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Processing, Microstructure, and Performance of Metallic Orthopaedic Medical Devices

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The relationships between metal alloy composition, component processing, resulting microstructure, mechanical properties, and the final component performance are the fundamental responsibilities of a successful Materials Science and/or Metallurgical Engineer in the development and utilization of engineering components. Metals and alloys have a diverse application in orthopaedics as structural, load-bearing materials in devices for fracture fixation, partial or total joint replacement devices, instruments, and external splints, braces, and traction apparatus [1, 2]. Metals and alloys may be fabricated into medical devices by a variety of conventional techniques and, in most cases, may have their mechanical properties adjusted before the final shape is attained for maximum device performance. When reasonable care is taken during fabrication, surface cleaning, and handling, metallic devices have a successful history in a variety of internal and external environments encountered in orthopaedic applications. The relationships between component processing, microstructure, and performance are critical in the successful utilization of metal orthopaedic devices, particularly with internal (in vivo) environments [1, 2].

Austenitic stainless steels, particularly 316L and 22-13-5, have been successfully used as orthopaedic implant materials for years due to their corrosion resistance, biocompatibility, strength, nonmagnetic properties, and ductility. Another important characteristic of these alloys is the variety of properties that can be attained from different processing methods such as casting, forging, annealing, and cold working. Yield and tensile strengths of 316L can range from approximately 30 ksi and 70 ksi, respectively, to over 155 ksi and 195 ksi, respectively. In addition, the hardness and fatigue performance will increase with proper cold work processing. However, these beneficial increases in properties also result in decreased ductility. Heat treat operations, such as annealing and forging, must be closely controlled to prevent sensitization of the microstructure that may alter the corrosion performance. Proper control of many processing parameters can be maintained with traditional metallographic techniques and accurate characterization of the microstructures [3-5].

Commercially pure titanium is another metal that is typically used for orthopaedic implant applications. Very small increases in the residual alloy content can significantly increase the yield and tensile strengths from 25 ksi and 35 ksi, respectively, to over 70 ksi and 80 ksi, respectively. Cold working the metal can also increase the strengths to even higher levels. In addition, the hardness and fatigue performance also increase with these changes, however, the ductility decreases significantly and this may have a profound impact on the application. Titanium alloys, particularly Ti-6Al-4V, have become popular for orthopaedic implant applications due to the high mechanical and fatigue properties when compared to commercially pure titanium. Ti-6Al-4V can have yield strengths that range from 100 ksi to over 140 ksi depending upon the processing history. Traditional metallographic techniques have been employed to characterize these changes in the microstructure and identify potential manufacturing problems associated with microstructural variations [3-5].

A cobalt-based alloy (Co-26Cr-6Mo) is typically used when fatigue and wear resistance are critical for the performance of the device. In the cast condition this alloy has yield and tensile strengths of 75 ksi and 105 ksi, respectively, with a reverse bending fatigue endurance limit of 40 ksi and a low ductility of approximately 10%. When this alloy is hot forged the yield and tensile strengths are 130 ksi and 180 ksi, respectively. The fatigue endurance limit increases to over 110 ksi and the ductility also increases. The improved properties of the hot forged alloy are due to finer microstructures and second phase particles when compared to the dendritic microstructure of the cast components [3-5].

Improved fixation of the implanted orthopaedic device to the adhering bone material may be accomplished by attaching a porous coating to the surface of the device. The coating material may be the same alloy composition as the substrate device or the coating may be made of a different material. Usually, additional heat treat operations are required to metallurgically attach the porous coating to the substrate device and care must be taken to maintain the proper microstructure of the substrate and coating materials, so detrimental mechanical properties do not result from the processing. Microstructural variations due to additional heat treatments may be beneficial or detrimental to device performance depending upon the processing methods employed [3].

The traditional metallographic techniques developed over the years can be used to successfully characterize the microstructures that result from different processing methods and the identified microstructures may be associated with particular mechanical properties and performance issues depending upon the application of the device. Proper metallographic sample preparation techniques and microstructural constituent identification are necessary to relate processing, microstructure, and performance of an orthopaedic device.

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