Product Design Specification: Polyaxial Vertebral Hook – 4th Draft (3.29.08)
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Problem
Spinal deformities, including scoliosis, hyperkyphosis, and hyperlordosis, can arise from congenital structural defects, postural habits, or trauma, can occur in any demographic, and can have debilitating effects on patients. Due to such etiological and patient variation, current medicine is limited to a handful of corrective strategies. Principle among such treatment is repositioning of the spinal column into a more physiological orientation and stabilization of vertebrae to allow vertebral fusion using a hip-derived bone graft. Replacing cumbersome and inefficient whole-torso braces, an array of vertebral implants are now available to effect temporary spinal fixation to allow acute vertebral fusion. These implements can be subdivided into vertebral hooks and pedicle screws, with each device offering unique advantages and disadvantages. Although current static hook designs offer a minimally invasive implantation possible in both structurally sound and cancerous vertebrae, current surgical trends have shifted towards pedicle screws due, in part, to ease of pedicle screw placement and rod positioning in lockable polyaxial screw heads. Pedicle screws exhibit certain drawbacks, however, including risk of irreversible spinal cord damage, and are not appropriate in all instances – notably, pedicle screws cannot be implanted into cancerous or otherwise compromised vertebrae, and most cervical vertebrae present pedicle geometries too small for drilling. These currently inoperable vertebrae warrant the consideration of an improved or alternative design integrating the advantages of polyaxiality into a safe, minimally invasive implant available to cancerous and/or cervical vertebrae.

Device Function
This project seeks to integrate polyaxiality into a sublaminar hook design to facilitate device implantation and corrective rod placement, as has been demonstrated previously with polyaxial pedicle screws. In addition, a modular sublaminar hook design is desired to establish the potential of a customizable implant to better suit individual patients. Overall, the purpose of this project is to expand current vertebral hook capabilities to provide a safe, efficient implant that may be combined with available, successful pedicle screw designs to extend corrective spinal fusion surgeries to cervical-level spinal deformities and/or structurally-compromised vertebrae. Functionally, the intent of this device is similar to current vertebral implants – to establish temporary vertebral fixation to allow physiological bone fusion across deformed or misaligned vertebrae.

Customer Requirements
1. Device must be functional under physiological conditions (37±4 °C, high humidity, pH7.4) and must withstand sterilization procedures.
2. Device must be of similar height profile (<24mm) and mass (2.75-4.00g) as currently-used static hook designs.
3. Polyaxiality will be defined as $\geq 5^\circ$ hook blade pitch (blade tip closer/farther from head) and yaw (blade side closer/farther from head) while maintaining full 360° roll rotation.
4. Polyaxial hook must demonstrate equivalent operation under physiological loads compared to a representative static hook.
5. Head component must fit 6.35±0.05mm diameter corrective rods.
6. Head component must be threaded to allow corrective rod fixation.
7. Compatible set screw must utilize square-cut threads to minimize radial translation of
forces during final set screw tightening to prevent splaying of the “tulip head” design.
8. Top of the hook head must present square-cut threads of 15° pitch and 0.030±0.01in width to be compatible with designed set screw.
9. Corrective rod fixation must be possible at all extremes of hook position.
10. Device must demonstrate equally low rates of corrective rod slip (rod fixation failure) at all extremes of hook position.
11. Corrective rod fixation must prevent further hook motion.
12. Implanted hook must minimize stress on the conjugate vertebrae by equally distributing stresses; vertebrae-hook purchase must include three distinct faces of the vertebral process (i.e. dorsal, ventral, and anterior faces of the lamina with respect to the spinal cord)
13. Polyaxial joint must demonstrate equivalent or greater pull-out mechanical strength compared to polyaxial screw heads currently available.
14. Hook must demonstrate equivalent or greater uniaxial mechanical strength compared to static hooks currently available.

Design Specifications
1. Performance
   1. Components: the total device comprises four different components: the head and blade are assembled into the vertebral hook; the head then receives the corrective rod, which is locked in place by a set screw. The blade passes through the head component, such that the spherical top of the blade rests in the spherical base of the head to establish a ball-and-socket joint capable of polyaxial motion.
   2. Rod fixation: when positioned within the hook assembly, the rod contacts the spherical top of the blade, the walls of the head, and the bottom of the set screw. Final tightening of the set screw places pressure onto the ball-and-socket joint between the blade and the head to prevent further polyaxial hook motion.
   3. Vertebrae-hook purchase: Proper implantation of the hook assembly leads to vertebrae-hook contact on three distinct faces of the vertebrae to prevent excessive loading at any one region of the vertebrae. Degrees of vertebrae-hook purchase will be governed by the hook contour. Hook blade length, radius and length of curvature, and opening-width will be modeled after current successful hook implants.
   4. Device dimensions: the hook assembly will not exceed an overall height (measured from the lowest possible point of the blade to the top of the head) of 24mm to provide a polyaxial hook of equal profile to currently available static hooks.
   5. Mechanical properties: ASTM active standard F1717-04 dictates standard guidelines for static and fatigue testing relative to vertebral location and implant use, for measuring displacements, for determining yield load, and for evaluating the stiffness and strength of the implant.

2. Testing
   1. Facility: testing will be performed within the Welch Neurosurgical Research Laboratory at the University of Pittsburgh Medical Center as well as the University of Pittsburgh’s Bioengineering Computer Lab.
   2. Machine: equivalent stress distributions and similar load capacities of polyaxial
vertebral hook compared to static hook designs will be demonstrated computationally using finite element analysis. Future mechanical testing of prototypes will be performed on a six-axis spine test frame with automated follower load capability to simulate physiological vertebrae/muscle response and uniaxial tensile loading capable of fulfilling active standard F1717-04.

3. Materials
   1. Sterilization: components must withstand a 30 minute exposure to 121°C under 15 PSI without detectable mechanical or size alteration.
   2. Biocompatibility: components must be constructed from materials previously sanctioned as inert and biocompatible, particularly nonoxidative materials. Thrombogenicity will be minimized but should not be an issue as the hooks will have no intravenous contact. Titanium is currently the optimum material for construction.
   3. Environment: each sublaminar hook variation must endure within a physiological environment (37±4°C, high humidity, pH7.4) without appreciable (< 0.05%) decrease in structural properties.

4. Safety
   1. Materials must comply with biocompatibility standards specified above.
   2. The designed hook must demonstrate similar stress distributions and load capacities compared to current static hook designs, as well as similar failure modes when mechanically loaded to failure.
   3. In future studies, the vertebral hook construct must comply with ASTM F1717-04-derived standards for static and fatigue testing.

5. Device Longevity
   1. The vertebral hook construct is intended to provide 4-6 months of vertebral stabilization without significant migration, dislodgement, or structural failure.