Unique Osseointegration Patterns in 3D Printed Trabecular-Architecture Porous Polyetheretherketone (PEEK). A CT Scan Study of the Inspire® Cervical Implant

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Introduction

Anterior cervical discectomy and fusion (ACDF) is a common procedure for the surgical treatment of degenerative pathologies of the cervical spine. The utilization of interbody fusion implants is a well-established technique to restore disk space height, alignment, decompress the exiting nerve roots, and provide surface area for fusion of the adjacent vertebrae. Successful fusion is critical for the long-term stability and function of the cervical spine and for maintenance of the overall clinical outcome.

Polyetheretherketone (PEEK) is a material commonly used for interbody fusion implants. Benefits of PEEK include radiolucency, less stress shielding compared to titanium implants and improved modulus which may provide better loading characteristic. The ability to better visualize the fusion at the osseous-implant junction is a benefit preferred by many surgeons.

Challenges

Traditional PEEK is a solid block of polymer. Bone must fuse *around* the implant rather than *deeply integrating with and/ or fusing to and through* the implant. PEEK Implants with surface-porosity modifications have bone ingrowth limited to less than a millimeter at the surface, after which the implant is fully solid polymer without further bony ingrowth[1]. Wear debris generation has been observed with surface porous PEEK.[2] Researchers have also reported on the PEEK Halo effect.[3] This halo effect is demonstrated by an area of radiolucency between the PEEK implant surface and the host bone as seen on CT imaging. (**Figure 1**) This is due to differences in densities of the bone and the PEEK implant along with poor osseointegration of the implant.

Basic Science

Solid PEEK implants may have limited ability to promote protein absorption, cell adhesion, and subsequent osseointegration. In addition, PEEK implants elicit a fibrous tissue interface with bone during osseointegration due to an inflammatory immune response, which can lead to poor fusion results.[4]

The Curiteva Inspire® implant is 3D printed using a modified fused filament fabrication technique (fused strand deposition). It is subsequently coated with submicron hydroxyapatite (HA) to promote enhanced osseous integration. Basic science research on these implants demonstrates novel cellular responses not previously reported with traditional PEEK.[5] Specifically, the Inspire® porous surface promoted stem cell differentiation into osteoblasts as well as macrophage polarization (immunomodulation) showing *decreased inflammation* and increased vascular growth factors (VEGF) promoting a positive osseointegrative micro-environment. Additional validated animal studies also demonstrated significant osseointegration in cortical and cancellous bone defects, confirmed by histology and microCT at 3 months.[6]

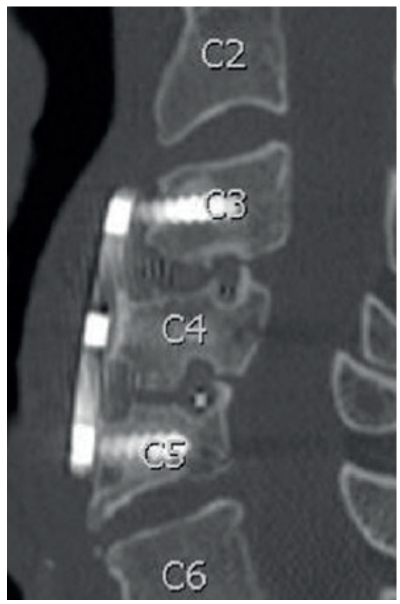

Figure 1: PEEK Halo

3D Printing PEEK

Curiteva is the only cleared US manufacturer currently capable of producing 3D printed, trabecular-like PEEK spine implants in the United States. (**Figure 2**) The 3D printing PEEK (fused strand deposition) is extremely complex as the temperature at the printer nozzle-implant interface must be narrowly controlled to prevent melting.

These highly specialized

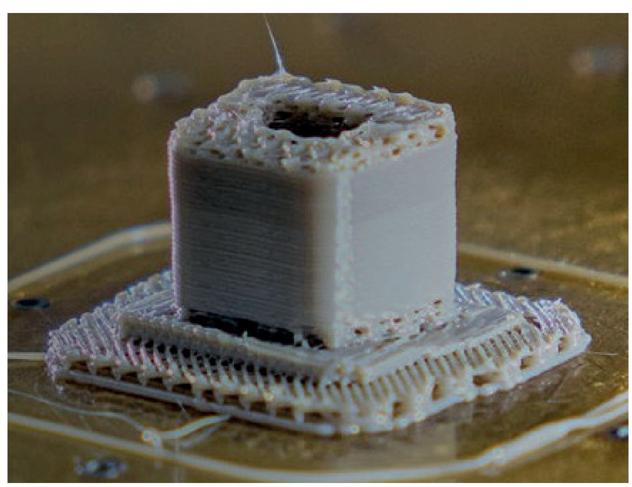

Figure 2: 3D Printing Inspire Implant

printers weave a single PEEK filament strand into an implant with fully interconnected porosity designed to mimic trabecular bone. (**Figure 3**) This unique, trabecular-like design provides ample room for deep endplate-implant osseointegration as well as bridging bony penetration throughout the implant. (**Figure 4**). Additionally, after printing, the Inspire® implant undergoes a proprietary surface coating (HA$^{FUSE®}$) with nano-hydroxyapatite (300 nm whiskers), which provides a favorable microenvironment to drive osteoblast activity in the early stages of osteogenesis and osseointegration.[7]

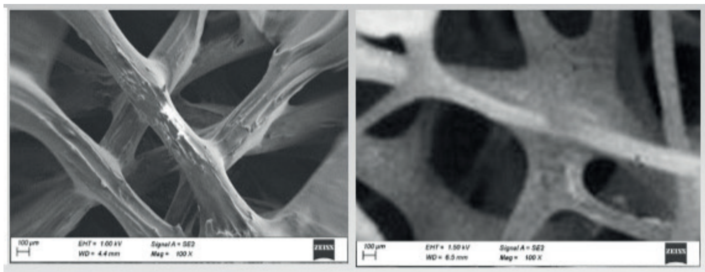

Figure 3: *Scanning Electron Micrograph Comparison of Inspire Trabecular-Like PEEK (L) with Human Trabecular Bone (R) (Bar=100 µm)*

Figure 4: *Inspire® Implant*

Methods

Computed Tomography scan analysis was performed to assess the surgeons' early Inspire® ACDF cases and to evaluate the pattern and extent of bone growth into and through the implants were occurring. An independent and highly experienced musculoskeletal radiologist reviewed the CT scans.

Imaging Assessment

The computed tomography (CT) scans were performed without contrast and had thin sections that were reconstructed into multiplanar reformatted images in the sagittal and coronal planes. These images were evaluated for fusion according to an adaptation of the fusion assessment by Bridwell et al. that defined a 4-point grading scale for spine fusions and has been extensively cited in the literature.[8]

In addition to fusion assessment the following CT criteria were evaluated: the presence or absence of of the PEEK halo effect, implant subsidence, loosening, erosive osseous changes, implant integration to the endplate or subchondral bone, and percentage of bone growth penetration throughout the the implant itself. (**Table 1**)

Results

Eleven CT scans comprising 32 surgical levels were reviewed. CT scan time points ranged from 6-12 months post-surgery (Mean 9.3 months).

Fusion Patterns

The Inspire® PEEK implant combined with submicron-hydroxyapatite coating (HA$^{FUSE®}$) produced far less attenuation and beam hardening artifact at the bone-implant interface than is typically seen with conventional PEEK. The lack of this artifact allowed for adequate assessment of the fusion interface between the remaining endplate and the adjacent implant.

PEEK Halo effects were absent (n=0) with none observed in any of the 32 surgical levels. 100% osseointegration between the endplates and implants was observed with subsidence noted in only 2 levels (6.25%), though not impacting Fusion Grade (1).

Figure 5: *CT Lateral Image*

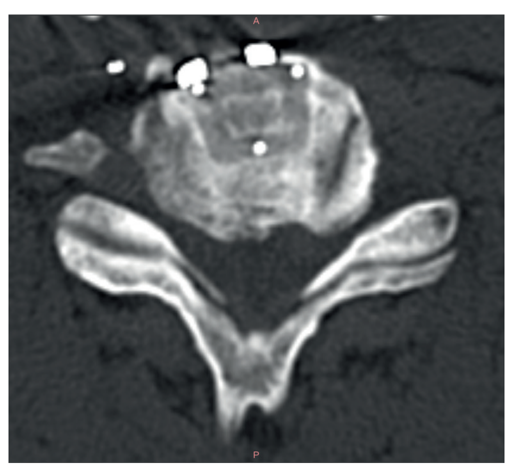

Figure 6: *CT Axial Image*

Table 1: Radiographic Assessment

Subject #	Fusion Levels	Fusion Grade (1-4)	PEEK Halo Effect (Yes/No)	Erosive bone changes (Yes/No)	Implant Osseo-integration Into Endplate (Yes/No)	Bone Growth Penetration through the Implant (%)	Subsidence (Yes/No)	Implant Loosening (Yes/No)	Device Migration/ Dislodgement (Yes/No)
1	C4-5 C5-6 C6-7	2 2 1	No No No	No No No	Yes Yes Yes	50% 75% 90%	No No No	No No No	No No No
2	C4-5 C5-6 C6-7	2 2 1	No No No	No No No	Yes Yes Yes	50% 40% 50%	No No No	No No No	No No No
3	C3-4 C4-5 C5-6	2 2 1	No No No	No No No	Yes Yes Yes	50% 40% 75%	No No No	No No No	No No No
4	C3-4 C4-5 C5-6	2 1 1	No No No	No No No	Yes Yes Yes	50% 75% 90%	No No No	No No No	No No No
5	C5-6 C6-7 C7-T1	1 1 1	No No No	No No No	Yes Yes Yes	60% 90% 95%	No No No	No No No	No No No
6	C4-5 C5-6 C6-7	2 1 1	No No No	No No No	Yes Yes Yes	30% 30% 30%	No No No	No No No	No No No
7	C3-4 C5-6 C6-7	1 1 1	No No No	No No No	Yes Yes Yes	75% 60% 50%	No No No	No No No	No No No
8	C4-5 C5-6 C6-7	2 1 1	No No No	No No No	Yes Yes Yes	50% 80% 90%	No No No	No No No	No No No
9	C3-4 C4-5 C5-6	1 1 1	No No No	No No No	Yes Yes Yes	75% 90% 90%	No No No	No No No	No No No
10	C3-4 C4-5 C5-6 C6-7	1 * 1 1	No N/A* No No	No N/A* No No	Yes N/A* Yes Yes	75% N/A* 90% 90%	No N/A* Yes Yes	No N/A* No No	No N/A* No No
11	C5-6	1	No	No	Yes	100%	No	No	No

*Indicates C4-5 level was non-evaluable due to CT artifact

Fusion Assessment Scale:

Grade 1 – Definitely Fused

Clear evidence of bridging bone through and/or around the device. No noticeable lucencies or areas of concern.

Grade 2 – Probably Fused

Evidence of bridging bone through and/or around the device (50-75% at least), but there may be minor lucencies or areas of incomplete bone bridging.

Grade 3 – Probably Not Fused

Some minor evidence of bone formation within a portion of the device but may not fully extend through the device (less than 50%). There may be lucency around a portion of the device.

Grade 4 – Definitely Not Fused

No clear evidence that appreciable bone formation has occurred and/or major lucencies indicating that the device is not solidly anchored in bone.

Bone Grafts

All commonly used bone graft types were represented incluging ICBG (n=2), local bone graft (n=3), DBM/allograft (n=3), and ceramic (n=3). Fusion and osseointegration was uniformly observed with all types of grafts.

No cases of erosive bone changes, loosening, or implant migration were noted. None of the implants showed any lucency at the graft/bone interface. **(Figure 5 and 6)** Bone growth penetration throughout the lattice (trabecular) structure of the implant (cephalad-caudal and superior-inferior) averaged 67% (range 30-100%). **(Figure 7)**

Discussion

Traditionally, PEEK implants used in spinal fusion surgeries faced significant challenges related to loosening and suboptimal osseointegration. CT images often revealed the halo effect and bone loss around PEEK implants, further indicating the failure of osseointegration. To address these issues, various implant surface modifications have been explored. Despite surface modifications, the bone cannot grow through the remaining solid dense PEEK located below the surface modifications of these implants.[1]

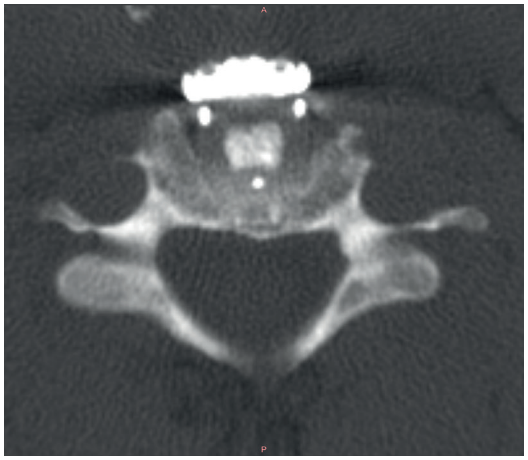

Figure 7: CT Axial image

The Inspire® implant is the only 3-D printed PEEK implant with a fully interconnected porous and trabecular-like architecture. (**Figure 3**) This study identified several unique fusion patterns of osseointegration and bone growth penetration that have not been achieved with other PEEK implants. Most notably there were no imaging halos, minimal subsidence, and no erosive changes were seen. In fact, imaging evidence of extensive bone penetration in a 3-dimensional fashion into the implant was noted. This deeply penetrating osseointegrative process between the host bone and a PEEK implant has not been previously reported.

Historically, multi-level fusions are more challenging and have higher pseudarthrosis rates than one and two level cases.[9] The results of this study, although limited by a small sample size, showed fusion rates and osseointegration bone growth patterns to be equal in both the shorter (1- and 2-level) and the longer (3- and 4-level) fusion constructs.

Further clinical investigations are ongoing but a recent outcomes survey of surgeons using the Inspire® implants (N=757 cases) reported similar findings in 3 and 4 level cervical fusions.[10]

Conclusion

This computed tomography imaging study of the Inspire® Cervical PEEK implant from Curiteva, with its unique and proprietary 3D printed and fully interconnected porous structure, demonstrated 100% endplate-implant osseointegration, no halo artifacts or subsidence, and an average of 67% bone penetration throughout the implant. The presence of bone growth deeply into, and penetration throughout, the implant structure itself has not been previously observed with other PEEK implants.

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