Carbon composite pedicle fixation and interbody cages*.
Retrospective analysis of 40 cases at 5 years.

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Carbon composite pedicle fixation

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Introduction

Spinal fusion implants with the properties of bone continue to elude to the surgeon. Changing from stainless steel to titanium, brought less radiological artifact, but still made fusion difficult to assess over time. Titanium's mechanical properties, while less rigid than steel, is isotropic and much stiffer than bone. Long fiber composite has been used to manufacture bone plates with anisotropic properties. In the literature, plates in new materials have shown to be beneficial for bone formation[1,2]. Now that composite's safety has been established in interbody cages[3,4,5], can the material be applied to spinal pedicle fixation?

Objective

This study attempts to determine over a five year period the reliability of a pedicle fixation construct consisting of lumbar plates and interbody cages constructed in long fiber Osta-Pek® carbon composite.

Materials and Methods

Between October 1997 and August 1998, forty patients (20 Men/20 Women) were treated with one level lumbar fusions using bilateral PLIF cages and lumbar plates, all made from long fiber Osta-Pek composite (66.7% carbon and 33.3% PEKEKK). Screws, washers and nuts were made of titanium alloy of the EVOS system**. The composite plates are an anisotropic structure where long fibers follow the curvature along the entire plate perpendicular to the screw, providing more flexibility in flexion and extension, yet stability in rotation. Autograft bone from the surgical decompression, and/or hydroxyapatite was placed in and around the cage. In this series, all surgeries were performed by the first author. Indications, levels and additional pathology are listed in the adjacent tables. At surgery the patient age ranged from 22 to 76 (mean 52 years) and weight ranged from 45 to 122 kg (mean being 72.9 kg). From hospital records, all patients were scored according to the five point Multi Center Cage Study (MCCS) scale, which provides values of zero to four, assessing pain, function, autonomy, work and patient satisfaction[6]. All patients with follow up greater than 5 years ranging from 68 to 78 months (mean 74) were sent MCCS questionnaires. To assess leg and back pain, a value of zero is intolerable, 1 severe, 2 moderate, 3 mild, and 4 no pain. To assess function or the ability to return to normal daily activity such as house work, a value of 0 to 4 was given in a similar manner to pain. A zero value is no work or normal life activity, a 1 value is 25%, a 2 value 50%, a 3 value 75%. A value of 4 is 100%.

Fusion evaluations

Radiological assessments were performed at 3 months, 1 year and at least 3 years. Fusion was defined as uninterrupted trabecular bridging through the composite cages into the bony endplates, no shadow around the pedicle screws, no traction spur formation or degenerative reactions at the facet joints.

Osta-Pek plate removal

For the cases where the patients were revised and the pedicle fixation was removed, the implants were inspected for nut loosening, mechanical wear between the long fiber composite plate and titanium nut washer and screw. Surrounding tissue was inspected for wear debris or "metalosis." Observations on the soft tissue were recorded.

Results

Twenty-eight patients responded to the five year enquiry. All but three were located, and nine remaining either could not or would not respond (see table). Bone graft formation could be observed next and through the Osta-Pek spinal implants. All patients showed radiographic fusion that remained stable until the last radiological visit. No breakages or loosening of the implants were observed. Eight patients had their Osta-Pek plates removed either because of adjacent level pathology or at the patient's request (see table). Plate removal was not for reasons related to implant stability. All tissue above and below the implant were free of debris or discoloration. Nuts were snug and required torsion for removal, which was similar to the time of surgery, showing a slight imprint upon the plate surface where the titanium washer and screw compressed the long fiber composite. Clinical outcome varied according to the general condition of the patient, and could not be correlated to fusion or performance of the implants. Back pain improved from a score to 0.8 pre op to 2.7 at 3 months and then passed to 2.0 at follow up beyond five years. Leg pain improved from a score of 1.4 to 3.8 at 3 months and then passed to 2.7 at follow up beyond five years. Capacity to work or perform normal daily activities improved from 1.6 pre op, to 2.2 at 3 months and continued to 2.5 beyond five years.

Discussion

The construct of long fiber composite plate and interbody cage with titanium screws performed in a similar manner to the author's experience, using titanium plates with the same screws. With such a varied group, a retrospective

study has limited clinical value, if the surgeon wishes to compare to other series. However the study does show new material can be used to provide reliable spinal constructs and radiographic fusions, which are stable over time. The first author's experience of absence of wear debris around the implant in situ was confirmed by the other authors, and an image from another series shows what was observed at each composite plate removal. This was due to long fiber encapsulation of the carbon fiber in PEKEKK matrix, and the manner which the titanium compresses the composite to achieve a stable fixation. Our results lead the authors to consider new applications. Long carbon fiber composite plates are more flexible than titanium rods or plate components of the same implant system, and this could be valuable to build constructs that vary strength and flexibility at a desired fusion level or in different directions. This might allow the surgeon to stress bone in a more refined manner specific to a pathology, a decompression or fusion site.

Conclusion

The Osta-Pek PLIF cage and lumbar plating procedure was found to fuse spinal motion segments in a safe and reliable manner, remaining stable more than five years for a broad series of patients and pathologies. The ability to observe bone through or around the composite devices was an asset. Soft tissue could be observed adjacent to the implant with MRI. The long fiber composite's varying strength, stiffness and anisotropic properties may be appropriate in more complex constructs of the spine. Additional study is required.

[1] Tonino, A. J., C. L. Davidson, et al. (1976). "Protection from stress in bone and its effects. Experiments with stainless steel and plastic plates in dogs." J Bone Joint Surg Br 58(1): 107-13.

[2] Bradley, G. W., G. B. McKenna, et al. (1979). "Effects of flexural rigidity of plates on bone healing." J Bone Joint Surg Am 61(6A): 866-72.

[3] Sigot-Luizard MF. Biological Evaluation of the Osta-Pek (Carbon-PEKEKK) Composite used in Spinal Surgery. Rachis, 2000; 12(1): 1-8.

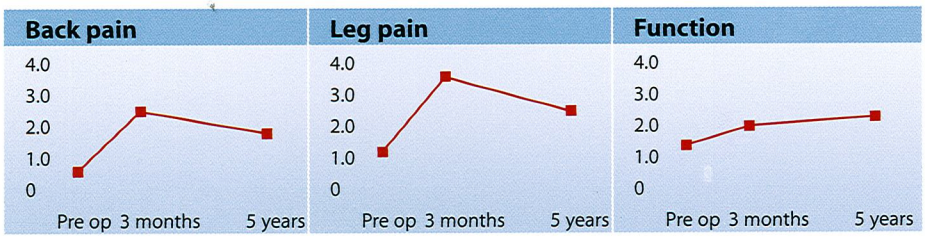
[4] Brantigan JW, Steffee AD. A carbon fiber implant to aid interbody lumbar fusion. Two-year clinical results in the first 26 patients. Spine, 1993; 18(14): 2106-2117.

[5] Elsig, J. P. et al. (2002). Lumbar interbody fusion with PEKEKK composite cages. Spinal restabilizaiton proceedures. Diagnostic and thearpeutic Aspects of Intervertebral fusion cages, artificial discs and mobile implants. D. L. Kaech. Amsterdam.Boston.London. New York. Oxford.Paris, Elsevier: 171-189.

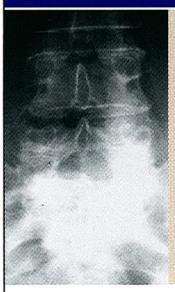
[6] Bisserié M, Elsig JP, Uelingher K, Laloux E, Sgier F. Posterior Lumbar Interbody Fusion (PLIF) with Carbon-Composite Cages. Riv Neuroradiol, 1999; 12 (Suppl 1): 103-106.

* Composite cages in Osta-Pek®, long carbon fiber reinforced PEKEKK.

** Co-Ligne AG, Zurich Switzerland.



Patient K. R. L5-S1 OP plate and cages

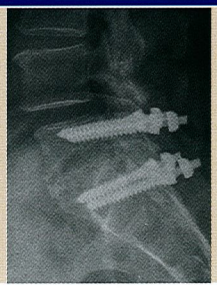

Pre op ap


Pre op lateral

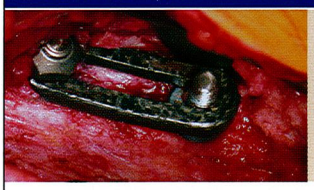

4 months post op ap

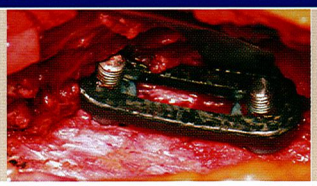

4 months post op lateral


6 years post op ap


6 years post op lateral

Patient P. D. L5-S1 18 months


L5 nut removed


S1 nut removed see imprint

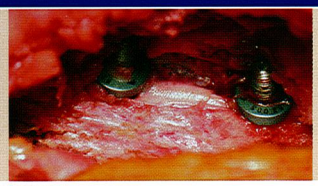
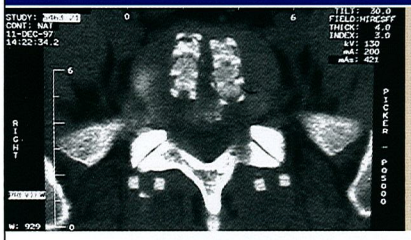


Plate removed

Patient S. R. MRI at 1 month


Long fiber composite plates and cages


Titanium pedicle screws

New application PLF L4-S1


L4-S1 posterolateral without cages

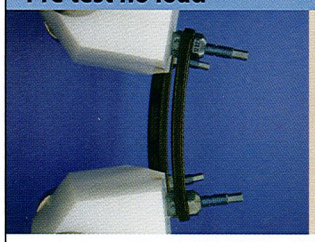
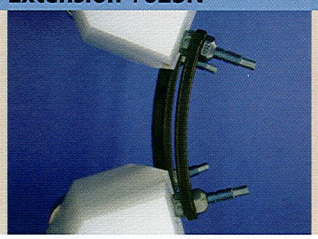
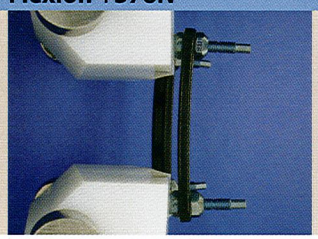
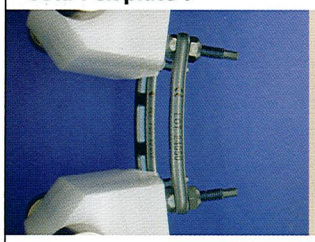
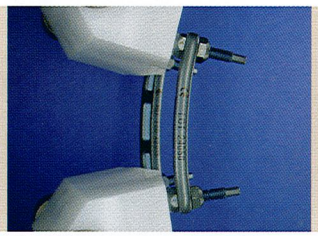
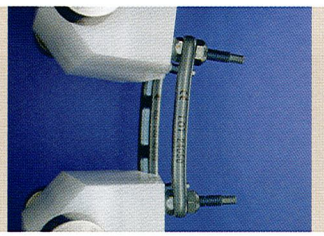
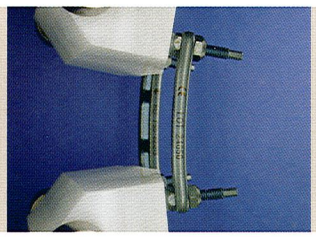
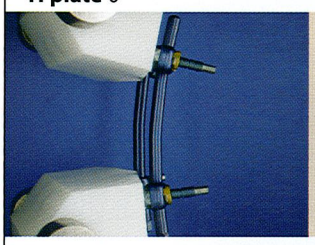
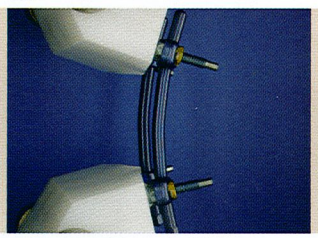
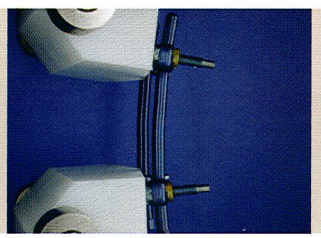
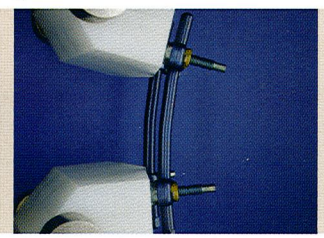
Series and outcome

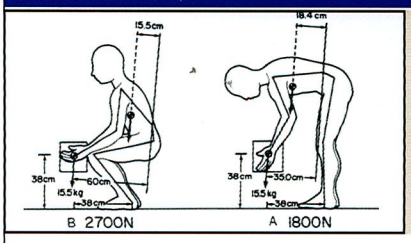
Level operated		Indications		Follow up		Additional pathology			
Record lost	1	DDD	21/28	Death	2	None	15	Diabetes	2
L2-L3	2	Spondylo-listhesis	5/28	Dementia unable to respond	2	Cardio-vascular	4	Psychiatric	1
L3-L4	2	Pseudo-arthrosis	2/28	Refused to respond	1	Obesity	9	Ethylism	1
L4-L5	11	(Revision)		Patient hospital records lost	1	Osteoporosis	2	Nicotin	1
L5-S1	24			Left country and health system	2			Abdominal	1
Total	**40**			Not reachable	4				
				Non response	12				
				Total response	**28/40 70%**				

Removals

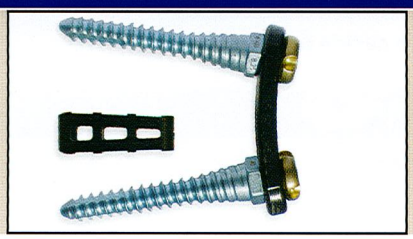
Patient	Months after implantation	Reason for removal	Fusion	Plate condition	Soft tissue debris
5	18	Adjacent segmental degeneration and subsequent fusion	Stable	Intact	None
12	25	Continuing lumbar and radicular pain, suspected scar but nothing found	Stable	Intact	Small dural adh.
16	24	Adjacent segment degeneration and subsequent fusion	Stable	Intact	None
23	65	Patient request	Stable	Intact	None
26	16	Local pain at implant site	Stable	Intact	No sign of infl.
27	4	Persistent pain. Patient request	Stable	Intact	None
29	10	Persistent pain at rest. Patient request	Stable	Intact	None
34	8	Persistent pain at rest. Patient request	Stable	Intact	None
	4-65/mean 21.25				

Varied stiffness and displacement according to material and construct

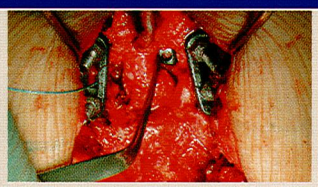
Pre test no load	Extension +623N	Flexion +378N	Post test no load
			
Osta-Pek plate 0°	+15°	-14°	0°
			
TI plate 0°	+5°	-5°	0°
			
TI rod 0°	+7°	-7°	0°



Posture and load



Implant construct. Osta-Pek®* composite plate and cage, titanium screw and nut



Intra operative

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