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Original article

Tantalum implants for posterior lumbar interbody fusion: A safe method at medium-term follow-up?

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ABSTRACT

Introduction: Intervertebral implants increase stability and improve results in lumbar interbody fusion (LIF). The aim of the present study was to assess clinical and radiological results of posterior lumbar interbody fusion (PLIF) using a tantalum intervertebral implant without associated interbody bone graft.
Materiel and methods: A single-center retrospective study included 52 cases of single-level PLIF, using 2 tantalum intervertebral cages, without interbody bone graft: 42 for degenerative disc disease, 10 for isthmic spondylolisthesis. Minimum follow-up was 2 years. Clinical assessment used a visual analog (pain) scale (VAS), the Oswestry Disability Index (ODI) and the Roland Morris (RM) scale. Tantalum osseointegration and intersegment mobility were assessed on static and dynamic X-ray.
Results: Forty-nine patients were included, with a mean 55 months' follow-up (range, 25–74 months). VAS, ODI and RM scores showed significant improvement at last-follow-up, at 4, 30 and 28 points respectively. There was no mechanical failure on static X-ray; all patients had less than 5° mobility on dynamic X-ray at last follow-up.
Discussion: PLIF with tantalum intervertebral implant without interbody bone graft provided satisfactory clinical and radiological results at medium-term follow-up. The present findings showed reliable primary stability and osseointegration of the tantalum implant.
Level of evidence: IV.

1. Introduction

Lumbar interbody fusion (LIF) is the present gold standard in surgical treatment of chronic low-back pain, with or without radiculalgia caused by degenerative disc disease, degenerative spondylolisthesis or isthmic spondylolisthesis. Interbody spinal implants enhance stability in LIF, restoring interbody height and hence segmental lordosis [1,2]. A variety of intervertebral biomaterials are used: PEEK, titanium, tantalum [3–5]; none, however, has demonstrated superiority over bone autograft for interbody fusion.

Tantalum has been used since the early 2000s. It is an extremely porous metal (80% porosity) with texture close to that of cancellous bone. Its high coefficient of friction provides strong primary stability and counters secondary implant mobilization. Its rigidity transmits forces and stress to the bone, enhancing osseointegration and reducing stress-shielding effects [6,7]. Several authors demonstrated its osseointegration capacity in acetabular revision of hip replacement and knee replacement revision [8,9]. In spinal surgery, use of tantalum is a matter of debate in cervical and lumbar fusion, although short-term (mean, ≤ 24 months) clinical results are similar to those of autograft [5,10–12].

The aim of the present study was to assess medium-term (mean, 55 months) clinical and radiological results of posterior lumbar interbody fusion (PLIF) with tantalum intervertebral implant without interbody bone graft.

2. Material and methods

2.1. Study design and inclusion criteria

A single-center continuous retrospective study included consecutive 52 PLIF procedures performed between October 2008 and November 2012 by a single surgeon. Patients presented degenerative disc disease ($n = 42$) or isthmic spondylolisthesis ($n = 10$) causing chronic lumbar radicular pain resisting medical treatment for more than 1 year. Isthmic spondylolisthesis was grade 1 or 2 on the Meyerding classification [13]. Three patients were lost to follow-up before 1 year, and the study analyzed 49 patients. Review

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Table 1
Population data.

Data	*n* (%)
Gender	
Male	21 (40%)
Female	31 (60%)
Mean age (years)	46.6 (27–72)
BMI (kg/m^2)	25.8 (20–42)
Smoker	26 (50%)
ASA score	1.6 (1–3)
Level	
L4–L5	11 (21%)
L5–S1	41 (79%)
Radiculalgia side	
Right	25 (48%)
Left	24 (46%)
Bilateral	3 (6%)
History	
Discectomy	13 (25%)
Laminectomy	3 (6%)
Indication	
DDD	42 (81%)
IS	10 (19%)

BMI: body-mass index; ASA: American Society of Anaesthesiologists; DDD: degenerative disc disease; IS: isthmic spondylolisthesis.

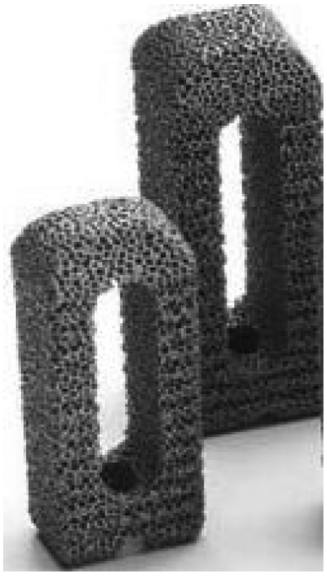

Fig. 1. TM500 (Zimmer Spine, Minneapolis, MN, USA) tantalum intervertebral implant.

board approval was obtained (n° 1791924v0); patients signed an informed consent form. Population characteristics are reported in Table 1.

2.2. Surgical technique

Under general anesthesia, the patient was positioned prone, with the abdomen free and the knees in slight flexion. On a posterior approach, bilateral complete lamino-arthrectomy allowed nerve root release with creation of a work-space for cage implantation. After complete discectomy, the vertebral endplates were freshened. Templates were used under fluoroscopic control to check cage height and length. Two cages (Fig. 1), without bone graft, were positioned between the vertebral bodies, passing on either side of the dural sheath, away from the nerve root shoulder. Posterior internal fixation was then performed on the 2 vertebrae of the pathologic mobile spine sector, using 4 polyaxial pediculated screws connected by 2 curved titanium stems. The bone product of the laminectomy was used for posterolateral autograft. The patient was allowed to rise the next day, with a rigid thoracolumbar brace for 3 months. At 3 months, rehabilitation was initiated.

2.3. Clinical assessment

Clinical assessment comprised: general information (occupation, smoking status, body-mass index [BMI], history of spine surgery), and satisfaction at last follow-up. Functional and quality of life scores (visual analog pain scale [VAS], Oswestry Disability Index [ODI] and Roland Morris score [RM]) were assessed preoperatively and at 3 months, 1 year and last follow-up [14,15]. Perioperative (mean hospital stay, blood-loss) and postoperative data (complications, surgical revision) were collated.

2.4. Radiologic assessment

Preoperative imaging comprised AP and lateral lumbar spine standing views and lateral dynamic views in maximal flexion/extension. MRI ($n = 40$) or myelography ($n = 12$) were performed. Preoperative MRI showed Modic I signal in 13 cases (32.5%), Modic II in 17 (42.5%) and no Modic signal in 10 (25%). On the Pfirrmann classification, all operated discs were grade 4 or 5 [16].

Postoperative imaging comprised:

- AP and lateral lumbar spine standing views at each follow-up consultation;
- lateral dynamic views in maximal flexion/extension at 1 year.

CT was not feasible due to metal artifacts generated by the tantalum. The contribution of MRI is currently under assessment in the same series of patients.

The following measurements were taken on follow-up radiographs by 2 examiners (senior surgeons other than the operator), using PACS 4.6 software (Telemis S.A., Louvain-la-Neuve, Belgium):

- lumbar lordosis: angle subtended by the superior L1 endplate and inferior L5 endplate;
- disc height of fused level, as described by Drain et al. [17];
- intersegment mobility in flexion/extension: angle subtended by the superior endplates of the overlying and underlying vertebrae (Fig. 2).

All changes in instrumentation (posterior fixation breakage or disassembly, radiolucency around screws, cage migration) and adjacent discs were collated.

2.5. Statistical analysis

Clinical and radiological results were analyzed on Student *t* test. The significance threshold was set at $p < 0.05$. Analyses were performed by a statistician, using SAS software, 9.2 (SAS Institute Inc., Cary, NC, USA, 2008).

3. Results

3.1. Demographic and operative analyses

Mean follow-up was 55 months (range, 25–74 months). Three patients were lost to follow-up before 1 year, with good clinical and radiologic results at 3 months.

Mean operative time was 239 minutes (range, 153–352 min); mean blood loss was 360 mL (range, 200–840 mL); mean hospital stay was 8 days (range, 6–14 days). Two dural breeches (4%) were

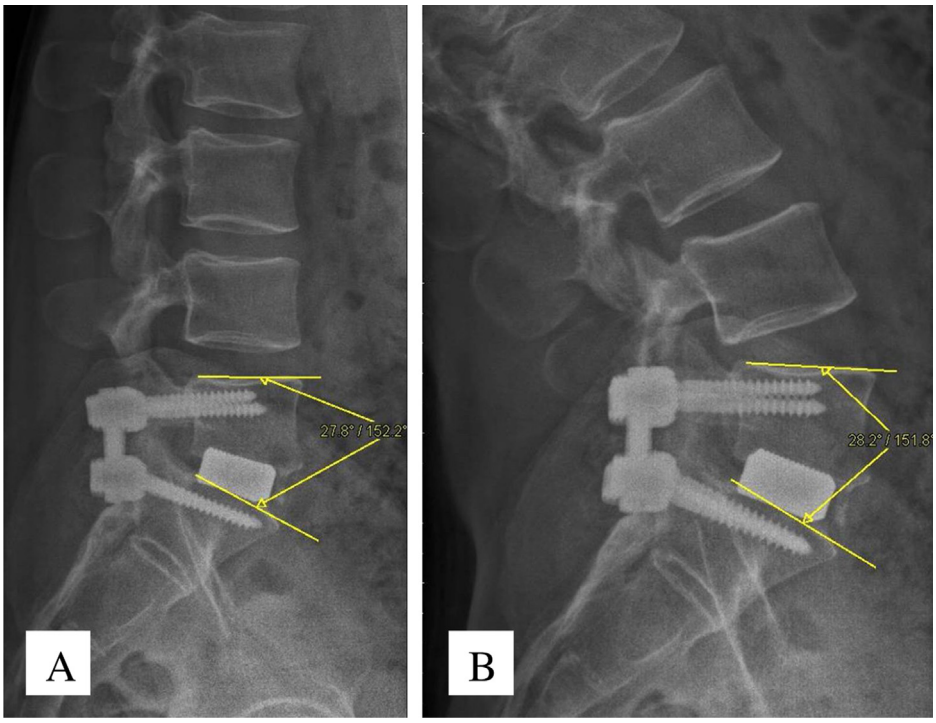

Fig. 2. Lateral radiographs in flexion (A) and extension (B) with calculation of intersegment mobility (27.8° in flexion and 28.2° in extension).

Table 2
Clinical results in DDD and SLL at 3 months, 1 year and last follow-up.

	Preoperative		3 months		1 year		Last follow-up	
	DDD	IS	DDD	IS	DDD	IS	DDD	IS
n	42	10	42	10	42	10	42	10
VAS	9 ± 1	9 ± 1	4 ± 2*	5 ± 3*	3 ± 2*	2 ± 1*	5 ± 3*	3 ± 2*
ODI	67 ± 17	67 ± 21	41 ± 17*	44 ± 18*	31 ± 16*	25 ± 13*	39 ± 19*	27 ± 18*
RM	71 ± 19	69 ± 21	46 ± 22*	50 ± 25**	34 ± 21*	24 ± 21*	45 ± 25*	28 ± 30*

DDD: degenerative disc disease; IS: isthmic spondylolisthesis; VAS: Visual analog scale; RM: Roland Morris score; ODI: Oswestry Disability Index.
* Significant ($p < 0.05$).
** Non-significant ($p > 0.05$).

sutured, without pseudomenigocele. There were no other peri- or post-operative complications.

3.2. Clinical analysis

Clinical results in degenerative disc disease and isthmic spondylolisthesis are shown in Table 2. VAS, ODI and RM showed significant improvement at 1 year (6, 37 and 38 points, respectively) and at last follow-up (4, 30 and 28 points, respectively) (Fig. 3). Thirty-nine patients (75%) were satisfied or very satisfied at 1 year and would recommend the procedure. Occupational status is shown in Fig. 4.

3.3. Radiographic analysis

There were no mobility chambers around the screws, and no hardware breakage or cage migration. All patients showed < 5° mobility on dynamic X-ray. Mean intervertebral height increased significantly, from 0.2 ± 0.1 mm preoperatively to 0.4 ± 0.1 at 3 months, 1 year and last follow-up ($p < 0.01$). Mean gain in lumbar lordosis was 5.1° ± 10° at last follow-up: from 38.6° ± 12.2° to 43.7° ± 11.4 ($p < 0.01$).

Three patients (6%) required revision surgery at 2–5 years, due to neo-hinge syndrome (fusion of level concerned).

4. Discussion

The aim of the present study was to assess medium-term clinical and radiological results in a continuous series of single-level PLIF with tantalum intervertebral implant without interbody bone graft.

4.1. Clinical results for PLIF with tantalum implant

The present clinical results, at the longest follow-up in the literature, were comparable to those reported elsewhere, with 30 points' improvement in ODI at last follow-up [4]. There have at present been 3 other studies of PLIF with tantalum implant [5,18,19], with results close to the present, notably in terms of quality of life (Table 3). On the other hand, Lequin et al. [18] reported a 15% revision rate for hematoma, pseudomenigocele or non-union, and none for neo-hinge syndrome, of which we report 3 cases at 2–5 years. Van de Kelft et al. [19] reported a 6% rate (2 cases) of radiolucent lines around tantalum interbody implants in a series without associated internal fixation; in the present series, in contrast, there was no mobility around the implants, even at last follow-up. The 3 cases of revision for neo-hinge syndrome showed fusion at the revision surgery. Results for PLIF without associated posterolateral fusion show higher rates of revision surgery and non-union [18,19].

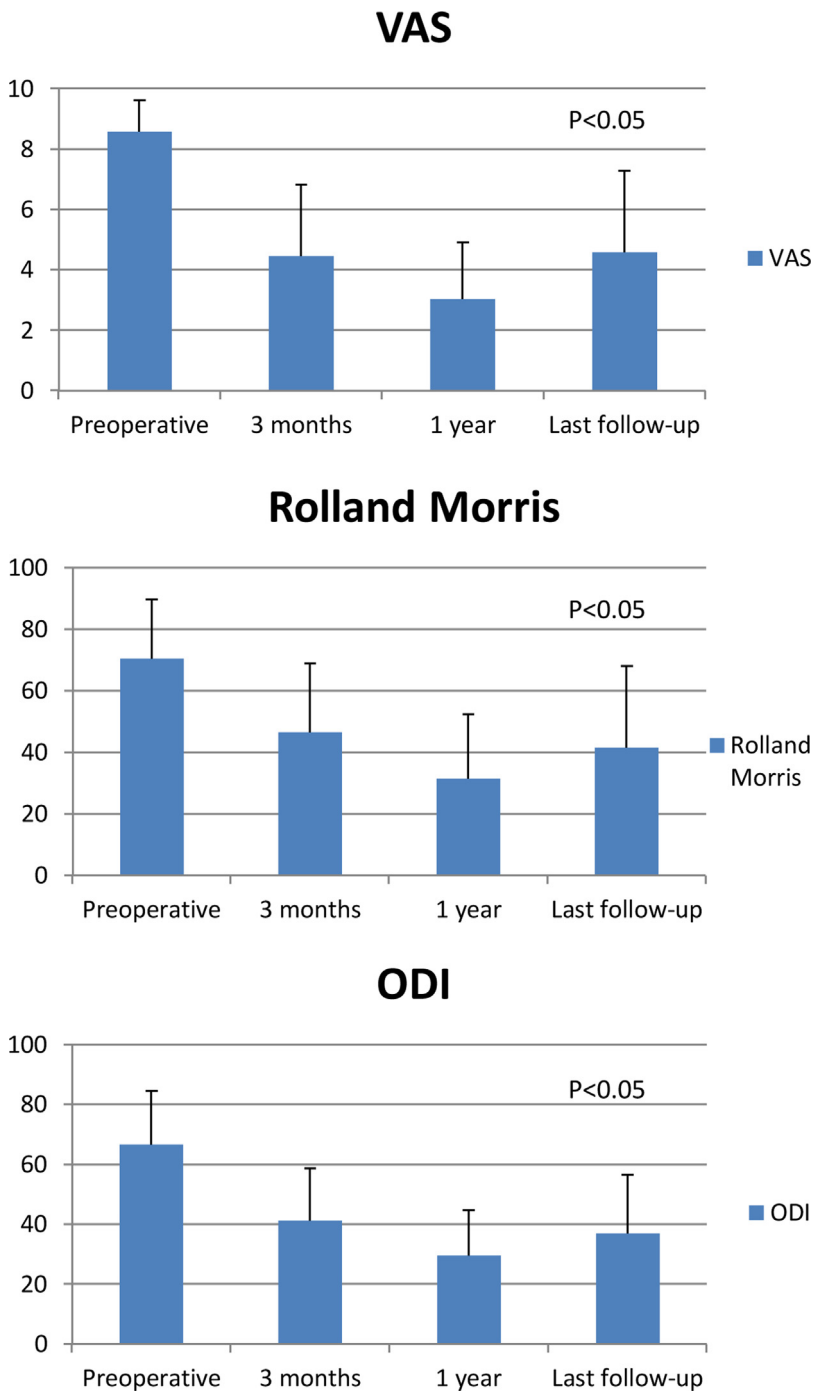

Fig. 3. Clinical results at follow-up time points for VAS, ODI and RM.

4.2. *The contribution of tantalum*

The coefficient of friction of tantalum provides good primary stability, unlike PEEK or titanium [20]. This reduces the risk of secondary cage mobilization, notably in the spinal canal, and none indeed was observed in the present study. Studies of minimally invasive PLIF with tantalum implant and no complementary posterior internal fixation confirm this absence of tantalum implant mobilization [18,19]. The present study showed that tantalum implants could be used as spacers to restore interbody height. Its osseointegration capacity provides a greater integrable contact surface than between bone and autologous graft in the central chamber of PEEK cages. For this reason, we did not consider it worth filling the cages with bone autograft. The tantalum can then be used as a spacer in anterior fusion, avoiding the morbidity associated with autologous grafting [21]. Unlike PEEK or titanium, tantalum is very difficult to assess on CT, due to metal artifacts [22,23], preventing CT assessment of fusion. MRI may allow reliable fusion assessment in PLIF with tantalum implant, as in PEEK [24], and we are assessing this in an ongoing study. The tantalum implant is used as an integrable spacer rather than as an interbody graft for fusion, and it is bone integration rather than interbody fusion that is to be assessed. We therefore included tantalum implant osseointegration on the standard radiographs and segmental mobility on dynamic radiographs [23].

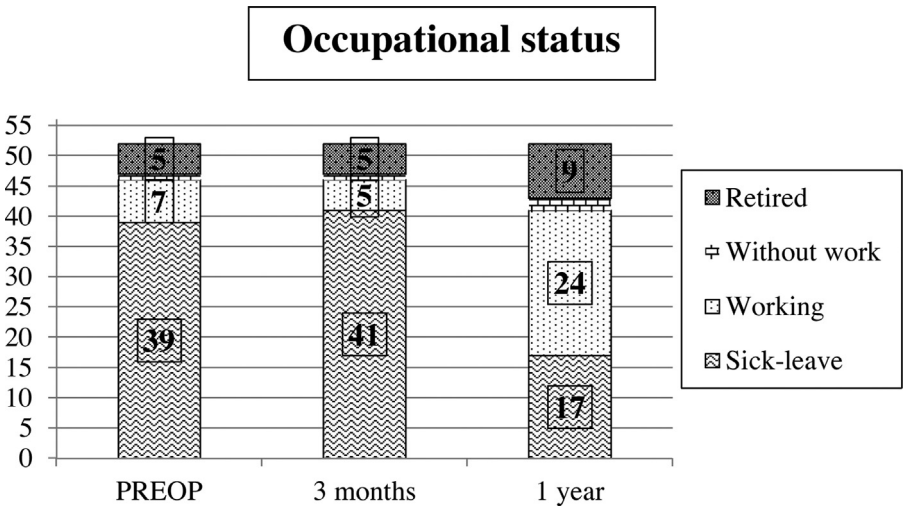

Fig. 4. Occupational status of the 52 patients at 3 months and 1 year.

Table 3
Results of studies of PLIF with tantalum intervertebral implant.

Reference, number of patients	Type of study	Follow-up (months)	Loss to follow-up	Procedure, number of levels	Clinical results	Complications	Fusion rate	Revision for non-union
Hoy et al. [5], $n = 100$	Prospective, randomized	24	6	PLF ($n = 49$) vs TLIF ($n = 51$) 1, 2 or 3 levels	Significant improvement; no difference	Neural lesion (0 vs 1); Dural breech (0 vs 1); Pneumothorax (0 vs 1); Hematoma (2 vs 1); Infection (0 vs 1)	PLF: 85.7% TLIF: 86.3%	PLF ($n = 3$); TLIF ($n = 1$)
Lequin et al. [18], $n = 26$	Retrospective	15,3	None	SA ($n = 26$) 1 level	Significant improvement	Neural lesion ($n = 4$); Dural breech ($n = 2$); Hematoma ($n = 2$); Infection ($n = 1$)	96.2%	1
Van de Kelft et al. [19], $n = 80$	Prospective, randomized	24	None	PLIF ($n = 40$) vs SA ($n = 40$) 1 level	Significant improvement; no difference	Dural breech (4 vs 2); Screw revision (1 vs 0)	PLF: 92.5% SA: 77.5%	No data
Present study, $n = 52$	Retrospective	55	3	PLIF ($n = 52$) 1 level	Significant improvement	Dural breech ($n = 2$)	94.2%	0

DPQ: Dallas pain questionnaire; PLF: posterolateral fusion; PLIF: posterior lumbar interbody fusion; TLIF: transforaminal lumbar interbody fusion; SA: stand-alone PLIF.

4.3. Study limitations

The present retrospective design incurs certain limitations. Several parameters could not be analyzed due to lack of data: implant-induced segmental lordosis, implant impaction, and pelvic and spinal parameters. The 3 cases of neo-hinge syndrome seemed to be due not to sagittal malalignment but to the rigidity of the fusion. There are no studies comparing tantalum to other types of interbody material; a randomized comparative study versus, for example, PEEK could assess perioperative complications (dural breech) and medium-term complications (non-union). The present low rate of perioperative complications (4%) demonstrates, at all events, that the technique is reliable.

5. Conclusion

PLIF with tantalum intervertebral implant without interbody bone graft provided satisfactory medium-term clinical and radiographic results. The advantages of tantalum consist in excellent primary stability and osseointegration capacity. The main drawback is the difficulty of using CT in follow-up due to metal artifacts generated by tantalum. The use of MRI is currently under assessment.

Disclosure of interest

The authors declare that they have no competing interest.

Sources of funding

No financing was received for the study.

Author contribution

Lebhar, Kriegel, Breton: data collection.
Lebhar, Ropars Huten: paper writting.

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