MATHYS
European Orthopaedics

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Preservation in motion

vitamys

Highly cross-linked polyethylene enriched with vitamin E

PIONEERING

A PIONEERING ACHIEVEMENT

In the late 1990s, the cross-linking of ultra-high molecular weight polyethylene (UHMWPE) aroused strong scientific and commercial interest. For these highly cross-linked polyethylenes (HXLPE), a reduction in wear by 35 to 84 % compared to conventional ultra-high molecular weight polyethylene (UHMWPE) after five years *in situ* [1] and a reduction in osteolysis risk by on average 87 % [2] have been described in the literature.

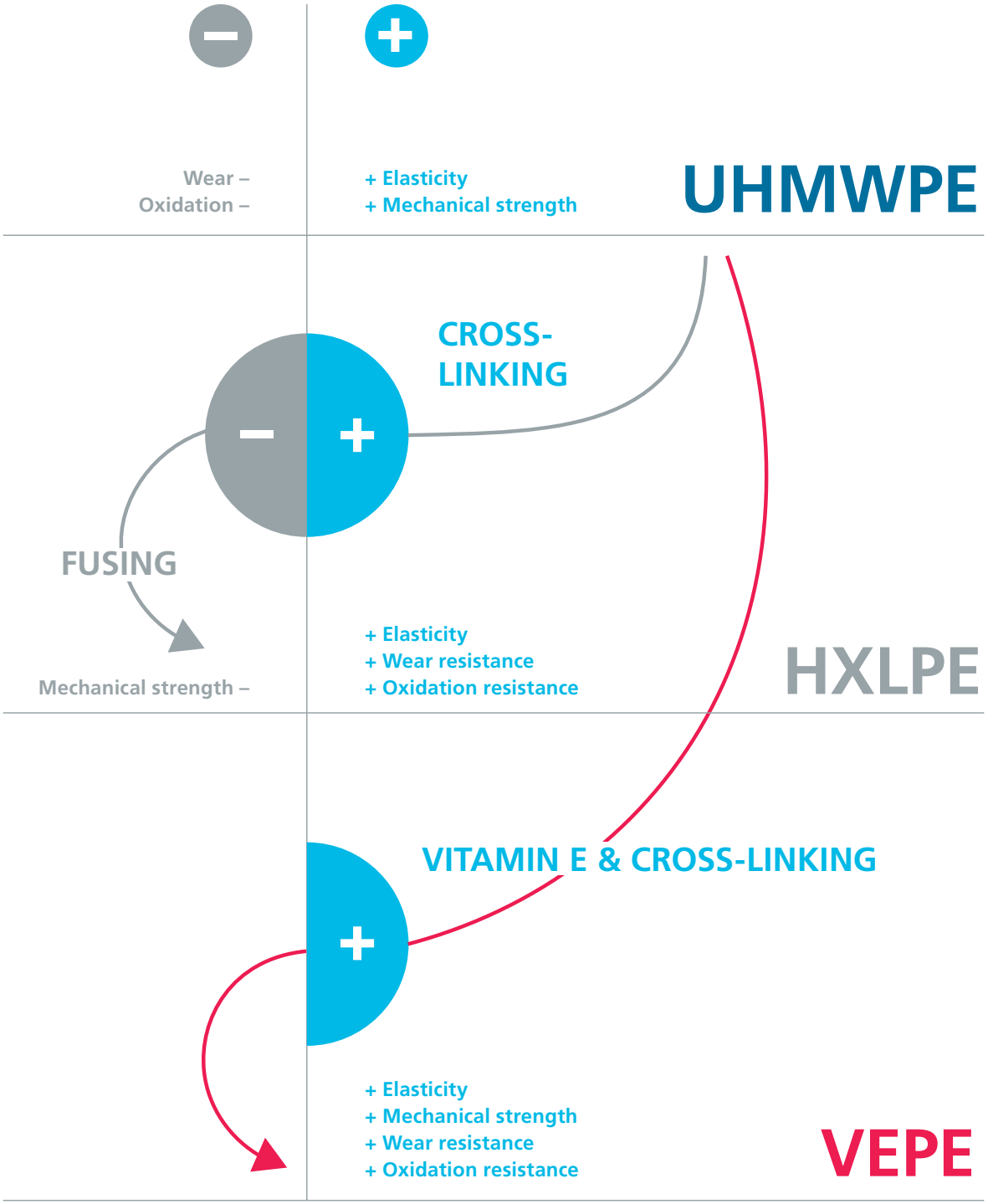
Despite numerous improvements over conventional UHMWPE, previous generations of HXLPE still had weaknesses. The high-energy radiation used during production to break the molecular chains also leads to formation of unstable, chemically active defects, so-called free radicals. A subsequent heat treatment above the melting point does cause these radicals to bind more easily to other molecule chains, which leads to optimisation of the oxidation resistance. However, this increased-temperature treatment weakens the mechanical properties of the polyethylene [3].

THE SOLUTION: VITAMYS

Mathys was the first manufacturer of orthopaedic prostheses to launch a highly cross-linked polyethylene enriched with vitamin E (VEPE) – a so-called «blended antioxidant highly cross-linked polyethylene (AO-HXLPE)» –, trademarked as vitamys. Addition of the natural antioxidant alpha-tocopherol (vitamin E) eliminates the need for heat treatment with fusing, thus preserving the good mechanical properties of polyethylene.

In September 2009, after several years of intensive research and development, the first RM Pressfit cup made of vitamys was implanted – a truly ground-breaking achievement in orthopaedics.

UHMWPE – HXLPE – VEPE



VITAMYS

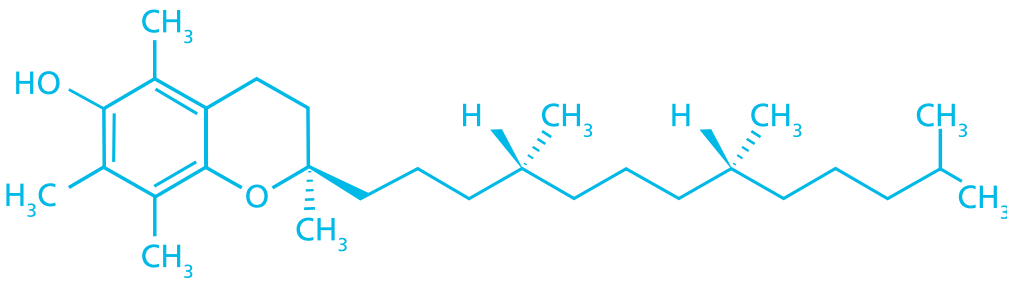
vitamys is the solution: a polyethylene with high wear resistance, high oxidation resistance, and good mechanical strength.

vitamys is a highly cross-linked polyethylene enriched with vitamin E (VEPE), which belongs to the class of antioxidative highly cross-linked polyethylenes (AO-HXLPE). It is manufactured from GUR 1020-E, an ultra-high molecular weight polyethylene containing 0.1 % of alpha-tocopherol (vitamin E).

In contrast to the first generation of highly cross-linked polyethylenes, vitamys is manufactured with only a stress relieving heat treatment well below the melting point, in order to ensure the dimensional stability of the material. This leads to the good mechanical strength of vitamys. By the addition of the natural antioxidant vitamin E, vitamys achieves its high oxidation resistance. This ensures that the excellent mechanical and tribological properties are maintained even over long periods of use [4].

VITAMIN E

Vitamin E is an umbrella term for the tocopherol group, among whose members alpha-tocopherol has the best antioxidant properties [5]. In the human body, but also in foodstuffs, it occurs as a natural substance; it is found e. g. in nuts, oils and some fruits such as avocados, where it protects the cell walls from oxidation and slows down the ageing process. Vitamin E is a fat-soluble vitamin and therefore soluble in and homogeneously miscible with polyethylene as well. The total quantity of vitamin E in vitamys implants is 50 to 100 mg, far below the maximum recommended daily dose of 300 mg [6].



ADVANTAGES

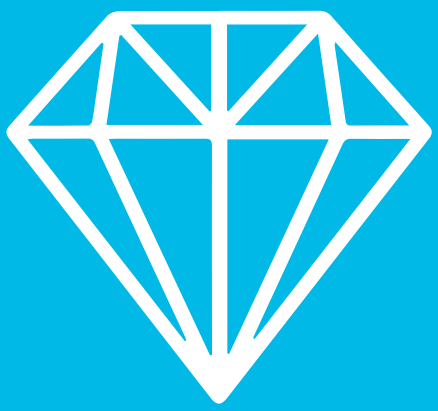
The pros of vitamys are obvious: VEPE is a material with high elasticity and therefore suitable for reducing stress shielding in joint replacement [7]. The good mechanical strength allows a long-term material performance. The high wear resistance reduces wear and thus the risk of osteolysis. The addition of vitamin E also ensures resistance to oxidation and thus a high resistance to ageing [4].

The advantage of vitamys lies in the beneficial combination of the four properties of elasticity, mechanical strength, wear resistance, and oxidation resistance:

- High elasticity for reduced stress shielding
- Good mechanical strength for long-term material performance
- High wear resistance for reduced risk of osteolysis
- High oxidation stability for high ageing resistance

ELASTICITY

STRENGTH



DURABLE AND BONE-PRESERVING

Reduced stress shielding and a reduced risk of osteolysis contribute significantly to bone preservation. Combined with a long-term material performance and with high resistance to ageing, this results in a durable prosthesis material.

«The excellent mechanical and tribological properties are maintained even over long periods of use.»[11]

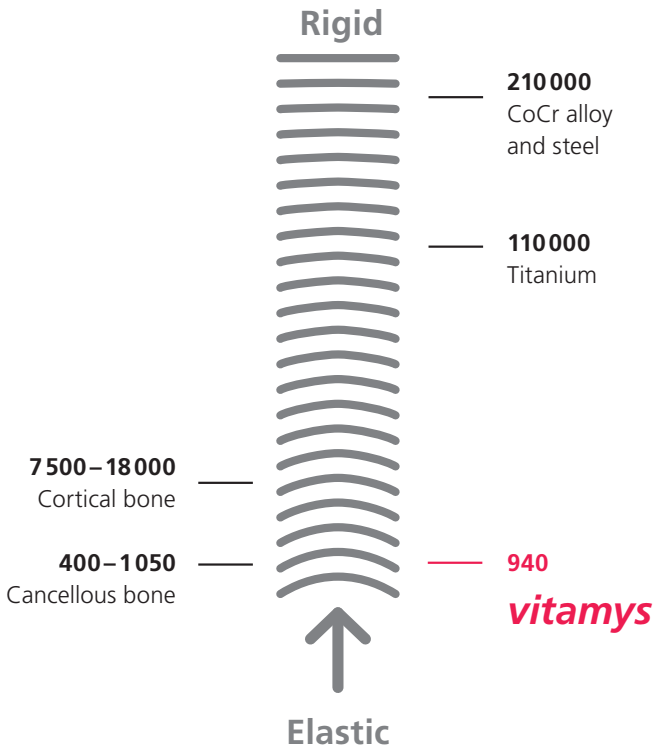
WEAR RESISTANCE

OXIDATION RESISTANCE

HIGH ELASTICITY

Despite good mechanical strength and high wear resistance, vitamys is extremely elastic. The high elasticity, which comes very close to that of cancellous human bone [8], helps to reduce stress shielding. Where hard materials can lead to bone resorption, vitamys helps to preserve the bone [7].

Modulus of elasticity (N/mm²)

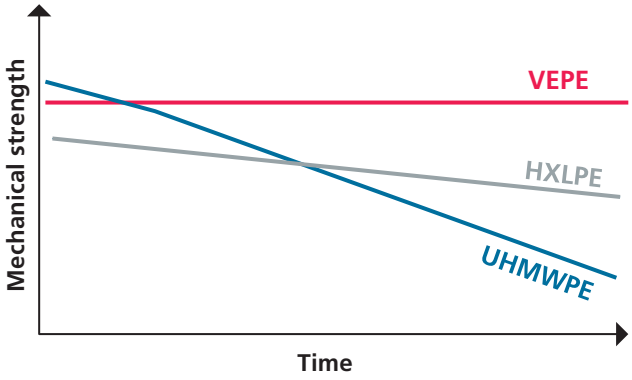


GOOD MECHANICAL STRENGTH

vitamys meets the requirements for an advanced polyethylene in terms of yield stress, ultimate tensile strength, elongation at break, and impact strength. These properties are essential for good mechanical strength and thus for the long-term performance of the material.

The illustration below shows vitamys (VEPE) compared to highly cross-linked (HXLPE) and conventional polyethylene (UHMWPE). The first generation of HXLPE is convincing in terms of wear resistance and oxidation resistance. However, the heat treatment above the melting temperature required to eliminate free radicals weakens the mechanical properties of the polyethylene [3].

vitamys does not require fusing and can therefore maintain its good mechanical strength initially and for a longer time. Thus, it deforms or breaks less quickly than highly cross-linked polyethylene of the first generation does [9, 10].



HIGH WEAR RESISTANCE

In hip, shoulder and knee simulator tests, vitamys was shown to have significantly lower wear rates than conventional polyethylene has, thanks to its high wear resistance. In hip, shoulder or knee components, vitamys reduces wear *in vitro* by 50 to more than 80 % compared to UHMWPE [11, 13, 14, 15, 16]. For hip prostheses, wear reduction by 65 % was demonstrated *in vivo* after 5 years [12].

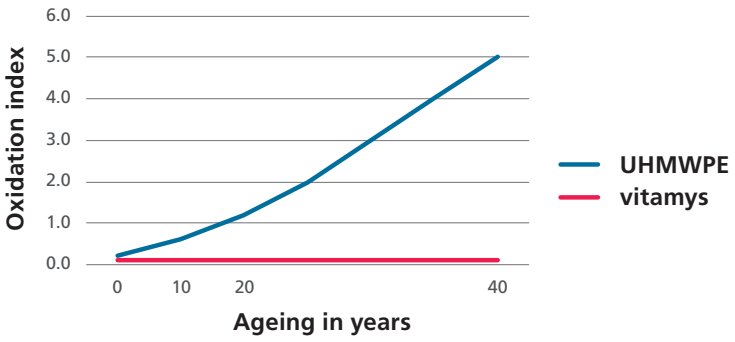
The wear reduction of the individual vitamys products is described in detail on the following pages.

HIGH OXIDATION RESISTANCE

By means of accelerated artificial ageing by the action of heat and oxygen, the long-term oxidation and ageing behaviours are simulated.

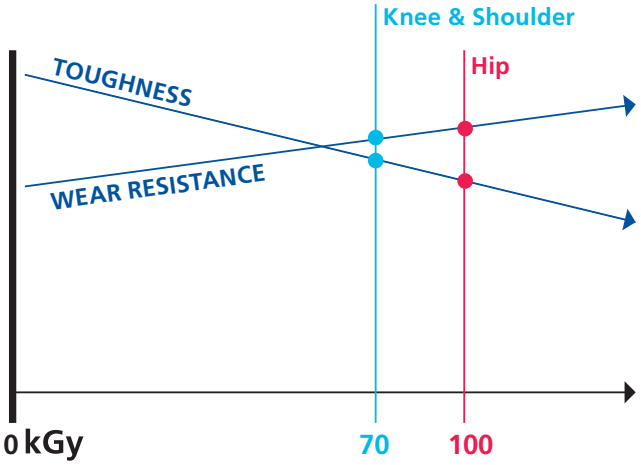
Comparison of conventional UHMWPE with vitamys in the accelerated ageing test under pure oxygen (5 bar O_2 at 70° C, tested unaged and after 14 to 60 days of artificial ageing) reveals the protective effect of vitamin E [4]. The test shows that vitamys proves to be resistant to oxidation in the long term, as it does not show any discernible signs of oxidation at any time over a simulated period of up to 40 years [4].

Long-term ageing behaviour

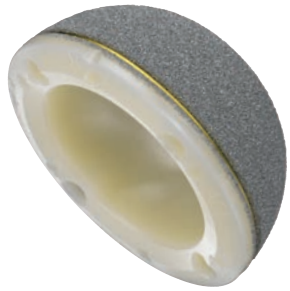


GAMMA IRRADIATION

The vitamys used for the acetabular cups is cross-linked with 100 kGy of gamma radiation. The dosage for the vitamys for knee and shoulder components is deliberately selected lower, at 70 kGy, than that for hip components. The reason for this lies in the optimum balance of toughness and wear resistance. The less complex design of an acetabular cup allows higher dosing of gamma irradiation in order to maximise wear resistance. The more complex design of the shoulder or knee components requires slightly higher toughness of the material and is therefore irradiated with a lower dosage, but still achieves good wear resistance.



VITAMYS PORTFOLIO

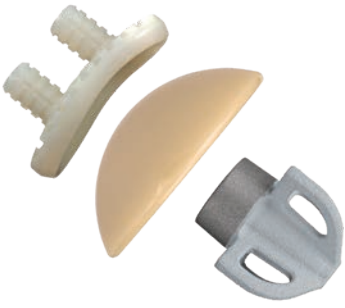


RM Pressfit vitamys

aneXys Inlays vitamys

balanSys UNI Inlays vitamys

balanSys BICONDYLAR Inlays vitamys



Affinis Glenoid vitamys

Affinis Inverse Glenosphere vitamys

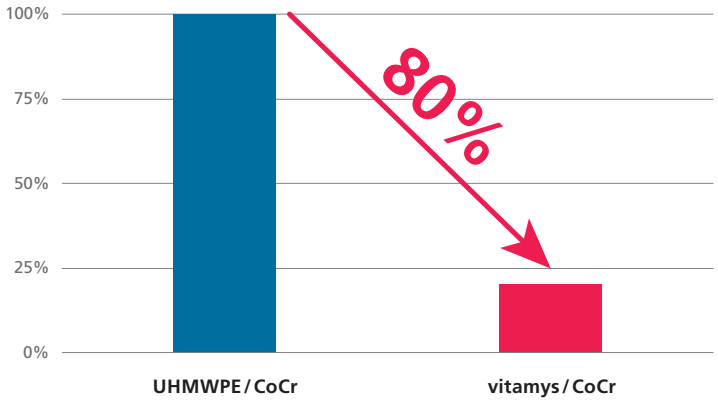
PROVEN

HIGH WEAR RESISTANCE

RM Pressfit

Reduction of wear [11]

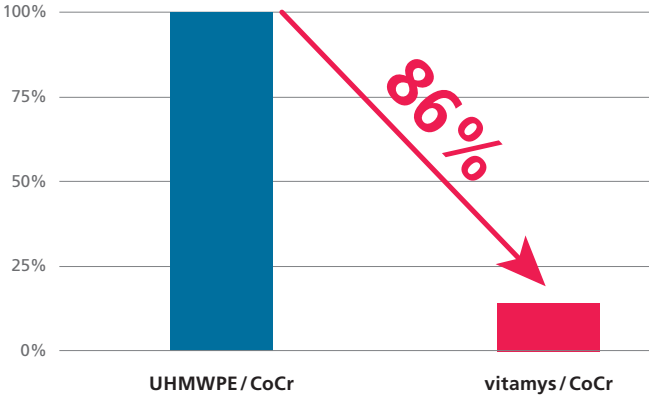
Wear reduction in % of the RM Pressfit sliding couplings



balanSys BICONDYLAR

Reduction of wear [13]

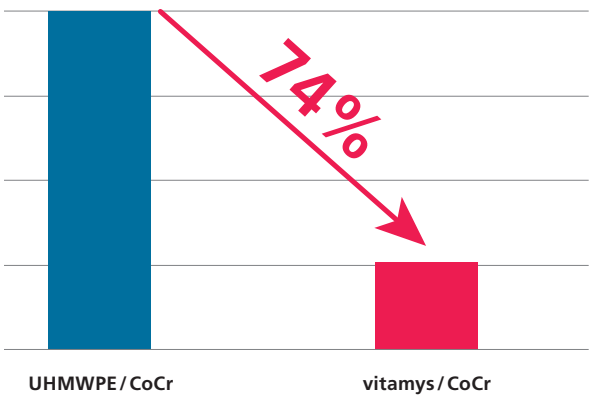
Wear reduction in % of the balanSys BICONDYLAR sliding couplings



balanSys UNI

Reduction of wear [14]

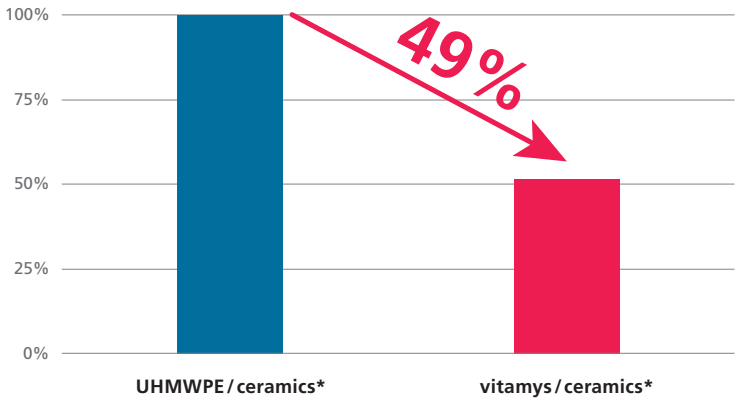
Wear reduction in % of the balanSys UNI sliding couplings



Affinis Glenoid

Reduction of wear [16]

Wear reduction in % of the Affinis Glenoid sliding couplings

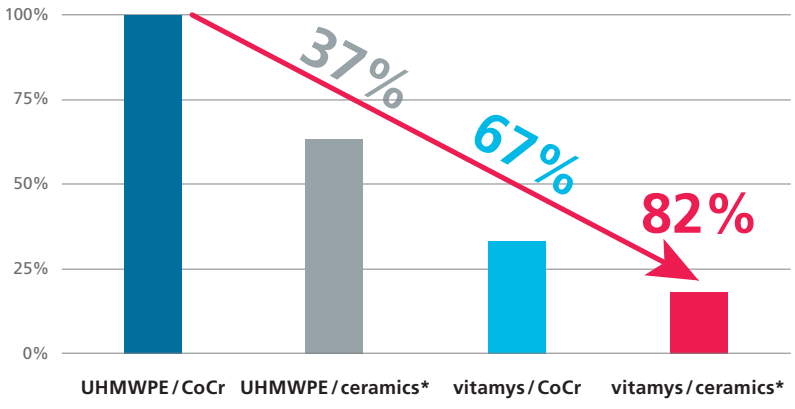


* Bionit (Al_2O_3)

Affinis Inverse

Reduction of wear [15]

Wear reduction in % of the Affinis Inverse sliding couplings



* ceramys

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