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The Spine Journal 14 (2014) 1417–1431

THE SPINE JOURNAL

Clinical Study

Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up

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Received 17 March 2013; revised 21 July 2013; accepted 22 August 2013

Abstract

BACKGROUND CONTEXT: The role of fusion of lumbar motion segments for the treatment of intractable low back pain (LBP) from degenerative disc disease (DDD) without deformities or instabilities remains controversially debated. Total lumbar disc replacement (TDR) has been used as an alternative in a highly selected patient cohort. However, the amount of long-term follow-up (FU) data on TDR is limited. In the United States, insurers have refused to reimburse surgeons for TDRs for fear of delayed complications, revisions, and unknown secondary costs, leading to a drastic decline in TDR numbers.

PURPOSE: To assess the mid- and long-term clinical efficacy as well as patient safety of TDR in terms of perioperative complication and reoperation rates.

STUDY DESIGN/SETTING: Prospective, single-center clinical investigation of TDR with ProDisc II (Synthes, Paoli, PA, USA) for the treatment of LBP from lumbar DDD that has proven unresponsive to conservative therapy.

PATIENT SAMPLE: Patients with a minimum of 5-year FU after TDR, performed for the treatment of intractable and predominant (≥80%) axial LBP resulting from DDD without any deformities or instabilities.

OUTCOME MEASURES: Visual analog scale (VAS), Oswestry Disability Index (ODI), and patient satisfaction rates (three-scale outcome rating); complication and reoperation rates as well as elapsed time until revision surgery; patient's professional activity/employment status.

METHODS: Clinical outcome scores were acquired within the framework of an ongoing prospective clinical trial. Patients were examined preoperatively, 3, 6, and 12 months postoperatively, annually from then onward. The data acquisition was performed by members of the clinic's spine unit including medical staff, research assistants, and research nurses who were not involved in the process of pre- or postoperative decision-making.

RESULTS: The initial cohort consisted of 201 patients; 181 patients were available for final FU, resembling a 90.0% FU rate after a mean FU of 7.4 years (range 5.0–10.8 years). The overall results revealed a highly significant improvement from baseline VAS and ODI levels at all postoperative FU stages ($p<.0001$). VAS scores demonstrated a slight (from VAS 2.6 to 3.3) but statistically significant deterioration from 48 months onward ($p<.05$). Patient satisfaction rates remained stable throughout the entire postoperative course, with 63.6% of patients reporting a highly satisfactory

FDA device/drug status: Approved (Pro DiscII (Synthes, Paoli, PA)).

Author disclosures: ***CJS:*** Consulting: Synthes; Speaking and/or Teaching Arrangements: Synthes (C); Trips/Travel: Synthes (C); Research Support (Investigator Salary, Staff/Materials): Synthes (C). ***FH:*** Nothing to disclose. ***KW:*** Nothing to disclose. ***WH:*** Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like: Paracelsus Medical University Salzburg, Austria, Research Office (statistical analysis) (A, Paid directly to institution). ***BI:*** Nothing to disclose. ***MHM:*** Consulting: Synthes, Paoli, PA (E); Speaking and/or Teaching Arrangements: Synthes, Paoli, PA (E); Trips/Travel: Synthes, Paoli, PA (E).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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1529-9430/$ - see front matter
http://dx.doi.org/10.1016/j.spinee.2013.08.028

or a satisfactory (22.7%) outcome, whereas 13.7% of patients were not satisfied. The overall complication rate was 14.4% (N=26/181). The incidence of revision surgeries for general and/or device-related complications was 7.2% (N=13/181). Two-level TDRs demonstrated a significant improvement of VAS and ODI scores in comparison to baseline levels ($p<.05$). Nevertheless, the results were significantly inferior in comparison to one-level cases and were associated with higher complication (11.9% vs. 27.6%; $p=.03$) and inferior satisfaction rates ($p<.003$).

CONCLUSIONS: Despite the fact that the current data comprises the early experiences and learning curve associated with a new surgical technique, the results demonstrate satisfactory and maintained mid- to long-term clinical results after a mean FU of 7.4 years. Patient safety was proven with acceptable complication and reoperation rates. Fear of excessive late complications or reoperations following the primary TDR procedure cannot be substantiated with the present data. In carefully selected cases, TDR can be considered a viable treatment alternative to lumbar fusion for which spine communities around the world seem to have accepted mediocre clinical results as well as obvious and significant drawbacks.

Keywords: Disc replacement; Arthroplasty; Artificial disc; Lumbar spine; Long term results; Outcome; Complications

Introduction

Fusion of lumbar motion segments performed for the treatment of intractable low back pain (LBP) from degenerative disc disease (DDD) without any deformities or instabilities are associated with a variety of negative side effects, including adjacent level pathologies, considerable complication and reoperation rates, symptomatic facet and sacroiliac joint complaints, cranial facet joint violations, adjacent segment stenosis, negatively altered sagittal alignment, pseudarthrosis, graft site morbidity, and others [1–13].

In an attempt to avoid these fusion-related negative side effects, motion-preserving technologies such as total lumbar disc replacement (TDR) have been introduced. Approximately 3 decades after the initial introduction of the SB Charité disc (DePuy, Raynham, MA, USA), a substantial amount of class I to class IV data has been published, the majority of which reported satisfactory clinical results. The data from prospective randomized controlled clinical trials confirmed at least noninferiority or even superiority in comparison to varying control cohorts using fusion procedures [14–22].

Despite these previously published evidence-based data, a variety of authors, surgeons, regulatory institutions, and health care insurers as well as health care providers have reported controversial and at times have displayed irrational perceptions related to TDR, including fears of deteriorating results as well as excessive late complications and revision surgeries [23–32].

To assess the role of any new treatment method, long-term clinical results need to be evaluated in clinical studies with adequately sized patient cohorts and sufficient mid- to long-term results. To date, the number of previously published long-term follow-up (FU) studies on TDR is scarce.

The aim of the current study was therefore to evaluate the mid and long-term clinical results as well as patient safety in terms of complications and revision surgeries in a cohort of TDR patients.

Materials and methods

Preoperative diagnosis and patient selection

All patients included in this study are part of an ongoing prospective clinical trial with ProDisc II (Synthes, Paoli, PA, USA). The minimum FU required for inclusion in this study was 5 years.

Disc replacement was performed for the treatment of patients with predominant (≥80%) axial LBP originating from lumbar DDD. Indications and contraindications for this procedure have been thoroughly outlined previously [15,17,33–37]. Radiculopathy was considered a clear contraindication against TDR. Patients with a history of previous revision surgery as well as patients with combined fusion and TDR procedures were excluded from participation in this study. A summary of exclusion criteria from this study is listed in Table 1.

All patients were nonresponders to an intensive inpatient and outpatient conservative treatment program conducted over a minimum 6-month period.

The preoperative diagnosis was made on the basis of lumbar radiographs taken in anteroposterior and lateral views, functional flexion/extension images, and preoperative magnetic resonance imaging of the lumbar spine. Patients with previous discectomies were excluded if they had significant leg pain, if Gadolinium-DTPA magnetic resonance imaging revealed any notable scar tissue formation in the spinal canal and/or morphological alterations of the facet joints.

Preoperatively, all patients underwent fluoroscopically guided spine infiltrations to rule out nondiscogenic pain sources. Patients who demonstrated significant and reproducible pain relief (≥50%) following infiltrations of the facet or the sacroiliac joints were not considered candidates for TDR because a discogenic origin of pain was less likely and nonsurgical treatment was the preferred treatment option.

The role of discography in identifying discogenic pain remains debatable. Previous studies showed an equally high