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Technical Report

Biomechanical comparison of a two-level Maverick disc replacement with a hybrid one-level disc replacement and one-level anterior lumbar interbody fusion

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Abstract

BACKGROUND CONTEXT: Multilevel lumbar disc disease (MLDD) is a common finding in many patients. Surgical solutions for MLDD include fusion or disc replacement. The hybrid model, combining fusion and disc replacement, is a potential alternative for patients who require surgical intervention at both L5–S1 and L4–L5. The indications for this hybrid model could be posterior element insufficiency, severe facet pathology, calcified ligamentum flavum, and subarticular disease confirming spinal stenosis at L5–S1 level, or previous fusion surgery at L5–S1 and new symptomatic pathology at L4–L5. Biomechanical data of the hybrid model with the Maverick disc and anterior fusion are not available in the literature.

PURPOSE: To compare the biomechanical properties of a two-level Maverick disc replacement at L4–L5, L5–S1, and a hybrid model consisting of an L4–L5 Maverick disc replacement with an L5–S1 anterior lumbar interbody fusion using multidirectional flexibility test.

STUDY DESIGN: An in vitro human cadaveric biomechanical study.

METHODS: Six fresh human cadaveric lumbar specimens (L4–S1) were subjected to unconstrained load in axial torsion (AT), lateral bending (LB), flexion (F), extension (E), and flexion-extension (FE) using multidirectional flexibility test. Four surgical treatments—intact, one-level Maverick at L5–S1, two-level Maverick between L4 and S1, and the hybrid model (anterior fusion at L5–S1 and Maverick at L4–L5) were tested in sequential order. The range of motion of each treatment was calculated.

RESULTS: The Maverick disc replacement slightly reduced intact motion in AT and LB at both levels. The total FE motion was similar to the intact motion. However, the E motion is significantly increased (approximately 50% higher) and F motion is significantly decreased (30%–50% lower). The anterior fusion using a cage and anterior plate significantly reduced spinal motion compared with the condition ($p<.05$). No significant differences were found between two-level Maverick disc prosthesis and the hybrid model in terms of all motion types at L4–L5 level ($p>.05$).

CONCLUSION: The Maverick disc preserved total motion but altered the motion pattern of the intact condition. This result is similar to unconstrained devices such as Charité. The motion at L4–L5 of the hybrid model is similar to that of two-level Maverick disc replacement. The fusion procedure using an anterior plate significantly reduced intact motion. Clinical studies are recommended to validate the efficacy of the hybrid model.

Keywords: Maverick; Total disc replacement; Fusion; Biomechanics

FDA device/drug status: investigational for this indication (Medtronic Maverick disc replacement).

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Introduction

Degenerative disc disease is a potential source of low back pain [1]. With the failure of conservative treatment, fusion is one of the treatment options that can reduce pain and improve disability [2]. The success rate of fusion has been reported varying between 65% and 93% [3–5]. Many biomechanical and clinical studies have suggested that fusion can lead to accelerated adjacent-level degeneration [6–8]. Based on these considerations, there is increasing interest toward different kinds of motion preservation devices. An artificial disc is one of the options that can preserve motion and presumably reduce stresses on adjacent levels [7].

Multilevel lumbar disc disease (MLDD) is common in many asymptomatic and symptomatic patients. MLDD originates from a multifactorial combination of traumatic, genetic/hereditary, social (tobacco), physical (obesity), and senescence factors [9–11]. Limited number of studies in the literature showed mixed success of the artificial disc surgery for MLDD. Bertagnoli et al. observed significant improvement in clinical and radiologic findings in patients with multilevel disc prosthesis using Pro-Disc. They demonstrated a patient satisfaction rate of 93% [9]. In contrast, Siepe et al. observed that multilevel disc replacement with Pro-Disc had significantly higher complication rate and inferior outcome compared with one-level disc replacement [11]. SariAli et al. emphasized that two-level disc replacement with Charité did not restore normal kinematics in 50% of the cases [10].

An alternative to the multilevel Maverick disc replacement procedure is to apply the hybrid model by combining fusion (L5–S1) and disc replacement (at L4–L5). The hybrid model may be useful for patients who are considering two-level disc replacement at L4–S1 or for patients who have pathologic conditions at L5–S1 that are not suitable for disc replacement. This hybrid model had promising early clinical results in 13 patients [12]. However, no studies have defined the comparative biomechanical characteristics between two-level Maverick total disc prosthesis at L4–S1 level and the hybrid model (one-level Maverick at L4–L5 and fusion with anterior lumbar interbody fusion [ALIF] and anterior Pyramid plate at L5–S1). Using multidirectional flexibility testing and an in vitro human cadaveric model, the goal of the current study is to describe the biomechanical properties of a two-level Maverick disc replacement at L4–L5, L5–S1, and a hybrid consisting of a L4–L5 disc replacement with a L5–S1 ALIF. The hypothesis of this experimental study is Maverick total disc replacement preserves motion in all directions; Maverick disc replacement at L4–L5 maintains the same motion pattern above fused L5–S1 or mobile L5–S1 using the total disc replacement (TDR).

Materials and methods

Specimen preparation

Six fresh human cadaveric lumbar spines from L4 to S1 (4 male and 2 female; average age range, 42–58) were harvested, after testing with anteroposterior and lateral radiographs to exclude specimens with gross spinal pathology. Dual-energy X-ray absorptiometry (Lunar Prodigy, GE, Louisville, KY, USA) was performed at L4–S1 in anteroposterior position to determine the average bone mineral density (BMD) of each specimen. The mean BMD score was 0.98 g/cm^2. The specimens that were potted using polyurethane resin in a similar manner are discussed in further detail in our previous studies [13,14].

Biomechanical testing

Unconstrained and nondestructive pure moments in axial torsion (AT), lateral bending (LB), and flexion-extension (FE) were applied to each specimen under 0.05 Hz and $\pm$7.5 Nm sinusoidal waveform with MTS Bionix 858II spine simulator (MTS, Eden Prairie, MN, USA).

Three load cycles were applied for each loading condition with the last cycle used for data analysis. The spine simulator consists of an AT actuator and two rotational actuators for LB and FE. These actuators were mounted on the upper side of the test machine. A low-friction slide table mounted on the lower side allowed pure-bending moments to be applied to the specimen.

One hundred Newton of axial compression load was maintained throughout each test. The small axial load was selected not to damage the specimen. The displacement of each marker in the three-dimensional space was recorded at 10 Hz with an OptoTrak Certus video tacking system (NDI, Ontario, Canada). The relative motion between L4 and L5 and L5–S1 was calculated with spatial coordinate transformations based on optical markers' positions. The video tracking system had 0.1 mm of spatial accuracy for each optical diode and approximately 0.1° in rotation for each vertebra.

All biomechanical tests were performed in the following sequence: intact, one-level Maverick disc arthroplasty at L5–S1 level, two-level Maverick disc arthroplasty at L4–S1 level, and a hybrid model using one-level Maverick disc arthroplasty and one-level fusion. (The caudal level, L5–S1 disc implant was removed and replaced with an ALIF using the Pyramid plate.)

Surgical technique

The Maverick total discs (Medtronic Sofamor Danek, Inc., Memphis, TN, USA) were implanted according to the manufacturer specifications (Fig. 1) [12,15]. The Pyramid plate (Medtronic, Memphis, TN, USA) was implanted to provide supplemental rigid fixation to ALIF at L5–S1 level. In vivo solid fusion was simulated as a fusion by using the technique, which is mentioned above (Fig. 2).

Data analysis and statistics

One-way repeated measures analysis of variance was used to analyze the motion data. Post hoc Student-Newman-Keuls