Project: Alterations in Segmental Stability with Differing Lumbar Interbody Cages, including Expandable Cages and Fusion Techniques – An In Vitro and Finite Element Investigation – Continutation to include more variations

Site: University of Toledo	
Site Director: Vijay Goel, PhD	
PI's name: Vijay K. Goel, PhD	**Proposed Budget:** **(including 10% indirects)**: $40,000
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Need and Industrial Relevance: The biomechanical goals of lumbar interbody fusion are to restore alignment, restore intervertebral and foraminal height, and promote fusion by providing immediate stability (ability to limit segmental motions under physiologic load). Interbody cages can aid in achieving these goals, especially bone graft resorption/disc height loss. Biomechanical and clinical data suggest that PLIF stand-alone cages may not provide adequate stability and supplemental stabilization may be needed for a more predictable biomechanical environment conducive to fusion. However, besides the PLIF approach to place cages, a number of other approaches (e.g., far lateral - LIF, transforaminal - TLIF and anterior – ALIF) are used. The hypothesis for the present study is that some of these approaches preserve the structures that impart stability to the segment and thus stand-alone cages placed using those approaches may provide sufficient stability without additional posterior instrumentation (360 constructs). Additionally, the size, footprint, and end plate support for the cages differ and may play a role in the surgical success. Such a comprehensive study is somewhat lacking in the literature. The outcome may enable industry with the design and development of an appropriate cage which will be very effective the imparting the stability to the decompressed segment.

Project Goals: To undertake a cadaver study and a finite element model study to investigate the effects of various surgical procedures, cage designs and shapes on the construct stability. Some of these aspects will be pursued in a cadaver model and remaining in an experimentally validated finite element model of the ligamentous L1-S1 spine.

Objectives: • In consultation with the Industrial Advisory Board and faculty, develop the testing protocol.

- Formulate the group comprising at least one graduate student, an undergraduate student, a post-doctoral fellow, and a senior faculty for the project. The group will interact with Industry clients and a team of surgeons to ensure that research is clinically relevant and will yield clinically relevant data.
- Undertake various steps listed below in the Approach Section.

Approach (Research Methods): Fresh spinal specimens will be used to assess the fixation ability of a few cages with and without the posterior spinal instrumentation. (We plan to use 10 spines specimens for this part of the project.) The protocol for such study has been well defined at the authors' lab, having done similar studies in the past. Since the cadaver studies are expensive and thus not practical to undertake the assessment of several cage variations using cadaver model, we will supplement the data using the finite element approach. The FE model relevant for such studies has been developed by our group in the past. Based on the model results thus far, it appears that the foot print and different

approaches to fuse the segment do effect the biomechanics. Thus, we will continue this work in the coming year, to include newer designs like the mini cages and wrap up the cases that couldn't be done in year 1. Scope of work far exceeded the time to complete in year 1.

Milestones:

- Develop protocol and finish pilot testing – ~~Sep~~ Dec 30, 2015~~4~~
- Finish collecting all data, and pursue the Finite Element Modeling – ~~Feb~~ April 28, 2016~~5~~
- Data Analyses , publications (abstracts and manuscripts) and report – July~~May~~, 30, 2016~~5~~

Outcome/Deliverables:
Including:

- *Presentation Update* - beginning of 2016~~5~~ at the University of Toledo, Ohio
- *Final Report including results* - July~~ne~~ 30, 2016~~5~~

Impact: How the project may be transformative and/or benefit society:
The outcome of the proposed project may enable industry with design and development of a new type of cage that will impart stability when used as a stand alone device.

Project Duration & General Budget Outline:

Personnel	$	15,000
Supplies/Specimens	$	16,000
Imaging	$	5,000
Total Direct	$	36,000
Indirects (10%)	$	3,600
Total	$	39,600

Duration: 1 year

Start Date: August 1, 2014 **End Date**: June 30, 2015

Please send this document along with your *IP Checklist for Projects* to
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