

Polyethylene Properties

(The major role of.....)

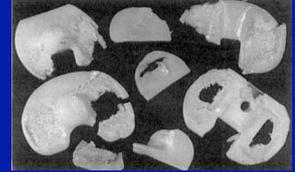
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Accelerated TKA Wear

- A problem of the 80s & 90s
- Caused by gamma irradiation in air sterilization
- Not a material problem



Williams et al, CORR, 1998

Accelerated TKA Wear

- Efforts to improve wear by changing the properties of poly failed miserably
 - Carbon-fiber reinforced polyethylene
 - Heat pressed polyethylene
 - Hylamer-M polyethylene
- The solution - *changing the method of sterilization*
 - Non-gamma
 - Gamma in inert environment

Non-Radiated Poly Always Performed Extremely Well

32 Ethylene Oxide:

- No delamination
- Negligible oxidation
- Penetration rate: < .1 mm/yr



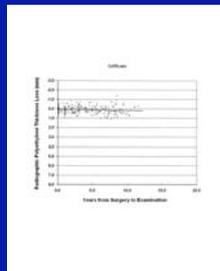
6 implants in vivo >15 years

Williams, CORR 1998

Low Dose Gamma-In-Inert Poly Has Very Low Wear Rates

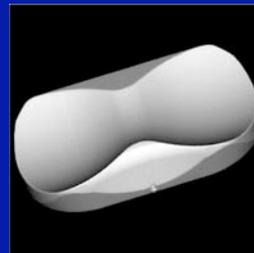
- 64 AMK implants
- 1.9-3.9 kGy (barrier package)
- 5-12 year follow-up
- Linear wear rates: 0.02mm/yr

Collier, JBJS 2008

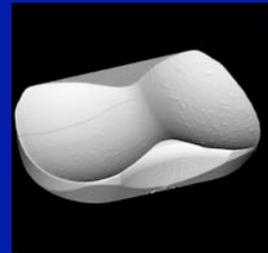


Volumetric Wear Rates

- MicroCT Scans: resolution 92 microns
- Annual volumetric wear rates 41.8 mm³



New Tibial Insert



Retrieved Tibial Insert

Wear of Conventionally Sterilized Tibial Inserts vs. Acetabular Cup Liners

Retrieval Study Wear Rates

	Linear (mm/year)	Volumetric (mm ³ /year)
Tibial Inserts	0.04	41.8
Acetabular Cup Liner	0.19	87.6

Results- Conventionally sterilized tibial inserts exhibit ¼ the linear wear and less than ½ the volumetric wear of acetabular cup liners.

Engh GA, *J Arthroplasty* 2009
 Engh CA Jr., *J Arthroplasty* 2006
 Heisel C, *JBJS* 2004

The Case Against Highly Cross-linked Polyethylene for TKA

- Reduced tensile strength ? > fatigue wear
- Smaller wear particles > bio-reactivity
- No clinical studies to date of reduced wear

Pitting (a form of fatigue wear) is greater even with low dose gamma-irradiated poly.

Gamma-Irradiated

111 Tibial Inserts
 In situ: 28.3 months

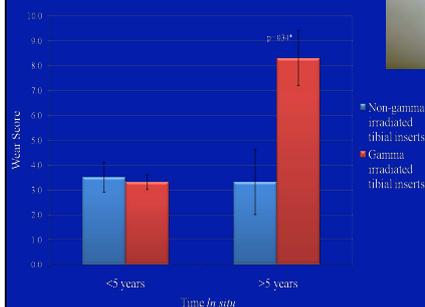
Gas Plasma

45 Tibial Inserts
 In situ: 31.9 months

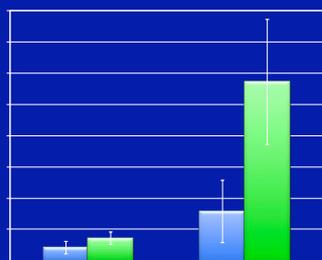
AORI Retrievals

Topside Pitting

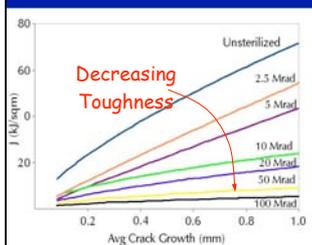
Topside Articular Surface Pitting Scores for Non-gamma vs. Gamma Irradiated Tibial Inserts



Backside Pitting



The Case Against Highly Cross-linked Polyethylene for TKA



Gillis et al, 1999

Highly Cross-linked Poly Has Reduced Strength

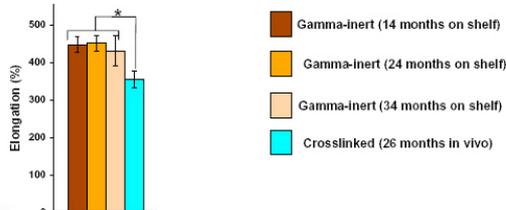


Image modified with permission from authors: Currier BH, Currier JH, Wright TM. COMSS Scientific Exhibit No. SE74 Characterization of Polyethylene Tibial Bearings of the Present. Presented 73rd AAOS Annual Meeting, Chicago, IL, March 2006.

Wear Debris Is Smaller And More Bio-Reactive

- A larger fraction of highly cross-linked particles were between 0.2 – 1.0 μm
- These particles have a more robust inflammatory response

J Huddleston, ORS 2006

Wear Debris Is Smaller And More Bio-Reactive

- 5-10 Mrad poly produced smaller particles (0.1-1.0 μm)
- TNF-alpha production stimulated with 0.1 μm^3 cross-linked poly, but only with 10 μm^3 non cross-linked poly

Ingram, Biomat, 2004

Wear Debris Is More Bio-Reactive

- In vivo calvarial model
- Cross-linked debris at 10MRad was more inflammatory than non cross-linked debris ($p < 0.05$)

Forsythe, 52nd ORS meeting

Wear Debris

Cellular response to wear debris

↑ Cross-linking ↓ Debris Size
↓ Debris Size ↑ Cellular Response

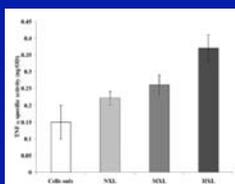


Figure 1: increased TNF- α activity for highly cross-linked poly debris

Image from Fisher J CORR 2004;428:114-119.

Retrieval Wear Scores

- 13 highly cross-linked (95kGy) tibial insert versus 18 g-nitrogen (25-40kGy) tibial insert
- No difference in % of pre- or post-melt surface damage

Willie et al, J Bio Med Mat Res, 2007

Highly Cross-linked Polyethylene

Retrieval Studies

	Total Wear Score
Highly Cross-linked	47.3 ¹
Conventional	58.6 ¹

Results: Highly cross-linked poly did not outperform conventional polyethylene sterilized by methods other than gamma-air²

¹ Muratoglu O JOA 2003;18(7):42-47.

² Willie B J Biomed Mater Res Part B: Appl Biomater 2007.

FDA-Reports of Implant Fractures

	Durasul (2001-2007) Highly Cross-linked E-beam	Sulene (1995-2007) Cross-linked (γ-inert)
tibial polyethylene insert fracture	7	1
all-polyethylene patella pegs shearing off	8	0

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

FDA-Reported Complications

	Durasul (2000-2007) Highly Cross-linked E-beam (95 kGy, No Free Radicals)
Revisions due to osteolysis	8
Years to revision due to osteolysis (Mean ± SD)	3.8 ± 1.3

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

Highly crosslinked poly for TKA *is a bad idea because.....*

- 1) Non-radiated poly has performed extremely well with TKA
- 2) Highly cross-linked poly has reduced strength
- 3) Wear-debris from highly cross-linked poly is smaller and more bio-reactive
- 4) Early retrieval studies show no improvement in either wear or osteolysis with highly cross-linked poly

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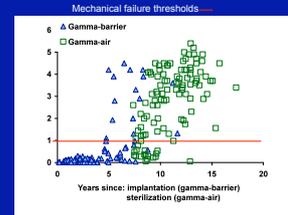
Thank You

Conclusions

- The use of highly x-linked poly for total knee arthroplasty comes with some risks and no proven benefits.
- Low dose gamma-in-inert poly has more pitting than non-irradiated poly.
- Clinical data that clearly proves that benefits out way risks is essential before the widespread use of highly crosslinked poly.

High Activity, Low Wear What wouldn't I use?

- Gamma-irradiated poly not annealed



Results: Gamma-barrier polyethylene continues oxidizing in vivo. Currier - KS Specialty Day 08

Polyethylene currently on the market Conventional Polyethylene

Manufacturer	Product name	Resin	Fabrication	Sterilization	Radiation Dose	Annealing Process
Straker	Conventional	GUR 3020	compression molded	Gamma-nitrogen	3 Mrad	None
Depuy	GVF	GUR 3020	machined	Gamma-vacuum foil	2.5-4 Mrad	None
Depuy	Enduron	GUR 3050	machined	Gas Plasma	N/A	N/A
Zimmer	Conventional	GUR 3050	majority direct compression molded (product specific)	Gamma-nitrogen	~3.7 Mrad	None
Zimmer	Sulena	GUR 3020	machined from compression molded bar stock	Gamma-nitrogen	~3.7 Mrad	None
Biomet	Accom	GUR 3050	isostatic compression molded and machined or direct compression	Gamma-barrier film package	3.3 Mrad	None
Smith & Nephew	Conventional	GUR 3020	slab	E/O	N/A	N/A

Efforts to Improve Wear properties of poly Failed Miserably

- Carbon-fiber reinforced polyethylene
- Heat pressed polyethylene
- Hylamer-M polyethylene

Carbon-Fiber Reinforced Poly

- 26 carbon-fiber reinforced vs. 20 plain polys
- Fatigue crack propagation an order of magnitude faster in carbon-fiber implants

Wright et al, JBJS, 1988

Heat Pressed Poly

- Early surface delamination in retrieved heat-pressed tibial inserts

Bloebaum et al, CORR, 1991

Hylamer-M Poly

- Early failure with the use of Hylamer-M

Ahn et al, JOA, 2001
Ries et al, JOA, 1996

Anderson Clinic Results

- 332 AMK implants
- gamma-in-air
- Revised < 10 years: 16
- Revisions for wear/osteolysis: 8
- 335 AMK implants
- Gas plasma
- Revised < 10 years: 6
- Revisions for wear/osteolysis: 0

Isolating regions

- Certain features can be isolated using Analyze software
- Analyze software will compute the volume separately for each region

