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Does the Use of Carbon Fiber Devices Allows Better and More Solid Lumbar Interbody Fusion Respect to Metal Ones in Degenerative Lumbar Disc Disease? Preliminary Results from a Multicentric Pilot Study

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Keywords: Degenerative disc disease; Low back pain; Carbon devices; Titanium devices; Interbody; Lumbar spine fusion; Transforaminal lumbar interbody fusion; Lumbar arthrodesis; Osseointegration; Computed tomography score.

Abstract

Study design: Prospective observational; multicenter randomized open label study; Preliminary results.

Objective: The aim of the present investigation was to compare the clinical and radiological outcomes in patients who underwent Transforaminal Lumbar Interbody Fusion (TLIF) procedures performed with carbon fiber devices or metal devices. Secondary objectives were the assessment of intra- and post-operative complications related to instrumentation: mobilization or breakdown of them, Adjacent Segment Syndrome (ASD).

Summary of background data: TLIF represent a common procedure for surgical treatment of degenerative lumbar disease. In the last years, many materials have been used for the realization of interbody devices such as Polyether Ether Ketone (PEEK), titanium, tantalum and carbon fiber. However, there is no evidence in the literature of the superiority of one material over another in terms of clinical and radiological outcomes.

Methods: This study included 40 adults' patients who underwent a primary, single- or multilevel, trans foraminal interbody fusion followed by posterior trans-pedicle screw fixation. The enrolled patients were randomly divided in two groups: Group 1 (carbon fiber group) and Group 2.

(titanium group). Clinical results were evaluated using pre-postoperative scores such as: Visual Analogue Scale (VAS), Euro QoL-5D (quality of life), Oswestry Disability Index (ODI). Fusion solidity assessed by Bridwell's score on TC scan [1]. The follow-up was 6, 12 and 24 months.

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Results: Bridwell's score was different in the two groups. Group 1 had a higher frequency of score 2 (60%) at 12 months follow-up, than group 2 (40%) and a lower score 3 frequency (30% vs. 70%) at final follow-up. Post-operative patient reported outcome measures improved with statistical significance in both groups ($p< 0.01$). Although, no significant difference could be highlighted between the two groups ($p=0.5$)

Conclusion: A significative better fusion rates with the use of carbon fiber instrumentation was observed. However, the clinical outcome is similar in the two groups.

Introduction

Degenerative lumbar disc disease has been acknowledged as one of the leading causes of disability worldwide and is increasingly diagnosed [2]. In fact, it has been recognized to be responsible for chronic Low Back Pain (LBP), with or without radiculopathy, causing significant decrease in patient-reported quality of life scores [3]. Although it is an easy radiographic diagnosis, selection of the most appropriate treatment always requires additional key information such as efficacy of previous treatments (physical therapy, drugs, injections), functional demand and expectations of the patient, concurrent pathologies, and, obviously, no decision can aside from a thorough physical examination [4]. All these elements are collected with the attempt to further sub-group patients in order to match any of them with the most appropriate treatment. Spinal fusion can be an option in a selected group of patients [5]. Since the early introduction of spinal instrumentation, fusion rates improved such that, nowadays, their application is a mainstay of spinal surgical techniques [6]. Standard instrumentation has always been mainly made out of metal (or metallic alloys) such as steel, titanium, tantalum, cobalt-crome. Among the main reasons for this must be accounted their mechanical performances, biocompatibility and ease of production (at low costs). However, their modulus of elasticity is much higher compared to that of the bone. This might lead to excessively stiff constructs causing some degree of stress shielding [7]. In the early 2000's polyether-ether-keton (PEEK) was introduced, dazzled by its excellent resistance and load distribution capacities and a modulus of elasticity close to that of the bone. These features turned out to be outmatched by PEEK not being biologically active (therefore not promoting osseointegration). It has also been used with the final goal to limit joint excursion, without causing fusion [8] (also known as "semi-rigid fusion"). In the last years, a combination of PEEK and Carbon Fiber (CFR/PEEK) has been introduced into clinical practice, mainly in spinal oncology patients, where has been appreciated for its radiolucency. Moreover, Carbon Fiber (CF) is a highly osteoinductive material that had been already used successfully to reconstruct the anterior column (i.e. Brantigan cages, Carbon Fiber Stackable Cage) achieving outstanding fusion rates [9]. To the best knowledge of the Authors there are no studies evaluating efficacy of CFR/PEEK instrumentation in achieving fusion in degenerative diseases of the lumbar spine. Therefore, the aim of the present investigation was to compare the clinical and radiological outcomes in patients who underwent TLIF procedures performed with CFR/PEEK devices or titanium devices. Secondary objectives were the assessment of intra- and post-operative complications rate related to instrumentation: Mobilization or breakdown of them, Adjacent Segment Syndrome (ASD).

Materials and Methods

Study design and settings

The present investigation consists in a multicenter prospective randomized controlled open label prospective study. Patients were enrolled from 2 different sites, both tertiary centers with high-volume spine surgery departments. All patients included in the study were treated between 1st January 2017 and 1st July 2018 After Institutional Review Board (IRB) approval, the study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent for scientific purposes and clinical data collection was obtained according to institutional protocols.

Eligibility criteria and participants

Patients scheduled to undergo TLIF procedure followed by posterior transpedicular screw fixation due to degenerative lumbar disease, in a period between January 2017 and July 2018 were potentially eligible for the study. Inclusion criteria were: (I) age ≥ 18; (II) mono- or bi-segmental degenerative disc disease (Pfirrmann grade 3 to 5) irresponsive to conservative treatments (for at least 6 months). Exclusion criteria were: (I) segmental deformity, such as spondylolisthesis (Meyerding grade ≥ 2), scoliosis, or kyphosis (i.e. post-traumatic); (II) previous spine fusions surgery; (III) presence of lumbosacral transitional vertebrae; (IV) tumor and infection (both active, and sequelae). Previous minimally invasive decompressive surgery (microdiscectomy or laminotomy) at the involved level has not been considered an exclusion criteria.

Forty patients matched inclusion and exclusion criteria therefore were enrolled in the study. Patients were divided in two groups and randomly assigned before the surgery, with a 1:1 allocation ratio. Randomization was conducted in blocks of 5. The randomization model was obtained by using the Web site Randomization.com (http:/ www.randomization.com).

The enrolled patients were divided in two groups as follow:

- Group 1: TLIF procedure followed by PTSF using CFR/PEEK instrumentation (Black Armor Icotec®) and interbody fusion cage.
- Group 2: TLIF procedure followed by PTSF using Titanium instrumentation

Surgical technique

All procedures have been performed by the two senior authors with the same standard TLIF technique, as reported by Harms and Jeszenszky. Patient was in prone position with slight flexion of the hips. Care was taken to relieve any pressure from the abdomen in order to decrease the epidural veins bleeding during the procedure. After identification of the involved level with C-arm, spine was exposed through a standard median approach with limited subperiosteal dissection of the paraspinal muscle [10]. Pedicle screws were placed with free-hand technique. The intervertebral disc was reached via the transforaminal route, performing a laminotomy and extending the decompression laterally to include the ipsilateral articular pillars. This allowed direct decompression of the nerve root and positioning of retractors to delimitate a safe working zone on the disc. Then, anulotomy was performed, the content of the disc was completely removed so as the cartilaginous layer covering the endplates. Sequential probe was inserted until firm sensation of primary stability was reached. At the end, the definitive, prop-

erly sized, cage filled with autogenous bone graft was implanted and hips were extended. Finally, slight compression was applied to restore segmental lordosis and further stabilize the cage [11]. Contralateral lamina and joint were decorticated, and autogenous only bone graft was positioned in order to enhance posterior fusion. All procedures were performed using a surgical microscope for the decompression and disc space preparation.

Follow up setting

All patients were evaluated pre-operatively, and follow-up has been scheduled at 3, 6, and 12 months. Standard pre-operative work-up includes upright standing full-length radiograph of the whole spine and dynamic flexion-extension radiograph and Magnetic Resonance Imaging (MRI) of the lumbar spine. Pre-operative Computed Tomography (CT) scan was included if a previous decompression was performed.

Post-operative monitoring includes upright standing and dynamic flexion-extension radiographs of the lumbar spine at 3 months intervals, and CT-scan at 6, and 12 months follow-up.

Clinical evaluation

Quality of life assessment questionnaires (ODI and EuroQoL-5D) were collected before surgery, and at 6 months intervals. Similarly, back and radicular pain were recorded using the Visual Analog Scale (VAS).

Radiological evaluation

Fusion was graded according to the Bridwell score (**See Table 1,2**) on CT-scan at 6- and 12-months follow-up. Grading was performed by two separate and independent observers (experienced spinal surgeons not involved in the care of the patients), having available the possibility for multiplanar (axial, sagittal and coronal) reconstructions.

Statistical analysis

Both clinical and radiological data were compared between the two groups, including intergroup review before and after surgical treatment.

Statistical analysis was performed using Fischer exact test for radiological data, for clinical data Wilcoxon-Mann-Whitney's test among 2 groups and for intra-group analysis was Wilcoxon signed rank sum test. The Inter- Rater Reliability (IRR) between the three evaluators was calculated using a Fleiss' kappa statistic.

Results

Participants

From 2017 to 2019, 40 consecutive patients were prospectively enrolled. Among the 20 patients (11 males and 9 females) in group 1, the mean age was 49, 75 years (range 27-75). Among enrolled patients, had previous minimally invasive decompressive procedures (3 microdiscectomies and 2 laminotomies). 12 patients required fusion of a single level, and 8 of two levels. Altogether 31 levels have been fused: L5-S1 in 14 patients (47%), L4-5 in 12 patients (36%) and remaining 5 (17%) at other levels of lumbar spine (**See Table 3**).

Among the 20 patients (10 males and 10 females) in group 2 the mean age was 55, 45 years (range 29-76). Among the enrolled3 had previous minimally invasive decompressive procedures (2 microdiscectomies and 1 laminotomies). Thirteen patients required fusion of a single level, and 7 of two levels. Altogether 27 levels have been fused: L4-L5 in 19 patients (70%), L5-S1 in 6 patients (22%) and remaining 2 (8%) at other levels of lumbar spine (**See Table 3**).

No remarkable intra-, or peri-operative complication occurred in both groups. Post-operative decrease in hemoglobin levels has been treated with oral iron supplementation in all cases. There was one case of surgical wound infection in group 1 and one in group 2. All patients were encouraged towards early mobilization and were able to stand within 24 hours of surgical treatment. The mean follow-up was 18.7 months (range 6-24).

Radiological outcomes

The fusion, assessed according to the Bridwell score, was different in the two groups (**Table 1**). Group 1 had a higher frequency of score 2 (60%) at 12 months follow-up, than group 2 (40%) and a lower score 3 frequency (30% *vs*. 70%) at final follow-up. Score 1 was observed only in 5 patients, all of which in group 1. The difference between the two groups reached statistical significance.

The test used for the analysis is Fisher exact test: Probability table (P) 0.0014, Pr <= P 0.0130. Inter observer variability showed no statistically significant difference.

Table 1: Frequency distribution of the Briwell score in the two groups.

Bridwell score	Group						Total	
	Carbon fiber devices			Titanium devices				
	N	Col %	Row %	N	Col %	Row %	N	%
I	5	25.00	100.00	.	.	.	5	100.00
II	9	45.00	60.00	6	30.00	40.00	15	100.00
III	6	30.00	30.00	14	70.00	70.00	20	100.00
Total	20	100.00	50.00	20	100.00	50.00	40	100.00

Clinical outcomes

The mean pre-operative ODI score was 36.5 (37.5 in group 1, and 35.6 in group 2), that decreased to 9.4 at 6 months follow-up (8.85 in group 1, and 10 in group 2) **(See Table 4)**.

The mean pre-operative EuroQoL-5D score was 11.95 (11.9 in group 1, and 12 in group 2), that decreased to 6.6 at 6 months follow-up (6.8 in group 1, and 6.3 in group 2) **(See Table 4)**.

The mean pre-operative VAS score was 8.7 for back pain (8.6 in group 1, and 8.8 in group 2) and 8.1 for leg pain (8.3 in group 1, and 8 in group 2), that decreased to 3.6 and 2.75 at 12 months follow-up, respectively (3.6 and 2.8 in group 1, and 3.7 and 2.7 in group 2) **(See Table 4)**.

Post-operative patient reported outcome measures improved with statistical significance in both groups (p< 0.01). Although, no significant difference could be highlighted between the two groups (p=0.5, **Table 3**). No mechanical complications (such as breakage or mobilization of the screws, rods or cages) occurred in both groups. Hospitalization time and recovery was done not different between the two groups: all patients returned to their work with increased level of daily activities.

Table 2: Bridwell interbody fusion grading system.

Grade	Description
	Fused with remodelling and trabeculae present
II	Graft intact, not fully remodelled and incorporated, but no lucency present
III	Graft intact, potential lucency present at top and bottom of graft
IV	Fusion absent with collapse or resoroption of graft

Table 3: Fused levels.

Level fused	Group 1 (n=20, 31 levels)	Group 2 (n=20, 27 levels)
L1-L2	1	0
L2-L3	1	1
L3-L4	3	1
L4-L5	12	19
L5-S1	14	6

Group 1: TLIF procedure followed by PTSF using CFR/PEEK instrumentation (Black Armor Icotec®) and interbody fusion cage.

Group 2: TLIF procedure followed by PTSF using Titanium instrumentation.

Table 4: Intra-group and inter-group mean variation of clinical outcomes.

	Carbon fiber devices			Titanium devices			P value between 2 groups
	pre-operative	Change	p value Intra-group	pre-operative	change	p value Intra-group	
VAS	8.55±0.94	-4.85±1.5	<.0001	8.75±0.91	-5.20±0.7	<.0001	0.2547
Euro Quol	12.45±1.47	-5.65±1.63	<.0001	11.95±1.43	-5.65±1.35	<.0001	0.9890
ODI	37.50±7.72	-28.65±11.48	<.0001	35.55±6.72	-25.55±3.68	<.0001	0.2735

The test used for the intra-group analysis is the Wilcoxon signed rank sum test.

The test used for the between-group analysis is the Wilcoxon-Mann-Whitney test.

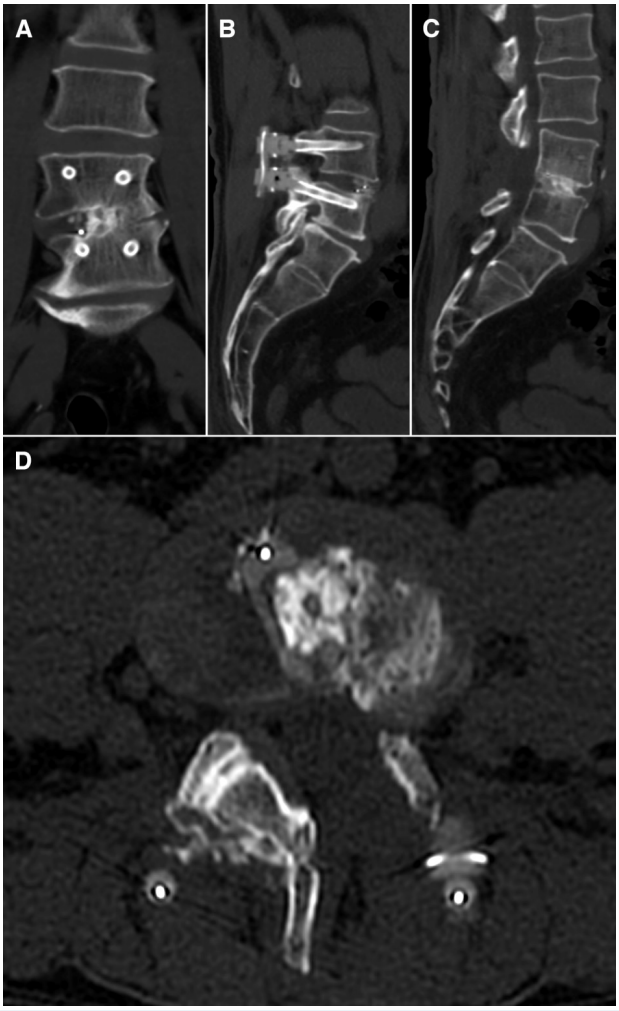

Figure 1: CT images, one year follow-up, according to Bridewell score, the grade is I.

Discussion

Spinal fusion is an established technique with proven effectiveness in properly selected cases of degenerative diseases of the lumbar spine. Spinal fusion can be achieved bridging the posterior elements and/or bridging adjacent vertebral bodies. This latter requires prior disc removal, disc space preparation and insert of a spacer device to maintain disc height until solid fusion. Combination of posterior and interbody techniques (named circumferential, or 360° fusion) provides some advantages over posterior-only, such as a more even load-sharing between the anterior and posterior columns, better for aminal decompression and restoration of proper segmental alignment [12]. There are several techniques to achieve interbody fusion, each named after the access route whether it is posterior (PLIF, TLIF), lateral (XLIF/LLIF), Oblique (OLIF), or Anterior (ALIF). Despite such variety of techniques, there is still no strong evidence on one being superior to the others in terms of clinical outcomes and fusion rates. The results of the reported study confirm efficacy of fusion in achieving a significant clinical improvement, along with radio graphically proven union [13].

Ricciardi and colleagues have shown that a good degree of anterior fusion is not sufficient to achieve segmental immobilization, their results seem to suggest that immobilization could influence the clinical outcomes stronger than fusion [14].

Better fusion rates in CRF/PEEK patients (**Group 1**) might have been influenced by the absence of magnetic artifacts that might have allowed more accurate imaging evaluation of the fusion mass [15]. This is consistent with previous reported data in the field of spinal oncology where follow-up evaluation is focused on early detection of local recurrences [16]. Such radiolucency might be particularly useful when patients complain late recurrence of mechanical pain. In such a scenario an MRI of the spine would be enough to evaluate eventual implant-related complications (i.e. screws loosening, or a rod fracture), without any radiation exposure [17,18]. On the other hand, radiolucency of the instrumentation might make correct placement of the

screws and cage slightly more difficult to assess intraoperatively (with C-arm), since just a thin lining of tantalum is visible.

The goal of a fusion of the lumbar spine is to obtain a primary solid arthrodesis so as to alleviate pain [19-25]. Modern CT imaging with fine-cut axial and multiplanar reconstruction views is recommended as a method to assess fusion status [26]. In the reported study, CT-scan shows images suggesting bridging bony trabeculation through 95% of the cages for group 1, no radiolucency around the cage or clear pseudarthrosis could be seen. Hoppe et al. claim that biological properties of the inert, hydrophobic surface, which is the main disadvantage of PEEK, can be improved with titanium coating, so that the carbon/PEEK composite cage, which has great advantages in respect of biomechanical properties, can be used safely in TLIF surgery [27].

The aim of the present study is to compare fusion rates of CRF/PEEK and titanium instrumentation in degenerative diseases of the lumbar spine. It is not always easy to assess fusion in the presence of metallic artifacts, as other authors have already reported. This limitation can be overcome with the latest and more sophisticated CT scan protocols. Eck et al. in their evaluation of fusion following use of titanium mesh cages, also found it difficult to evaluate intra-cage fusion mass using plain radiographs [28]. Shah R. and colleagues showed that high-quality CT scans show images suggesting bridging bony trabeculae following the use of titanium interbody cages [29].

The presence of PEEK, which is biologically inactive, does not seem to reduce CF performance. This is consistent with previous *in vivo* and *in vitro* studies reported by Willems et al. that show coated PEEK becoming biologically active [30]. Several studies *in vitro* and *in vivo* on animals, showed that exfoliated carbon nanofibers serve as excellent scaffolds for promoting and guiding bone-tissue regeneration [31]. Yasuhisa Arai et al. compared the fusion between carbon devices and autologous bone showing the superiority of the carbon devices [32]. Finally, CFR/PEEK showed promising mechanical properties due to its modulus of elasticity that is the closest to cortical bone: Lindtner et al. showed that CFR/PEEK pedicle screws resisted a similar number of load cycles until loosening, as titanium screws [33]. Therefore, a potential superiority of CFR/PEEK over titanium instrumentation might be suggested by both mechanical and biological properties.

The reported results show CFR/PEEK being an excellent material for load-bearing orthopaedic implants. In particular it may promote interbody fusion, particularly when the interbody graft is slightly undersized or partially subsided [34,35].

On the contrary, these preliminary results do not allow conclusions on whether the strength of CFR/PEEK screws fixation points might, or not, be comparable to that of standard titanium screws [36]. Carbon fiber implants offer some potential advantages over traditional metallic implants: Radiolucency allows for improved, artifact-free imaging, the lower elasticity module is better suited to that of the bone and the resistance to fatigue is greater than most metal implants.

These factors led Authors to conclude that the use of CFR/PEEK instrumentation needs to be at least considered when planning a lumbar fusion for degenerative diseases [37-42]. Further studies with larger sample size and longer follow-ups, will help to confirm these preliminary observations and, in particular, establish rates of late complications (such as adjacent segment degeneration/failure).

Conclusions

This pilot study shows a slightly, thus significative, improved fusion rates with the use of CFR/PEEK instrumentation. However, the clinical outcome is similar in the two groups. Although the goal of lumbar fusion is clinical improvement, this is achieved *via* a reliable achievement of a solid bony bridge between adjacent vertebrae. Further studies will be needed to clear if CFR/PEEK instrumentation might really improve fusion rates, and if this will have an impact on clinical outcomes.

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