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Insertion loads of the X STOP interspinous process distraction system designed to treat neurogenic intermittent claudication

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Abstract An interspinous process implant has been developed to treat patients suffering from neurogenic intermittent claudication secondary to lumbar spinal stenosis. As most patients who suffer from spinal stenosis are over the age of 50 and may have weaker bones, it is imperative to know how bone mineral density (BMD) correlates with lateral spinous process strength. The study was undertaken to characterize the lateral failure loads of the spinous process, correlate the failure loads to BMD, and compare the failure loads to the loads required to insert an interspinous process implant. Spinous process lateral failure loads were assessed, correlated to BMD, and compared to the loads required to insert an interspinous process implant. Mean spinous process

failure loads were significantly greater than the lateral insertion load of the interspinous process implant. There was a significant relationship between the BMD and spinous process failure load. The technique used to insert the interspinous implant poses little risk to spinous process failure. There is ample margin of safety between the insertion loads and spinous process failure loads. The significant relationship between BMD and spinous process failure load suggests that patients with lower BMD must be approached with more caution during the implant insertion procedure.

Keywords Spinous process · Neurogenic intermittent claudication · Stenosis · Lumbar · Bone mineral density

Introduction

Lumbar spinal stenosis, which typically affects a patient population beyond their fifth decade, was first described by Verbiest as neurogenic intermittent claudication (NIC) [18, 19]. Degenerative changes of the intervertebral discs, intervertebral joints, and ligamentum flavum result a decrease in the dimensions of the lumbar spinal canal and neural foramina, causing compression of the spinal cord, cauda equina, and nerve roots [1, 2, 5, 12, 14, 16]. Symptoms of compression of the lumbar neural structures are manifested as weakness, fatigue, or heaviness of the legs, and occur when patients stand or walk, but not in flexion or while

sitting [4, 14, 19]. Patients with NIC assume flexed postures and avoid extension, which causes bulging of the ligamentum and intervertebral discs [2, 6, 17]. This compression is thought to disrupt neural metabolism as well as mechanically impinge upon neural tissue [1, 2, 12, 13].

Standard treatment of NIC begins with conservative therapy including epidural steroid injections, physical therapy, and anti-inflammatory medications [8–11, 15]. When these modalities are no longer effective, decompressive surgery is the next therapeutic option. Decompressive surgery alone has variable satisfaction rates providing the spine remains stable from previous surgery, degenerative spondylolisthesis is absent, and

lumbar scoliosis is less than 20° [7–11]. However, risks are inherent with this procedure [10, 11, 16].

A consequence of an elderly patient population is that decompressive surgery with general anesthesia may not be a therapeutic option, due to high risk comorbid conditions [7, 8, 10, 11]. Previous studies have shown that the decompressive surgery success rate significantly decreases when comorbid conditions exist [8, 10]. Katz et al. [10] reported poor results for the long-term outcome of decompressive laminectomy, where 17% had a repeat operation, 43% met the criteria for a poor outcome, and increased comorbidity increased the risk of a poor outcome [11]. Hilibrand et al. [8] associated major postoperative complications with the decompressive surgical procedure. To treat these patients and others suffering from lumbar spinal stenosis, researchers have developed a novel implant, the X STOP interspinous process distraction system (X STOP). The X STOP is placed between the spinous processes at the stenotic level under local anesthesia. The implant prevents narrowing of the spinal canal and neural foramina during extension. The implant is inserted between the spinous processes from a lateral approach through the interspinous ligament, and its position is maintained by the supraspinous ligament posteriorly, the lamina anteriorly, and two wings located on the implant laterally (Fig. 1).

Bone quality is a concern, as some patients in this patient population may have weaker bones. It is there-

fore important to know how bone mineral density (BMD) correlates with lateral spinous process strength, as a means to assess the risk of spinous process failure during the interspinous implant insertion procedure. A correlation between the square of the BMD and insertion load allows a comparison to be made between the strength of the spinous process and the force necessary to insert an interspinous implant. Wren et al. [21] have shown BMD^2 to be a better predictor than BMD of failure load, as BMD overestimates the failure load.

The purpose of this study was to measure 1) the lateral loads necessary to place the implant, 2) the lateral failure loads of the spinous processes if the implant was forced against the spinous process during insertion, and 3) determine if a significant relationship existed between BMD and the spinous process failure load. We hypothesized that the insertion loads would be significantly lower than the failure loads of the spinous processes, and that the spinous process failure load would increase with BMD.

Materials and methods

Insertion loads

Ten lumbar motion segments (L3–L5) were procured from four cadaver specimens and cleaned of all muscle and adipose tissues. The most caudal and cranial vertebrae from each specimen were secured in polymethylmethacrylate (PMMA) and placed in an axial loading frame (MTS 858, Eden Prairie, MN, USA). Interspinous space between adjacent spinous processes was measured using the same technique that is used clinically to determine an appropriately sized interspinous implant (X STOP, St. Francis Medical Technologies, Alameda, CA, USA). Implant sizes ranged between 10 mm and 12 mm. A spacer and adjoining tapered tissue expander were secured to the load cell and the hydraulic cylinder of the loading frame, and the interspinous process space of individual specimens was positioned directly beneath the spacer (Fig. 2a). The spacer was advanced through the interspinous process space at 50 mm/min until the implant was between the spinous processes (Fig. 2b). The maximum load during insertion was measured, and descriptive statistics of the mean insertion load were calculated and compared to the mean spinous process failure load as described below.

Spinous process failure loads

Seven lumbar (L3–L5) cadaveric spine specimens, average age 64, were procured and cleaned of all muscle and adipose tissues. Specimens were then placed in 15 cm of water and BMD was measured using DEXA (QDR

Fig. 1 A schematic of the X STOP interspinous implant

Fig. 2 Schematic of the procedure used to measure the insertion load of the X STOP. **a** The X STOP is placed above the interspinous space. **b** The crosshead of the axial loading frame is advanced until the implant is placed between the spinous processes

4000, Hologic, Bedford, MA, USA). The specimens were then further dissected into individual vertebrae and secured in PMMA such that only the spinous process and part of the lamina were exposed. Prior to testing, each vertebra was randomized into one of three categories based on where the spinous process was to be loaded in the lateral direction: cranial, middle, and caudal (Fig. 3). The cranial-caudal height of each spinous process was measured. The processes randomized into the cranial group were contacted by the implant at 75% of the spinous process height from the caudal

Fig. 3 A schematic of the three loading positions used to test the lateral failure strength of the spinous processes. The processes randomized into the Cranial group were contacted by the implant at 75% of spinous process height from the caudal surface. The Middle and Caudal groups were contacted by the implant at 50% and 25% of the spinous process height from the caudal surface respectively

surface. The middle and caudal groups were contacted by the implant at 50% and 25% of the spinous process height from the caudal surface, respectively. A tapered tissue expander was secured to the hydraulic cylinder of the loading frame and each specimen was secured to the base of the loading frame in the lateral position such that each spinous process was in a horizontal position and parallel to the base of the loading frame. The tissue expander was placed lateral to the spinous processes in the cranial, middle, or caudal position, and its posterior tip was positioned 4 mm from the posterior aspect of each process. The tissue expander was advanced toward each spinous process at 50 mm/min and loaded each process until failure. The mean failure load was compared to the previously measured insertion loads using an unpaired, two-tailed *t*-test with a level of significance of 0.05. Also, a correlation was performed between the square of the vertebral BMD and the spinous process failure load for each specimen, with a forced regression line through the origin.

Results

There were no spinous process failures during insertion of the X STOP implant. The mean lateral insertion load of the X STOP (65.6 ± 46.2 N, range: 10.5–150.2 N) was significantly less ($P < 0.0001$) than the mean spinous process failure load (316.9 ± 196.5 N, range: 94.7–786.4 N) (Fig. 4). There was no significant difference between the mean failure loads of specimens loaded in the cranial, middle, or caudal aspect of the spinous processes (334.8 ± 217.3 N, 309.4 ± 152.1 N, and 306.5 ± 240.5 N, respectively). There was a significant relationship between the square of vertebral BMD 0.84 ± 0.49 (g/cm²)², range: 0.22–1.99 (g/cm²)² and the spinous process failure load ($P < 0.0001$, Fig. 5).

Fig. 4 The mean insertion load of the X STOP and lateral failure loads of the spinous processes

Fig. 5 The relationship between lateral spinous process failure load and bone mineral density (BMD). The load increases with the square of BMD. The solid horizontal line represents the mean insertion load (65.6 N), the adjacent dashed lines represent $\pm$ one standard deviation (46.2 N)

Discussion

The results of the current study indicate that the X STOP insertion technique poses little risk to spinous process failure. The mean failure load of the spinous process was significantly greater than that of the mean

insertion load of the interspinous implant, and there were no spinous process failures during insertion of the X STOP. Furthermore, the results of the present study are consistent with previous studies. Coe et al. [3] found that a significant correlation exists between spinous process strength and BMD. Wenger et al. [20] showed the spinous process lateral wire pullout strength to be 404 N, and Drummond et al. [4] showed that the spinous process failure load to be 532 N. Differences between the failure loads reported in the current study and those reported by Coe et al. [3], Wenger et al. [20], and Drummond et al. [4] can be attributed to the differences in experimental techniques. The previously cited studies assessed strength using a lateral wire pullout technique and the current study laterally failed the spinous process with a blunt tissue expander.

The mean lateral failure load of the lumbar spinous process is over 4.5 times greater than the load required to insert the X STOP implant. Although, the implants were not inserted manually as is the case clinically, it can be inferred that a sufficient factor of safety is placed on the insertion technique. The technique seems to pose little risk to spinous process failure during insertion. Furthermore, a previous study by Yerby et al. [22] has shown that the maximum in-situ implant loads on the spinous process are an average of 16.3% of the spinous process failure load. Thus, the implant poses little risk to spinous process failure in vivo as well.

A difficult parameter to measure is the increase or decrease in strength over time as implants interface with spinous processes. The goal of this study though, was to determine whether or not forcing an interspinous implant against the spinous process during insertion posed a risk to spinous process failure. The results of this study suggest that the insertion technique provides a sufficient margin of safety, and the technique seems to pose little risk to spinous process failure. However, patients with a lower BMD must be approached with extra caution due to the significant relationship between BMD and spinous process strength.

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