Suitability of carbon fiber–reinforced polyetheretherketone cages for use as anterior struts following corpectomy

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OBJECTIVE Fibular allograft remains a widely used strut for corpectomy surgeries. The amount of graft material that can be packed into an allograft strut has not been quantified. Cages are an alternative to fibular allograft for fusion surgeries. The authors of this study assessed the suitability of carbon fiber–reinforced polyetheretherketone (CFRP) cages for anterior corpectomy surgeries. They further explored the parameters known to affect fusion rates in clinical practice.

METHODS Six fibular allografts were tested at standard lengths. Three sets of carbon fiber cages (Bengal, DePuy Spine), each with a different footprint size but the same lengths, were tested. The allografts and cages were wrapped in adhesive, fluid-tight transparent barriers and filled with oil. The volume and weight of the oil instilled as well as the implant footprints were measured. The fibular allografts and cages were tested at 20-, 40-, and 50-mm lengths. Two investigators independently performed all measurements 5 times. Five CFRP cubes (1 × 1 × 1 cm) were tested under pure compression, and load versus displacement curves were plotted to determine the modulus of elasticity.

RESULTS Significantly more oil fit in the CFRP cages than in the fibular allografts ($p < 0.0001$). The weight and volume of oil was 4–6 times greater in the cages. Interobserver ($r = 0.991$) and intraobserver ($r = 0.993$) reliability was excellent. The modulus of elasticity for CFRP was 16.44 ± 2.07 GPa.

CONCLUSIONS Carbon fiber–reinforced polyetheretherketone cages can accommodate much more graft material than can fibular allografts. In clinical practice, the ability to deliver greater amounts of graft material following a corpectomy may improve fusion rates.

<http://thejns.org/doi/abs/10.3171/2016.1.SPINE14291>

KEY WORDS cage; fibular allograft; strut; corpectomy; technique

TRADITIONAL interbody fusion techniques have used either structural autograft or allograft material.^{4,13,29,44} Although allograft and autograft have shown good results, problems related to graft expulsion and migration, graft site morbidity, and pseudarthrosis have been reported.^{6,7,18,24,25,30,31,33,38,40,49,50} For autologous bone, the quality of harvested bone, especially in elderly patients, and pain at the donor site have been additional issues.^{19,24,27,31,36,40} Concerns related to allograft include poor osteoconductive and osteoinductive properties, increased risk of infection, possible disease transmission, and poor biocompatibility.^{24,25,27,36,40,49}

In an attempt to overcome these problems with autografts and allografts, the use of interbody fusion cages has been advocated. Advantages of interbody cages include immediate anterior column support and biocompatibility.^{20,26,45} Interbody fusion cages have been developed using a wide range of biomaterials, including metals (most notably titanium), as well as carbon derivatives such as polyetheretherketone (PEEK) and carbon fiber polymers.

Typically, these cages are filled with autologous bone graft material to promote bony fusion.^{1,3} Historically, greater initial graft volumes have been purported to lead to a higher percentage of fusion successes.^{22,41,52} Another fac-

ABBREVIATIONS CFRP = carbon fiber–reinforced polyetheretherketone; PEEK = polyetheretherketone.

SUBMITTED March 17, 2014. **ACCEPTED** January 21, 2016.

INCLUDE WHEN CITING Published online April 8, 2016; DOI: 10.3171/2016.1.SPINE14291.

tor known to affect spinal fusion is the surface area available for fusion. A larger surface area has been attributed to improving the final mechanical result of the procedure.²² Therefore, the volume of graft material that can be packed into an anterior column construct as well as the surface area available for fusion may affect the rates of spinal fusion (Fig. 1). To our knowledge, no study has compared these factors among the different anterior column fusion constructs.

Therefore, we investigated a carbon fiber–reinforced PEEK (CFRP) cage for stabilizing and reconstituting the anterior spine. The perceived advantages of this cage include the ability to impart immediate stability to the spine, the opportunity to place a significant amount of bone graft material inside the cage, a modulus of elasticity similar to that of adjacent bone, and radiolucency.

Our aim in this study was to compare the amount of material that could be placed into a CFRP cage with a fibular allograft of similar lengths by performing both weight and fluid quantitative analysis. In addition, to confirm suitability as a strut material, the area of the footprint for each strut was determined, the load versus displacement characteristics of the CFRP cage (modulus of elasticity) were calculated, and the radiolucency of the CFRP cage was assessed.

Methods

A random sample of 6 human fibular allograft segments was procured from commercially available bone banks. Each segment was sectioned to a length of 50 mm using a sagittal saw to simulate a routine multilevel corpectomy procedure. One end of each graft was covered using an adhesive, fluid-tight transparent barrier (Tegaderm transparent dressing, 3M Health Care). The weight of each graft with its corresponding wrapping was measured using a Mettler Toledo AL54 analytical balance. Olive oil with a density of 0.899 ± 0.015 g/ml was instilled into each allograft strut using a syringe, and the volume of oil was recorded. The weight of each graft with both the wrapping and the oil was again measured. The weight of the oil instilled was measured by taking the difference between the weight of the graft with the wrapping and the oil, and the weight of the graft with the wrapping alone. The above procedure was repeated 5 times. Two investigators individually repeated these 5 measurements at separate time points to allow for the assessment of interobserver and intraobserver variability.

The grafts were then sectioned to 40-mm segments, rewrapped, weighed, instilled with oil, and reweighed as previously described. The grafts were then sectioned to

20-mm segments (Fig. 2 left), and the weighing procedure was repeated with the same protocol. For each length, 2 separate investigators repeated the 5 measurements at separate time points.

The surface area of the internal and external footprint of each allograft was measured for each end of the strut. The internal and external circumference of each end of the allograft was first traced. Next, the area enclosed by the circumference was determined using a standard graphic Minkowski-Bouligand dimensioning technique.

Three sets of CFRP cages (Bengal, DePuy Spine) with a footprint size of 12×14 mm and lengths of 20, 40, and 50 mm were obtained. The internal and external footprint of each cage was traced. For each footprint, internal and external footprint areas were calculated according to the protocol previously described for the allograft struts (these measurements confirmed the specifications provided by the manufacturer). One end and all 4 sides of each cage were wrapped with the adhesive, fluid-tight transparent barrier to ensure no fluid would leak from the construct. Each 12×14 -mm cage was wrapped (Fig. 2 right), weighed, instilled with oil, and reweighed a total of 5 times. Two separate investigators repeated all 5 measurements on separate occasions.

The same process was performed for cages with footprint sizes of 14×16 mm and 16×18 mm at the 50-, 40-, and 20-mm construct lengths. Statistical analyses were performed using SAS System for Windows 9.0 (SAS Institute Inc.).

Five CFRP (70% PEEK + 30% carbon) cubes ($1 \times 1 \times 1$ cm) were obtained from the manufacturer. A pure compressive load was applied at the rate of 1 mm/min using a mechanical fatigue-testing instrument (Instron 8821S, Instron Corp.). Load versus displacement curves were plotted in real time. Young's modulus of elasticity was calculated using the slope of the load versus displacement curves.

Interobserver Reliability

Interobserver reliability was assessed to determine any differences in the measurements made by the separate investigators. The weight and volume of olive oil used to fill the device and the size of the footprints of each strut (allograft and CFRP) were evaluated. Interobserver reliability was computed using the formula for the Pearson product-moment correlation coefficient:

$$r_{xy} = \frac{\sum x_i y_i - n \bar{x} \bar{y}}{(n-1) s_x s_y} = \frac{n \sum x_i y_i - \sum x_i \sum y_i}{\sqrt{n \sum x_i^2 - (\sum x_i)^2} \sqrt{n \sum y_i^2 - (\sum y_i)^2}}$$

where $\bar{x}$ and $\bar{y}$ are the sample means of x , which represents Investigator 1's measurements, and y , which represents Investigator 2's measurements, and where s_x and s_y are the sample standard deviations of x and y and the sum is from $i = 1$ to n .²

Intraobserver Reliability

Intraobserver reliability was assessed to determine the consistency of the measurements obtained from the same

FIG. 1. Relative areas of fibular allograft (far right) and 3 different sizes of CFRP cages (far left to right: 16×18 mm, 14×16 mm, 12×14 mm).

FIG. 2. Fibular graft wrapped with fluid-tight transparent barrier filled with olive oil (left) and CFRP cage wrapped with fluid-tight transparent barrier filled with olive oil (right).

experimenter at 5 different time points. Intraobserver reliability was also computed using the formula listed above.² In addition, we obtained plain film radiographs and CT scans of cadaver spines into which CFRP cages were placed into a corpectomy defect at the T2 vertebral level to verify radiolucency. The cages were packed with morselized bone graft prior to implantation to simulate the clinical situation.

Results

All values represent the weight (g) and volume (ml) of the oil that could be instilled into the fibular allografts and CFRP cages so that the oil was flush to the top of the construct. All values were recorded as the mean $\pm$ standard deviation (Table 1).

The average external and internal areas of the allograft

footprints were compared with those of the cages for each of the 3 footprints. The external and internal cage footprints were significantly larger ($p < 0.0001$) for all cage sizes than those for the allografts. The amount of olive oil in the 3 allograft lengths was compared with that in the equal-length cages of all 3 cage footprints. For all sizes of cages and allografts, the volume and weight of oil that fit into the cages was significantly greater than the volume and weight contained by the allograft struts ($p < 0.0001$). Comparing both the weights and volumes of oil instilled, we found that the 12 $\times$ 14-mm cages could accommodate more than 4 times the amount of material, the 14 $\times$ 16-mm cages could accommodate more than 4.5 times the material, and the 16 $\times$ 18-mm cages could accommodate more than 6 times the material, compared with allografts of the same length (Figs. 3 and 4). The standard deviations of the volumes and weights of oil instilled were 5–10 times less for the cages, indicating the variability in sizes of the fibular allografts compared with sizes of the CFRP cages.

Interobserver reliability for volume measurements was 0.991, and intraobserver reliability was 0.993. Interobserver reliability for weight measurements was 0.987, and intraobserver reliability was 0.990. Interobserver reliability for area measurements was 0.986, and intraobserver reliability was 0.982. These values indicate extremely high precision and accuracy of data collection during the experiment both for different measurements by the same observer and between different observers.

Load versus displacement graphs were plotted for the CFRP cubes. The average Young's modulus of elasticity of the 5 CFRP cubes, calculated by measuring the slope of the load versus displacement curves, was 16.44 ± 2.07 GPa (Fig. 5).

Discussion

Traditional interbody fusion techniques have been used for over 40 years with good outcomes. Fusion rates for

TABLE 1. Comparison of weights and volumes of olive oil in allografts and 3 cages

Measurement	Allograft	12 $\times$ 14-mm Cage	14 $\times$ 16-mm Cage	16 $\times$ 18-mm Cage	p Value*
No. of cases	6	3	3	3	
20 mm					
Weight (g)	0.3306 $\pm$ 0.14	1.34 $\pm$ 0.0087	1.49 $\pm$ 0.020	2.04 $\pm$ 0.07	<0.0001
Vol (ml)	0.38 $\pm$ 0.16	1.51 $\pm$ 0.012	1.66 $\pm$ 0.026	2.24 $\pm$ 0.023	<0.0001
Internal surface area (mm ²)	22.48 $\pm$ 1.13	65 $\pm$ 1.414	57.6 $\pm$ 0.57	92 $\pm$ 2	<0.0001
External surface area (mm ²)	104.8 $\pm$ 2.1	165.6 $\pm$ 0.57	219.8 $\pm$ 0.28	2893 $\pm$ 1.15	<0.001
40 mm					
Weight (g)	0.578 $\pm$ 0.25	2.69 $\pm$ 0.033	3.07 $\pm$ 0.038	4.33 $\pm$ 0.038	<0.0001
Vol (ml)	0.65 $\pm$ 0.27	3.01 $\pm$ 0.017	3.42 $\pm$ 0.033	5.15 $\pm$ 0.06	<0.0001
Internal surface area (mm ²)	21.22 $\pm$ 0.55	65 $\pm$ 1.414	57.6 $\pm$ 0.57	92 $\pm$ 2	<0.0001
External surface area (mm ²)	93.65 $\pm$ 6.5	165.6 $\pm$ 0.57	219.8 $\pm$ 0.28	2893 $\pm$ 1.15	<0.0001
50 mm					
Weight (g)	0.71 $\pm$ 0.26	3.51 $\pm$ 0.037	3.93 $\pm$ 0.065	5.93 $\pm$ 0.14	<0.0001
Vol (ml)	0.80 $\pm$ 0.30	3.90 $\pm$ 0.035	4.41 $\pm$ 0.063	6.15 $\pm$ 0.04	<0.0001
Internal surface area (mm ²)	20.35 $\pm$ 0.85	65 $\pm$ 1.414	57.6 $\pm$ 0.57	92 $\pm$ 2	<0.0001
External surface area (mm ²)	90.16 $\pm$ 0.83	165.6 $\pm$ 0.57	219.8 $\pm$ 0.28	2893 $\pm$ 1.15	<0.0001

* p values for all 3 cage footprints compared individually to allograft of the same length.

FIG. 3. Comparison of weight of olive oil that can be placed into 6 fibular allografts and 3 CFRP cages with different footprints. Asterisk indicates significant difference ($p < 0.01$), compared with allograft. $p < 0.0001$ for each of the 3 sizes of cages.

single-level anterior discectomy and fusion are between 83% and 99% for structural autograft and between 82% and 94% for structural allograft.^{5,10,35,53} Fusion rates are appreciably lower for multilevel anterior surgeries than for single-level fusion surgeries.^{7,42} Iliac crest is the most common site for harvesting structural autograft because of convenient surgical accessibility and the quantity of available bone. Issues related to autologous iliac crest bone graft harvest are predominantly related to donor site morbidity.^{19,24,26,31,33} The disadvantages of using autograft bone include increased surgery time, increased blood loss, donor site infection, and donor site pain.¹⁹ In addition, the quality of iliac crest bone in elderly patients is not always optimal.³⁶ Concerns with allograft utilization include poor osteoconductive and osteoinductive properties, increased risk of infection, possible disease transmission, and biocompatibility.^{24,25,27,36,40,49} Complications with pseudarthrosis have been observed with both autograft and allograft fusions.^{6,18,50}

In attempts to overcome the problems with bony strut grafts, interbody fusion cages have been developed. These cages can be made of metal, such as titanium or stainless steel, carbon fiber, or PEEK materials. Most often, the cages are filled with autograft material that can be obtained

from the corpectomy procedure. The advantages of cages include elimination of donor site morbidity, immediate anterior column support, and uniform size or footprint of the anterior column support.

Several factors must be considered when evaluating the various interbody struts such as autograft and allograft bone grafts and cages made of titanium, steel, PEEK, or carbon fiber. These factors include radiolucency, mechanical properties, and device geometry. Radiolucency is an important factor when considering fusion constructs in order to noninvasively evaluate the progress of fusion. Conventional radiographs, CT scans, and MR images can be used to assess the presence of fusion postoperatively (Figs. 6 and 7). In the case of conventional radiographs, while noninvasive evaluation of fusion progress is possible using radiolucent carbon fiber and PEEK implants, such evaluations are limited when using radiopaque, or titanium, implants (given the artifacts produced by the titanium).⁹ Diedrich et al. have indicated that with MRI analysis, it is possible to differentiate between atrophic tissue and bony fusion within PEEK and carbon fiber cages, while such differentiation is impossible within metal cages.¹⁴

Mechanical properties of the interbody implants should also be considered when implanting interbody devices.

FIG. 4. Comparison of volume of olive oil that can be placed into 6 fibular allografts and 3 CFRP cages with different footprints. Asterisk indicates significant difference ($p < 0.01$), compared to allograft. $p < 0.0001$ for each of the 3 sizes of cages.

FIG. 5. Stress-strain curves for 5 CFRP cubes allowed for the calculation of Young's modulus of elasticity. Based on the load versus deformation curves, the mean modulus of elasticity for CFRP is 16.44 ± 2.07 GPa.

In particular, analysis of Young's modulus of elasticity, a measure of the stiffness of a material, is important to ensure stability of both the implant and the spine. One of the major problems associated with metallic implants is the modulus mismatch between the fusion devices and the surrounding vertebrae.³⁹ Cages with stiffness much

greater than that of surrounding bone, such as cages made of titanium, have been shown to accelerate the degenerative process at adjacent levels.^{28,47} Less stiff implants, such as those made of CFRP as opposed to titanium, are associated with fewer occurrences of cage subsidence,^{15,17,48} perhaps augmenting the recent clinical success of those constructs made from carbon fiber.^{1,8,12,34,43} Our results show that the modulus of elasticity for CFRP is 16.44 ± 2.07 GPa. This value is much closer to the modulus values for both cortical and trabecular bone (18.6 and 10.4 GPa, respectively), as reported by Rho et al.,³² than those for titanium and steel (110 and 210 GPa, respectively).^{11,16,46} This relative modulus compatibility allows for an even distribution of physiological loads to the bone graft inside the implant.^{37,47}

The geometry of fusion implants is another factor when considering bony fusion through the device. In the case of allograft, bony fusion involves creeping substitution during which new bone is formed on the nonviable allograft bone. This process involves degradation of the allograft bone while the new bone is formed. The stability of the spinal section during this substitution process has been a point of concern.²¹ Cage designs eliminate this concern as the strength of the construct itself remains unchanged throughout the fusion process. Furthermore, the hollow and holed design of these cages allows for bony fusion growth both through and around the cage. Note that the present study does not account for the possibility of additional bony fusion around the cage. This means that the advantages may be even greater than the values reported in this study.

When it comes to evaluating interbody fusion devices, while the aforementioned factors (Young's modulus and radiolucency) have been greatly studied, the ability of a device to create a milieu that promotes bony fusion is of equal, if not greater, importance. Yet few studies have evaluated the ability of an interbody device to promote fusion. To address this issue, the primary concerns addressed in our study were the characteristics of an interbody device that allow it to promote bony fusion. We identified 2 measurable quantities, in particular, from which the ability of

FIG. 6. Conventional radiograph, lateral view, showing CFRP cage implanted at the T-2 vertebral level. Morselized bone graft was packed into the cage prior to implantation. Radiolucency of the cage on a plain film radiograph is demonstrated. Tantalum beads embedded in the ends of the CFRP cage are visible and delineate the margins of the cage.

FIG. 7. Sagittal reconstructed CT scan showing CFRP cage implanted in thoracic spine at the T-2 vertebral level. Morselized bone graft was packed into the cage prior to implantation. Ability to visualize the cage on CT scanning is demonstrated.

a device to allow for bony fusion could be determined: the amount of material that could be packed in a device and the total area of interface between the fusion material and the vertebral bodies.

Multiple studies have indicated that larger amounts of fusion material (that is, autologous bone packed into interbody devices) result in greater success of fusion.^{1,22,23,52} An in vivo human study by Kim et al. has shown that 55% of the initial graft volume is lost 18 months after surgery. Therefore, the greater the initial graft volume, the larger the fusion mass at 18 months after surgery.²³ Allograft packed with autologous bone material also has fusion occurring through the center of the allograft lumen (by autograft material). As shown in our study, the weight and volume of autograft material is much less ($p < 0.0001$) with fibular allograft than with CFRP cages. Furthermore, far lower standard deviations for the CFRP cages indicated that the consistency of the volume packed into the CFRP implant can be maintained.

Studies have also shown that the total area of interface

between autologous bone graft and vascularized vertebral body bone is an important consideration when promoting bony fusion.^{45,51} A study by Biederman indicates that a maximum of only 10% of the surface area of a vertebral body serves as an interface between graft and bone in Bagby and Kuslich (BAK) cages.⁵¹ Our results show that the footprint area of the CFRP cage available for fusion, which can be measured through the internal area, is significantly greater than that of the fibular allografts.

Of note, clearly the consistency of the oil is very different from any graft material. Likewise, the ability to determine the amount of graft material that can be incorporated may also be different. For instance, since oil is a liquid, it is very easy to place the maximal amount of material in the cage just by pouring. However, the volume of solid intragraft material used in clinical practice is limited by the ability of the surgeons to pack the cage or allograft. Therefore, our model may overestimate the volume available for packing and accentuate the differences between cages and allograft.

Conclusions

Our results demonstrated that carbon fiber cages can accommodate significantly ($p < 0.0001$) more olive oil (both weight and volume) than can fibular allografts. We determined that the surface area available for fusion is 4–6 times more for CFRP cages than for fibular allograft samples. The modulus of elasticity of CFRP was found to be similar to cortical bone; thus, a modulus mismatch between the implant and surrounding bone is minimized. If the goal of spinal reconstruction is to achieve long-term stable fusion, then filling a CFRP cage with autograft bone will allow a 4- to 6-fold increase in the amount of bone that can be packed into the carbon fiber cages. The ability to place more graft material within cages may result in higher fusion rates in clinical practice.

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Disclosures

Dr. Heary has been the recipient of research support and royalties from DePuy Spine for the Bengal device. No other authors have disclosures or potential conflicts of interest. All testing was performed with strict adherence to the highest ethical standards, and the authors believe that industry funding has had no effect on the results or interpretation of the results presented in this paper.

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Conception and design: Heary, Parvathreddy. Acquisition of data: Heary, Parvathreddy, Qayumi, Ali. Analysis and interpretation of data: all authors. Drafting the article: Heary, Parvathreddy, Agarwal. Critically revising the article: Heary, Parvathreddy, Agarwal. Reviewed submitted version of manuscript: all authors. Statistical analysis: Heary, Parvathreddy. Administrative/technical/material support: Heary. Study supervision: Heary.

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