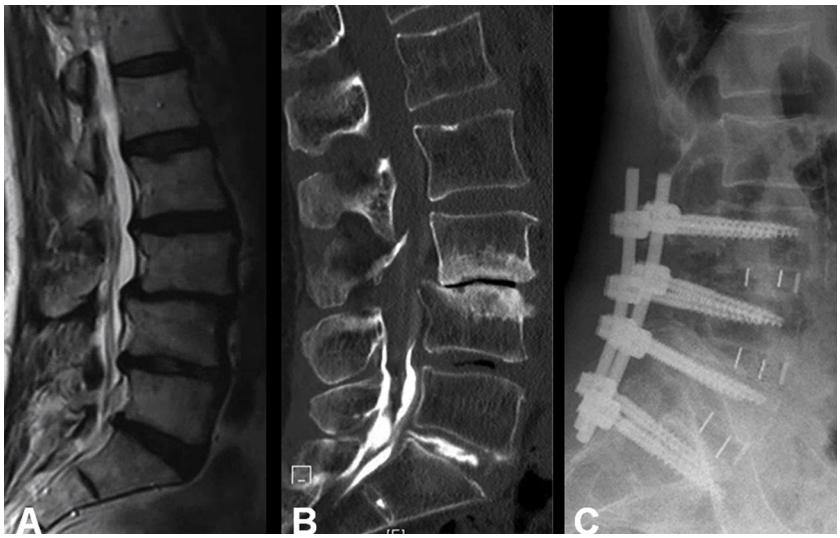

Fig. 5. Preoperative T2-weighted sagittal MRI (A) and sagittal CT myelogram (B) of a 73-year old female patient showing degenerative disc disease L3-S1. Lateral standing x-ray following three-level TLIF with SYNCHRO® cages demonstrates disc space height restoration as well as reconstruction of segmental lordosis 12 months after surgery (C). Presence of trabecular bony bridging is seen (C).

4.1. Complications

Cage migration with nerve root impingement requiring surgical revision was seen in one patient. Fortunately, we did not observe any neural injuries in these patients. This has also to do with the fact that we use spinal navigation during cage implantation, which is especially favorable in cases with an extensive scar tissue and a totally lost anatomy, which is common in patients with previous (sometimes multiple previous) surgeries. The two wound healing disturbances were most likely due to the fact that patients had undergone previous lumbar surgery; one patient had an infected hematoma, the other superficial necrotizing tissue, however no germs were found in both cases and antibiotics were given. Two dural tears occurred during preparation of the intervertebral disc space of patients having had previous surgery, and were successfully fixed intraoperatively.

4.2. Literature

Little is known about articulating cages for TLIF procedures. In fact, to our knowledge, no studies exist for TLIF cages which have a joint connecting the anterior and posterior part. There are only two retrospective studies with an articulating cage, which were used for minimally invasive TLIF procedures [14,27]. The cage used in both studies was an expendable titanium cage with articulation (Altera®, Globus Medical, Audubon, Pennsylvania, USA). The principal focus in both articles was the possibility to gain segmental lordosis of the operated segment and to evaluate the influence of improvements in sagittal balance. Hawasli et al. compared 16 patients with 19 static interbody devices to 28 patients with 29 articulating expandable interbody devices. The authors concluded that the cage design did not affect radiographic pelvic parameters, despite a larger increase in segmental lordosis in the group with the expandable articulating TLIF cage [27]. A second study using an articulating expandable cage has recently been published by Massie et al. in 2018. A total of 44 patients with 49 cages were included. The authors reported an endplate violation in 14 patients (32%) during placement of the cage with a progression of subsidence in 6% over time. A significant segmental correction of lordosis with a mean improvement of 4.9° could be achieved within the sagittal plane. Whether or not the increased segmental correction has a positive effect, e.g. concerning adjacent level degeneration, still remains unclear [14]. Most of the available TLIF cages already have a built-in lordotic configuration to achieve further lordosis.

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Table 4
Results from radiological X-ray measurements. A significant increase in all parameters was noted postoperatively ($p < 0.0001$). At 12 months follow-up, a slight decrease was seen but without statistically significant difference to the postoperative results ($p > 0.05$).

	Preop: mean (SD)	Postop: mean (SD)	12 months po: mean (SD)	Difference (pre–post): 95 % CI for difference
Anterior disc height [mm]	8.2 (± 3.3)	14.7 (± 3.6)	13.8 (± 3)	6.6: (5.4 to 7.5)
Posterior disc height [mm]	3.5 (± 1.3)	6.9 (± 1.3)	6.5 (± 1.3)	3.4: (3.0 to 3.9)
Foraminal height [mm]	15.1 (± 4.1)	17.3 (± 3.8)	17.1 (± 2.8)	2.2: (1.2 to 3.2)
Segmental lordosis [°]	9.7 (± 5.4)	12.6 (± 2)	12.3 (± 2.5)	2.9: (1.7 to 4.1)
Lumbar lordosis (L1-S1) [°]	38.8 (± 5.4)	47.7 (± 4.4)	46.9 (± 6.2)	8.9: (7.1 to 10.6)

SD = standard deviation.

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In comparison to our prospective study, the previous described cages have had another design and advantages for patients, despite an increased lordosis, were beyond the scope of these articles. Benefits in term of handling were not addressed. Furthermore, over 71% of our patients have had previous surgery, which makes the cases technically more demanding.

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4.3. Limitations

This study has several limitations. The major limitation is that a routine follow-up CT scan could not be obtained to precisely verify bone fusion or the ratio of fibrous fusion owing to concerns of the ethics committee that this did not necessarily represent the standard of care in Germany and would lead to unnecessary and medically not indicated additional radiation exposure of patients. It is a single surgeon's experience with a relatively small sample size. There is a lack of an internal control group of patients who underwent lumbar fusion using a standard TLIF cage. Our 12 months follow-up is relatively short to demonstrate whether our clinical and radiological outcome remains feasible. Large prospective randomized controlled studies are needed to underline our findings and to determine the long-term benefit of this novel cage design. Intraoperative SYNCHRO® cage placement failed in 8 of 89 (9%) planned lumbar levels due to a small intervertebral disc height of 5 mm or less.

5. Conclusions

The data from this current study reveal satisfactory clinical and radiological results with acceptable complication rates. The articulating SYNCHRO® cage is a novel, safe, and effective treatment option for TLIF procedures and may have advantages over non-articulating cage implants in revision procedures. The implantation of this cage failed in 9% of previously planned lumbar levels. Further prospective comparative studies are needed to underline these findings.

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