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Transforaminal Lumbar Interbody Fusion Using LOOP® PEEK Cage Implants: Safety, Feasibility, Radiographic and Clinical Outcome

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Abstract

Objective: A variety of newly designed grafts for transforaminal lumbar interbody fusion (TLIF) have been introduced for clinical application. Biomechanical properties of the LOOP® PEEK cage (Medtronic GmbH, Meerbusch, Germany) have been shown in cadaver laboratory investigations, but not in clinical studies so far. In this study we analyze the safety, clinical and radiological outcome of the LOOP® PEEK cage implant in a clinical setting.

Methods: Forty one consecutive patients undergoing fluoroscopic-guided posterior pedicle screw fixation combined with TLIF using the LOOP® PEEK cage for degenerative spine diseases between January 2010 and December 2011 were included. Time intervals for follow-up, clinical and radiological outcome data collection were at 1, 3 and 12 months. Visual analog pain scales (VAS), neurological exam, patient-reported SF-12®, CT- scans and plain x-rays of the lumbar spine were used as clinical and radiologic outcome measures. Following data were recorded for safety evaluation: procedure duration, intraoperative blood loss, number of levels fused, intraoperative complications, hospitalization time, and postoperative complications.

Results: A total of 49 cages were implanted during 41 procedures with an average procedure time of 225.25 minutes. Four patients (9.8%) experienced a dural tear, While new sensory and motor deficits were seen in 2 (4.9%) and 1 (2.4%) patients respectively. complications were not associated with implant insertion. Significantly reduced pain scores ($p<0.05$, paired t-test) were reported by 29 patients (70%) at 1, 3 and 12 months. SF-12® results showed PCS and MCS scores below the healthy population average, one year post-op. Cage dislocation was observed in 2 (4.9%) patients, one required late revision. Implant fracture did not occur. Inchoate fusion of the vertebra was seen in 39 patients (95.1%) at one year.

Conclusion: TLIF procedure combined with lumbar fusion using LOOP®-PEEK cage, provides a safe and feasible intraoperative alternative as well as good clinical and radiologic outcome, without increasing the overall complication rate of TLIF procedures.

Keywords: Interbody grafts; Transforaminal lumbar interbody fusion; Spinal fusion; Pedicle screw fixation; Spinal cage implant; Lumbar fusion

Introduction

Various surgical techniques for lumbar interbody fusion combined with posterior pedicle screw fixation have been proven being reasonable for treatment of degenerative spinal disorders. Posterior lumbar interbody fusion (PLIF) [1,2], transforaminal lumbar interbody fusion (TLIF) [3,4], and anterior lumbar interbody fusion (ALIF) [5] are the most frequently performed whereby all three columns of the spine are stabilized, resulting in a circumferential fusion [6,7]. The advantage of TLIF and PLIF procedures over ALIF is that they only require a single approach. In addition, ALIF procedures are associated with a risk of retrograde ejaculation, injury of abdominal vessels and greater blood loss due to the trans- or retroperitoneal approach [3,8-10]. PLIF procedures show increased risk of epidural bleeding, arachnopathy and peridural fibrosis. Furthermore, they are limited to segments L3-S1 due to the risk of conus medullaris damage [3,11,12]. The TLIF technique - a modification of PLIF by Harms - seems to be simpler than and as safe as PLIF [4,6]. The advantage of TLIF is its unilateral approach, less arachnoiditis, and avoidance of excessive nerve root retraction and coagulation of the epidural vessels, resulting in less epidural scaring [3,6,11,13,14].

Over the years, a variety of interbody grafts have been designed and studied; including bone grafts from different sites (iliacal crest autograft and femoral ring or corticocancellous allograft) [15-17], resorbable implants, such as poly-L-lactide-co-D, L-Lactide (PLDLLA) [18], carbon cages, titan cages [17], and polyetheretherketone (PEEK) cages [15-18]. PEEK cages have gained wide acceptance due to the excellent reported clinical outcomes, reduced stress at the endplates adjacent to the cage, and increased load transfer and stability [16-19]. The PEEK cage appears to be superior to PLDLLA cages [18], bone grafts [20-22], and titan cages [17]. Unlike their metallic counterparts, PEEK cages are radiolucent, allowing better assessment of bone fusion [17] Still many of the introduced products have not been tested and evaluated in a clinical setting. Clinical data of newly introduced implants is furthermore important in the future in order to legitimate their application in times of health care policy restrictions and growing patients demand for information.

The LOOP® PEEK cage implant (Medtronic GmbH, Meerbusch, Germany) was introduced for clinical use in 2005. Its advantages include a tapered and bullet-nosed tip, providing an easier approach within the intervertebral disc space, optimal angle from the dorsal approach to the full lateral trajectory at each implant phase, good end plate contact, ample room for bone graft within the implant, and the ability to locate the anterior edge of the implant as well as the tapered

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tip on x-ray [23]. Until now, biomechanical properties of the LOOP® PEEK cage implant have only been demonstrated in cadaver laboratory investigations [24].

Many studies have proven the efficiency of TLIF procedures, yet many interbody graft products are introduced to the market without primary evaluation in a clinical setting. The aim of our study was to analyze the safety, as well as the clinical and radiological outcome of patients undergoing TLIF, using the LOOP® PEEK cage implant combined with posterior pedicle screw fixation in a clinical setting.

Materials and Methods

Patient characteristics

Data were collected and analyzed between January 2010 and December 2011 for all patients undergoing TLIF using the LOOP® PEEK cage implant combined with fluoroscopy-guided free hand posterior pedicle screw fixation. The study was approved by the IRB of the Kantonsspital Aarau, Aarau, Switzerland. Inclusion criteria were: failed period of conservative therapy for at least 3 months combined with clinical and/or radiologic lumbar instability, recurrent herniated disc, symptomatic spinal- or foraminal stenosis, spondylolisthesis Meyerding grade I or II [25], or degenerative osteochondrosis. Patients with arachnoiditis, infection, severe osteoporosis, tumor, or life expectancy under 3 months were excluded from the study. Demographic data were retrospectively collected from patients' charts in addition to following parameters: patients' history (BMI, smoking status, occupation, working disability, previous spine operations, preoperative pain, duration of ailment and neurologic deficits), conservative therapy (analgesics, physiotherapy, infiltration), pathologies on preoperative radiographic scans (spondylolisthesis grade, osteochondrosis grade, foraminal stenosis, instability), intraoperative findings (operation time, intraoperative blood loss, operated level, number of levels fused, operative technique, intraoperative complications), hospitalization time, postoperative complications, clinical outcome and radiographic outcome.

Pre- and postoperative assessment

Pre- and postoperative clinical outcome was assessed prior to the procedure, then at 6 weeks, 3 months, and 1 year post-op. Clinical outcome was evaluated using the visual analogue pain scale (VAS), neurological exams and SF-12® self-reporting surveys at one year. Preoperative radiological assessment included plain and functional x-rays, in addition to magnetic resonance imaging (MRI) of the lumbar spine. Radiographic outcome measures included computer tomography (CT) scan on first postoperative day and plain x-rays at 1, 3, and 12 months.

Operative techniques

All patients were operated using an open surgical technique. The patient is placed in a prone position under general anesthesia. The posterior elements of the spine are exposed to the base of the transverse processes. After fluoroscopic guided pedicle screw insertion, the superior and inferior articular processes of one facet joint are resected and the disc is exposed in the neuroforamen. Laminectomy, interlaminotomy, recessotomy or foraminotomy procedures are completed depending on the patient's clinical and specific symptoms. The epidural veins are coagulated before incising the disc. The disc is subtotally resected using rongeurs and curettes. After scraping the endplates, the LOOP® PEEK cage implant is filled with bone chips taken from resected lamina. It is then inserted under fluoroscopic guidance into the anterior-central region of the disc space. The radius between cage and introducer can be adjusted in each phase of the implantation. Finally, both rods are mounted under light compression. The muscle fascia and skin are then sutured in the customary manner. All patients were operated by the same team using the described standardized surgical technique.

Data analysis

The SF-12® surveys were analyzed using QualityMetric's QM Certified Scoring Software (QualityMetric, Lincoln RI, USA). Analysis of the final data set was performed using JMP software (SAS Institute Inc., Cary NC, USA) and Superior Performing Software System (SPSS; IBM SPSS Inc., USA). For statistical data analysis, the paired t-, Mann-Whitney U, Fisher's extract, and Spearman's rho test were used. Values were expressed as mean ± SD. A p value <0.05 was considered significant. The authors did not receive any funding and there is no conflict of interest.

Results

Patient Characteristics

A total of 41 consecutive patients underwent TLIF using the LOOP® PEEK cage implant combined with fluoroscopy-guided free hand posterior pedicle screw fixation. The mean age was 51.9 years (± 13.0 years, range 21-78 years) with 16 (39%) females and 25 (61%) males. The mean BMI was 29.5 kg/m^2 (± 4.7 kg/m^2; men: 27.7 kg/m^2 ± 3.3 kg/m^2; women: 32.2 kg/m^2 ± 5.3 kg/m^2). Of the 41 patients, 22 (53.7%) were smokers (men: n=17, 68%; women: n=5, 31.3%).

In 27 (66%) cases, the patient performed a heavy physical job, while 7 (17.1%) patients were retired, 1 (2.4%) patient was unemployed, 1 (2.4%) patient received occupational disability annuity, 3 (7.3%) and 20 (48.8%) patients had 25-50% and 75-100% working disabilities respectively, and 9 (22%) patients worked fulltime.

48.8% (n=20) had undergone a prior lumbar operation, 14 (34.1%) at the same level, 2 (4.9%) at an adjacent level, and 4 (9.8%) at the same and an adjacent level. Patients' clinical characteristics are presented in Table 1, and the most common secondary diagnoses are listed in Table 2.

Preoperative clinical findings

A preoperative VAS of 7-8 or 4-6 was each reported by 18 patients (43.9%), and 5 (12.2%) patients expressed a VAS of 1-3. Radicular or lumbar pain alone was experienced by 0 (0%) and 3 (7.3%) patients respectively. In 38 (92.7%) cases the pain was combined; 22 (57.9%) mostly lumbar pain, 11 (18.9%) mostly radicular pain, and 5 (13.2%) equal levels of lumbar and radicular pain. The mean duration of preoperative alignment was 128.3 weeks (± 153.1 weeks, range 4 - 480 weeks).

Patients' characteristics			
	Male	**Female**	**Total**
Number of patients	25 (61%)	16 (39%)	41
Mean age (years ±SD)	49.4 (±12.9)	55.8 (±12.7)	51.9 (±13.0)
BMI (kg/m²)	27.7 (±3.3)	32.2 (±5.3)	29.5 (±4.7)
Smoker (%)	68	31.3	53.7
Previous lumbar surgery (n)			
	Male	**Female**	**Total**
Same level	9	5	14
Adjacent level	2	0	2
Same and adjacent level	2	2	4
None	12	9	21

SD: Standard Deviation

Table 1: Patients' characteristics.

Secondary Diagnosis	Number of Patients
Hypertension	11 (26.8%)
Diabetes mellitus	4 (9.8%)
Coronary Heart Disease	3 (7.3%)
Hypercholesteremia	2 (4.9%)
DVT	2 (4.9%)
COPD	1 (2.4%)
Scheuermann's disease	1 (2.4%)
Asthma bronchiale	1 (2.4%)
Allergic Asthma	1 (2.4%)
Graves' disease	1 (2.4%)
Depression	1 (2.4%)

DVT: Deep Venous Thrombosis; COPD: Chronic Obstructive Pulmonary Disease

Table 2: Most common secondary diagnosis.

	Pre-op (n=41)	Post-op 1 (n=41)	Post-op 2 (n=32)	Post-op 3 (n=25)
VAS 9-10	none	none	none	none
VAS 7-8	18 (43.9%)	3 (7.3%)	1 (3.1%)	4 (16%)
VAS 4-6	18 (43.9%)	5 (12.2%)	8 (25%)	8 (32%)
VAS 1-3	5 (12.2%)	23 (56.1%)	18 (15.6%)	8 (32%)
VAS 0	none	10 (24.4%)	5 (15.6%)	5 (20%)
New neurologic deficit		4 (24.4%)	none	none
Reduction of lumbar pain post-op			37 (90.2%)	
Reduction of radicular pain post-op			34 (82.9%)	
Complete resolution of neurologic deficits post-op			24 (58.5%)	
No new neurologic deficits post-op			37 (90.2%)	

Table 3: Preoperative clinical findings compared to 1, 3, and 12 months post-op. Pre-OP: Preoperative; Post-OP: Postoperative; VAS: Visual Analog Pain Scale

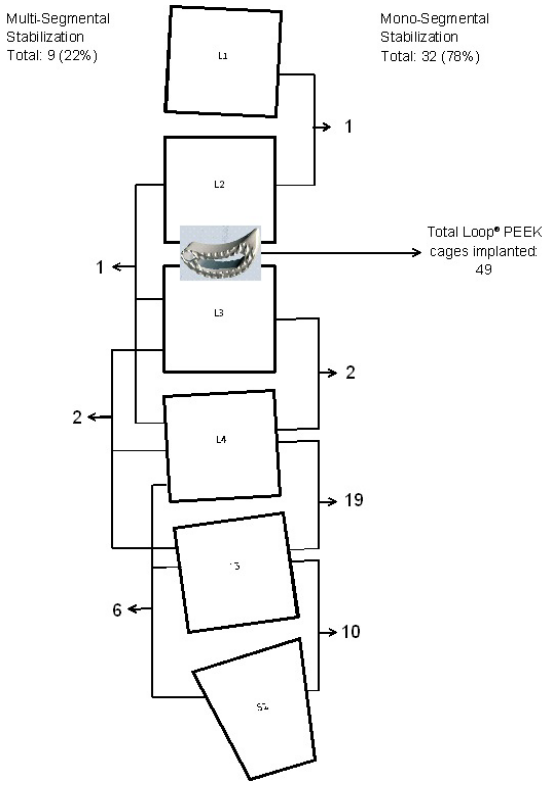

Figure 1: Segmental heights of stabilization, number of mono- and multi-segmental stabilizations, and number of LOOP®-PEEK cages implanted.

Non-steroidal anti-inflammatory drugs (NSAID) were prescribed in 61% (n=25) of the cases, an opiate was combined with a NSAID in 26.8% (n=11), and 2.6% (n=1) received an opiate exclusively. In 9.8% (n=4), no analgesic therapy was prescribed.

Neurologic deficits were detected in 25 (65%) patients; 12 (29.3%) sensitive, 2 (4.9%) motoric, and 11 (26.8%) combined. There was no case of cauda symptomatic.

Preoperative radiologic findings

All patients were given a preoperative lumbar spine MRI and additional plain and functional x-rays were taken in 31 (75.6%) cases.

Spondylolisthesis Meyerding grade I was seen in 24 patients (58.5%), grade II in 5 patients (12.2%), and 12 (29.3%) showed no spondylolisthesis. Osteochondrosis was detected in 29 patients (70.7%; Modic grade I: n=24, 58.5%; Modic grade II: n=5, 12.2%), and 11 of the 31 patients with functional x-rays (35.5%) showed radiologic instability. No bone bridges were found. In 36 cases (87.8%), a foraminal stenosis was seen on MRI. Table 3 summarizes the radiologic findings.

Intraoperative findings

Multisegmental stabilization was carried out in 9 patients (22%; L2/3/4: 1 patient, L3/4/5: 2 patients, L4/5/S1: 6 patients), and monosegmental stabilization in 32 patients (78%; L1/2: 1 patient, L3/4: 2 patients, L4/5: 19 patients, L5/S1: 10 patients; Figure 1).

Decompression of the spinal canal was performed by laminectomy, interlaminotomy, foraminotomy and recessotomy in 23 (59%), 7 (17%), 12 (29.3%) and 25 (60%) patients respectively.

In total, 49 cages were implanted. Cage implantation was possible without total facet joint removal in 29 patients (71%). Implant handling and placement was performed easily according to the manufacturer's instructions and without incident in all cases. The non-radiolucent implant markers guided implantations reliably in all cases.

Dural tear occurred in 4 (9.8%) patients during decompression and wasn't associated with implant insertion. In 3 (60%) cases of dural tear, the patients had undergone prior lumbar surgery at the same level.

The average length of surgery was 225.25 minutes (min; ± 48.83 minutes; range 90-335 min), whereby mono-segmental (219.36 min ± 48.01 min; range 90-290 min) operation time was not significantly ($p>0.05$) longer than multi-segmental procedures (245.56 min ± 48.83 min; range 180-335 minutes). Age had no influence on the duration, although a higher BMI, and female sex was associated with increased surgery time ($p<0.05$).

Average blood loss was 552 ml (±463.77 ml; range 100-2500 ml). Although age, sex and number of fused segments did not influence blood loss significantly ($p>0.05$); a higher BMI, and longer operating time resulted in significantly more intraoperative blood loss ($p<0.05$).

Postoperative early clinical and radiologic findings

The mean hospitalization time was 9.3 days (±5.3 days; range 5-38 days). Sex, age, BMI, number of fused segments and intraoperative complications (e.g. dural tear) did not influence the length of stay ($p>0.05$).

Of 4 (9.8%) patients with intraoperative dural tear, one patient developed a diffuse swelling in the operation field causing caudal symptomatic and neurologic deficits, requiring reoperation. New sensory and motor deficits were seen in 2 (4.9%) and 1 (2.4%) patients,

respectively. Three (7.3%) patients required a postoperative blood transfusion. One (2.4%) patient developed a deep venous thrombosis in the lower extremities and was treated with oral blood thinners. Postoperative infections or bleedings did not occur.

CT scans on the first postoperative day showed 2 (4.9%) pedicle screw misplacements; reoperation was necessary in both cases. No cage dislocation was detected.

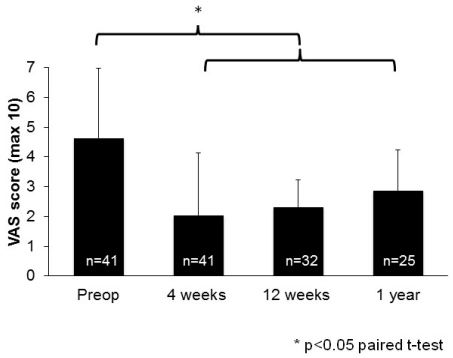

Figure 2: Significantly (p<0.05, paired t-test) reduced pain scores (Visual Analogue Scale) at 1, 3 and 12 months compared to preoperatively. Preop: Preoperatively; VAS: Visual analog pain scale

	1 month post-op (n=33)	3 months post-op (n=27)	1 year post-op at (n=21)
Cage dislocation	1 (3%)	1 (3.7%)*	none
Pedicle screw loosening	none	none	1 (4.7%)
Adjacent segment disease	none	none	2 (9.5%)
Progression of spondylolisthesis	none	none	none
Cage migration into endplates	none	none	none
Cage dislocation		2 (4.9%)§	
Pedicle screw loosening		1 (2.4%)	
Adjacent segment disease		2 (4.9%)	
Progression of spondylolisthesis		none	
Cage migration into endplates		none	
High fusion rate		39 (95.2%)	

Table 4: Radiographic findings at 1, 3, and 12 months, and summarized throughout entire follow up (n, %).
* Due to late infection; § one needed revision surgery; Post-OP: Postoperative

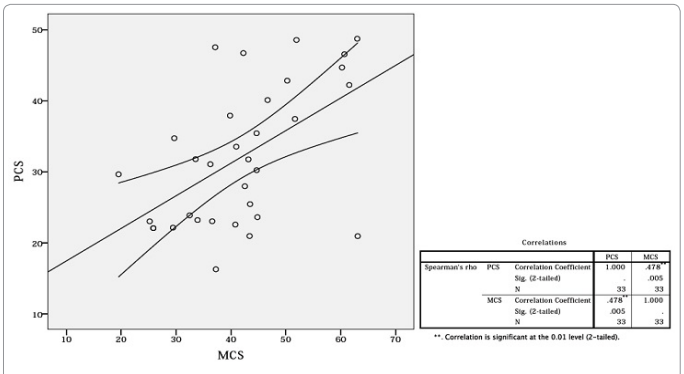

Figure 3: Distribution of PCS and MCS scores of SF12® surveys at one year. Significant (p<0.01) correlation between PCS and MCS scores was found. PCS: Physical Component Summary; MCS: Mental Component Summary

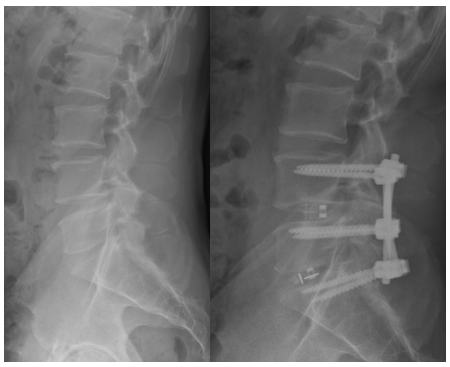

Figure 4: Preoperative (on the left) and 3 months postoperative (on the right) images of a 46 year old male suffering from back pain and pain to both his legs. In addition to the degenerative changes to the lumbar spine, the patient presented with lumbar disc herniation of the segment L4/5 on the left side and L5/S1on the right side. We indicated fluoroscopic guided pedicle screw insertion in the segments L4 - S1 and microscopic dorsal decompression, discectomy and cage implantation in L4/5 and L5/S1.

Clinical and radiologic findings at 1, 3, and 12 months postoperative

Clinical follow-up at 1, 3 and 12 months showed significant reduction in VAS pain scores (p<0.05, paired t-test; Figure 2).

Reporting 1 month postoperatively (n=41), VAS scores of 7-8, 4-6, and 1-3 were expressed by 3 (7.3%), 5 (12.2%), and 23 (56.1%) patients respectively, while 10 (24.4%) patients experienced a complete resolution of pain. After 3 months (n=32), a VAS of 7-8 was reported by 1 patient (3.1%), VAS of 4-6 by 8 patients (25%), and VAS of 1-3 by 18 patients (56.3%). Five patients (15.6%) were pain-free. After 12 months (n=25), 4 patients (16%) reported a VAS of 7-8, whereas a VAS of 4-6 and 1-3 was experienced by 8 patients (32%) each (Table 3). Throughout the entire follow-up time, 37 patients (90.2%) showed no new neurologic deficits. While postoperatively and at 1 month follow up new postoperative neurologic deficits occurred in 4 patients (9.8%), after 12 months these deficits recovered completely in 3 of these patients and were probably due to postoperative swelling caused by manipulation of the nerve root. However, in the patient showing persistent neurologic deficits after 12 months, a postoperative spondylitis, spondylodiscitis and arachnoiditis occurred, causing these permanent postoperative deficits. New postoperative neurologic deficits were never caused directly by the LOOP®-PEEK cage.

Radiology films obtained after 1 month (n=33) showed 1 (3%) cage dislocation with no further migration at 1 year post-op. After 3 months (n=27), further cage dislocation (3.7%) occurred in one patient together with late infection, which required surgical implant removal and antibiotic therapy. After 12 months (n=21), 1 patient (4.7%) showed radiographic signs of pedicle screw loosening and 2 patients (9.5%) showed signs of adjacent segment disease. Throughout the whole follow-up time none of the patients showed a progression of spondylolisthesis or cage subsidence into the vertebral endplates. Conclusive evaluation of the fusion rate after 1 year was not possible however, 39 patients (95.1%) showed an inchoate fusion of the vertebra (Table 4). Figures 4-6 demonstrate three representatives

SF-12® surveys outcome

The SF-12® surveys at 1 year were completed by 33 patients (80.5%). The mean Physical Component Summary (PCS) score was 32 (±9.8; range 16-49), and the mean Mental Component Summary (MCS) score 42 (±11.5; range 20-63). Both PCS and MCS scores were below healthy

population average, 1 year post-op. The PSC scores correlated with the MCS scores (Spearman's rho test; Figure 3).

Since mean PCS and MCS scores are age dependent, we divided the patients into four groups: group1: 45-54 years (mean score of general population: PCS 50; MCS 50), group 2: 55-64 years (mean: PCS 47; MCS 51), group 3: 65-74 years (mean: PCS 44; MCS 52) and group4: >74 years (mean: PCS 39; MCS 50). Group 1 (n=16, 48.5%) showed a mean PCS score of 30 (±10.5; range 16-48) and MCS score of 40 (±11.8; range 20-63). Group 2 (n=10, 30.3%) showed a mean PCS score of 35 (±9.6; range 22-49) and MCS score of 45 (±13.3; range 26-63). Group 3 (n=6, 18.2%) showed a mean PCS score of 31 (±9.6; range 22-49) and MCS score of 40 (±7.8; range 29-52). Group 4 (n=1, 3%) showed a mean PCS score of 37 and MCS score of 52. With exception of the MCS score in group 4, all scores were below healthy population average.

PCS and MCS scores showed no statistical difference (Mann-Whitney U test and t-test) when age (median 55, <55 years vs. ≥55 years), sex (female vs. male), number of fused segments (1 segment vs. >1 segment), and cage height (7 & 8 mm vs. 9, 10 & 11 mm) were compared (Table 5). Once two groups of PCS and MCS scores were created (PCS <30 vs. ≥30 and MCS ≤42 vs. >42), age (using the t-test), sex, number of fused segments, and cage height (all using the Fisher's extract test) showed no significant difference (Table 6). Patients with a PCS score <30 were younger on average (47.5 years vs. 55.6 years; p=0.09).

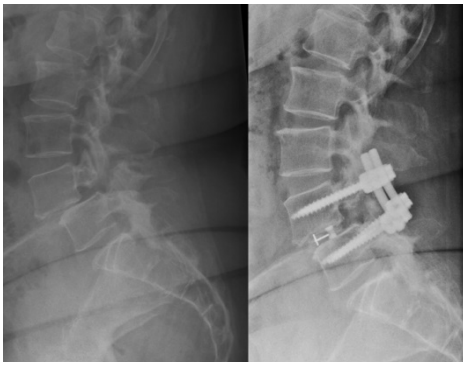

Figure 5: Preoperative (on the left) and 3 months postoperative (on the right) images of a 61 year old female suffering from back pain and pain to both his legs. A degenerative anterolisthesis with secondary spinal canal stenosis was seen and therefore a fluoroscopic guided pedicle screw insertion in the segments L4 – L5 with microscopic dorsal decompression, discectomy and cage implantation in L4/5 was concluded.

		Sex		Age		Number of segments		Cage height	
		female	male	<55	≥55	1 segment	>1 segment	7 & 8 mm	9, 10 & 11mm
		(n=14)	(n=19)	(n=16)	(n=17)	(n=23)	(n=10)	(n=25)	(n=8)
PCS	Mean score	30	34	30	34	34	28	32	33
	± SD	10	9.5	10.5	9.1	10	8.7	10.6	7.4
	Man-Whitney U	n.s. (0.267)		n.s. (0.305)		n.s. (0.203)		n.s. (0.659)	
	T-test	-		n.s. (0.36)		n.s. (0.158)		n.s. (0.756)	
MCS	Mean score	41	42	40	44	41	42	43	38
	± SD	12	11.4	11.7	11.3	12.4	9.6	11.9	10
	Man-Whitney U	n.s. (0.841)		n.s. (0.418)		n.s. (0.860)		n.s. (0.303)	
	T-test	-		n.s. (0.389)		n.s. (0.977)		n.s. (0.293)	

Table 5: SF 12® PCS and MCS scores compared by age (<55 years vs. ≥55 years), sex (female vs. male), number of fused segments (1 segment vs. >1 segment), and cage height (7 & 8 mm vs. 9, 10 & 11 mm). Statistical significance p<0.05.

PCS: Physical Component Summary; MCS: Mental Component Summary; SD: standard deviation; n.s.: non-significant

		PCS<30		PCS≥30		MCS≤42		MCS>42	
		(n=15)		(n=18)		(n=16)		(n=17)	
Age	Mean	47.5		55.6		53.8		50.2	
	±SD	12.5		14.3		11.4		16	
	t-test	n.s. (0.09)				n.s. (0.469)			
Sex		female	male	female	male	female	male	female	male
	n	8	7	6	12	8	8	6	11
	Fisher test	n.s. (0.304)				n.s. (0.491)			
Number of segments		one	multiple	one	multiple	one	multiple	one	multiple
	n	9	6	14	3	12	4	11	6
	Fisher test	n.s. (0.448)				n.s. (0.708)			

Table 6: SF 12® survey scores (PCS and MCS) divided into two groups and compared for age (<55 years vs. ≥55 years), sex (female vs. male), number of fused segments (1 segment vs. >1 segment), and cage height (7 & 8 mm vs. 9, 10 & 11 mm). Statistical significance p<0.05.

PCS: Physical Component Summary; MCS: Mental Component Summary; SD: standard deviation; n.s.: non-significant

Discussion

Our study shows that TLIF using a LOOP® PEEK cage implant combined with posterior pedicle screw fixation provides a surgically safe, feasible and effective alternative resulting in good clinical and radiological outcomes. The main findings of this study show a significant reduction of the VAS pain score at 1, 3 and 12 months postoperative compared to preoperative. Reduction of lumbar and radicular pain was shown in 90.2% and 82.9% of the patients respectively. The majority (90.2%) showed no new postoperative neurologic deficits, while 4 (9.8%) presented with new neurologic deficits. Neither these, nor dural tears were associated with LOOP®-PEEK cage handling and implantation.

Transforaminal interbody fusion

Multiple studies have demonstrated equally good clinical and radiographic results of the TLIF procedure compared to PLIF and ALIF [3,4,6,11,13]. The most important advantage over ALIF is the elimination of an additional ventral approach and its complications. Unlike PLIF, nerve root retraction and associated complications are also prevented. Hee et al. claims TLIF as the preferred technique because it is associated with shorter operating time, less blood loss, shorter hospital stay, and lower incidence of complications [9]. TLIF was found to be a safe procedure with good clinical outcome in several recent studies [3,13,26-28]. Our study confirms these results with an overall good clinical outcome of 90.2%, significant reduction of pain score after one year, high surgical safety and no cage-associated intraoperative complications.

The use of PEEK cages in the literature

PEEK biomaterials in the human body were first employed in the field of spinal implants in the early 1990's and are now widely accepted as the material of choice for fusion cages [29]. PEEK was tested in vitro for implant related complications and appears to be as safe as titanium or other metal-based cages [29,30]. Clinical data on neat PEEK implants in lumbar spine fusion has not yet been published in the literature. The first study evaluating PEEK cages in spinal surgery was conducted by Brantigan et al., starting in May 1989 [31]. This two-year

clinical study in 26 patients undergoing PLIF combined with posterior pedicle screw fixation and axial rods or plates, evaluated 32 interbody PEEK cages. Excellent results were achieved in 21/26 patients and fair or poor results were caused by problems unrelated to the cages. Due to their radiolucency, interbody fusion could be identified in 100% of the cage levels. A further prospective multi-center study published in 2000, showed equal results with successful fusion in 98.9% (176/178), clinical success in 86% (79/92), and fusion rate in 100% (91/91) of the patients [32]. However, carbon (68%) reinforced PEEK cages were used in these studies. Neat PEEK cages for anterior cervical fusion have also been investigated and findings published [33-35]. For lumbar spine fusion, however, the literature is generally limited to in vitro biomechanical, animal or cadaver studies [36-38]. Similarly, the LOOP® PEEK cage has only been analyzed in cadaver laboratory investigations [24]; our study is the first to evaluate a PEEK cage implant usage for lumbar spine fusion in a clinical context.

Feasibility of the LOOP® PEEK cage

In our experience, surgical handling and feasibility of the LOOP® PEEK cage appears to be safe. Implantation did not increase overall complication rates of TLIF procedures, as compared to other series. Thanks to the LOOP® hinge, cage angle adjustment is possible in each phase of the implantation. This enables simple and accurate placement in the median intervertebral space, using a unilateral approach. Due to the pointed tip, we also found insertion in narrow intervertebral spaces easier than with other spinal cages. The LOOP® PEEK cage had its limitations though, in cases where the intervertebral space was very narrow. The titanium x-ray markers and the radiolucency are helpful during the insertion, facilitating optimal cage positioning (Figures 4-6).

Patient characteristics and intraoperative findings compared to the literature

The mean patient age in our study (51.9 years) was higher than usually described in the literature (mean 44.2 years range 37.2-54.2 years) [26-28,39-41]. This might be due to the indications and heterogeneous nature of our patient group, as the majority was operated due to degenerative lumbar disorders. Mean blood loss (552 ml) was greater than TLIF procedures described in the literature (474 ml, range 320-609 ml) [3,11,13,19,27], however, the SD (±463.77 ml) was very high and the range (100-2500 ml) very broad. As obesity can lead to significantly higher intraoperative blood loss, and over 70% of our patients were obese (BMI>25 kg/m^2), this might explain the findings. Mean surgery time in the literature (187.67 min) [3,11,13,19,42] is lower than that in our study (225.25 min). Mean hospital stay in our study (9.3 days) is also higher compared to the literature (5 days); this might be due to the varying health care systems in each country.

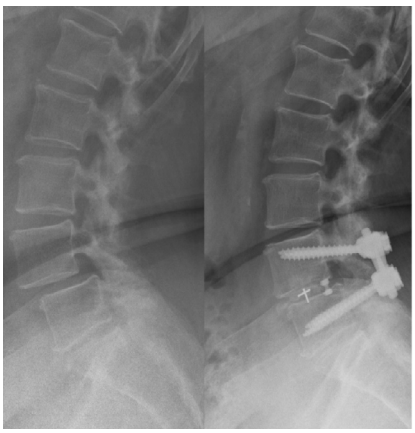

Figure 6: Preoperative (on the left) and 3 months postoperative (on the right) images of a 61 year old female suffering from back pain and pain to both his legs. A degenerative anterolisthesis with secondary spinal canal stenosis was seen and therefore a fluoroscopic guided pedicle screw insertion in the segments L4 – L5 with microscopic dorsal decompression, discectomy and cage implantation in L4/5 was concluded.

Clinical and radiological outcome compared to the literature

Our results show a significant reduction of the postoperative VAS pain score at 1, 3, and 12 months compared to preoperative. In fact, at one year, the SF-12® surveys showed PCS and MCS scores below the healthy population average. Reduction of lumbar and radicular pain was shown in 90.2% and 82.9% of patients respectively. The majority (90.2%) showed no new postoperative neurologic deficits. These results correlate with previous TLIF studies published [3,26,27,39-43].

Although the VAS pain scores were reduced significantly postoperatively, they had risen again at 12 months. This could explain the low PCS and MCS scores in the SF-12® surveys completed at one year, compared to the healthy population. Comparison of SF-12® scores at admission and during follow-up would provide better information about the outcome of the chronic pain sub-group. The difference between the chronic back pain cohort post-surgery and healthy population is not significant. Nevertheless, the SF-12® survey allows patients to describe their actual life quality in an understandable and objective manner, providing surgeons with a clearer picture of the situation.

Complication rates in the literature vary from 20 to 30.7% and a revision rate of 7.6% has been reported [19,39,41,42]. General complications include ileus and pseudomembranous colitis. Specific complications include pseudoarthrosis, pedicle screw malposition, hematoma, symptomatic contralateral disc herniation, dural tears, wound infection, wound dehiscence, seroma formation, donor-site infection, as well as transient and persistent radiculopathy [3,19,39,41,42]. In our cohort, 4 (9.8%) patients experienced new neurologic deficits, 1 late donor site infection (2.4%), and 2 (4.9%) pedicle screw misplacement, while dural tears occurred in 4 (9.8%) cases. Revision rate was 9.7% (n= 4; 2 pedicle screw misplacements, 1 dural tear, 1 late donor site infection with cage dislocation). Our complication and revision rates are congruent with those found in the literature.

In this study 4.9% of the patients (n=2) showed pedicle screw misplacements on postoperative CT scans; both needing operative revision. Cage dislocation within 1 year occurred in 2 cases (4.9%); in one case due to late infection, which needed surgical implant removal and antibiotic therapy. The second case was followed up conservatively and showed no further dislocation after a year, eliminating the need for revision surgery. Radiographic signs of pedicle screw loosening and symptoms of adjacent segment disease were seen in 4.9% and 2.4% of all cases respectively. No patients showed progression of spondylolisthesis or cage subsidence into the vertebral endplates throughout the entire follow-up period. 95.1% of patients showed an inchoate fusion of the vertebra. Our radiological outcome results correlate with previously published literature [3,26,27,39-42].

Study limitations

The heterogeneous nature of our patient group with mixed causes of instability was a limitation in our study. The age range was very broad (21-78 years), whereby the mean age was 59.1 years. This indicates that most patients suffered from degenerative lumbar conditions, resulting

in worse outcomes as compared to young patients with dysplastic and isthmic spondylolisthesis. Approximately 20% of patients were lost to follow-up after 3 months, and 40% after 1 year. Even though all data was prospectively collected, this study is retrospective in nature and the patients were not randomly selected. There was no control group to compare the LOOP® PEEK cage directly with a different intervertebral cage. However, with the growing number of implants available for degenerative or traumatic spine diseases, clinical evaluation of these products is of utmost importance in order to improve surgical techniques and patients' outcome.

Conclusions

We conclude that the safety and feasibility profile of the LOOP®-PEEK cage supports the introduction in routine application with good clinical and radiologic outcome without increasing the overall complication rate of TLIF procedures. Careful evaluation and follow-up is required in larger series from multiple centers.

Conflict of Interest

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

References

1. Cloward RB (1953) The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. I. Indications, operative technique, after care. J Neurosurg 10: 154-168.
2. Devkota P Shrestha SK, Krishnakumar R, Renjithkumar J (2011) Posterior lumbar interbody fusion for the management of spondylolisthesis. Nepal Med Coll J 13: 46-49.
3. Hackenberg L Halm H, Bullmann V, Vieth V, Schneider M, et al. (2005) Transforaminal lumbar interbody fusion: a safe technique with satisfactory three to five year results. Eur Spine J 14: 551-558.
4. Harms JG Jeszenszky D (1998) Die posteriore, lumbale, interkorporelle Fusion in unilateraler transforaminaler Technik. Oper Orthop Traumatol 10: 90-102.
5. Loguidice VA, Johnson RG, Guyer RD, Stith WJ, Ohnmeiss DD, et al. (1988) Anterior lumbar interbody fusion. Spine (Phila Pa 1976) 13: 366-369.
6. Sim HB, Murovic JA, Cho BY, Lim TJ, Park J (2010) Biomechanical comparison of single-level posterior versus transforaminal lumbar interbody fusions with bilateral pedicle screw fixation: segmental stability and the effects on adjacent motion segments. J Neurosurg Spine 12: 700-708.
7. Steffee AD Sitkowski DJ (1988) Posterior lumbar interbody fusion and plates. Clin Orthop Relat Res 227: 99-102.
8. Baker JK, Reardon PR, Reardon MJ, Heggeness MH (1993) Vascular injury in anterior lumbar surgery. Spine (Phila Pa 1976) 18: 2227-2230.
9. Comer GC, Smith MW, Hurwitz EL, Mitsunaga KA, Kessler R, et al. (2012) Retrograde ejaculation after anterior lumbar interbody fusion with and without bone morphogenetic protein-2 augmentation: a 10-year cohort controlled study. Spine J 12: 881-890.
10. Tiusanen H Seitsalo S, Osterman K, Soini J (1995) Retrograde ejaculation after anterior interbody lumbar fusion. Eur Spine J 4: 339-342.
11. Humphreys SC Hodges SD, Patwardhan AG, Eck JC, Murphy RB, et al. (2001) Comparison of posterior and transforaminal approaches to lumbar interbody fusion. Spine (Phila Pa 1976) 26: 567-571.
12. Okuyama K, Abe E, Suzuki T, Tamura Y, Chiba M, et al. (1999) Posterior lumbar interbody fusion: a retrospective study of complications after facet joint excision and pedicle screw fixation in 148 cases. Acta Orthop Scand 70: 329-334.
13. Hee HT, Castro FP, Majd ME, Holt RT, Myers L (2001) Anterior/posterior lumbar fusion versus transforaminal lumbar interbody fusion: analysis of complications and predictive factors. J Spinal Disord 14: 533-540.
14. Rihn JA, Patel R, Makda J, Hong J, Anderson DG, et al. (2009) Complications associated with single-level transforaminal lumbar interbody fusion. Spine J 9: 623-629.
15. Cutler AR, Siddiqui S, Mohan AL, Hillard VH, Cerabona F, et al. (2006) Comparison of polyetheretherketone cages with femoral cortical bone allograft as a single-piece interbody spacer in transforaminal lumbar interbody fusion. J Neurosurg Spine 5: 534-539.
16. Rousseau MA Lazennec JY, Saillant G (2007) Circumferential arthrodesis using PEEK cages at the lumbar spine. J Spinal Disord Tech 20: 278-281.
17. Smith AJ Arginteanu M, Moore F, Steinberger A, Camins M (2010) Increased incidence of cage migration and nonunion in instrumented transforaminal lumbar interbody fusion with bioabsorbable cages. J Neurosurg Spine 13: 388-393.
18. Jiya TU, Smit T, van Royen BJ, Mullender M (2011) Posterior lumbar interbody fusion using non resorbable poly-ether-ether-ketone versus resorbable poly-L-lactide-co-D,L-lactide fusion devices. Clinical outcome at a minimum of 2-year follow-up. Eur Spine J 20: 618-622.
19. Villavicencio AT, Burneikiene S, Bulsara KR, Thramann JJ (2006) Perioperative complications in transforaminal lumbar interbody fusion versus anterior-posterior reconstruction for lumbar disc degeneration and instability. J Spinal Disord Tech 19: 92-97.
20. Abdul QR Qayum MS, Saradhi MV, Panigrahi MK, Sreedhar V (2011) Clinico-radiological profile of indirect neural decompression using cage or auto graft as interbody construct in posterior lumbar interbody fusion in spondylolisthesis: Which is better? J Craniovertebr Junction Spine 2: 12-16.
21. Landriel FA Hem S, Goldschmidt E, Ajler P, Vecchi E, et al. (2013) Polyetheretherketone interbody cages versus autogenous iliac crest bone grafts with anterior fixation for cervical disc disease. J Spinal Disord Tech 26: 61-67.
22. Liebensteiner MC Jesacher G, Thaler M, Gstoettner M, Liebensteiner MV, et al. (2011) Restoration and preservation of disc height and segmental lordosis with circumferential lumbar fusion: a retrospective analysis of cage versus bone graft. J Spinal Disord Tech 24: 44-49.
23. http://www.spinesource.net/links/LOOP%20TLIF%20Brochure1.pdf.
24. Kettler A, Schmoelz W, Kast E, Gottwald M, Claes L, et al. (2005) In vitro stabilizing effect of a transforaminal compared with two posterior lumbar interbody fusion cages. Spine (Phila Pa 1976) 30: E665-670.
25. Meyerding H (1932) Spondylolisthesis. Surg Gynecol Obstet 54: 371-377.
26. Figueiredo N Martins JW, Arruda AA, Serra AR, Figueiredo MA, et al. (2004) TLIF--transforaminal lumbar interbody fusion. Arq Neuropsiquiatr 62: 815-820.
27. Mura PP Costaglioli M, Piredda M, Caboni S, Casula S (2011) TLIF for symptomatic disc degeneration: a retrospective study of 100 patients. Eur Spine J 20 Suppl 1: S57-60.
28. Takahashi T, Hanakita J, Minami M, Honda F, Kuraishi K (2011) Surgical outcome and postoperative work status of lumbar discogenic pain following transforaminal interbody fusion. Neurol Med Chir (Tokyo) 51: 101-107.
29. Kurtz SM Devine JN (2007) PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials 28: 4845-4869.
30. Rivard CH Rhalmi S, Coillard C (2002) In vivo biocompatibility testing of peek polymer for a spinal implant system: a study in rabbits. J Biomed Mater Res 62: 488-498.
31. Brantigan JW Steffee AD (1993) A carbon fiber implant to aid interbody lumbar fusion. Two-year clinical results in the first 26 patients. Spine (Phila Pa 1976) 18: 2106-2107.
32. Brantigan JW, Steffee AD, Lewis ML, Quinn LM, Persenaire JM (2000) Lumbar interbody fusion using the Brantigan I/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system: two-year results from a Food and Drug Administration investigational device exemption clinical trial. Spine (Phila Pa 1976) 25: 1437-1446.
33. Cho DY Liau WR, Lee WY, Liu JT, Chiu CL, et al. (2002) Preliminary experience using a polyetheretherketone (PEEK) cage in the treatment of cervical disc disease. Neurosurgery 51: 1343-1349.
34. Mastronardi L, Ducati A, Ferrante L (2006) Anterior cervical fusion with polyetheretherketone (PEEK) cages in the treatment of degenerative disc disease. Preliminary observations in 36 consecutive cases with a minimum 12-month follow-up. Acta Neurochir (Wien) 148: 307-312.
35. Sekerci Z UÄŸur A, ErgÃ¼n R, Sanli M (2006) Early changes in the cervical foraminal area after anterior interbody fusion with polyetheretherketone (PEEK) cage containing synthetic bone particulate: a prospective study of 20 cases. Neurol Res 28: 568-571.

36. Ferguson SJ Visser JM, Polikeit A (2006) The long-term mechanical integrity of non-reinforced PEEK-OPTIMA polymer for demanding spinal applications: experimental and finite-element analysis. Eur Spine J 15: 149-156.

37. Spruit M, Falk RG, Beckmann L, Steffen T, Castelein RM (2005) The in vitro stabilising effect of polyetheretherketone cages versus a titanium cage of similar design for anterior lumbar interbody fusion. Eur Spine J 14: 752-758.

38. Toth JM Wang M, Estes BT, Scifert JL, Seim HB 3rd, et al. (2006) Polyetheretherketone as a biomaterial for spinal applications. Biomaterials 27: 324-334.

39. Lauber S, Schulte TL, Liljenqvist U, Halm H, Hackenberg L (2006) Clinical and radiologic 2-4-year results of transforaminal lumbar interbody fusion in degenerative and isthmic spondylolisthesis grades 1 and 2. Spine (Phila Pa 1976) 31: 1693-1698.

40. Lowe TG Tahernia AD, O'Brien MF, Smith DA (2002) Unilateral transforaminal posterior lumbar interbody fusion (TLIF): indications, technique, and 2-year results. J Spinal Disord Tech 15: 31-38.

41. Potter BK, Freedman BA, Verwiebe EG, Hall JM, Polly DW, et al. (2005) Transforaminal lumbar interbody fusion: clinical and radiographic results and complications in 100 consecutive patients. J Spinal Disord Tech 18: 337-346.

42. Poh SY Yue WM, Chen LT, Guo CM, Yeo W, et al. (2011) Two-year outcomes of transforaminal lumbar interbody fusion. J Orthop Surg (Hong Kong) 19: 135-140.

43. Houten JK Post NH, Dryer JW, Errico TJ (2006) Clinical and radiographically/neuroimaging documented outcome in transforaminal lumbar interbody fusion. Neurosurg Focus 20: E8.