i- PolyMat 2010

i-Polymers for *i*-Arthroplasty

New Polymer Technologies for HIP Arthroplasty

Leo Smit
Business Director Implant Solutions

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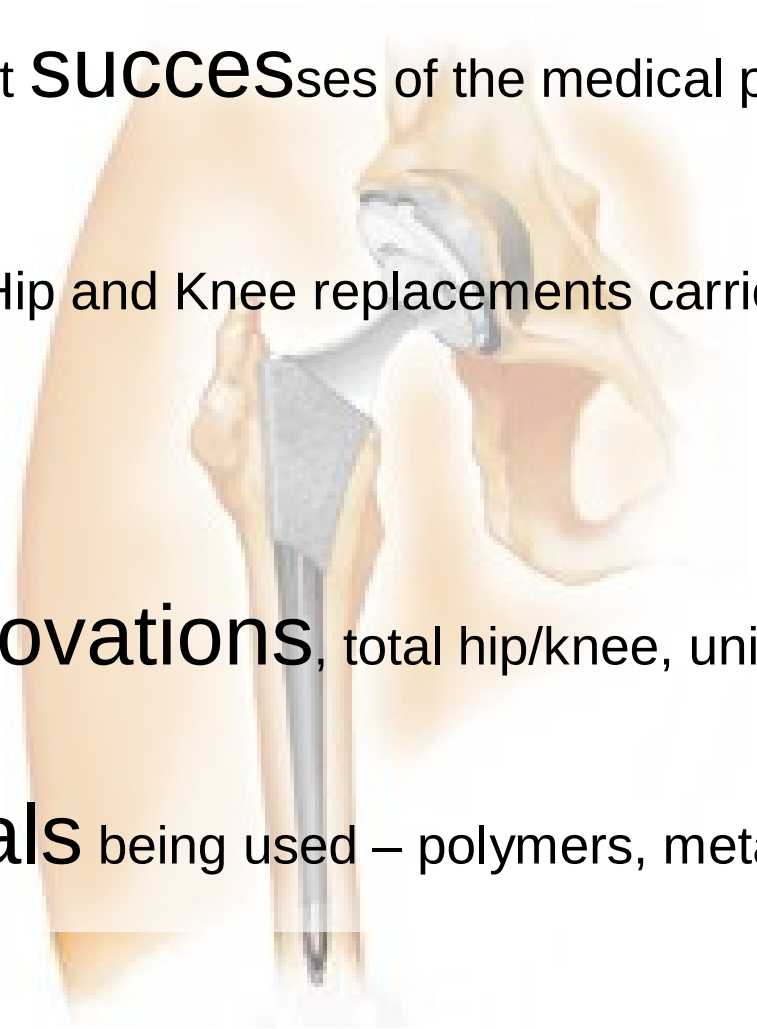
Total Hip Arthroplasty

One of the largest **succes**ses of the medical profession

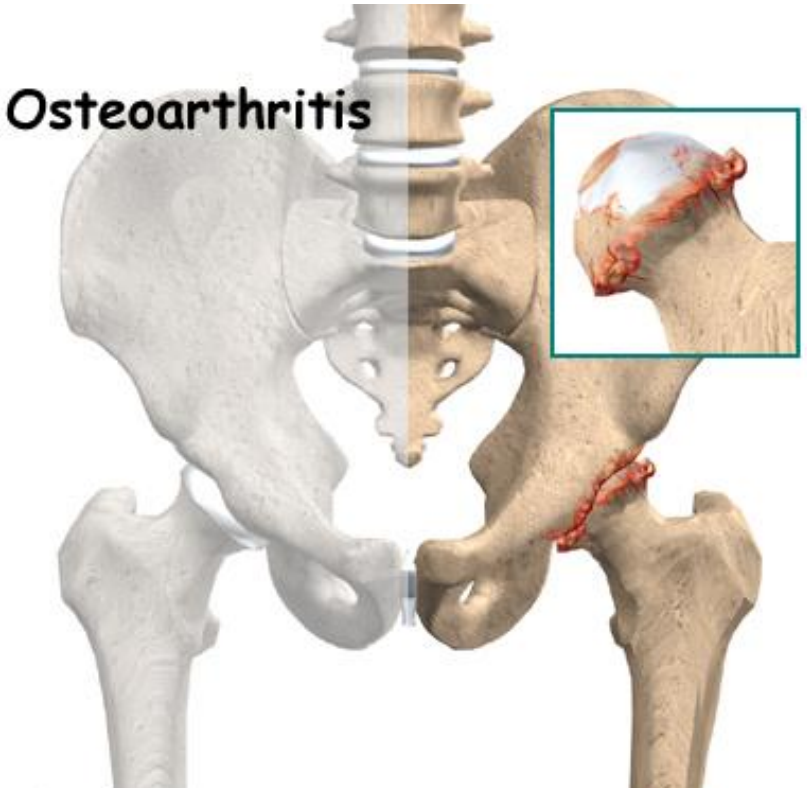
>2 Million Hip and Knee replacements carried out annually

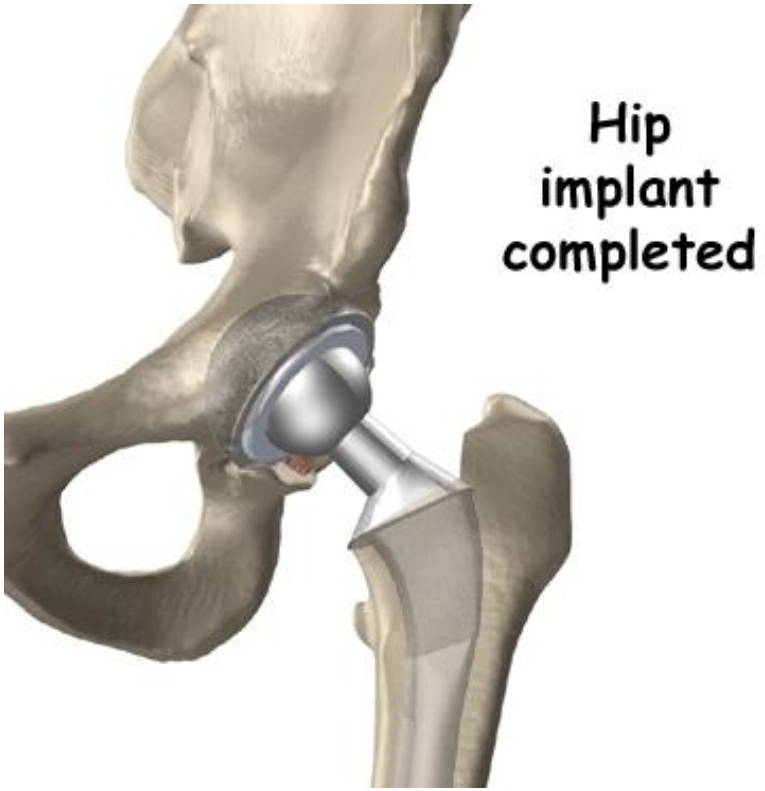
Multitude of **innovations**, total hip/knee, uni-knee, hip resurfacing

Many **materials** being used – polymers, metals, ceramics



Total Hip Replacement





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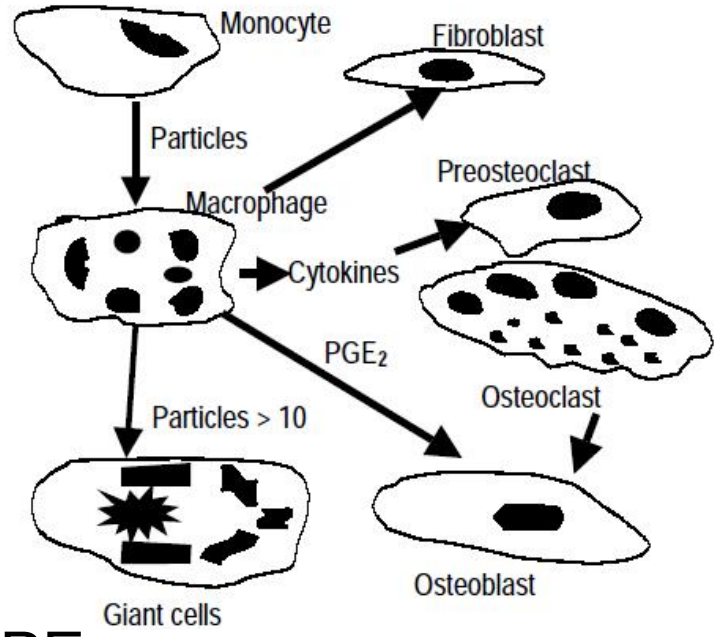
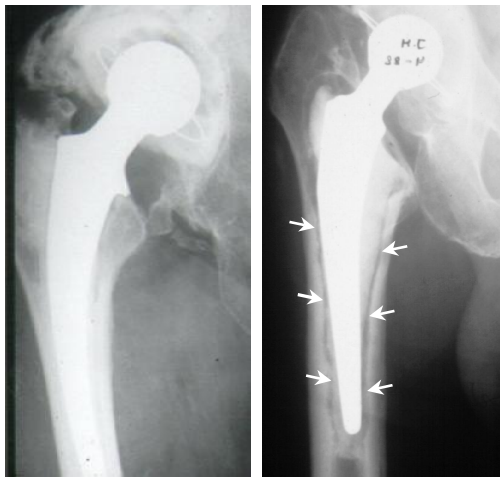
Wear: the central theme in HIP Arthroplasty

Picture from Gomez-Barena





Teflon too soft → UHMwPE

"Hit by friendly fire" : Macrophage attacks on PE wear particles cause human biological/physiological responses leading to osteolysis.

Current artificial hip lifetimes are app 10 – 15 years

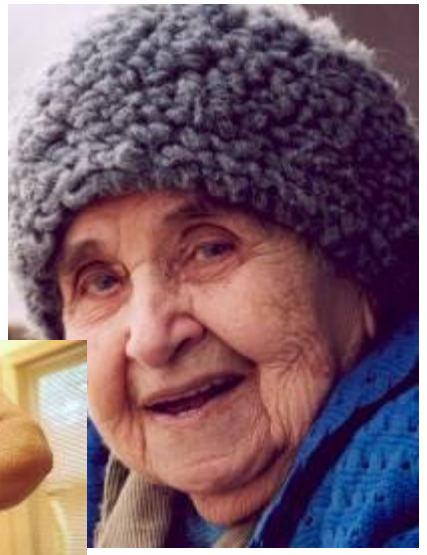
→current demographics ask for more!

Demographics make things worse

People are reaching

higher ages,

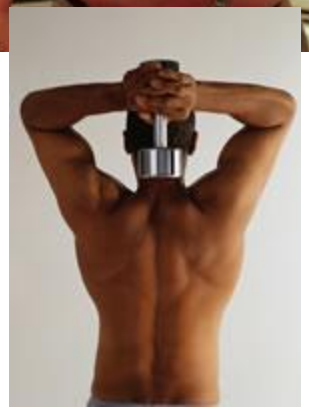
which is good, yet



people are more obese and/or

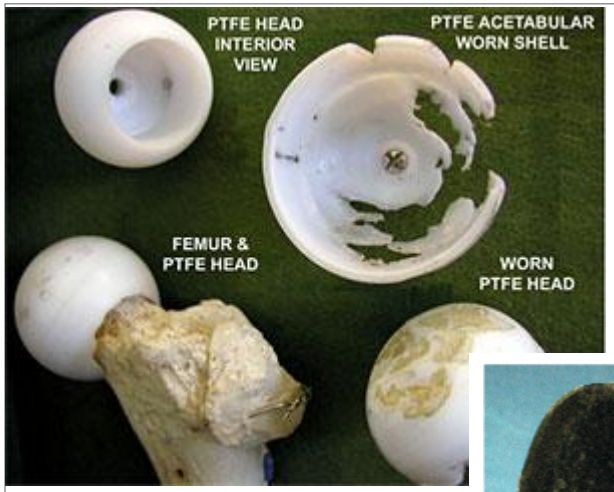
our lifestyle is aimed at staying

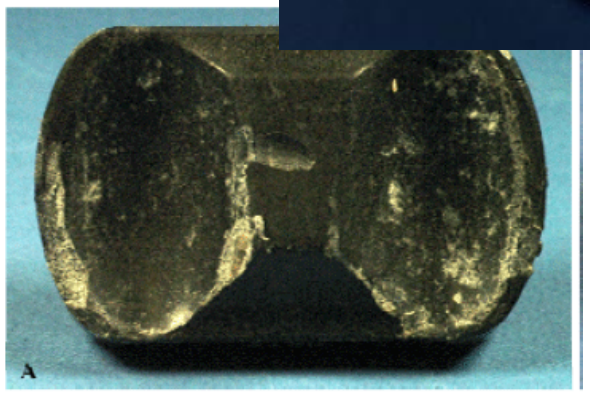
more active



so the pressure on our joints increases

Alternative material approaches…….





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Materials options compared

Pros
- Longest clinical history
- Low wear when XL'd
- Excellent biocompatibility
- Highest clinical usage

Cons
- Oxidative susceptibility
- Processing steps

Pros
- Low wear
- Large head sizes

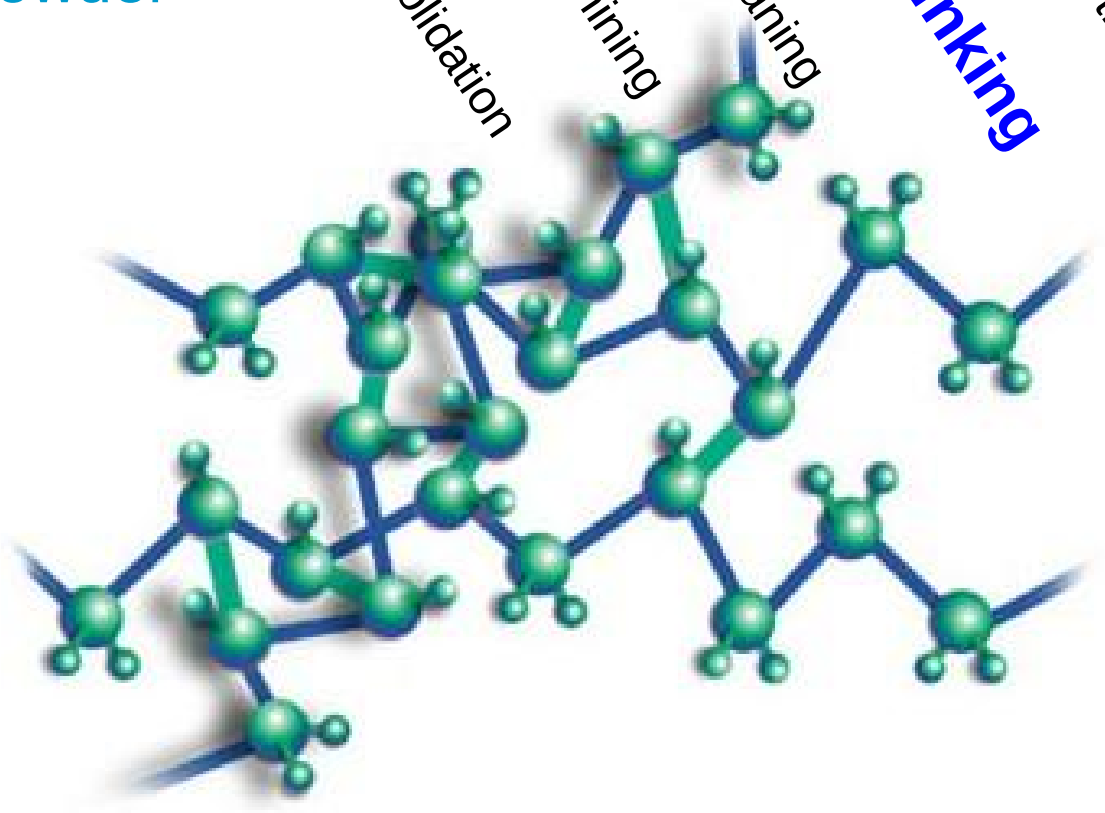
Cons
- Metal ion release
- Implant noise
- High cost of fabrication

Pros
- Low wear
- Excellent biocompatibility

Cons
- Fracture is clinical disaster
- High material cost
- Implant noise

Crosslinking – THE breakthrough in UHMwPE

Powder → Consolidation → Machining → Cleaning → **Crosslinking** → Thermal treatment → Packaging → Sterilization → Implant



Stryker:	**Crossfire® X3™**
Zimmer:	**Longevity™ Prolong™**
DePuy:	**MARATHON**
Biomet:	**ArCom® XLT**
S&N:	**XLPE**

Picture: Zimmer

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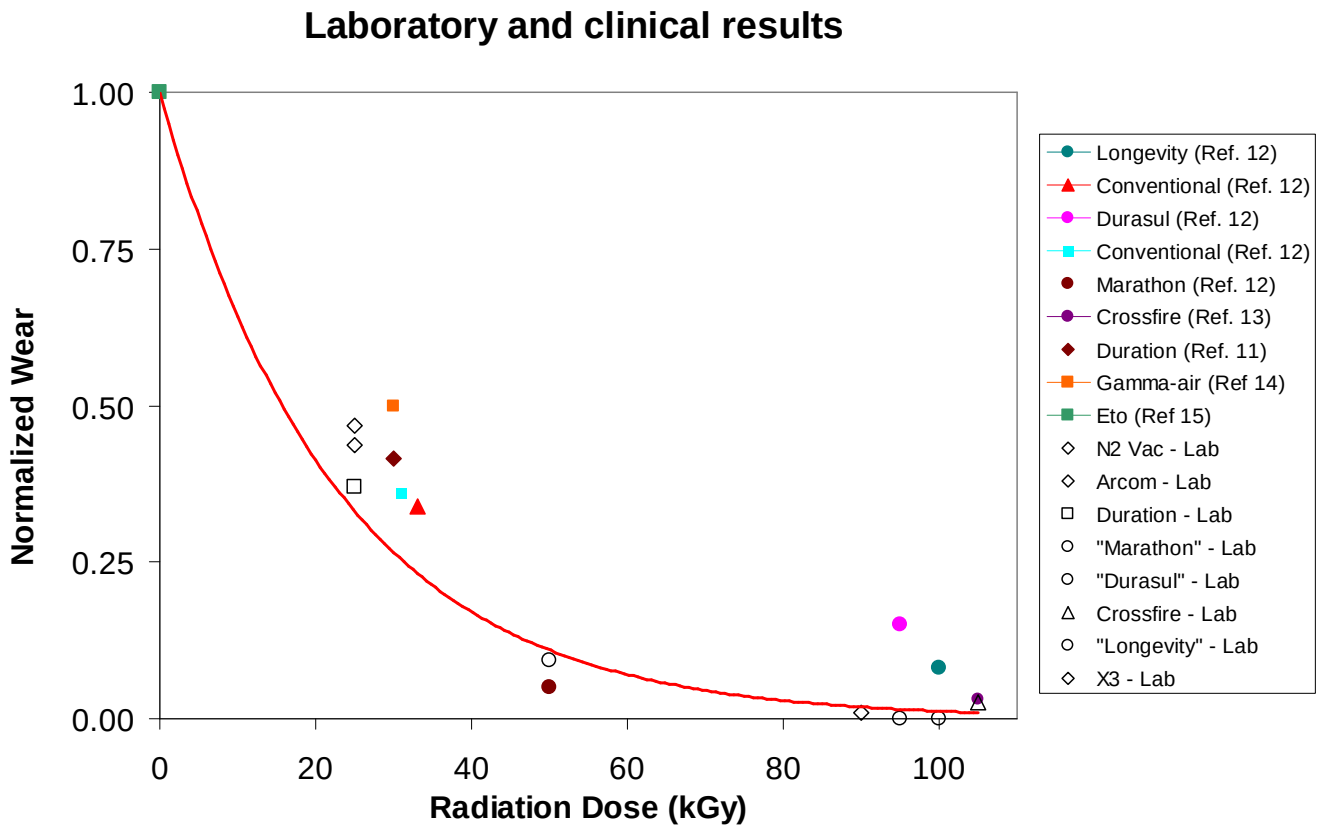
Significant reduction in wear rate

Both in-vitro as well as in-vivo wear
reduced as function of the Radiation Dose



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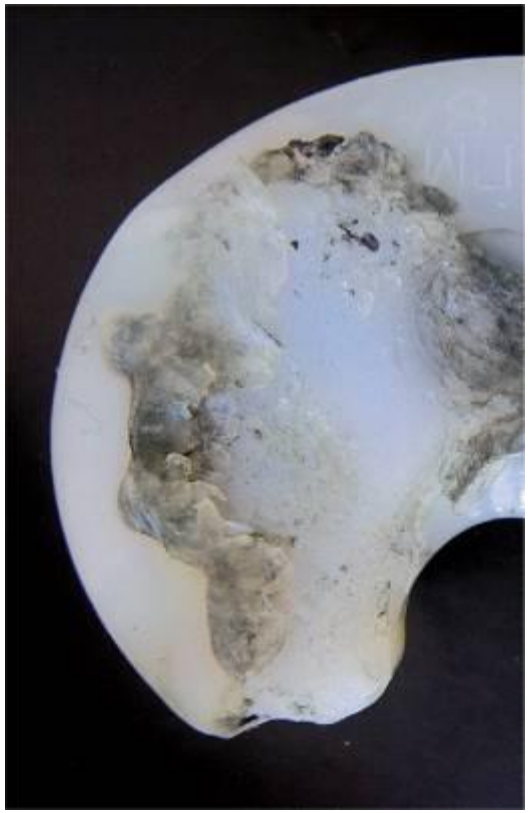
Edge-Loading Wear of Metal-on-Metal and Metal-on-X3® Highly Crosslinked Polyethylene: Survival of the Fittest
Aiguo Wang, Ph.D., VP, Reconstructive Technologies, Stryker Orthopaedics, Mahwah, New Jersey, USA.

Radicals form new challenge



Macro-radicals are created during irradiation

Macro-radicals react with oxygen - causing oxidative degradation of the bearing material

Current radical removal options

Thermal treatment

Remelting OR Annealing

Additional step - time consuming, costs

Loss of mechanical properties

Vitamin E stabilization

Diffusion into the final Implant OR Pre-blending with the polymer

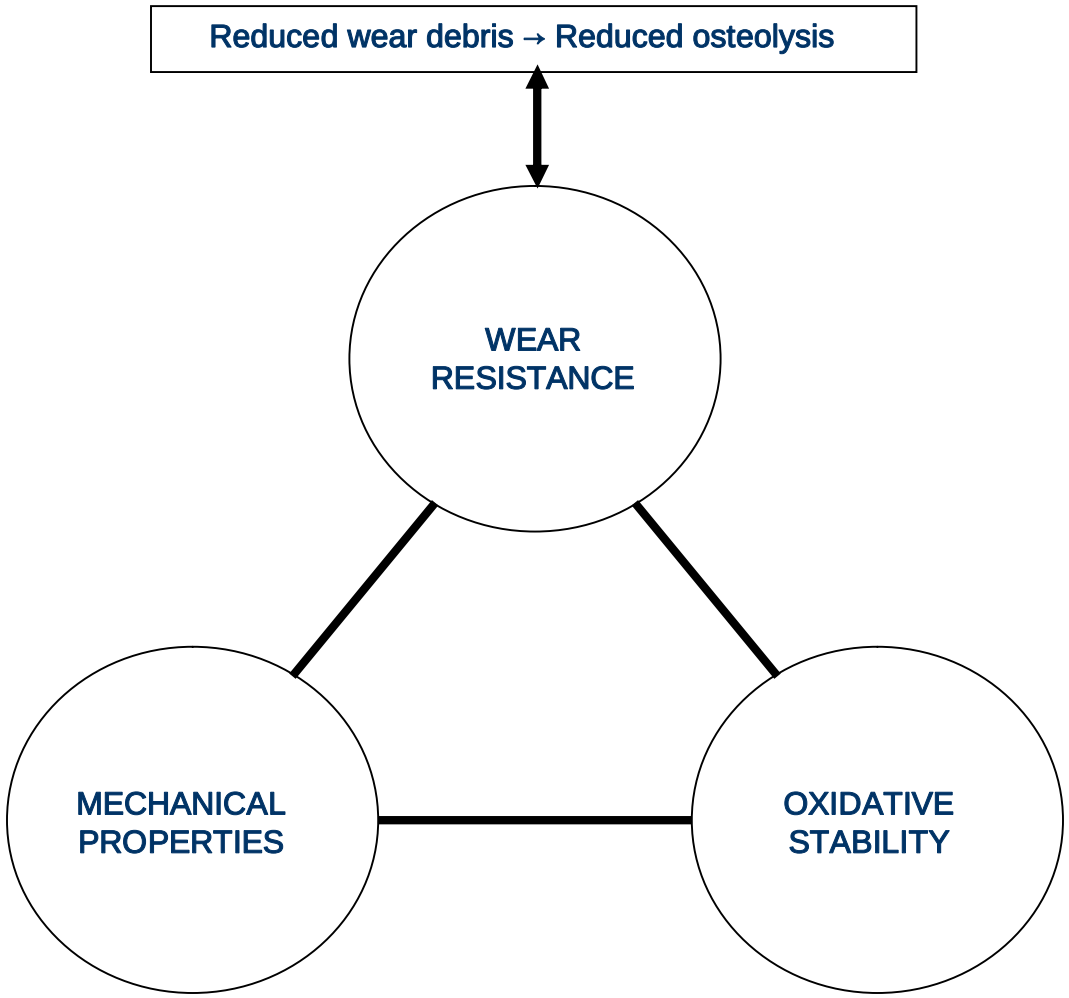
Pre blended Vitamin E **interferes** with crosslinking process *

Vitamin E is **consumed** in the crosslinking process

Material turns **yellow**

* (Oral, E et al, Biomaterials (2005), 26(33), 6657-6663)

UHMwPE Paradigm



Ideally:

- wear resistance ↑
- oxidation resistance ↑
- mechanical properties ↑

REAL WORLD so far not ideal – Wear optimization causes compromises

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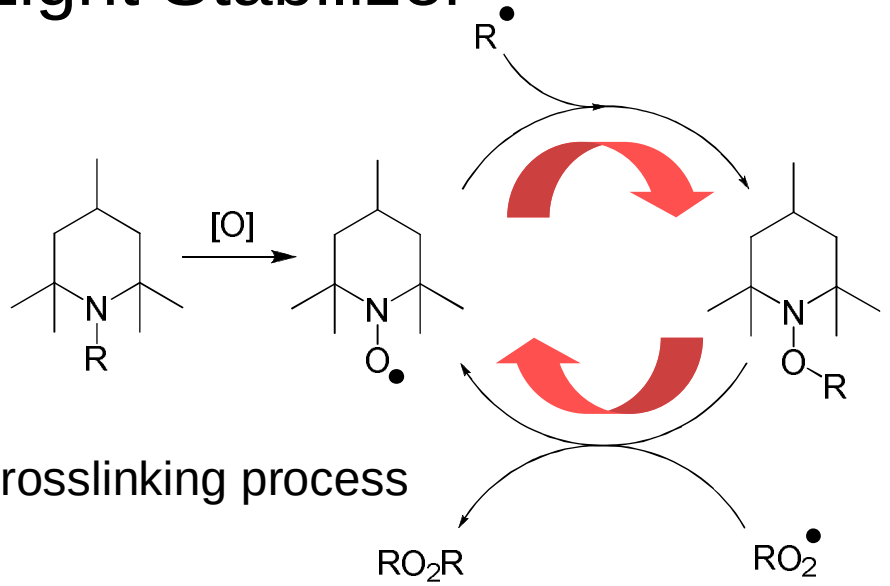
Gomez-Barrena, E et al. *Acta Orthopaedica* **2008**, *79 (6)*, 832.

Alternative stabilizer : HALS

HALS : Hindered Amine Light Stabilizer



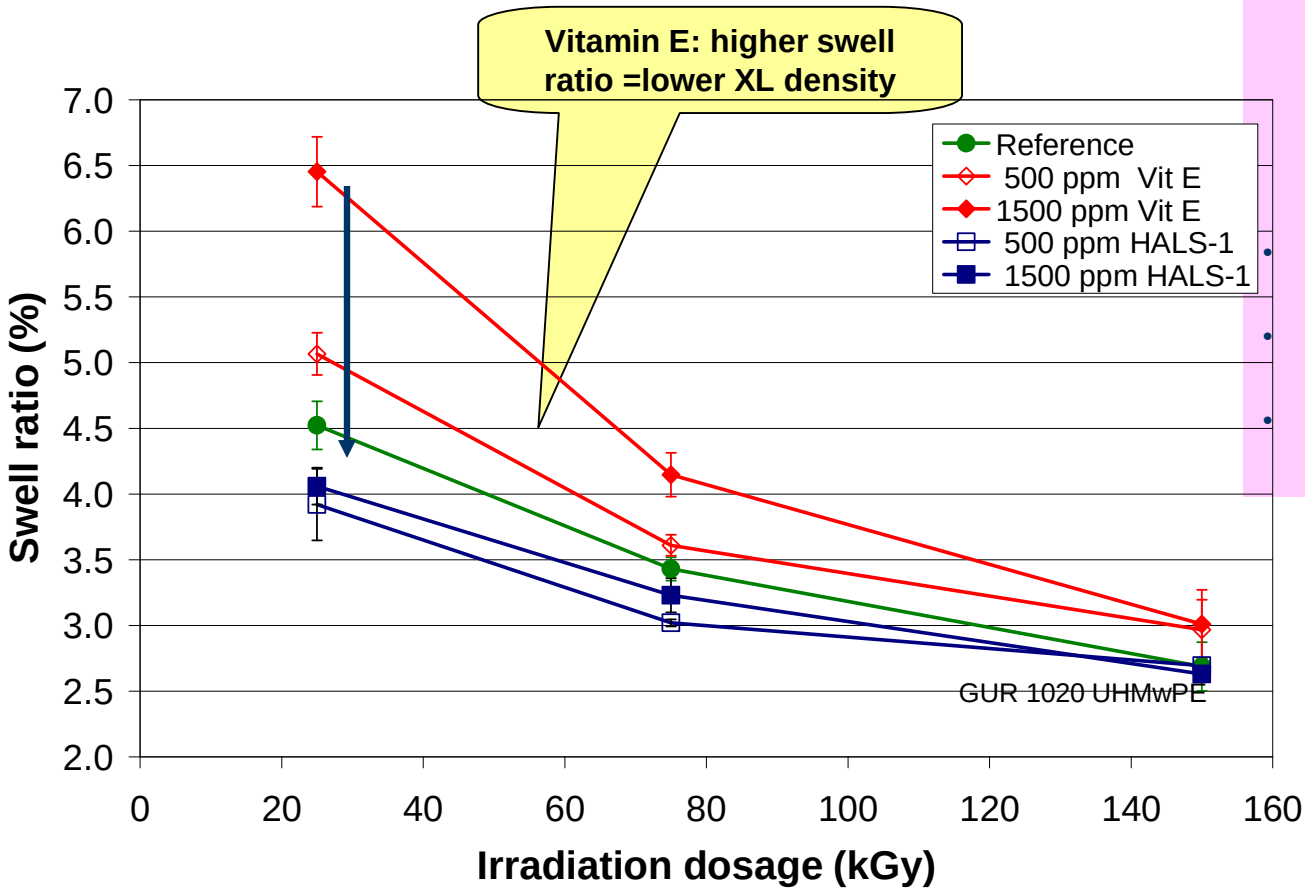
No radical scavenging during radiation

→ no interference with the crosslinking process

Regenerative - Less stabilizer needed

No yellowing (consistent color) because no degradation components are formed

HALS : Crosslinking improvement



Higher crosslink density for HALS than for Vitamin E stabilized UHMwPE

Tested 0.05 and 0.15 wt.% Vitamin E versus 0.05 and 0.15 wt.% HALS

No significant differences between 0.05 and 0.15 wt.% HALS

No influence type of HALS

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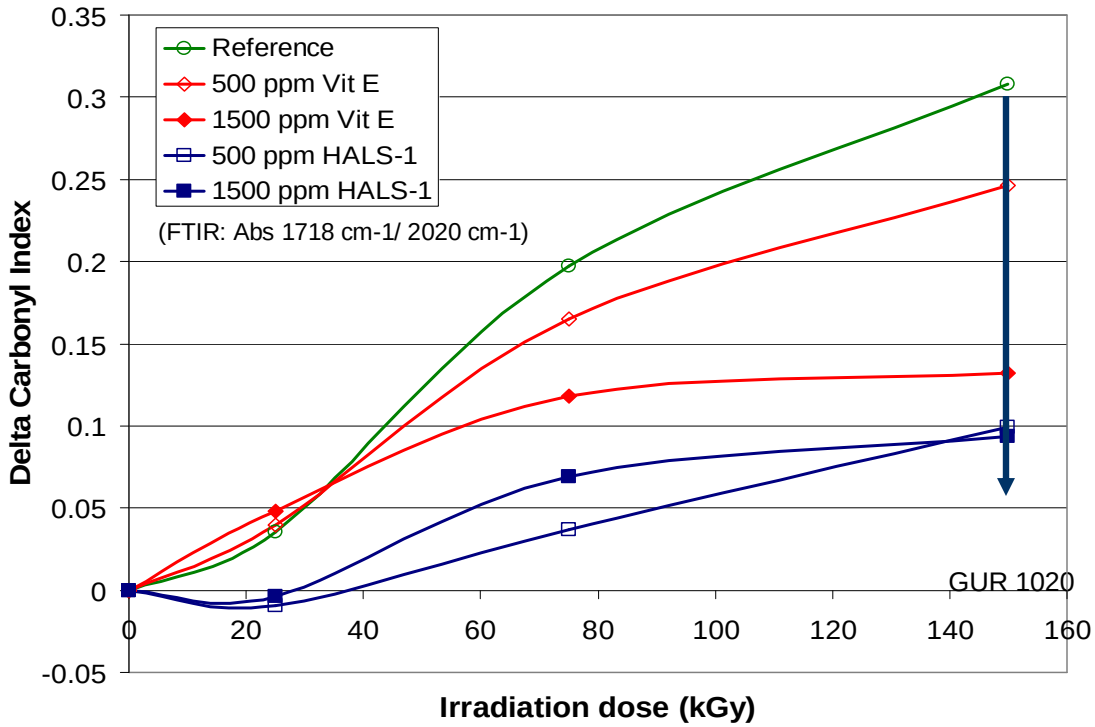
HALS-UH shows effective stabilization



Change in Carbonyl Index as a result of ageing during 6 weeks at room temperature shows better stabilization compared to vitamin E

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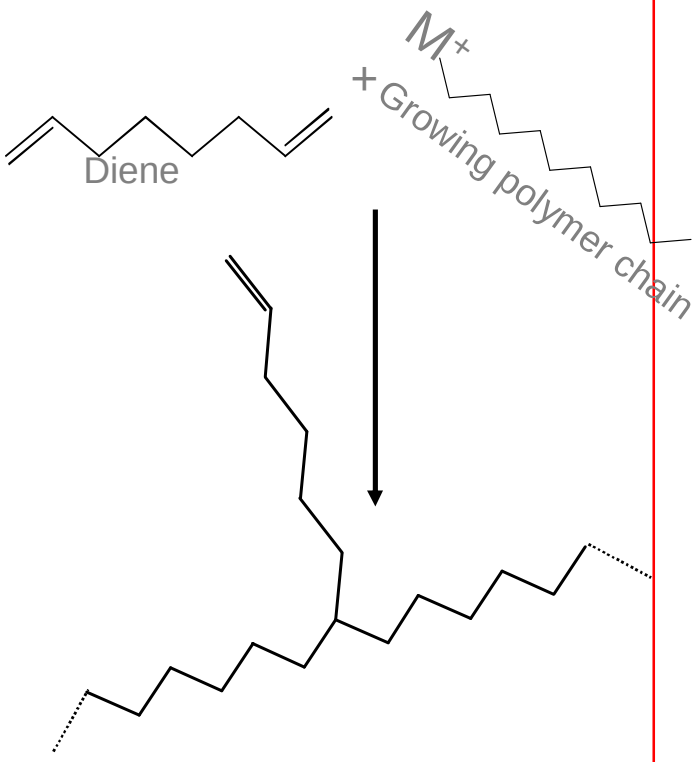
Easy-XL™ : better crosslinkable UHMwPE

Incorporate dienes in growing PE chain:



Hypothesis :

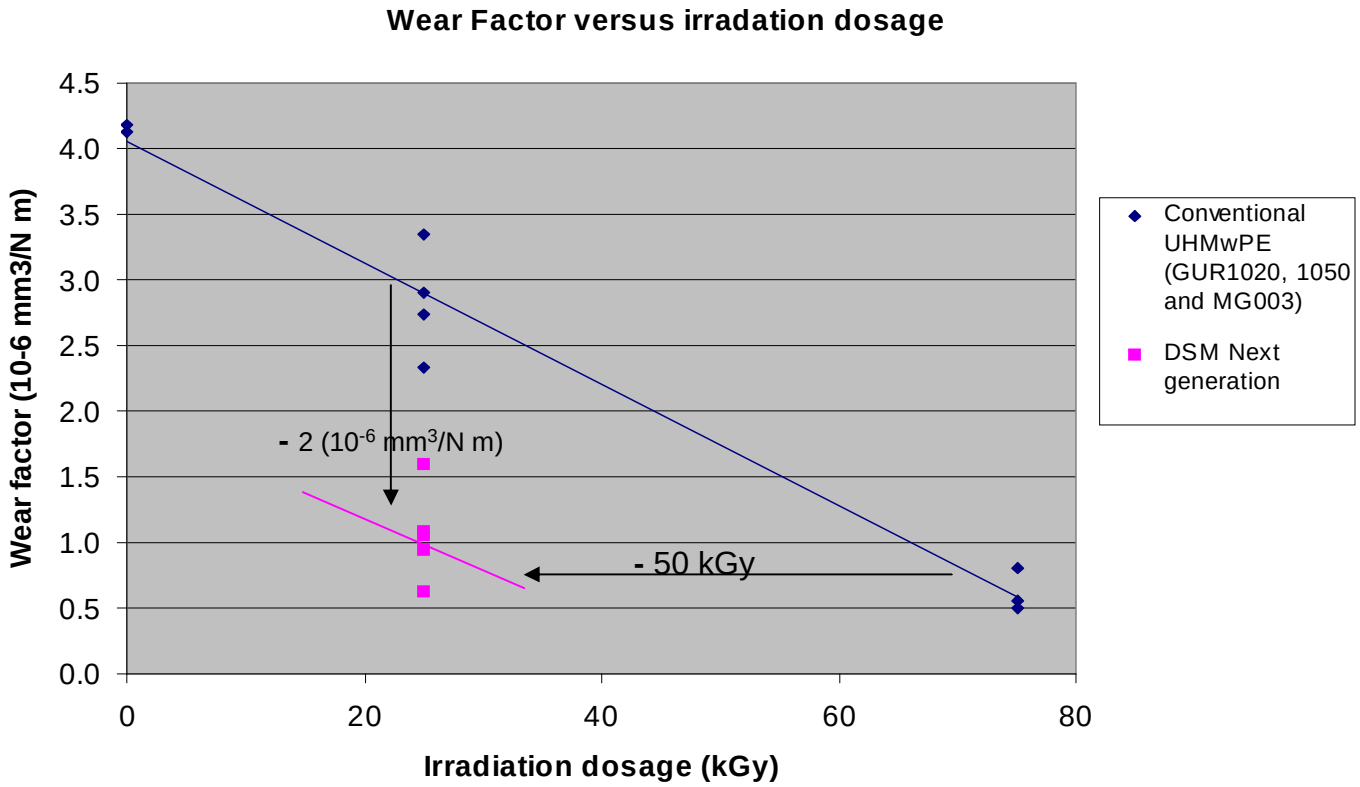
Incorporation of diene in UHMWPE will leave a pendant unsaturation which is believed to make crosslinking more efficient.

This enables the use of lower radiation doses, so less radicals stay behind which will potentially reduce oxidative degradation.

Further by adapting molecular architecture we can optimize mechanical properties

Easy-XL needs significantly less radiation for low wear

Results show that 25 kGy irradiation (i.e. sterilization dose) resulted in a wear resistance comparable to highly XL materials



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Pin on Disk wear measurements.
See Eva Wisse et.al. 4th International UHMWPE Meeting, Turin, 2009

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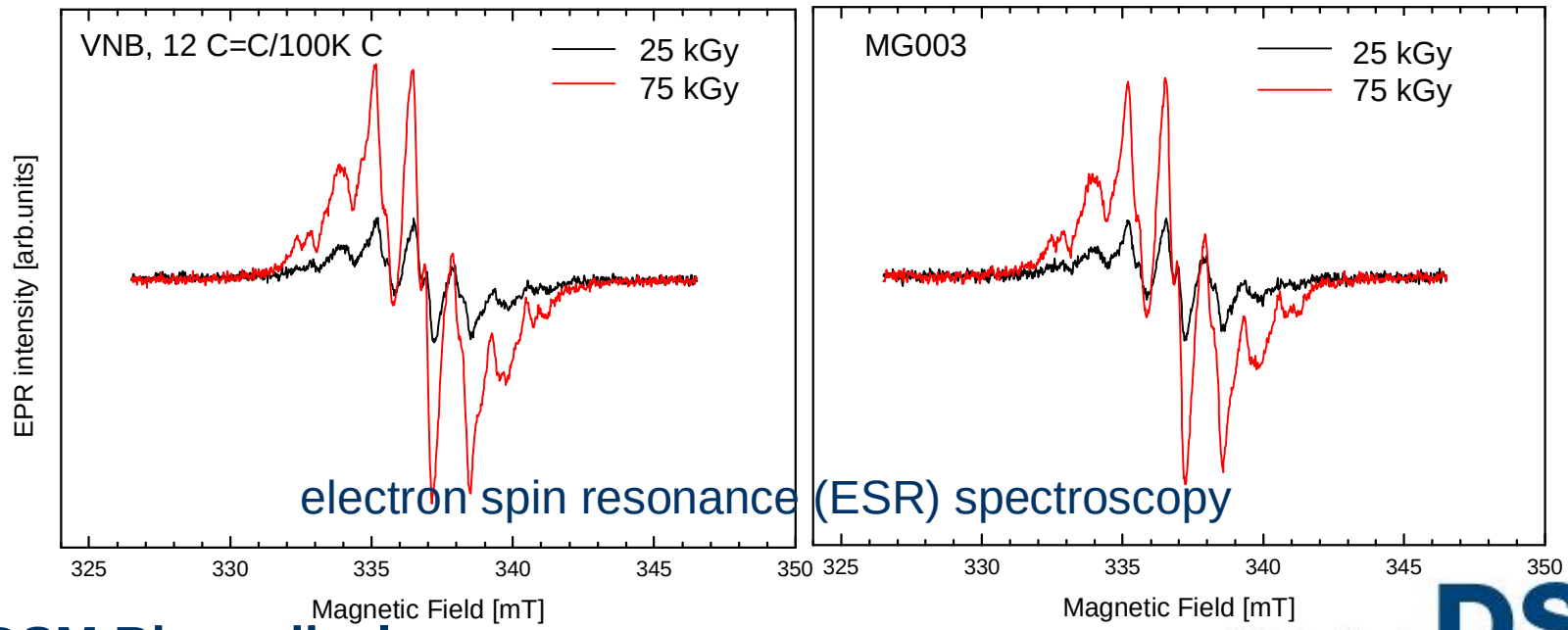
Less remaining free radicals with Easy-XL

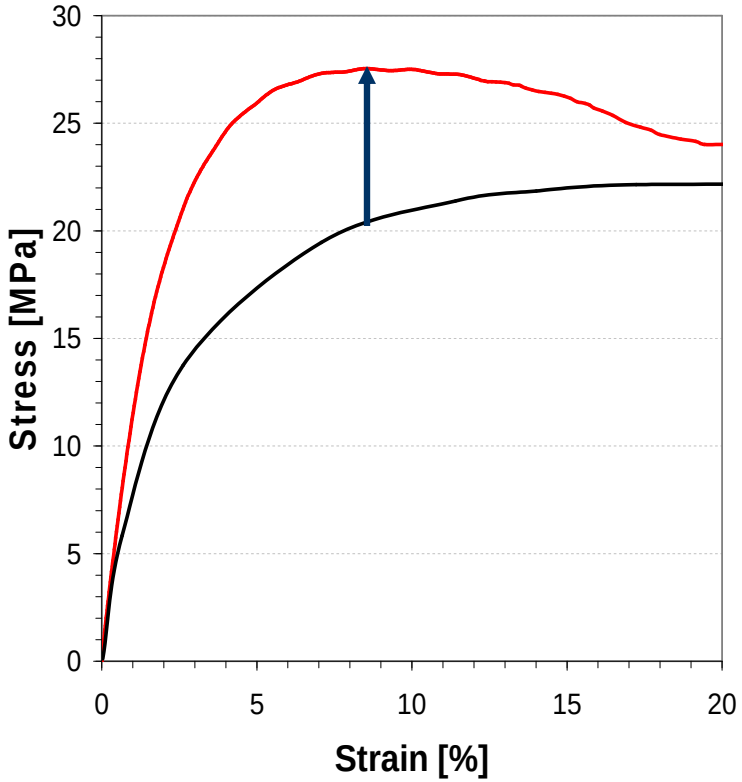
For both conventional UH and Easy-XL it was shown that 75 kGy radiation leaves behind 2-3 times higher radical content than 25 kGy

→ Easy-XL crosslinked material has much less residual radicals!



electron spin resonance (ESR) spectroscopy

Better Mechanical Properties



Optimizing the Molecular Architecture enables us to find a new balance in mechanical properties.

Easy-XL is a stronger material:

- a.o. 30% higher Yield Stress

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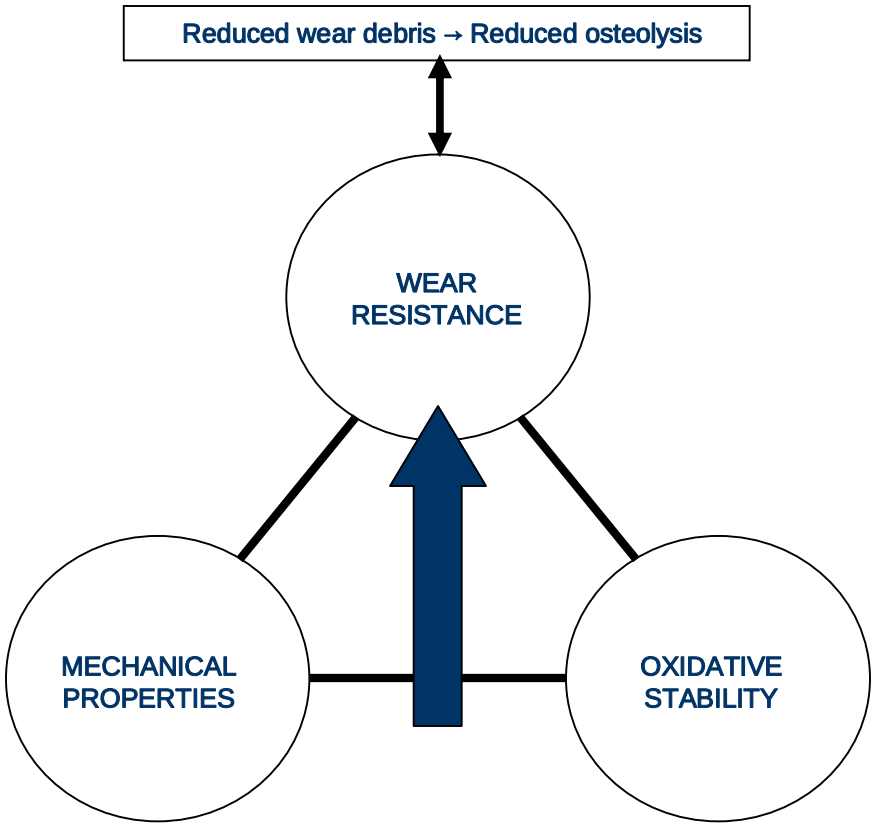
Conclusion – will we break the paradigm?



HALS-UH and Easy-XL,

separate or combined,
form a strong vehicle to

break the paradigm,

creating novel polyethylenes for arthroplasty,
having

better wear resistance,
better mechanical properties
and
better oxidative stability

all at the same time.

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But…….

- ALL innovations thus far have been aimed at increasing the hardness of the bearing material
- This is opposite of what is present in the human body: Cartilage is much lower in hardness than polyethylene

Arthroplasty – real cartilage

Biomechanics of Musculoskeletal Tissues

By
David Hawkins, Ph.D.
Exercise Biology Program,
Exercise Science Graduate Group
Biomedical Engineering Graduate Group
University of California - Davis

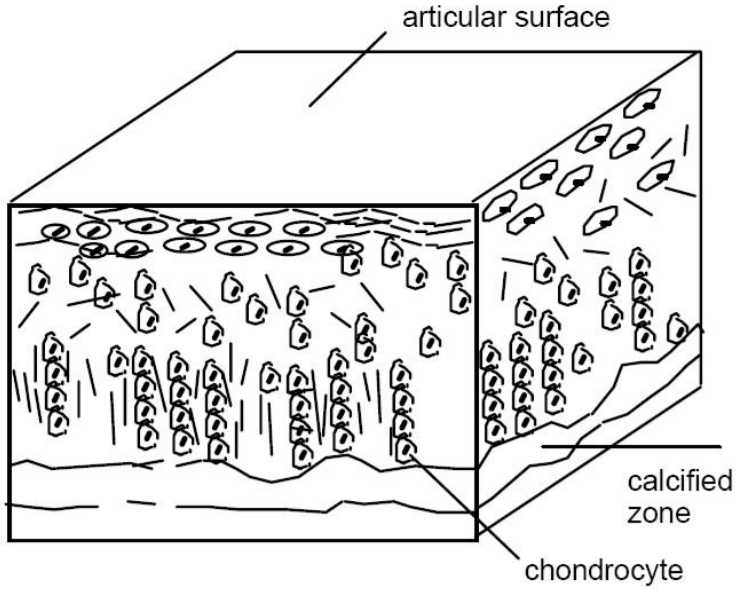

Figure 1 - Illustration of the organization of articular cartilage. Chondrocytes make up less than 10% of cartilage volume. Collagen fibers are arranged parallel to the articular surface in the outer zone and perpendicular to the surface in the deep zone.

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Arthroplasty – real cartilage

- **Spongy and Lubricated…..**

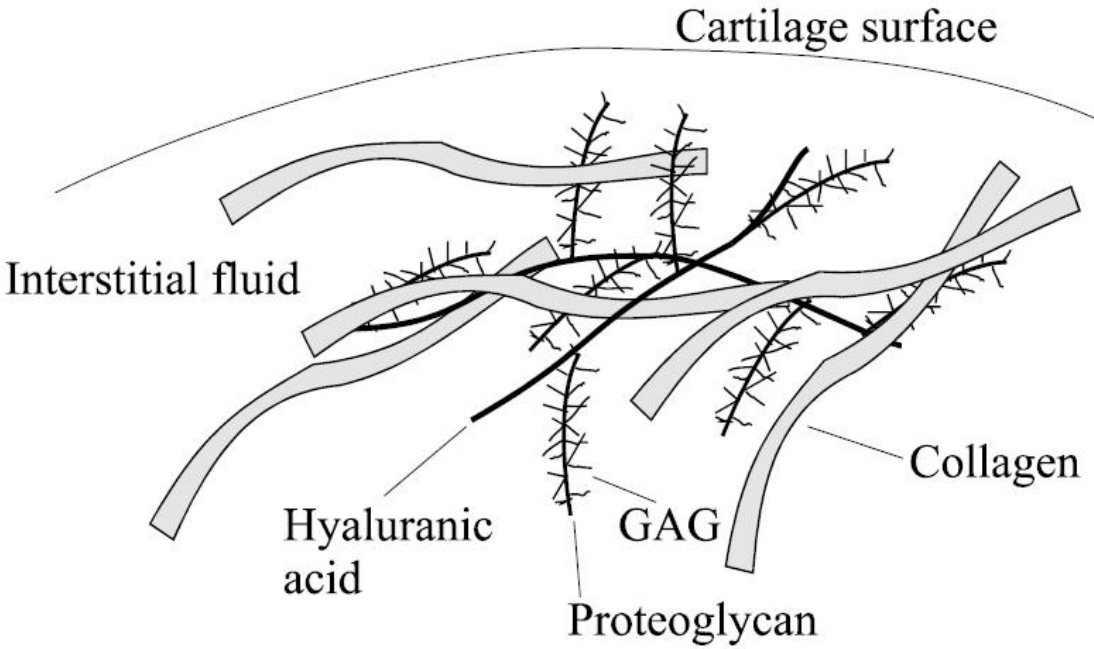

Figure 2: Illustration of the constituents of cartilage and their arrangement. Collagen molecules provide tensile strength. Glycosaminoglycans (GAGs) are negatively charged and repel each other. Proteoglycans are hydrophilic and attract water. If a compressive load is applied to the articular surface, then fluid flows out of the cartilage due to the membrane permeability.

Hypothesis

Increased Compliance (compressibility) and Lubrication can lead to breakthrough technology

→PolyCarbonate Urethanes

Bionate®

Compliance: Active Implants

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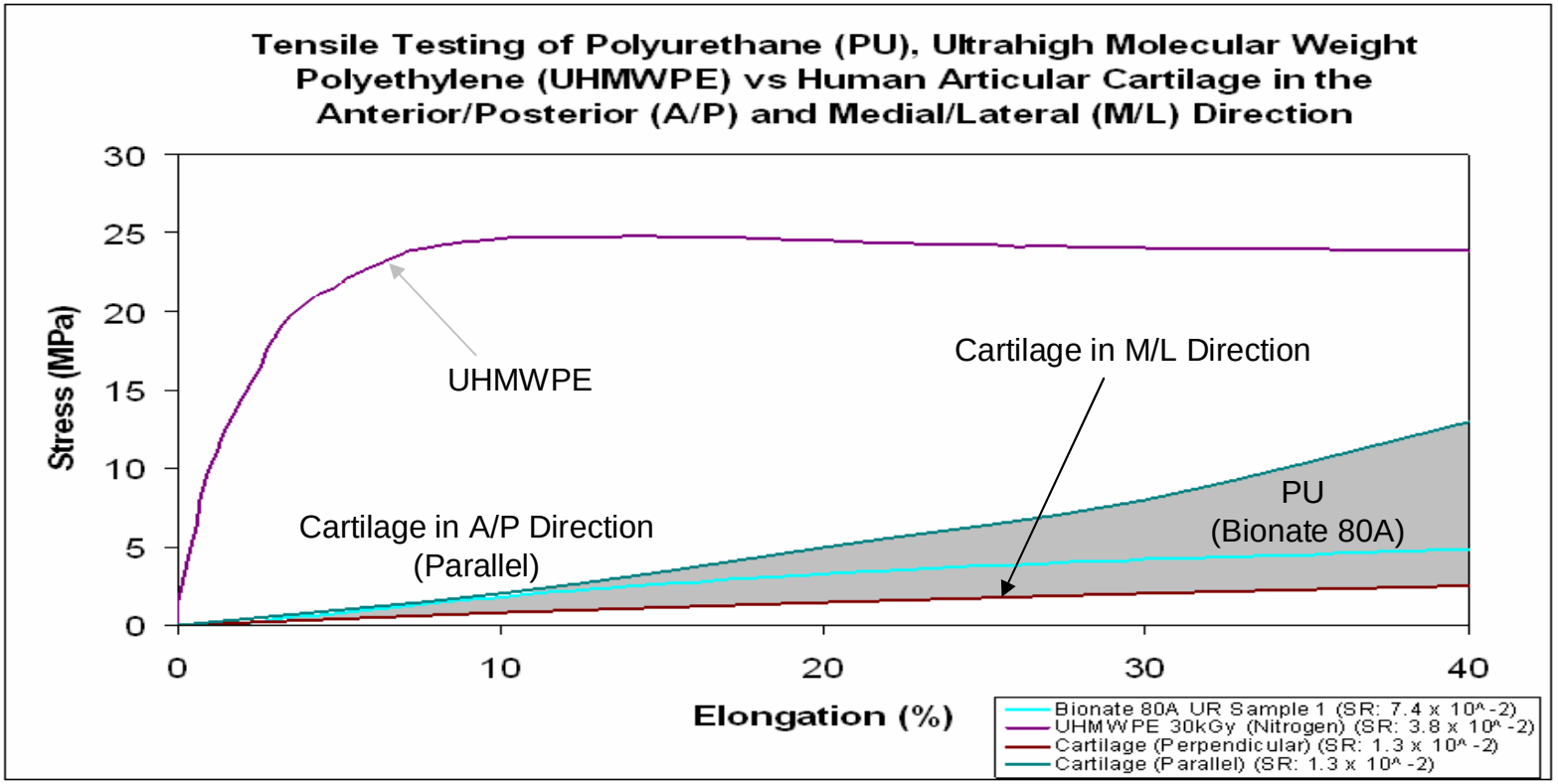
Imitating Joints vs Replacing Joints



Graph compiled b y Active Implants; IMUKA 2010 PolyCarbonate Urethane, A compliant soft bearing material in THA, Emanuele Nocco
Articular cartilage data from middle depth values of human distal femur in Adult Articular Cartilage by MHR Freeman,1974;
UHMWPE Data from Steve Kurtz, PhD, Exponent, Inc.
PU Data from DSM PTG SR = Strain Rate

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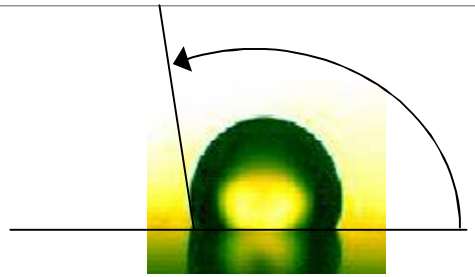
Contact Angle



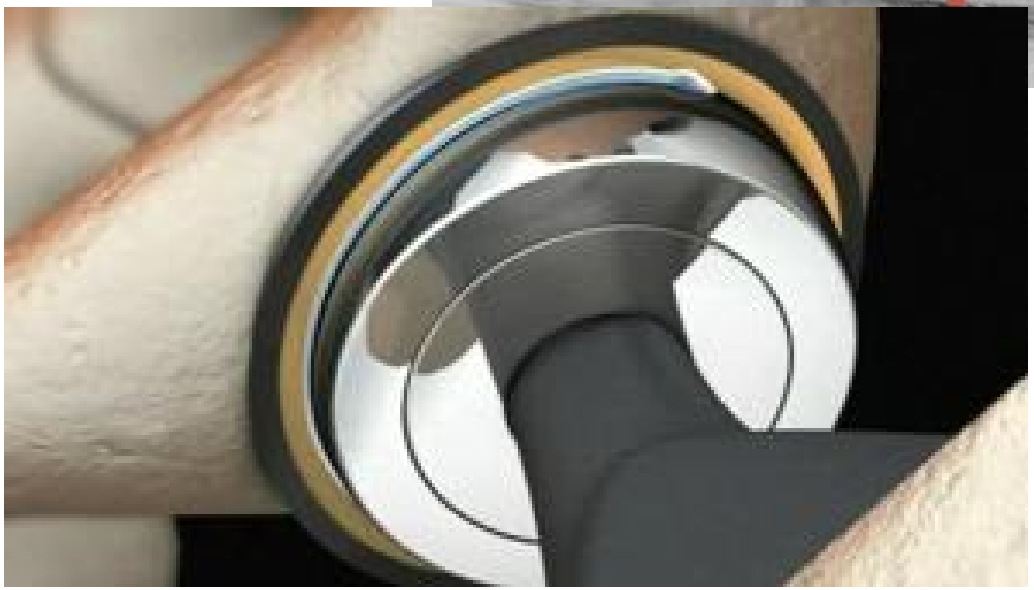
	Average	Std. Dev.
Bionate® 80A PCU	76.5	0.5
UHMWPE	104	2.6

PCU Material More Hydrophilic

All done with distilled water.

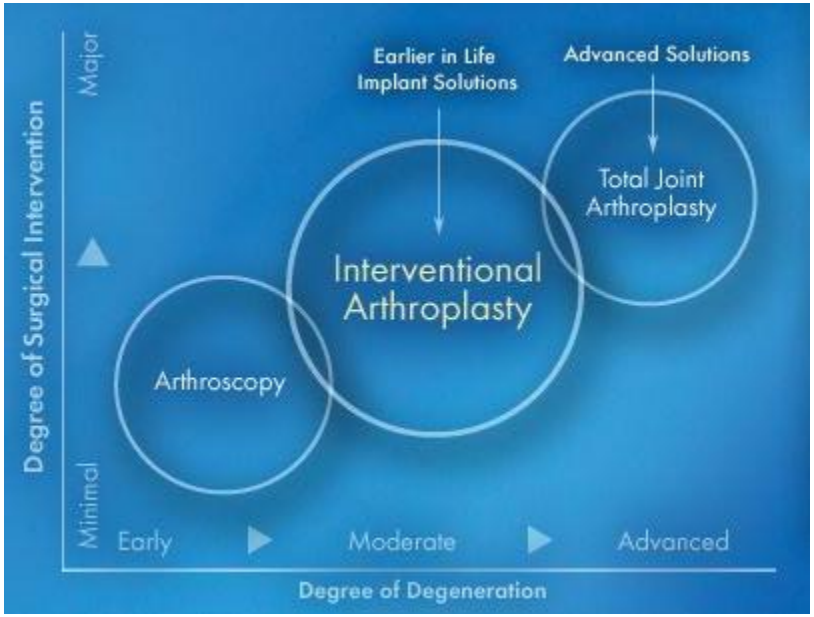
The effect: Hydroplaning

- The lower contact angle helps to establish a full fluid film between the bearing surfaces, enabling them to "hydroplane" with very low level of friction.



Enabling Technology for Early Intervention

- The “body-like” characteristics of PCU’s also make them very likely candidates for earlier interventions: e.g. direct use against Cartilage



Interventions at all stages of the disease continuum

Pharma Products
"controlled / sustained release formulations"

(Personalized)
Nutritional Products

regenerative medicine

drug-device
combination
products

Future Entry Point(s)

Prosthetic
implants /
medical devices

Wellness

At Risk

Critical
Episode

Recurrence

Advanced
Disease

Population Size

Disease continuum

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DSM approaches to joint health

i-flex – a joint health food supplement from DSM Nutritional Products, containing vitamins, carotenoids and galactolipids mixture that has been demonstrated in vitro to have protective and even regenerative effects on human cartilage.

DSM is the world's leading producer of **Vitamin E**

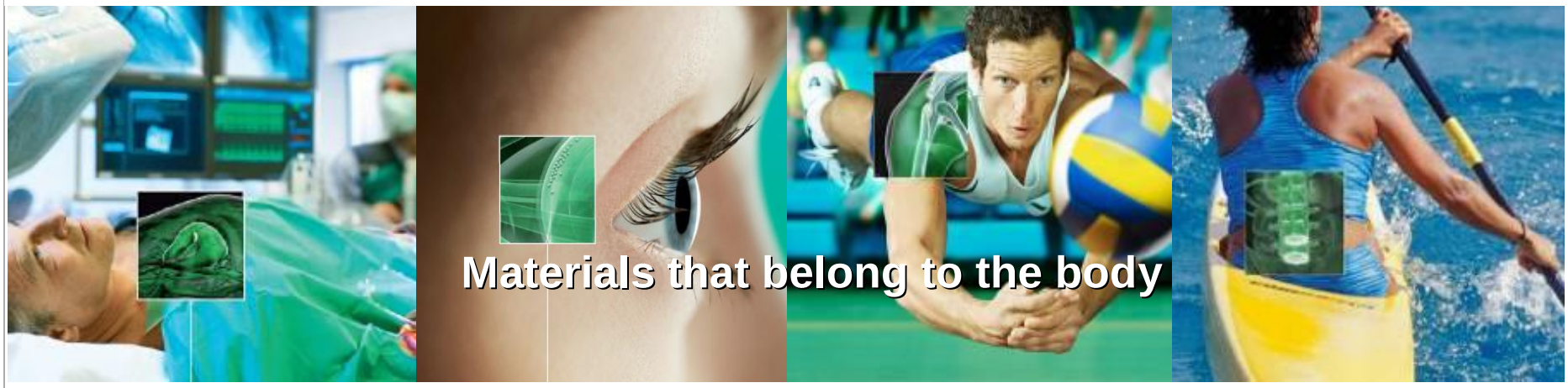
Easy-XL – a novel family of UHMwPE grades with a new molecular architecture to increase crosslinking efficiency

HALS-UH – an Alternative Stabilizer that provides for stabilization of UHMwPE powder

Bionate® Poly Carbonate Urethane polymers for soft bearing applications and Early Interventional Arthroplasty.

THANK YOU

Leo Smit
Business Director Implant Solutions



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