

## ORJİNAL ÇALIŞMA / ORIGINAL ARTICLE

# DOES THE NECESSARY PEDICLE SCREW FIXATION OF THE TLIF PROCEDURE FOR THE FUSION? A RANDOMIZED CLINICAL TRIAL

## TLIF UYGULAMASINDA FÜZYON İÇİN PEDİKÜLER VİDA FİKSASYONU GEREKLİ Mİ? RANDOMİZE KLİNİK ÇALIŞMA

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#### SUMMARY:

Object: Transforaminal lumbar interbody fusion (TLIF) is widely used with pedicular screw fixation. In this comparative randomized study, we aimed to search effect of the instrumentation to clinical results of patient with TLIF.

Methods: 60 patients with lumbar degenerative diseases underwent single level TLIF with or without posterior segmental pedicle screw fixation. The Oswestry disability index (ODI) and Visual Analogue Scale (VAS) was used before surgery to the latest evaluation. Fusion was investigated both coronal and sagittal computerized tomography (CT) images.

Results: All patients were evaluated after a mean follow-up of 44 +/- 12 months. ODI and VAS scores were both better in Group C, (p < 0.05). Group A patients showed significant changes in back pain (p < 0.05). There was no difference in any score between groups after the 1 year (p > 0.05). The mean preoperative scores of VAS for low back pain for Groups A, B, and C were 6, 6.5, and 5.8, respectively, and decreased after the early surgery to 1.8, 1.5,

and 0.6, respectively. The mean preoperative scores of the VAS for leg pain for Groups A, B, and C were 7.1, 7.6, and 6.9, respectively, and decreased after surgery to 2.1, 2.5, and 2.3, respectively. Group C was the cost effective group (p < 0.005). No patient required revision surgery for instrumentation failure and cage displacement in all groups. Delayed hardware failure without asymptomatic 14 months after surgery radiologic pseudarthrosis was observed in 1(5 %) patients in GroupA, in 1(5 %) patient B, and in 2 (10 %)patient in C. There was no adjacent segment degeneration in any spine until the last evaluation.

Conclusion: TLIF alone, when compared with TLIF with adjunctive bilateral or unilateral pedicular fixation is a sufficient amount for the fusion and cost effective treatment in lumbar degenerative diseases as a new treatment technique.

**Key words:** Fusion, pedicle screw, TLIF, lumbar spine

**Level of evidence:** Prospective clinical study, level II

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## ÖZET:

Amaç: Transforaminal lomber cisimler arası füzyon (TLIF) lomber dejeneratif hastalıklarda yaygın olarak kullanılmaktadır. Bu çalışmada enstrümantasyonun TLIF uygulaması yapılan hastaların klinik sonuçlarına bir etkisinin olup olmadığın araştırılması amaçlanmıştır.

Metod: Bu karşılaştırmalı rastgele seçmeli klinik çalışmada bilateral pedikül fiksasyonlu (Grup A), tek taraflı pedikül vida uygulamalı (Grup B), pedikül vida uygulamasız (Grup C) olmak üzere 3 farklı grup oluşturulmuştur. Toplam 60 olgu oluşan bu 3 grup TLIF tekniğin klinik sonuçları Visuel Analog Skala (VAS) ve Oswestry Disability İndeks (ODI) ve radyolojik olarak koronal ve sagital plandaki CT ile füzyon sonuçları araştırılmıştır.

Sonuç: Hastaların tümü ortalama  $44 \pm 12$  ay takip edilmişlerdir. ODI ve VAS skorları, Grup C de en iyi idi, (p < 0.05). Grup A da bel ağrısı aşikar derecede fazla idi (p < 0.05). 1 yıl sonrasında skorlarda değişiklik yoktu (p > 0. ortalama preoperatif VAS bel ağrısı skoru

Grup A' da 6, B'de 6.5, C'de 5.8 bulundu. Postoperatif 3 ayda Grup A'da 1.8, B'de 1.5, C'de 0.6 bulundu. Ortalama VAS skoru bacak için Grup A'da 7.1, B'de 7.6, C'de 6.9 bulundu. Postoperatif erken dönemde Grup A'da 2.1, B'de 2.5, C'de 2.3 bulundu. Grup C maliyet açısından en avantajlı olan idi.(p < 0.005). Hiçbir grupta enstrümantasyon yetmezliği veya kafes kayması veya yetmezliği saptanmadı. Operasyon sonrası 14. ayda Grup A' da 1 (% 5), Grup B'de 1 (% 5), Grup C' de 2 olgu (% 10) da füzyon gecikmesi oluşmuş ama asemptomatik olduğundan izlem yapılmıştır. Son değerlendirmeye kadar komşu segment hastalığı gelişmemiştir.

Tartışma: Yeni bir teknik olarak tek başına TLIF, unilateral veya bilateral pediküler fiksasyonlu grupla kıyaslandığında füzyon sonuçları aynı ve maliyeti daha ucuz olduğu belirlenmiştir.

**Anahtar kelimeler:** Fusion, edicle screw, TLIF, lumbar spine, prospective study

Kanıt Düzeyi : Prospektif klinik çalışma, Level II

#### INTRODUCTION:

Harms and Jeszenskky were the first to describe transforaminal lumbar interbody fusion (TLIF) technique with cage in 1998 (13). When interbody fusion techniques are combined with discectomy in degenerative conditions, fusion caused by the interbody cage is known to relieve pain (6,12-13,17,22). Besides anterior (ALIF) and posterior lumbar interbody fusion (PLIF), many other intervertebral fusion techniques such as XLIF and TLIF gained popularity and they have been used with open or minimally invasive approaches. Among them, TLIF is one of the most popular techniques. Although TLIF is a unilateral procedure, it is accomplished by bilateral pedicle screw support (6,13) or by the support of unilateral pedicle screw and translaminar screw

Most of the studies indicate stronger fusion with pedicle screw (22). Conventional pedicle screwing techniques involve bilateral manipulation of muscle and soft tissue, resulting in tissue injury and blood loss. These techniques are also associated with increased costs. Therefore, less costly minimally invasive methods have been searched, in order to get the advantage of avoiding the injury to the surrounding tissues and vascular structures. Clinically important instability did not develop during follow-up of patients with total unilateral facetectomy in clinical or biomechanical studies (12,18-19). In another study with A-level evidence, even facetectomy performed without cage or screwing had similar results compared to patients instrumented after five years (8).

Is TLIF technique alone sufficient in stabile patients with disease at single level? If so, it

would be possible to prevent tissue injury and decrease costs. In this procpective comparative randomized study, for the first time in the literature, we compared patients with TLIF having adjunctive bilateral (group A), unilateral pedicular screw fixation (group B) and patients having no pedicular support (group C).

#### **MATERIALS AND METHODS:**

Since this is an operation routinely performed with pedicle screwing, no financial support was received from the manufacturer. Lumbar spinal disease patients with single interbody space involvement admitting between February 2005 and May 2009 were assigned to treatment groups. 220 patients were operated by TLIF technique in this period. 60 patients were selected in whom had similar demographical characteristics and lumbar pathologies. Following facetectomy, patients underwent TLIF procedure either with pedicle screwing (Group A, n: 20) without unilateral pedicle screwing (Group B, n: 20), and patients having no pedicular support (group C, n: 20). Patients with additional pathological conditions, multi-level disease and unstable patients were excluded. There were 24 males and 36 females. Three subgroups each numbered 20, were randomly selected. Group A was composed of patients with bilateral pedicular fixation, group B unilateral, and group C none. Demographic characteristics were similar among these groups. The Oswestry disability index (ODI) and Visual Analogue Scale (VAS) was used before surgery to the latest evaluation. All patients had detailed roentgenographic study

including computed tomography (CT) scan and magnetic resonance imaging (MRI) before surgery to the latest follow-up observation. The following roentgenographic parameters were measured and compared in all spines All of them were assessed before surgery, and then at 1, 3, 12 and last (44 months) years by an independent researcher.

In order to get VAS pain score, the paint was asked to locate the severity of the pain on a horizontal line with scores 0 to 10, with zero representing no pain and 10 representing the most severe pain. Oswestry low back pain disability questionnaire is an international tool where disability is scored as follows: 0-20, minimal disability; 20-40, intermediate degree of disability; 60-80, disabling pain; and 80-100, the patient is bedridden with severe pain.

Fusion rates of the patients were compared using these scales. Detailed data on intraoperative bleeding and complications were recorded. All patients had disease confined to a single intervertebral space at single level, and the mean age was 45.5 years (range: 29-78). Distribution of the patients by disease levels were same number in all groups: L3-4, n=6 (30 %); L4-5, n=7 (35 %); and L5-S1, n=7 (35 %) (Table-1). The 3 groups were matched for disease level. Overall, 18 patients (30 %) had lumbar spinal stenosis, 15 (25 %) had recurrent disc herniation, 12 (20 %) had foraminal disc herniation, and 15 (25 %) had degenerative disc disease. The clinical data is demonstrated by Table-1. Since patients with listhesis and unstable patients undoubtedly require supporting with pedicle screws, these patients were not included in the study.

**Table - 1.** The outcome and characteristic signs of the patients.

	Group A	Group B	Group C	
Patient number	20	20	20	
Mean age	48.9 (32-71)	45.3(33-74)	45.5(29-78)	
Sex				
M (%)	2	12	12(60%)	
F (%)	8	8	8 (40%)	
Pathology				
Lumbar spinal stenosis	6 (10%)	6 (10%)	6(10%)	
Reherniation	5 (8.3%)	5 (8.3%)	5(8.3%)	
Foraminal disc herniation	4 ( 6.6%)	4(6.6%)	4(6.6%)	
Degenerative disc disease	5 (8.3%)	5 (8.3%)	5(8.3%)	
Level of the disease				
L3-4	6 (30%)	6(30%)	6 (30%)	
L4-5	7 (35%)	7 (35%)	7 (35%)	
L5-S1	7 (35%)	7(35%)	7 (35%)	
Mean follow-up time (mo)	44 +/- 12	44 +/- 12	44 +/- 12	
Pseudoarthrosis	1/20 (95%)	1/20 (95% )	2/20(90%)	
Bleeding (cc)	410 (330-550)	320 (180-350)	10(190-250)	
Operation time (Sec)	50 (140-175)	115(95-130)	90(79-115)	
Subsuidence of the cage	No	No	No	
Cost	3000 USD	2000 USD	1000 USD	

## - Surgical procedure:

patients had single level fusion performed. The **TLIF** procedure was performed in the standard fashion reported in previous studies, with one cage packed with both autologenous and allograft bone grafts. Approximately 5 cc of autograft and allograft bone fragments were placed in front of the disc space and then the cage filled with autograft and allograft was placed into the intervertebral space taking care not to injure the nerve root. In Group C, a 2-mm larger cage was used in order to assure sufficient compression. The mean size of the cages was 12 mm in all Groups. The cage was positioned at middle one third of the disc space. After fluoroscopic examination, in Groups A and B, unconnected pedicle screws were placed and tightened in compression mode unilateral or bilateral.

Pedicle screw instrumentation was used groups having adjunctive bilateral (group A), unilateral pedicular screw fixation (group B) and patients having no pedicular support (group C).

Operation time was 150 minutes in group A, 115 minutes in group B, and 90 minutes in group C. Mean blood loss during operation was maximal in group A with a total loss of 420 cc, in Group B; 320 cc and Group C; 210 cc. All patients were evaluated after a mean follow-up of 44±12 months.

The mean duration of hospitalization was 43.2 hours (range: 28-52) in Group A , 30.3 hours (range: 35-28) in Group B and 20 hours (range:18-27) in Group C. All patients were instructed to use lumbar corset for two months.

## - Statistical analysis:

All measurements were performed by a single observer and are expressed as means ± SD. Using the SPSS 11.5 statistics software,

classic t-test and chi-square test were performed.

#### **RESULTS:**

The mean values for VAS and ODI scores throughout the follow-up period are depicted in Table 2. Pseudoarthrosis developed in 1 (5%) patients in Group A, and in 1 (5%) patients in Group B, in 2 (10%) patients Group C. Nevertheless, clinical improvement was evident in these patients at 12th month despite insufficient fusion. Development of fusion was assessed by CT by examining both coronal and sagittal images (Figure-1.a,b). Complete fusion was evident at 7 months in 95%, 95% and 90% of patients in Group A, Group B, Group C, respectively. Later, all patients developed at least partial fusion but VAS scored did not change.

ODI and VAS scores were both better in Group C, (p < 0.05). Group A patients showed significant changes in back pain (p < 0.05). There was no difference in any score between groups after the both 1 and 2 years (p > 0.05). The mean preoperative scores of VAS for low back pain for Groups A, B, and C were 6, 6.5, and 5.8, respectively, and decreased after the early surgery to 1.8, 1.5, and 0.6, respectively. The mean preoperative scores of the VAS for leg pain for Groups A, B, and C were 7.1, 7.6, and 6.9, respectively, and decreased after surgery to 2.1, 2.5, and 2.3, respectively (Table 2). Group C was the cost effective group (p < 0.005). No patient required revision surgery for instrumentation failure and cage displacement in all groups. Delayed hardware failure without asymptomatic 14 months after surgery radiologic pseudarthrosis observed in 1 (5 %) patients in Group A, in 1 (5 %) patient B, and in 2 (10 %) patient in C. There was no adjacent segment degeneration in any spine until the last evaluation.





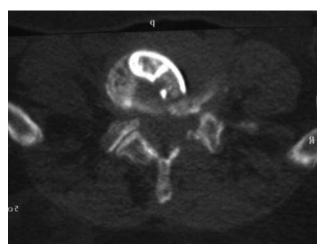
Figures-1 Development of fusion was assessed by computerized tomography by examining both sagittal (a) and coronal (b) images.

**Table - 2.** The comparative values between three groups.

	Preop	1 mo	3mo	12 mo	24 mo	Last
Group	A / B/C	A / B/C	A /B/C	A/B/C	A/B/C	A/B/C
Back pain VAS	6.0/6.5/ 5.8	3.8/3.5 /1.6	1.8/1.5/1.0	1.8/1.6/1.0	1.8/1.6/1.0	1.8/1.6/1.0
Leg pain AS	7.1/ 7.6/6.9	2.1/2.5/ 2.3	2.1 /2.4/2.3	2.1/2.3/2.5	2.8/2.2/2.3	2.1/2.3/2.3
ODI	52/ 52/55	28/18/15	22/14/12	22/14/12	20/18/14	20/18/14

Final positions of the cages within the intervertebral space were as follows: Except one, all of them were observed in ideal position (Figure-2). None of the patients developed major complication. One patient in Group A developed superficial skin infection, one patient in Group B had contralateral sciatic pain of intermediate severity lasting about one week.

Case 1. A 55-year-old female patient was experiencing neurogenic claudication at 40 meters. She had had a spinal stenosis and disc herniation. For this patient, right unilateral facetectomy combined with contralateral spinal canal decompression was done and ligamentum flavum was bilaterally excised. Following massive discectomy, TLIF and fixation of four pedicles were done (Figure 3).



**Figure-2** Final positions of the cage within the intervertebral disc space is showed by axial CT.

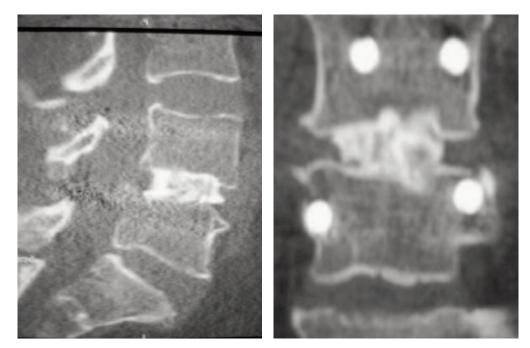


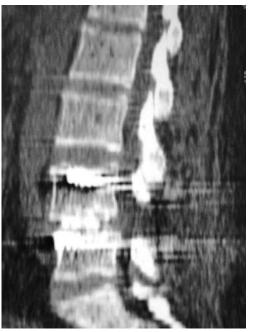
Figure-3 Sagittal and axial CT shows cage, bilateral pedicle screws, and fusion at the level of L4-L5.

At her most recent examination, VAS score was 2 and ODI score was 14. (Group A)

Case 2. A 45-year-old male patient had undergone two microdiscectomy operations one year apart at the same intervertebral space (right L4-5) and presented with reherniation and neurological findings related to the L5 root. Decompression and fusion using

TLIF technique with unilateral pedicle screw fixation was performed and complete fusion was obtained at 6 months (Figure 4). At the most recent examination, VAS score was 2.1 and ODI score was 16. (Group B)

Case 3. A 39-year-old male patient had undergone two microdiscectomy operations 15 months apart at the same intervertebral



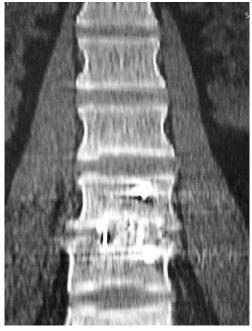


Figure-4 Sagittal and axial CT shows cage, unilateral pedicle screws, and fusion at the level of L4-L5.

space (right L4-5) and presented with reherniation and neurological findings related to the L5 root. Decompression and fusion using TLIF technique was performed and complete fusion was obtained at 6.5 months (figure 5). At the most recent examination, VAS score was 2.1 and ODI score was 14. (Group C)

#### - Cost-effectiveness:

The cost of TLIF combined with four pedicle screwing was 3000 USD (2000 plus 1000) in Group A, 2000 USD in Group B, whereas TLIF alone cost 1000 USD. Thus, total cost of the procedure was three times higher in Group A.

### **DISCUSSION:**

Various techniques have been described for lumbar interbody spinal fusion, each with its advantages and disadvantages over others (7). Interbody cages are used together with osteoinductive graft material in order to maintain the intervertebral disc height and to

keep lumbar lordosis and the balance at sagittal plane. They are supported with pedicle screwing, which is believed advantageous over simple decompression. The most ideal fusion technique is the use of interbody PEEK (polyetheretherketone) cage together with autograft (6-8,11,13,17,19), since cage prevents the collapse of the graft. However, the ideal route through which these cages containing autograft should be placed into interbody space is still debated. Placement through anterior route (ALIF) bears the risks of iliac artery or vein injury, retrograde ejaculation and vaginal dryness (8,11,19). In addition, this method precludes intervention to posterior neural structures; and if such an intervention is required, it would be associated with tissue injury and increased cost since pedicle screwing will be required (3).

Relative advantages and disadvantages of posterior lumbar interbody cages (PLIF), ALIF and TLIF have been reported (4,10,14,20,21). Minimal neural retraction and minimal intervention to





Figure-5 Sagittal and axial CT shows cage and fusion at the level of L4-L5.

neural tissue are the advantages of TLIF technique. In addition, this technique eliminates the need for the dissection of scar tissue during revisions (13). This technique also provides the restoration of lumbar lordosis. Since the cage distracts the space, foraminal narrowing of the lumbar canal is relieved. On the other hand, the need for a support with bilateral pedicle screwing increases the cost and this is associated with the risk of neural and muscular injury. In an attempt to minimize muscular injury, percutaneous methods have been developed but these increase the already high cost of the procedure for an additional 3-fold (6). Fusion rates range between 89% and 100% with interbody fusion techniques supported with pedicle screwing and this method is advocated as an effective procedure; however, no relation has been found between fusion and clinical improvement (1-5,16-17).

Currently, studies on spinal surgery have mainly focused on the development of cost-effective and minimally invasive techniques. Bilateral separation of the muscles in unilateral disc pathology may not be regarded as minimally invasive and such an approach is associated with increased costs. Thus, the search for unilateral applications has gained popularity <sup>(4)</sup>. Bilateral decompression and fixation through a unilateral approach is minimally invasive and has the advantages of more rapid healing and low costs over bilateral approach <sup>(4-6)</sup>.

Shift of the segment has not been observed in the long term after unilateral facetectomy followed by decompression, even fixation was not performed (18). This formed rationale of the present study. If favorable results can be obtained in a case that underwent compression without the placement of cage, then TLIF technique alone could be sufficient.

Findings of this study suggest that support with pedicle screws is not necessarily required. In the present comparative study, functional and radiological evaluations add to the reliability of the results. In this technique, first unilateral facet osteotomy is performed and then the cage is placed after decompression and supported by abundant amounts of bone lamellae. To prevent shift or removal, a slightly larger case is used (at a 1 or 2 mm larger size), which provides the adequate contact of endplates and the cage. We also believe that free bone lamellae placed over the surface just before the placement of the cage have greater contribution to fusion.

We performed physiological and biomechanical assessments of the vertebra in our patients that underwent TLIF procedure through single opening and without pedicle screws. None of the patients developed shifting or instability. None of the patients developed infection. Localization of the cage does not seem to affect the recovery of the patients.

In patients without pedicle screws, MR imaging will be possible and artifacts due to the screws will be avoided, representing another advantage over the use of pedicle screws. These will be particularly important when radiological imaging is required during the postoperative period, for a diseased neighboring segment or for other reasons. For thus, TLIF associated with unilateral pedicle screw couldn't be superior for the high quality MR images.

Development of disease in the neighboring segments was not assessed in this study, since none of the patients developed relevant symptoms during follow-up. 5-y and 10-y follow-up of these cases are planned and this will provide information on the development of

neighboring segment disease, which will be the subject of another study.

In patients with lumbar disease involving single interbody space, except unstable cases, decompression followed by TLIF procedure has several advantages over TLIF technique supported by pedicle screws. TLIF alone include the following: (i) minimally invasive; (ii) allows future MRI examinations and artifacts in radiological images are avoided; associated with shorter hospital stay and duration of operation; (iv) associated with less cost; (v) complications of pedicle screws are avoided; and (vi) provides sufficient fusion and favorable long term outcomes. The results are encouraging in that almost all patients had improved by after the 1 year operation. The similar clinical and radiologic data in all three groups TLIF alone, when compared with TLIF with adjunctive pedicular fixation is clinically same standard and cost effective treatment in lumbar degenerative diseases as a new treatment technique. Also, we need a new clinical trials providing A-level evidence rather than B-level evidence and biomechanical assessments are warranted to draw more evidence based conclusions

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