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Biomechanical Benefits of Bezier Surface Tapered Transition Rods

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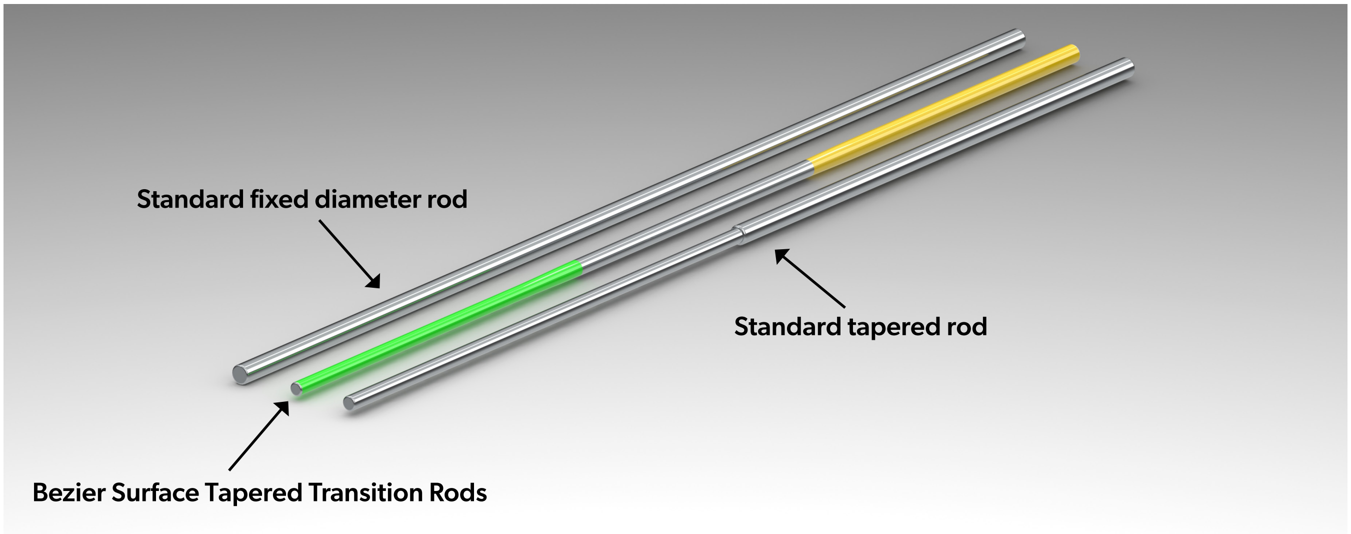
Introduction

Spinal fixation rods are implanted to provide additional stability across spinal segments. Initially, spinal fixation rods aimed to provide maximum stiffness and durability. However, maximizing fixation rod stiffness can potentially lead to stress shielding, implant loosening, proximal junction kyphosis or failure (PJK / PJF), and/or implant failure.[1]

To mitigate implant loosening, adjacent segment degeneration, and PJK / PJF, a number of different semi-rigid and/or mobile devices have been developed.[2-8] It has been shown that using more flexible instrumentation at the proximal segments to allow for a smoother transition from the highly rigid posterior fusion rods to the non-fused mobile proximal adjacent motion segments allows for a reduction in proximal junction angle, flexion force, moment, and lower intra-discal pressure.[5,9] All of these can lead to a reduction in PJK/PJF.[2,7-10]

One such proximal fixation method includes posterior spinal fixation rods that are augmented with discrete stepped reductions in outer diameter (Figure 1).[10-12] These are now widely available and it has been shown that the decreased proximal stiffness of the stepped rods allows for a more gradual transfer of loads from the implant to the screw-bone interface and to the adjacent proximal segment.[2,10,12] Consequently, the stepped spinal fixation rods can potentially reduce stress shielding, thereby mitigating the propensity for implant loosening. It is also believed that the more gradual transfer of load to proximal segments aids in reducing the risk of PJK / PJF.[2,10] Rudimentary multi-diameter rods have been implanted in patients and have been well-tolerated and have not been shown to exhibit biomechanical failure.[12]

Figure 1. Spinal fixation rods come in various configurations including constant diameter (left), smooth variably tapered rods (middle), and multi-diameter stepped (right).



However, despite the above mentioned benefits of a stepped rod, the current stepped diameter fixation rods are subject to a number of surgical and biomechanical limitations. In both unilateral and bilateral spinal fixation rod implantation, screw placement presents a challenge. Screw placement is often determined by pedicle location in the vertebral body. The distance to the adjacent screw is determined by the height of the adjacent body and the intervertebral disc and or interbody cage. The stepped transition rods, when placed, must therefore be positioned such that the rod's transition junction (i.e. where the diameter steps down) is not above a pedicle screw head. Furthermore, the rod must be positioned in a way allowing adequate room for compression of the screw heads when necessary. Screw heads must also not encroach upon the stepped transition. The requirement of placing screws along rods away from transitions introduces intra-operative variability and, indeed, often results in non-ideal rod placement. Specifically, the benefits in spatially varying rod flexibly offered by stepped rods are undermined because the surgeon is forced to accommodate the step, rather than accommodating the patient's anatomy.

Bezier Surface Tapered Rods with a variable bending stiffness based on local diameter addresses each of these issues, offering the surgeon complete freedom to place screws even at rod transitions. Continuous tapered rods (Figure 1) also offer the patient biomechanical benefits.

The relationship between stress shielding and orthopedic implant loosening

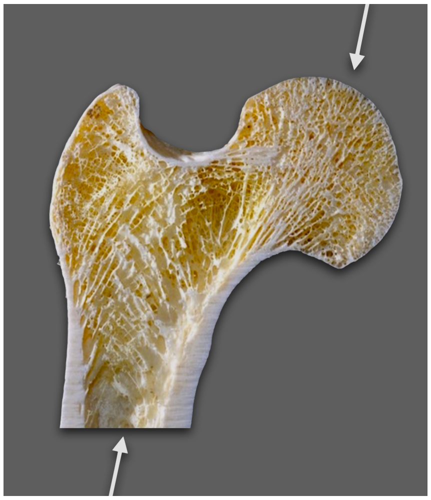
Bone is a hard tissue that accumulates microscopic damage (microdamage) under conditions of normal physiological loading. This microdamage accumulates over time when unchecked. Microdamage in bone is naturally repaired through a process known as bone remodeling.[13,14] Through this process, osteoclasts and osteoblasts remove damaged bone and replace it with newly formed bone, respectively. The bone remodeling process is a localized phenomenon and occurs within millimeter-scale regions where microdamage is detected by the body. The bone remodeling process also optimizes bone microarchitecture for maximum strength and minimum weight. Figure 2 demonstrates an cross section of a proximal femur and how bone density is preferentially higher in the direction of loading from the socket of the hip and, likewise, in the vertical loading direction of vertebral spongy bone [Perilli, et al. 2007], [Hildebrand, et al. 1999].

Bone cells also sense where minimal load exists and remove bone where it is not needed in an effort to reduce the overall weight of the bone. With the implantation of stiff metallic implants, much of the load around the anchor points (often orthopedic screws) is sustained by the implant itself, rather than the bone. Consequently, bone tends to atrophy around the implant.[15] Re-distribution of load away from the bone to the implant that results in bone atrophy is commonly referred to as stress shielding.[16]

Stress shielding is of particular concern because it induces local removal of bone directly around the orthopedic implant (i.e. screws). The gap between the surrounding bone surfaces and the screw leads to micro-motion. Micro-motion can result in localized bone damage which further induces bone removal (i.e. as a damage repair process). Stress shielding thus produces a positive feedback loop (a vicious cycle), causing increased loading on the implant itself, which can exceed design tolerances. This reduces the life of the implant and often results in premature clinical fatigue failure. Fatigue failure occurs well below the maximum sustainable load of a material, but occurs due to exposure to high numbers of load-unload cycles. Subsequent revision surgery is then required to replace the implant. An effective approach towards reducing stress shielding is to reduce load sustained by the implant (and thus taken away from the surrounding bone) by reducing its stiffness. The ideal fixation system provides adequate anatomical support to the patient without being sufficiently stiff to induce bone atrophy.

Additionally, the implantation of rigid fixation rods often involves fusing intermediate vertebrae within the length of the rod. This effectively increases the stiffness of that segment of the vertebral column. Consequently, there is a sudden drop in stiffness from the extreme ends of the rod to the adjacent vertebrae. There is, therefore, increased risk of high loading in the adjacent vertebral segments, especially in patients with osteoporosis, which leads to proximal junctional kyphosis (PJK) / proximal junctional failure (PJF).[17] This phenomenon is exacerbated by the addition of a fixation rod. More flexible fixation, therefore, helps to mitigate the sudden change in stiffness that results in the above-mentioned clinical failures. Clearly, there is an opportunity to reduce the prevalence of PJK/PJF by providing patients with spinal fixation that is optimally tuned to the local spinal anatomy, such as offered by a continuous tapered rod platform. Therefore, the goal of the current study was to evaluate the biomechanical properties using standardized computer simulations to highlight the differences and potential clinical benefits between various fixation rod platforms.

Figure 2. Bone microarchitecture preferentially forms in the direction of primary loading. A cross section of a human Femur illustrates alignment of cancellous bone to sustain the load from supporting body weight. This phenomenon is present in cancellous bone throughout the body, including the hip, wrist, and vertebrae.



Methods

In this study, estimates of the relative differences in implant (rod and screw) material stresses as well as screw-bone contact pressures were achieved using computer models of spinal fixation rods virtually subjected to anterior flexion using finite element analysis (FEA). FEA is a widely-used computer simulation technique for predicting the mechanical performance (strength, durability, etc.) of structures and devices. FEA has been applied in the automotive and aerospace industries for over 60 years[18,19] and for nearly 50 years in the orthopedic device industry.[20]

Here, two FEA studies were conducted to:

1. Determine the mechanical and biomechanical benefits of gradual tapering 5.5mm spinal fixation rods over stepped and constant diameter rods
2. Show the benefits of the continuous Bezier surface tapered 5.5-5.0-4.75mm rod over a 6.35mm (1/4") constant diameter and stepped rod commonly used in deformity-based surgeries

Following established best practices of FEA, fully non-linear simulation models were created.[21] In each comparative study, 220mm rods were used along with seven spinal fixation screws with intervertebral spacing common to the T11-L5 levels. Each screw was inserted into blocks of material equivalent to human vertebral cancellous bone to simulate bone-screw interactions. Each block of bone was subjected to 1.5 degrees of rotation (flexion) for a total of 9 degrees. Physiologically, this represents a high level of loading, but is adequate for highlighting the relative differences between fixation rod platforms. Furthermore, applying equal rotations to each block of bone produced constant curvature of each fixation rod. Consequently, the screw material stresses and screw-bone contact pressures described here are independent of rod length. The relative trends in this study are therefore applicable and representative of clinically-relevant rods of shorter and longer lengths.

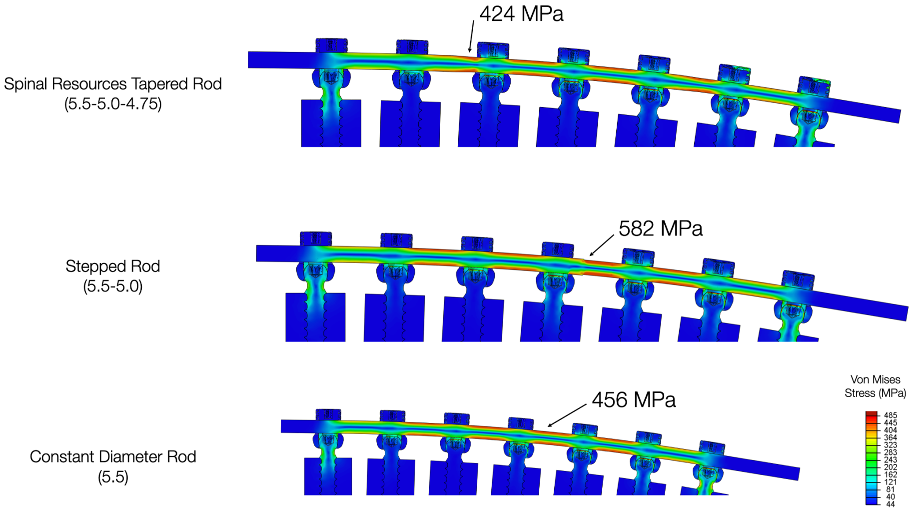
Furthermore, because the tulip design for this system accepts a range of rod diameters independent of screw size, a single screw size was used for all rod designs in the current study.

Since it is believed that stress shielding is related to the amount of load sustained by an implant, it is possible to develop comparative estimates of the negative biomechanical impact of various spinal fixation rod designs using screw-bone contact pressure (local contact force normalized by contact area) as a correlate to stress shielding. High contact pressures are, therefore, considered here to be equivalent to a biomechanical environment with higher levels of stress shielding. With a contact pressure as a metric for stress shielding, this study provides a comparison of the negative biomechanical consequences of various spinal fixation rod designs.

Results

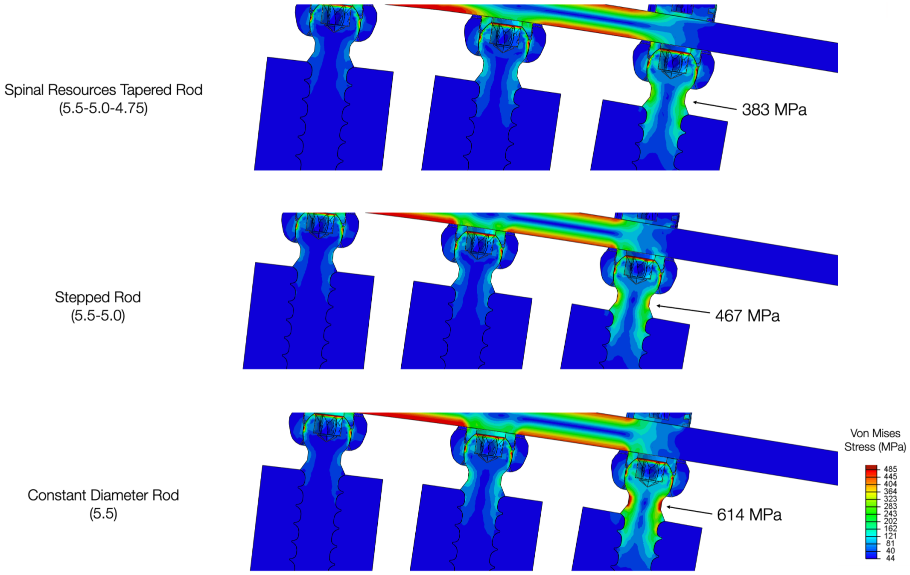
When comparing 220mm rods of 5.5mm constant diameter, 5.5-5.0mm stepped, and 5.5-5.0-4.75mm gradually tapered, rods the FEA-predicted material stress at the transitions from larger to smaller diameters were 27.1% lower as compared to the stepped rod (Figure 3).

Figure 3. Anterior flexion of 1.5 degrees per screw was applied to create a constant curvature of each fixation rod. Flexion produced material stresses that were particularly high at the transition region (Middle) of the stepped rod. The transition regions in the tapered rod were 27.1% lower (Top).



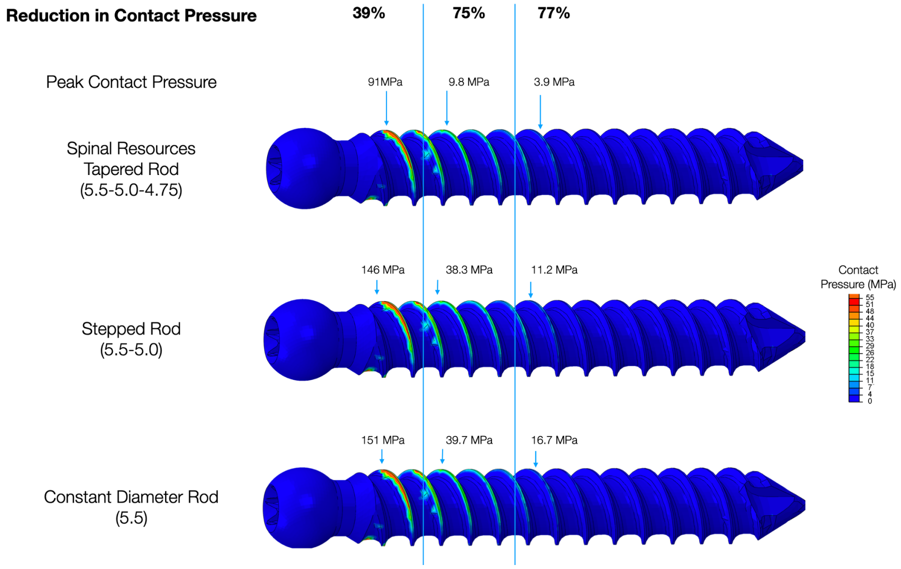
Focusing on the material stresses in the neck of the most proximal screws, FEA showed a 37% reduction in peak screw stress in the tapered design, compared to a constant diameter rod (Figure 4).

Figure 4. Material stresses at the neck of each screw are shown. The proximal-most screw of the tapered rod (Top) was 37% lower than that of the 5.5mm constant diameter rod (Bottom).



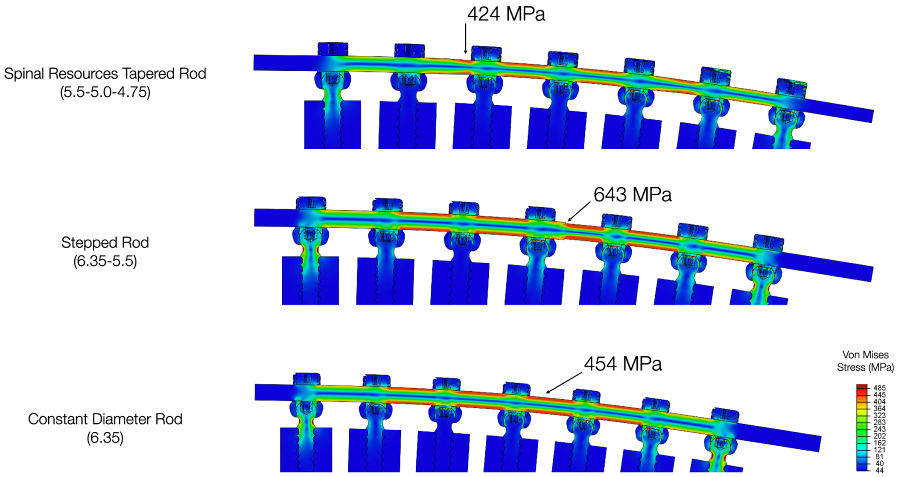
Tapered rods improved screw-bone contact pressures along the entire length of the most proximal screw. The contact pressures were 39% lower in the tapered rod design as compared to that of the constant diameter rod, indicating that load is indeed more gradually distributed into the vertebral segments along the rod. This reduction was increasingly pronounced along the length of the screw. Screw-bone contact pressures were reduced by as much as 77% at the mid-point of the proximal screw (Figure 5).

Figure 5. Screw contact pressures were reduced along the entire length of the proximal-most screw in the tapered rod design (Top) by up to 77% as compared to the constant diameter rod (Bottom).



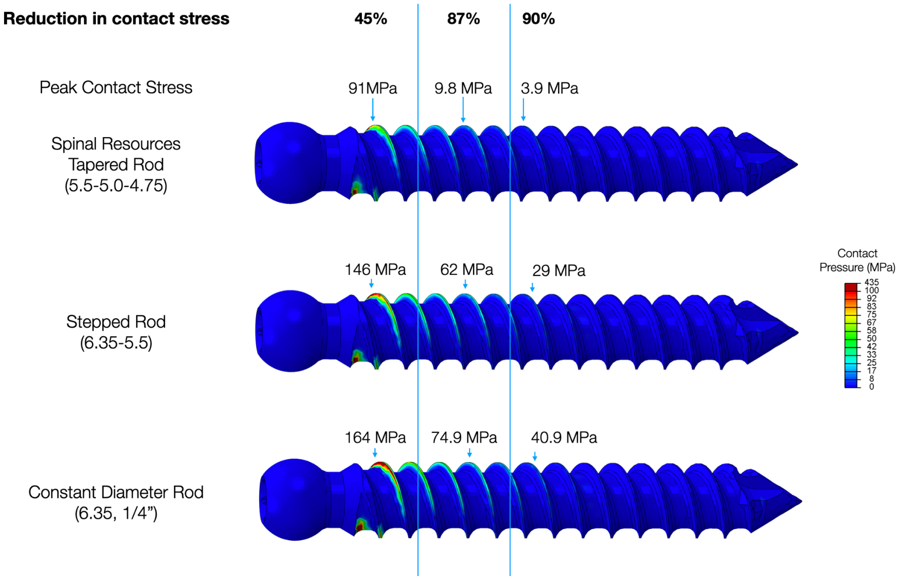
To ascertain the clinically-relevant benefits of continuous tapered 5.5-4.75mm tapered rods, another FEA-based study was conducted using 6.35mm (1/4") constant diameter and 6.35-5.5mm stepped rods. FEA demonstrated stress concentrations at the stepped rod transition was reduced by 34% (Figure 6).

Figure 6. Peak flexion stresses in the tapered rod transitions were reduced 34% as compared to those at the stepped transition (Middle).



And lastly, material stresses at the neck of the screw were also reduced in the tapered rod. Stresses were 51.3% lower in the most proximal screw of the tapered rod as compared to that of the 6.35mm constant diameter rod (Figure 6). Again, a drastic reduction in screw-bone contact pressure was observed in the tapered rod as compared to that of the 6.35-5.5mm stepped rod. Contact pressure was 45% lower at the top of the screw and was 90% lower at the midpoint of the screw (Figure 7).

Figure 7. Contact pressures were drastically reduced with the 5.25-5.0-4.75mm gradually tapered rod (Top) as compared to that of the 6.35mm (1/4") constant diameter rod (Bottom). At the midpoint, contact pressures were reduced by as much as 90%.



Discussion

In the present study, FEA was used to compare a continuous tapered rod with other standard posterior spinal fixation rod constructs, including a stepped rod and constant diameter rod. The continuous tapered rod demonstrated lower material stresses at transitions and in screw necks as well as reduced screw-bone contact stress, indicating improved implant life and the potential for reduced stress shielding and risk of PJK, respectively.

The stepped fixation rods in the present study did not perform as well as the tapered rod. Stepped fixation rods provide reduced stiffness that aids in a more gradual transition in loading to adjacent proximal segments and are considered an improvement over constant diameter rods. However, there are several drawbacks to a stepped design.

From a surgical perspective, stepped designs may pose issues when the transition from large to small diameter lies directly above a screw placement. Thus, the surgeon is not afforded flexibility in stepped rod placement; a stepped rod often must be moved to accommodate its transition region. A gradually tapered rod addresses this limitation, giving the surgeon complete freedom in rod placement, regardless of the location of its transitions.

While stepped rods provide reduced stiffness and a more gradual load transfer to proximal segments, stepped rods feature a sudden reduction in outer diameter that creates a highly localized stress concentration. Stress concentrations in implanted devices reduce their life and can lead to premature rod failure. A tapered design replaces these sudden discrete reductions in rod diameter with smooth, gradual reduction in outer diameter, thus removing any stress concentrating effects.

The tapered transition feature of rods with smooth transitions along rod diameter reductions provide the benefits of local flexibility of stepped rods without the restriction of stepped transition rods or the material stress concentrating effects at stepped transitions (as seen in the present study), which act as points of weakness that can lead to rod breakage. Similarly, as the stepped transition serves as a stress concentrator, the proximal vertebral segment to a fixation rod is subjected to amplified loading, which clinically often results in PJK / PJF.

The tapered rod platform addresses the drastic drop in stiffness at the proximal end of a fixation rod by providing a reduction in rod stiffness. The reduction in rod stiffness thus transfers physiological loading more gradually from the implant to the proximal unsupported vertebral segment, thus potentially mitigating the risk of PJK. The more gradual transfer of physiological loading in tapered rods is evidenced by the lower screw-bone contact pressured shown here. Tapered rods therefore provide a commensurate level of stability mitigating PJK and PJF as well as implant loosening and screw failure due to stress shielding-induced bone atrophy and screw loosening.

The gradually tapered fixation rod platform is also well-suited for long construct deformity cases as well as degenerative cases. As mentioned in this study, rod stresses and contact pressures were normalized by rod length. In each case, the continuous tapered rod showed improved rod and screw stress as well as substantial reductions in screw-bone contact pressures.

These results indicate that the continuous tapered rod platform should lead to reduced stress shielding, implant loosening and, ultimately, failure.

Moreover, the continuous rod should provide lower clinical risk factors for standard degenerative cases as well long construct deformity cases. The continuous tapered rod platform can also be used with 4.75-5.0mm and 5.0-5.5mm configurations and will also offer superior performance to single diameter and stepped rods of the same length and geometry.

This study has been designed such that its results are applicable to constant diameter, stepped, and curved rods that have been pre-bent. Clinical pre-bending of fixation rod does induce plastic (permanent) deformation. However, when subjected to normal physiological loading after being implanted, curved rods perform precisely similarly to un-bent rods both geometrically and mechanically.

Similarly, the trends between constant diameter, stepped, and tapered rods are applicable to rod designs of other materials, as the results are linearly proportional to material stiffness (i.e. the elastic modulus of other orthopedic materials such as stainless steel, cobalt chrome, titanium, etc.). In other words, while the magnitude of the material stresses changes with material stiffness, the relative differences in stresses and stress concentrators will remain the same between constant diameter, stepped, and tapered rods, independent of material. Also, because we have induced a constant anterior flexion in each rod (1.5 degrees per rod), the simulation results are independent of biological or anatomical variability as well as rod length.

The study was intentionally designed to avoid any dependence on length and geometry, thus rendering the results applicable to short and long constructs as well.

Conclusion

Proximal junction kyphosis and failure can result in increased pain, neurological deficit and, ultimately, the need for reoperation. Proximal fixation strategies that smooth the transition from a rigid posterior fixation rod to the mobile adjacent motion segments has been shown to reduce the risk of developing PJK/PJF.

There are a number of different semi-rigid proximal fixation techniques being studied, including posterior fixation rods with a stepped decrease in outer diameter.

However, when using stepped outer diameter rods, the surgeon is limited by the steps in placing the rod in the screw heads. Continuous tapered rods with a variable elastic modulus based on the diameter allows the surgeon complete freedom to place the rod over the screws, dictated by the patient's anatomy. Based on the current study, these continuous tapered rods showed a number of improvements over a standard single diameter rod as well as the stepped reduction in diameter rods.

The continuous rods showed a reduction in stresses at the diameter transition junctions, better screw-bone contact pressures, and reduced material stresses in screw necks as compared to both constant diameter and stepped rods. These results demonstrate that the continuous tapered rods do, in fact, distribute the load more gradually over the vertebral segments along the rod. The improvement in screw neck stress should, therefore, lead to a reduced risk of neck breakage. This study also demonstrates that the continuous tapered rod could ultimately aid in the prevention of biomechanical failures leading to PJK/PJF, and thereby reduce future revision surgeries and costs to hospitals and insurance firms.

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Dr. Ames is the director of spinal deformity and spine tumor surgery and co-director of the combined high risk spine service, the Neurospinal Disorders Program, and the UCSF Spine Center. He is board certified in neurosurgery. While at UCSF, Dr. Ames developed and published the transpedicular approach to previously unresectable cervical and cervical thoracic tumors. He serves as Spine Section Lead editor for Operative Neurosurgery and has served as chairman for over 150 national and international courses to teach advanced tumor and deformity techniques to neurosurgeons and orthopedic surgeons around the world.

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