Replication of Impact Parameters from Cadaveric Lumbar Interbody Fusion Using a Benchtop Device

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INTRODUCTION: Transforaminal lumbar interbody fusion (TLIF) involves the insertion of an interbody fusion device (IFD) into the disc space to relieve lower back pain caused by various disc pathologies.[1] The IFD is attached to an insertion tool and inserted via malleting, which can damage the IFD due to the high forces and energies imparted into the system.[2] While cadavers have been used to refine surgical approaches, limited data exist on impact force and energy during insertion of IFDs, and inconsistency in cadaveric anatomies and pathologies introduces variances in data and testing conditions.[2] The objective of this work was to design and validate a drop weight benchtop device which replicates cadaveric loading conditions for quantifying impaction forces and energies during insertion of IFDs. Four key impact waveform parameters were quantified: (i) duration of the impact event, (ii) area under the impulse curve, (iii) peak force, and (iv) initial slope of the waveform.

METHODS: The benchtop device is composed of four main components integrated into an aluminum frame: an insertion tool and implant; a compression system; a drop weight and tower; and impact, displacement, and compression sensors (**Fig. 1**). Pilot testing of the effect of drop weight material on impact duration revealed the impact duration with an aluminum weight most closely matched cadaveric impact duration, compared to steel and zinc (60 cm drop height, 1.0 lb. drop weight) (**Fig. 2**). Additionally, the drop height range was increased from 20-60 cm to 60-120 cm to replicate cadaveric peak force. To improve alignment and ease of testing, two platens were attached to a frictionless rail. Compression clamps and alignment bolts secured to the frame improved consistency of the lateral compressive forces acting on the platens (**Fig. 1**). To prepare for insertion testing, an IFD was attached to the insertion tool, and the nose of the IFD was seated between two 3-mm thick pieces of 20 PCF SAWBONES® placed on the interior of the platens. Springs on each side were each laterally compressed to 200 N to simulate the compressive load of supine patients.[2,3] For each insertion test, a 1.0 lb. aluminum drop weight was released from a prescribed height (60, 70, 80, 90, 100, 110, or 120 cm) and struck the insertion tool, which was repeated until the IFD had traveled 1.5 times its height. For each drop height, 8 insertions were performed (n=8). Using the TLIF approach, discectomies of two cadavers without spinal pathologies were performed at each level from T10 to S1, and an IFD was inserted at each level using a mallet, for a total of n=8 insertions per cadaver. Data from both cadavers was consolidated into a single group. In benchtop and cadaver groups, an impact sensor fixated atop the insertion tool measured the impact waveform for each strike. Statistical analyses were performed to compare the cadaver group to each benchtop group, and significance level was set at $\alpha = 0.05$.

RESULTS: Three of the four impact waveform parameters from cadaver testing were replicated in the benchtop system. The duration of the impact event for the cadaver group was matched by all drop heights (**Fig. 3a**). The area under the impulse curve for the cadaver group was matched by the two largest drop heights of 110 and 120 cm (**Fig. 3b**). The peak force for the cadaver group was matched by drop heights of 90, 110, and 120 cm (**Fig. 3c**). In contrast, the initial slope of the waveform for the cadaver group was higher than that for all drop heights tested in the benchtop system (**Fig. 3d**).

DISCUSSION: A sensor-outfitted benchtop impaction device has been developed and validated for the replication of impact parameters from cadaveric lumbar interbody fusion. The device was validated by performing insertions across a range of drop heights and comparing the waveforms to cadaveric data. Aluminum drop weights and higher drop heights resulted in improved replication of impact duration, area under the curve, and peak force from cadaveric impaction data. Frictionless rails, compression clamps, and alignment bolts allowed for easier setup and more consistency between insertions. Ongoing work includes outfitting the device with velocity sensors to further investigate energy absorption in the system and modifying the device to allow for the testing of anterior lumbar interbody fusion (ALIF) devices.

SIGNIFICANCE/CLINICAL RELEVANCE: As cadavers are not readily available and vary with anatomy, using a benchtop model enables accurate and repeatable simulation of the loading conditions during TLIF procedures. Additionally, the testing method developed herein may enhance IFD design and analysis, and accelerate the refinement of LIF surgical techniques, to ultimately mitigate intra-operative device damage and failure.

REFERENCES: 1. R. Verma, S. et al. *HSS Journal®.* 2020. **2.** M. A. Adams et al. *Spine.* 2006. **3.** E. F. Owens et al. *J. Manipulative Physiol. Ther.* 2007.
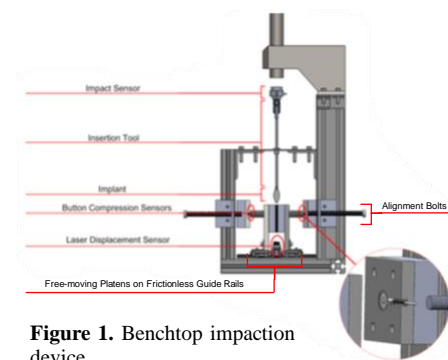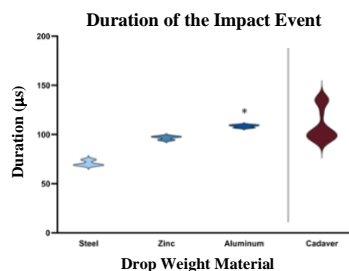
Figure 1. Benchtop impaction device

Figure 2. Duration of impact event for the benchtop device using steel, zinc, and aluminum drop weights at 60 cm drop height with a 1.0 lb. drop weight, compared to that for cadaveric impaction. *not different from cadaveric data
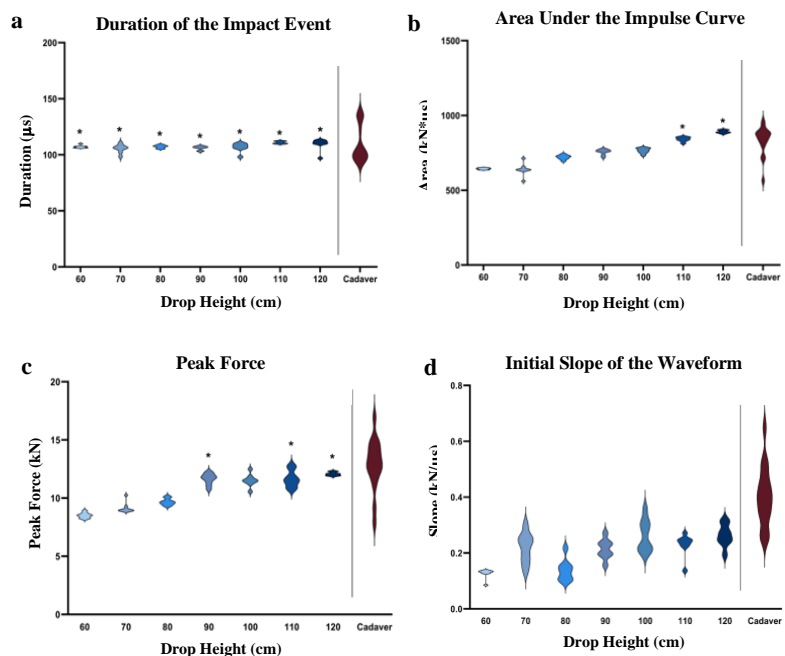

Figure 3. (a) Duration of impact event, (b) area under the impulse curve, (c) peak force, and (d) initial slope of the waveform for the benchtop device as a function of drop height, compared to those for cadaveric impaction. *not different from cadaveric data