

Lumbar Spinal Rahisynthesis with Plif: a Retrospective Study of 58 Patients Demonstrating Imaging and Clinical Outcomes with One Year Follow-up

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ABSTRACT

Background/objectives: Nowadays, posterior lumbar cages remain a popular choice among the available options for interbody fusion even when compared with anterior approaches. As the posterior lumbar anatomy permits a relatively easy exposure to the spinal anatomy of interest, expandable cages prove to be a reliable tool for 360-degree fusion. Our study aspires to investigate the postoperative effects of Flarehawk 9 after open posterior lumbar fixation.

Materials and methods: We retrospectively analyzed 58 patients (36 males and 22 females) with a mean age of 59.8 years (age range of 33 to 79 years) who underwent open posterior lumbar fixation and decompression using Flarehawk 9 as an interbody cage between September 2021 and February 2023, with a minimum follow-up of 12 months. Patients fit for surgery and with adequate surgical indications suffered from spinal canal stenosis, failed back surgery syndrome, or in need of revision surgery, recurrent disc herniation, spondylolisthesis with mechanical back pain and adjacent segment disease.

Results: Based on the Odeswery index, most of the patients who underwent posterior fixation presented a significant clinical improvement postoperatively. The rate of bony fusion can be affected by the number of fused levels and whether the patient underwent revision surgery. Our study suggested that the number of lordosis that the patients gained on average is 2 ± 0.4 degrees.

Conclusions: The posterior lumbar approach is the golden standard of degenerative spinal surgery even compared to modern anterior approaches. Interbody cages can offer an improvement in fusion rate, lordosis and disc height. Large follow-ups are mandatory for the evaluation of each type of cage.

Keywords: clinical outcomes, posterior lumbar fusion, posture alignment.

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Article received on the 26th of August 2024 and accepted for publication on the 18th of September 2024

INTRODUCTION

The first attempts at posterior lumbar interbody fusion can be traced back to the 1940s, when their performance was marked by animosity due to high rates of failure. Initially, in the early 1940s, Ralph Cloward, during an open discectomy, observed a residual large void in the disc space after excision, and it occurred to him that this void should be filled with bone. However, he abandoned that idea since the patient died after surgery due to a pulmonary embolism (1). A couple of years later, a large group of successful spine surgeons made new attempts at posterior interbody fusion due to lasting postoperative low back pain. Nevertheless, despite clinical success, the outcomes were still poor, as this method did not offer higher fusion rates compared to other available methods, while holding a higher risk of neurological impairment and blood loss (2). This concept persisted until the mid-1980s, when Cloward reported fusion rates of over 92% for the same procedure (3). Nowadays, interbody fusion involves a much more complicated consideration of factors such as global alignment, disc height, fusion rates and operative risk, all combined at once. In response to the increased needs and preferences of patients, there has been a sudden growth in the development of innovative surgical techniques.

Sagittal malalignment significantly impacts the quality of life scores and serves as a source of pain and disability. Several studies have analyzed the correlation between sagittal radiographic parameters and Oswestry disability index (ODI) scores (4). Furthermore, these studies have highlighted the improvement in patient-related outcomes and the significant clinical advantages associated with the correction of sagittal parameters (5). Any condition that disrupts those parameters initiates sagittal malalignment and its compensatory mechanisms. As a result, sagittal malalignment is not confined solely to adult spinal deformities; its occurrence encompasses most spinal disorders. Given this wide spectrum, sagittal imbalance alone doesn't always require surgical correction as this necessity is based on the severity of symptoms (6). Nowadays, a variety of new approaches enables us to address both spinal alignment and pathologies at the same time.

These new approaches aim to reduce operative time, improve recovery, and minimize intraoperative complications. Consequently, traditional methods such as anterior/posterior lumbar interbody fusion (ALIF/PLIF) are being reconsidered in light of advancements like the transforaminal approach. Additionally, an increasing number of surgeons are dedicated to refining surgical outcomes through minimally invasive techniques (MI-TLIF). (7). In the procedure known as PLIF, patients are placed in a prone position on a Jackson breakable table to ensure a natural lordotic curvature of the lumbar spine. Despite the limitations of the posterior approach, expandable cages can be inserted through a minimal anatomical corridor while offering a significant amount of lordosis. The evolution of expandable cages has been influenced by various surgical approaches, including lateral, anterior, and direct posterior access. As a result, a range of expansion mechanisms such as anterior to posterior, medial to lateral, vertical and translating methods have been used.

Clinical follow-up has revealed certain drawbacks associated with expandable interbody fusion cages such as PLIF, where the visualization of the implant site is not available. Overexpansion can lead to a breach of the endplate, resulting in subsidence, migration and a reduction in intervertebral and neural foraminal height, potentially causing symptom recurrence, particularly in patients with osteopenia, osteoporosis and high values of the body mass index (BMI). (8). Their biomechanical profile consists of expansion in a single plane to lengthen the anterior column, increase the foraminal space and decrease the risk of endplate breach. Interbody fusion devices propose variations not only in their geometry and shape but also in their material. These different materials possess distinct intrinsic properties that can affect their performance. The value of elasticity, which measures a material's stiffness, is of utmost importance. If the stiffness of the device surpasses that of the surrounding bone, it heightens the risk of subsidence and related complications.

Our study aims to examine the effects of Flarehawk 9 on posterior spinal fusion and patients' quality of life as a means of posterior lumbar interbody fusion through the same surgical approach for various spinal pathologies. □

MATERIALS AND METHODS

Patients

A total of 58 patients, of which 36 were males and 22 females, underwent open posterior lumbar surgery using Flarehawk 9 between September 2021 and February 2023 at KAT General Hospital of Athens, Greece. All patients were operated by the same surgical team. Their mean age was 59.8 years (age range 33 to 79 years). The diagnostic groups included spinal canal stenosis (n=40), failed back surgery syndrome (FBSS)-revision surgery (n=5), spondylolisthesis with slip percentage 25% (n=4), recurrent herniated disc (n=7) and adjacent segment disease (n=2). The fusion levels varied depending on the extent of the pathology but it strictly involved the lumbar spine. Sixteen patients had a history of previous spine surgery. Patients with a history of previous spine infections were excluded from this study.

Ethical approval was obtained from both the scientific committee and the spinal surgery unit at the hospital where the study took place with approval code 806/07 February 2023. Furthermore, a consent form was signed by all participants in the study.

Imagistic assessment

The imagistic assessment included preoperative full spine standing x-rays, postoperative standing spine x-rays and CT of the lumbar spine to evaluate the bone fusion and spinal alignment at one year of follow-up. The lumbar lordosis is measured by plain standing lateral view x-rays at the intersection between the extending line of the upper endplate of L1 body and the lower endplate of L5 body. The reliability of error is acceptable up to 5 degrees. The pelvic morphology and spine parameters were measured before and after surgery, but the data was not included in our study since we did not focus on spinal deformity correction even though each case can be a potential spinal misalignment case. The terms adequate union, delayed union or absence of union were used to determine the quality of bone fusion. In our study, we considered delayed union in any asymptomatic or symptomatic patient who did not present 360° fusion at the 10-month follow-up. The follow-up included 96.5% as two patients due to health-related problems could not undergo a computed tomography (CT) scan.

Clinical assessment

The clinical outcome was assessed using ODI. This is a patient-completed questionnaire regarding low back pain which provides a subjective percentage score indicating the level of function or disability in 10 daily routine activities (pain intensity, lifting, sitting, walking, standing, sleeping, personal care, social, sex if applicable and traveling). Each item comprises six statements, scored on a scale from 0 to 5, where 0 represents minimal disability and 5, severe disability. The total score is then calculated as a percentage, ranging from 0%, which denotes no disability, to 100%, indicating the utmost level of disability. In the result section, the preoperative and postoperative disability values are expressed as a percentage and as a mean value for each category.

Statistical analysis

All patients included in the present study completed the SRS outcome survey, either during their latest follow-up appointment or remotely. Analysis of the survey results was conducted using IBM SPSS Statistics v12.0.1 (IBM Corp., Armonk, NY). This analysis included descriptive statistics, such as frequencies for categorical and ordinal variables, and measures like means, percentages and ranges for continuous variables calculated for each group separately and not totally. Additionally, independent t-tests were utilized for univariate analyses and determined that the sample was adequate for this study, with statistical significance being set at a p-value ≤ 0.05 . Our study has reached a 0.05 p value for the sample size which makes our sample reliable with a minimum sample size of 40 patients. This study has several limitations such as a bigger sample size would be more reliable especially in certain diagnostic group categories as the percentages are calculated separately for each group (n) and the fact that the ODI results are self-reported. □

RESULTS

Imagistic outcomes

The imagistic outcomes are summarized in Table 1, which categorizes patients into different diagnostic groups, including spinal canal stenosis, failed back surgery syndrome (FBSS), recurrent herniated disc, spondylolisthesis and adja-

cent segment disease, where 5.2% of all cases had delayed union and only 1.7% absence of union at follow-up. Patients were categorized based on whether they had previous surgery or not, and the percentages indicated that 12.5% of patients with a history of spine surgery had delayed union, while 6.25% had absence of union. Only 2.3% of subjects in the group without previous surgery had delayed union, while the percentage of absence of union was 0%. The mean value of lordosis added postoperatively per case was 2 ± 0.4 degrees, but practically it varied depending on the case, since some cases did not require correction of lumbar lordosis. Finally, increased age and the number of levels fused seem to have an impact on the time of complete union. The rate and amount of cage subsidence or migration did not affect the bone fusion in our study group. Below can be found a preoperative (Figure 1) standing x-ray of a 74-year-old patient with multilevel spinal canal stenosis programmed for a L2-S1 spinal fusion with wide decompression and cage at L3-L4 and L4-L5 levels along with the postoperative standing x-ray demonstrating the radiographic outcome (Figure 2). Additionally, a postoperative CT scan image of a one level fusion at one year of follow-up can be observed in (Figure 3).

Clinical outcome

Tables 2 and 3 summarize the clinical outcomes based on ODI. Significant improvement after spinal surgery can be observed in all % ranges of ODI. Upon comparing all percentages, the highest rate of least improvement can be seen within the range of 51-60%, where the number of patients is larger. In this group, there were two patients with surgical site infection who underwent successful irrigation and debridement, followed by intravenous and oral antibiotics. Additionally, in the range of 61-70% there was one subject with FBSS whose CT scan at the one-year follow-up showed an incomplete union, but the patient was asymptomatic. Because the time of rehabilitation may vary depending on the preoperative condition of the patient or the extension of the surgical approach, all patients completed the ODI questionnaire after one year of follow-up. When comparing the preoperative with postoperative mean values of patients who benefited from surgery, we observe that the ODI score is double preoperatively, suggesting a sig-



FIGURE 1. Preoperative x-ray of a 74-year-old patient, with the sagittal plane showing multilevel degenerative disc disease and the coronal plane revealing space narrowing

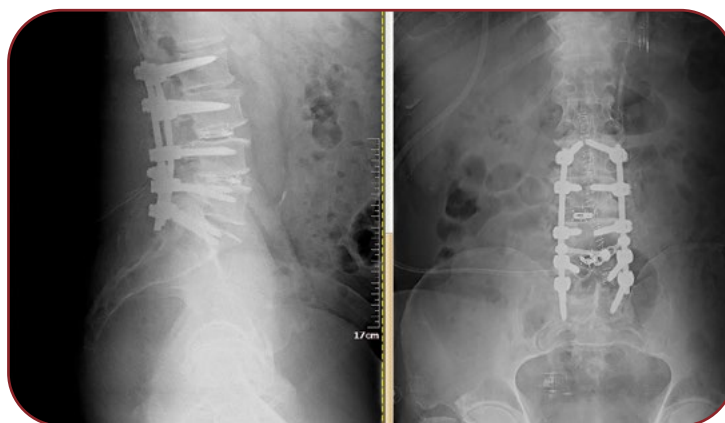


FIGURE 2. Postoperative standing x-ray of the patient from Figure 1 demonstrating in the sagittal plane a satisfactory amount of lordosis and disc height, coronal plane of the posterior fixation and interbody fusion



FIGURE 3. Postoperative computed tomography scan of one level posterior fixation with interbody fusion after one year of follow-up demonstrating satisfactory bone formation with adequate bone union

nificant improvement. Additionally, even though some patients report that they are worse after surgery, the mean value only increased by 4. Statistically, the percentage of improvement in % ranges

Diagnostic group	Adequate union N (%)	Delayed union N (%)	Absence of union N (%)	P-value
Spinal canal stenosis (n=40)	37 (92.5%)	2 (5%)	1 (2.5%)	<0.001
FBSS (n=5)	4 (80%)	1 (20%)	0	N/S
Recurrent herniated disc (n=7)	7 (100%)	0	0	N/S
Spondylolisthesis (n=4)	4 (100%)	0	0	N/S
Adjacent segment disease (n=2)	2 (100%)	0	0	N/S
Previous surgery				
Yes (n=16)	13 (81.2%)	2 (12.5%)	1 (6.3%)	<0.001
No (n=42)	41	1	0	<0.001
Fused levels				
L5-S1 (n=8)	8 (100%)	0	0	N/S
L4-L5 or L3-L4 (n=14)	13 (92.8%)	1 (7.2%)	0	<0.001
Two or more fused levels (n=36)	33 (91.6%)	2 (5.5%)	1 (2.9%)	<0.001
Age				
33-50 years (n=17)	17 (100%)	0	0	<0.001
51-79 years (n=41)	37 (90.2%)	3 (7.3%)	1 (2.5%)	<0.001
Sex				
Male (n=36)	35 (97.2%)	1 (2.8%)	N/A	<0.001
Female (n=22)	19 (86.3%)	2 (9%)	1 (4.7%)	<0.001
Lordosis	Degrees of lumbar lordosis			
Preoperative	23±8.6 degrees			<0.001
Postoperative	25±9 degrees			<0.001

TABLE 1. Imagistic and demographic data using Flarehawk 9 as an interbody cage

Range	Oswestry disability index			
	Before surgery	12 months after surgery		
	N%	% improved	% unchanged	% worse
0%-10%	1 (1.7%)	100%	0%	0%
11%-20%	3 (5.2%)	100%	0%	0%
21%-30%	2 (3.4%)	50%	50%	0%
31%-40%	8 (13.8%)	75%	12.5%	12.5%
41%-50%	17 (29.3%)	82.3%	11.7%	6%
51%-60%	19 (32.7%)	78.9%	10.5%	10.5%
61%-70%	4 (6.8%)	75%	25%	0%
71%-80%	4 (6.8%)	50%	25%	25%
81%-90%	0 (0)	N/A	N/A	N/A
91%-100%	0 (0)	N/A	N/A	N/A

TABLE 2. Comparison of Oswestry disability index domains before and after spinal surgery

Patient status (n=58)	N	Mean preoperative value (SD)	Mean postoperative value	P value
Improved	45	48.6 (13.6)	23.1 (13.7)	0.05
Unchanged	8	49.7 (14)	48.1 (14.4)	0.05
Worse	5	50 (12.8)	54.2 (13)	0.05

TABLE 3. Preoperative and postoperative mean values of Oswestry disability index scores. SD=standard deviation

and mean values consisting of a small number of patients may not hold a significant value. □

DISCUSSION

Spinal alignment

The alignment of the spinopelvic region following lumbar fusion significantly affects the long-term outcomes. In recent years, there has been a great focus on achieving optimal fusion angles, even in single-segment fusions, as a cru-

cial aspect of surgical planning to correct or maintain an optimal sagittal and coronal plane (9). The reasons for realignment following lumbar fusion surgery can be broadly divided into the impacts of decompression and the correction of segmental alignment at the fused segment (10). However, in elderly patients, fusion *in situ* can prove to be most beneficial, as the correction of global alignment may be a risky intervention because it often requires extensive soft tissue release with osteotomies and long fusion.

Certain studies have recorded reactive lumbar and overall sagittal improvement following decompression without fusion when discussing decompression effects (11). Particularly in individuals with degenerative lumbar stenosis, protective mechanisms, including anterior displacement of the C-7 plumb line and loss of lordosis, occur to mitigate neurological symptoms such as spinal canal stenosis, where the forward body bending can increase the canal space and ameliorate the symptoms (12).

However, correction with fusion alone can fail or prove to be challenging most of the time. In a retrospective radiographic evaluation of 42 patients who underwent short-segment fusion, Gödde *et al* reported that the impact of posterior lumbar interbody fusion in the restoration of spinal alignment was positive (13). Additionally, another retrospective study of 67 patients found that more lordotic cages were more likely to maintain the amount of correction given intraoperatively without subsidence (14).

A significant factor contributing to sagittal plane deterioration is the decrease of lumbar lordosis. A study conducted by Kim *et al* in 2014 suggested that this decrease was specific to a degenerated lumbar spine rather than a typical aging spine (15). Due to the wide range of normal values and the influence of pelvic morphology on spinal curves, it is essential to assess lumbar lordosis in comparison with the pelvic incidence using the PI-LL methodology. Patients with a lumbar lordosis loss exceeding 10 degrees compared to their pelvic incidence angle should undergo further clinical evaluation and assessment of daily functions and disability (16). The gradual forward placement of the head away from the pelvis is measured by the sagittal vertical axis (SVA) parameter. The SVA provides insight into the overall alignment of the trunk and is directly influenced by the decrease of lumbar lordosis, even when the pelvis compensates by tilting backward (increased pelvic tilt). Therefore, assessing spinopelvic parameters (such as PI-LL and pelvic tilt) alongside SVA offers a more thorough evaluation of the sagittal spinal alignment (17). Pelvic tilt is considered a highly sensitive indicator of spino-pelvic mismatch. If measurements of SVA or PI-LL suggest sagittal malalignment, a normal pelvic tilt should raise concern and might indicate the presence of an underlying pathology (14).

Spine fusion

Lumbar interbody fusion (LIF) typically requires bone grafting to stimulate bony fusion and the insertion of a lordotic cage to maintain the disc height and increase the foraminal space (18). The attainment of a solid bony fusion within the disc space hinges on successful osteogenesis in the empty disc space (19). An early sufficient volume of osteogenesis can stabilize the lumbar segment and prevent a potential cage migration and endplate breach (20). However, some patients may lack the required biological mechanisms due to comorbidities to create bone tissue to bridge the disc space, thereby increasing the risk of nonunion and implant failure (21). Various approaches have been utilized for LIF, including anterior (A), oblique (O), lateral (X), transforaminal (T) and posterior (P) approaches. Manzur *et al* performed a systematic review to evaluate the rate of fusion for stand-alone ALIF and reported that the anterior approach offered high rates of fusion, but there were still cases of pseudarthrosis especially in the smoking population (22). In a retrospective cohort study of 54 patients, Tanaka *et al* compared L5-S1 OLIF vs L5-S1 TLIF for adult spinal deformity and reported that the clinical outcomes were similar but OLIF created more lordosis (23). Additionally, in a retrospective study of 48 patients, Aono *et al* found that the fusion rate of a two-level PLIF was 85%, while all incidents of delayed union or non-union were at the caudal level (24).

Depending on the chosen techniques, the fusion rate can vary between 89% for the lateral approach and 93% for the anterior approach (25). Factors such as disc space preparation, end plate breach, cage position and patient comorbidities can affect a fusion rate analysis (26). This is mainly attributed to the fact that several surgeons may use the same approach but in different patients, for different pathologies and with different intraoperative difficulties. Another issue that can affect a fusion rate analysis is the method used to assess the quality of fusion. Static or dynamic radiographs even in asymptomatic patients can provide limited information in most of the cases. A CT scan can highly evaluate the quality of bone formed in the surgical area even in cases where union seems to be adequate in plain X-rays (27). In a retrospective study of 81 patients who underwent a posterior lumbar interbody fusion with more than one year of fol-

low-up, Nakashima *et al* demonstrated that CT extension was more reliable for assessing the non-union at the fusion site compared to x-rays. Parameters including patient's position during the imagistic examination and dilating anterior disc space can affect the quality of the images (28). Additionally, since a variety of terminology is widely accepted to describe the results such as "undetermined" and "inadequate union", and not fixed terminology, the results may differ from each surgeon's perspective.

Functional status

Various studies have analyzed and compared the preoperative and postoperative functional status of patients who underwent lumbar interbody fusion (29). In a recent retrospective study of 33 patients who underwent posterior lumbar interbody fusion, Marques *et al* reported that patients with a poorer preoperative score based on ODI scale were more likely to benefit from a surgical intervention (30). On the contrary, Abduljabbar FH *et al* reported that there was no correlation between ODI and the preoperative status (31). Since revision surgeries are often demanding, they can sometimes yield poor outcomes in the hands of inexperienced spine surgeons. Montenegro TS *et al* studied the clinical outcomes of revision lumbar surgery (32). The findings from this study on a prospective quality demonstrate that primary lumbar fusions yielded superior outcomes compared to revision surgeries. Nevertheless, revisions performed in accordance with evidence-based medicine (EBM) guidelines showed greater changes in ODI scores, suggesting that adhering to specific EBM criteria for reoperations could reinforce the clinical outcomes of revision lumbar fusions. In our study, indeed statistically the rates of delayed union or non-union were higher in the revision surgery group. Moreover, all patients whose CT scan revealed the absence of bone union were aged above 60. Finally, our study is also in accord with the findings of Aono *et al*, since 75% of patients with delayed or non-union had more than two levels fused.

Utility of magnetic resonance imaging in correlation with ODI scores

The most common findings presented in the preoperative magnetic resonance (MRI) scan of the lumbar spine include foraminal stenosis, disc herniation and spinal canal stenosis (33). In a

prospective study carried out by Gebreworld *et al*, the association between ODI scores and the grades of spinal canal stenosis were found to be weak ($r=0.3$) (34). Additionally, in a study of 75 patients, Hurri *et al* suggested that the severity of the canal stenosis was a strong predictive factor of disability (34). In the same study, the authors reported that the mean ODI score was 28.4 for moderate stenosis and 39.1 for severe stenosis (34). Finally, Sigmundsson *et al* tried to correlate the canal stenosis by taking the most narrowed space shown by the MRI scan and other disc levels with narrowing $< 70 \text{ mm}^2$ with the ODI scores in 109 consecutive patients. The correlation was found to be of no statistical significance (35).

Long-term considerations

Long-term functional and imagistic outcomes are required to examine and demonstrate the effectiveness of a surgical instrument or surgical approach. In a retrospective cohort study, Naredran *et al* compared the posterior and anterior approaches for a single-level spinal fusion and demonstrated there were no significant differences between those two approaches on long-term reoperation rates (36). Factors such as whether the patient underwent previous surgery or not, or even if the surgeon chooses to fuse the affected area may play an important role in the outcome. Musa *et al* suggest that interbody fusion for a recurrent disc herniation is preferred to a repeated discectomy, since it is related to a higher risk of intraoperative complications and poorer long-term outcomes (37). Finally, pain relief and clinical improvement are the major goals of each surgical long-term outcome (38). To achieve an optimal result, the peak of a learning curve must be reached by each surgeon. □

CONCLUSIONS

Even though anterior approaches become more and more popular and advanced nowadays, posterior fusion with interbody cages remains a safe and effective method to treat various spine surgical pathologies with optimal results. Posterior lumbar interbody fusion may be inferior compared to anterior techniques in deformity cases due to the decreased amount of lordosis it offers but it is still a golden tool for degenerative cases. □

Authors' contributions:
conceptualization – K.A. and K.Z.;
methodology – T.G.; software, P.I.;
validation – C.I. and K.A.; formal analysis – K.Z.;
investigation – M.S.; resources – P.I.;
data curation – C.I.; writing/original draft
preparation – K.Z.; writing/review and editing –
K.Z.; visualization – M.S.; supervision – T.G.;
project administration – K.A.

Institutional Review Board: The present study
was conducted in accordance with the

Declaration of Helsinki and approved by the
Institutional Review Board of
KAT General Hospital of Athens, Greece.

Informed consent: Written informed consent
has been obtained from the patient(s) to publish
this paper.

Data availability: All data are available upon
reasonable request.

Conflicts of interest: none declared.

Financial support: none declared.

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