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Basic Science

Kinematic and fatigue biomechanics of an interpositional facet arthroplasty device

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Abstract

BACKGROUND CONTEXT: Although approximately 30% of chronic lumbar pain can be attributed to the facets, limited surgical options exist for patients. Interpositional facet arthroplasty (IFA) is a novel treatment for lumbar facetogenic pain designed to provide patients who gain insufficient relief from medical interventional treatment options with long-term relief, filling a void in the facet pain treatment continuum.

PURPOSE: This study aimed to quantify the effect of IFA on segmental range of motion (ROM) compared with the intact state, and to observe device position and condition after 10,000 cycles of worst-case loading.

STUDY DESIGN/SETTING: In situ biomechanical analysis of the lumbar spine following implantation of a novel IFA device was carried out.

METHODS: Twelve cadaveric functional spinal units (L2–L3 and L5–S1) were tested in 7.5 Nm flexion-extension, lateral bending, and torsion while intact and following device implantation. Additionally, specimens underwent 10,000 cycles of worst-case complex loading and were testing in ROM again. Load-displacement and fluoroscopic data were analyzed to determine ROM and to evaluate device position during cyclic testing. Devices and facets were evaluated post testing. Institutional support for implant evaluation was received by Zyga Technology.

RESULTS: Range of motion post implantation decreased versus intact, and then was restored post cyclic-testing. Of the tested devices, 6.5% displayed slight movement (0.5–2 mm), all from tight L2–L3 facet joints with misplaced devices or insufficient cartilage. No damage was observed on the devices, and wear patterns were primarily linear.

CONCLUSIONS: The results from this in situ cadaveric biomechanics and cyclic fatigue study demonstrate that a low-profile, conformable IFA device can maintain position and facet functionality post implantation and through 10,000 complex loading cycles. In vivo conditions were not accounted for in this model, which may affect implant behavior not predictable via a biomechanical study. However, these data along with published 1-year clinical results suggest that IFA may be a valid treatment option in patients with chronic lumbar zygapophysial pain who have exhausted medical interventional options.

Keywords: Biomechanics; Facet joint; Facet pain; Facet resurfacing; Interpositional arthroplasty; Motion preservation

FDA device/drug status: Investigational (Glyder Facet Restoration System).

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Introduction

Although the leading cause of chronic low back pain is degenerative disc disease, the facet joints are responsible for approximately 30% of chronic lumbar pain [1,2]. Unfortunately, limited treatment options and difficulties in differential diagnoses leave many patients with only temporary palliative management such as medial branch blocks or rhizotomy [3]. Although lumbar arthrodesis exists as a long-term treatment option, this invasive procedure is not generally supported for facetogenic pain [4–6].

Previous efforts at facet dysfunction treatment have been attempted with total facet replacement devices, such as the TOPS (Premia Spine, Israel) and ACADIA (Globus Medical, Audubon, PA, USA) systems. Because of the requirement of extensive anatomic structure removal and limited success in the treatment of specific facetogenic pain, they have been repurposed for the treatment of lumbar stenosis [7,8].

Although similar in concept to the artificial resurfacing of other synovial joints, the application of interpositional arthroplasty to the facet joint is novel, and no biomechanical testing has been published. To characterize the effect of an interpositional facet arthroplasty (IFA) device on the facet joint, kinematic testing of human cadaver functional spinal units (FSUs) was performed in the general manner described by Wilke et al. [9]. In addition, a worst-case loading profile was applied over 10,000 repetitions to determine the robustness of device fixation. By testing specimens via load-displacement and comparing intact and implanted conditions, as well as imparting worst-case cyclic loading, it is hypothesized that an IFA device can be shown to maintain placement and facet functionality.

Materials and methods

Specimen preparation

Seven lumbar sacral spines with mild to moderate degeneration and fatalities unrelated to pathology of the lumbar spine were used to create 12 FSUs, 6 test units each for L2–L3 and L5–S1 (Table 1). Two of the seven FSUs were unable to be used because of advanced degeneration. These FSUs were dissected down to osteoligamentous tissues and embedded in rigid polyurethane. These FSU levels (L2–L3 and L5–S1) represent the anatomical extremes of the lumbar spine that are indicated for use with the device. The other indicated levels, L3–L4 and L4–L5, have characteristics such as facet orientation angles, compliance, and ROM that lie between the bounds of L2–L3 and L5–S1. Therefore, because of this ability to interpolate acquired results to these center levels as well as cost and time considerations, the L2–L3 and L5–S1 sections were determined to provide a full representative device usage range. Specimens were all male with age ranging from 43 to 69 years (mean 54.7 years). Tests were performed at room temperature and specimens kept moist with saline soaked gauze.

Testing equipment

Testing was performed using an 858 Mini Bionix II frame with a six-axis spine gimbal (MTS, Eden Prairie, MN, USA; used in previously published studies) and pneumatic follower load actuators running through bilateral cables attached to the cups holding the specimen (Fig. 1) [10,11]. Displacements were tracked using a Vicon camera tracking system with MX20+ cameras (Vicon Motion Systems, Denver, CO, USA). Infrared reflecting marker arrays were attached to vertebral bodies via screws, and dorsal facet fiducial points were registered with a reflective stylus. Radiographic imaging was performed with a C arm (Philips BV Pulsera, Type: 718093; Philips, Andover, MA, USA). The IFA test article used was the Glyder Facet Restoration Device (Zyga Technology, Inc, Minnetonka, MN, USA), which consists of two articulating PEEK-OPTIMA wafers, each constructed with one smooth articulating surface and one textured fixation surface and an encapsulated radiographic marker.

Test protocol

ROM testing

After initial imaging and fiducial point registration, specimens were tested in the intact condition. The preload path

Table 1
Cadaveric demographics and lumbar sections used for testing

Specimen	Age (y)	Sex	Height (cm)	Weight (kg)	COD
#1 L2–L3	54	Male	185	101	Brain cancer
#1 L5–S1					
#2 L2–L3	55	Male	165	68	Cardiac failure
#2 L5–S1					
#3 L2–L3	53	Male	173	68	COPD
#3 L5–S1					
#4 L2–L3	47	Male	191	100	Cardiac failure
#5 L5–S1	43	Male	188	122	Renal failure
#6 L2–L3	69	Male	178	104	Cardiac failure
#6 L5–S1					
#7 L2–L3	62	Male	185	48	Lung cancer
#7 L5–S1					
Average (SD)	**54.7 (8.7)**	—	**180.7 (9.2)**	**87.3 (26.2)**	—

COD, cause of death; COPD, chronic obstructive pulmonary disease; SD, standard deviation.