Molybdenum-Rhenium Implantable Medical Devices

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Medical Applications of Refractory Metals

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Introduction

• An overview of Medical Applications and Properties
• Review of molybdenum 47.5% rhenium Properties
• Review results of MRI examination
• Applications of molybdenum 47.5% rhenium medical devices
• An overview of the powder metallurgy processing methods for molybdenum 47.5% rhenium rods and sheet manufacturing
• An examination of mechanical properties at room temperature of molybdenum 47.5% rhenium rod and sheet
• Review of the microstructures and fractography of the molybdenum 47.5% rhenium rod and sheet.
# Comparison of Properties for Metals Used in Medical Application

<table>
<thead>
<tr>
<th>Property</th>
<th>Stainless Steel</th>
<th>Cobalt Chromium</th>
<th>Titanium</th>
<th>Nitinol</th>
<th>Mo47.5%Re</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear Resistance</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Corrosion Resistance</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Machinability</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Fatigue Resistance</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Design Latitude</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Mo47.5%Re Medical Device Properties

- Biocompatible
  - ISO & FDA Guidance
    - ISO 10993-1, 4, 5, 10, 11 Biological Evaluation of Medical Devices – Permanent Blood Contact: Interactions with blood; \textit{in vitro} cytotoxicity; irritation and delayed-type hypersensitivity; systemic toxicity
    - Over 100 samples tested
  - GLP Animal safety studies
    - 1.5 years follow-up in 27 patients

- MRI Compatible
- CT Compatible
- Bone Compatibility (cell line study)
- Corrosion Resistant - No galvanic corrosion with Titanium Alloys
Examination of Various Metals in Magnetic Resonance Imaging (MRI)

- Copper
- Nitinol -Nickel titanium
- MP35N - nickel-cobalt-chromium-molybdenum alloy
- Niobium
- Mo47.5%Re
- Ti6Al4V
- Tantalum
Mo47.5%Re Fixation and Reconstructive Applications

• Implantable Load Bearing Devices:
  • Orthopedic Reconstruction
  • Spinal and Extremities Fixation
  • Cranial Fixation & Reconstructive
  • Scaffolds: to prevent tissue collapse
  • Stents: Vascular, Tracheal, and Biliary
  • Dental: Posts and Implants.
Mo47.5%Re Medical Devices

Improved Outcomes

• Less Invasive, easier to implant, better contour
• Reduced Profile / Better Fatigue / Stiffness

Craniotomy Closures

Titanium

Chiari Mesh

Mo47.5%Re
Orthopedics and Spinal Reconstruction Applications

Mo47.5%Re Sheet and Rod

Polyaxial Screws and Rod

Spinal Plate and Screws

Volar Plate and Screws
Cranial Fixation & Reconstructive Applications

Mo47.5%Re Sheet and Rod

Chiari Mesh

Craniotomy Closures
Mo47.5%Re Cardiovascular Stent

1.55mm (0.061”) Outside Diameter x 1.37mm (0.054”) Inside Diameter
Wall Thickness 0.0889mm (0.0035”)

Typical Mechanical Properties for the Tubing
UTS 1190 MPa (170 KSI)
YS 1050 MPa (150 KSI)
Elongation 35%
Properties of Molybdenum 47.5% Rhenium

Properties

Atomic Number

Density, g/cc 13.52

Crystal Structure bcc

Melting Point 2550°C

Rx Temperature 1500°C

Tensile Strength MPa 1095 (160 KSI)

Modulus of Elasticity GPa 365 (52.9 Msi)

DBTT -196°C (Recrystallized)
## Chemistry of Mo47.5%Re for Medical Applications

<table>
<thead>
<tr>
<th>Element</th>
<th>Sample</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mo²</td>
<td>52.19</td>
<td>52.0 - 53.0</td>
</tr>
<tr>
<td>Re²</td>
<td>47.80</td>
<td>47.0 - 48.0</td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>S</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Si</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Zr</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Ni</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Fe</td>
<td>0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>N³</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>O⁴</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Cu</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>C⁵</td>
<td>0.002</td>
<td>0.050 Maximum</td>
</tr>
<tr>
<td>H⁶</td>
<td>0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>B</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Ti</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>W</td>
<td>0.009</td>
<td>0.050 Maximum</td>
</tr>
<tr>
<td>Mn</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Co</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Sn</td>
<td>&lt;0.001</td>
<td>0.010 Maximum</td>
</tr>
<tr>
<td>Mo² + Re²</td>
<td>99.99</td>
<td>99.9 Minimum</td>
</tr>
</tbody>
</table>
Powders

Molybdenum

Rhenium

Mo47.5%Re Blended and Compacted
The as sintered density of molybdenum 47.5% rhenium rods and bars were 98.5%. No additional densification from sintering can occur, so mechanical compaction swaging and rolling are employed to increase density and reduce the diameter/thickness.
Processing
Rod and Sheet
Compaction
Sintering
Hot
Swaging/Rolling
## Tensile Properties of Mo47.5%Re Rods

<table>
<thead>
<tr>
<th>Condition</th>
<th>Rod Dia. mm (inches)</th>
<th>Ultimate Tensile Strength MPa (KSI)</th>
<th>Stress at Offset Yield MPa (KSI)</th>
<th>Elongation %</th>
<th>Area Reduction %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swaged</td>
<td>14.22 (0.560)</td>
<td>1029 (147.0)</td>
<td>896 (128.1)</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td>Swaged</td>
<td>8.03 (0.316)</td>
<td>1121 (160.1)</td>
<td>1001 (143.2)</td>
<td>23</td>
<td>33</td>
</tr>
<tr>
<td>Swaged</td>
<td>5.54 (0.218)</td>
<td>1213 (173.3)</td>
<td>1106 (158.2)</td>
<td>25</td>
<td>43</td>
</tr>
<tr>
<td>Swaged</td>
<td>4.57 (0.179)</td>
<td>1393 (199.0)</td>
<td>1316 (188.3)</td>
<td>15</td>
<td>54</td>
</tr>
<tr>
<td>Swaged</td>
<td>3.99 (0.157)</td>
<td>1355 (193.6)</td>
<td>1283 (183.3)</td>
<td>24</td>
<td>60</td>
</tr>
</tbody>
</table>
Rod Microstructures and Fractures

14.22mm (0.560”) Diameter

Cleavage fracture with some secondary intergranular tearing

8.03mm (0.316”) Diameter

Cleavage fracture, ductile fracture (dimples) with secondary intergranular tearing
Rod Microstructures and Fractures

5.54mm (0.218”) Diameter

Cleavage fracture with secondary intergranular tearing

4.57mm (0.179”) Diameter

Ductile fracture (dimples) with secondary intergranular tearing
Rod Microstructures and Fractures

3.99mm (0.157”) Diameter

Ductile fracture (dimples) with secondary intergranular tearing
Microstructures of Hot Rolled Sheet

10.16 mm (0.400")
9.0 mm (0.354")
7.87 mm (0.309")
6.68 mm (0.263")
5.92 mm (0.233")
5.1 mm (0.201")
Microstructures of Hot Rolled Sheet

- 4.09 mm (0.161")
- 3.25 mm (0.130")
- 2.87 mm (0.112")
- 2.33 mm (0.092")
- 2.0 mm (0.078")
## Tensile Properties of Mo47.5%Re Sheets

<table>
<thead>
<tr>
<th>Condition</th>
<th>Thickness mm (inches)</th>
<th>Ultimate Tensile Strength MPa (KSI)</th>
<th>Stress at Offset Yield MPa (KSI)</th>
<th>Elongation %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annealed</td>
<td>2.08 (0.082)</td>
<td>1047 (149.5)</td>
<td>559 (79.8)</td>
<td>29</td>
</tr>
<tr>
<td>Annealed</td>
<td>0.97 (0.038)</td>
<td>1071 (153.0)</td>
<td>908 (129.7)</td>
<td>24</td>
</tr>
<tr>
<td>Annealed</td>
<td>0.53 (0.020)</td>
<td>1080 (154.3)</td>
<td>960 (137.1)</td>
<td>23</td>
</tr>
<tr>
<td>Annealed</td>
<td>0.28 (0.011)</td>
<td>1039 (148.4)</td>
<td>924 (132.0)</td>
<td>21</td>
</tr>
</tbody>
</table>
Sheet Microstructures and Fractures

2.08mm (0.082”) Thickness

0.97mm (0.038”) Thickness

Ductile fracture (dimples) with intergranular tearing
Sheet Microstructures and Fractures

0.53mm (0.020”) Thickness

Ductile fracture (dimples) with intergranular tearing

0.28mm (0.011”) Thickness

Ductile fracture (dimples) with some cleavage fracture and intergranular tearing
## Tensile Properties of Mo47.5%Re Sheets

<table>
<thead>
<tr>
<th>Condition</th>
<th>Thickness mm (inches)</th>
<th>Ultimate Tensile Strength MPa (KSI)</th>
<th>Stress at Offset Yield MPa (KSI)</th>
<th>Elongation %</th>
</tr>
</thead>
<tbody>
<tr>
<td>As Rolled T</td>
<td>1.02 (0.040)</td>
<td>1863 (266.1)</td>
<td>1656 (236.5)</td>
<td>10</td>
</tr>
<tr>
<td>As Rolled L</td>
<td>1.02 (0.040)</td>
<td>1688 (241.1)</td>
<td>1221 (174.4)</td>
<td>14</td>
</tr>
</tbody>
</table>
Sheet Microstructures and Fractures

1.02mm (0.040”) Thickness Transverse

Ductile fracture (dimples) with laminar tearing

1.02mm (0.040”) Thickness Longitudinal

Ductile fracture (dimples) with laminar tearing
Conclusion

• Mo47.5Re is ideal for designing orthopedic and other small load bearing medical devices.
• Mo47.5%Re has proven to be biocompatibility, MRI and CT compatibility, and corrosion resistance.
• Combination of tensile strength and ductility can be tailored for implanted devices will be low profile.
• Over Sintering is used to overcome the powder segregation issues.
• Hot swaging and rolling are dynamic process of deformation and recovery.
• The fractography is consistent with mechanical results for rod and sheet.