POLYETHYLENE [UHMW PE]

Charnley originally chose polytetrafluoroethylene (PTFE) as a bearing material sometime between 1956 and 1958, based on its general chemical inertness and low coefficient of friction.
The wear of PTFE against a stainless steel head in this prosthesis provided 7 to 10 mm of linear wear in less than 3 years. These clinical failures were attributed to creep deformation of PTFE.
The first hips using UHMWPE as a bearing surface were implanted in the early 1960s. The UHMWPE family remains the material of choice as the bearing surface in total joint replacements today.
The 3 most notable efforts to use polymers other than UHMWPE involved the use of polyacetal (in the Christiansen hip), polyester and Poly II (a carbon fiber-reinforced). Several groups reported significantly higher rates of revision of these devices and found that the wear was, in fact, over 7 times higher than for the Charnley prostheses.
Polyacetal is still in orthopaedic use today, it is the common material used in the production of the colored trial components used to check the fit of the prosthesis during surgery.

Ultra High Molecular Weight Polyethylene
The material used in orthopaedics, UHMWPE, has often been incorrectly called high density polyethylene in the literature.
A comparison of properties of UHMWPE versus high density polyethylene.

<table>
<thead>
<tr>
<th>Property</th>
<th>High Density Polyethylene</th>
<th>UHMWPE</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>50,000–100,000</td>
<td>&gt; 2,000,000</td>
<td></td>
</tr>
<tr>
<td>Density</td>
<td>.952–.965</td>
<td>.930–.945</td>
<td>g/cc</td>
</tr>
<tr>
<td>Melting point</td>
<td>130–137</td>
<td>125–135</td>
<td>°C</td>
</tr>
<tr>
<td>Tensile yield</td>
<td>26.2–33.1</td>
<td>19.3–21</td>
<td>MPa</td>
</tr>
<tr>
<td>Tensile modulus</td>
<td>.9–1.6</td>
<td>.8–1.0</td>
<td>GPa</td>
</tr>
<tr>
<td>Elongation @ break</td>
<td>10–2200</td>
<td>200–350</td>
<td>%</td>
</tr>
<tr>
<td>Impact strength</td>
<td>.4–4.0</td>
<td>&gt; 20, no break</td>
<td>ft-lb/in</td>
</tr>
</tbody>
</table>

* UHMWPE, Ultra high molecular weight polyethylene
UHMWPE has a much higher molecular weight, significantly higher impact strength and toughness, and better abrasive wear characteristics than high density polyethylene.

**STRUCTURE**

Structure \[ \text{CH}_2-\text{CH}_2-\text{CH}_2 \ldots \]

3 million molecules
Density: 0.930
Melting point 125º

4150HP: commonly used Poly
4150HP: 4 resin name
4150HP: 0 or 1 Calcium stearate is added or not
4150HP: 50 or 20 [ie 2 or 5million]

**MANUFACTURING**

1. **Ram Extrusion**
   - Extrude the resin under heat and pressure
   - Reciprocating ram
   - Poor quality than others types of manufacturing

2. **Compression Mold**
   - The resin in to a rectangular heated cavity mold
   - Subjected to pressure and heat
   - Sheath of UHMWPE
   - Machine the component from the sheet.
   - Better than ram

3. **Direct Mold**
   - Mold the resin into the small molded cavity representing the exact complex shape
   - No need for subsequent machining
   - High quality and excellent smooth surface
4. **Isostatic molding**

   - Cold compaction of powder
   - Heated in a bag under uniform pressure

Traditional UHMWPE Survival is 90% at 10 yrs and 80% at 20 yrs

In elderly patients: Not an issue.

In younger patients: Poly-wear is important

**Sterilization** The dominant method for the sterilization of UHMWPE components has been gamma irradiation. It is known for some time that UHMWPE oxidizes after gamma sterilization. Postirradiation oxidation of UHMWPE adversely affects the properties of UHMWPE.

The extent of oxidation is determined by the dose of irradiation. The gamma rays break either carbon-hydrogen (C-H) or carbon-carbon (C-C) bonds, which results in the formation of free radicals.

These free radicals undergo one of three reaction pathways: (1) recombination, (2) chain scission, or (3) cross-linking. Each pathway has different consequences.

Recombination simply reforms the bonds that were broken and provides no net change in chemistry.

In chain scission, a fragment of the polymer chain is removed from the original polymer chain. This process is driven by the presence of oxygen, which reacts readily with free radicals resulting in loss of molecular weight of the original polymer chain.

With cross-linking, 2 radicals from different polymer sections combine to form chemical bonds between 2 polymer chains. A cross-linked polymer may be harder and more Abrasion-resistant than its non-cross-linked precursor.
The level of degradation due to post irradiation may be altered by irradiating in an environment with no oxygen present. This would also include packaging the polyethylene in a vacuum or in an inert atmosphere such as nitrogen or argon. Irradiation in the absence of oxygen will minimize degradation and maximize cross-linking.

Alternative bearings has been suggested in younger patients

1. Cross link Poly
2. Ceramic
3. Metal on metal

1. **CROSS LINK POLY**
   Cross link occurs [Absence of Oxygen]

   Presently cross link poly is manufactured

   **Radiation**
   - Dose: 2.5 MRad in Vacuum or nitrogen
   - Then subjected 50º C for 10 hours.
   - Less chance of oxidation
   - Vacuum packed to improve shelf life
   - Cross link occurs only in the amorphous region of the poly and not in the crystalline region

2. **Cross link poly may reduce wear.**
   - 30% reduction at III yr in Vivo
   - Graph demonstrating a 90 % reduction in wear at 5 million cycles
   - (approximately 5 years normal wear) based on hip simulator studies

   Cross link has a detrimental effect:
   - on yield strength, UTS and elongation

3. **Discrepancy in clinical and lab result**
   - Latest clinical results: good wear property
   - Some retrieval study: properties were not same as reported in the lab but it’s importance not known.
   - Intermediate reports indicate good outcome with cross link poly compared to traditional poly.
The crystallinity of the polymer should be considered as well. Parts of the polymer that are random are the noncrystalline or amorphous sections of the polymer. Virtually all polymers are semicrystalline in that only some areas of the structure are ordered. The degree of crystallinity can greatly influence the properties of the polymer. Crystalline regions can form lamellae.

II CERAMIC

Biomaterial

The alumina (A12O3); pressed in a mould at a very high temperature (1600°C).
Density and grain size (< 2 µm)
Scratch resistant; brittle
Alumina is a wettable material.
The contact angle of alumina is 44° [whereas the contact angle of polyethylene is 80°]

Requisite

The thickness of the alumina acetabular insert must be at least 6 mm
Avoid initiation of a crack the use of a hammer to impact the femoral head onto the cone
A more horizontal placement with an angle of abduction of < 45° is preferable
Problem

1. Possibility of acute fracture: Is less with improved metallurgy. 0.004% incidence

2. Impingement.[ceramic on ceramic]
   Impingement between the femoral neck and the acetabular component is a major problem. Alignment is very critical

3. When revision required: Can be Catastrophic and needs urgent revision. It is difficult in removing all particles this may cause III body wear in revision. Revise to metal head, change liner and thorough synovectomy.

4. Head size is usually 28 mm

5. Chipping of the liner during insertion [2%]

6. An alumina-on-alumina combination is safe.

Indications

The younger, more active patients

Results: 98% survival at 5 years: Trident

An alumina-on-alumina combination is safe

The advantages

- Minimal wear,
- Minimal reaction to wear debris and lower rates of osteolysis

Ceramics include compounds such as silica (SiO2) and alumina (Al2O3), formed from a nonmetallic and a metallic element.
As with metals, ceramics have tightly packed atomic structures that are dictated by requirements of spatial coordination for covalent bonds and of charge neutrality for ionic bonds.
Ceramic materials are very stiff and brittle. They have high purity, they possess excellent biocompatibility and exceptional wear resistance (with hard, hydrophilic surfaces).

2 quite different applications.

I. Its use in total joint replacement components: alumina and zirconia
II. Involves the use of ceramics as bone graft substitutes and as coatings for metallic implants: calcium phosphate and bioglass (SiO2-Na2O-CaO-P2O5), that are osteoconductive providing surfaces to which bone will bond. The mineral phase of bone is hydroxyapatite, a calcium phosphate (Ca10(PO4)6(OH)2). The stability of calcium phosphate ceramics depends on the temperature and the environment, and can be affected by substitution (for example, of a carbonate for a phosphate)
Ceramic materials are held together by covalent bonds. Covalent bonds are formed through the mutual sharing of electrons. As with materials that are ionically bonded, materials that are covalently bonded are also good insulators. Most ceramic materials have polygranular microstructures similar to metals and metallic alloys.

Tougher than alumina with a much smaller grain size (less than half a micron), zirconia has found clinical use as an alternative bearing material to metallic alloys for articulating against UHMWPE.

<table>
<thead>
<tr>
<th>Properties of Orthopaedic Ceramics*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Property</strong></td>
</tr>
<tr>
<td>Strength (MPa)</td>
</tr>
<tr>
<td>Grain size (µm)</td>
</tr>
<tr>
<td>Density (g/cc)</td>
</tr>
<tr>
<td>Elastic modulus (GPa)</td>
</tr>
</tbody>
</table>

**METALS**

**Young’s Modulus [GPA]**

<table>
<thead>
<tr>
<th>Young’s modulus</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Ceramic</td>
</tr>
<tr>
<td>II Chr-Co [210]</td>
</tr>
<tr>
<td>III Stainless Steel [190]</td>
</tr>
<tr>
<td>IV Ti [110]</td>
</tr>
<tr>
<td>V Cortical</td>
</tr>
<tr>
<td>VI Cement</td>
</tr>
<tr>
<td>VII Cancellous</td>
</tr>
</tbody>
</table>

**Stress/Strain (MPa/Microstrain)**

- Metal
- Glass
- Bone
- Strain
Stress and strain are calculated from the measured load and deformation and the stress-strain curve is plotted, the solid line

Strain values (mm/mm) are plotted along the horizontal axis, and the stress values (N/m²) are plotted along vertical axis.

Elastic Region  The straight-line portion of the diagram up to almost the yield point.

In this range of stress, the deformation is elastic. That is, the material will return to its original dimensions when the load is removed.
This elastic behavior is described by Hooke's Law.: Youngs Modulus = stress / strain

<table>
<thead>
<tr>
<th>COMPONENTS OF STEEL, VITALLIUM [CO-CROME] AND TITANIUM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Fe/Co/Ti</td>
</tr>
<tr>
<td>CR Mo</td>
</tr>
<tr>
<td>Ni Al/V</td>
</tr>
<tr>
<td>Carbon</td>
</tr>
</tbody>
</table>
### BIOMECHANICAL PROPERTY

<table>
<thead>
<tr>
<th></th>
<th>Stainless Steel</th>
<th>Cr-Co [vitallium]</th>
<th>Titanium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elastic Modulus (GPa)</td>
<td>190</td>
<td>210</td>
<td>110 (less stiff)</td>
</tr>
<tr>
<td>Ultimate Strength (MPa)</td>
<td>600-900</td>
<td>650-1500</td>
<td>750-950</td>
</tr>
<tr>
<td>Hardness: Diamond tip</td>
<td>Hard +++</td>
<td>++++</td>
<td>++</td>
</tr>
<tr>
<td>Notch sensitivity</td>
<td>++</td>
<td>++</td>
<td>+++++</td>
</tr>
<tr>
<td>Corrosion Resistance</td>
<td>++</td>
<td>+++</td>
<td>+++++</td>
</tr>
<tr>
<td>Resistance to crevice</td>
<td>+</td>
<td>+++</td>
<td>+++++</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>++</td>
<td>+++</td>
<td>+++++++</td>
</tr>
</tbody>
</table>

### Metallic Bonding

The elements in a metallic alloy are held together by metallic bonds. These bonds are quite strong, accounting for the high strengths and high melting points of the alloys.

### Metallic Microstructures

When atoms in a molten state are cooled to form a solid material, many small crystals of atoms nucleate and grow until they begin to impinge on one another.

When all the molten liquid has solidified, the resulting solid is a polycrystalline array of individual crystals, typically of irregular shape and of a size visible in the light microscope or macroscopically.

Grain size is one of the most important micro structural features of metals and metallic alloys. The finer the grain size, the more homogeneous and isotropic the material will be, but more importantly, the greater its strength.

Unacceptably large grain sizes have been shown to be responsible for insufficient fatigue strength in the alloy, resulting in clinical failures.

**Stainless steel:** Carbon concentration must be kept low in 316L stainless steel to maintain corrosion resistance. At higher carbon concentrations, there is a tendency for the carbon to combine with the chromium to form a brittle carbide that robs the microstructure of much of the chromium and that tends to segregate to the grain boundaries, significantly weakening the material by making it prone to corrosion related fracture. Such a condition, called sensitization, has been directly responsible for mechanical failures of orthopaedic implants made from stainless steels in which carbon content has been too high.

A potential disadvantage of stainless steel in implant applications is its susceptibility to crevice and stress corrosion.
Because of concerns about corrosion and subsequent long-term biocompatibility, stainless steel has been used primarily in fracture and spinal fixation applications. These applications often allow removal of the device or require strength only until healing occurs.

Permanent implants, such as femoral components of the Charnley design of hip replacements, have also been made from stainless steel, demonstrating that stainless steel can be used safely even in these high-demand applications.

**Cobalt-Chromium Alloys**

All of these alloys are primarily cobalt with significant amounts of chromium added for corrosion resistance. The F75 alloy, for example, has commonly been used for investment (or so-called lost wax) casting.

Molten F75 alloy is poured or pressurized into the molds and allowed to solidify. The ceramic mold is broken away from the underlying metal part, which can then be finished into the final device.

If solidification proceeds too quickly, air from inside the mold and gases that are released during the solidification process can become entrapped in the microstructure, causing undesirable stress concentrations that can cause premature failure.

F75 alloy is used to fabricate porous coatings for biologic fixation of orthopaedic implants.
The F90 and F562 alloys obtain substantial mechanical properties through more than 40% cold-working. In addition, the material can be thermally treated to precipitate a uniform distribution of very fine cobalt-molybdenum (Co3Mo). The result is among the strongest of the orthopaedic implant alloys.

Titanium Alloys
Their corrosion resistance, provided by an adherent passive layer of titanium oxide (TiO2), significantly exceeds that of stainless steel and the cobalt alloys.

The most common form of titanium used in orthopaedic applications is titanium-aluminum-vanadium alloy (ASTM F-136).

The microstructure of Ti-6Al-4V contains 2-phase grains, the alpha phase being a hexagonal-close packed phase that is stabilized by the aluminum alloying element and the body-centered cubic beta phase stabilized by the vanadium.

The elastic modulus for the alloy is about half that of stainless steel and the cobalt alloys, making the alloy an ideal candidate for lowering the structural stiffness of a device without changing its shape.

A disadvantageous trait of titanium alloy is its notch sensitivity. A stress concentration, such as a notch or scratch, on the surface of a titanium alloy implant significantly reduces the fatigue life of the part. The same is true for the type of stress concentrations that occur when a porous coating is applied to the surface of a titanium alloy total joint component.

Another disadvantage of titanium alloy is its lower hardness (in comparison, for example, to the cobalt alloys). The decreased hardness of titanium alloy that must be considered in total joint applications is due to its wear resistance.

Clinical observations have demonstrated significant scratching and wear of total hip femoral heads made from titanium alloy.

The observations suggest that titanium alloy that has not undergone additional surface processing (for example, ion implantation) should not be used as an articulating surface.
METAL ON METAL ARTICULATION

Metal on Metal: Recent resurgence should be credited to McMinn [Birmingham Hip]

Advantages

Large head and hence stable and chance of dislocation is less

Less wear. Wear rate: 0.003 cu mm/yr

Why less wear?

(1) High carbon content
(2) Wrought manufacturing
(3) Large diameter
(4) Diametric clearance. [Differential radii of femoral head and cup]

Concerns

1. Metal ions in the blood and urine
2. ? Carcinogenic
3. Metal sensitivity
4. Fracture neck of femur
5. Immune modulation

Local biological response to the metal ions

Histologically perivascular lymphocytic response
Its importance is not known

Wear particles

Size: 0.1 to 5 u
5 x 10^{12} Particles produced/year
Peak at 1 year and then stabilizes with time [McMinn]
Chromium particles more than cobalt in the serum
Can present in Lymph node, spleen
Dissolution of metal particles because of size: elevation of Co and Cr in RBC, serum and urine
Can transfer through placenta: controversial.
Toxicology effect not know
Resurface Technique?
Need training
No problem. At 5 yrs any hip may work.

Do you need to monitor for kidney failure?
No one knows
Obligation of the surgeon to inform this in the informed consent.
Need for serum level of metals: not required to measure