## CASE REPORT

# Clinical, radiological, histological and retrieval findings of Activ-L and Mobidisc total disc replacements: a study of two patients

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### Abstract

*Introduction* This study evaluates the short-term clinical outcome, radiological, histological and device retrieval findings of two patients with second generation lumbar total disc replacement (TDR).

*Materials and methods* The first patient had a single level L4-L5 Activ-L TDR, the second patient a L4-L5 Mobidisc and L5-S1 Activ-L TDR. The TDRs were implanted elsewhere and had implantation times between 1.3 and 2.8 years.

*Results* Plain radiographs and CT-scanning showed slight subsidence of the Activ-L TDR in both patients and facet joint degeneration. The patients underwent revision surgery because of recurrent back and leg pain. After removal of the TDR and posterolateral fusion, the pain improved. Histological examination revealed large ultrahigh molec-

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Department of Orthopaedic Surgery, Viecuri Medical Center, P.O. Box 1926, 5900 BX Venlo, The Netherlands ular weight polyethylene (UHMWPE) particles and giant cells in the retrieved tissue surrounding the Mobidisc. The particles in the tissue samples of the Activ-L TDR were smaller and contained in macrophages. Retrieval analysis of the UHMWPE cores revealed evidence of minor adhesive and abrasive wear with signs of impingement in both TDR designs.

*Conclusion* Although wear was unrelated to the reason for revision, this study demonstrates the presence of UHMWPE particles and inflammatory cells in second generation TDR. Long-term follow-up after TDR is indicated for monitoring wear and implant status.

**Keywords** Total disc replacement · Disc degeneration · (Un)constrained · Revision surgery · Polyethylene wear

#### Introduction

Total disc replacement (TDR) has been developed as an alternative to spinal fusion for the treatment of degenerative disc disease [1-3]. Presumed advantages of TDRs are motion preservation, prevention of adjacent level degeneration and restoration of disc height [2-4]. Second generation TDR designs, such as the Mobidisc (LDR Spine, Troyes, France) and Activ-L (Aesculap AG, Tuttlingen, Germany) were developed from the first generation biconvex SB Charité III (Waldemar link, Hamburg, Germany) and Prodisc (Synthes, West Chester, PA, USA) [3, 5–7]. Second generation TDRs have a sliding, convex design with a spherical superior endplate combined with a flat inferior endplate and an ultrahigh molecular weight polyethylene (UHMWPE) core [2, 3, 5, 6]. These new designs were developed because of varying long-term success rates of the Charité TDR [1, 3, 8]. They were supposed to minimize UHMWPE wear debris, allow easier implantation and improve implant stability [7].

A TDR is semi-constrained or unconstrained depending on whether the centre of rotation (COR) is fixed or mobile [5, 6]. Semi-constrained TDRs are divided in designs with and without anterior-posterior (AP) translation [5, 6]. The Mobidisc is an unconstrained TDR and the Activ-L TDR is a semi-constrained design with absence of lateral translation and limited AP translation [7, 9–11]. In a clinical case series on the Mobidisc TDR, the back pain decreased from 6.8 to 2.6 on the visual analog scale (VAS) 2 years after implantation [7, 12]. The back pain of Activ-L patients decreased from 8.2 to 1.5 on the VAS 2 years postoperatively in a prospective clinical trial [13].

There are few retrieval studies available for TDR and little is known about the clinical effects of UHMWPE wear debris in the lumbar spine [14–17]. UHMWPE particles can activate an inflammatory response, which may result in osteolysis and failure of total knee and hip replacements [18, 19]. Punt et al. described the presence of UHMWPE particles and inflammatory cells in periprosthetic tissue after revision of Charité III TDR [14, 15, 17]. It is currently unknown whether UHMWPE wear particles and inflammatory cells are present after second generation TDR. The aim of the present study is to report on the clinical, radiological, histological and device retrieval findings of retrieved Activ-L and Mobidisc TDRs.

#### Materials and methods

Two patients with a TDR presented with recurrent back and leg pain at our outpatient clinic. The first patient had a single level L4-L5 Activ-L TDR, the second patient a L4-L5 Mobidisc and L5-S1 Activ-L TDR. The TDRs were implanted elsewhere. Radiographs and VAS pain scores were obtained during routine controls at our outpatient clinic. The TDRs were extracted during revision surgery and periprosthetic tissue was randomly collected. Bright field microscopy (Leica DM5000B) was used for examining the presence of inflammatory cells and grading them according to the Mirra classification [20]. Polarized light was used for detection and morphometric analysis (Leica Qwin software V3, Cambridge, UK) of the UHMWPE particles  $(100 \times)$ . Damage to the retrieved components was analyzed using light microscopy and scanning electron microscopy (SEM). The UHMWPE cores were inspected for evidence of abrasive, adhesive, third body and fatigue wear mechanisms as well as evidence of impingement.

## **Case reports**

## Case 1

A 48-year-old male had experienced low back pain since the age of 20 with irradiation to the right leg and left buttock non-radicular in origin. A herniated disc was removed at L5–S1 when he was 30 years old. After 2 years of pain relief, the pain recurred after an automobile accident. The patient was dissatisfied with the result of corset treatment and a pain management program. In July 2006 at the age of 43, he received an Activ-L TDR at L4–L5, and intercorporal cage fusion with anterior spinal instrumentation at L5–S1 because of two-level degenerative disc disease.

The patient reported some pain relief for several weeks, however, the pain exacerbated to the pre-operative level. At presentation in February 2007 at our outpatient clinic, the pain was localized in the lower back with irradiation and numbness in the buttocks and both legs. Walking was limited to 10 min, standing to 10 min and sitting to 20 min. He woke up approximately four times a night due to pain. The VAS was 8 for the back, 4 for the right leg and 2 for the left leg.

Plain radiographs demonstrated that the TDR was slightly undersized, eccentrically positioned (Fig. 1). Limited motion of the Activ-L TDR was visible on flexion–extension radiographs [range of motion (ROM): 3°]. CT- and MRI-scanning revealed facet joint degeneration at L4–L5, but no signs of disc herniation, spinal stenosis or post-operative scarring. Therefore, the recurrent back pain was assumed to be due to facet joint degeneration. It was decided to remove the TDR by a left sided lumbotomy in October 2007, 1 year and 4 months after initial surgery



Fig. 1 Lateral (*left*) and AP (*right*) radiographs showing a slightly undersized L4–L5 Activ-L TDR that slightly subsided



Fig. 2 Hematoxylin and eosin stained sections of retrieved periprosthetic fibrous tissue surrounding the Activ-L TDR, with light microscopy (*left*) and polarized light (*right*), containing small round polyethylene particles in macrophages

because the patient strongly posed for TDR removal. Despite good fixation of the TDR to the bone, there was no osseous integration of the bone into the coating. The disc space was filled with a strut allograft. A small peritoneal lesion was sutured without remaining complaints. Instrumented posterolateral fusion of L4–L5 was performed during the same session. Intra-operative cultures were sterile.

The mean number of UHMWPE particles in the periprosthetic tissue was 3 particles/mm<sup>2</sup> with a mean curve length of 3.89  $\mu$ m (range 2.05–9.59  $\mu$ m). The particles had a round to oval shaped morphology. Histological examination showed a mild inflammatory reaction with mainly macrophages and an incidental giant cell (Fig. 2). An overview of the size and morphology of the UHMWPE particles and the amount of inflammatory cells is summarized in Table 1. There was no evidence of metallosis in the periprosthetic tissue.

Overall, this retrieved UHMWPE core exhibited minimal wear. Burnishing and multi-directional scratching was observed on the backside and the articulating dome of the core. However, the original machining marks were still present, indicative of material removal on the order of micrometers. There was also evidence of the metallic endplates contacting one another at the anterior portion of the device. Impingement was confirmed using SEM. At high resolutions  $(38-2,000\times)$ , the areas where the endplates impinged were burnished and very smooth as compared to the unimpinged areas (Fig. 3).

Three years and 5 months after removal of the TDR, the patient experienced relief of the back pain (VAS 3.5) and no leg pain (VAS 0). The back pain consisted of a cramping sensation in the lower back at night which did not disturb sleeping. Radiographs showed fusion of the operated segment with slight anterior collapse into the allograft (Fig. 4).

#### Case 2

A 49-year-old female patient had low back complaints with non-radicular irradiation to the right buttock since 2001.

Discography revealed painful disc degeneration at L4–L5 and L5–S1. She received a Mobidisc TDR at level L4–L5 in August 2004 at age 42 and an Activ-L TDR at L5–S1 in September 2005.

The back and buttock complaints were relieved after insertion of the Activ-L TDR but recurred in 2006. When the patient presented in August 2006 at our outpatient clinic, walking was limited to 30 min, standing to 10 min and sitting to 60 min. At night she woke up approximately three times and had to get out of bed to relieve the pain. The pain did not improve with pain medication, physical therapy and nerve blockage.

Plain radiographs showed slight subsidence of the Activ-L TDR and a slight eccentric position of the Mobidisc TDR (Fig. 5). Flexion-extension radiographs showed a ROM of 7° for the Mobidisc and 4° for the Activ-L TDR. CT-scanning revealed facet joint degeneration at L4-L5 and L5-S1, with no signs of spinal stenosis or compression. The facet joint degeneration could be a feasible explanation for the recurrent back pain. It was the patient's preference to have both TDRs removed. In June 2007, the Mobidisc and Activ-L TDR were retrieved using a left sided lumbotomy extended distally. 2 years and 10 months and 1 year and 5 months after implantation, respectively [21]. The TDRs were well fixed to the bone, but there was no osseous integration. The disc spaces were filled with a strut allograft and bone chips. Two days after the operation the patient developed respiratory complaints due to acute respiratory distress syndrome most likely caused by an allergic reaction to medication. She recovered without remaining complaints. Six weeks later, after a delay of 5 weeks, posterior instrumentation and fusion at L4-S1 was performed. All intra-operative cultures were sterile.

The mean number of UHMWPE particles in the retrieved periprosthetic tissue was 1 and 2 particles/mm<sup>2</sup> for the Activ-L and Mobidisc, respectively (Table 1). The particles retrieved from the Activ-L TDR had a round to oval shaped morphology, the particles from the Mobidisc were more flake shaped. The mean curve length was 3.07  $\mu$ m (range 2.05–4.10  $\mu$ m) for the Activ-L and 39.48  $\mu$ m (range

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Case number	Type TDR	Level	Implantation time (years)	Macrophages <sup>a</sup>	Giant cells <sup>b</sup>	Mean particles/mm <sup>2</sup>	Mean curve length particles (µm)	Range curve length particles (µm)	Mean curve width particles (µm)	Mean roundness <sup>c</sup>
Case 1	Activ-L	L4-L5	1.3	2+	1+	3	3.89	2.05-9.59	1.74	1.45
Case 2	Activ-L	L5–S1	1.6	2+	<del>1</del> +	1	3.07	2.05 - 4.10	1.02	1.61
	Mobidisc	L4-L5	2.8	0	+1	2	39.48	2.05-73.56	7.96	2.12
<sup>a</sup> 1+: 1-9 mac	rophages/high 1	power field	(500×), 2+: 10−	49 macrophages/hi	gh power	field (500×), 3+:	≥50 macrophages/high	power field $(500\times)$ , fiv	e microscopic fields w	ere scored
<sup>b</sup> 1+: 1–2 cell	s/medium powe	sr field (250	0×), 2+: 3–8 cell	s/medium power fit	eld (250×	), $3+: \ge 9$ cells/m	edium power field (250)	×), five microscopic fiel	ds were scored	
<sup>c</sup> A mean rour	idness of 1.00 ii	ndicates a p	perfectly round sh.	aped UHMWPE pi	article					

 $2.05-73.56 \mu$ m) for the Mobidisc. Surrounding the Activ-L TDR we observed macrophages and on both levels a small amount of giant cells (Fig. 6). No metal particles were found in the tissue surrounding both TDRs.

The UHMWPE cores in both retrievals exhibited minimal wear. Although machining marks were still present on the superior and inferior articulating surfaces of the Activ-L core, they were eroded at locations on the Mobidisc core. Nevertheless, we were unable to measure any deviation in total height of the core from the manufacturer's specifications (accuracy 0.001 mm). Multi-directional scratching and burnishing was observed for both the Activ-L and the Mobidisc TDR on both the dome and the backside of the cores. There was evidence of metal-on-metal impingement on the left side of the superior endplate of the Activ-L TDR. In the case of the Mobidisc TDR, the right lateral wing of the core had impinged with the superior endplate (Fig. 7).

Three years and 9 months after removal, the back complaints were relieved (VAS 3) and there was no buttock pain (VAS 0). Initially, the back pain varied in severity but gradually decreased after a revalidation program and epidural injections. She resumed sports activities and was able to refrain from pain medication. Radiographs showed a solid fusion with unaltered position of the instrumentation (Fig. 8).

## Discussion

Two patients with second generation Activ-L and Mobidisc TDRs had recurrent back and leg pain, which improved after TDR removal and subsequent posterolateral fusion. Plain radiographs and CT-scanning showed slight subsidence of both Activ-L TDRs and facet joint degeneration. UHMWPE particles and inflammatory cells were present in the tissue surrounding the TDRs. The UHMWPE cores exhibited minimal abrasive and adhesive wear, but showed evidence of impingement.

The mean number of UHMWPE particles was two orders of magnitude lower in the Activ-L (1–3 particles/mm<sup>2</sup>) and Mobidisc (2 particles/mm<sup>2</sup>) compared to a previous study on the SB Charité III TDR (231 particles/mm<sup>2</sup>) [14, 17]. The lower wear in the present study can be explained by a combination of factors, including implantation time, TDR design and material factors. The higher number of UHMWPE particles in the Charité TDR study can result from differences in mean implantation time (1.6 vs. 10.0 years) [14, 17]. Further, the Charité retrievals were gamma sterilized in air, in a first generation oxygen permeable package [14, 17, 22–24]. The cores of the Mobidisc and Activ-L TDR were gamma irradiation sterilized in a second generation barrier package, designed to preserve the mechanical properties of UHMWPE [3, 7, 22].



Fig. 3 Retrieved Activ-L TDR, 1.3 years after insertion. Note the impingement in the anterior portion of the superior endplate (*center*). The impinged region has a smoother appearance (*lower right*) than the unimpinged region (*upper right*)



Fig. 4 Lateral (*left*) and AP (*right*) postoperative radiographs after removal of the Activ-L TDR and posterolateral fusion of L4–L5

The difference in UHMWPE particle size between the Activ-L and Mobidisc TDR could be explained by having an unconstrained and semi-constrained TDR design. In total knee replacement (TKR), the same phenomenon is described [25, 26]. Larger UHMWPE particles are found in tissue surrounding failed mobile bearing TKR than in tissue surrounding failed fixed bearing TKR [25, 26]. Design-dependant differences in loading and wear mechanisms can be an explanation for these size differences [3, 7]. Large flake shaped UHMWPE particles, present in the tissue surrounding the Mobidisc TDR, were associated with fewer inflammatory cells. It could be possible that the particles of the Mobidisc TDR have a tendency to be less bioactive.

Faint signs of impingement were observed in all three TDRs, which is perhaps not surprising since the devices had subsided into biomechanically unfavorable positions. Unnatural motion patterns also could have contributed to the impingement. Impingement has been observed in many



**Fig. 5** Lateral (*left*) and AP (*right*) radiographs showing a Mobidisc TDR at L4–L5 and an Activ-L TDR at L5–S1. The Mobidisc is correctly sized and correctly positioned, the Activ-L TDR is adequately sized but subsided (*arrow*)

types of joint replacement, including the hip and shoulder, as well as previous TDR designs [27–30]. It may lead to UHMWPE degradation and increased amounts of wear [27–30]. Because of the short implantation times, the longterm implications of impingement of the two designs in this study are unknown. However, the metal-on-metal wear observed in the Activ-L TDR is of particular concern, as it may produce metal wear debris.

The presence of UHMWPE wear particles results in the activation of an inflammatory response, associated with osteolysis and aseptic loosening of joint replacements [18, 19]. Macrophages and giant cells release various cytokines, such as tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-1 (IL-1) and interleukin-6 (IL-6). These cytokines are considered to be potent inducers of osteoclasts [18, 19]. They also play a role in the development of neuro-inflammatory pain [31, 32]. Since osteolysis after TDR is



Fig. 6 Hematoxylin and eosin stained sections of retrieved periprosthetic fibrous tissue surrounding the Mobidisc TDR, with light microscopy (*left*) and polarized light (*right*), containing large flakes of polyethylene in giant cells



Fig. 7 Retrieved Mobidisc TDR (left), 2.8 years after implantation, with impingement on right lateral wing (center and right)



Fig. 8 Lateral (*left*) and AP (*right*) postoperative radiographs after removal of the Mobidisc and Activ-L TDR and posterolateral fusion of L4–S1

rarely observed, it could be possible that the UHMWPE particle concentration after TDR is too low for causing osteolysis in most cases, but is potent enough to initiate neuro-inflammation and recurrent back pain. Therefore, the

presence of wear after TDR continues to be of clinical concern. This is especially true for the younger and active patients who frequently receive TDR.

Facet joint degeneration can contribute to recurrent back pain after TDR [10, 33–35]. The patient in case 1 had an anterior spinal fusion at L5–S1, which can accelerate facet joint degeneration, as well as unnatural motions in the L4–L5 Activ-L TDR [36–38]. In case 2, the patient received a two-level TDR which can lead to hypermobility and accelerates facet joint degeneration [39–41]. It is stated that a fixed COR should prevent overloading of the facets [6, 10]. While, others state that a mobile COR leads to a lower facet contact force by an equilibrium between facet loading and ligament tension [5, 9]. Also malpositioning of the TDR causes higher stresses on the facets [11, 42]. Nevertheless, facet joint degeneration was present at L4–L5 and L5–S1 in both cases with both TDR designs.

There is an ongoing discussion about the optimal revision strategy for failed TDRs [21, 43–45]. With acceptable implant status and position, posterior fusion can be addressed for treatment of recurrent back pain due to facet joint degeneration [44, 45]. When the TDR has subsided, migrated or mechanically failed, the pain can be addressed by TDR removal [45]. The outcome of secondary fusion with the TDR in situ has not been well reported. In our case load of failed TDRs we started with posterolateral fusion without removal of the TDR. Unfortunately, the results were disappointing in most patients [21, 46]. Thereafter, we combined fusion with TDR removal if the patient accepts the risks of retrieval surgery.

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**Conflict of interest** None of the authors has any potential conflict of interest.

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