



Rebuttal to Pitkin *JRRD* Guest Editorial, *J Rehabil Res Dev*. 2008;45(4):vii–xiv.

Dear Editor:

In a recent guest editorial, Dr. Mark Pitkin states that “adopting the medullary canal as a holding compartment for the pylon’s shaft creates a problem of shaft loosening, which has not yet been solved in arthroplasty.” [1]. I wish to emphatically disagree!

If one reviews the data from Norwegian Arthroplasty Registry (Helse-Bergen, et al., Annual Report 2007, page 2, ISBN: 978-82-91 847-1 2-2; <http://www.haukeland.no/nrl/eng/Report2007.pdf>), it is documented that in following 104,316 total hip arthroplasties (THA), uncemented femoral stems had a failure rate of only 1 to 2 percent at the 10 to 15 year follow-up periods [2]. In the Swedish Hip Arthroplasty Register (Karrholm, et al., Annual Report 2006, page 47), 270,000 primary THA operations were followed since 1979 through 2006, following 19 types of uncemented femoral components; patients could expect only a 3 to 4 percent risk of revision at 10 years follow-up in younger patients [3]. A careful review of the THA world literature supports that if a THA system is properly sized and aligned by the surgeon, that infection (1%–2%) should be the only concern in the first two years.

The next major clinical concern is the aseptic loosening caused by wear debris from the articulating

bearing surfaces. This usually leads to acetabular component loosening first, but may contribute to femoral component loosening.

The femoral component in THA, unless inappropriately aligned, sized or poorly designed, captured in the medullary canal of the human femur, or humerus for that matter, could last a patient’s lifetime if it were not for infection (1%–2%) or osteolysis caused by wear debris. Osteointegrated, transcaneous implants have no moveable joint to produce wear debris induced osteolysis, therefore, infection should be the only cause of failure in the properly placed and designed porous coated implants.

The implant design advocated by Dr. Pitkin (Figure 5) will fail very early on (6–18 months) either by breakage of the implant at the terminal end of the bone or within the side elements. Another obvious region of possible failure will be between the most proximal side element and bone interface.

Stripping the muscle and periosteum away from the bone will lead to the loss of the outer third of the blood supply to bone leading to osteopenia of the cortical bone [4–5]. Early THA designs attempted to attach the femoral component to the periosteal surface of the cortex with early failures (<1 year). This concept has been abandoned since 1938 [6].

It would be interesting if Dr. Pitkin could find a fellowship-trained orthopaedic surgeon in total hip arthroplasty who would agree with the premise of his design, his statement of problems with femoral component

attachment to the endosteal bone in the medullary canal of long bone or would even attempt to implant his design in patients. I believe a large animal trial would prove that Newton’s Third Law also applies to his dangerous design as well.

My best regards,

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RESPONSE

Dear Editor:

I am grateful to *JRRD* for the opportunity to hold an open dialogue with Dr. Bloebaum following his rebuttal to my article “One lesson from arthroplasty to osseointegration in a search for better fixation of in-bone implanted prosthesis” [1]. The term “osseointegration” relates to the emerging technology of direct skeletal attachment (DSA) of limb prostheses when a metal rod is implanted to the medullary canal of the bone remnant of an amputee’s residuum [2]. The candidates who would benefit most from this procedure are young active traumatic above-knee amputees, including recent U.S. veterans. Since DSA uses medullary canal implantation, the lesson of loosening from arthroplasty must be learned and addressed before DSA can be introduced to practice.

In my article, I have pointed to several biological reasons for loosening, including the natural widening of the canal when the outer diameter of the bone increases [3]. A brief description of this process called “appositional growth” can also be found on the U.S. National Cancer Institute’s Surveillance, Epidemiology and End Results (SEER) Program Web site.* In young patients, appositional growth is more pronounced than in elderly. As a result, chances for success of improvements in methodology based on in-canal implantation are limited, as such a

methodology goes against developmental process.

In an attempt to address the problem of loosening due to the developmental widening of the medullary canal, in my article I suggested utilizing in the DSA implantation another mechanism of bone widening: circular ossification. Circular ossification was shown by Dr. Ilizarov in his pioneering studies on distractional osteogenesis [4]; longitudinal ossification is widely used in the Ilizarov bone elongation procedure. As a possible solution, a design of the implant with side elements (fins) was introduced in my article (Figure 5). It was hypothesized that after implantation, circular ossification would fill the spaces between the fins and thus provide additional “osseo-locking.” The hope is that with this approach, fixation of the implant would go not against nature as in prior art, but along with natural mechanism of circular ossification.

DR. BLOEBAUM’S CRITIQUE

Dr. Bloebaum’s rebuttal has two parts. The first is devoted to statistics of arthroplasty outcomes. The two references cited (the Norwegian and Swedish registries) and his general analysis of the literature indicate that—

- Uncemented femoral stems in total hip arthroplasty (THA) had a failure rate of only 1 to 2 percent at the 10 to 15 year follow period.
- A 3 to 4 percent risk of revision in younger patients can be expected at 10 year follow-up.

The second part of Dr. Bloebaum’s rebuttal is devoted to the critique of my design of a stem with side elements (fins). He says that—

- “. . . It will fail early on (6–18 months) either by breakage of the implant at the terminal end of the bone or within the side elements.”
- “. . . Another obvious region of possible failure will be between the most proximal side element and bone interface.”
- “. . . Stripping the muscle and periosteum away from the bone will lead to the loss of outer third of blood supply to bone leading to osteopenia of the cortical bone.”

Dr. Bloebaum concludes the rebuttal with a suggestion to conduct animal and human trials for the device I have invented.

MY RESPONSE TO DR. BLOEBAUM’S CRITIQUE

In response to the first part of Dr. Bloebaum critique, relating to statistics, I have to say that in my article I refer to very similar outcomes of arthroplasty, that is, up to 2 percent loosening within 10- to 15-year period [5]. However, the averaged data are not applicable to the younger patients as the authors of that study urge on page 567: “A younger person should not be denied the benefits of a total hip arthroplasty but must accept that the risk of future failure is increased.” Moreover, as the observation period after implantation increases, the rate of failure increases correspondingly. In the section “Longevity and Outcomes” on the Web page of the American Academy of Orthopaedic Surgeons (<http://www.aaos.org>) co-developed in 2008 with the American Association of Hip and Knee Surgeons (<http://www.aahks.org>), one finds that: “The chance of a hip

*http://training.seer.cancer.gov/module_anatomy/unit3_3_bone_growth.html

replacement lasting 20 years is approximately 80%.”*

What I am arguing here is that these outcomes are not satisfactory for young amputees who could benefit from direct skeletal attachment, whose life expectancy is 30 to 50 years, whose short residuum bone significantly reduces the contact area between the bone walls and the implant, and who are willing to be involved in active sports like standing amputee ice hockey (<http://www.isihf.org>). Circular ossification is a natural mechanism for fracture healing, and its efficiency is close to the ossification in the longitudinal direction. In his study [4], Ilizarov widened the bone up to more than two initial diameters. A hypothesis was presented in the article [1] that circular ossification will counter the increase in diameter of the medullary canal [3] which diminishes the long-term reliability of the bond between the canal's inner walls and the implant. So, if circular ossification could be utilized in implantation, a more reliable and long-lasting fixation of the implants is to be foreseen.

Dr. Bloebaum's concerns about durability of the implant with side ele-

ments have been addressed in a recent mechanical and fatigue study [6].

As far as Dr. Bloebaum's final concern, the technology does not require “stripping the muscle and periosteum away from the bone.”

Regarding Dr. Bloebaum recommendation for conducting animal and human studies, Poly-Orth International is currently in preparation for an animal study to verify experimentally the osseo-locking hypothesis prior to its being tested in humans. A technology has been developed to manufacture implants with fins to be used for animals of any size [7]. Interested surgeons and veterinarians who would like to conduct this independent study are welcome to contact me at mpitkin@tuftsmedicalcenter.org.

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*<http://orthoinfo.aaos.org/topic.cfm?topic=A00355>