stryker

X3®

Clinical evidence

Introduction

For over 20 years, Stryker has pioneered polyethylene-bearing technology for joint replacement. With each iteration, the objective remained the same: reduce wear through crosslinking without sacrificing strength or oxidation resistance.

In 1996, Stryker debuted Duration, its first moderately crosslinked polyethylene, which employed a single-step process with 3MRads of gamma radiation and annealing. Early Duracon TKA devices were implanted with Duration, and Duracon showed 92.8% survivorship at 16 years in the 2017 Australian Joint Registry.[1] A recent TKA study from the Journal of Arthroplasty showed 95.6% survivorship at a minimum follow-up of 10 years with Duration polyethylene.[2]

Stryker enhanced its polyethylene offering for hips in 1998 with its first-generation highly cross-linked polyethylene, Crossfire. Crossfire featured a total of 10.5 MRads of gamma radiation through its single-step process of irradiation, thermal treatment and sterilization. A THA study from the Journal of Arthroplasty reported an average 0.03 mm/year linear wear rate and 100% survivorship at a mean follow-up of 14 years with Crossfire polyethylene.[3] Furthermore, a recent clinical study of Crossfire showed a mean 0.056 mm/year linear wear rate at 18-year follow-up.[4]

Building upon the clinical success of Duration[1,2] and Crossfire,[3-5] Stryker further advanced its polyethylene with the introduction of X3 in 2005. X3 features a patented[6] three-step process of irradiation with 3MRads (total 9MRads) of gamma radiation and annealing.[7] This particular development of X3 allows for wear resistance,[8,9] mechanical strength[10] and oxidation resistance[11] without the use of additives. Stryker's irradiation and annealing process for X3 has not changed since its development, allowing X3 to maintain its core properties and positive performance attributes. Since its first use in orthopaedics, there have been over 5 million X3 implantations worldwide across hip and knee arthroplasty.[12] The significant amount of clinical and joint registry data on X3 supports its use in TKA[1,14,16,18] and THA.[19-24]

Clinical outcomes

This compendium serves to showcase the clinical evidence on X3 across Stryker's knee and hip portfolios.

Knee

Oxidation, Damage Mechanisms, and Reasons for Revision of Sequentially Annealed Highly Crosslinked Polyethylene in Total Knee Arthroplasty[13]

Authors: D.W. MacDonald, G.B. Higgs, A.F. Chen, A. Malkani, M.A. Mont, S.M. Kurtz.

Journal: The Journal of Arthroplasty. 2018;33(4):1235-1241.

Study materials and methods

A total of 456 revised tibial inserts from 2 cohorts (X3 sequentially annealed, N2Vac control) were collected in a retrieval program from 15 surgical centers. The study compared the outcomes of X3 HXLPE and N2VAC conventional polyethylene that were retrieved between 0 and 9.5 years.

Results

None of the inserts examined in the study were subject to mechanical failures related to oxidative damage. The control cohort had more cumulative surface damage, backside damage, subsurface fatigue, and cracking, as well as more burnishing than the HXLPE cohort. Kurtz et al. studied the largest cohort of X3 retrievals commissioned for any published study to date, showing that X3 exhibits a similar profile for oxidation in-vivo to conventional polyethylene.

Multicenter Study of Highly Cross-linked vs Conventional Polyethylene in Total Knee Arthroplasty[14]

Authors: R. M. Meneghini, P.H. Ireland, M. Bhowmik-Stoker.

Journal: The Journal of Arthroplasty. 2016;31(4):809-814

Study materials and methods

A prospective multicenter study of 307 posterior-stabilized TKAs (168 conventional and 139 X3 HXLPE) was performed. 224 TKAs (129 conventional and 99 X3) were available for analysis at a minimum 4- to 5-year follow up. Radiographs, Knee Society Score (KSS), Lower Extremity Activity Score (LEAS), Short-Form-6D health-related quality of life outcomes, and Short-Form 36 were collected preoperatively and evaluated postoperatively at 6 weeks, 3 months, 1 year, and annually out to 5 years. The Mental Composite Score and Physical Composite Score (PCS) of the Short-Form 36 were reported.

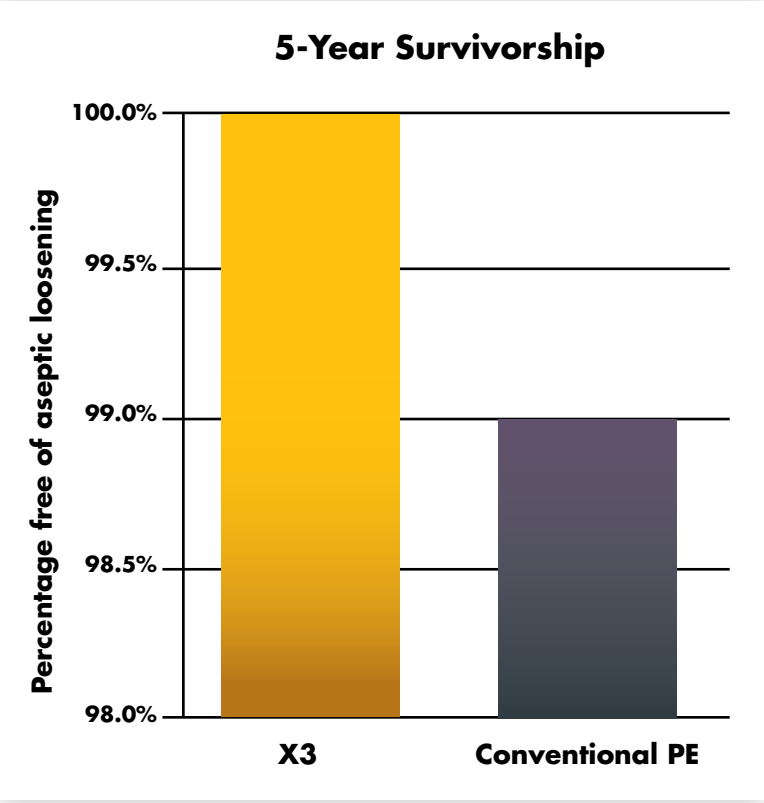
Results

No mechanical failure or radiographic osteolysis was observed with either conventional or HXLPE in this PS single radius TKA design at midterm follow-up. The HXLPE group showed statistically significant greater mean KSS and SF-36 physical function subset at latest follow-up. The other tests showed similar results between the two materials. The study findings support comparative safety and outcomes of HXLPE in TKA.

Randomized Clinical Trial of Conventional vs. Highly Cross-Linked Polyethylene in Total Knee Arthroplasty[15]

Authors: M. Abdel, A Viste, C. Ortiguera, H. Clarke, M. Spangehl, M. Pagnano, A. Hanssen, and M. Stuart.

Presented at: AAHKS 26th Annual Meeting; November 10-13, 2016; Dallas, TX



Study materials and methods

A multicenter randomized control trial of 396 TKA patients (194 PE and 202 X3 HXLPE) was performed. Survivorship rate was evaluated between conventional polyethylene and X3 at a mean 5-year follow-up. All patients received a Triathlon cemented PS fixed-bearing insert.

Results

Both groups showed good survivorship with 99% of the conventional group free of aseptic loosening and 100% of the X3 group free of aseptic loosening.

X3 Clinical evidence

Clinical and Patient-reported Outcomes of Primary TKA With a Single-radius Design[16]

Authors: S. Harwin, K. Issa, K. Given, K. Hitt, K. Greene, R. Pivec, M. Kester, M. Mont.

Journal: Orthopedics. 2013;36(7): e877-e882.

Study materials and methods

A prospective multicenter study of 287 TKAs from 7 centers evaluated for survivorship, Knee Society Score, Short Form 36, and activity scores. Kaplan-Meier analysis was used for implant survivorship. Mean follow-up was 5 years, with each patient undergoing year re-evaluation. Patients undergoing TKA had either an N2Vac or X3 polyethylene insert.

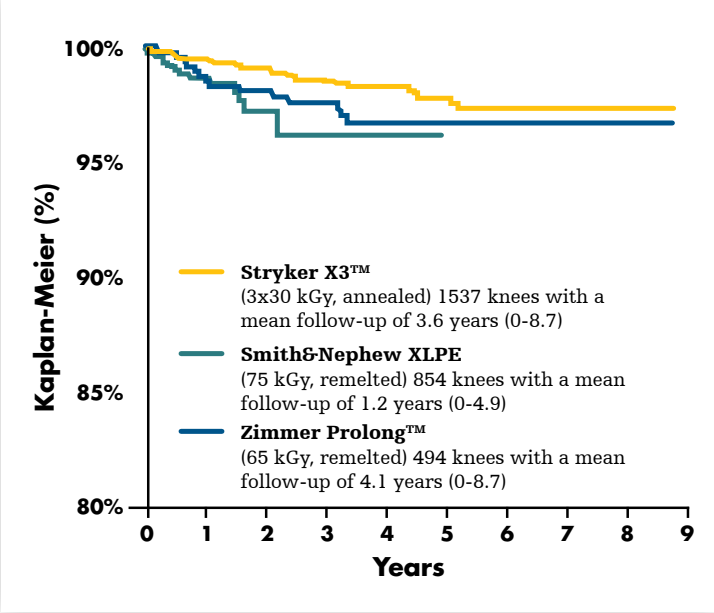
Results

Results showed Triathlon survivorship at 99.7% (excluding infection) with no revisions for mechanical failure of the insert at a final follow-up of 7 years. Clinical outcomes demonstrated significant improvements in Knee Society, Short Form 36, and activity scores at a mean follow-up of 5 years.

Is Cross-Linked Polyethylene an Improvement Over Conventional Ultra-High Molecular Weight Polyethylene in Total Knee Arthroplasty?[17]

Authors: B. Boyer, B. Bordini, D. Caputo, T. Neri, S. Stea, A. Toni.

Journal: The Journal of Arthroplasty. 33(3):908-914.



Study materials and methods

A study analyzing the Emilia-Romagna Italian registry was conducted to measure the effect of cross-linking on TKA survival. Patient data from 2000-2015 in the Emilia-Romagna Italian registry was assessed. Kaplan-Meier analysis on survivorship was performed among the most common HXLPE in the registry. All three HXLPE use different manufacturing processes: annealing (X3) and remelting (Smith & Nephew HXLPE and Prolong).

Results

No differences were found when looking at survival for any cause or aseptic loosening. Wilcoxin test (Gehan-Breslow method) analysis found X3 to have statistically significant (P=.036) greater survivorship than Prolong or Smith & Nephew XLPE.

Joint registry data

International joint registries are important to analyzing the success of an implant as they incorporate large numbers of patients undergoing arthroplasties to analyze implant revisions.

Australian Joint Registry[1]

Triathlon shows strong results with X3 polyethylene in registries around the world.[1,18] The Australian Joint Registry data has shown there is a long-term benefit in preventing loosening using HXLPE compared to non-HXLPE. The registry also states there is an increase in survivorship at 10 years with Triathlon PS and X3 compared to non-HXLPE, with a sample size of thousands of patients.[1]

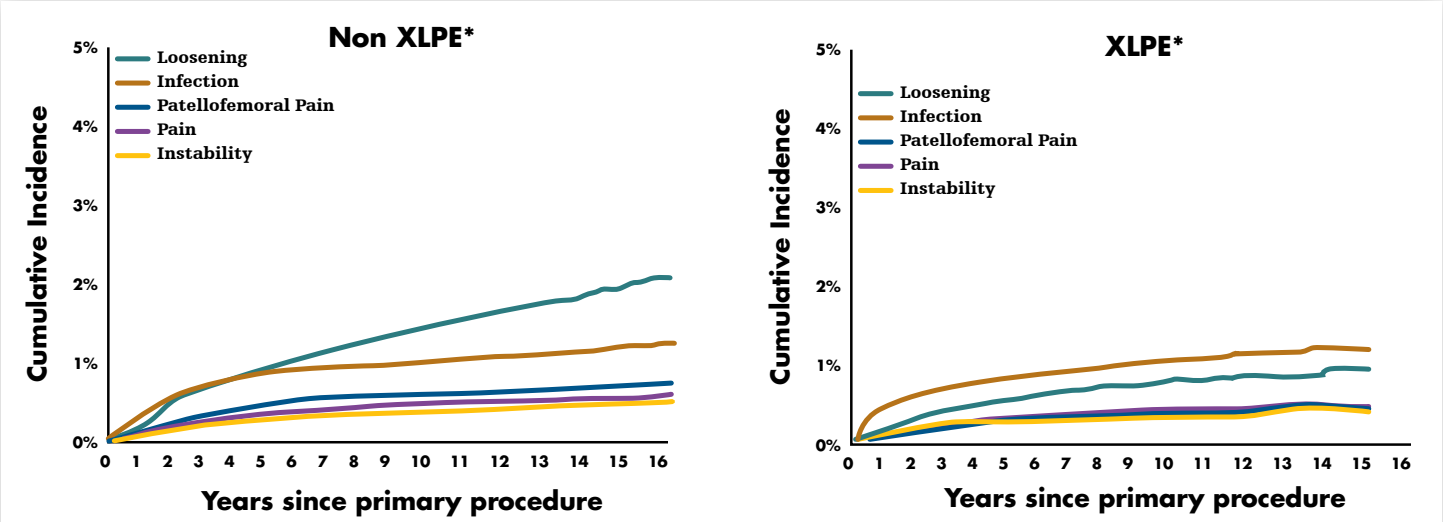


*Figure KT32 in 2017 Australian Joint Registry. Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement by Polyethylene Type (Primary Diagnosis OA)

Hip

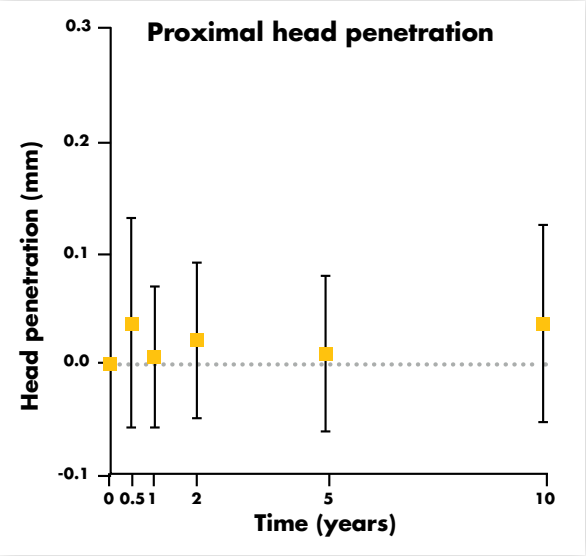
Wear of a Second-Generation XLPE Liner Remains Low at 10 Years: An RSA Study[19]

Authors: D. Campbell, S. Callary, and J. Field.

Presented at: 2017 ANZORS-RSA Joint Conference; October 6-8, 2017; Adelaide, SA, Australia.

Study materials and methods

A prospective study of 21 THA patients were evaluated for X3 HXLPE liner wear. All patients received a primary cementless implant with an X3 insert and a 32 mm head articulation. RSA radiograph analysis was used to measure mean wear at 10-year follow-up.



Results

The median proximal, two-dimensional, and three-dimensional wear rates calculated showed an overall 10-year wear rate of less than 0.01 mm/year, with no patient recording a wear rate of more than 0.040 mm/year. No increases in wear rate were reported between 5 and 10 years.

Wear Rates with Large Metal and Ceramic Heads on a Second Generation Highly Cross-Linked Polyethylene at Mean 6-Year Follow-Up[20]

Authors: M. Gaudiani, P. White, N. Ghazi, A. Ranawat, and C. Ranawat.

Journal: The Journal of Arthroplasty. 33(2):590-594.

Study materials and methods

A retrospective study assessed 120 THA patients for linear and volumetric wear rates between large metal and ceramic head cohorts. 60 patients who received a non-cemented THA with a 32- or 36-mm delta ceramic head were matched against 60 THAs with a 32- or 36-mm metal head. Both cohorts had X3 bearings and patients were evaluated at mean 6-year follow-up.

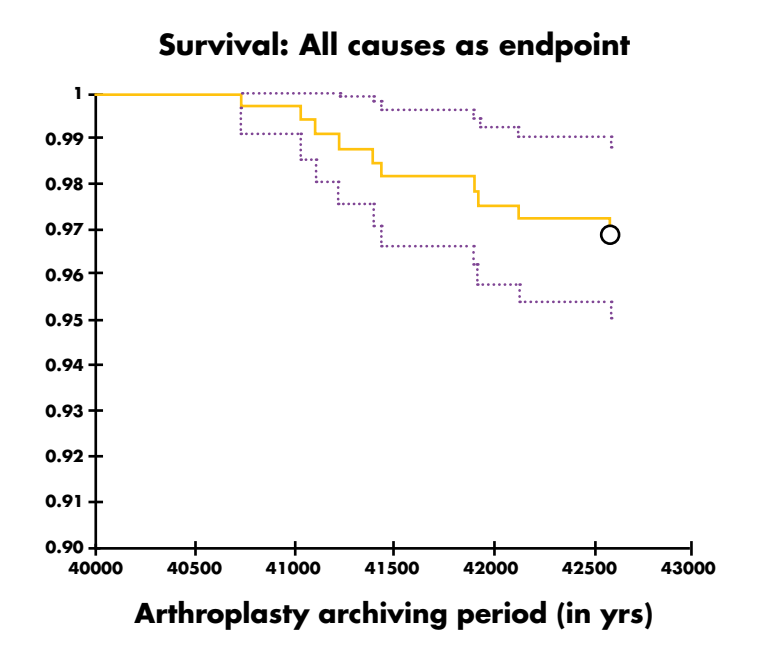
Results

There were no significant differences in mean linear wear rates with 0.012 mm/y and 0.017 mm/y wear reported for metal and ceramic groups, respectively. Radiographic analysis revealed no instances of osteolysis on AP or false profile radiographs. The researchers believed the tribological properties of X3 contribute to the low wear rate.

Early Experience with Dual Mobility Acetabular Systems Featuring Highly Cross-Linked Polyethylene Liners for Primary Hip Arthroplasty in Patients Under Fifty-Five Years of Age: An International Multi-Centre Preliminary Study[21]

Authors: J. Epinette, S. Harwin, F. Rowan, P. Tracol, M. Mont, M. Chughtai, G. Westrich.

Journal: International Orthopaedics. 2017;41(3):543-550.



Study materials and methods

An international multi-center observational study evaluated 321 THA patients for implant survivorship at 5-year follow-up. All patients received a dual mobility acetabular system with an X3 liner. Patients were assessed for causes of revision, hip instability, intra-prosthetic dissociation, Harris hip score and radiological signs of osteolysis. Kaplan-Meier analysis was used to measure survivorship.

Results

Stryker's dual mobility acetabular systems with X3 liners demonstrated 97.51% survivorship for all cause revision and 99.68% survivorship for acetabular component revision at 5-year follow-up. There were no reported dislocations and no intra-prosthetic dissociations.

Second-Generation Annealed Highly Crosslinked Polyethylene has Low Wear at Mean Seven Year Follow-up[22]

Authors: J. D'Antonio, J. Mesko, W. Capello, R. Ramakrishnan.

Journal: Surgical Technology International. 2014;25:219-226.

Study materials and methods

A prospective multicenter trial assessed 118 THA cases for linear wear measurement. All patients received a cementless titanium acetabular shell with an X3 insert. Patients were evaluated yearly through 5 years with 43 of the original cohort available for 7-year follow-up. Radiograph analysis was performed to measure linear head penetration.

Results

The mean linear wear rate was reported at 0.015 mm/yr at both 5 and 7-year follow-up. No osteolysis was found and no revisions for bearing surface failure occurred.

Comparison of Wear Rate and Osteolysis Between Second-Generation Annealed and First-Generation Remelted Highly Cross-Linked Polyethylene in Total Hip Arthroplasty. A Case Control Study at a Minimum of Five Years[23]

Authors: R. Takada, T. Jinno, D. Koga, K. Miyatake, T. Muneta, A. Okawa.

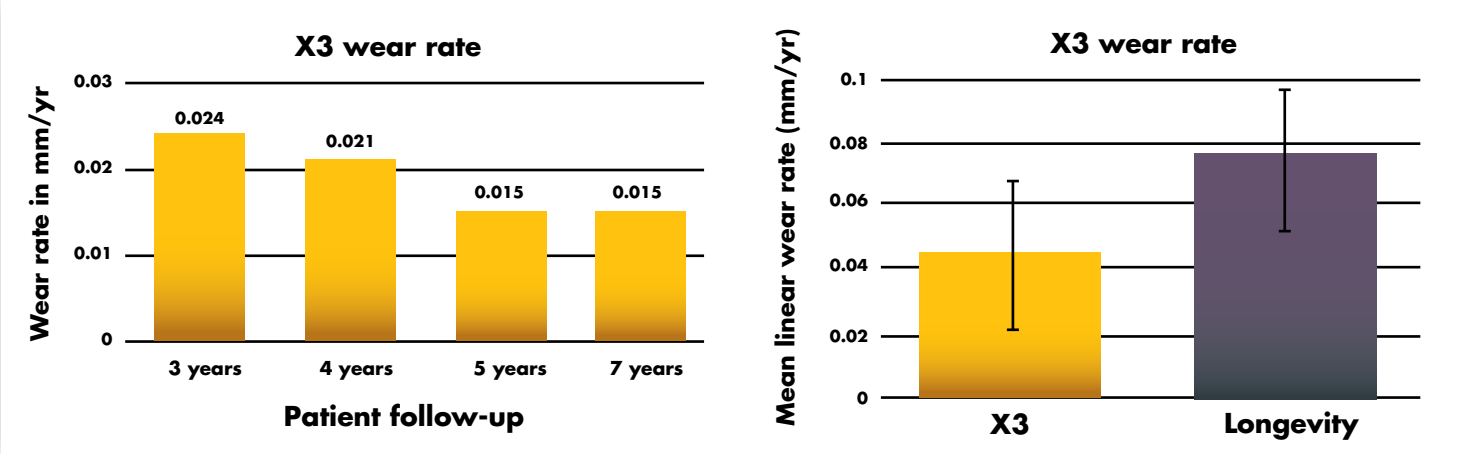
Journal: Orthopaedics and Traumatology: Surgery and Research. 103(4):537-541.

Study materials and methods

In a single center study, 109 THA patients were evaluated for mean wear rate and the incidence of osteolysis at minimum 5-year follow-up. Patients received either a second-generation annealed polyethylene (X3) or a first-generation re-melted (Longevity) highly cross-linked polyethylene liner. X3 and Longevity were used in 54 and 55 cases, respectively.

Results

The mean linear wear rate of X3 (0.045 ± 0.023 mm/yr) was significantly lower than Longevity (0.076 ± 0.031 mm/year). No osteolysis was found on plain X-rays in both groups and no specific complication was related to these highly cross-linked components.



Comparative Results from a National Joint Registry Hip Data Set of a New Cross Linked Annealed Polyethylene vs Both Conventional Polyethylene & Ceramic Bearings[24]

Authors: J. Epinette, B. Jolles-Haeberli.

Journal: The Journal of Arthroplasty. 31(7):1483-1491.

Study materials and methods

Data released by the National Joint Registry of England and Wales addressing 45,877 hips with the same Trident uncemented cup was used in two comparative global studies analyzing survivorship rates. The first study compared HXLPE acetabular bearings (X3: 21,420) to conventional polyethylene (N2vac: 8225). The second study measured a X3 cohort of 5232 cases to a ceramic-on-ceramic bearing cohort of 16,182 cases. Both studies assessed patients at 6-year follow-up. The main endpoint in survivorship was first defined as revision related to a failure of the bearing couple.

Results

A statistically significant higher cumulative survivorship rate was observed in X3 liners (99.6%) compared to conventional ultrahigh molecular weight polyethylene liners (98.8%). In the second parallel study, X3 (99.8%) showed a statistically significant better survivorship rate compared to CoC bearings (99.4%).

Comparative survival rates at 6 yrs in study A (X3 vs N2vac Liners)

Endpoint	X3		N2vac		Rank	P Value
	N	Survival (%)	N	Survival (%)		
Bearing related	21,470	99.6	8,525	98.8	X3>N2vac	P<.0001

Comparative survival rates at 6 yrs in study B (X3 vs CoC Bearings)

Endpoint	X3		CoC		Rank	P Value
	N	Survival (%)	N	Survival (%)		
Bearing related	5,232	99.8	16,182	98.4	X3>CoC	P<.0001

References

1. National Joint Replacement Registry. Hip, Knee & Shoulder Arthroplasty Annual Report 2017. Australian Orthopaedic Association; 2017.
2. Jauregui JJ, Cherian JJ, Pierce TP, Beaver WB, Issa K, Mont MA. Long-term survivorship and clinical outcomes following total knee arthroplasty. J Arthroplasty. 2015;30(12):2164-2166. doi:10.1016/j.arth.2015.05.052
3. Gaudiani MA, Ranawat AS, Ranawat CS. Wear analysis of highly cross-linked polyethylene in young and active patients at average fourteen years: a concise follow-up of a previous report. J Arthroplasty. 2018;33(2):586-589. doi:10.1016/j.arth.2017.09.007
4. Feng JE, Novikov D, Chen K, et al. Up to 18-year follow-up wear analysis of a first-generation highly cross-linked polyethylene in primary total hip arthroplasty. J Arthroplasty. 2018;33(10):3325-3328. doi:10.1016/j.arth.2018.06.013
5. D'Antonio J, Capello WN, Ramakrishnan R. Once annealed highly cross-linked polyethylene exhibits low wear at 9 to 15 years. Orthopedics. 2016;39(3):e565-e571. doi:10.3928/01477447-20160414-03
6. Wang A, Dumbleton JH, Essner A, Yau S, inventors; Howmedica Osteonics Corp, assignee. Sequentially cross-linked polyethylene. US patent 7,517,919. April 14, 2009.
7. Wang A, Zeng H, Yau S-S, Essner A, Manely M, Dumbleton J. Wear, oxidation and mechanical properties of a sequentially irradiated and annealed UHMWPE in total joint replacement. J Phys D Appl Phys. 2006;39(15):3213-3219. doi:10.1088/0022-3727/39/15/S12
8. Bonutti P, Essner A, Herrera L, Longaray J, Kester M. Influence of design and bearing materials on wear: comparing two different TKA designs. Poster presented at: 25th Annual Congress of the International Society for Technology in Arthroplasty; October 3-6, 2012; Sydney, Australia.
9. Stryker Test Report RD-13-109. Wear evaluation of a hindered-phenol polyethylene compared to X3 polyethylene. 2013.
10. Yau S-S Essner A, Manley MT, Dumbleton JH. Sequential irradiation and annealing of highly crosslinked polyethylenes: resist oxidation without sacrificing physical/mechanical properties. Poster presented at: 51st Annual Meeting of the Orthopaedic Research Society; February 20-23, 2005; Washington, D.C.
11. Yau S-S, Le K-P, Blitz JW, Dumbleton JH. Real-time shelf aging of sequential crosslinked and annealed UHMWPE. Poster presented at: 55th Annual Meeting of the Orthopaedic Research Society; February 22-25, 2009; Las Vegas, NV.
12. Sales data on file at Stryker.
13. MacDonald DW, Higgs GB, Chen AF, Malkani AL, Mont MA, Kurtz SM. Oxidation, damage mechanisms, and reasons for revision of sequentially annealed highly crosslinked polyethylene in total knee arthroplasty. J Arthroplasty. 2018;33(4):1235-1241. doi:10.1016/j.arth.2017.09.036
14. Meneghini RM, Ireland PH, Bhowmik-Stoker M. Multicenter study of highly cross-linked vs conventional polyethylene in total knee arthroplasty. J Arthroplasty. 2016;31(4):809-814. doi:10.1016/j.arth.2015.10.034
15. Abdel MP, Viste A, Ortiguera CJ, et al. Randomized clinical trial of conventional vs. highly cross-linked polyethylene in total knee arthroplasties. Poster presented at: AAHKS 26th Annual Meeting; November 10-13, 2016; Dallas, TX.
16. Harwin SF, Issa K, Given K, et al. Clinical and patient-reported outcomes of primary TKA with a single-radius design. Orthopedics. 2013;36(7):e877-e882. doi:10.3928/01477447-20130624-17
17. Boyer B, Bordini B, Caputo D, Neri T, Stea S, Toni A. Is cross-linked polyethylene an improvement over conventional ultra-high molecular weight polyethylene in total knee arthroplasty? J Arthroplasty. 33(3):908-914. doi:10.1016/j.arth.2017.10.005
18. National Joint Registry for England, Wales and Northern Ireland and Isle of Man. 14th Annual Report. 2017.
19. Campbell D, Callary S, Field J. Wear of a second-generation XLPE liner remains low at 10 years: an RSA study. Abstract presented at: 2017 ANZORS-RSA Joint Conference; October 6-8, 2017; Adelaide, SA, Australia.
20. Gaudiana MA, White PB, Ghazi N, Ranawat AS, Ranawat CS. Wear rates with large metal and ceramic heads on a second generation highly cross-linked polyethylene at mean 6-year follow-up. J Arthroplasty. 33(2):590-594. doi:10.1016/j.arth.2017.09.006
21. Epinette JA, Harwin SF, Rowan FE, et al. Early experience with dual mobility acetabular systems featuring highly cross-linked polyethylene liners for primary hip arthroplasty in patients under fifty five years of age: an international multi-centre preliminary study. Int Orthop. 2017;41(3):543-550. doi:10.1007/s00264-016-3367-0
22. D'Antonio JA, Capello WN, Mesko JW, Ramakrishnan R. Second-generation annealed highly crosslinked polyethylene has low wear at mean seven year follow-up. Surg Technol Int. 2014;25:219-226.
23. Takada R, Jinno T, Koga D, Miyatake K, Muneta T, Okawa A. Comparison of wear rate and osteolysis between second-generation annealed and first-generation remelted highly cross-linked polyethylene in total hip arthroplasty. A case control study at a minimum of five years. Orthop Traumatol Surg Res. 103(4):537-541. doi:10.1016/j.otsr.2017.02.004
24. Epinette JA, Jolles-Haeberli BM. Comparative results from a national joint registry hip data set of a new cross-linked annealed polyethylene vs both conventional polyethylene and ceramic bearings. J Arthroplasty. 31(7):1483-1491. doi:10.1016/j.arth.2015.12.041

stryker

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

t: 201 831 5000

Orthopaedics

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker's product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. The products depicted are CE marked according to the Medical Device Regulation 2017/745 or the Medical Device Directive 93/42/EEC. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

Please contact your sales representative if you have questions about the availability of products in your area.

X3-COM-10_Rev-1_24099