MoRe® unique implants

Molybdenum-based alloys containing rhenium have been used primarily for high-temperature applications. However, the traditional "Mo-50 Re" alloy has now been clinically evaluated for a cardiovascular stent and is certified for this application. Furthermore, an ASTM standard covering its use in implants has been published recently. The alloy's high strength, excellent toughness, ductility and biocompatibility make MoRe® an excellent alternative to traditional implant materials.

People in the refractory metals field typically associate Mo-Re alloys with applications such as infra-red halogen lamp filaments, heating elements for chemical vapor deposition furnaces, thermocouple sheathing, heat shields, and space-vehicle thrusters, all of which operate at extremely high temperatures. Recently however, the traditional "Mo-50 Re" alloy, actually a 52.5% molybdenum - 47.5% rhenium alloy, has found new applications at body temperature that exploit its mechanical and biological properties. MiRus, a medical device manufacturer in Atlanta, Georgia, is at the forefront of this exciting work.

The cardiovascular connection: a Mo-Re stent

Most cardiovascular stents are made from a solid tube by micro-machining or laser cutting intricate patterns to create a tubular mesh. This mesh, or stent, is used to expand an occluded artery to restore its blood flow. To place a stent, a surgeon makes a small incision in an artery located in the arm or groin, inserts a catheter containing one or more stents into the artery, maneuvers it to the affected vessel, and expands the stent using a balloon. Traditionally, stents have been made from small-diameter stainless steel, titanium, cobalt-base, or nickel-titanium (Nitinol) alloy seamless tubing. Outside diameters are typically less than 2 millimeters for use in small arteries and 2–5 millimeters for large arteries.

Stent-placement is monitored using real-time radiography, allowing the surgeon to see the stent on a screen and direct it to the required location. Since radiation absorption is proportional to a material's density, Mo-Re, with a density of 13.5 grams per cubic centimeter, is superior to traditional materials with densities ranging from 4.5 (titanium) to 8.8 grams per cubic centimeter (cobalt-chromium). With Mo-Re stents absorbing much more radiation than traditional alloys, these stents are much easier to see during implantation. Surgeons can therefore manipulate and place them more safely and precisely than traditional stents.

The Nuloy® coronary stent using Mo-Re alloy. © MiRus

In the last decade, a Mo-Re stent design was successfully developed by Icon Interventional, a predecessor of MiRus, and is now available for clinical use in Europe. The high strength of the alloy has allowed production of a stent with a 0.06 millimeter wall, the thinnest on record. This success led MiRus to confer with a number of orthopedic specialists about other potential applications for the alloy. The ensuing discussions identified a number of unique opportunities to develop new surgical implants for spinal and craniomaxillofacial (head, face, and jaw) applications. Device designers, design engineers, and orthopedic surgeons are now focusing on applications in these areas.

Mo-Re material properties

Mechanical properties – Cold working increases the strength of Mo-Re alloy, as it does for metals generally. However, when cold worked, much of the deformation in Mo-Re is accommodated by an unusual process called twinning-induced plasticity (TWIP). TWIP simultaneously imparts high strength and high ductility, and MoRe® implants benefit from this unique phenomenon. The newly issued ASTM standard, *F3273-17 Standard Specification for Wrought Molybdenum-47.5 Rhenium Alloy for Surgical Implants (UNS*

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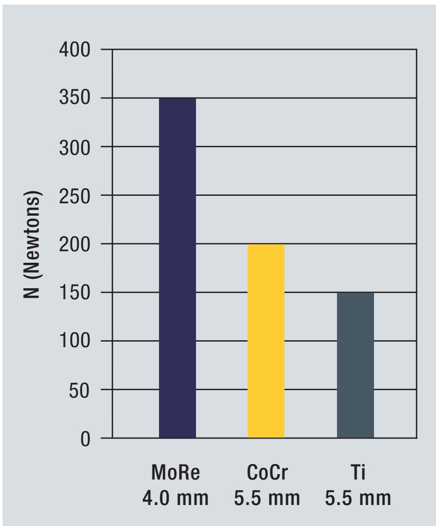


Fatigue runout load (N) of bent spine rods @ 2.5M cycles. Source: MiRus

R03700), defines several different strength levels of Mo-Re alloy based on the amount of cold working done. The strongest has minimum yield and ultimate tensile strengths in excess of 1300 MPa with double-digit percentage ductility. Higher strength allows designers to create smaller and lighter implants that disturb less of the bone structure into which they are placed. They also protrude less, blending better with the bone's natural shape.

A lowprofile MoRe® craniomaxillofacial (CMF) plate (right) demonstrates its size advantage over a titanium alloy plate (left). © MiRus

Surgical implants are often subjected to cyclic loading. Therefore, a large proportion of implant breakage occurs as a result of fatigue failure, so fatigue resistance is an important property for implant alloys. Fatigue tests comparing Mo-Re, Co-Cr, and Ti-6Al-4V bent spine rods showed a great advantage for Mo-Re alloy even though its rod's cross-sectional area was only 53% of the other rods'. Improved fatigue strength offers better implant reliability, lower probability of implant failure, and less product liability exposure.

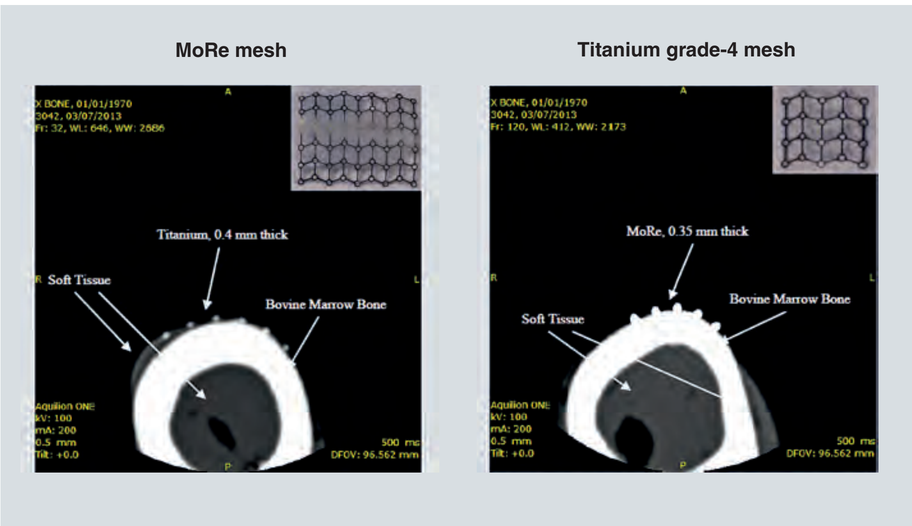
Magnetic properties – Magnetic resonance imaging (MRI) procedures present special challenges to implant designers. The extremely high magnetic fields present in MRI equipment exert enormous stresses on magnetic materials. Implant alloys must be nonmagnetic to eliminate torque, displacement, or heating during MRI procedures. MoRe is completely nonmagnetic, so it presents no problems in this regard. Another potential problem is artifact, or 'starburst' patterns in MRI images, a function of the implant's magnetic susceptibility. Artifact can interfere with diagnostic interpretation. Unalloyed titanium implants exhibit the least MRI artifact of the traditional metallic-implant alloys. Due to its lower magnetic susceptibility, Mo-Re reduces MRI artifact below that of pure titanium, a major clinical advantage.

Density and elastic modulus – The higher density of Mo-Re alloy is not so important for small and medium-sized surgical implants because the additional implant weight is minimal. However, a high modulus of elasticity is normally undesirable for orthopedic applications because the stiff implant reduces the load on the bone, a phenomenon called stress shielding. It can result in a reduction in bone growth because the body has less load to support. The effect becomes more important as implant size increases, so designers must work to keep implant dimensions at a minimum. This means high-modulus alloys must also have high strength to allow thinner cross-sections, a plus for Mo-Re.

Design freedom

The high strength and high ductility of Mo-Re alloy implants allow designers to significantly reduce implant dimensions compared to current materials, enabling thinner implants that are less prominent and provide greater aesthetic appeal. This is especially important when skin coverage is minimal, as in the skull. Implants with smaller cross-sectional area also reduce the amount of disturbed bone, leading to more robust structures.

Small and medium-sized trauma plates used for cranial, midface, mandible, wrist, finger, pelvic, and ankle fractures may have anatomically designed shapes, but surgeons often must contour these implants to fit a specific patient's bone structure. For example, spine rods are bent to establish correct alignment for patients with scoliosis. The high ductility of Mo-Re alloy permits this deformation without forming superficial cracks, a problem that may occur during intraoperative contouring of other high-strength orthopedic alloys. Eliminating cracks maximizes implant fatigue life.



Reduced MRI artifact for MoRe® mesh implant compared to titanium. © MiRus

Bone friendly

Mo-Re alloy implants do not present the biocompatibility problems or allergic reactions sometimes seen in implants containing nickel, cobalt or chromium. A number of biocompatibility tests › have been performed comparing Mo-Re and Ti-6Al-4V alloy; summary results are included in ASTM F3273-17. Osteoconduction (the process of bone growth on the implant surface) is another important property because it is observed mainly on highly biocompatible implant materials. In a bone implantation study where test pins were implanted in animal femurs, osteoconduction was similar for both MoRe and Ti-6Al-4V pins after 4, 13, and 26 weeks' implantation.

This new application of Mo-Re alloys in implants is an exciting field that is only in its infancy. It has the potential to provide better solutions to the problems seen by orthopedists every day.   (John Shields)

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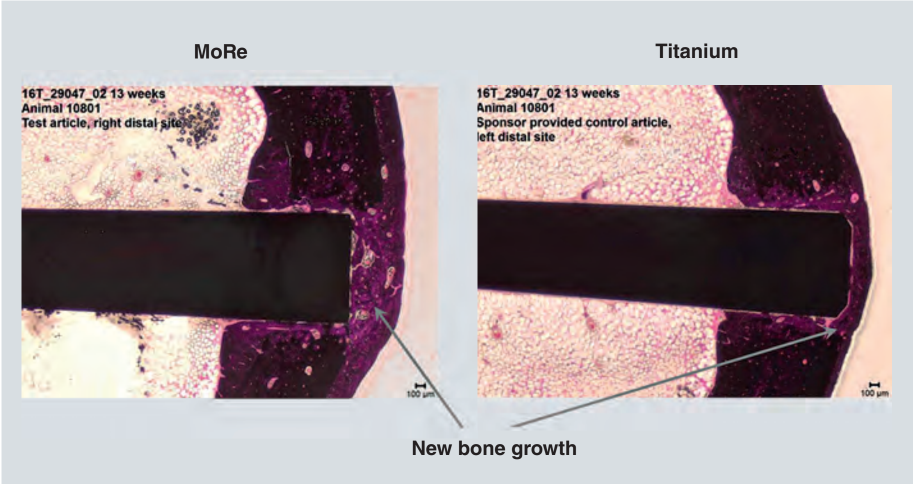

Bone growth after 13 weeks showing continuous bone maturation at the implant-hard tissue interface.