Vertebral Cage Subsidence is a Function of the Cage Design coupled with Bone Mineral Density (BMD)

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Introduction

Spinal fusion surgery with inter body cages is most commonly used technique. Cage subsidence is observed post-surgery in some patients and it is defined as the sinking of the cage into the adjacent vertebral body. There is no standard method to classify and report the cage subsidence. In some studies [1], subsidence was graded as mild (<2 mm), moderate (3–5 mm), and severe (>6 mm). Marchi et al proposed a scale based on % loss of postoperative disc height. It was graded as Grade 0 (0-24%), Grade I (25–49%) Grade II (50–74%) and Grade III (75–100%).The picture on the right is from that study showing the different grades of subsidence. In that study 98 levels were operated with standalone lateral cages and out of 98, 57(58 %) levels were found with grade 0 subsidence, 19 levels were found to be with grade I subsidence, 16 levels were found with grade II subsidence and 6 levels were found with grade III subsidence [2]. Subsidence may lead to imbalance of the spine and decrease the effect of decompression of neural foramina.

Subsidence may be affected by cage size, integrity of the endplates, BMD and cage – endplate interface characteristics. There are different cage designs like solid, ring, rectangular, truss. The main objective of this study is to evaluate the effects of different cage designs, on the construct stiffness and vertebra-device interface failure. Cages of significantly different designs will be tested. The null hypothesis is that “Shape doesn’t affect cage subsidence keeping other parameters constant”.

Materials and Methods

This study will be done in two parts

1) In vitro study using two significantly different cages on isolated vertebral bodies

2) Using different cages on foam blocks of varying PCF

3) Finite element Analyses (FEA)

In vitro study:

In the in vitro study, fresh frozen lumbar (L1-L5) spines were used in this study. The spines were radio graphed to check for any deformities and DEXA scanned to check the bone quality. Table 1 shows the specimen information. The spines were thawed, and the tissue surrounding carefully removed and each vertebra was separated. Each vertebra was cleaned without damaging the endplate and the inferior endplate of each vertebra was potted using bondo (a 2-part epoxy resin).

Table 1: Specimen Information

Specimen ID	**Age**	**Sex**	**T Score**	**Condition**	**Cause of death (COD)**
GL1503651	43	Male	-2.4	osteopenia	Coronory artery disease
GL1504189	38	Female	-2	osteopenia	Melanoma
GL1604777	53	Female	-2.3	osteopenia	Hypertensive Atherosclerotic CV disease
GL1503616	58	Female	-3	Osteoporosis	COPD
68822	63	Female	-2.1	osteopenia	pending
65762	20	Male	-1.7	osteopenia	Prostate cancer
65155	52	Male	-1.7	osteopenia	Pulmonary thromboebolous
63060	53	Male	-1.3	osteopenia	Heart disease
GL1604504	40	Female	0	Normal	Metastatic endonetrial carcinoma
GL1604691	45	Female	0.8	Normal	Coronory artery disease
GL1504474	43	Male	-0.3	Normal	Gunshot to head
65175	63	Male	0.4	normal	N/A
68830	74	Male	-0.1	Normal	pancreatic cancer

In this study, two cages of different designs were evaluated. Cage A is made out of Carbon fiber reinforces PEEK (CFRP) material with standard design (DePuy Sythes spine) and Cage B is 3D printed with truss based 4 WEB medical)design (Figure 1). Cage B type had two design variations, one with convex shape and other with flat shape. Each cage group had four subgroups as shown in the figure 2. In group I, vertebrae with intact endplate and relatively short cage not extending to the ring apophysis were tested. In group II, vertebrae with intact endplate and long cage extending over the ring apophysis were tested. In group III, vertebrae with decorticated endplate and relatively short cage not extending to the ring apophysis were tested. In group IV, vertebrae with decorticated endplate and long cage extending over the ring apophysis were tested. 4 WEB Design

1 (convex shape) cage was tested on 27 vertebrae. 4 WEB Design 2 (Flat shape) cage was tested on 24 Vertebrae.

The potted vertebra was placed on a fixture clamped in 3 axis vice fixed on XY table, which was attached to the load cell of MTS. The vice was adjusted to ensure that the superior endplate is horizontal (figure 3). Cages relevant to each sub group was placed on superior endplate and it will be loaded until failure.

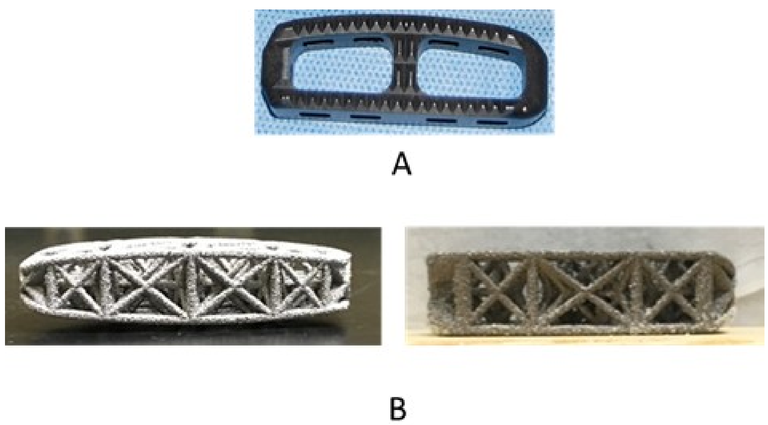

Figure 1: A. PEEK Cage and B. 3D printed truss cages

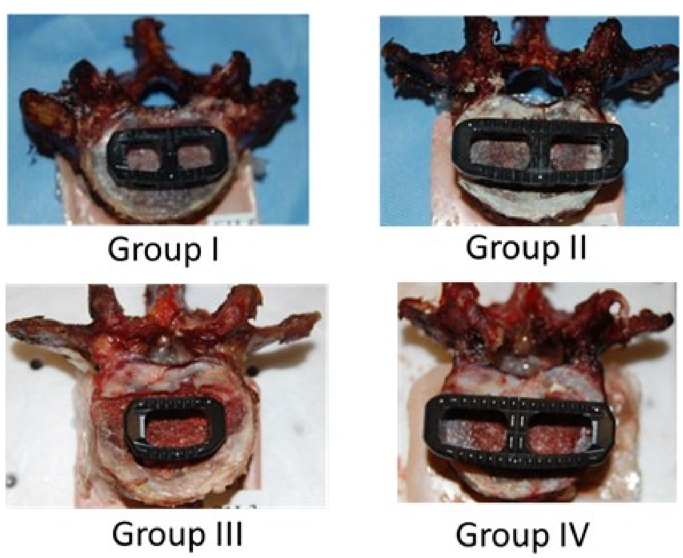

Figure 2: Study groups involved in the Invitro study

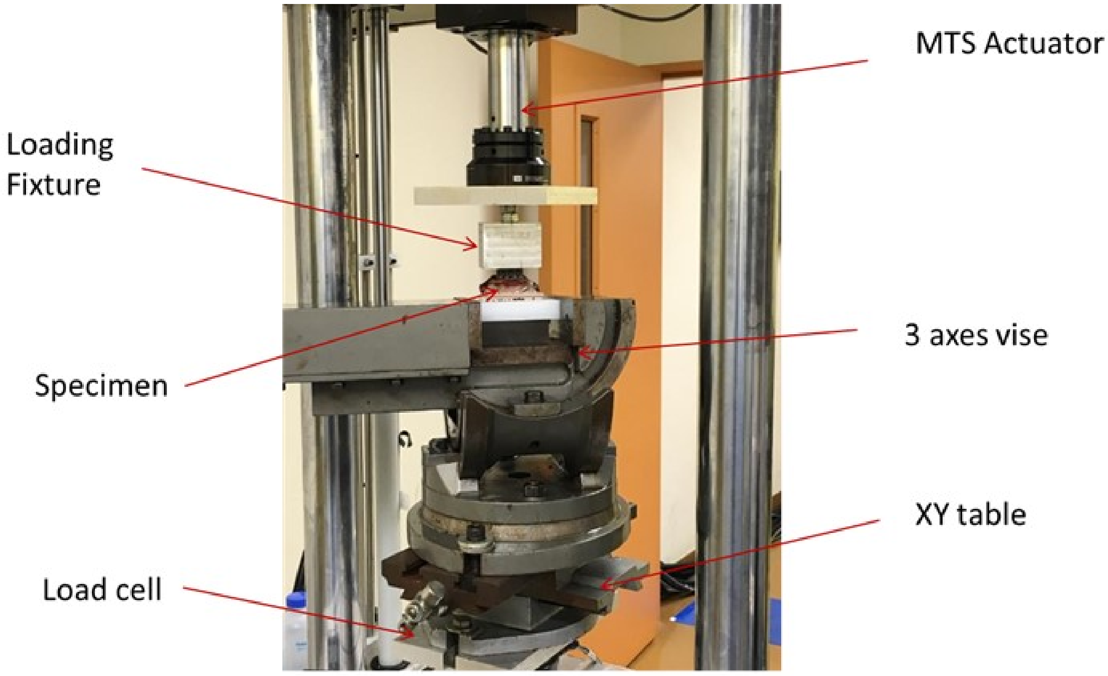

Figure 3: Invitro study test setup.

Load-displacement data was recorded. The compressive load at failure was computed. Statistical analysis was performed using unpaired t test.

Study on Foam Blocks

Cages of different designs, sizes and type were tested on foam blocks of 5, 10 15 and 20 PCF. Different cages test in this part include

1. CERP cage of 40, 50, 55 and 60 mm lengths.
2. 4 WEB design 1 (Convex) cage of 40, 50, 55 and 60 mm lengths.
3. 4 WEB design 2 (Flat) cage of 40, 50, 55 and 60 mm lengths.
4. Anterior lumbar interbody fusion (ALIF) cage of 26 x 32 x14 mm (Short) with and without integrated screws (IS).
5. Anterior lumbar interbody fusion (ALIF) cage of 27 x 37 x12 mm (Long) with and without integrated screws (IS).

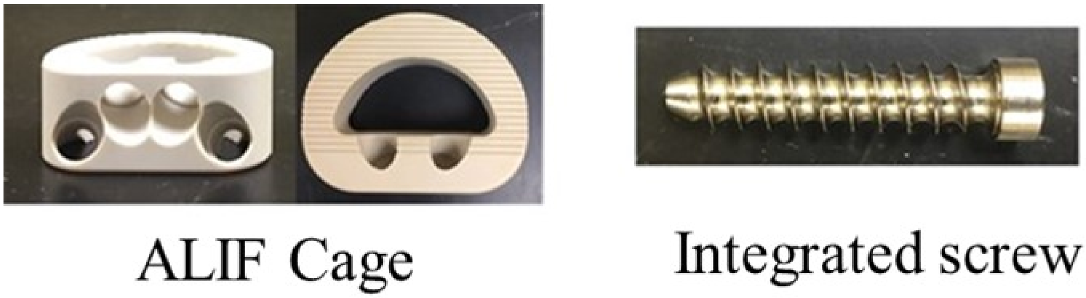

Figure 4: ALIG cage and integrated screw

The foam block test set up is shown in figure 5. In consists of MTS test system with actuator, loading fixture, cages, foam block and load cell. Figure 6 depicts the test setup for all other cages. The cages were compressed up to 7 mm. The sample size was 6 except for 4 WEB design 1 where the sample size was 3. Load-displacement data was recorded. The maximum load in compression were computed. Analysis of variance (ANOVA) was used to evaluate the significant difference between all the cages in resisting the compression.

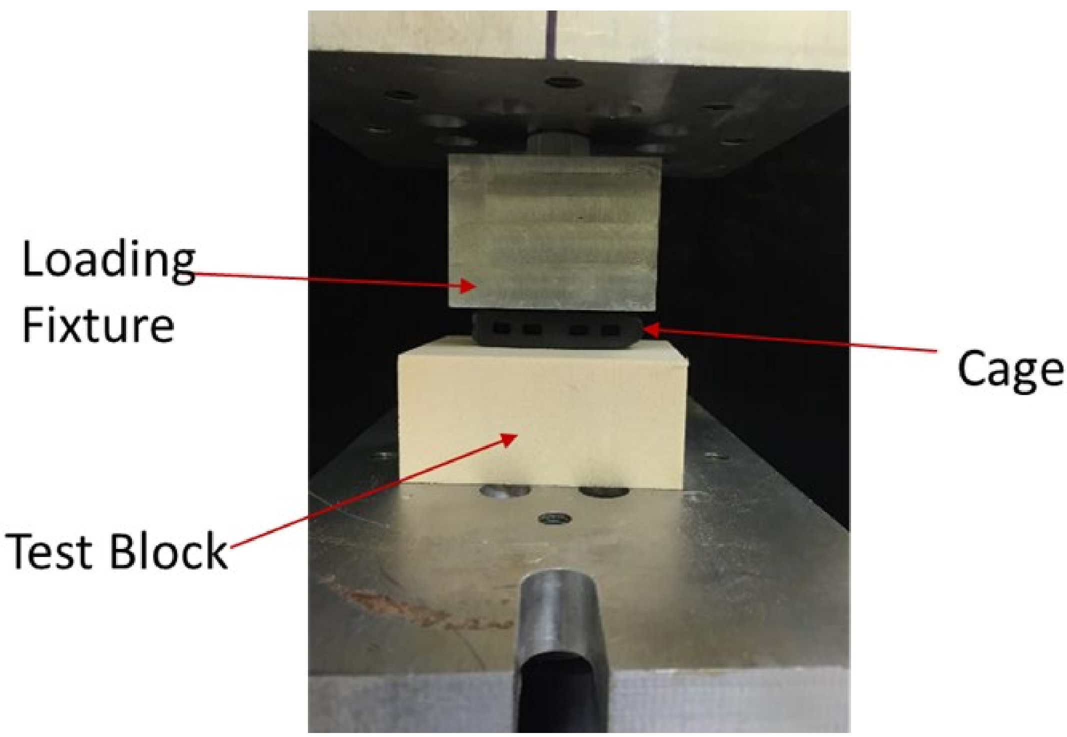

Figure 5: Foam block study test setup with CFRP cage.

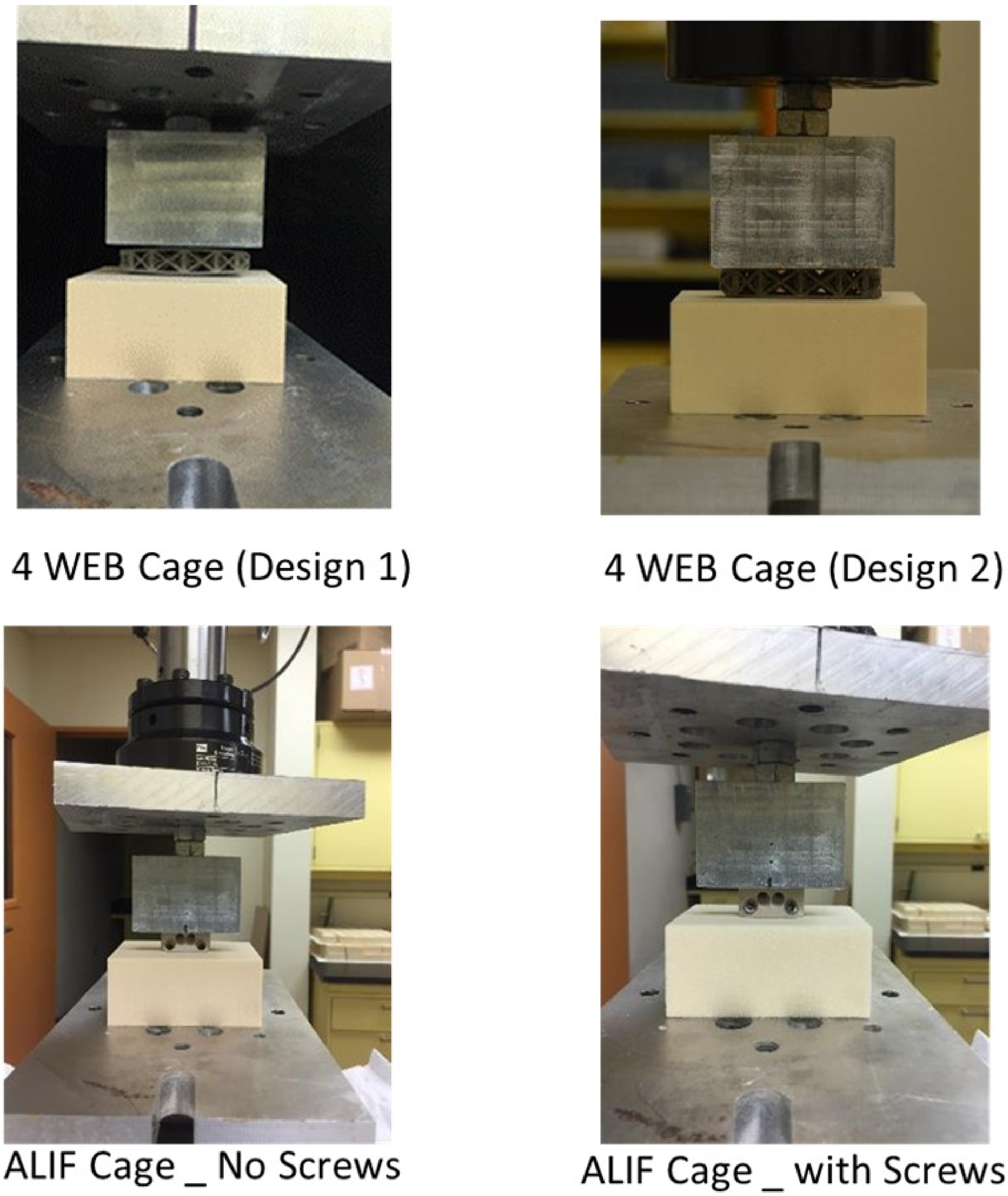

Figure 6: Foam block test set up for different cage types

Finite element analysis (FEA)

In addition to the in-vitro and foam block study, finite element analysis (FEA) was used to compare the subsidence phenomena between different cages and material properties. For this study, an L4-L5 motion segment was extracted from a previously validated thoracolumbar spinopelvic model. The L5 vertebral body was separated from the L4-L5 disc and ligaments. For the vertebral body, cortical (E= 12 GPa & Poisson's ratio = 0.3) and cancellous bone (E= 50 MPa & Poisson's ratio 0.2) were assigned as material properties. The Depuy lateral CFRP cage was created in a CAD program and then imported into the finite element package. The two cage footprints (short and long length) were simulated with PEEK (E= 3.6 GPa & Poisson's ratio= 0.4) and Titanium (E= 116 GPa and Poisson's ratio= 0.3) material property in this study. The cage placed on the vertebral body and a hard contact with a friction coefficient value of 0.8 was defined between the bottom surface of the cage and cranial endplate. Finally, a 5-millimeter displacement was applied on top surface of the cage to simulate the experimental setup. The reaction load with respect to the displacement was tabulated for all scenarios.

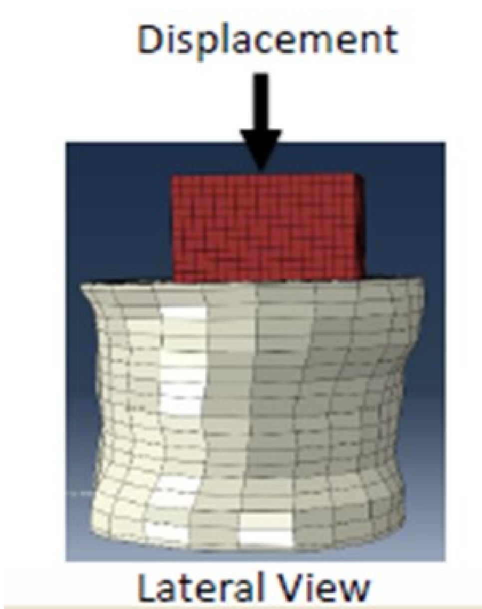

Figure 7: Lateral view of the finite element model.

RESULTS

Invitro study

The data in Table 2 illustrates the maximum load observed in compression of CFR PEEK cage in different groups tested. This study was done previously and the used here for comparison. The long cages resist more in compression compared to short cages on intact and decorticated endplates. The long cages resist more in compression on intact endplates than decorticated endplates. The short cages resist more in compression on intact endplates than decorticated endplates.

Table 2: Max load in Compression for CFR PEEK cage

G1 (n=10)		G2 (n=10)		G3 (n=10)		G4 (n=10)	
Specimen ID	**Max Load (N)**	**Specimen ID**	**Max Load (N)**	**Specimen ID**	**Max Load (N)**	**Specimen ID**	**Max Load (N)**
S1L1	2166	S1L2	3277	S1L3	1571	S1L4	2503
S1L5	2892	S2L1	2406	S2L2	1360	S2L3	2152
S2L4	1612	S2L5	3437	S3L1	1633	S3L2	2581
S3L3	2972	S3L4	3808	S3L5	2245	S4L1	3003
S4L2	2817	S4L3	4741	S4L4	2730	S4L5	3458
S5L1	2203	S5L2	3518	S5L3	1500	S5L4	2579
S5L5	2341	S6L1	4153	S6L2	2535	S6L3	3593
S6L4	3984	S6L5	5356	S7L1	2239	S7L2	3288
S7L3	3817	S7L4	4348	S7L5	3941	S8L1	2644
S8L2	2312	S8L3	4154	S8L4	3315	S8L5	4697
Mean	**2712**	**Mean**	**3920**	**Mean**	**2307**	**Mean**	**3050**
SD	**747**	**SD**	**826**	**SD**	**848**	**SD**	**741**

As mentioned earlier, 3D printed cages from 4 WEB design 1 were tested on some vertebrae. Table 3 shows the maximum load data presented for G1 (n=6), G2 (n=10), G3 (n=3) and G4 (n=8). When we compared this data with previous study conducted in the past with CFR PEEK cages, shown in the table 2, the trend looks similar for all the groups.

Table 3: Max load in Compression for 4 WEB design 1

G1 (n=6)		G2 (n=10)		G3 (n=3)		G4 (n=8)	
Specimen ID	**Max Load (N)**	**Specimen ID**	**Max Load (N)**	**Specimen ID**	**Max Load (N)**	**Specimen ID**	**Max Load (N)**
S2L4	2904	S3L4	4802	S3L1	2620	S4L1	2993
S4L2	2133	S4L3	3497	S6L2	1143	S5L4	2742
S5L1	1766	S7L4	4083	S7L1	2335	S8L1	1798
S5L5	2481	S8L3	2276			S2L1	3499
S6L4	1481	S3L3	4173			S2L2	2574
S7L3	2577	S5L2	2362			S3L2	3057
		S5L3	2692			S1L2	2832
		S1L1	3536			S4L5	5041
		S1L3	3981				
		S7L5	4975				
Mean	**2224**	**Mean**	**3638**	**Mean**	**2033**	**Mean**	**3067**
SD	**534**	**SD**	**952**	**SD**	**783**	**SD**	**934**

Table 4 shows the maximum load data for 4 WEB cage Design2 (n=6) and the trend looks similar to the previous study (Table 2).

Table 4: Max load in Compression for 4 WEB design 2

G1 (n=6)		G2 (n=6)		G3 (n=6)		G4 (n=6)	
Specimen ID	**Max Load (N)**	**Specimen ID**	**Max Load (N)**	**Specimen ID**	**Max Load (N)**	**Specimen ID**	**Max Load (N)**
S1L4	5254	S1L1	5748	S1L3	5568	S1L2	5558
S2L4	2327	S1L5	8495	S3L4	2352	S3L1	3254
S4L1	3247	S2L1	3847	S4L3	3297	S3L2	2442
S4L2	3748	S2L2	3273	S5L2	1685	S3L3	3550
S4L4	4701	S2L3	2624	S5L3	3429	S5L1	1767
S4L5	4953	S2L5	3640	S5L4	3079	S5L5	6376
Mean	**4038**	**Mean**	**4605**	**Mean**	**3235**	**Mean**	**3825**
SD	**1131**	**SD**	**2175**	**SD**	**1318**	**SD**	**1792**

Foam Block Study:

Figures 8, 9 10 and 11 shows the load displacement graphs for 40, 50, 55 and 60 mm cages of CFRP and 4 WEB design 1. The dotted lines are for CFRP cages and the solid lines are for 4 WEB Design cages. The load before 3mm displacement for 4 WEB cages is less compared to CFRP cages and the load is more at the end for 4 WEB cages. This could be due to the lower contact profile of the convex cage in the beginning.

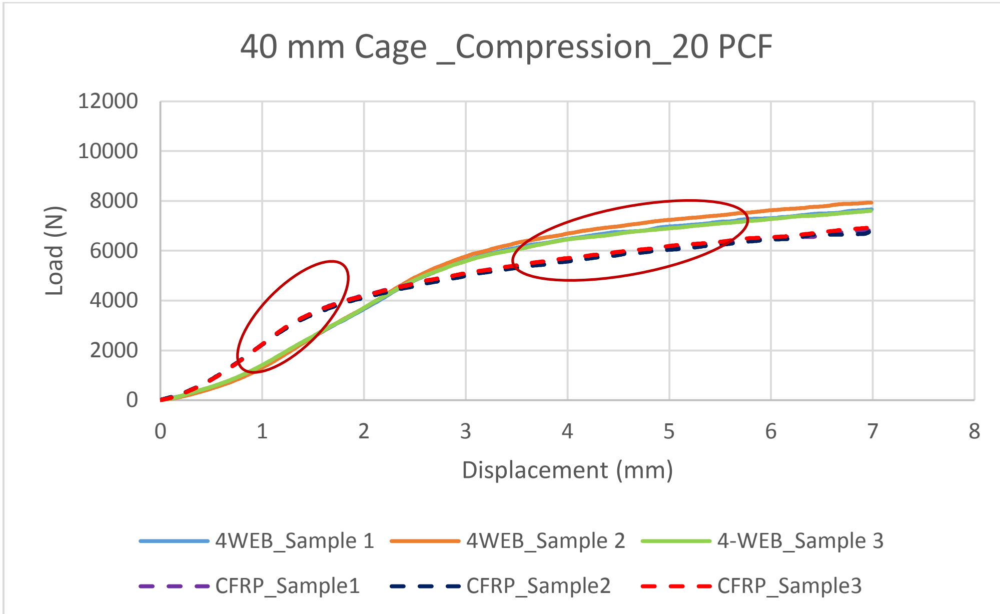

Figure 8: Load Displacement graph for CFRP vs 4 WEB Design 1 cages (40 mm)

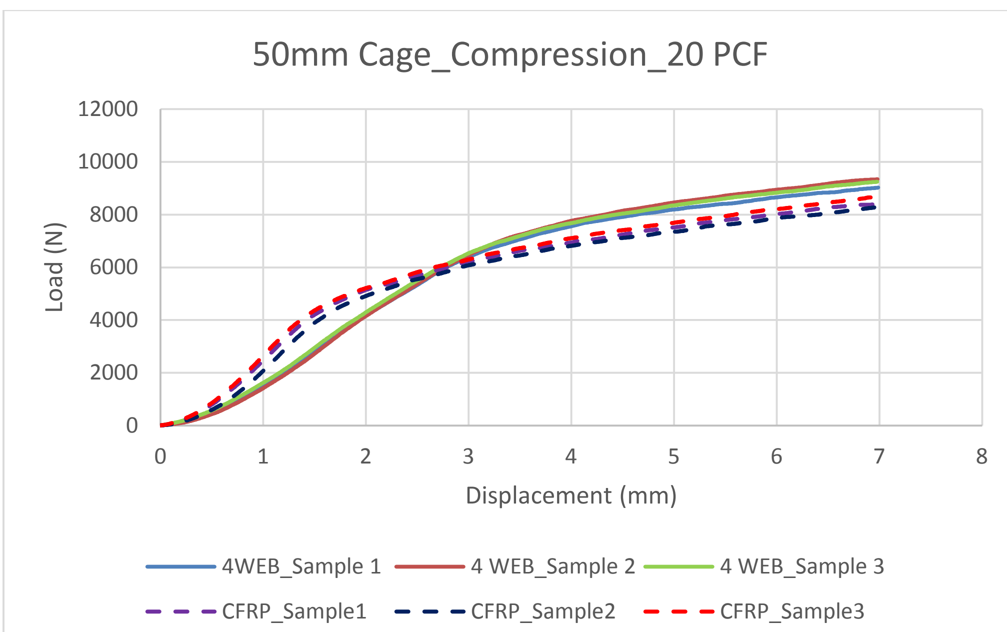

Figure 9: Load Displacement graph for CFRP vs 4 WEB Design 1 cages (50 mm)

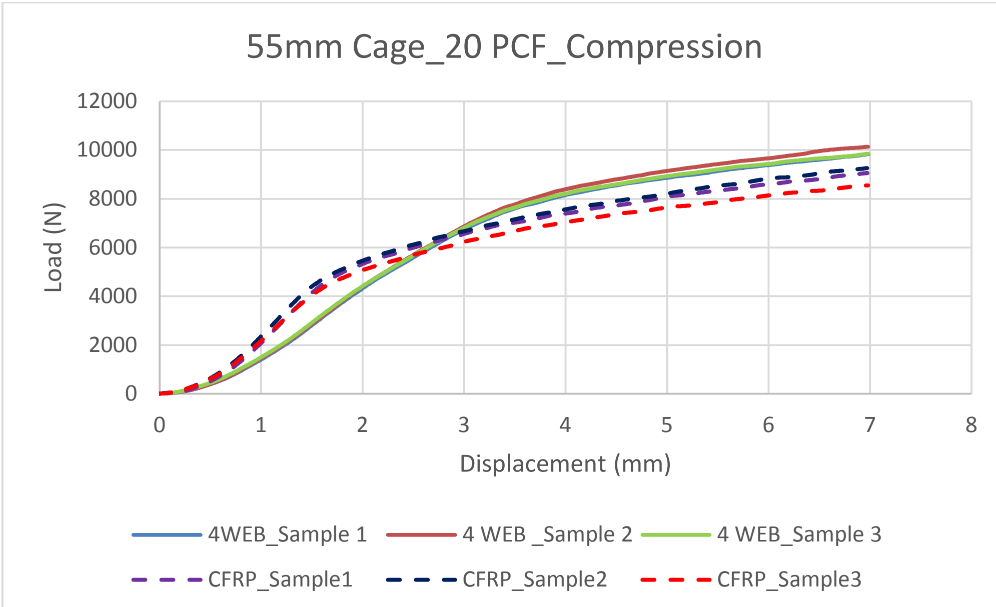

Figure 10: Load Displacement graph for CFRP vs 4 WEB Design 1 cages (55 mm)

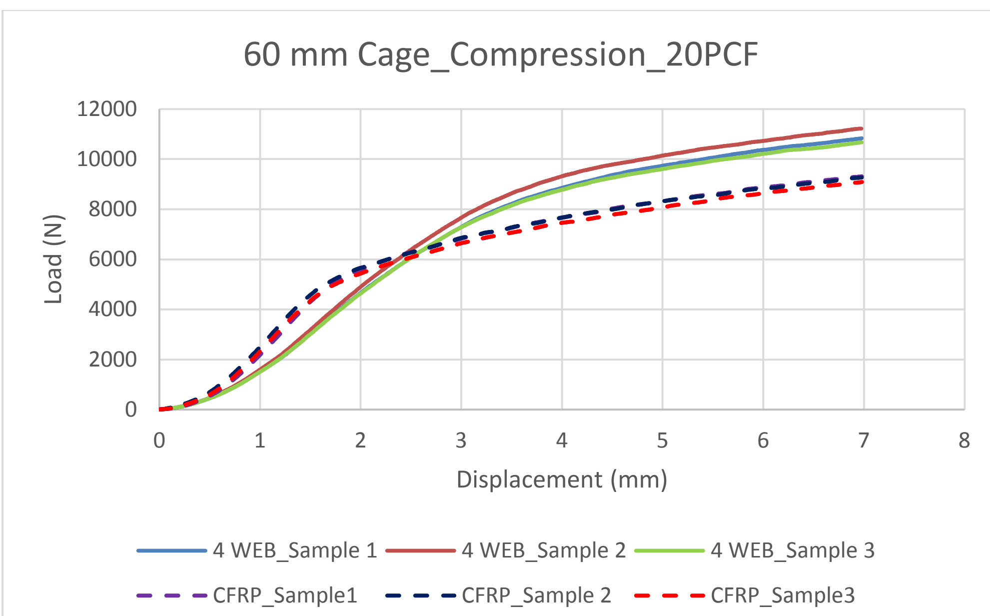

Figure 11: Load Displacement graph for CFRP vs 4 WEB Design 1 cages (60 mm)

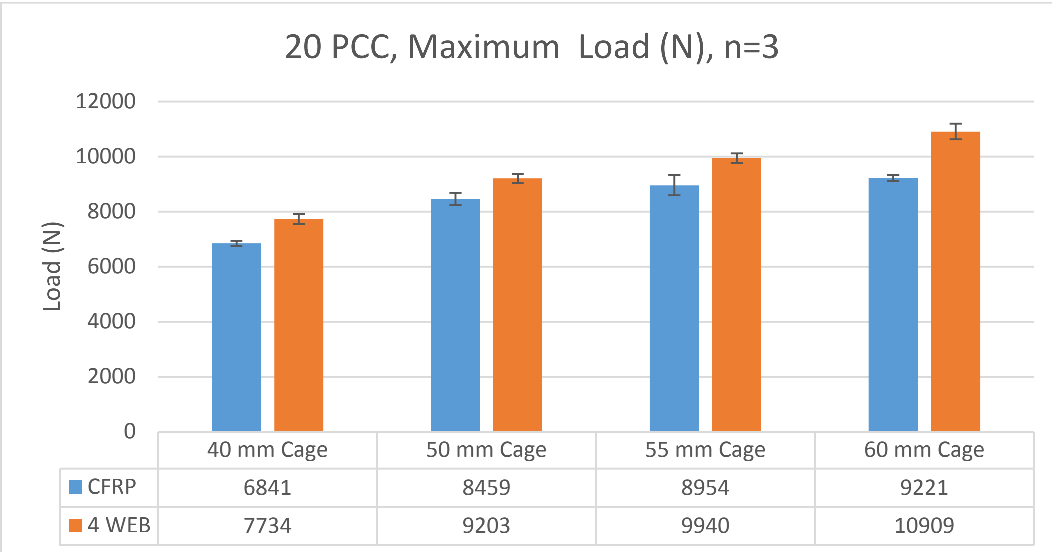

Figure 12: Maximum load in compression for CFRP vs 4WEB design 1 (20 PCF, (N=3))

The bar graph shown in figure 12 illustrates the mean max load in compression for both cage types (n=3). Compared to CFRP, the 4 WEB cages (Design 1) showed more resistance to subside 7mm displacement. Only 20 PCF test blocks were used to evaluate the difference between CFRP and 4WEB design 1.

The bar graphs shown in in figures 13-16, illustrates the mean max load in compression for both 4 WEB Design 2 and CFRP cage types of different lengths tested on 20, 15, 10 and 5 PCF foam blocks. Compared to CFRP, the 4 WEB cages showed more resistance to subside 7mm displacement for all cage sizes and for all foam grades. The percentage increase in load for 4 WEB cages is 20-36% (Table 5).

Table 5. Percentage increase in maximum load for 4 WEB Design 2

% Increase	Length	5 PCF	10 PCF	15 PCF	20 PCF
4 WEB Compared to CFRP	40mm	29	25	20	22
	50mm	30	29	22	27
	55mm	35	28	27	29
	60mm	36	31	27	32

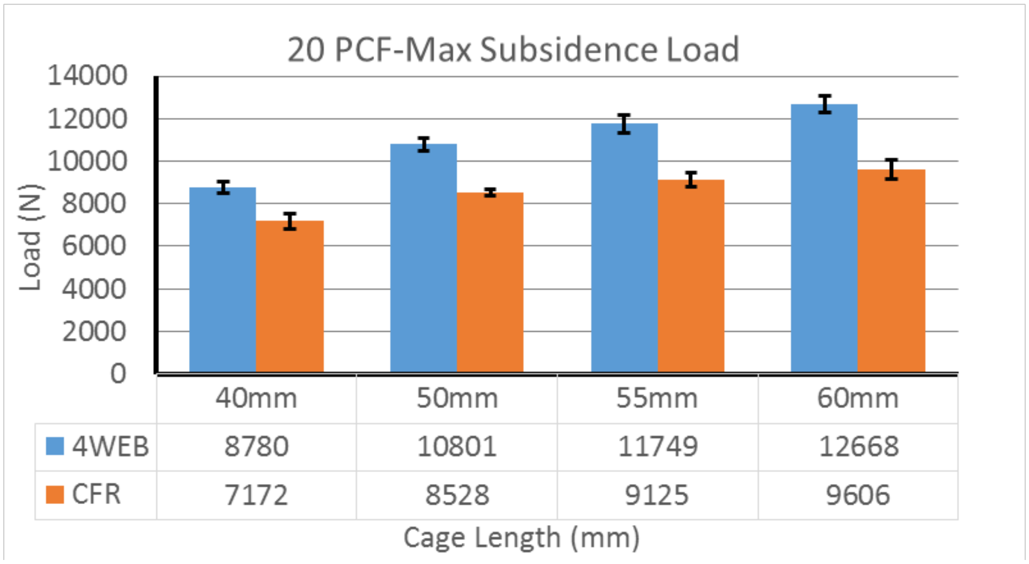

Figure 13: Maximum load in compression for CFRP vs 4WEB design 2 (20 PCF, (N=6))

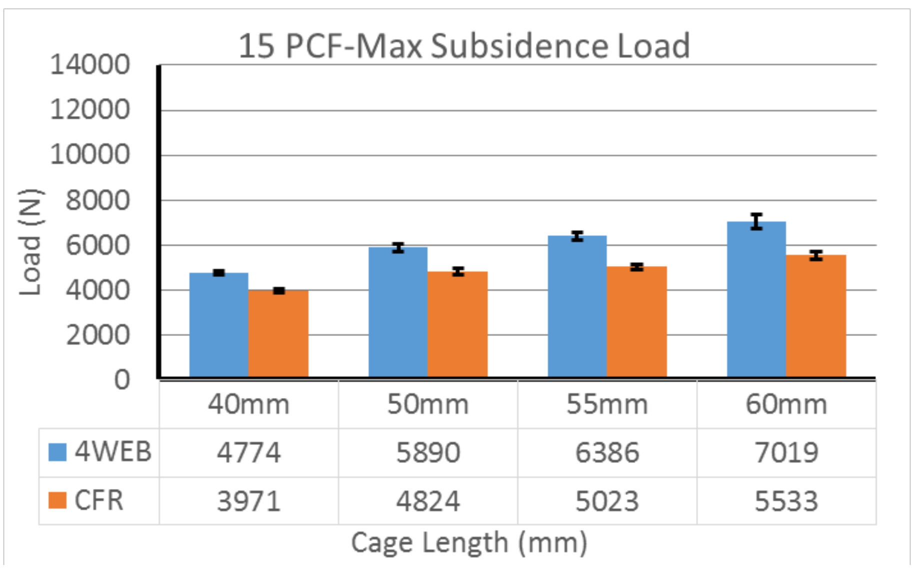

Figure 14: Maximum load in compression for CFRP vs 4WEB design 2 (15 PCF, (N=6))

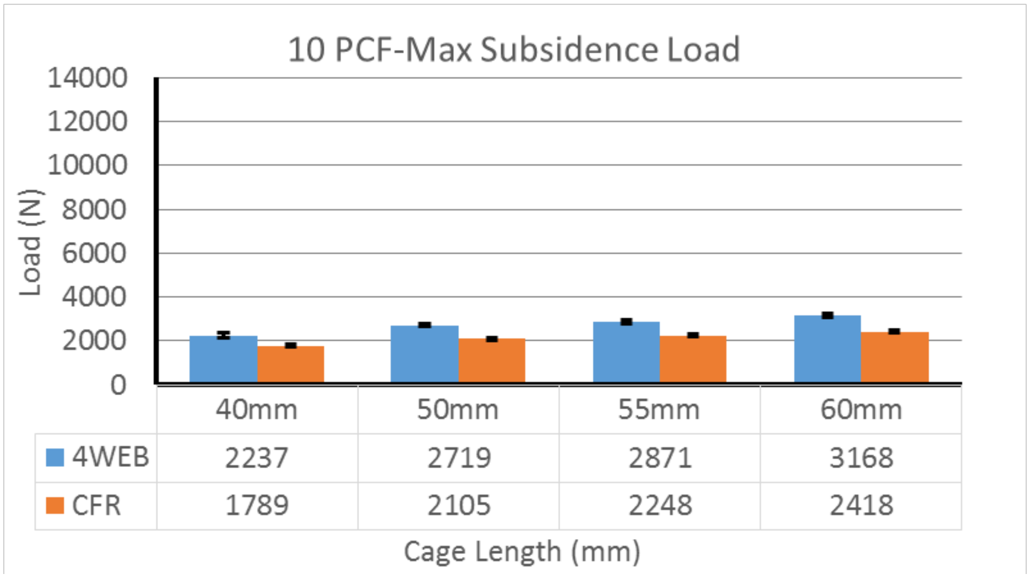

Figure 15: Maximum load in compression for CFRP vs 4WEB design 2 (10 PCF, (N=6))

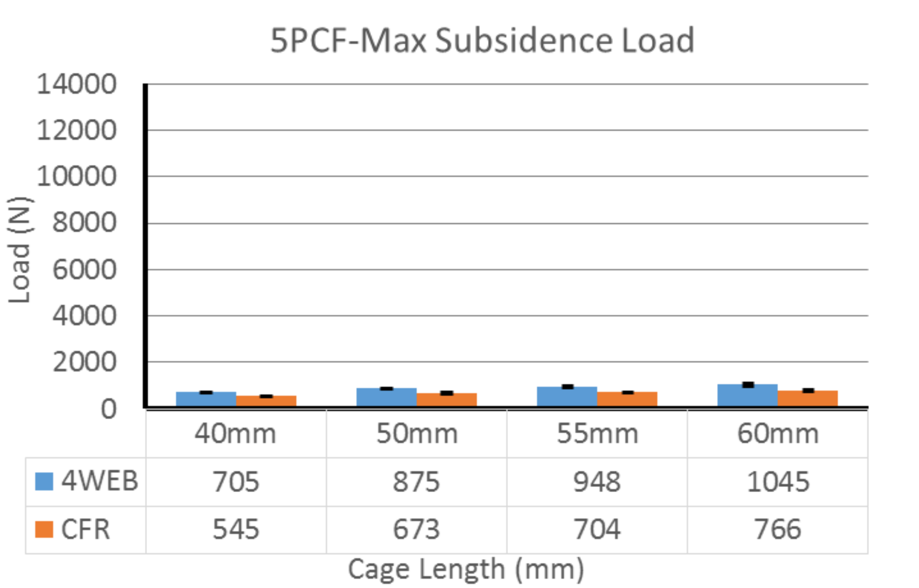

Figure 16: Maximum load in compression for CFRP vs 4WEB design 2 (5 PCF, (N=6))

The bar graphs shown in figures 17-20, illustrates the mean max loads in compression for both ALIF cages, with and without screws tested on 20, 15, 10 and 5 PCF foam blocks. Compared to ALIF without screws, the ALIF cage with two screws showed more resistance to subside 7mm displacement for both the cage sizes and for all foam grades. The percentage increase in load for ALIF with screws is 10-24%.

Table 6. Percentage increase in maximum load for ALIF cages with and without IS

% Increase	Length	5 PCF	10 PCF	15 PCF	20 PCF
IS vs. No IS	Short	24	21	14	10
	Long	19	18	13	10

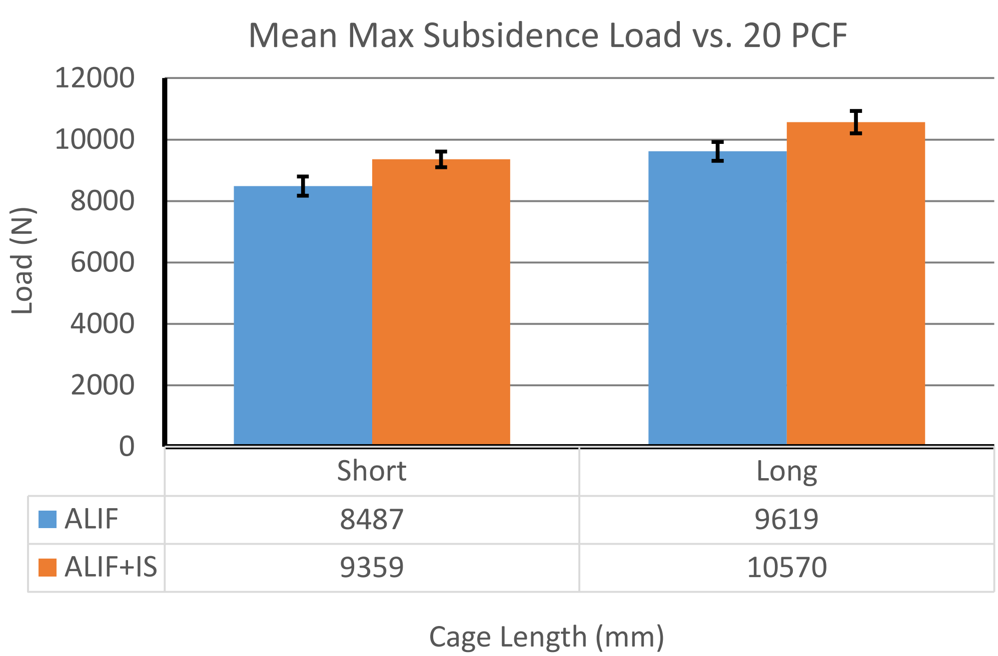

Figure 17: Maximum load in compression for ALIF vs ALIF with IS cages (20 PCF, (N=6))

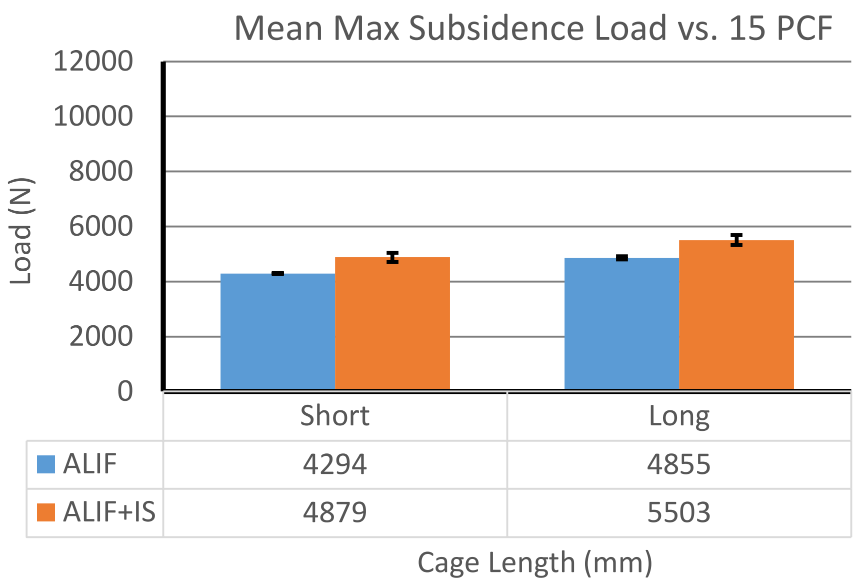

Figure 18: Maximum load in compression for ALIF vs ALIF with IS cages (15 PCF, (N=6))

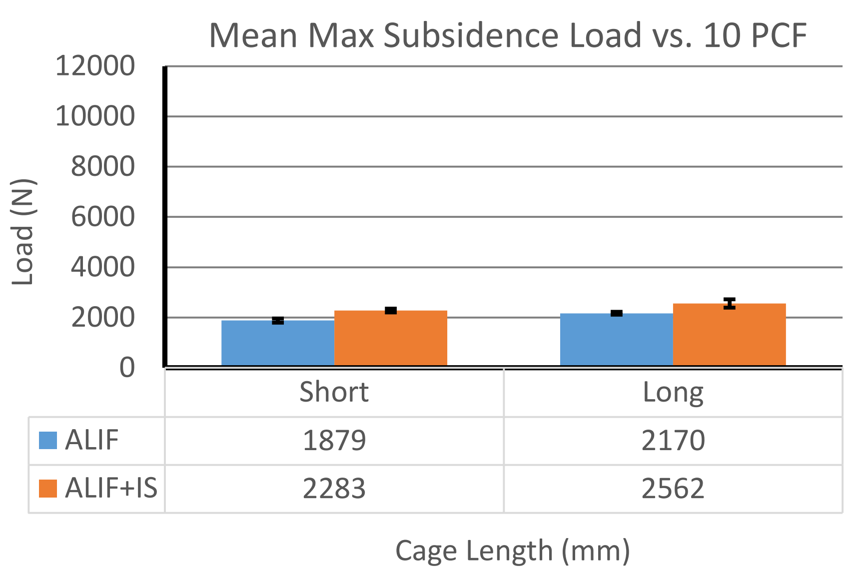

Figure 19: Maximum load in compression for ALIF vs ALIF with IS cages (10 PCF, (N=6))

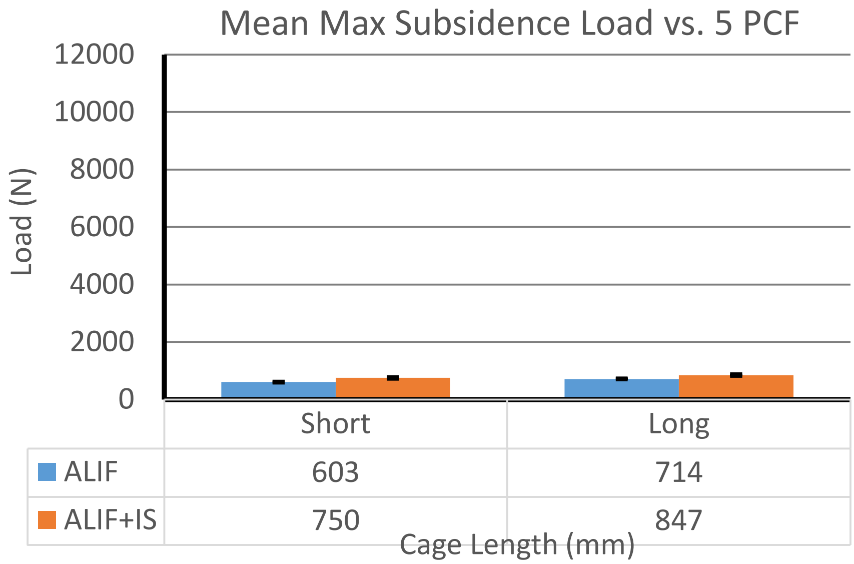

Figure 20: Maximum load in compression for ALIF vs ALIF with IS cages (5 PCF, (N=6))

Finite element analysis (FEA)

The FEA models showed that the long cage produced higher maximum endplate load than the short cage for the intact endplate and decorticated endplate. The intact endplate simulations also produced higher maximum endplate load than the decorticated endplate simulations. Finally, our models also showed that changing the material property while maintain the design constant did not affect the maximum endplate load. This indicated that subsidence is a function of bone density.

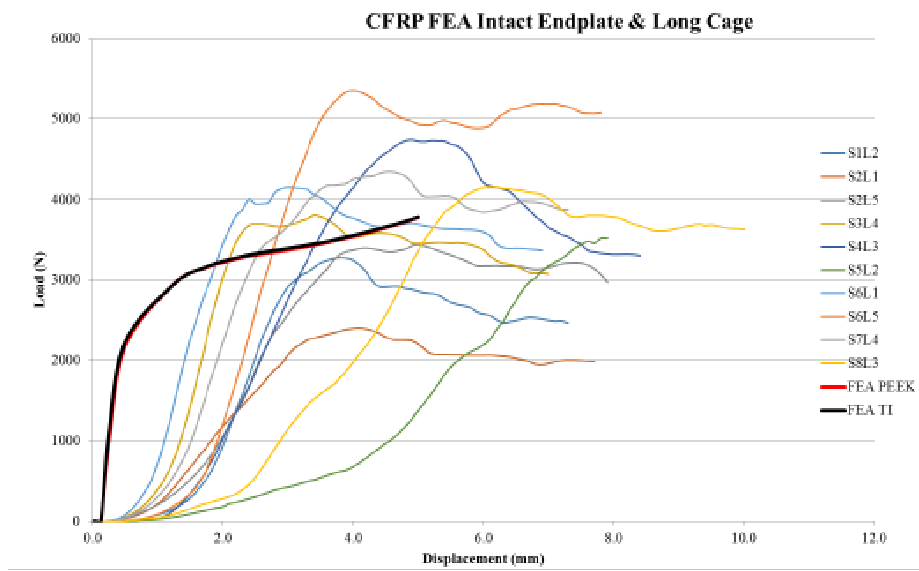

Figure 21: The endplate load for the PEEK and TI long cage simulated for the intact endplate

We noticed that the difference in material property while maintaining the design constant did produce comparable results c

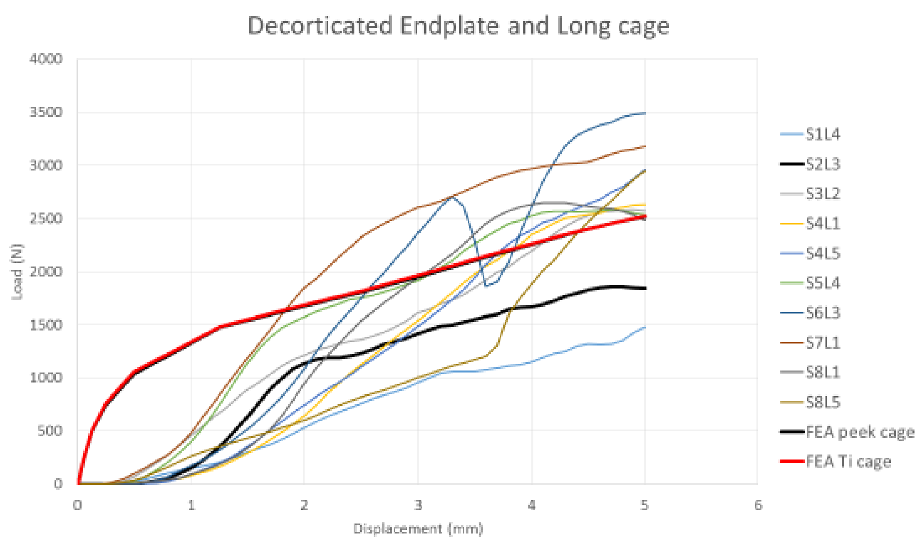

Figure 22: The endplate load for the PEEK and TI long cage simulated for the decorticated endplate case.

We noticed that the difference in material property while maintaining the design constant did produce comparable results (figure 22). However, the decorticated endplate simulation produced a lower maximum endplate load than the intact endplate case (figures 21& 22).

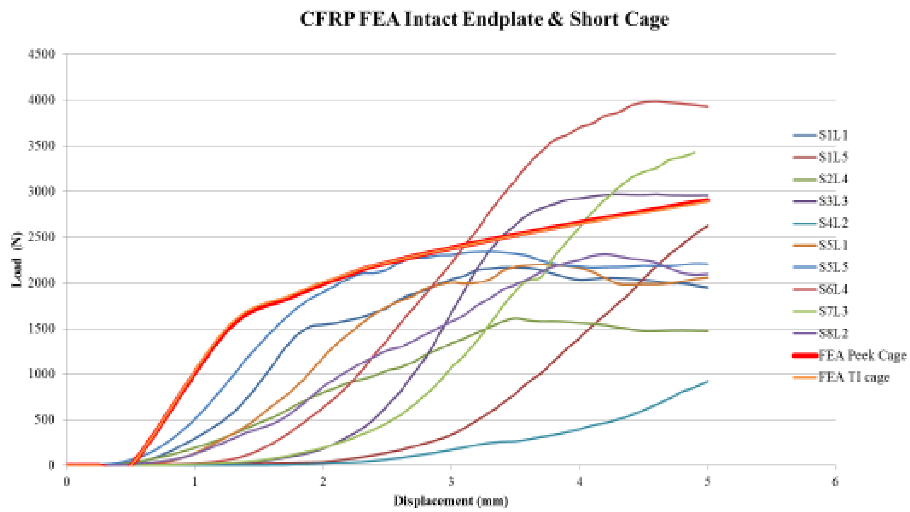

Figure 23: The endplate load for the PEEK and TI short cage simulated for the intact endplate

We noticed that the difference in material property while maintaining the design constant did produce comparable results (figure 23).

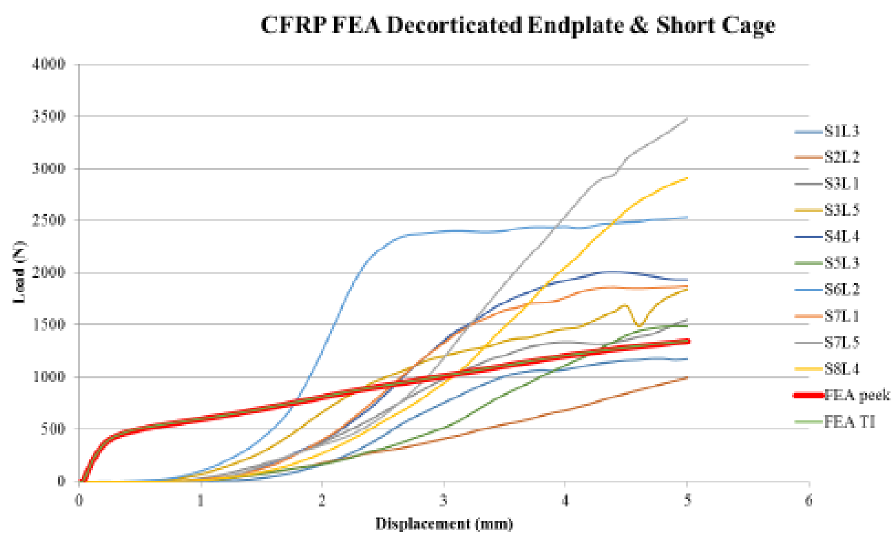

Figure 24: The endplate load for the PEEK and TI short cage simulated for the decorticated endplate case.

We noticed that the difference in material property while maintaining the design constant did produce comparable results. The short cage echoed trend to the long cage where the intact endplate showed higher load than the decorticated endplate (figures 23& 24).

Conclusions:

Invitro study:

CFRP cages:

1. Long cages on the intact and decorticated endplates significantly increased the strength in compression to resist subsidence when compared to small cages (G1 vs G2 and G3 vs G4).

2. Long cages on the intact endplate significantly increased the strength in compression to resist subsidence when compared to large cages on the decorticated endplate (G2vsG4).

3. Short cages on the intact endplate not significantly increased the strength in compression to resist subsidence when compared to small cages on the decorticated endplate (G1 vs G3).

4WEB Design 2 cages (n=6)

1. Similar trend as above was observed but it was not significant for 4 Web design 2 cages.

4WEB Design1 cages

Similar trend as above was observed but statistically, could not come to conclusion due to the different sample size in each group.

The variation in BMD could be the contributing factor for varied results.

Foam Block study

Lateral Cages

- The results show that 4 WEB cages performed better than CFRP cages and this could be due to the truss based design.

• The 40 mm truss design cage showed a significant resistance to subsidence than CFRP 40 mm and comparable resistance to subsidence than the larger 50 and 55 CFRP cages at 7 mm displacement for all foam densities.

ALIF Cages

• The results show that ALIF cages with screws performed better than ALIF cages without screws.

• The resistance to subsidence is significant for all the cage conditions and foam densities except for the comparison between short and long cages without screws. Overall, the design and size of the cage had an effect on the subsidence load irrespective of the foam density of the test block.

FEA Simulations

• Model predicted similar behavior of the in vitro data.

• Material did not affect the load-displacement behavior.

• PEEK and Titanium performed closely.

Limitations

• The limitation was that one cage was made of CFRP and the other of Titanium.

• The difference in material for both cage types may have effect on the outcome and it needs further investigation.

• For FEA, the 3-D printed titanium cage drawings or models were not accessible.

References

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2. Luis Marchi, Nitamar Abdala, Leonardo Oliveira, Rodrigo Amaral, Etevaldo Coutinho, and Luiz Pimenta. Radiographic and clinical evaluation of cage subsidence after stand-alone lateral interbody fusion. J Neurosurg Spine 19:110–118, 2013.