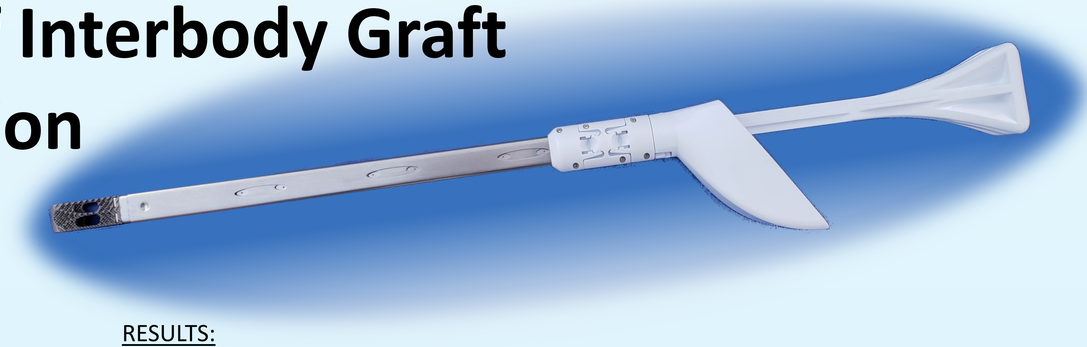
Effects of Cannula Geometry on Flowability of Interbody Graft Material in Spinal Interbody Fusion



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INTRODUCTION:

A critical but often overlooked component of spinal interbody fusion is effective grafting of the interbody space. A variety of graft materials are used to assist with lumbar interbody fusion. These include local bone graft, iliac crest, allografts and a variety of synthetic materials. However, delivery to the interbody space is limited to round end-dispensing funnels, very small cannulas for grafting after cage insertion, or by manual means. Additionally, newer graft materials are often granular or fibrous which increases the challenge of delivering them through current graft delivery instrumentation. A novel interbody fusion implant system[i] has been developed which is intended to address interbody grafting. The system uses a rectangular shaped cannula (Figure 1) attached to an interbody cage with a flow-thru bi-portal geometry that enables a wide variety of materials to be delivered to the full discectomy site after cage insertion and disk height restoration. In this work, we present the results of a flowability study examining the capacity of the system to deliver a variety of graft materials. We also contrast the flowability of the rectangular cannulas with traditional round, end dispensing cannula funnels (Figure 2).

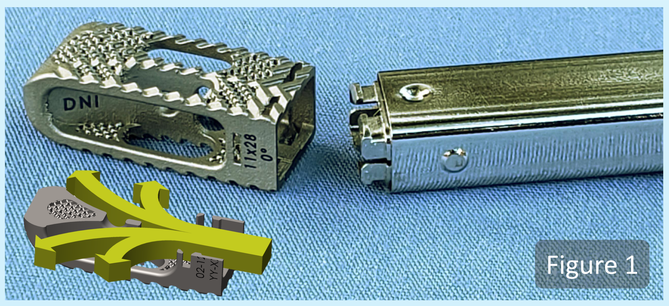

Figure 1

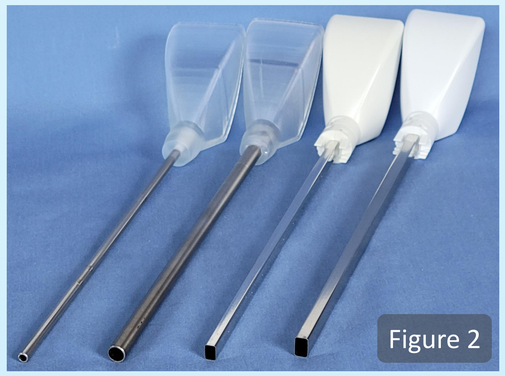
Figure 2

METHODS:

Four different cannula geometries were tested using 4 commercially available graft materials. Two geometries had a round cross-section and two had a rectangular cross-section. The large round cannula had an internal bore diameter of 6.3mm with a cross-sectional area of 31.7mm^2 and represented a commonly used, end-dispensing funnel for interbody grafting prior to cage placement. The small round cannula had an internal bore diameter of 3.2mm with a cross-sectional area of 7.9mm^2. This geometry is representative of a cannula used to post-pack an interbody cage through the inserter interface after cage implantation. The rectangular cannulas had internal dimensions of 4.5mm x 6.7mm and 5.5mm X 8.7mm with cross-sectional areas of 29.8mm^2 and 47.4mm^2, respectively. Figure 3 shows the end view of each cannula and a relative graphic comparison of cannula cross-sections.

A simulated disk space was used to test and visualize the flowability of tested materials (Figure 4). For testing, graft was dispensed directly from the end of the round cannulas as would be seen clinically. The rectangular cannula were attached to small and large bi-portal flow-thru interbody cages[i] with the graft flowing through the cannula as well as through the cage. Again, this simulates the clinical use of the designs. Figure 5 shows the large posterior graft window, open side ports, and central wedge on the cage allowing and directing graft flow-thru.

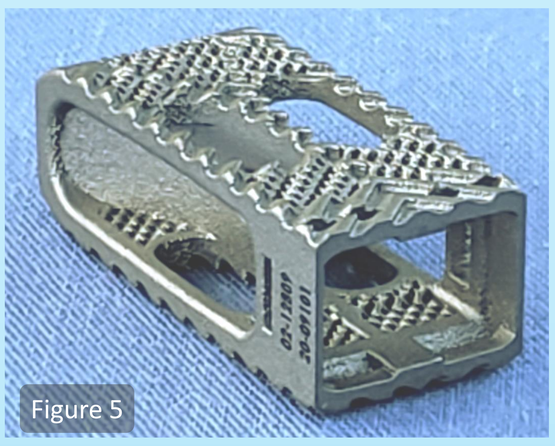
Figure 5

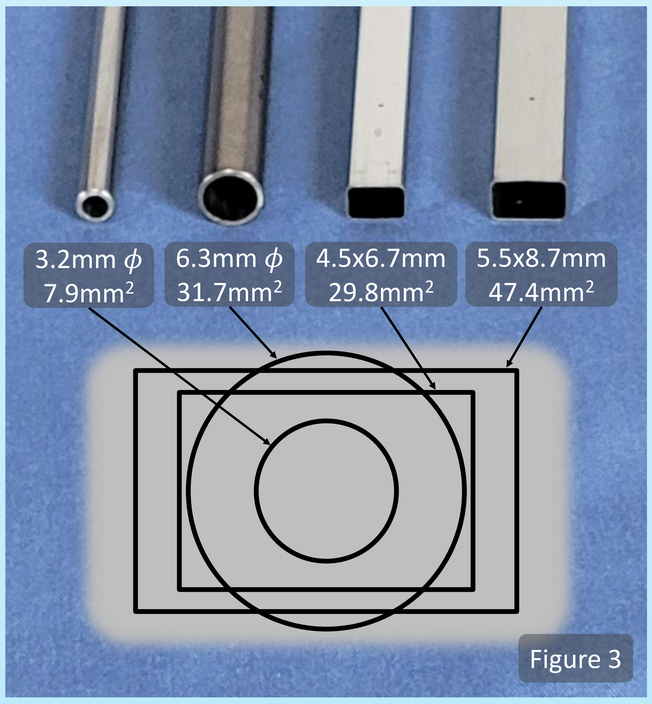

Figure 3

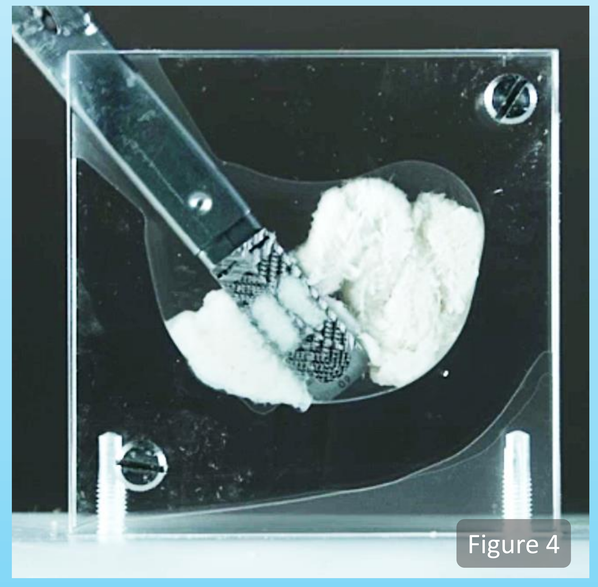
Figure 4

Flowability was manually tested by the lead author and graded on a scale of 1-4 as described below. For each material and cannula geometry tested, the following protocol was used. The cannula was loaded with an amount of bone graft material equal to its internal volume. A plunger was then used to expel the material out the distal end of the cannula. Material with a 1 rating would easily expel from the funnel without resistance. Material with a 2 rating could not be passed unless the cannula was initially filled to only one half its internal volume. Material with a 3 rating would not pass thru the cannula unless small increments of 1-2 ml of graft material was fully expelled from the cannula at a time. Material with a 4 rating could not be passed through the cannula utilizing any method.

Graft materials included (A) entangled allograft fibers, (B) demineralized bone fibers, (C) mineralized allograft chips in a demineralized bone matrix binder, and (D) demineralized bone putty with cortical fibers.

RESULTS:

Table 1 shows the results of the flowability study. In general, more compressible, fibrous, or granular materials proved more difficult to flow. All cannulas were able to pass the materials (C) and (D), although the round cannulas proved more challenging than the rectangular cannula for material (C). Materials (A) and (B) could not be passed through the small round cannula while they could pass through the other cannula sizes. Overall, the flowability of graft material through the rectangular cannulas was superior to the traditional round cannulas.

Cannula Geometry \ Graft	(A)	(B)	(C)	(D)
Rectangular Cannula – 4.5x6.7	2	1	2	1
Rectangular Cannula – 5.5x8.7	2	1	2	1
Round Cannula – 3.2mm	4	4	3	1
Round Cannula - 6.3mm	2	2	3	1

Table 1

DISCUSSION:

While grafting is a critical component of the interbody fusion procedure, few studies have been performed evaluating the flowability of graft material through commonly available funnels. Kleiner, et.al.[ii] reviewed the increase in graft material delivered to the disk space in MIS TLIF procedures through a novel funnel with a rectangular cannula and bi-portal exit ports. An increase in fusion was shown, however this was a single surgeon / single center study utilizing the surgeon's personal custom instrument. Another benchtop study by Ozgur, et.al.[iii] examined the ability to post-fill the disk space after implantation of a lateral cage in a cadaveric model. CT analysis revealed a statistically significant increase in graft material in the disk space after post-fill graft delivery as compared the graft delivered solely thru pre-packing the lateral cage prior to insertion.

Few commercially available systems have been designed specifically to address the challenges of interbody grafting. Multiple implant systems make marketing claims of post-fill grafting capabilities, however most can only graft inside the cage through a small diameter cannula with no option for flowing the graft material into the surrounding disk space. We have shown a rectangular cannula with a flow-thru bi-portal cage design to be more effective at delivering a wider variety of graft materials to the interbody space. The increase in cross sectional area achievable with a rectangular cannula provides the space through which more difficult materials may flow, including challenging material which tended to clog funnels with round cross sections. Additionally, the bi-portal implant enabled the complete filling of the disk space with graft material, both within the cage as well as the surrounding area, after implant insertion and disk space distraction which may be more advantageous for fusion to occur[ii].

SIGNIFICANCE/CLINICAL RELEVANCE:

Grafting the interbody space during spinal fusion is a critical step in ensuring a successful outcome. The use of a rectangular cannula and flow-thru interbody implant has shown the ability to more fully pack the complete interbody space and more easily enable the use of advanced graft materials.

Initial clinical use of the bi-portal interbody cage with a rectangular cannula has confirmed an increase in the amount of graft material routinely delivered to the disk space as well as shown the ability to deliver graft materials traditionally considered difficult to flow. Over the course of the initial 12 cases an average of 12cc of graft material has been delivered to the distracted disc space with as much as 15cc in one case. Graft materials have included challenging materials such as dry cancellous chips and milled local autograft (lamina) passed twice through a Stryker bone mill. Figure 6 shows a 1-week follow-up CT scan of an 11x28x9 lordotic cage with 10cc of dry cancellous chips filling the cage and surrounding disc space. Figure 7 demonstrates the delivery of graft material intra-operatively. Figure 8 shows milled autograft delivered to a simulated disk space during validation testing which closely mirrors the clinical results seen in Figure 7.

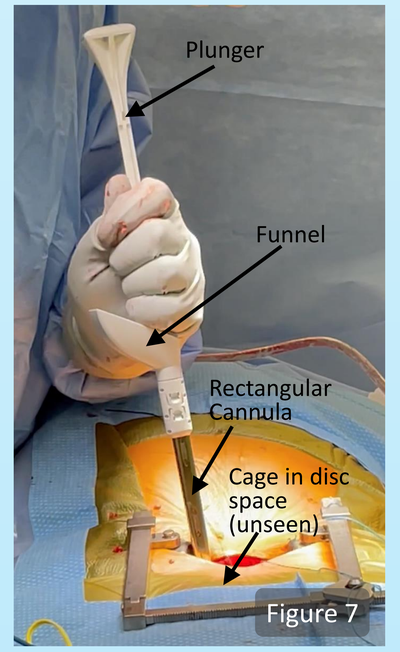

Figure 7

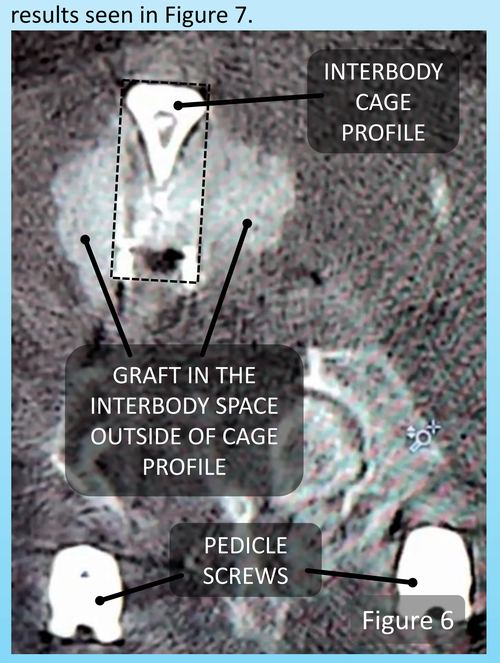

Figure 6

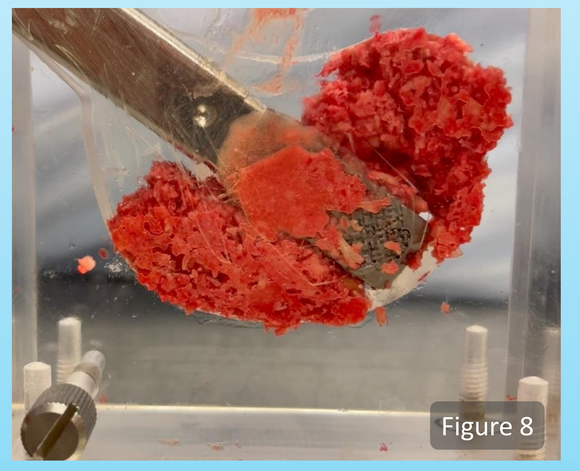
Figure 8

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[i]Kleiner Device Labs, KG2 Surge™
[ii]Kleiner, et.al., https://dx.doi.org/10.2147/MDER.S100098
[iii]Ozgur, et.al., https://doi.org/10.1016/j.inat.2018.04.015