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Basic Science

Closure of the annulus fibrosus of the intervertebral disc using a novel suture application device—in vivo porcine and ex vivo biomechanical evaluation

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Abstract

BACKGROUND CONTEXT: Defects in the annulus fibrosus (AF) remain a challenge in the surgical treatment of lumbar disc herniations with persistent defects, allowing potential re herniation of nucleus pulposus (NP) tissue. A cervical porcine model was chosen to simulate human lumbar intervertebral disc (IVD).

PURPOSE: The aim of this study was to determine the technical feasibility of closure of the AF of the IVD using a novel minimally invasive Kerrison-shaped suture application device.

STUDY DESIGN: Ex vivo biomechanical and in vivo porcine device evaluations were performed.

METHODS: Ex vivo biomechanical evaluation: 15 porcine spinal units were explanted and subjected to mock discectomy. The annular defect was closed using 2-0 non-absorbable (ultra-high molecular-weight polyethylene, UHMWPE) suture and Dines knot. The knot was backed up with two, three, or four throws. The spinal unit was subject to 4000 cycles of flexion/extension with 1500 N of axial load, and assessed for knot slippage. In vivo porcine device evaluation: three pigs (53–57 kg) were anesthetized and underwent a ventral surgical approach to the cervical spine. The AF of two discs was incised, and simulated partial NP discectomy was performed. The defect was closed at one level using the AnchorKnot device to apply the suture with a Dines knot and four throws. The pigs were observed for 4 weeks before euthanasia, allowing 7T magnetic resonance imaging (MRI) and histological evaluation.

FDA device/drug status: Not approved for this indication (AnchorKnot Suture Passer, AnchorKnot Knot Pusher).

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

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RESULTS: A Dines knot with four throws experienced no slippage after 4000 cycles. This configuration was tested in vivo. Clinically, the neurological examination in treated pigs was normal following surgery. Histological and MRI assessment confirmed sustained defect closure at 4 weeks. There was no reaction to the suture material and no NP extrusion at any of the sutured levels.
CONCLUSIONS: This study demonstrates that it is technically feasible to perform AF defect closure in a porcine model. This novel device achieved AF defect closure that was maintained through 4 weeks in vivo.

Keywords: Annular repair; Annulus fibrosus closure; Disc repair; Discectomy; Intervertebral disc; Minimally invasive; Porcine model; Re-herniation; Surgery; Suture application device

Introduction

Herniation of the nucleus pulposus (NP) through the annulus fibrosus (AF) of the intervertebral disc (IVD) is a recognized cause of low back and radicular leg pain [1]. The surgical treatment of this condition involves partial NP discectomy with good clinical outcomes reported [2]. The procedure involves surgical removal of herniated NP tissue including any sequestered or detached fragments of NP and endplate. It does not, however, address the tear or fissure in the AF, which is the path through which the herniation occurred. In some cases, a surgical annulotomy may be required to perform the partial NP discectomy, and this leaves a persistent defect in the AF immediately postprocedure. AF defects may be important to consider when recognizing the risk of reherniation following lumbar discectomy [3]. Carragee et al reported that larger AF defects postdiscectomy are a risk factor for recurrent disc herniation and poor outcome [3]. The same group reported recurrent IVD herniation requiring surgery in 10% of cases following NP discectomy. They also observed a 25% loss of disc height 2 years postprocedure and showed higher recurrent herniation rates associated with larger annular defects [4].

Defects in the AF of the IVD thus remain a surgical challenge, and efforts have been made to develop new techniques for their closure and repair. Various techniques have been developed to effect closure of AF defects and stimulate healing and regeneration. The IVD is a relatively avascular structure with low cell numbers available for a healing response to injury. It is therefore likely that achieving AF repair will involve combined mechanical and biological strategies [5].

With the advent of minimally invasive surgical (MIS) approaches for lumbar microdiscectomy, surgical access and anatomy limit the types of devices that permit AF repair. Devices are currently being developed to allow surgical closure of the AF through standard and minimally invasive approaches to the spine [6–9]. In this study, a novel Kerrison-shaped AF closure device (AnchorKnot Tissue Repair System, Anchor Orthopedics XT Inc.) was evaluated. This device delivers a 2-0 ultra-high molecular-weight polyethylene (UHMWPE) suture with Dines knot to the AF, facilitating closure through commonly used surgical approaches. The purpose of this study was to evaluate the feasibility of AF closure in an ex vivo biomechanical and in vivo preclinical model.

Materials and methods

The AnchorKnot suture-passing device is designed for use in the lumbar spine. A pig cervical spine model was chosen to model human lumbar IVDs based on the comparative size of the discs. Porcine cervical IVD is a well-recognized animal model for human lumbar spine comparison based on its geometry, anatomy [10], and function [11]. Due to anatomical similarities, the ventral surgical approach to the cervical spine of a pig is similar to the anterolateral (Smith-Robinson) surgical approach.

We performed bench-top evaluation of the suture-knot constructs, followed by ex vivo biomechanical testing of AF closures performed on explanted pig cervical spinal units. Based on biomechanical results, additional in vivo evaluation was performed to assess the feasibility of defect closure and determine knot integrity for 4 weeks postoperatively.

The suture used throughout the study was 2-0 UHMWPE.

A Dines knot (Fig. 1) was selected and used throughout the study based on biomechanical and engineering factors. It is commonly used in arthroscopic surgery and has shown superiority over other arthroscopic knots in several biomechanical studies [12–15].

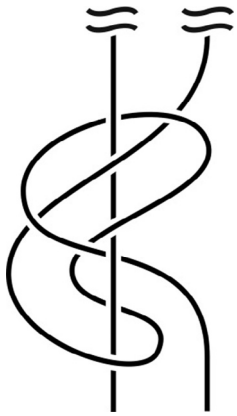

Fig. 1. A Dines knot.