POSTER 45

Title: Design elements of an intramedullary stem utilizing a mechanical integration rationale

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Abstract
Background: A novel method of interfacing metal and bone has recently been introduced, which relies on mechanical integration of the implant and bone, without the need for bone ingrowth. This method is derived from building sciences and utilizes a specific and unique thread form which has radically different mechanical properties that of a standard screw. This design rationale may have significant impact when applied to the fixation of arthroplasty implants to bone using stems. Traditional stems require either bony ingrowth, which takes time to occur or may fail to occur, or cementation, which can loosen over time and is very difficult to remove. A mechanically integrated stem would be one in which the interface between the stem and the bone immediately and evenly shares the multi-axial loads applied to the stem. This load sharing is based on the mechanical relationship alone, without the use of cement and without the need for bone ingrowth. This type of design would permit immediate weight bearing, would be more compact than traditional stems, and could be easily removed without bone destruction in the case of infection or need for revision. These benefits are of particular interest in patients with bone deficits or biologic healing limitations, such as oncology patients. For these reasons, there is significant rationale behind designing an intramedullary stem which interfaces with the bone utilizing mechanical integration.
Question/Purpose: Therefore, the purpose of this study was to evaluate how a mechanically integrated intramedullary stem performs using both FEA and biomechanical testing and to compare results with those of a more conventional stem design.
Methods: FEA testing: Comparative FEA studies have shown that the mechanically integrated implant demonstrated improved load distribution when compared to a press-fit stem. Load is distributed around the circumference of the mechanically integrated implant as the UnifiMI threads pull bone toward the center of the implant rather than separating from the contact under load. Figure 2 shows an example where a Wagner-style stem and a mechanically integrated UnifiMI stem are inserted in identical bone and immediately subjected to identical off-axis loads. It is also interesting to note that the maximum stress is similar for both implant types despite the mechanically integrated UnifiMI stem being less than two-thirds the length of the Wagner stem (92mm vs 155mm).
Results: Biomechanical studies in cadaveric tissue and in bone analog material (SawBones foam) have further demonstrated the ability of mechanical integration to immediately secure metal to bone such that the bone and implant work in tandem to handle loading. Cadaveric tests have consistently shown surprising implant stability, even in compromised bone. When purposefully loaded statically to catastrophic failure, the implant has either broken proud of the bone surface or has broken away with bone still attached and integrated to the implant. This demonstrates the bone plus metal implant construct is a stronger unit than either individual component alone.
Conclusion: A mechanically integrated intramedullary implant represents an entirely novel approach and may have significant benefits over traditional methods of fixation of implants to bone, particularly in the orthopedic oncology population. Initial Early FEA and biomechanical testing are encouraging and demonstrate more even force distribution and more intimate contact between the bone and the implant under dynamic conditions. Further testing will be needed to refine the design and evaluate the performance of this type of fixation in vivo.
Level of Evidence: III