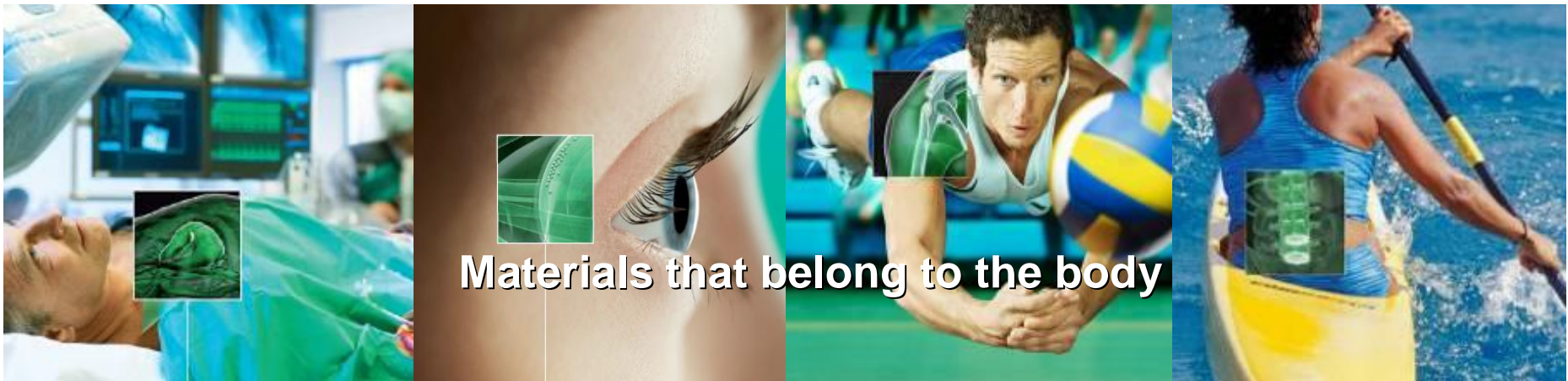


Optimizing the Golden Standard

New PolyEthylene Technologies for HIP Arthroplasty

Leo Smit
Business Director Implant Solutions



DSM Biomedical

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Total Hip Arthroplasty



One of the largest **SUCCESS**es 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

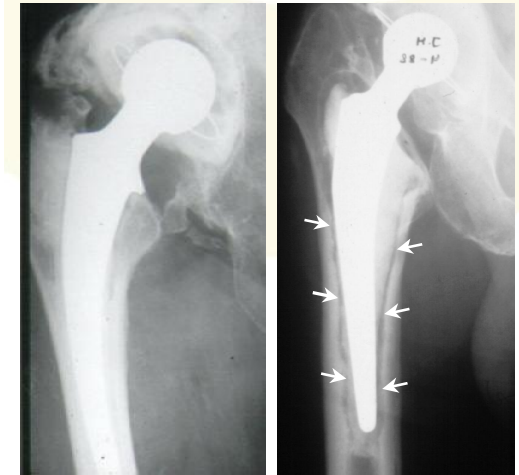
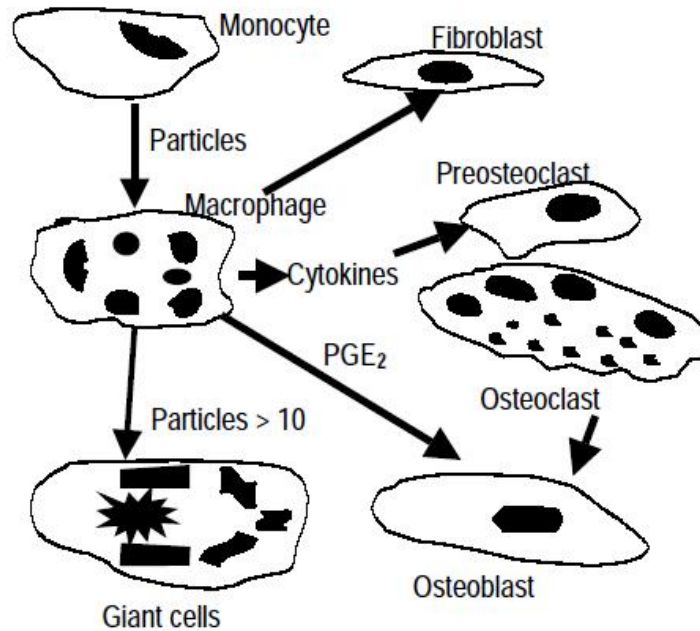
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Wear: the central theme in HIP Arthroplasty

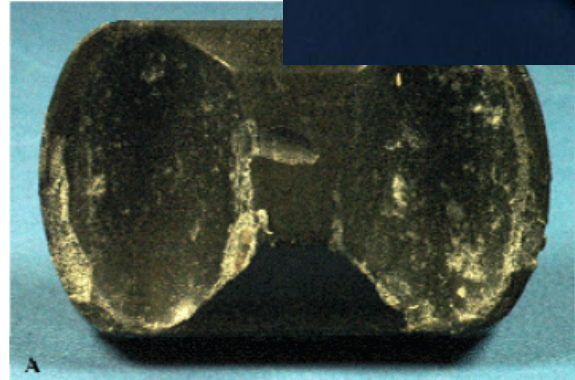
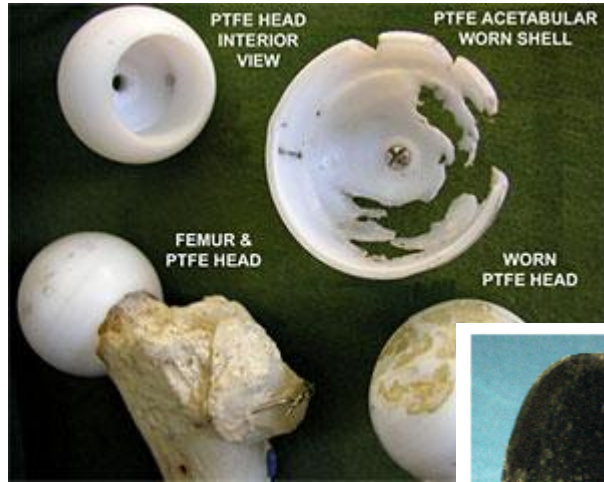


Picture from Gomez-Barena



- 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! *Unlimited.* **DSM**

Alternative material approaches.....

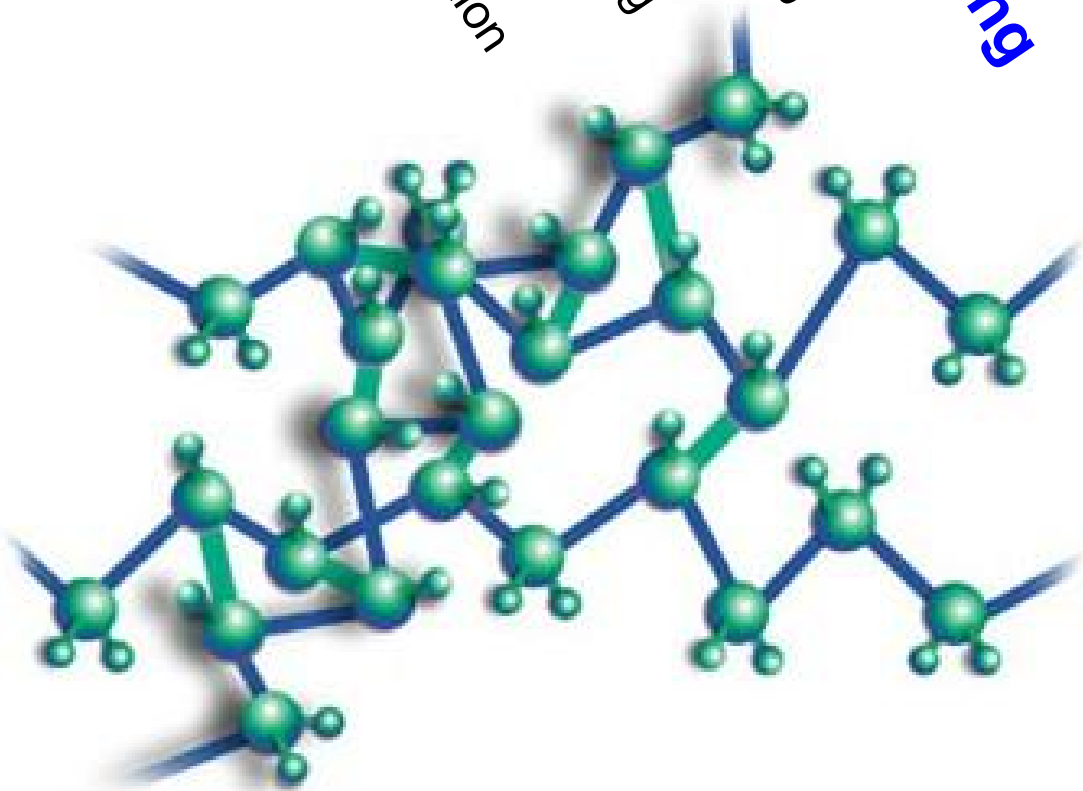
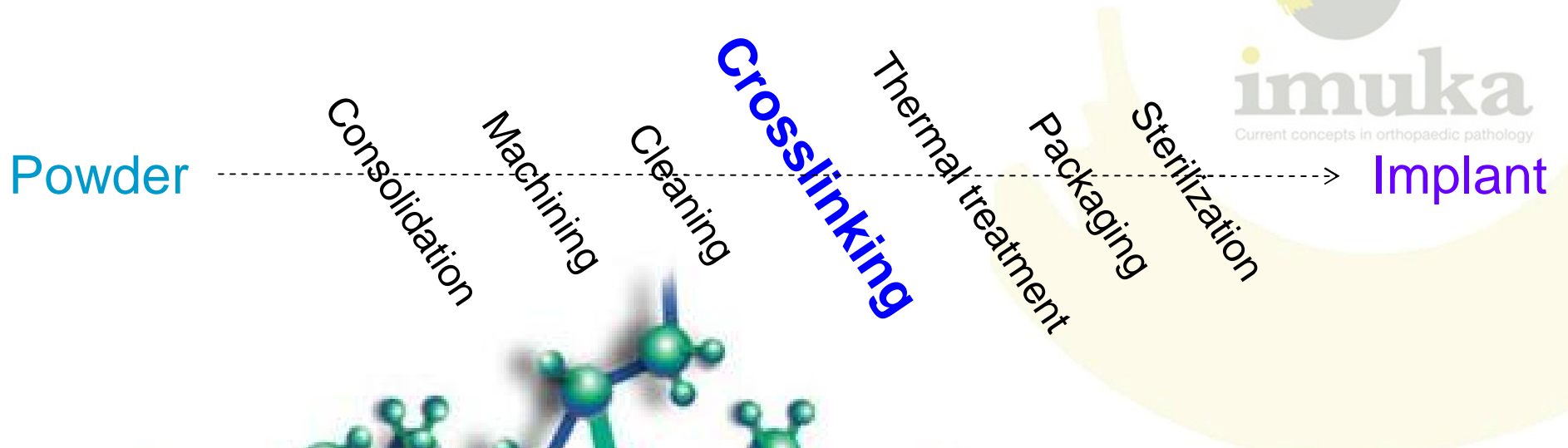


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Crosslinking – THE breakthrough in UHMwPE



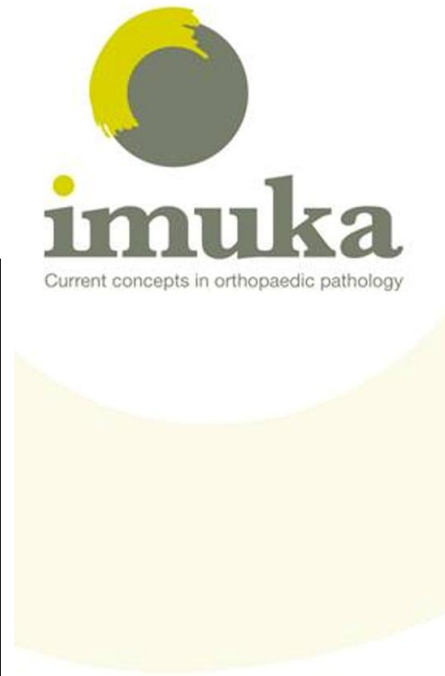
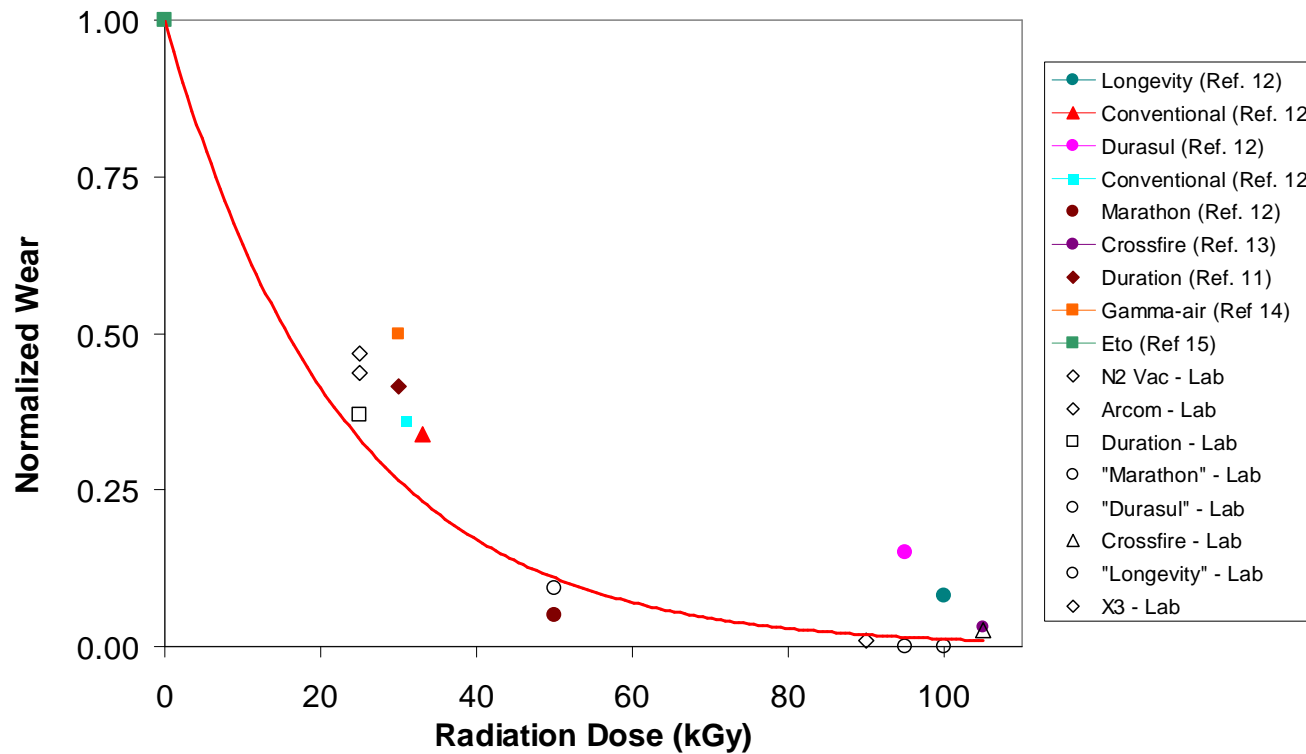
Stryker:	Crossfire® X3™
Zimmer:	Longevity™ Prolong™
DePuy:	MARATHON
Biomet:	ArCom® XLT
S&N:	XLPE

Picture: Zimmer

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Significant reduction in wear rate

Laboratory and clinical results



Both **in-vitro** as well as **in-vivo** wear

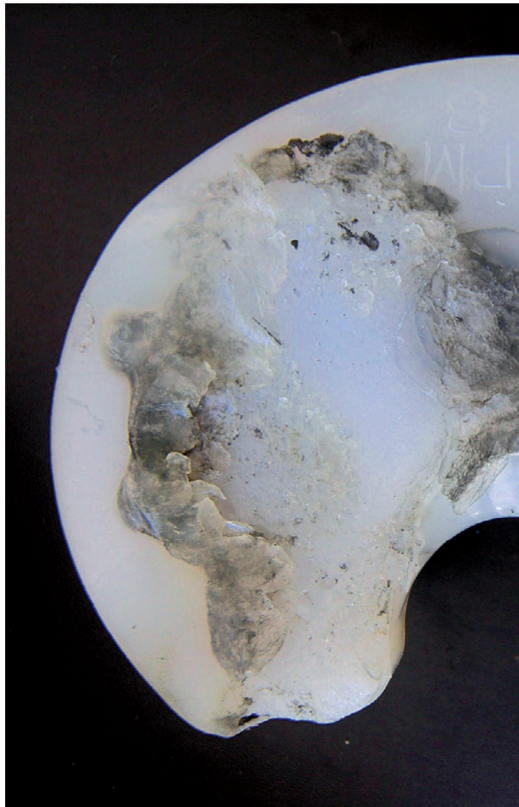
reduced as function of the Radiation Dose

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.

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Radicals form new challenge



Macro-radicals are created during irradiation

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

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Current radical removal options

Thermal treatment

Remelting OR Annealing

Additional step - time consuming, costs

Loss of mechanical properties

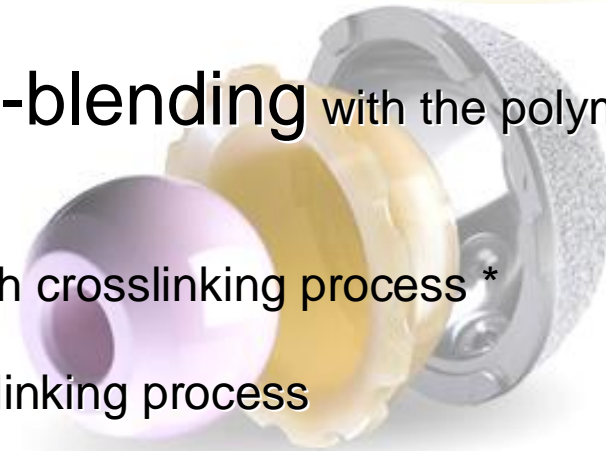
Vitamin E stabilization

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

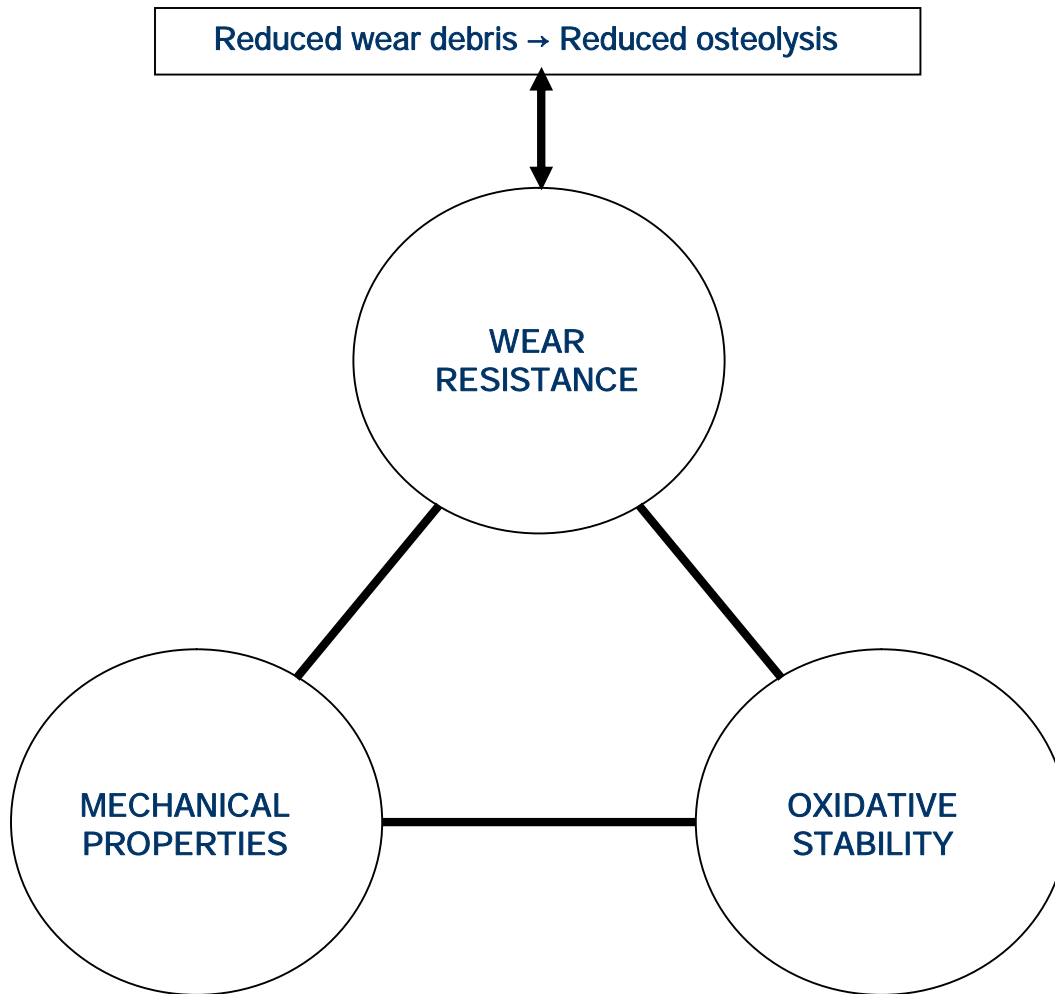
Material turns **yellow**



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

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UHMwPE Paradigm



Ideally:

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

REAL WORLD so far not ideal – Wear optimization causes compromises

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

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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

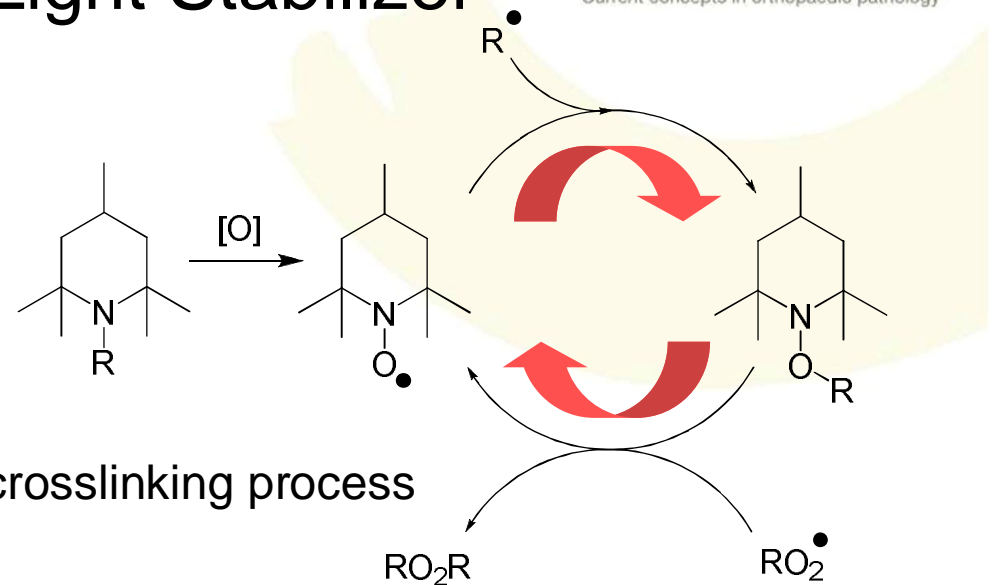
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Alternative stabilizer : HALS



HALS : Hindered Amine Light Stabilizer



No radical scavenging during radiation

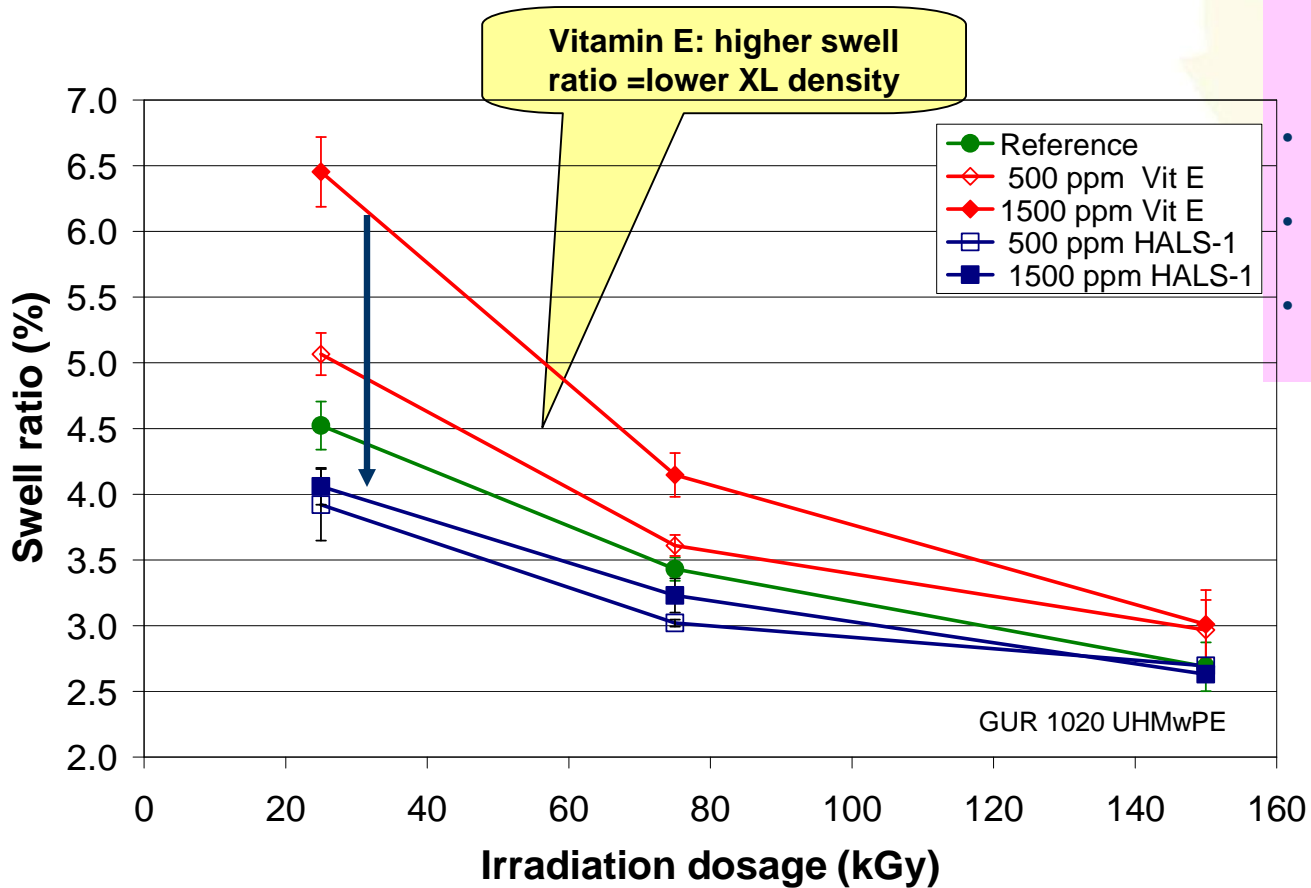
→ **no interference** with the crosslinking process

Regenerative - Less stabilizer needed

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

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HALS : Crosslinking improvement

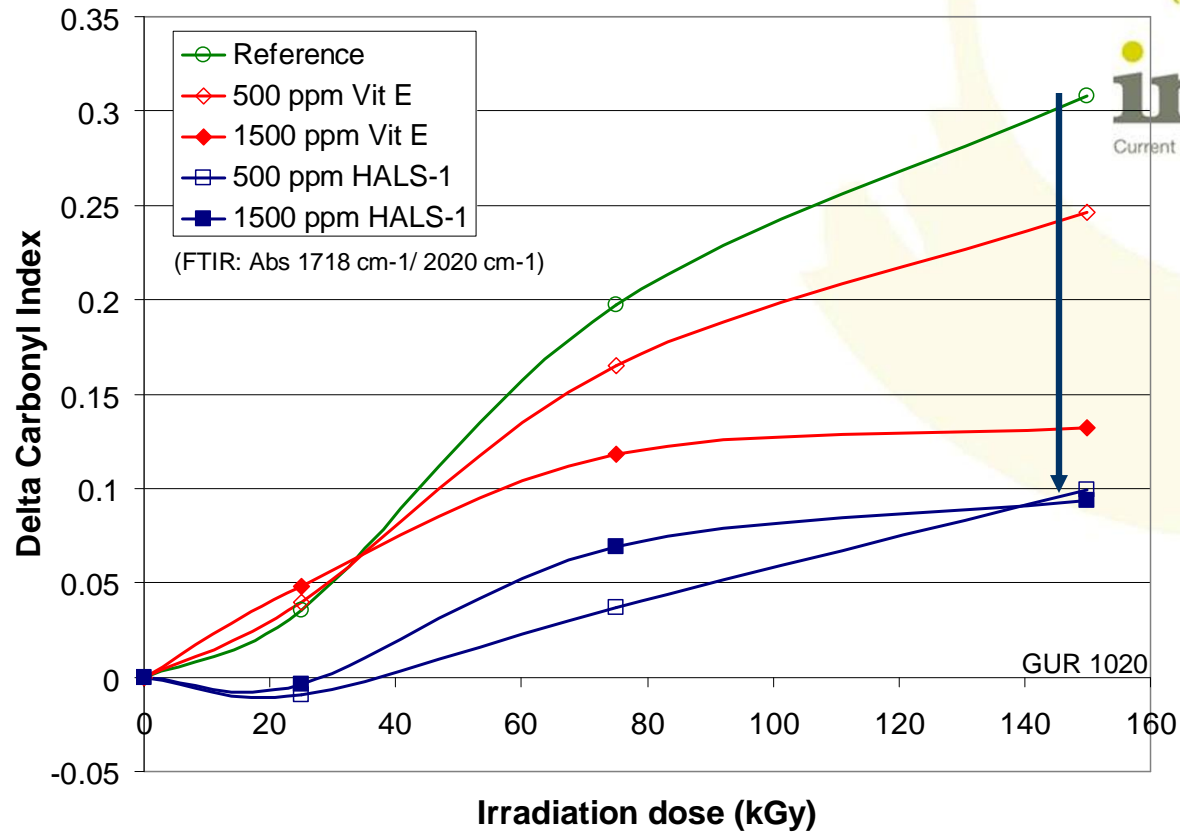


Higher crosslink density for HALS than for Vitamin E stabilized UHMwPE

- 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



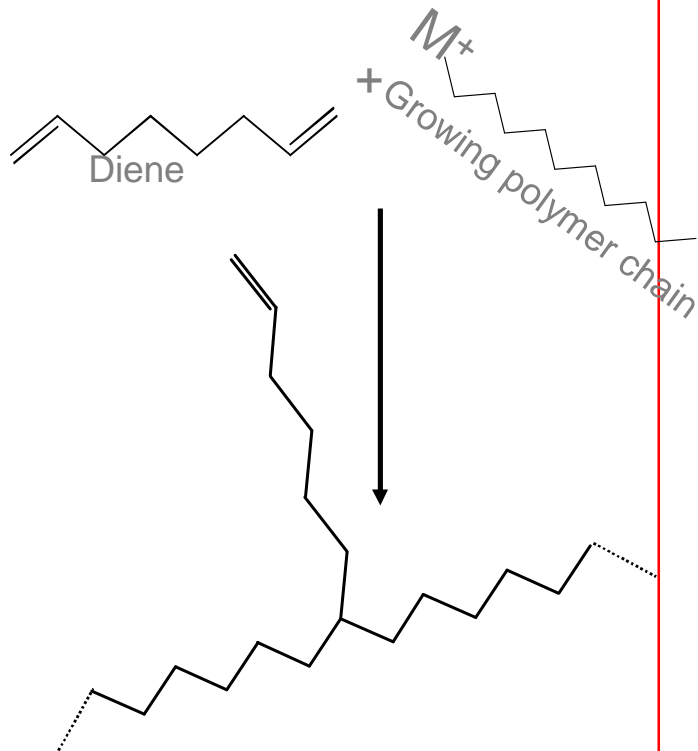
Change in Carbonyl Index as a result of ageing during 6 weeks at room temperature shows better stabilization compared to vitamin E

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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.**

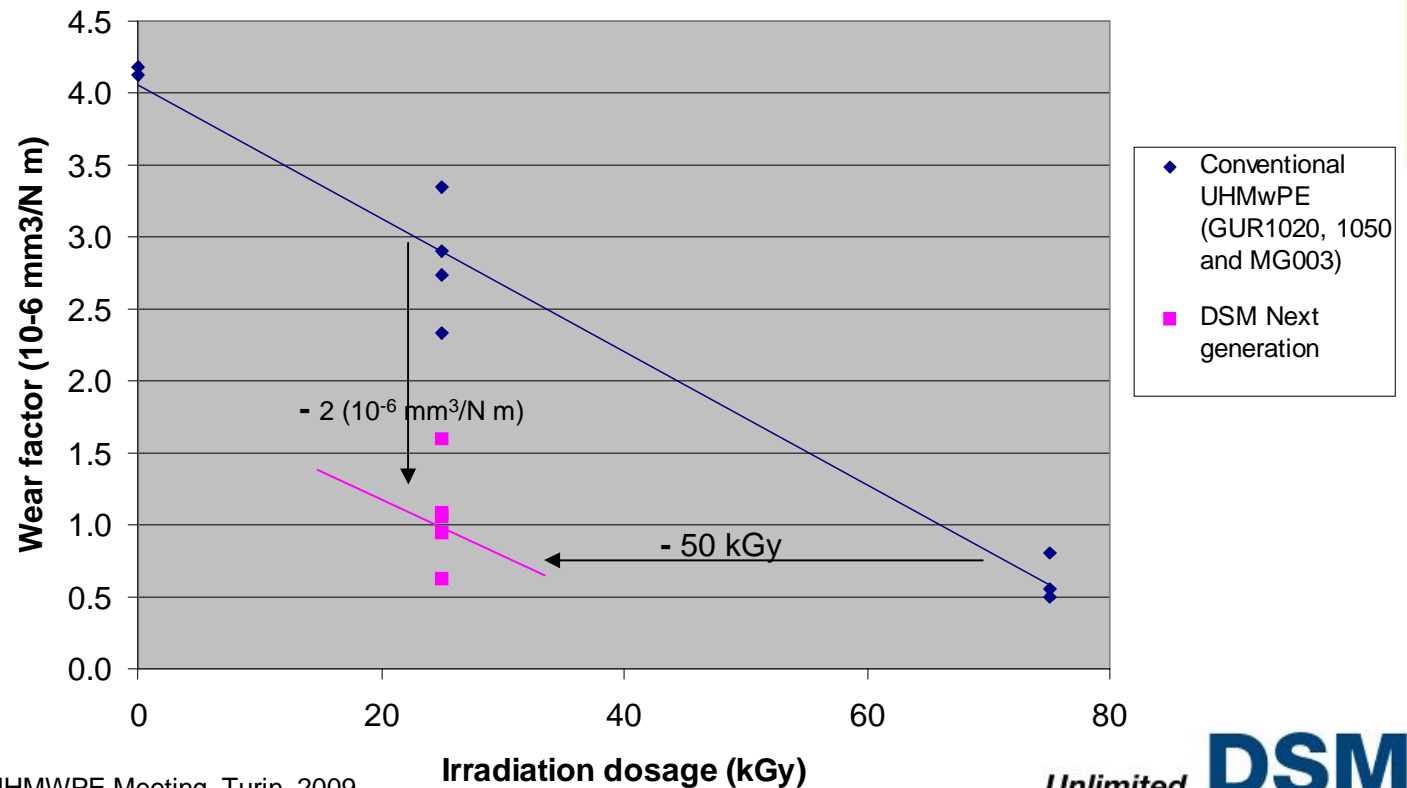
Further by adapting **molecular architecture** we can **optimize mechanical properties**

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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

Wear Factor versus irradiation dosage



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

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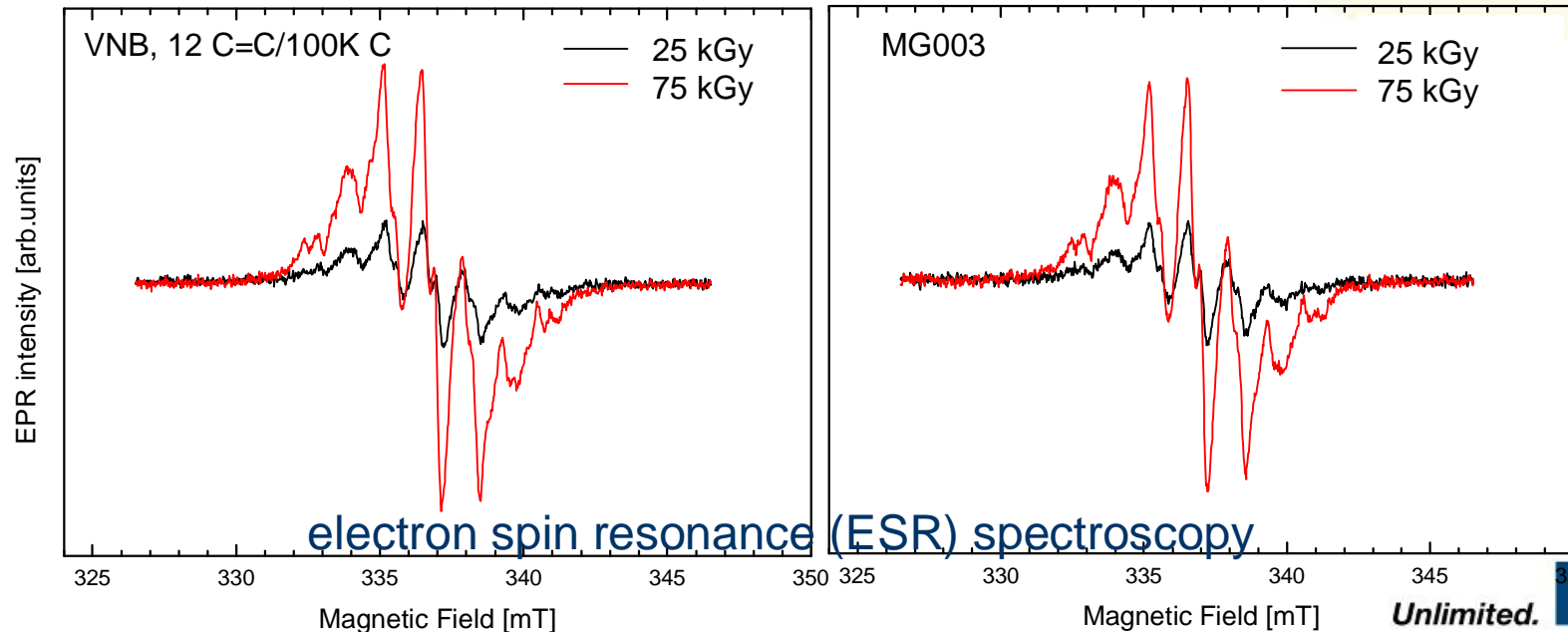
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Less remaining free radicals with Easy-XL

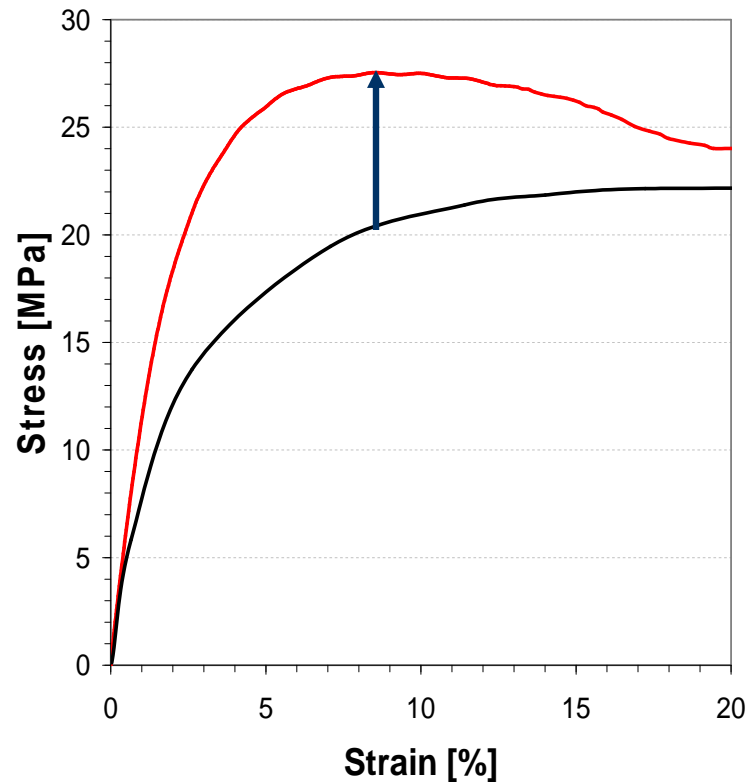


For both conventional UH and Easy-XL it was shown that 75 kGy radiation leaves behind 2-3 times higher radical content than 25 kGy

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



Better Mechanical Properties



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

Easy-XL is a **stronger** material:

- 30% higher Yield Stress
- 30% higher Crystallinity (better fatigue)

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Conclusion – will we break the paradigm?



HALS-UH and Easy-XL,

Current concepts in orthopaedic pathology

separate or combined,
form a strong vehicle to

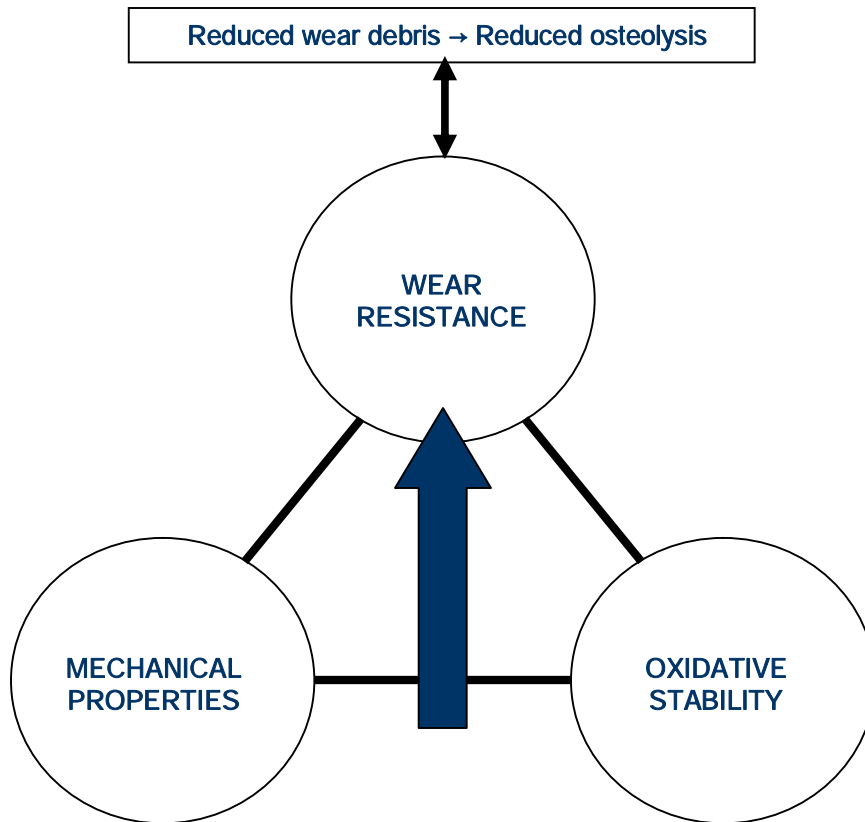
break the paradigm,

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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Acknowledgements



In 2007 DSM Biomedical initiated a new R&D program to develop new polyethylene materials for use in Arthroplasty.

Our Team:

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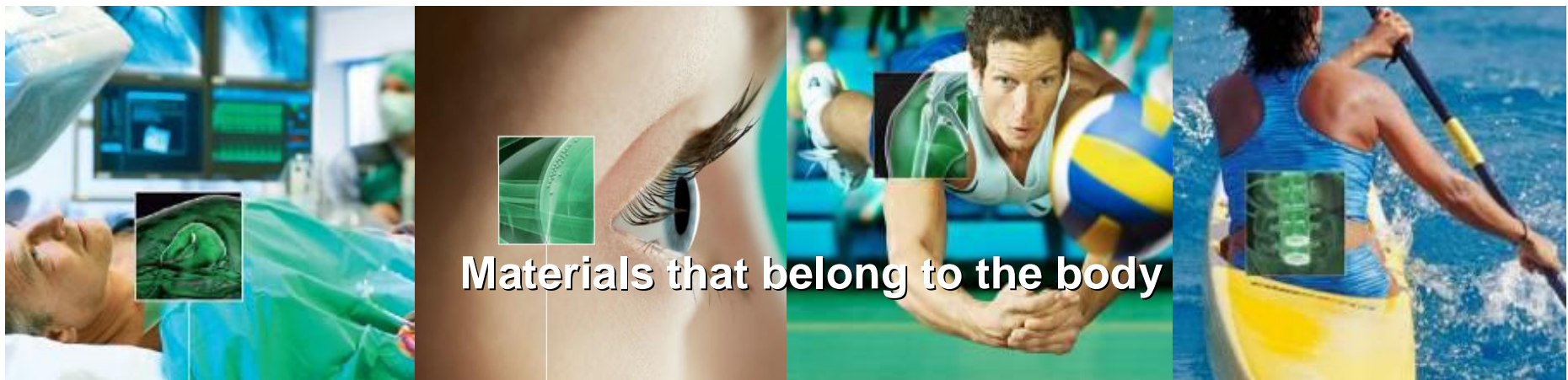
Marc Hendriks

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THANK YOU

Leo Smit
Business Director Implant Solutions



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