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Some Comments on Orthopaedic Implant Infection: Biomaterials Issues

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Recently we described the fabrication of so-called functional Ti-alloy biomedical implants by electron beam melting [1]. There were several issues which were particularly highlighted, including the prospects for fabricating patient-specific, open-cellular implants or orthopaedic appliances with closely matched stiffness to avoid any significant bone stress shielding, as well as the inducement of bone cell ingrowth to create a more stable appliance without cement. The issue of infection was also briefly addressed with the proposal that such open-cellular structures might accommodate nano silver particles to serve as a long-term antibiotic within the implant; similar to the incorporation of antibiotics within implant cement compositions.

As illustrated in figures 1 and 2 representing figures 19 and 21 respectively from the original publication [1], the ability to control the implant density and corresponding porosity will not only allow control of the stiffness, but also the optimum open-cellular dimensions to accommodate bone cell in growth. As shown in figure 2, the strut surface structure exhibiting some roughness-related, partial alloy melting or sintering, may also optimize the bone cell attachment. However, in contradiction to this cellular attachment optimization, Wu et al. [2] have shown, in support of related studies, that surface roughness also encourages the growth of infectious staphylococci as well as osteoblasts. According to supporting case studies of commercial orthopedic implant infections, roughly 64 percent were *Staphylococcus* species [2-5]. In contrast, the majority of infectious organisms found as the cause of dental implant bacteremias are *Streptococcus*, although other pathogens have been observed.

The major problem in orthopedic implant infection is the growth of massive mattes or biofilms of infectious bacteria which can form over the metal surface, especially roughened surface areas. The immune system cannot counter these massive infection systems, and the only recourse in most instances is the removal of the appliance and its sterilization along with the healing of the wound area using intense antibiotic regimes. Most infections are hospital acquired and of the

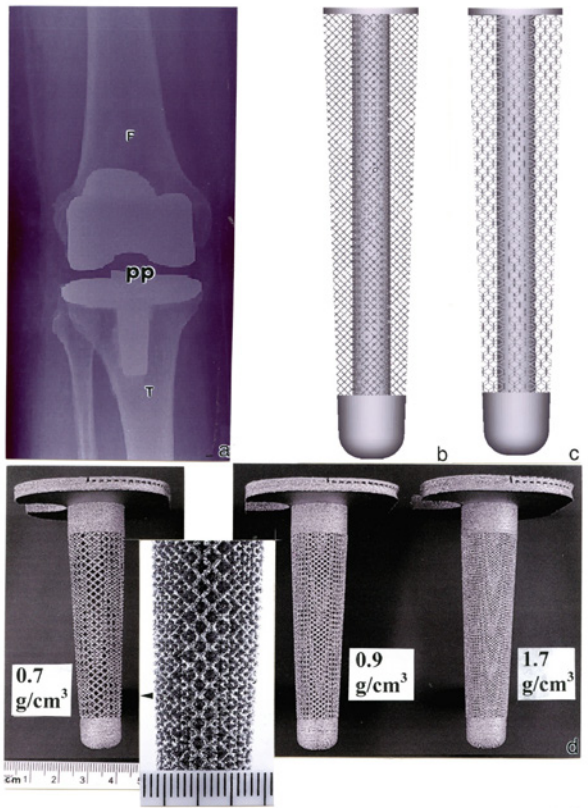

Figure 1: Examples of Ti-6Al-4V tibial (knee) stem design and fabrication by EBM. (a) X-ray image of total knee replacement. (b) and (c) show two design views. (d) Examples of EBM fabricated Ti-6Al-4V tibial mesh structures. From Murr et al. [1].

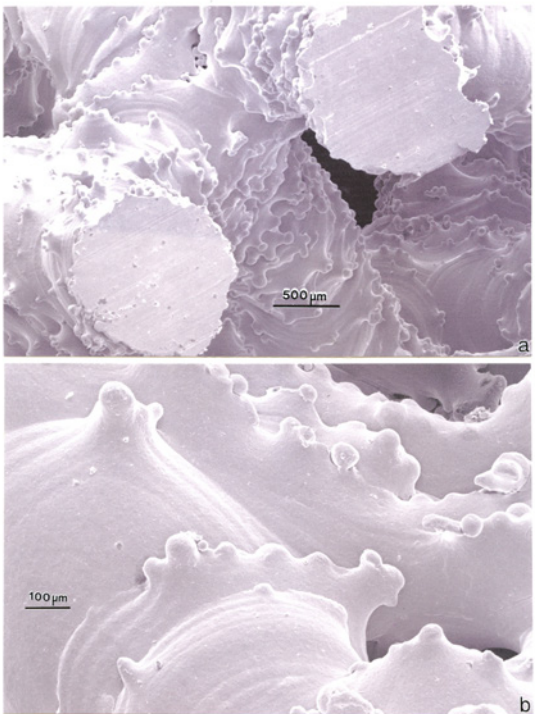

Figure 2: SEM images of mesh strut structure in Figure 1. (a) Partially sintered surface particles of Ti-6Al-4V. Cut sections show internal strut structure. (b) Magnified view showing strut surface. From Murr et al. [1].

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various infections which strike roughly 2 million people annually in the U.S., 0.05 percent cause death. Orthopaedic implant infection rates range from 0.3% to 8.3% [6] and occur by entry of pathogens into the wound during surgery, the spread of infection from a local source, hematogenous (blood transport) spread, or the recurrence of sepsis in a previously infected joint. With roughly 400,000 primary hip arthroplasties and nearly 1 million total knee anthroplasties in the U.S. in 2012, the market exceeds $20 B. While this market represents mostly smooth and highly polished implant components, prospects for 3D-printed or electron beam and laser beam melt-fabricated, patient-specific open-cellular appliances will require careful evaluation of the infection issue, especially in light of the continued mutation of pathogens against the most effective antibiotics. Pearson et al. [7] have recently discussed novel strategies for using bacteriophage to attack complex, infectious biofilms on surfaces. The first observations of lytic phages to cure infections date to the late 19th and early 20th centuries [8], and it was only in the 1960's where prophylaxis and treatment of bacterial infections achieved recovery efficacy in excess of 90%.

It is of interest to note in a recent executive summary on the current state of evidence, the American Academy of Orthopaedic Surgeons (AAOS) and the American Dental Association (ADA) developed some clinical guidelines regarding infection strategies [6]. In the first related recommendation, the summary concludes:

The practioner might consider discontinuing the practice of routinely prescribing prophylactic antibiotics for the patients with hip and knee prosthetic joint implants undergoing dental procedures …. patient preference should have a substantial influencing role. In the absence of reliable evidence linking poor oral health to prosthetic joint infection, it is the opinion of the work group that patients with prosthetic joint implants or other orthopaedic implants maintain appropriate hygiene. These recommendations were based on the fact that no clear association between the organisms found in implant infections and those involved in bacteremia exist.

It is apparent that some thought must be given to the complex issues involving infection in the manufacture of open-cellular components represented typically in figure 1, since these implants will promote bone cell ingrowth and will be more difficult to remove if an infection necessitates their removal. The placement of these implants must consider extreme levels of sterilization and maintenance of sterile environments during surgery. Furthermore, the patient must be completely free of infection, and measures taken to eliminate bacterial vectoring and attachment to the implant surfaces, since it appears that once they have breached the protective protocols, only radical measures involving the implant removal seem successful.

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