EXECUTIVE SUMMARY

Problem: Pedicle screws are the leading device for effecting temporary vertebral stabilization for spinal fusion procedures but 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 and serve as the motivation of the described project. Vertebral hooks combine feasible implantation within cancerous and/or compromised vertebrae independent of pedicle size with a safer, less invasive corrective strategy compared to pedicle screws, yet require optimization to streamline implantation and corrective rod placement while maintaining biomechanical stability.

Solution: The proposed 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. A polyaxial joint will make initial implant positioning simpler; will reduce the constraints of head angle and position on implant position, thereby increasing available implantation area of the sublaminar vertebra and potentially decreasing the amount of necessary bone-shaping prior to implantation; will reduce anterior blade movement during fixation by instead allowing the polyaxial head to move during final set screw tightening; and will reduce necessary initial rod bending to seat the corrective rod into the hook head. In addition, a modular sublaminar hook design is desired to establish the potential of a customizable implant to better suit individual patients. Overall, these improvements are poised to increase the efficacy of vertebral hooks and thus present surgeons with a viable alternative device for vertebral fixation at any spinal level as well as a device for previously inoperable cases of metastasized cancer or cervical deformity.

Competition: Vertebral stabilization systems containing both polyaxial pedicle screws and variations of vertebral hooks for effecting temporary vertebral fixation for spinal fusion procedures are currently available. These spinal systems are manufactured by large medical device companies such as Zimmer (ST360 Spinal Fixation System), Medtronic Sofamor Danek (CD Horizon Legacy System), DePuy Spine (of Johnson & Johnson) Fixation Systems, and Synthes (Click'X Spine System). The vertebral hooks contained within all of these products are static, uniaxial devices.

Polyaxial pedicle screws provide the most popular fixation method. These devices provide flexibility in the surgery since the alignment of adjacent screws for rod fixation is eased by the polyaxial head. To our knowledge, no form of a polyaxial hook is currently being manufactured.

Unique Aspects: The proposed device will integrate polyaxiality into a sublaminar vertebral hook design. This alteration of the sublaminar hook follows similar trends of polyaxial versus static pedicle screws, but utilizes a unique ball-and-socket interface to effect polyaxial motion. This interface not only allows simple locking by direct translation of forces through set screw to hook head, corrective rod, and hook blade to prevent further motion after implantation, but also presents a modular design that can potentially enable a customizable implant to better suit individual patients.

Technical Feasibility: A polyaxial sublaminar vertebral hook is subject to all constraints that impact design of a standard static hook. Foremost among these constraints are device dimensions, especially height profile, and mechanical stability. Device height limitations preclude integration of several polyaxial joint mechanisms; however, a ball-and-socket joint embedded into the base of the head presents a viable option that does not significantly increase device profile. Adaption of polyaxiality to a sublaminar hook also does not impact relevant mechanical properties of the implant as both the static and polyaxial designs demonstrated equivalent failure modes at the curve of the hook blade, not at the polyaxial joint. Finally, use of a set screw with square-cut threads is a proven method for corrective rod fixation. The proposed device is thus technically feasible and is projected to function successfully in clinical settings.

Regulatory and Reimbursement: The novel hook design will follow the 510(k) regulatory pathway, as similar spinal fixation systems follow the 510(k) pathway. These devices include the BAR Pedicle Screw Spinal Fixation System, ISOBAR TTL Spinal System, Dynesys Dynamic Stabilization System, and SATELLITE Spinal System.

The FDA Guidance Document under 21CFR888.3050 lists spinal interlaminar fixation orthosis as Class II devices.

Sales and Marketing: Five companies dominate the world spine device market: Medtronic Sofamor Danek (35%), DePuy Spine of Johnson & Johnson (20%), Synthes-Stratec (13%), Stryker Corporation (8%), and Zimmer Holdings (5%).

In addition to dollar share, Medtronic and DePuy own a large proportion of the mindshare of surgeons, thus reinforcing their leading market positions. Medtronic has the majority of the world market, and their leading vertebral implant system is the CD Horizon Legacy.

The proposed device is intended to complement pedicle screw constructs as they bridge cancerous vertebrae or transition from thoracic to cervical levels, and will consequently be marketed to a larger company, such as Medtronic Sofamor Danek, for inclusion in their pedicle screw spinal fusion system.

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. An array of vertebral implants is currently 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.

Current trends indicate that pedicle screws are utilized significantly more often than vertebral hooks due, in part, to ease of screw placement and rod positioning in lockable polyaxial screw heads compared to static hook designs. Pedicle screws exhibit certain drawbacks, however, including pull out risk due to excessive vibrations and reduced bone integrity from vertebral drilling, 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. Vertebral hooks combine feasible implantation within cancerous and/or compromised vertebrae with a safer, less invasive corrective strategy compared to pedicle screws, yet require optimization to streamline implantation and corrective rod placement while maintaining biomechanical stability.

PROJECT OBJECTIVE STATEMENT

The proposed project is intended to augment current vertebral hook capabilities to provide a safe, efficient implant that may complement proven pedicle screws to extend corrective spinal fusion surgeries to cervical-level spinal deformities as well as structurally-compromised vertebrae. Specifically, 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. A polyaxial joint will make initial implant positioning simpler; will reduce the constraints of head angle and position on implant position, thereby increasing available implantation area of the sublaminar vertebra and potentially decreasing the amount of necessary bone-shaping prior to implantation; will reduce anterior blade movement during fixation by instead allowing the polyaxial head to move during final set screw tightening; and will reduce necessary initial rod bending to seat the corrective rod into the hook head. In addition, a modular sublaminar hook design is desired to establish the potential of a customizable implant to better suit individual patients. Such modular design will enable the combination of a lumbar level blade with smaller corrective rod diameters in less severe caudal deformities or similarly a cervical level blade with larger corrective rod diameters in more severe rostral deformities. Overall, these improvements are poised to increase the efficacy of vertebral hooks and thus present surgeons with a viable alternative device for vertebral fixation at any spinal level as well as a device for previously inoperable cases of metastasized cancer or cervical deformity.

RISK ANALYSIS

Risk analyses of the proposed polyaxial vertebral hook performed include an initial hazards analysis, a risk management summary, a fault tree analysis, and a failure modes and effects analysis. Potential hazards identified range from catastrophic (class I) to critical (class II), marginal (class III), and negligible (class IV), and include pseudarthrosis/failed vertebral fusion (III), tissue damage (III), vertebral fracture (II), undesired spinal curvature (II), irreversible spinal cord damage (I), and immunogenic/thrombogenic response (II).

Potential causes of pseudarthrosis/failed vertebral fusion include inadequate vertebral-pair stabilizing force due to improper or incomplete device implantation, inappropriate hook fitting due to tolerance summation error, hook splaying as a result of excessive force during set screw tightening, loss of stabilizing force due to hook mechanical failure or corrective rod-fixation slip, inadequate locking of polyaxial joint following rod fixation leading to excessive construct motion and lack of stabilizing force, and loss of stabilizing force due to hook migration or dislodgement.

Potential causes of tissue damage include improper device implantation or inappropriate hooking fitting or fixation.

Potential causes of vertebral fracture entail inappropriate stabilizing force applied due to improper device implantation and excessive forces used for *in situ* bending of corrective rods.

Undesired spinal curvature may arise from imbalance of bilateral vertebral-pair stabilizing force due to improper device implantation or mechanical failure of hook or corrective rod or rod-fixation slip.

Irreversible spinal cord damage may occur if excessive force is used in implanting the device or from improper or accidental misuse of implantation tools.

An immunogenic or thrombogenic response to the implanted device is possible, though not likely, as materials sanctioned as biocompatible will be used in final device manufacture. Infection due to inadequate device sterilization and/or improper implantation procedures can also result in an immunogenic response.

Controls for preventing the above hazards include reducing improper implantation through adequate device training and instruction, mechanically optimizing hook design using finite element analysis and mechanical testing of instrumented cadaveric spines, and proper sterilization procedures and sterile device packaging.

In addition, quantification of severity and likelihood of each risk as well as further consideration of failure modes are presented in an attached risk management matrix (Appendix IA) and failure modes and effects analysis (Appendix IB), respectively.

CONCEPTUAL DEVELOPMENT AND PROTOTYPE DESIGN

In developing a polyaxial vertebral hook, we began by identifying the relevant and driving constraints of our design. Similar to design of static hooks, maintaining sound structural properties of the device while minimizing device profile to prevent excessive implant prominence, patient discomfort, and soft tissue irritation were considered paramount objectives. Guided by these requirements, a patent search was performed to identify potential polyaxial joint mechanisms utilized in current polyaxial pedicle screws for adaptation to a vertebral hook. To maximize polyaxial angulation while minimizing device profile, a prototype centered on a simple ball-and-socket joint embedded into the base of the hook body was ultimately planned. An additional design strategy was the selection of square-cut threads for the locking set screw to minimize radial translation of thrust forces during final screw tightening and thereby prevent splaying of the tulip hook head and rod-fixation failure.

SolidWorks computer-aided design (CAD) software was used to three-dimensionally model all prototypes. A collection of various static vertebral hooks were referenced to supply general dimensions and contours of the hook blade, head, and set screw, as well as to establish various verification requirements. The first prototype accomplished several of our initial design goals. Foremost, a functional polyaxial joint was created by sliding the hook blade component through the opening in the base of the hook head component and resting the spherical boss of the blade into the spherical cut opening of the head base. This joint functionally met the definition of polyaxiality established *a priori* and did not extend the device past the height maximum. In addition, Prototype I demonstrated a measure of compatibility between square-cut threads of the head and the designed set screw, but suggested that slight dimensional optimization and further account of design tolerances were necessary. Restructuring of the blade portion that forms the polyaxial joint was also necessary to present a more rigid rod fixation following set screw tightening. Further, polled clinicians suggested that sharp edges be rounded in design revisions. Part drawings and graphical representation of Prototype I are attached as Appendix IIA.

Beyond incorporating more accurate dimensional tolerances and a restructured joint, Prototype II was modified to seat a slightly thicker blade to provide improved mechanical properties, as determined through finite element analyses. Further, the second prototype was rebuilt to fit larger, 6.35mm diameters rods more applicable to severe deformity cases that may also benefit from a polyaxial vertebral hook. Stereolithography rapid-prototyping and nickel-plated ceramic composite prototypes of this latter design were utilized for verification and validation procedures. A standard static hook to serve as a testing control was designed in parallel to mimic the contours of the polyaxial hook. Part drawings and graphical representations of Prototype II are attached as Appendix IIB. Part drawings and graphical representations of the control static hook are attached as Appendix IIC. In addition, graphical representation of a model spine instrumented with pedicle screws during prototype validation are attached as Appendix IIIB.

FUNCTIONAL VERIFICATION AND VALIDATION

The below guidelines were established to present the viability of a polyaxial vertebral hook. Prototypes for verification were constructed using stereolithography rapid-prototyping, while prototypes for validation were constructed of a nickel-plated ceramic and assumed comparable to titanium units in all aspects except for mechanical properties and biocompatibility.

Verification

1. Hook assembly must not exceed an overall height (measured from base of blade to apex of head) of 24mm to provide a polyaxial hook of equal or lesser profile to currently available uniaxial hooks. Dimensions will be determined during computational design.
2. Hook assembly and set screw must come to an overall mass of 2.75-4.00g to provide a polyaxial hook of similar mass compared to currently available uniaxial hooks, ensuring surgeon comfort and familiarity. Mass will be determined during computational design.
3. Hook head must fit 6.35±0.05mm diameter corrective rods.
4. The blade must pass through the base of the head, with the spherical top of the blade resting on the spherical cut of the head base to establish a polyaxial ball-and-socket joint.
5. Polyaxiality will be defined as ≥5° blade pitch (blade tip closer/farther from head) and yaw (blade side closer/farther from head) while maintaining full 360° roll rotation. Compliance with this will be quantitatively determined during computational design.
6. Head must present square-cut threads of 15° pitch and 0.030±0.001in width to be compatible with designed set screw. Screw-head compatibility will be determined during both computational design of hook head and set crew and confirmed manually.
7. Rod fixation must be possible at all extremes of blade angle and prevent further motion.

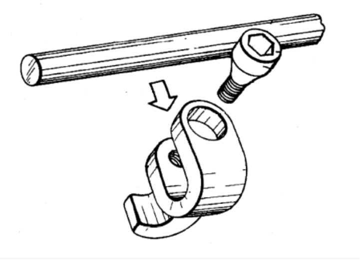
Validation

1. Qualitative physiologic evaluation of the designed device will be performed by *in vitro* implantation of polyaxial hook constructs (hook, blade, set screw, rod) at the L3-L4 spine level of a representative model spine by surgeon mentor Dr. Adam S. Kanter of the University of Pittsburgh Medical Center (UPMC), who currently performs spinal fusion procedures. Equivalent implantation of uniaxial hook constructs will serve as a control. An additional polyaxial screw-hook construct was implanted at the thoracic-cervical junction to provide further qualitative evaluation, with a uniaxial screw-hook control.
2. Further evaluation of the designed device will be assessed by presenting the prototype design, spinal constructs, and the uniaxial control to a panel of twelve full-time UPMC spine faculty members and conducting a survey (Appendix IIIA) evaluating our design.

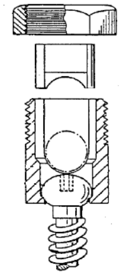
All verification requirements were met; the device stands at 23.5mm, has a mass of 3.16g, fits 6.35±0.05mm diameter corrective rods, meets the established definition of polyaxiality, and demonstrates locking functionality with compatible set screw tightening. Appendix IIB and Appendix IIIB depict our final design, verified prototype, and instrumented model spine. Additionally, finite element analyses reveal equivalent failure modes of polyaxial and comparable static hook designs, verifying no loss in mechanical strength due to introduction of polyaxiality (Appendix IIIC-D). Results of a clinician survey (Appendix IIIE) project our design to ease implantation, reduce necessary bone shaping, and reduce surgical durations while maintaining procedural safety and imparting equivalent stabilization, further suggesting that the designed prototype has potential for acceptance among the medical community.

PATENT SEARCH

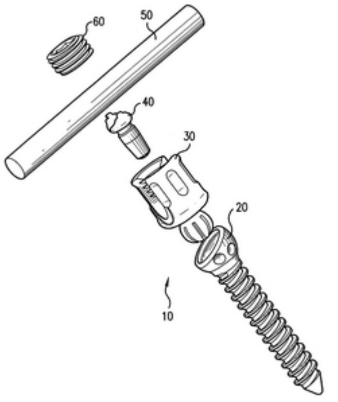
Many patents exist for vertebral stabilization devices. Two hook variations predominate within the stabilization systems: pedicle hooks and sublaminar hooks. Patent 5,676,665 (below figure) is an example of a simple sublaminar hook system. The rod inserts into the c-shaped head and is tightened down by a set screw.



All hook patents are for uniaxial hooks, but polyaxial screws are a common alternative to hooks. Patent 5,474,555 (below figure) describes an original polyaxial screw design that serves as a gold standard in current devices. The figure shows the spherical screw head sitting flush with the rod, creating a rotating component that is locked into place by a cap which is further secured by an exterior set screw.



While the above design is the simplest and dominant patent for the polyaxial screw, more complex designs exist, such as under patent 7,163,539 (below figure). This design is composed of a ball and socket joint that requires compression of components during assembly and includes a fixating cap, rod, and set screw.



REGULATORY PATHWAY

The novel hook design will follow the 510(k) regulatory pathway, as similar spinal fixation systems follow the 510(k) pathway. These devices include the BAR Pedicle Screw Spinal Fixation System, ISOBAR TTL Spinal System, Dynesys Dynamic Stabilization System, and SATELLITE Spinal System.

The FDA Guidance Document under 21CFR888.3050 lists spinal interlaminar fixation orthosis as Class II devices.

ESTIMATED MANUFACTURING COSTS

The proposed device consists of three separate components: the hook blade, the tulip head, and the compatible set screw. Each component is to be manufactured out of medical grade titanium (although stainless steel variations are also available for current spinal implants and possible for this device). The titanium alloy, Ti-6A1-4V, is a common choice in spinal implant and fixation devices. Dynamet is one supplier of implant grade titanium bars that fall under ASTMF1472 standards for medical implants.

One Dynamet titanium bar measures 2x2x12in., which we conservatively estimate is enough for approximately ten total devices, and costs $434. Manual machining costs are estimated to range up to $100/hr for up to 5 hours, resulting in an estimated cost per device of <$100. This estimate is expected to drop with automated injection molding after the initial costs of machinery.

MARKET ANALYSIS AND SALES STRATEGY

The musculoskeletal business sector composes approximately 10% of the global health care industry. Of this portion, 16% consists of spinal treatments, as reported by www.devicelink.com/mx/archive/05/01/viscogliosi.html.

By the age of 50, 85% of the population will show evidence of disc degeneration. Each year, 27,000 cases of scoliosis are serious enough for surgery. In 2002, an estimated 190,000 lumbar spinal fusion surgeries were performed. (Medtronic, Inc., Minneapolis, MN).

Spinal-fusion surgery has an average cost of more than $34,000, excluding professional fees, as reported by Deyo RA, Nachemson A, and Mirza SK, (2004) "Spinal-fusion surgery – the case for restraint. N Engl J Med, *350:* 643-644.

Five companies dominate the world spine device market: Medtronic Sofamor Danek (35%), DePuy Spine of Johnson & Johnson (20%), Synthes-Stratec (13%), Stryker Corporation (8%), and Zimmer Holdings (5%).

In addition to dollar share, Medtronic and DePuy own a large proportion of the mindshare of surgeons, thus reinforcing their leading market positions. Medtronic has the majority of the world market, and their leading vertebral implant system is the CD Horizon Legacy. According to their quarterly fiscal report, sales are increasing.

	2006				Total	2007				Total
Spinal & Navigation	$524	$539	$563	$619	$1566	$599	$625	$629	----	----
Spinal Instrumentation	$376	$382	$387	$420	$1566	$412	$421	$429	----	----

($ in millions)

Companies that market these implants sell entire systems consisting of hooks, screws, and all the tools necessary for implantation. Therefore, the most feasible option is to interface our hook with Medtronic tools and market it to this company.

APPENDIX IA
Risk Management Summary: Polyaxial Vertebral Hook
Mentor: Dr. Boyle Cheng, UPMC Welch Neurosurgical Research Laboratory
Team: Shawn Burton, Kate Campbell, Amy McCarty, Ben Schmidt

Definition of Risks

Risk Level	Description
1	Intolerable risk
2	Tolerable only if risk mitigation is impractical and/or costs are excessive
3	Tolerable if cost of risk mitigation cannot be compensated by projected sales
4	Negligible risk

Risk Quantification Matrix

	Severity			
Probability	Negligible	Marginal	Critical	Catastrophic
Frequent	III	II	I	I
Probable	III	II	I	I
Occasional	IV	III	II	I
Infrequent	IV	III	III	II
Improbable	IV	IV	III	III
Incredible	IV	IV	IV	IV

APPENDIX IA

Risk Management Summary: Polyaxial Vertebral Hook
Mentor: Dr. Boyle Cheng, UPMC Welch Neurosurgical Research Laboratory
Team: Shawn Burton, Kate Campbell, Amy McCarty, Ben Schmidt

Hazard ID	Hazard	Severity	Cause	Probability of Occurrence	Risk	Control Mode	Control Measures	New Probability of Occurrence	New Risk
1	Pseudarthrosis/failed vertebral fusion	Marginal	1.1 Improper implantation	Infrequent	III	Post-Design	Labeled for use by trained neurosurgeon; kit encloses comprehensive manual on static vs. polyaxial hook selection	Improbable	IV
			1.2 Inappropriate hook fitting	Occasional	III	Design	Utilize optimization methods for blade contour design using computational modeling and testing	Improbable	IV
			1.3 Tulip head failure	Infrequent	III	Design	Optimize set screw design and threads to minimize splaying	Improbable	IV
			1.4 Hook mechanical failure	Improbable	IV	Design	Locate, restructure stress points using finite element analysis	Incredible	IV
			1.5 Rod-fixation slip	Infrequent	III	Design	Optimize rod fixation (adjust set screw thread pitch and size, blade top shape); analyze using physiologic loading	Improbable	IV
			1.6 Excessive hook motion	Infrequent	III	Design	Optimize rod fixation (adjust set screw thread pitch and size, blade top shape); analyze using physiologic loading	Improbable	IV
			1.7 Hook migration	Infrequent	III	Design	Utilize optimization methods for blade contour design using computational modeling and testing	Improbable	IV
			1.8 Hook dislodgement	Infrequent	III	Design	Utilize optimization methods for blade contour design using computational modeling and testing	Improbable	IV
2	Tissue Damage	Marginal	2.1 Improper implantation	Infrequent	III	Post-Design	Labeled for use by trained neurosurgeon; kit encloses comprehensive manual on static vs. polyaxial hook selection	Improbable	IV
			2.2 Inappropriate hook fitting	Occasional	III	Design	Utilize optimization methods for blade contour design using computational modeling and testing	Improbable	IV
3	Vertebral fracture	Critical	3.1 Improper implantation	Infrequent	III	Post-Design	Labeled for use by trained neurosurgeon; kit encloses comprehensive manual on static vs. polyaxial hook selection	Improbable	III
			3.2 Excessive *in situ* rod-bending forces	Infrequent	III	Design	Optimize polyaxial joint to reduce *in situ* rod bending necessary for rod placement	Improbable	III
4	Undesired spinal curvature	Critical	4.1 Improper implantation	Infrequent	III	Post-Design	Labeled for use by trained neurosurgeon; kit encloses comprehensive manual on static vs. polyaxial hook selection	Improbable	III
			4.2 Hook mechanical failure	Improbable	III	Design	Locate, restructure stress points using finite element analysis	Incredible	IV
5	Irreversible spinal cord damage	Catastrophic	4.1-4.2 Improper implantation	Infrequent	II	Design	Labeled for use by trained neurosurgeon; kit encloses comprehensive manual on static vs. polyaxial hook selection	Improbable	III
6	Immunogenic or thrombogenic response	Critical	5.1-5.3 Poor material selection	Incredible	IV	Design	*In vitro* biocompatibility assay	Incredible	IV
			5.4 Inadequate sterilization	Improbable	III	Prod-uction	Quality control management	Improbable	III

APPENDIX IB

Failure Modes and Effects Analysis: Polyaxial Vertebral Hook
Mentor: Dr. Boyle Cheng, UPMC Welch Neurosurgical Research Laboratory
Team: Shawn Burton, Kate Campbell, Amy McCarty, Ben Schmidt

Definition of Risks

Risk Level	Description
1	Intolerable risk
2	Tolerable only if risk mitigation is impractical and/or costs are excessive
3	Tolerable if cost of risk mitigation cannot be compensated by projected sales
4	Negligible risk

Risk Quantification Matrix

	Severity			
Probability	Negligible	Marginal	Critical	Catastrophic
Frequent	III	II	I	I
Probable	III	II	I	I
Occasional	IV	III	II	I
Infrequent	IV	III	III	II
Improbable	IV	IV	III	III
Incredible	IV	IV	IV	IV

APPENDIX IB

Failure Modes and Effects Analysis: Polyaxial Vertebral Hook
Mentor: Dr. Boyle Cheng, UPMC Welch Neurosurgical Research Laboratory
Team: Shawn Burton, Kate Campbell, Amy McCarty, Ben Schmidt

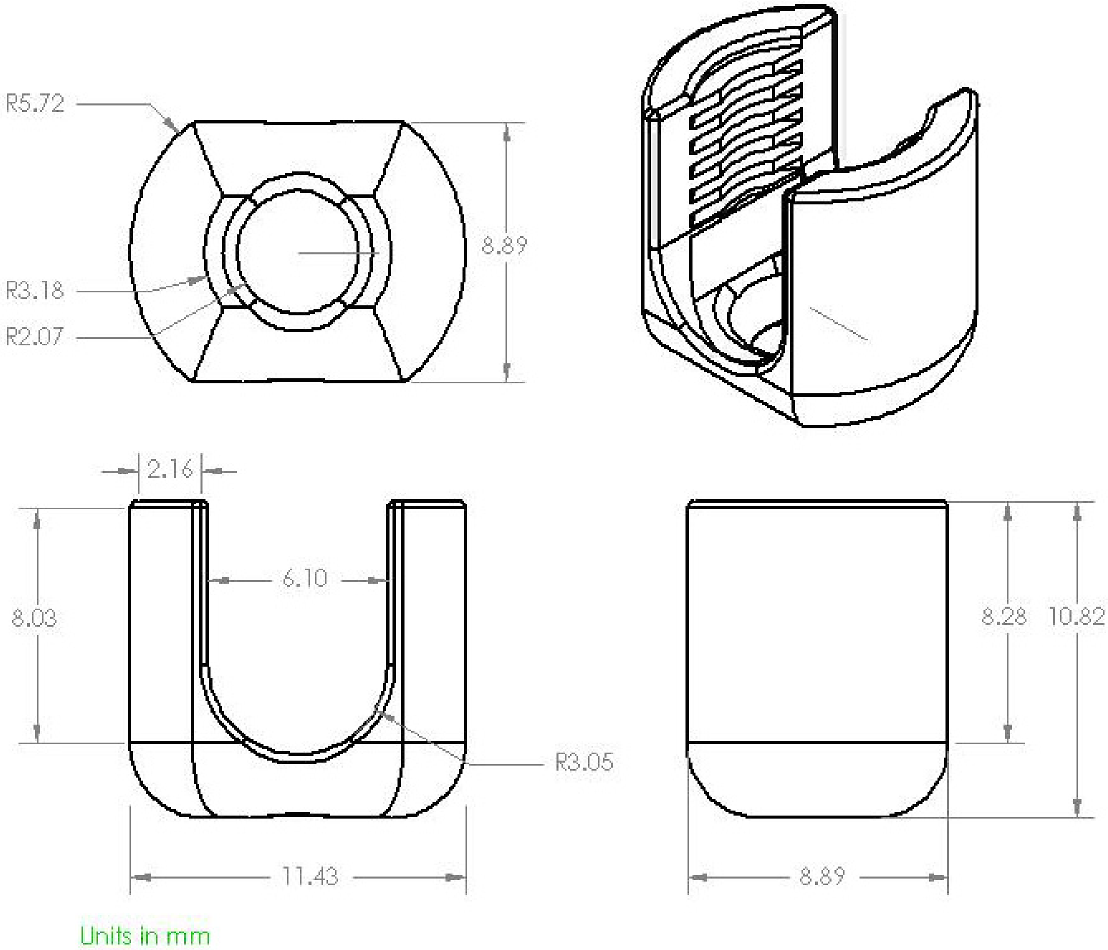
Failure Modes and Effects Analysis

Component	Failure Mode	System effect	Possible Hazards	Risk Probability	Severity	Risk Index	User Detection Means	Applicable Controls
Hook Blade	Blade bends	Construct migration	Vertebral motion; pseudarthrosis	Infrequent	Marginal	III	Follow-up X-ray	Locate and restructure stress points using finite element analysis
		Construct dislodgement	Vertebral motion; pseudarthrosis		Critical	III	Follow-up X-ray	
			Excessive construct prominence; skin irritation				Patient pain	
			Perispinal tissue damage by dislodged construct				Patient pain	
	Blade fractures	Construct dislodgement	Vertebral motion; pseudarthrosis	Improbable	Critical	III	Follow-up X-ray	Locate and restructure stress points using finite element analysis
			Excessive construct prominence; skin irritation				Patient pain	
			Perispinal tissue damage by dislodged construct				Patient pain	
Hook Head	Head bends	Corrective rod slip	Vertebral motion; pseudarthrosis	Infrequent	Marginal	III	Follow-up X-ray	Finite element analysis, mechanical testing
		Set screw dislodges	Vertebral motion; pseudarthrosis				Follow-up X-ray	
			Excessive construct prominence; skin irritation; may puncture skin				Patient pain	
			Perispinal tissue damage by screw				Patient pain	
			Perispinal tissue damage by free rod				Patient pain	
Corrective Rod	Rod bends	Hook unaffected	Unphysiological spine alignment	Improbable	Critical	III	Follow-up X-ray	Proper diameter rod selected
	Rod fractures	Hook unaffected	Vertebral motion; pseudarthrosis				Patient pain	
			Fractured rod may puncture skin				Patient pain	
Set Screw	Threads deformed	Set screw dislodges	Vertebral motion; pseudarthrosis	Infrequent	Marginal	III	Follow-up X-ray	Simulate physiologic loading to detect set screw dislodgement
			Excessive construct prominence; skin irritation; may puncture skin				Patient pain	
			Perispinal tissue damage by screw				Patient pain	
			Perispinal tissue damage by free rod				Patient pain	

APPENDIX IIA

Prototype I Figures

All measurements in mm unless otherwise stated



APPENDIX IIA

Prototype I Figures

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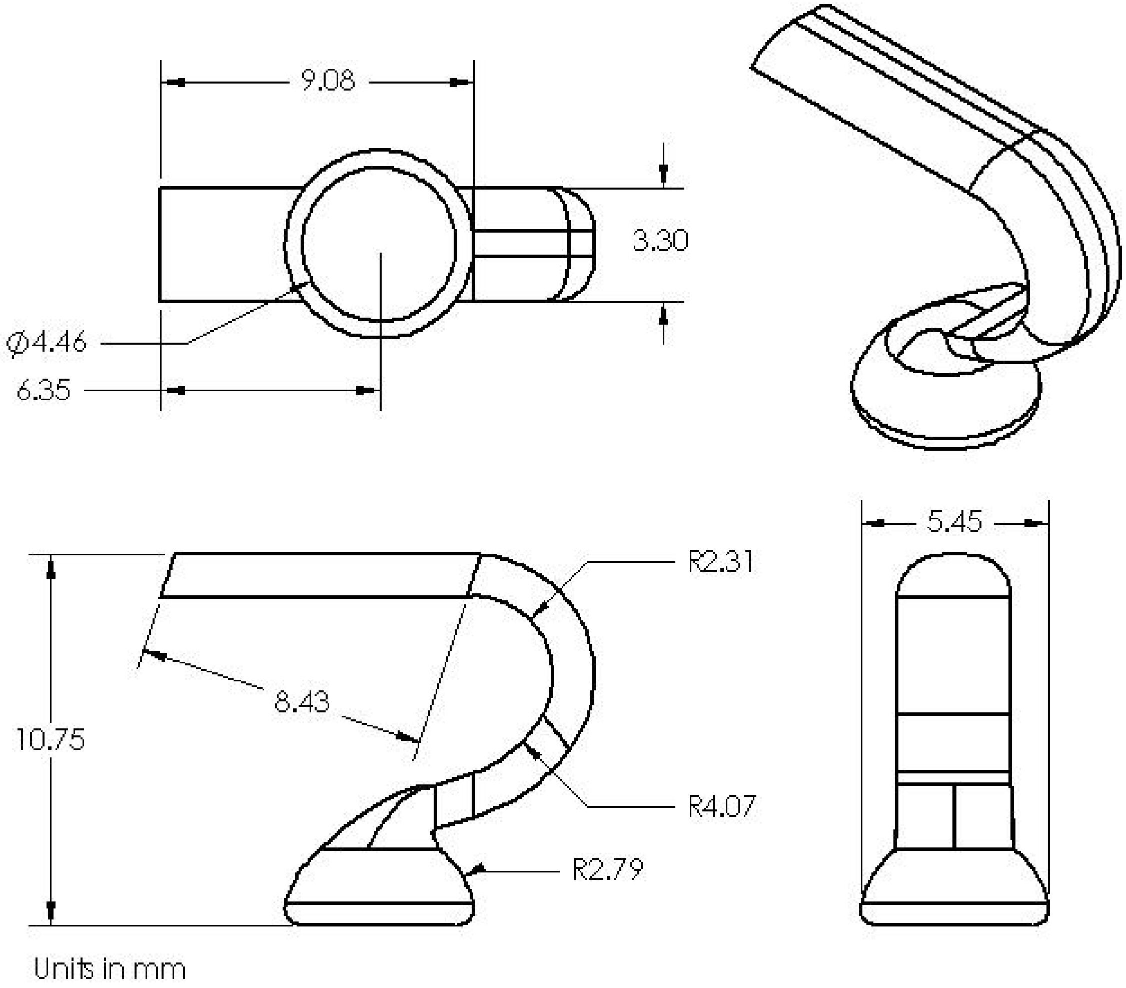

APPENDIX IIA

Prototype I Figures

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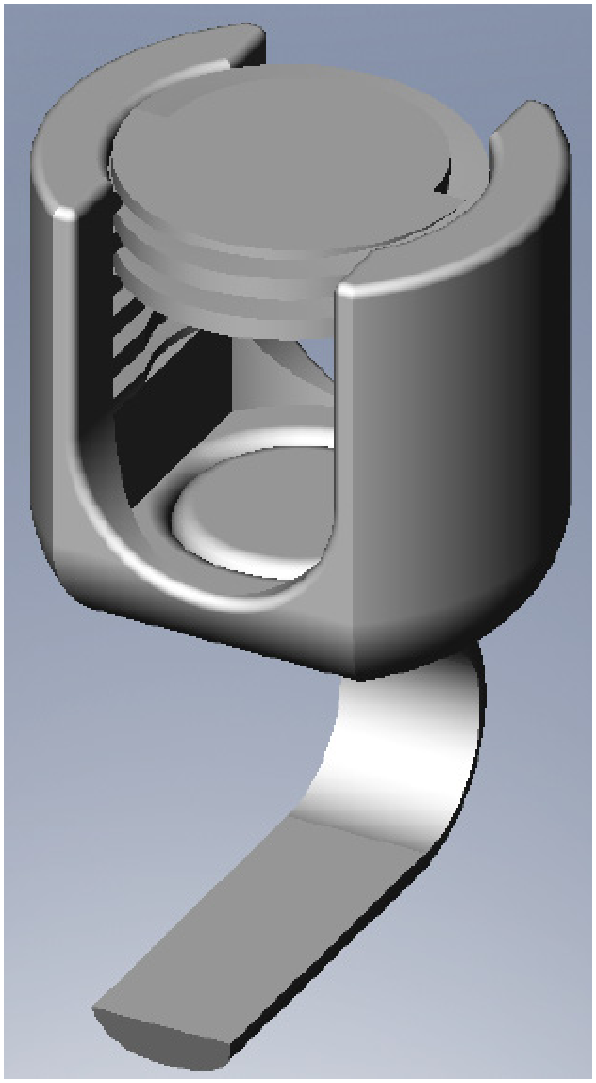

APPENDIX IIB

Prototype II Figures

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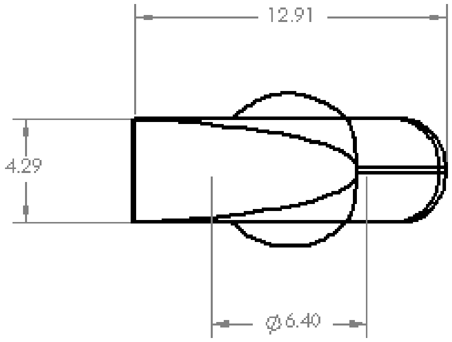

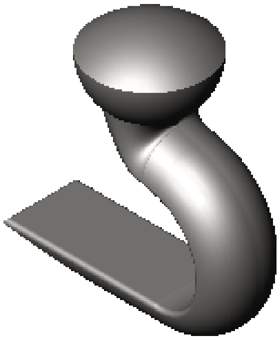

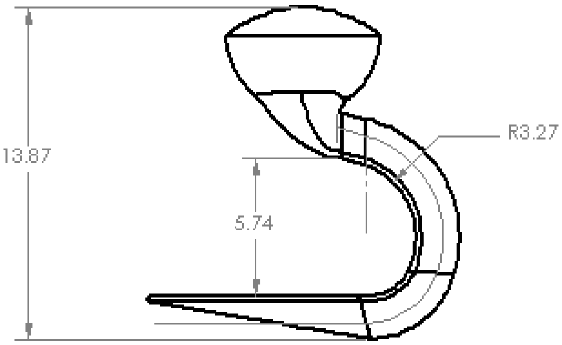

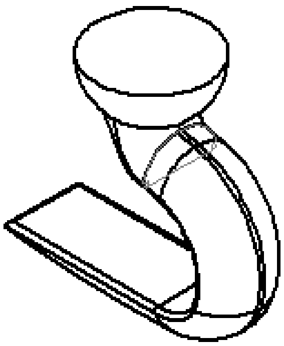

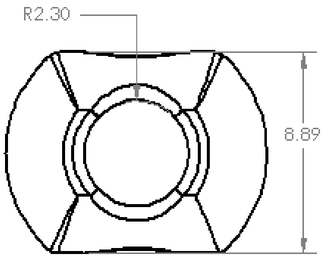

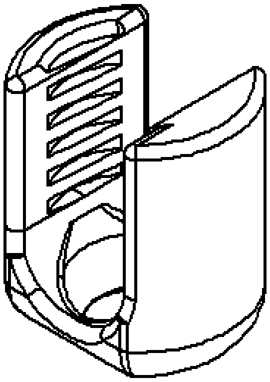

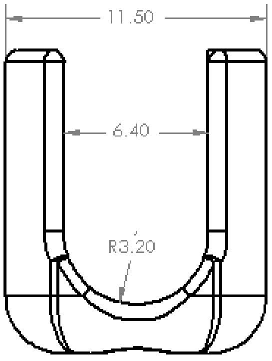

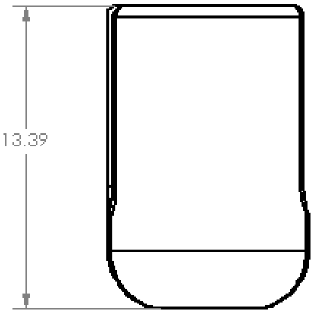

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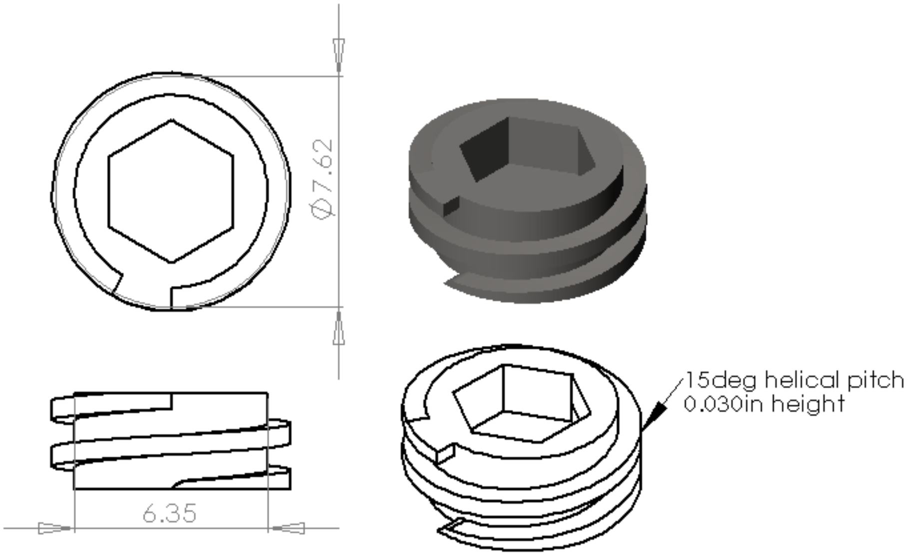
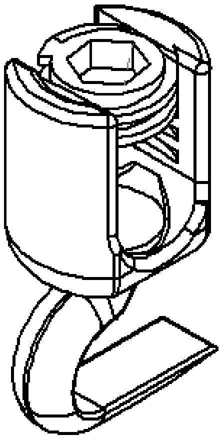
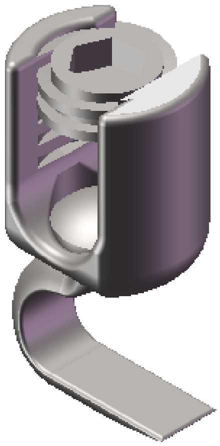
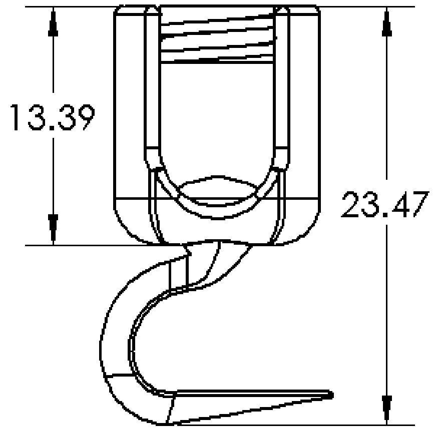
Prototype II Figures

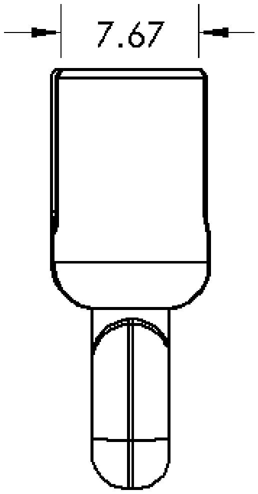
All measurements in mm unless otherwise stated







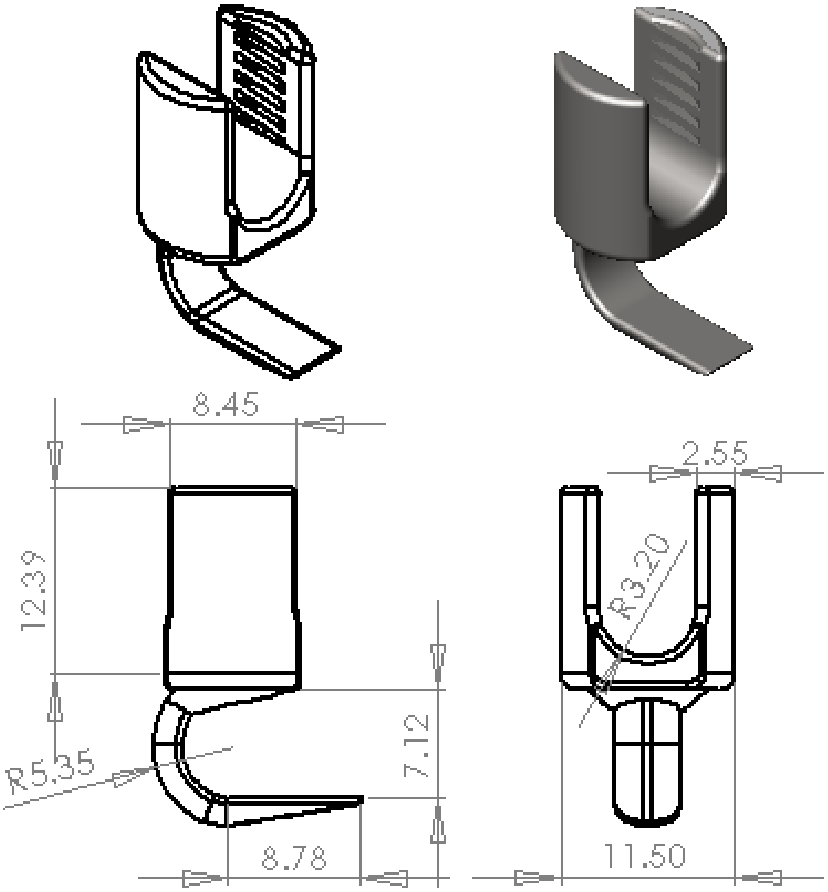




APPENDIX IIC

Control Figures

All measurements in mm unless otherwise stated



APPENDIX IIIA

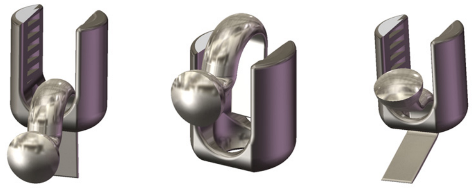
Surgeon Validation Survey – Polyaxial Vertebral Hook

Please complete the following questions in regards to a spinal deformity case (or similar situation) where the pedicle may not provide a stable anchor for screws and a hook is necessary for effecting spine fixation.

In comparison to current hooks, a polyaxial hook is potentially:
1: much worse 2: worse 3: the same 4: better 5: much better

	_1_	_2_	_3_	_4_	_5_
Ease of Implantation					
Supplied Biomechanical Stability					
Necessary Bone Shaping					
Surgery Time					
Safety					
Commercial Feasibility					

Additional Thoughts/Comments:



<u>Ease of implantation</u> refers generally to all procedures performed during spine realignment, device implantation, and ultimately spinal fusion, including necessary bone carpentry, hook positioning, corrective rod placement, rod fixation, and final rod bending.

<u>Supplied biomechanical stability</u> refers to the overall strength of the hooks in regard to the implant construct.

<u>Amount of bone shaping</u> refers to the amount of carpentry necessary in order to ensure a sufficient purchase area while allowing proper rod fitting between adjacent hooks.

<u>Surgery time</u> refers to the amount of overall implantation time, accounting for bone shaping and rod alignment.

<u>Safety</u> refers to overall safety of the procedure, especially in regards to spinal cord proximity

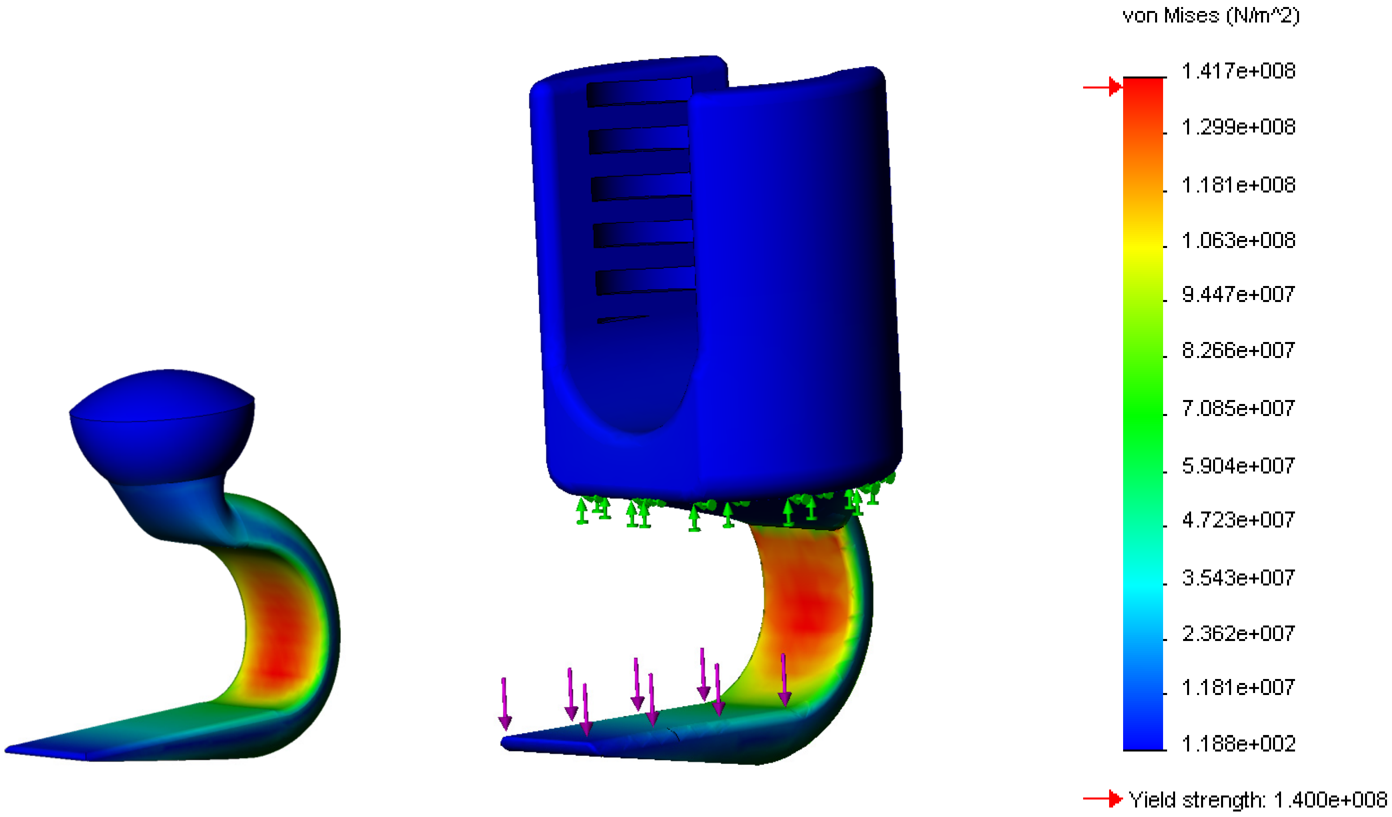
<u>Commercial Feasibility</u> refers to any supposed need/market for this device

APPENDIX IIIB

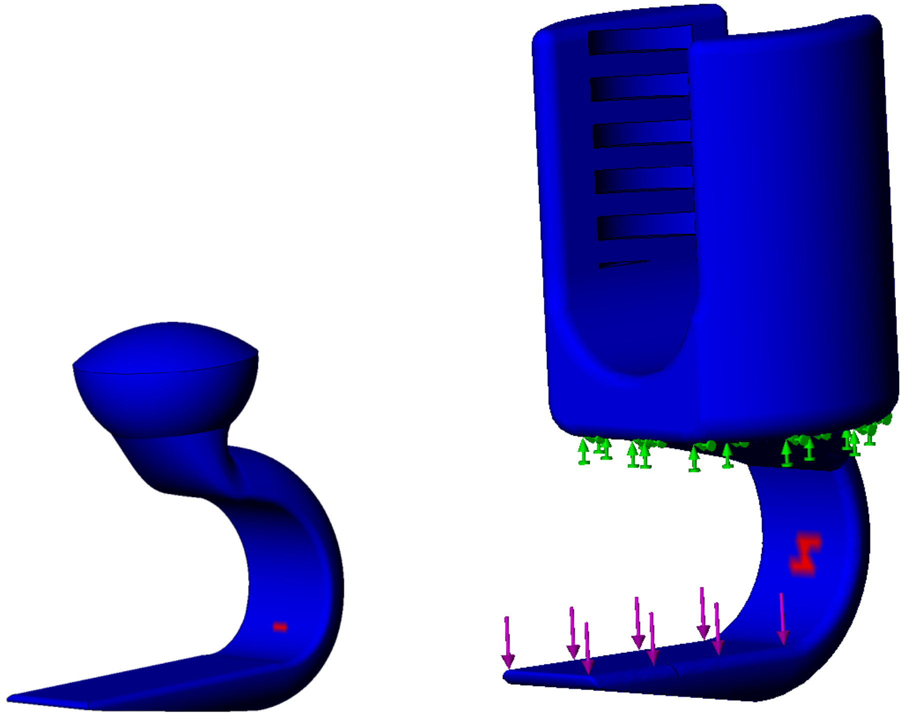
Surgeon Validation: Polyaxial Vertebral Hook

Appendix IIIC

Finite Element Analysis: Blade Loading



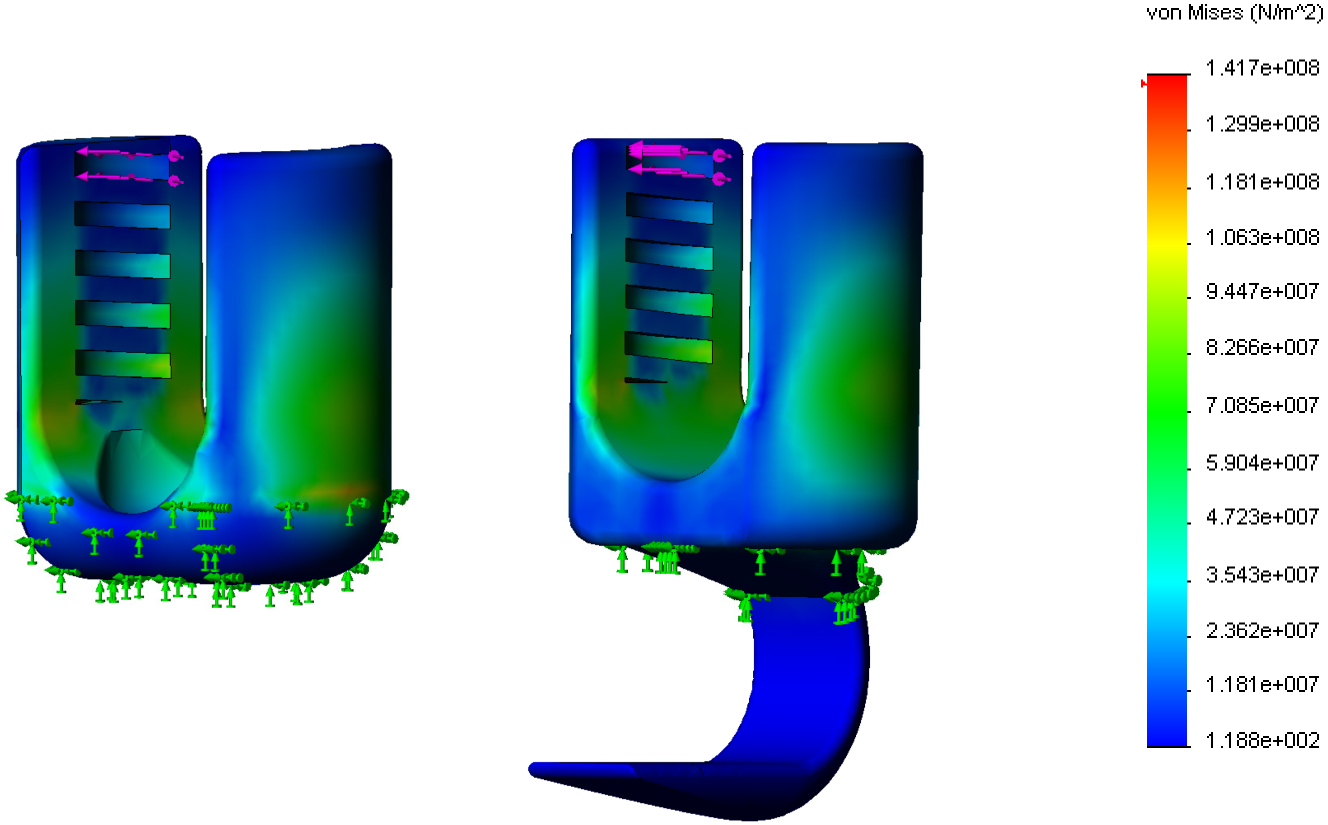
Equivalent mesh grades were used in analysis of polyaxial hook blade (left) and standard static hook (right).
Normal force was applied to the top surface of each hook blade (exemplified by pink arrows on right).
Parts were similarly fixated at the apex of the hook blade (exemplified by green arrows on right).
Force was applied until factor of safety by von Mises stress exceeded 1. Both constructs failed at $\sim 1.4\mathrm{x}10^{8}$ N/m^{2}.
Stress distribution is colorized, as shown in the scale.



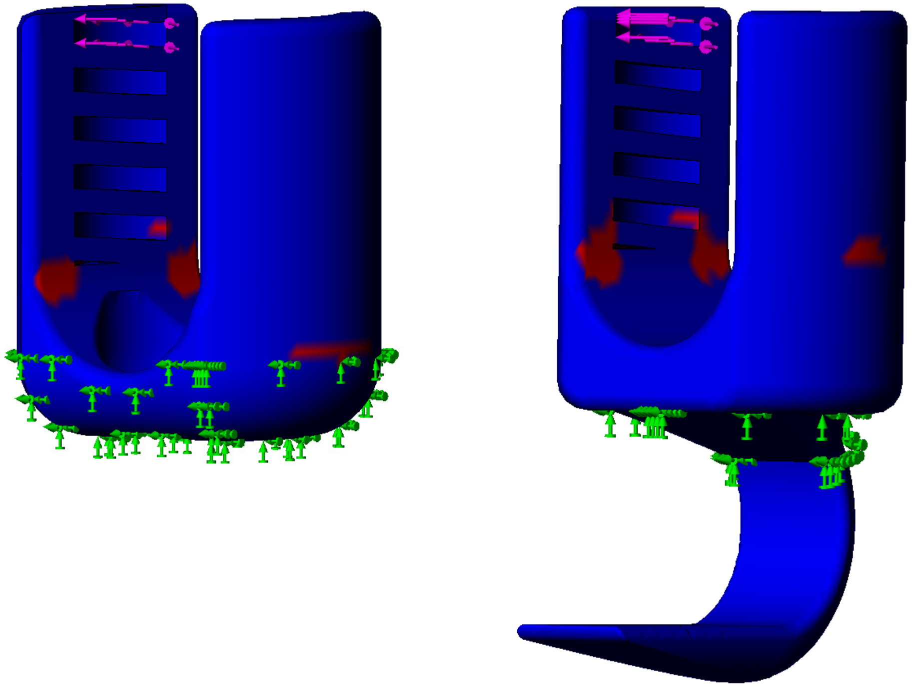
Equivalent mesh grades were used in analysis of polyaxial hook blade (left) and standard static hook (right).
Normal force was applied to the top surface of each hook blade (exemplified by pink arrows on right).
Parts were similarly fixated at the apex of the hook blade (exemplified by green arrows on right).
Force was applied until factor of safety by von Mises stress exceeded 1. Both constructs failed at ~1.4x10^8 N/m^2.
Factor of safety is colorized, with regions in red representing FOS > 1.

Appendix IIID

Finite Element Analysis: Head Loading

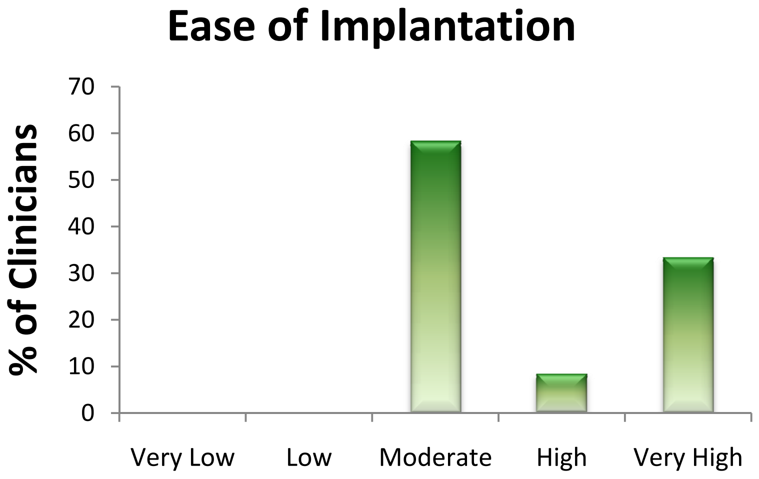


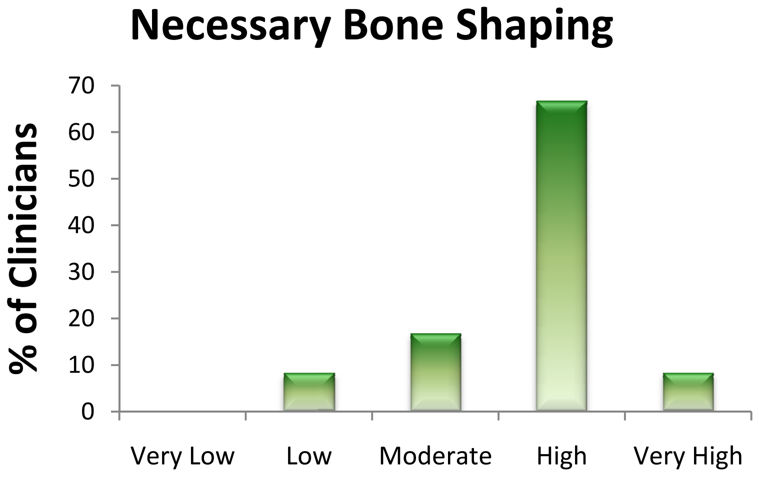
Equivalent mesh grades were used in analysis of polyaxial hook head (left) and standard static hook (right).
Radial normal force was applied to the top set screw thread of each hook head (exemplified by pink arrows).
Parts were similarly fixated at the base of the hook head (exemplified by green arrows).
Force was applied until factor of safety by von Mises stress exceeded 1. Both constructs failed at equal stresses.
Stress distribution is colorized, as shown in the scale.

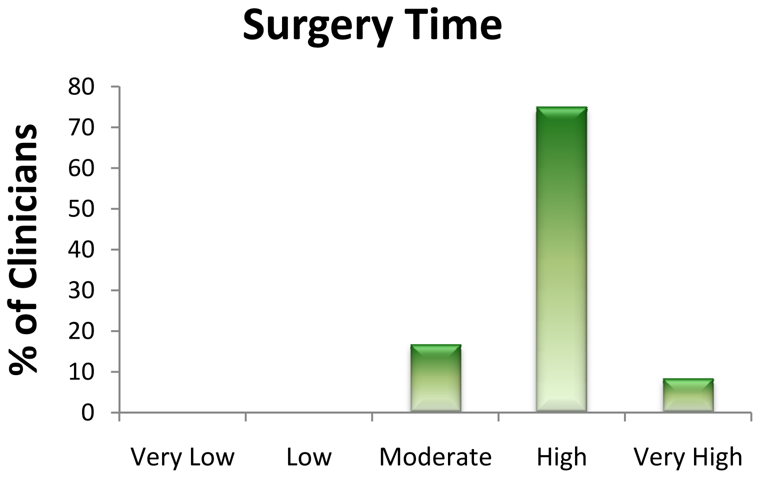


Equivalent mesh grades were used in analysis of polyaxial hook head (left) and standard static hook (right).
Radial normal force was applied to the top set screw thread of each hook head (exemplified by pink arrows).
Parts were similarly fixated at the base of the hook head (exemplified by green arrows).
Force was applied until factor of safety by von Mises stress exceeded 1. Both constructs failed at equal stresses.
Factor of safety is colorized, with red representing FOS > 1.

Appendix IIIE
Surgeon Validation Survey Results: Polyaxial Vertebral Hook







Appendix IIIE

Surgeon Validation Survey Results: Polyaxial Vertebral Hook