Correlation of cross-linking as measured by the trans-vinylene index and in vitro wear of polyethylene from various acetabular liner brands

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Aims
Highly cross-linked polyethylene (HXLPE) greatly reduces wear in total hip arthroplasty, compared to conventional polyethylene (CPE). Cross-linking is commonly achieved by irradiation. This study aimed to compare the degree of cross-linking and in vitro wear rates across a cohort of retrieved and unused polyethylene cups/liners from various brands.

Methods
Polyethylene acetabular cups/liners were collected at one centre from 1 April 2021 to 30 April 2022. The trans-vinylene index (TVI) and oxidation index (OI) were determined by Fourier-transform infrared spectrometry. Wear was measured using a pin-on-disk test.

Results
A total of 47 specimens from ten brands were included. The TVI was independent of time in vivo. A linear correlation (R^2 = 0.995) was observed between the old and current TVI standards, except for vitamin E-containing polyethylene. The absorbed irradiation dose calculated from the TVI corresponded to product specifications for all but two products. For one electron beam-irradiated HXLPE, a mean dose of 241% (SD 18%) of specifications was determined. For another, gamma-irradiated HXLPE, a mean 41% (SD 13%) of specifications was determined. Lower wear was observed for higher TVI.

Conclusion
The TVI is a reliable measure of the absorbed irradiation dose and does not alter over time in vivo. The products of various brands differ by manufacturing details and consequently cross-linking characteristics. Absorption and penetration of electron radiation and gamma radiation differ, potentially leading to higher degrees of cross-linking for electron radiation. There is a non-linear, inverse correlation between TVI and in vitro wear. The wear resistance of the HXLPE with low TVI was reduced and more comparable to CPE.

Bone & Joint Research

Article focus

- The polyethylene from 47 total hip arthroplasty liners/cups from ten different brands from eight manufacturers was assayed.
- The degree of cross-linking of the polyethylene, respectively the absorbed dose of radiation, was determined using the trans-vinylene index (TVI).
- The TVI was correlated to in vitro wear as determined by a pin-on-disk test.

Key messages

- The TVI may be used to determine the absorbed irradiation dose of polyethylene, as the correlation between both parameters is linear in the range of irradiation of interest, and as the TVI does not alter over time in vivo.
- There is an inverse relation between wear, as determined by a pin-on-disk test, and the TVI, with polyethylenes with a higher irradiation, and consequently a higher TVI, showing lower wear.
- Electron beam irradiation may lead to a higher degree of cross-linking of polyethylene than gamma irradiation at equivalent doses, but one commonly used brand of gamma-irradiated highly cross-linked polyethylene shows absorbed irradiation doses of less than half of product specifications.

Strengths and limitations

- Implant/retrieval selection was limited by availability from a single centre, respectively regional and national preferences.
- Both the TVI and wear results clearly group by polyethylene brand.
- Conversion formulae from the old to the new TVI standard and irradiation absorption models in polyethylene are provided.

Introduction

The introduction of highly cross-linked polyethylene (HXLPE) is one of the most important advances in total hip arthroplasty (THA).[1-3] This innovation greatly reduced revision requirements due to wear and development of osteolysis, compared to conventional ultra-high molecular weight polyethylene (CPE).[2-4] While cross-linking of polyethylene is commonly used in various domains of engineering to improve material properties, it was only during the late 1990s that it became readily available in THA.[5,6] Still, HXLPE liners were not commonly used in clinical practice until approximately ten years after its introduction.[3,7-9]

Cross-linking of polyethylene may be achieved through chemical reaction or through creation of free radicals by irradiation.[9-12] Typically, irradiation is preferred for technical reasons. However, many other parameters have to be considered to obtain the desired material properties.[5,11-13] In particular, if no vitamin E addition is performed, thermal treatment after irradiation is essential to minimize the concentration of free radicals and avoid accelerated oxidation and degradation of the material.[5,6,9,12,14] A multitude of products are available in THA, differing mainly regarding ultra-high molecular weight polyethylene resin used, irradiation dose and type, thermal treatment after irradiation, the sterilization process, and potentially the addition of an antioxidant such as vitamin E.[6,11,12,15] Irradiation dose and thermal treatment are the main material determinants of revision after THA identified thus far.[5,16]

Determining the degree of cross-linking is difficult, as the material is composed solely of carbon and hydrogen. While small- and wide-angle x-ray scattering (SAXS and WAXS) may provide information regarding conformation of the polymers, even these techniques do not allow direct measurements of cross-links.[17,18] Indirect measurements are commonly used, such as determination of the trans-vinylene index (TVI) by means of Fourier-transform infrared (FTIR) spectrometry or by measuring the swell ratio, respectively determination of the gel content.[18-22] The purpose of this study was to determine the TVI as an indirect measurement of the degree of cross-linking across a cohort of consecutively retrieved as well as unused acetabular polyethylene cups and liners from various manufacturers, and correlate it with in vitro generated wear rates of the same materials. It was our hypothesis that the TVI would vary as a function of the specific processing parameters applied by different manufacturers, with direct implications for the in vitro wear performance.

Methods

Collection of THA cups and liners

From 1 April 2021 to 30 April 2022, a continuous series of 47 polyethylene acetabular liners and cups were collected from one centre, either retrieved at revision (n = 12 for periprosthetic fracture, n = 12 for malposition/instability, n = 9 for periprosthetic infection, n = 4 for aseptic loosening, n = 1 for heterotopic ossifications) or obtained unused, respectively unworn, from failed implantations (n = 6). The number of components of the same type was limited to a maximum of 20, collected consecutively. A total of 16 HXLPE liners Highcross (Medacta, Switzerland) were not included, being in excess. Another five retrievals (three Highcross, one Durasul (Zimmer Biomet, USA), and one CPE liner from Implant Design (manufacturer no longer exists) were not available due to requirements for other analysis, or were not made available by the patient. Samples were rinsed after recovery, but were not sterilized, and were kept at ambient temperature until analysis. Clinical data regarding patient demographics, time in situ, and reason for revision were collected prospectively from clinical files. For all retrievals, informed consent was obtained from the patients for publication of anonymized clinical data and for destructive analysis of the liner/cup. Legal requirements regarding written informed consent, data management, and anonymization have been fulfilled. Furthermore, Swiss law waives the requirement for submission to an ethical committee for such a quality control study. The three Vitamys HXLPE cups were provided unused for this study directly by Mathys (Switzerland). Manufacturer specifications for each product, numbers, and time in vivo of the retrievals included are summarized in Table I. Details regarding irradiation and sterilization were extracted from available publications,[12,14,22-26] as well as from packaging labels, or were provided by the manufacturers.

Polyethylene characterization

The TVI was determined using a FTIR microscope (Lumos; Bruker, USA). The analysis was performed in triplicate

Table I. Summary of the essential manufacturer specifications (type and dose of irradiation) and of the retrieval data (number of samples and time in vivo) of the polyethylene total hip arthroplasty liners, respectively cups, included in this study.[12,14,22-26]

Manufacturer	Brand name	Type	Vit. E	Irradiation for crosslinking	Sterilization	Number of samples	Median time in vivo, yrs (range)
Corin	ECiMa	HXLPE	Yes	120 kGy gamma	Ethylene oxide	1	0.8
Implantcast	Implacross E	HXLPE	Yes	75 kGy gamma	Ethylene oxide	1	1.2
Mathys	Vitamys	HXLPE	Yes	100 kGy gamma	30 kGy gamma	3 (3 new)	0.0 (0.0 to 0.0)
Medacta	Standard	CPE	No	No crosslinking	Ethylene oxide	1	16.1
Medacta	Highcross	HXLPE	No	100 kGy gamma	Ethylene oxide	20 (4 new)	2.1 (0.0 to 15.1)
Microport	UHMWPE	CPE	No	No crosslinking	Ethylene oxide	1	0.8
Smith & Nephew	XLPE	HXLPE	No	100 kGy gamma	Ethylene oxide	4	2.9 (0.3 to 7.7)
Unknown	Unknown	Unknown	No	Unknown	Unknown	1	6.3
Zimmer Biomet	Sulene	CPE	No	No crosslinking	25 to 40 kGy gamma	1	16.5
Zimmer Biomet	Durasul	HXLPE	No	95 kGy electron beam	Ethylene oxide	14 (2 new)	0.5 (0.0 to 18.1)

Details regarding irradiation and sterilization were extracted from available publications,[12,14,22–26] as well as from packaging labels, or were provided by the manufacturers.
CPE, conventional polyethylene; HXLPE, highly cross-linked polyethylene; UHMWPE, ultra-high-molecular-weight polyethylene; Vit. E, vitamin E.

following the ASTM F2381-19 standard from bulk samples obtained at least 2 mm below the surface from a block cut out of the inferior rim of the liner/cup.[27] This position was chosen to characterize the bulk with as little tribological or mechanical influence on the polyethylene as possible. More than 2 mm was not possible as a general rule, due to the geometry of some liners, especially the E/36 from Versafit (Medacta) cups, which is particularly thin-walled. Readings were standardized both for the peak at 1,370 cm^{-1} (TVI_{1370}) and for the peak at 1,900 cm^{-1} (TVI_{1900}). The oxidation index (OI) was determined from the same scan, following the ASTM F2102-17 standard.[28] Readings were made in two batches in August 2021 and September 2022 to minimize shelf oxidation. The irradiation doses were calculated from the measured TVI_{1370} using the calibration curve established previously for gamma-irradiated, remelted polyethylene with verification of irradiation by classical dosimetry, using the following equation:

$$\text{Irradiation dose in kGy} = 4196.8 \times TVI_{1370} - 12.331$$

This had been shown to have a correlation factor R^2 = 0.9898.[22]

Monte Carlo simulations of polyethylene irradiation

Depth dose curves of the polyethylene samples resulting from photon and electron irradiation were calculated using the general-purpose Monte Carlo (MC) code FLUKA version 2023.3.3.[29] The simulation setup and post-processing were conducted with the graphical user interface Flair.[30] The chemical composition of materials used in the MC simulations was taken from the Flair material database. As a photon source, a cylinder (diameter 0.7 cm, length 43.7 cm) made of ^{60}Co was used, encased in 0.2 cm stainless steel (density 8,000 kg*m^{-3}). This design of the source resembled an industrial standard source for radiation processing from the Institute of Isotopes, Budapest, Hungary. The branching ratio of the decay radiation was simulated as implemented in FLUKA, with two main gamma emission lines at 1.17 MeV and 1.33 MeV. The electron source was implemented with a rectangular beam shape (width 5 cm, height 100 cm), a kinetic energy of 10 MeV, and a beam direction perpendicular to the target. The shape of the polyethylene target was a cuboid (quadratic base side 100 cm, depth 40 cm) with a density of 940 kg*m^{-3}. Both sources were placed at a distance of 50 cm to the square base. The setup of source and target was symmetrical with regard to a centre-line running through the centre of the quadratic base and top side. The simulations for both radiation sources each consisted of 12 independent runs. For the ^{60}Co source, $20*10^9$ decays were simulated per run, whereas for the electron source, $1*10^6$ primary electrons were simulated per run. The depth-dose curves were evaluated along the centreline using the built-in USRBIN scoring card, which estimates absorbed dose within regular spatial binning. The scoring volume was a cuboid (quadratic base side 2 cm, depth 40 cm) with one bin in the lateral directions and 400 bins in the depth direction, resulting in 400 stacked dose scoring volumes of 0.4 cm^3.

Wear test

Pin-on-disk wear tests were performed following the ASTM F732-17 standard as far as possible.[31] Four pins with a diameter of 5 mm and a length of 5 to 8 mm each were punched out from the thickest part of the liners/cups, i.e. between the rim and the pole, so that the articulating surface of the pin corresponded to the bearing surface. Subsequently, the articulating surfaces of the pins were ground using sandpaper (grits 600, 1,200, and 2,500), to obtain a perpendicular and smooth surface and to remove any worn surface from used liners/cups. After pre-soaking in test liquid of all pins, three of them were articulated against cobalt-chromium-molybdenum alloy (CoCrMo) disks (Ø 30 mm), previously polished using diamond paste, reaching a mean roughness R_a of 5 nm (SD 2). Tests were performed on a six-station wear tester (Ortho-POD; AMTI, USA) with a rectangular motion (5 × 10 mm) at a frequency of 2 Hz. The applied load was alternating, reaching 10 N, 100 N, 50 N, and 100 N (maximal contact pressure of 5.1 MPa) at the corners of the rectangular motion. The test was performed at 37°C ± 1°C in a testing solution based on newborn calf serum (batch no. S00FV10015; Biowest, Costa Rica), diluted with deionized water to a protein concentration of 30 g/l according to ISO 14242-1:2014.[32] To inhibit bacterial growth and to bind metallic ions, 2 g/l of sodium azide and 3 g/l of ethylenediaminetetraacetic acid were added. The testing solution was filtered with 2 µm filters to remove microorganisms and stored at -20°C. A soak-control pin was exposed to the same test liquid at 37°C ± 1°C, but was neither exposed to motion nor to load. The pins were weighed before the test and after 500,000 cycles. Before weighing, the samples were cleaned in an ultrasonic bath, first for 15 minutes with a cleaning detergent (Deconex 12 PA; Borer Chemie, Switzerland) followed by deionized water for five minutes. After rinsing and immersion in isopropanol, the samples were dried in a cold air flow and subsequently for 20 minutes in a vacuum chamber. The mean of two weight measurements was taken per sample. If the two measurements differed by more than 0.03 mg, the samples were weighed again. Wear was determined by measuring the weight loss of the samples during the test, corrected with the weight gain of the reference pin due to soaking. The volumetric wear factors were calculated by dividing the wear rates by the density of 936 kg/m³ for polyethylene and by the applied load-distance curve.

Statistical analysis

Data description was made with mean and SD for normally distributed scalar variables and using median and range in case normal distribution was not ensured. Pearson's correlation coefficient was used to assess the association between TVI_{1370} and TVI_{1900}. The calculated absorbed irradiation dose was compared to specifications with an independent-samples *t*-test or a Wilcoxon signed-rank test if sample size was ≤ 4, using one-sided statistics. Otherwise, a two-sided 95% CI was calculated. Statistical significance was accepted for a p-value < 0.05 for all analyses. All statistical analyses were conducted using R version 4.2.0 (R Foundation for Statistical Computing, Austria). To control for multiple statistical comparisons, the Bonferroni correction was applied to adjust p-values and minimize the risk of type I errors.

To compare absorbed irradiation doses calculated with our model to the literature, linear regressions of the relation between TVI and gamma irradiation dose, for samples with post-irradiation thermal treatment if available and for the dose range of interest, were calculated from published data.[19,20,33,34] When data points were not available in tables, reconstruction was performed digitalizing figures using DigitizeIt (Bormann, Germany).[20,33] The regression formulae obtained to calculate the irradiation dose in kGy were $1369.5 * TVI_{1900} - 96.238$,[19] $230.3335 * TVI_{1900} - 16.8162$,[33] $726.7374 * TVI_{1900} - 27.5519$,[20] and $2216.51043 * TVI_{1370} + 7.12579377$.[34]

Results

TVI results are presented in Table II, where both data description using mean (SD) and median and range are indicated for reasons of clarity and comparability, respectively in Figures 1 and 2. A very strong linear correlation could be observed between the TVI_{1370} and TVI_{1900} (Figure 1). For all samples, Pearson's correlation coefficient was $R^2 = 0.9848$. Excluding vitamin E-containing HXLPE samples, correlation increased ($R^2 = 0.9945$). The absorbed irradiation doses calculated from the measured TVI_{1370} were brand-dependent (Figure 2). As expected from product specifications of irradiation during the manufacturing process (Table I), there were differences between the individual products. All calculated irradiation doses were within specifications or slightly above, except for two products (Table II). The results for Highcross were clearly below (mean 41% (SD 14)) specifications of 100 kGy ($p < 0.001$, independent samples *t*-test; 95% CI 31 to 47), and showed a relatively high variability compared to other products. Results from Durasul showed a much higher (mean 241% (SD 18)) absorbed irradiation dose than the expected 95 kGy ($p < 0.001$, independent samples *t*-test; 95% CI 220 to 239). No degradation of the TVI could be observed over time for the liners with long time in vivo, compared to new ones, for the three groups with enough comparators (Highcross from Medacta, XLPE from Smith & Nephew (UK), and Durasul from Zimmer Biomet) (Figure 3). The results of the OI are solely presented in Table II, as there was no correlation with time in situ or any specific product. Only one Durasul sample (12.7 years in vivo) had a relevantly increased mean OI (0.724 (SD 0.056)),[35] but the TVI remained in line with the other samples of the same brand.

Depending on the type of radiation, energy is absorbed differently in polyethylene (Figure 4). The depth-dose curves for electron beam irradiation show that total absorption is expected within 5 to 6 cm (Figure 4a). For gamma irradiation with ^{60}Co, half the dose is absorbed at 11.3 cm depth (Figure 4b). Additionally, there is a build-up effect to consider for electron irradiation, increasing the effective dose over the first 3 to 4 cm (Figure 4a).

Wear rates determined with pin-on-disk tests were in the order of 0.2 to 3.3 mg/million cycles (MC) (Table II and Figure 5). This corresponds to wear factors in the range of 1.1 E-07 to 1.8 E-06 mm³/Nm. A non-linear relation was observed between wear and TVI, with lower wear being associated overall with higher TVI. Some exceptions were present. Highcross had a significantly higher wear than all other HXLPE, excluding Vitamys (mean 2.05 vs 0.4 mg/MC; $p < 0.001$, independent samples *t*-test). Also, the vitamin E-containing HXLPE Vitamys had slightly higher wear than all other HXLPE, excluding Highcross (mean 1.01 vs 0.4 mg/MC; $p = 0.030$, independent samples *t*-test). Durasul performed slightly better, but not significantly, than all other HXLPE, excluding Highcross and Vitamys (mean 0.34 vs 0.55 mg/MC; $p = 0.080$, independent samples *t*-test). Sulene showed relatively low wear despite being CPE, but having solely one sample resulted in limited analysis. Wear of the Sulene sample (0.73 mg/MC) was 117% higher than for Durasul (mean 0.34 mg/MC), and 83% higher than for all other HXLPE, excluding Highcross and Vitamys (mean 0.4 mg/MC). The unknown polyethylene was clearly CPE with gamma irradiation for sterilization.

Table II. Results of the measurements of the trans-vinylene index, the oxidation index, and wear rates from all the samples included.[22]

Manufacturer	Brand name	Type	Vit. E	Number of samples	Mean OI (SD)	Mean TVI_{1900} (SD)	Mean TVI_{1370} (SD)	Mean calculated irradiation, kGy (SD)	Mean calculated irradiation, % of specifications (SD) (p-value; 95% CI)	Mean wear in mg/MC (SD)
Corin	ECiMa	HXLPE	Yes	1	0.028	0.136	0.034	132	110	0.30
Implantcast	Implacross E	HXLPE	Yes	1	0.037	0.050	0.021	77	103	0.83
Mathys	Vitamys	HXLPE	Yes	3	0.058 (0.012)	0.144 (0.002)	0.040 (0.002)	155 (7)	119 (5) (0.250*; 115 to 125)	1.01 (0.23)
Medacta	Standard	CPE	No	1	0.036	0.0	0.0	-12	N/A	2.63
Medacta	Highcross	HXLPE	No	20	0.045 (0.031)	0.057 (0.015)	0.013 (0.003)	41 (13)	41 (13) (< 0.001*; 35 to 47)	2.05 (0.37)
Microport	Standard	CPE	No	1	0.020	0.0	0.0	-12	N/A	3.30
Smith & Nephew	XLPE	HXLPE	No	4	0.026 (0.010)	0.138 (0.022)	0.028 (0.003)	105 (12)	105 (12) (0.625*; 97 to 122)	0.54 (0.21)
Unknown	Unknown	Unknown	No	1	0.074	0.036	0.010	29	N/A	2.09
Zimmer Biomet	Sulene	CPE	No	1	0.076	0.042	0.012	36	N/A*	0.73
Zimmer Biomet	Durasul	HXLPE	No	14	0.084 (0.185)	0.281 (0.015)	0.058 (0.004)	229 (17)	241 (18) (< 0.001*; 231 to 251)	0.34 (0.15)
Manufacturer	**Brand name**	**Type**	**Vit. E**	**Number of samples**	**Median OI (range)**	**Median TVI_{1900} (range)**	**Median TVI_{1370} (range)**	**Median calculated irradiation, kGy (range)**	**Median calculated irradiation, % of specifications (range) (p-value; 95% CI)**	**Median wear, mg/MC (range)**
Corin	ECiMa	HXLPE	Yes	1	0.028	0.136	0.034	132	110	0.30
Implantcast	Implacross E	HXLPE	Yes	1	0.037	0.050	0.021	77	103	0.83
Mathys	Vitamys	HXLPE	Yes	3	0.059 (0.046 to 0.069)	0.145 (0.141 to 0.145)	0.039 (0.039 to 0.042)	152 (150 to 163)	117 (115 to 125) (1.000*; 115 to 125)	0.92 (0.84 to 1.26)
Medacta	Standard	CPE	No	1	0.036	0.0	0.0	-12	N/A	2.63
Medacta	Highcross	HXLPE	No	20	0.036 (0.012 to 0.117)	0.058 (0.034 to 0.086)	0.013 (0.008 to 0.019)	42 (21 to 68)	42 (21 to 68) (< 0.001*; 34 to 47)	2.10 (1.40 to 2.93)
Microport	Standard	CPE	No	1	0.020	0.0	0.0	-12	N/A	3.30
Smith & Nephew	XLPE	HXLPE	No	4	0.028 (0.013 to 0.035)	0.139 (0.115 to 0.157)	0.027 (0.026 to 0.032)	101 (97 to 122)	101 (97 to 122) (1.000*; 97 to 122)	0.56 (0.27 to 0.77)
Unknown	Unknown	Unknown	No	1	0.074	0.036	0.010	29	N/A	2.09
Zimmer Biomet	Sulene	CPE	No	1	0.076	0.042	0.012	36	N/A	0.73
Zimmer Biomet	Durasul	HXLPE	No	14	0.035 (0.016 to 0.724)	0.283 (0.252 to 0.301)	0.059 (0.050 to 0.064)	234 (198 to 255)	246 (208 to 269) (0.004*; 219 to 240)	0.32 (0.13 to 0.73)

TVI = trans-vinylene index, determined following the ASTM F2381 standard and normalized both for the peak at 1900 cm-1 (TVI1900) and for the peak at 1370 cm-1 (TVI1370). The irradiation dose was calculated based on the TV1370, using a previously published calibration curve for gamma-irradiated, remelted polyethylene, using the following formula: Irradiation dose in kGy = 4196.8 * TVI1370 - 12.331. This was shown to have a correlation factor r^2 = 0.9898.[22] OI = oxidation index, determined following the ASTM F2102-17 standard.

*For Sulene, a gamma irradiation ranging 25 to 40 kGy is specified for sterilization, the result corresponds to this range but no ratio is calculated for just one sample with an irradiation within the given range. For products with at least three samples available, the absorbed irradiation dose was compared to specifications using an independent-samples *t*-test (marked with *), respectively a Wilcoxon signed rank-test for smaller sample size.

CPE, conventional polyethylene; HXLPE, highly cross-linked polyethylene; MC, million cycles; N/A, not applicable; OI, oxidation index; TVI, trans-vinylene index; Vit. E, vitamin E.

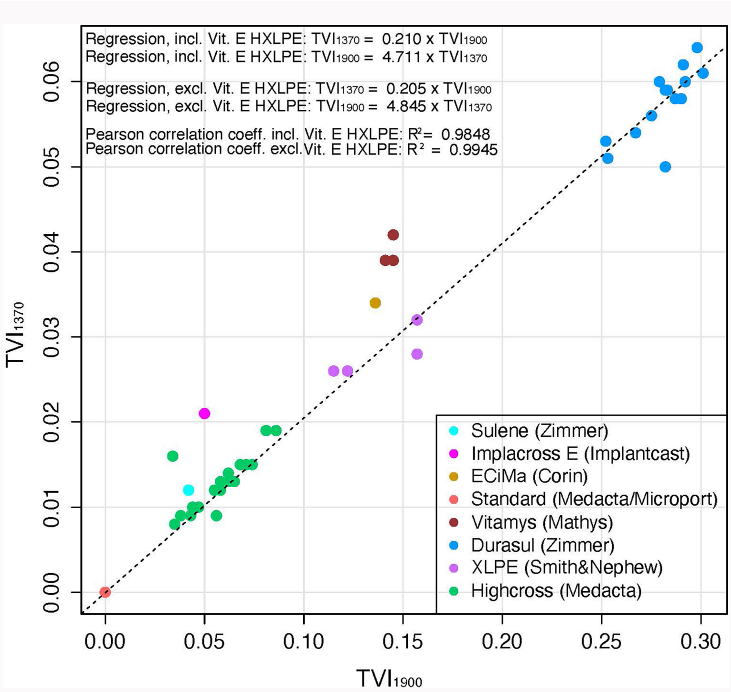

Fig. 1
Correlation of TVI_{1370} and TVI_{1900} measured on the 47 polyethylene samples included. There is a very good linear correlation ($R^2 = 0.9845$) between both TVI standards. Excluding the vitamin E blended samples, which behave slightly differently, the correlation increases to $R^2 = 0.9945$. Formulae for conversion from TVI_{1370} to TVI_{1900} and vice versa are provided in the figure. HXLPE, highly cross-linked polyethylene; TVI, trans-vinylene index.

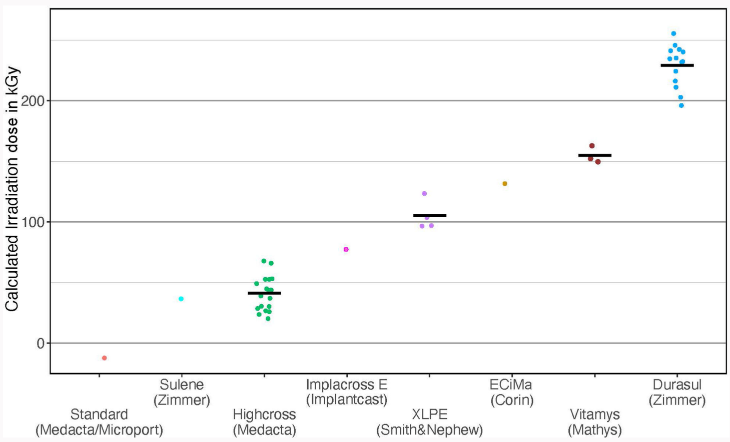

Fig. 2
The TVI_{1370} value measured on all the samples was converted to the absorbed irradiation dose, using the calibration curve for remelted highly cross-linked polyethylene (HXLPE) published previously. Results are grouped by product, with individual points indicating individual values. The horizontal bar indicates the mean. TVI, trans-vinylene index.

Discussion

In this study, the degree of cross-linking, as estimated by the TVI, and in vitro wear of polyethylene samples from a cohort of 47 retrieved as well as new THA acetabular liners/cups was determined. The TVI, and thereby the degree of cross-linking, clustered clearly by product, demonstrating a strong influence of the absorbed irradiation dose. While there appeared to be no linear relationship between TVI and in vitro wear rate, the materials with the lowest TVI exhibited higher wear rates compared to the others, with the one Sulene sample made from CPE being a notable exception. While a fairly large series of polyethylenes from various manufacturers used in THA could be analyzed, the cohort was limited to components collected during surgery at a single centre. Thus, the variety of samples and group sizes were limited by availability from a single hospital serving as regional referral centre and therefore by regional preponderance of implants.[36] This also explains the very high proportion of HXLPE liners in this series.[36] While it was not possible to test products from all major providers, this study nevertheless provides several important observations.

There was a strong agreement between both TVI standards. Older references performed normalizing against the peak at 1,900 cm^{-1} (TVI_{1900}),[19,20,33] whereas the ASTM standard requires normalization against the peak at 1,370 cm^{-1} (TVI_{1370}). Arguments in favour of one or the other would be considerations regarding which peak better measures

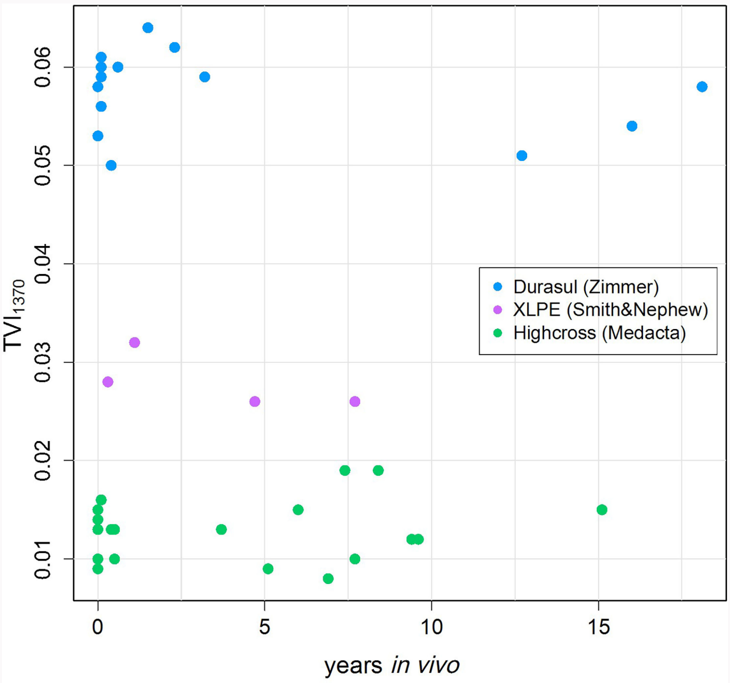

Fig. 3

Illustration of TVI_{1370}, as measured following the ASTM F2381-19 standard and grouped by brand, for the products with multiple samples available, including retrievals. There was no significant degradation of TVI over time, despite long exposure times in vivo, compared to new samples or retrievals with a shorter time in vivo. For Durasul (Zimmer Biomet), Pearson correlation over time R^2 = -0.301, for cross-linked polyethylene (XLPE) from Smith & Nephew R^2 = -0.703, and for Highcross from Medacta R^2 = 0.229. TVI, trans-vinylene index.

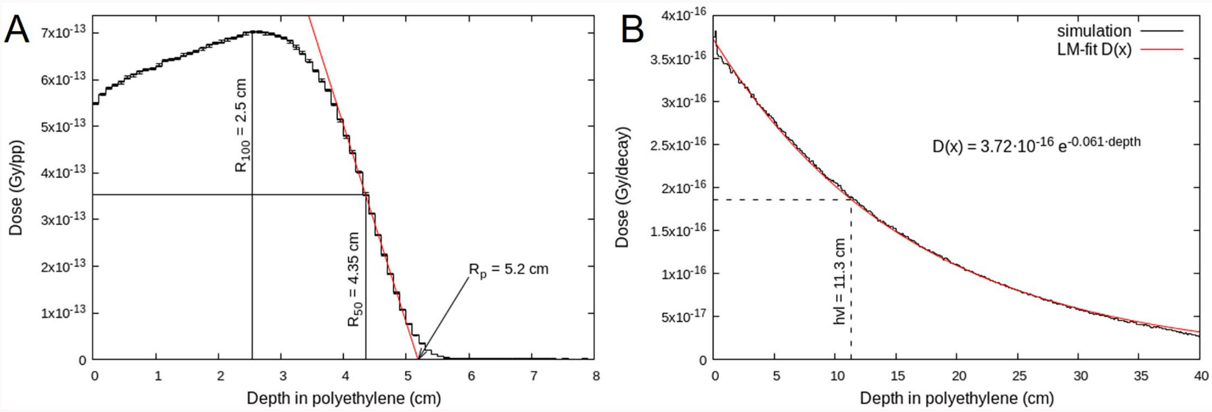

Fig. 4

Depth-dose curves in polyethylene for: a) 10 MeV electron beam (beta) radiation; and b) gamma radiation emitted by decay of ^{60}Co. Note that the dose maximum is 2.54 cm below the surface for electron beam radiation, followed by a rapid and complete absorption of the electrons at a depth of 5 to 6 cm. For gamma radiation, the decrease is exponential, with half value layer (hvl) at 11.3 cm of depth. Large volumes would require multidirectional irradiation to obtain homogenous dose absorption. Respectively, the maximum depth for electron beam irradiation would be approximately 10 cm applying bidirectional irradiation.

the amorphous or crystalline part of the polyethylene chains,[19,20,33,37,38] specifically how precisely the normalization peak can be defined on the scan. As TVI_{1900} provides a larger spread of values, it may provide a better differentiation. TVI_{1370} may, however, be more precise, as this normalization peak is easier to define and therefore less prone to errors. Regardless, both metrics had a linear relationship, independent of the irradiation dose applied within the observed range (conversion formulae provided in Figure 1). The ability to reliably convert results from the older to the current standard should be invaluable to incorporate evidence from older publications into modern studies.[19,20,22,33,34,37,39] The only deviation occurred for vitamin E blended HXLPE (Figure 1). Methylene groups of vitamin E are associated with a high peak at 1,377 cm^{-1}, potentially interfering with the normalization peak at 1,370 cm^{-1}. Another characteristic peak at 976 cm^{-1}, being rather wide, may interfere with the determination of the measured value at 965 cm^{-1}. Potential difficulties in interpretation of FTIR scans are illustrated in Figure 6. It remains to be seen if the old standard (TVI_{1900}) is more reliable for vitamin E added polyethylene. This study also demonstrated that the TVI does not alter with time in vivo

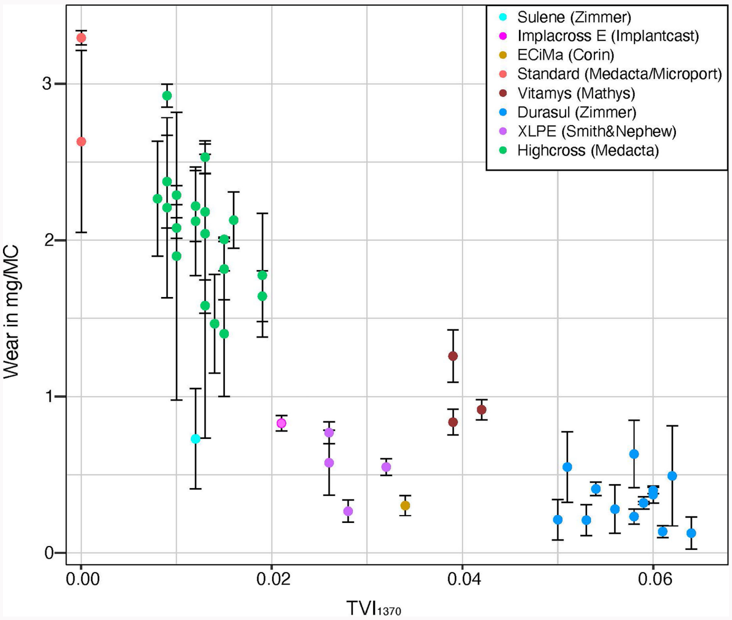

Fig. 5
Wear in dependence of TVI_{1370}, as determined in a modified pin-on-disk test. Dots mark mean values of n = 3 samples per liner/cup, colour-coded by brand. The error margin corresponds to the SD. There is a correlation between TVI and in vitro wear, with overall lower wear for higher TVI. TVI, trans-vinylene index; XLPE, cross-linked polyethylene.

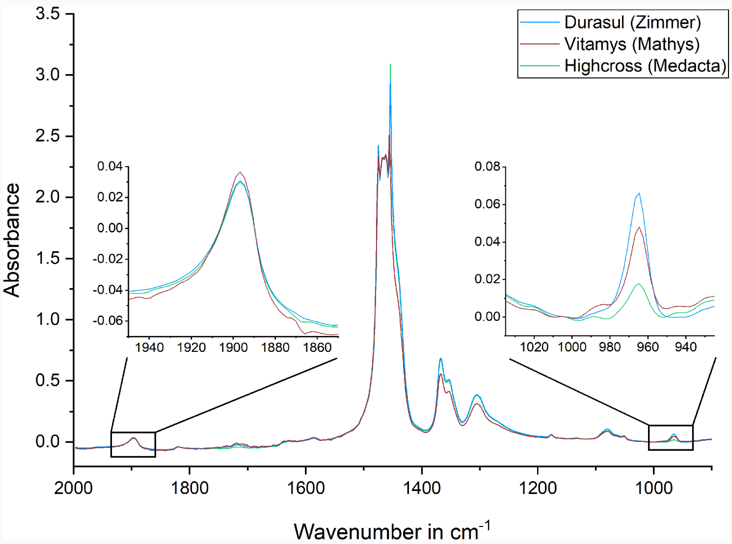

Fig. 6
Exemplary Fourier-transform infrared (FTIR) spectra of the cross-linked polyethylene (XLPE) Highcross, Durasul, and Vitamys, the latter being vitamin E blended. The trans-vinylene index (TVI) is the ratio between the area under the peak at 965 cm^{-1}, considered characteristic for vinylenes, and a normalization peak at 1,370 cm^{-1} (acc. ASTM F2381-19) or 1900 cm^{-1}. Note the differences between the materials as well as the relevance of minor differences, with a potentially larger effect on the results.

(Figure 3). As sampling was performed at least 2 mm below the surface of the liners/cups, oxidation did not interfere. In addition, none of the samples had an OI within a range expected to influence mechanical properties.[40] The TVI was shown to be a reliable measurement of the irradiation dose of polyethylene.[19,20,22,33,34,37–39] The differences in TVI between the various products were partly expected, considering specifications (Table I), but two products, Durasul (Zimmer Biomet) and Highcross (Medacta), provided unexpected results (Figure 2). For the former, the calculated absorbed irradiation dose was much higher than expected, despite TVI values within specifications,[41] while for the latter, the calculated absorbed irradiation dose was markedly below product specifications (Tables I and II, Figure 2).[22,23]

Cross-linking of Durasul is performed via electron beam irradiation (beta irradiation), while gamma irradiation (photons from decay of a radioisotope) is applied to most other products available in THA, either for cross-linking or for sterilization (Table I).[9,11,12,15,16,35] As ionizing radiation is defined as a quantity of absorbed energy by mass (Gy = J/kg), any difference in effect between both types of irradiation for identical doses is not obvious. Even the biological effect of both beta (electrons) and gamma (photons) irradiation is considered equivalent, but this incorporates biological repair processes.[42] Nevertheless, the effect on polyethylene may differ. The electrons used for the cross-linking process of Durasul are accelerated to an energy of 10 MeV.[43] ^{60}Co, the most commonly used radioisotope for gamma irradiation, emits two photons, one at 1.1732 and the other at 1.3325 MeV, while decaying to nickel. Absorption of both types of radiation in the given range of energy is quite similar, with penetration being limited. In water, a material with similar density to polyethylene, the majority is being absorbed within 6 to 8 cm for electrons and 10 to 20 cm for gamma irradiation.[44,45] Depth-dose curves for polyethylene treated with both types of irradiation (Figure 4) clearly show a significant absorption within the material. Measurements by another group using dosimeters sandwiched in between layers of polyethylene confirm the depth-dose curve for electron irradiation.[19] As the nominal dose is defined at the surface of the material being irradiated, the geometry of the sample is highly relevant. While the nominal irradiation dose may be identical, excessive volumes of material during the irradiation process may potentially explain inconsistencies in absorbed radiation and effect. This may remain undetected when using only thin polyethylene samples during development stages.[18,19,39] Samples of the Highcross showed a noticeable variability, with a TVI_{1370} varying from 0.008 to 0.019. Considering the known linear relation between TVI and irradiation dose within this dose range,[19,20,22,33,34] this represents a variability in absorbed ionizing radiation by a factor of approximately 2.4 from one product to another of this brand. The variability observed in all other products was proportionally far lower (Table II). According to manufacturer specifications, this product should have been exposed to a gamma irradiation of 100 kGy, applied in four steps using a ^{60}Co source (Table I).[22,23] Yet, the TVI measured from all Highcross samples indicates absorbed irradiation doses clearly below the expected values. This finding is unlikely to be a sampling error, because Highcross was the largest and only subgroup with the maximum of 20 samples included (Tables I and II, Figure 2), as the calibration curve used had been established with samples processed as for manufacture of this product,[22,23,46] and as the results of the other gamma-irradiated products corresponded to their individual specifications. The results in this series are in line with the TVI measured in another report, where revision was required for early failure of a HXLPE liner of the same brand.[22]

Application of other conversion models of gamma-irradiated polyethylene from the literature uniformly indicates an absorbed irradiation dose for Highcross far below XLPE, the only other gamma-irradiated HXLPE without vitamin E addition in this series, which also has the same specified irradiation dose of 100 kGy, of 52% at best[34] and mostly much less.[19,20,33] This observation aligns with the established linear relationship between TVI and irradiation dose within the dose range of interest,[19,20,22,33,34,37] even if there is a certain variability among the various formulae, as evidenced by the variability of the regression parameters (available in the Methods), considering the TVI values measured. Our model may however be considered more reliable, as it demonstrates closer adherence to specifications across other products (weighted by sample number $R^2 = 0.99$, excluding Highcross, Durasul, and the unknown CPE). In contrast, other models consistently underestimate absorbed irradiation by 20% to 30%[20,34] or more,[33] or largely overestimate the dose,[19] compared to specifications. Also, our calibration curve had been established using known manufacturing parameters of Highcross as far as possible,[22,23,46] limiting the risk of a generalization error.

Commonly, dose rates of 2 to 5 kGy/h are applied for gamma irradiation.[15] Thus, exposure times of around 24 hours are necessary to obtain 100 kGy for cross-linking of polyethylene by gamma radiation.[15] Reducing the dose rate from 2.5 kGy/h to 0.25 kGy/h approximately doubled the OI, but had no relevant effect on the TVI.[38] Without details provided, Highcross is indicated to be irradiated at a proprietary, low dose rate.[22,23] Thus, the dose rate is not a valid explanation for such absorbed radiation doses much lower than specifications observed throughout the samples of this brand. Expected values could be observed for all other gamma-irradiated polyethylenes (Table II and Figure 3). The electron beam irradiation for Durasul only lasts for several seconds, corresponding to a dose rate nearly 10,000 times higher than for gamma irradiation.[15] The short duration also allows warm irradiation with all polyethylene chains in an amorphous state, without crystalline phase, potentially facilitating cross-linking.[5,6,9,11,15,43] Such a high dose rate substantially heats up the material due to the absorbed energy. For irradiation with electrons accelerated to 1 MeV only, temperature increases of ~ 7°C/10 kGy have been reported.[17] Heating up by approximately 40°C was reported in a setup with electrons accelerated to 2.5 MeV, administered at 20 kGy/min to reach 25 kGy/pass.[18] Such heating up may interfere with dose verification, as classical dosimeters are temperature-dependent.[47] Additionally, there is a build-up effect for electron irradiation to consider (Figure 4a),[19] as interaction of electron radiation with any absorbing medium causes secondary radiation. Thus, Durasul may exhibit a much higher degree of cross-linking than any of the other products examined in this study, despite administration of a similar nominal irradiation dose. This may have remained unrecognized so far due to application of specific calibration curves.[41]

It should, however, not be forgotten that the TVI is a measure of the density of double bond carbon-carbon links (vinylenes) within the polyethylene chains, not a measure of cross-linking itself.[11,17–19,37,39] Vinylenes are created as kind of an aberrant cross-linking of two adjacent free radicals on the same polyethylene strand, forming instead of links between two separate strands.[11,17] Therefore, wear was determined using a pin-on-disk test.

Considering the geometry of the samples extracted from THA liners/cups, and the large number of samples to be tested, the ASTM F732-17 standard was modified to allow testing smaller samples over a reduced number of cycles (500,000 instead of two million cycles). Results from the pin-on-disk tests showed an inverse, non-linear relation between the TVI and wear (Figure 5). Previously, only an exponential decrease had been described.[10] This study, however, provides a larger distribution of measurement points. This test also confirmed that Highcross showed wear characteristics closer to CPE than to any of the other HXLPE tested (Table II and Figure 5). Highcross had a significantly higher wear than all other HXLPE, excluding Vitamys (mean 2.05 vs 0.4 mg/MC; $p < 0.0001$). Also, Vitamys had a slightly higher wear than all other HXLPE, excluding Highcross (mean 1.01 vs 0.4 mg/MC; p = 0.032). Of note, Vitamys is now no longer being sterilized with ethylene oxide, but rather by irradiation. TVI measurements corresponded with the expected total irradiation dose of 100 kGy for the cross-linking step and 30 kGy for final sterilization (Tables I and II). However, this modification of the manufacturing process introduced a second irradiation step after irradiation for cross-linking. The irradiation dose for sterilization, however, is similar to the one used for Sulene, a CPE associated with relatively good long-term revision rates.[48] Despite being CPE, the one sample of Sulene showed relatively low wear, comparable to HXLPE other than Highcross. This finding illustrates the importance of other manufacturing details than irradiation and thermal treatment. Comparison to the literature is often limited due to the lack of relevant technical details of pin-on-disk tests.[49,50] In particular, comparison to the wear curve provided in the product brochure of Highcross is not possible.[23] Of note, the reference indicated in this brochure corresponds to a conference abstract of a study of inflammatory reaction to polyethylene wear particles, and does not provide the presented pin-on-disk test data.

The tests performed in this study may also be used for characterization of unknown products, as recommended by other authors.[47] For correct interpretation of TVI, interference by oxidation must first be excluded. The one unknown sample appeared to be CPE, which had been sterilized by gamma irradiation. It is of note that products without any identification markings are still marketed in Europe, despite all the certification steps required by current legislation.

In conclusion, this study identified broad differences in TVI and in vitro wear rates between polyethylene THA liners/cups from various brands/manufacturers. Both new and retrieved components within each group had similar properties. The TVI was not altered over time in vivo. There is a clear correlation between the TVI and in vitro wear properties of the polyethylenes tested, with lower wear observed with higher TVI values. The much higher TVI observed in samples from Durasul may well indicate a much higher cross-linking density than for any other of the products tested, which may be explained by warm electron-beam irradiation instead of cold gamma irradiation, despite similar nominal irradiation doses. Further work is warranted to determine if in vivo wear rates match the in vitro wear rates observed here, and if wear correlates to early loosening, potentially due to particle-induced osteolysis. TVI measurements and calculated irradiation doses of the Highcross did not reach expectations according to specifications. In vitro wear resistance correlated as poor, more similar to CPE than to other HXLPE. THAs from Medacta exhibit higher revision rates in both the Swiss and Australian national arthroplasty registries than equivalent products from other manufacturers, even when considering other surgical factors.[36,47,51] Excessive wear may well be an explanation for early loosening observed in THA using Highcross liners, particularly in younger and more active patients, as observed in single institution studies.[52,53] Separating solely CPE and HXLPE may not be sufficient to identify properly the performance of individual products available in THA.[16]

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