Biomaterials

Classes of biomaterial

Julian R Jones

Department of Materials

Imperial College London

Learning outcomes

Your should be able to:

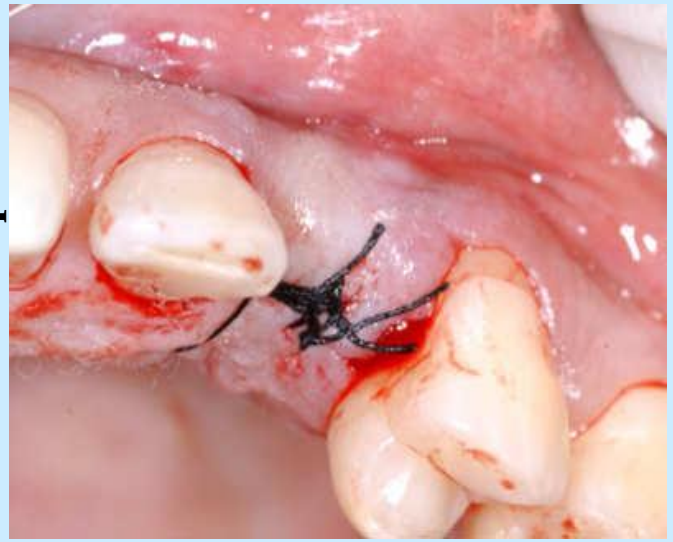
- Discuss the different classes of biomaterials that are available to orthopaedic surgeons
- Explain why joint replacements have a limited lifespan: environmental factors that affect performance.
- Discuss potential benefits of bioactive versus bioinert materials, including cemented v non-cemented implants
- Compare the now controversial metal-on-metal implants with ceramic on ceramic
- Discuss how we can ensure new medical devices are safe

Classes of biomaterial

- Bioinert

- Biodegradable

www.dental-implants.com



Sutures

- Bioactive,

e.g. bone bonding

Key points

- Tissue replacement v tissue regeneration
- Effect of loading (biomechanics) on implant survival
- Cemented v un-cemented implants
- Metal on metal v ceramic on ceramic

Biomaterials

Joint replacements:

Pluses and minuses

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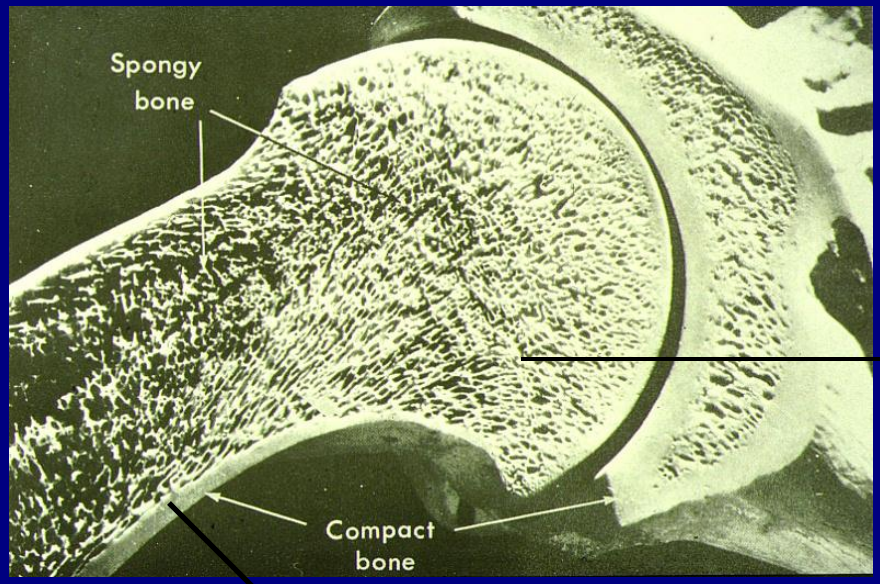
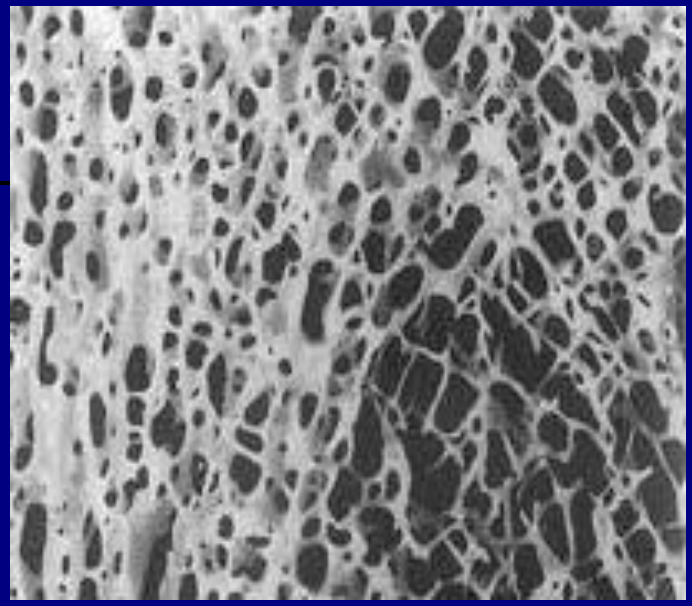
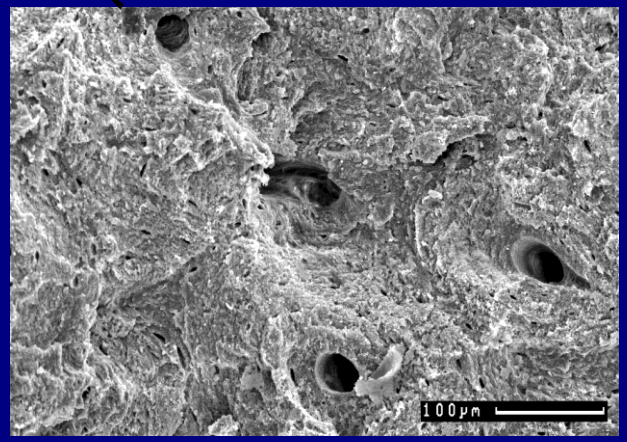
A hip joint



Trabecular bone

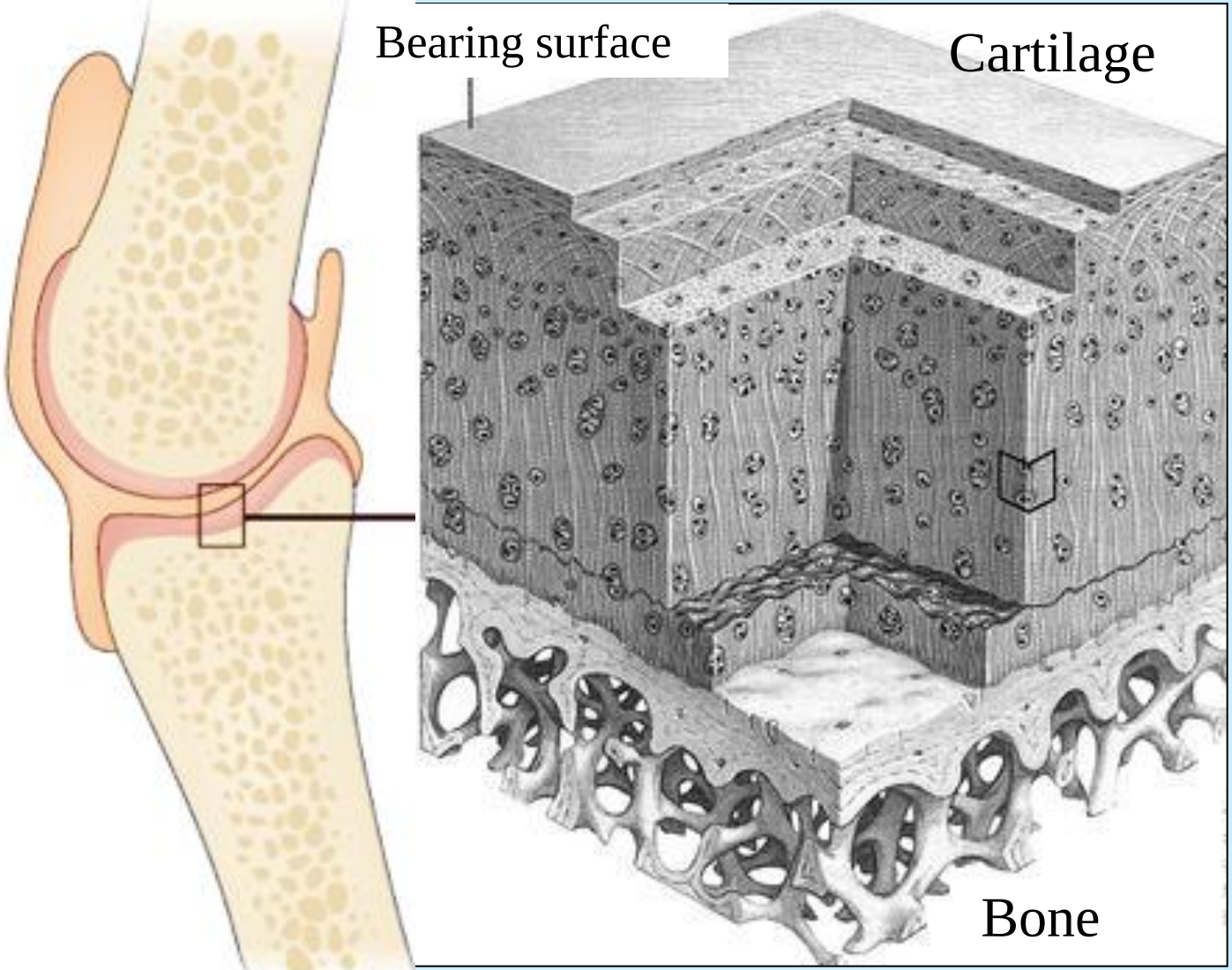


Cortical bone



Compressive strengths:
trabecular bone 2-12 MPa
cortical bone 100-230 MPa

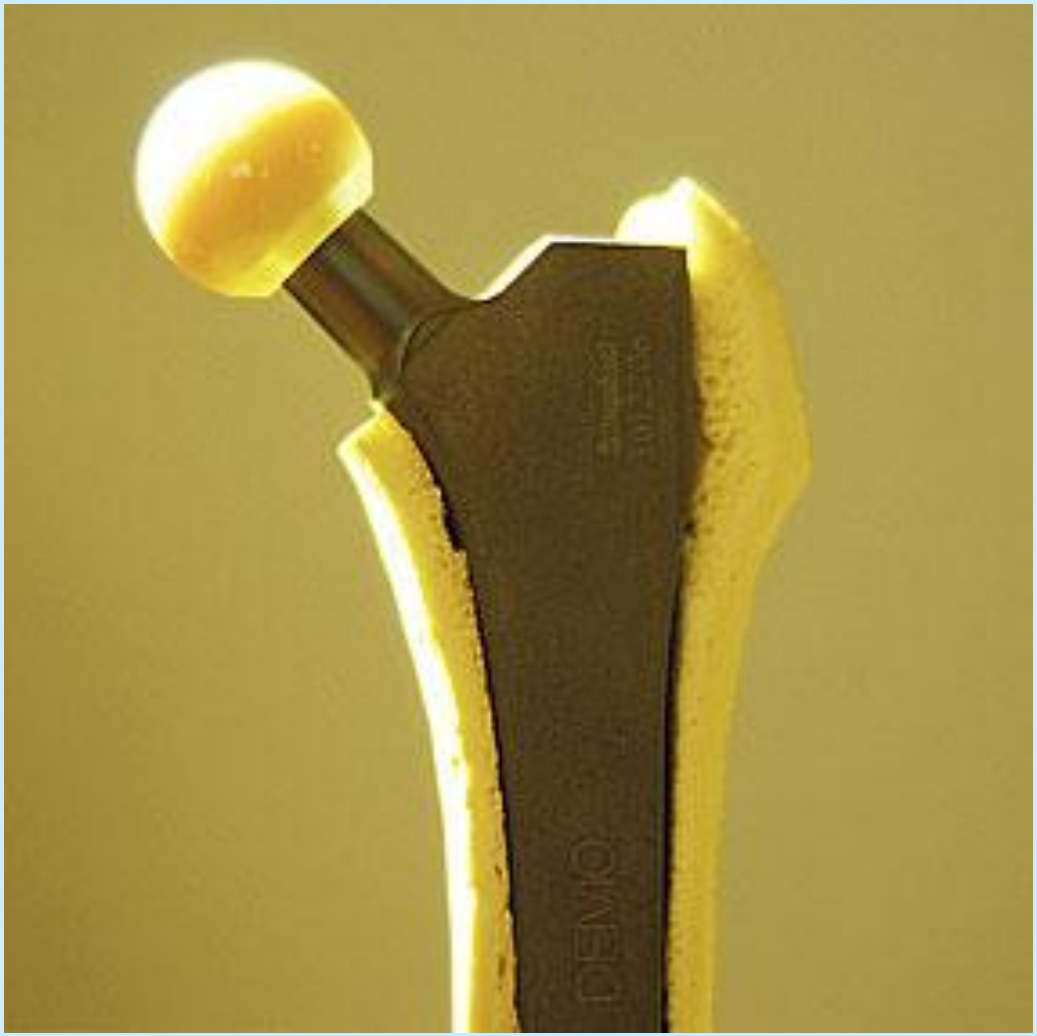
Ideal solution is ostochondral regeneration



Articular cartilage has a unique structure and regenerates very slowly

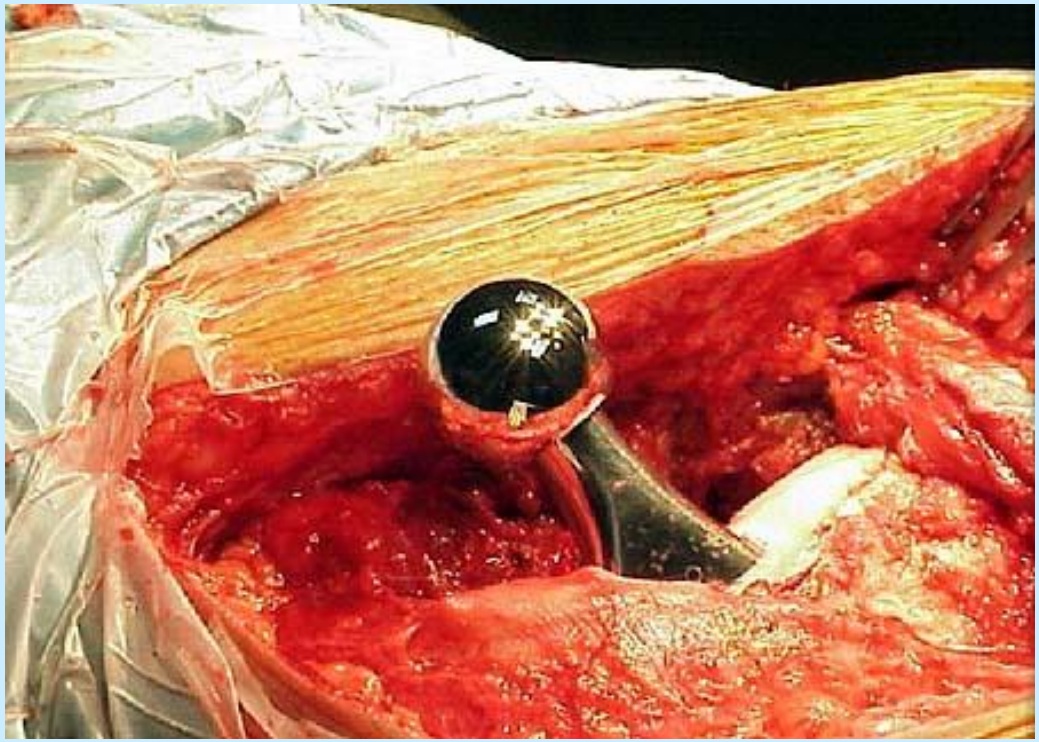
Total hip replacement

Destructive or reconstructive?



Two types of THR

Cemented
(original Charnley)



Uncemented
(bioactive coating)

The Charnley hip prosthesis

Ball/ head:

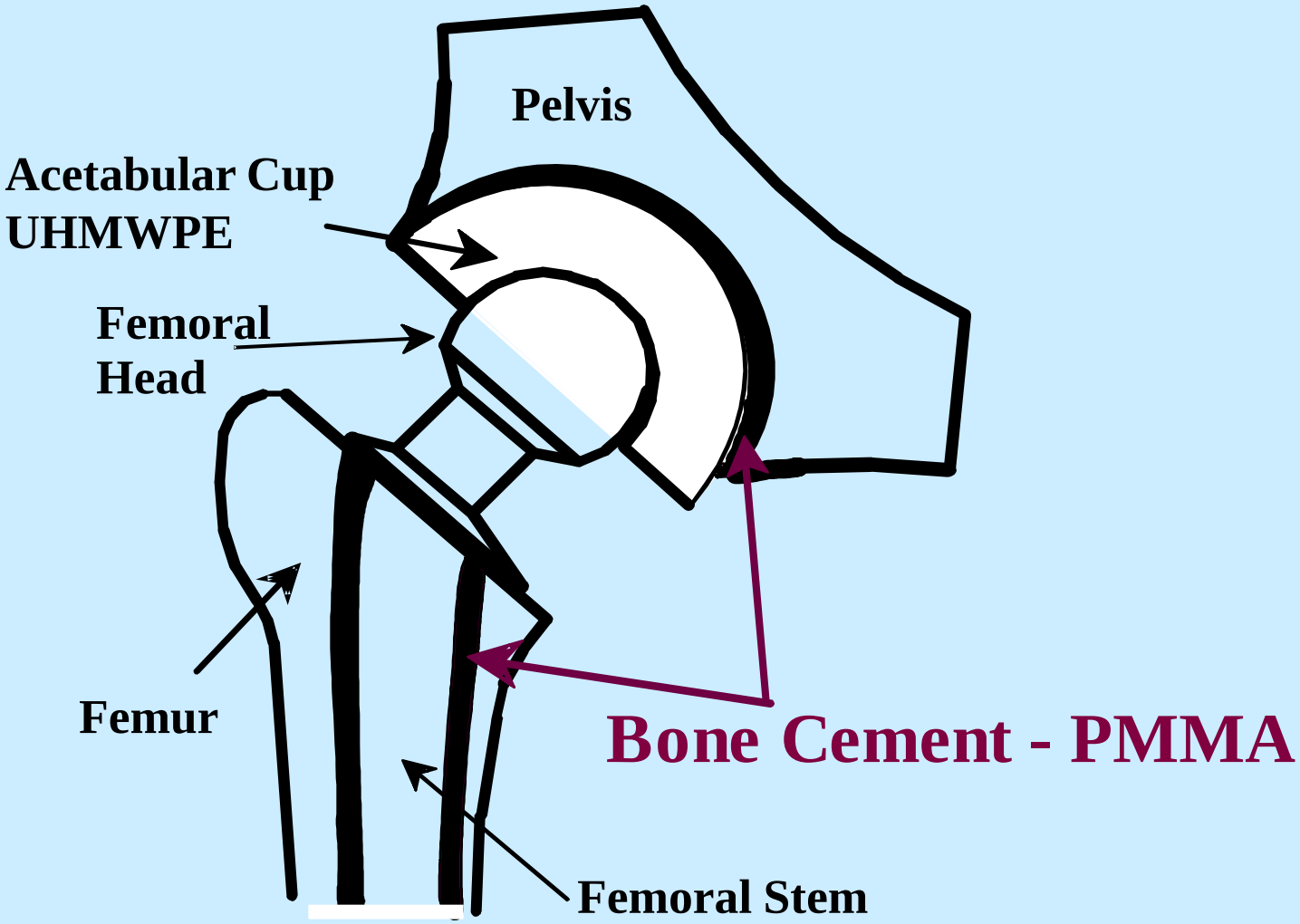
Acetabular Cup:

Cement:

Stem:

Cup backing and Stem surface treatment:

Cemented Total Hip Replacement



Clinical results for total hip replacements

The cemented low friction (Charnley-type) total hip arthroplasty (THA) using a metallic femoral component and UHMWPE cup has the highest level of clinical success. Predicted survival rates are:

5 years 99.41 ± 0.02%

10 years 95.48 ± 0.04%

15 years 83.12 ± 0.18%

20 years 66.53 ± 0.35%

Materials Selection: Cement: PMMA

- A cement works by starting as a solution and hardening
- Monomer polymerised to form a rigid polymer
- Two solutions mixed by surgeon, cures to form a hard rigid glassy but brittle polymer.
- In situ setting forms (cold curing) are used as bone cements.

PMMA Bone cement

2-component system: powder and liquid mixed 2:1

1. Powder
   - PMMA spheres 30-150um (>90%)
   - Radiopacifiers ($BaSO_4$) (4-10%)
   - Initiator (benzoyl peroxide) (2-3%)
2. Liquid
   - MMA monomer (>95%)
   - Co-monomers (0%)
   - Inhibitor 50ppm

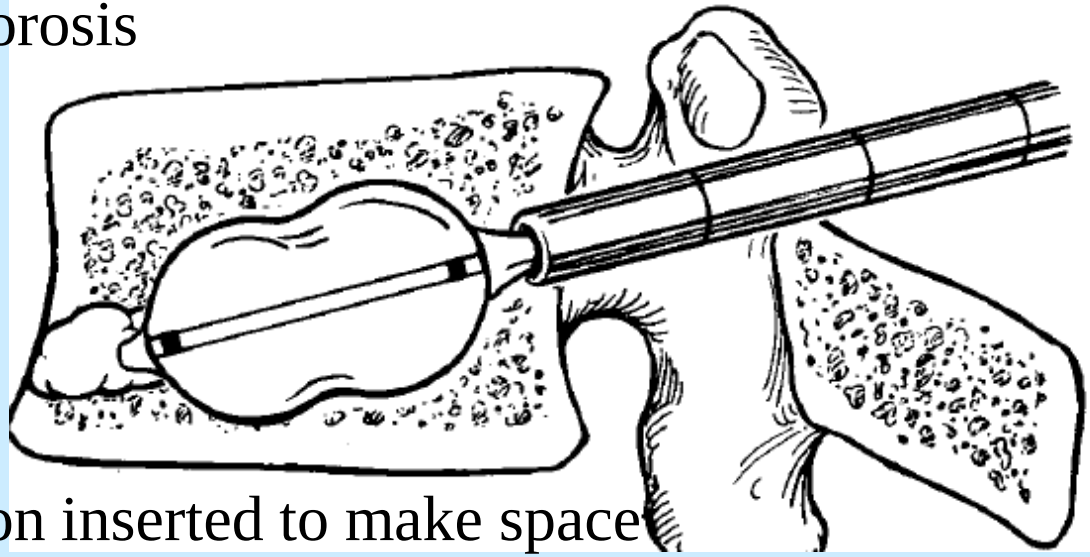
Activator (Dimethyl-p –toluidine) (2-3%)

- Mix components together to a doughy stage
- Injected into prepared site, and allowed to cure

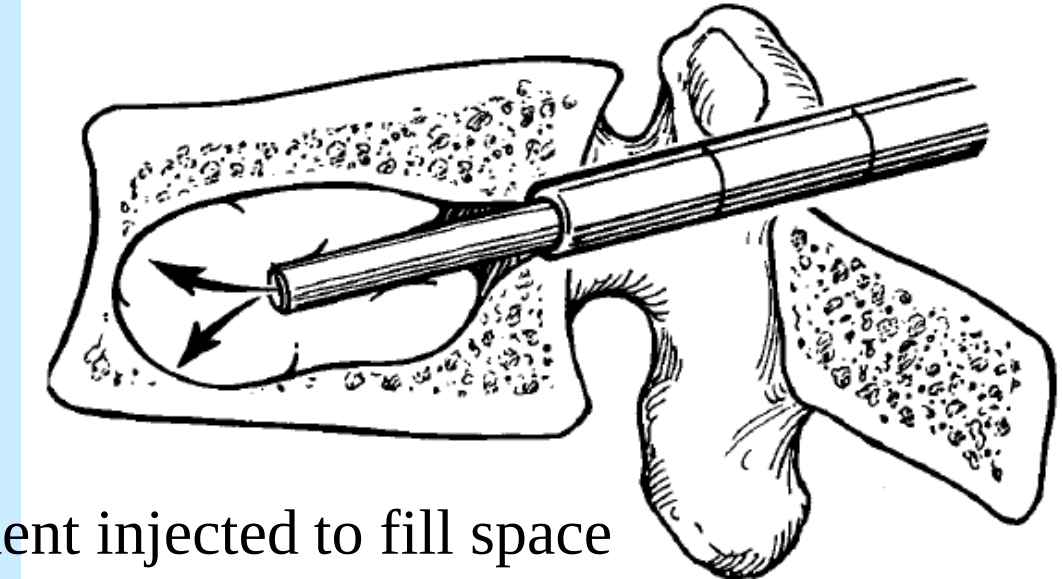
The leading brand Simplex® has not changed significantly in 40 years

Also used in vertebroplasty

Treatment for severe osteoporosis in the spine



Balloon inserted to make space



Cement injected to fill space

Implant/ tissue interface

Note the formation of a radiolucent layer as a result of fibrous capsule layer Formation and stress shielding that leads to failure.

Bioactive Coatings

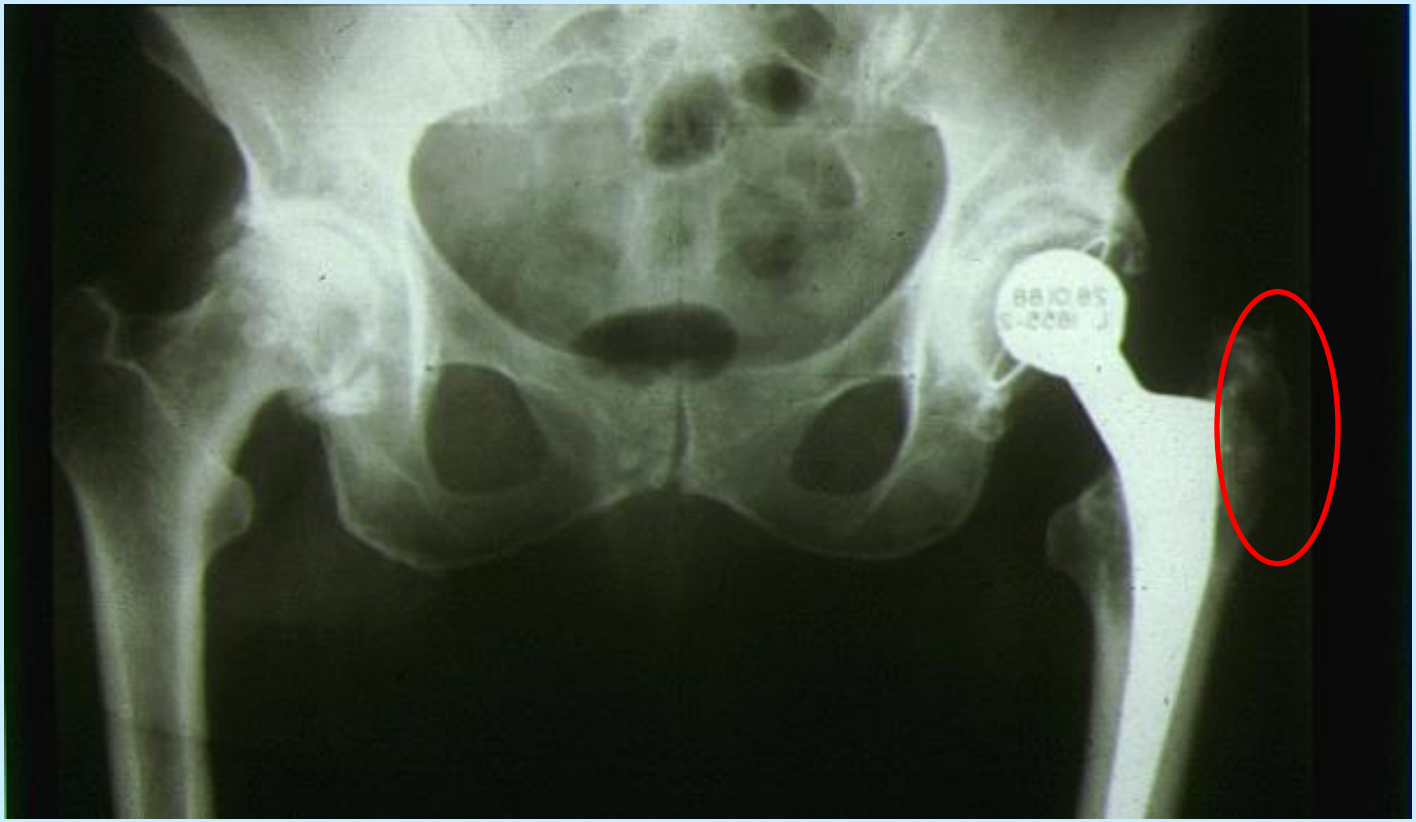
- Synthetic hydroxyapatite, HA = $Ca_{10}(PO_4)_6(OH)_2$
- Ca:P ratio = 1.67
- Plasma sprayed onto metal
- Bonds to bone over time
- ~20 years clinical use
- Any better than cement?

The real problems – Asceptic Loosening

- **Stress Shielding:** Overloading the implant-bone interface or shielding it from load transfer may result in bone resorption and subsequent loosening of the implant
- **Wear:** The articulating surfaces of the joint should function with minimum friction and produce the least amount of wear products

The effect of loading environment

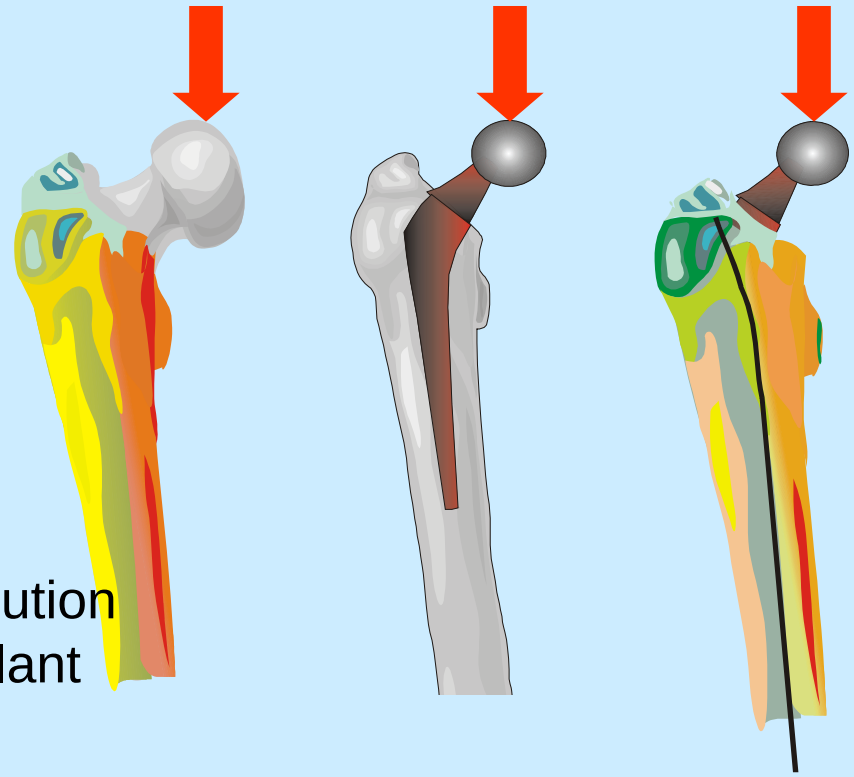
High stress concentration or stress shielding may result in bone resorption around the implant. The metal implant has higher stiffness (Young's modulus) than bone (4-10x)



Bone Loss - Stress Shielding

- Wolff's Law (1869): "bone adapts (remodels) in response to the mechanical loads placed on it"
- Stiff implant changes mechanical loads on femur "modular mismatch".

X-Ray indicating bone loss



Load distribution without implant

Load distribution with implant

<u>Solution:</u> Make implant more flexible – less stiff, lower Young's modulus

Component advantages and disadvantages

Metal alloys for femoral stem

- Advantages

- Disadvantages

Component advantages and disadvantages

Bone cement

- Advantages

- Disadvantages

Advantageous Properties of UHMWPE Cup

- Low friction and good sliding properties.
- Good impact strength.
- Very bioinert.
- Good cyclical fatigue resistance.

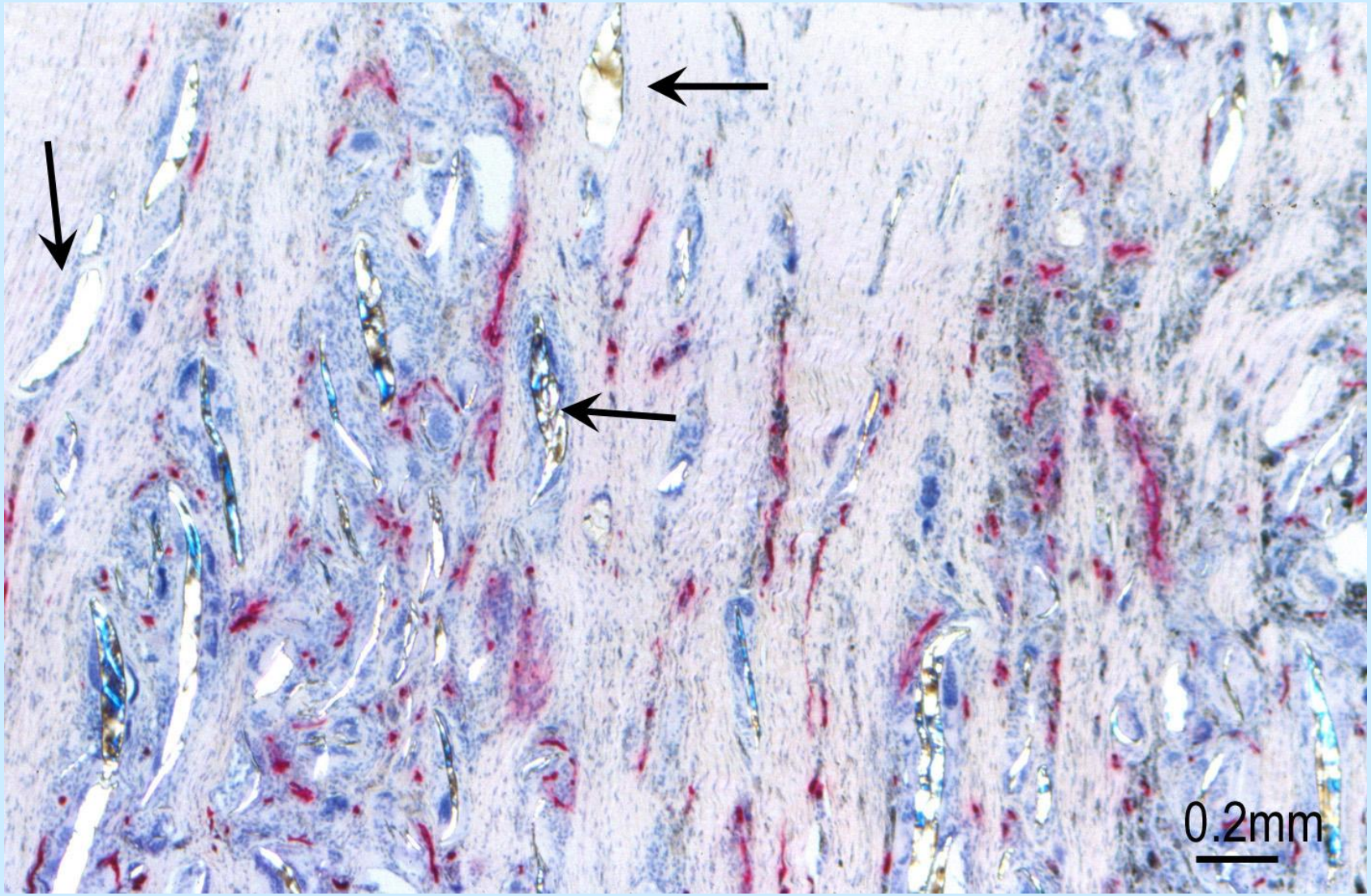
Disadvantages of UHMWPE Cup

- Poor wear resistance. (Good for a polymer but insufficient for joint replacement)
- Sterilisation by gamma irradiation lowers properties
- Difficult to process into shape

Wear particles

- Several hundred thousands of particles are generated with each step, and a large proportion of these particles are smaller than 1μm.
- Cells from the immune system of the host are able to identify the particles as foreign and initiate a complex inflammatory response.
- The combination of wear and deterioration of the bone-implant interface can be rapid focal bone loss (osteolysis), bone resorption, loosening, and/or fracture of the bone. Wear particles cause the largest proportion of failed orthopaedic implants.

PE particles in the bone-implant interface



UHMWPE: Two Major Problems

- **Wear** rate of 15μm /year. This is negligible in terms of wearing out the joint. But the fine particulate wear debris produced cause an acute biological reaction.
- Wear debris generally migrates from the acetabulum down the cement bone interface and causes osteolytic lesions in the bone.
- Wear particles have also been associated with some cancers in tissues far removed from the site of implantation.

Component advantages and disadvantages

Ceramic/ metal ball and UHMW PE cup

- Advantages

- Disadvantages

Latest developments

- “Minimally invasive” surgery
- Metal on metal
- Ceramic on ceramic

The Birmingham Hip

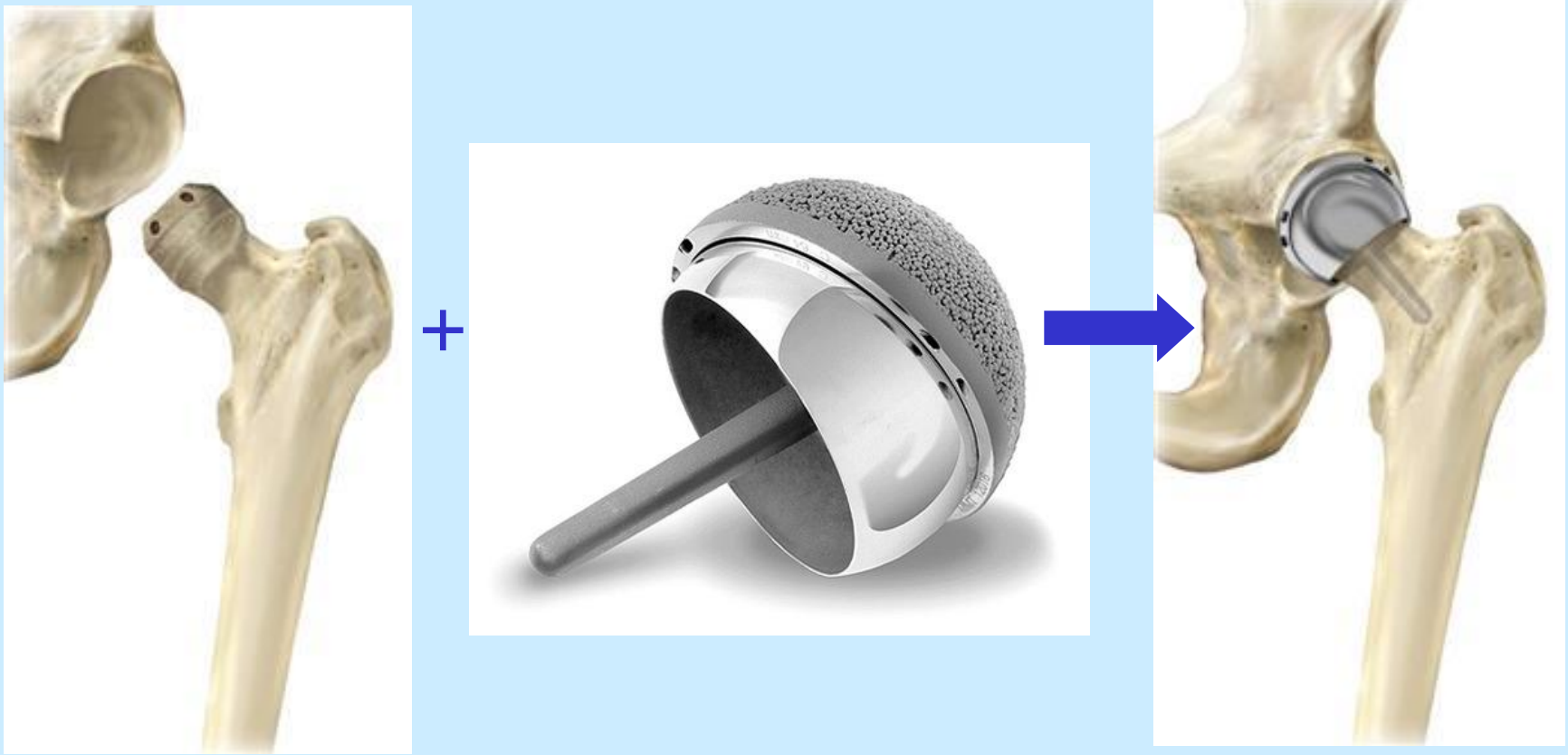
Introduced in 1997, now in >60,000 patients in 26 countries.

Aim: to restore bone in younger patients so a THR can be used later

The Birmingham Hip

two-part system:

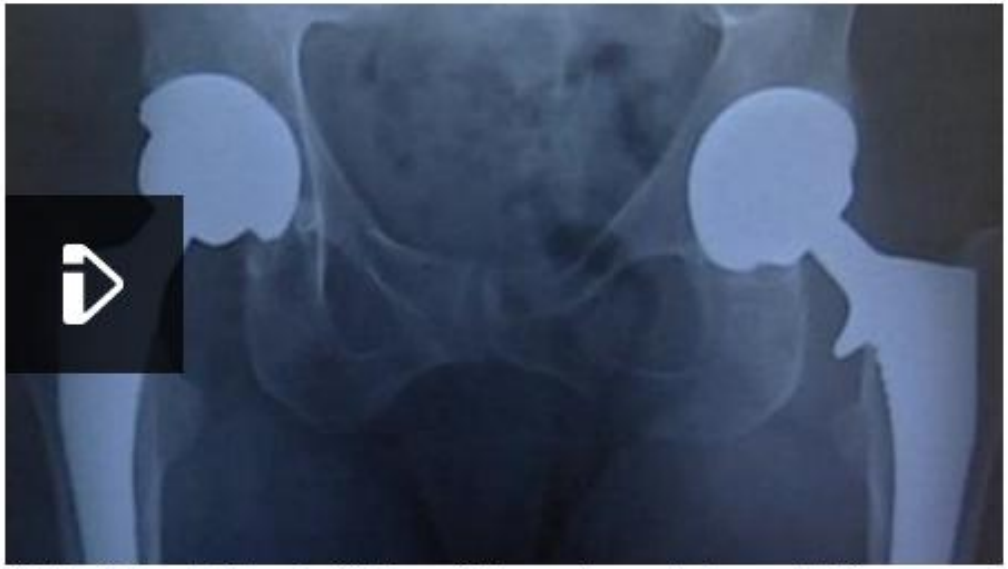
1. **cobalt chrome alloy cap is placed over the resurfaced femoral ball.**
2. **A cobalt chrome alloy cup fits into the acetabulum.**



Metal-on-metal RESURFACING

28 February 2012 Last updated at 16:49

MHRA: Metal hip implant patients need life-long checks



Watch Deborah Cohen's full Newsnight report on metal-on-metal hip replacements

The government's health regulator has advised that patients who have undergone large head metal-on-metal hip replacements should be monitored annually for life

Related Stories

Component advantages and disadvantages

Metal ball and metal cup

- Advantages

- Disadvantages

Ceramic on Ceramic

- Alumina

slow crack growth that leads to failure with time in service

- Zirconia (Yttria stabilised form)

600 000 femoral heads implanted worldwide

Yttria stabilises the tetragonal form on cooling

Ages – slow tetragonal to monoclinic phase transformation at the surface in humid environment, followed by embrittlement

Ceramic on Ceramic

- Zirconia toughened alumina

Zirconia phase transformation toughening

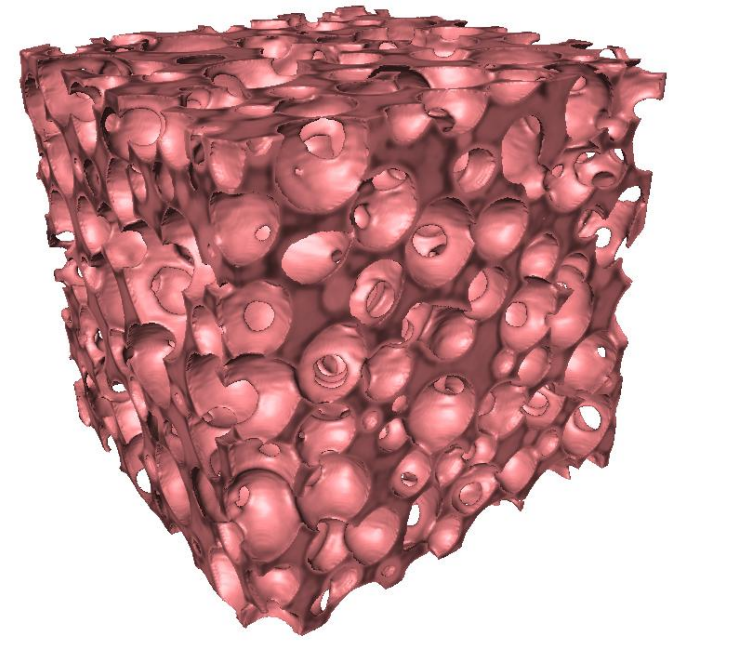
Prevents crack propagation if well dispersed

SQUEAKING?

- Biolox delta® (Ceramtec.com) = 25% zirconia in alumina. Toughness of 8.5 $MPam^{1/2}$ and strength of 1150MPa
  - Nanoparticles of zirconia in an alumina matrix

- A.H. De Aza, J. Chevalier, G. Fantozzi, M. Schehl, R. Torrecillas, Biomaterials 23 (2002) 937–945

The future is now: Scaffolds for Bone Regeneration



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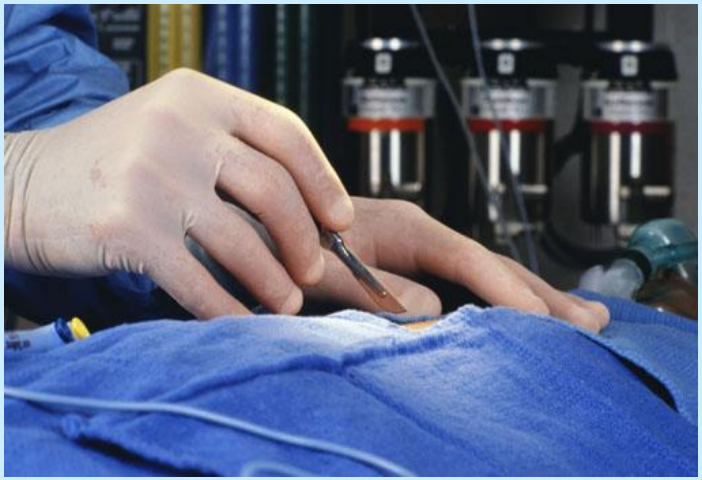

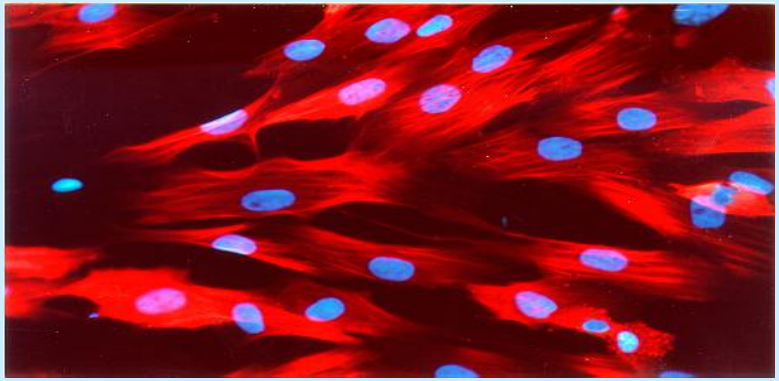

Summary

- Total hip replacements have been revolutionary but they have limited survival
- They can improved but to a limited degree
- Improvements but be checked through carefully through the technology transfer process
- The bioinert materials cannot adapt to their surroundings (e.g. biomechanical loads) like the host tissue can
- Move towards regeneration rather than replacement

Reading

"Biomaterials, Artificial Organs and Tissue Engineering", Hench LL, Jones JR, Cambridge; Woodhead Publishing 2005

"New Materials and Technologies in Healthcare, Hench LL, Jones JR, MB Fenn, Imperial College Press, 2011