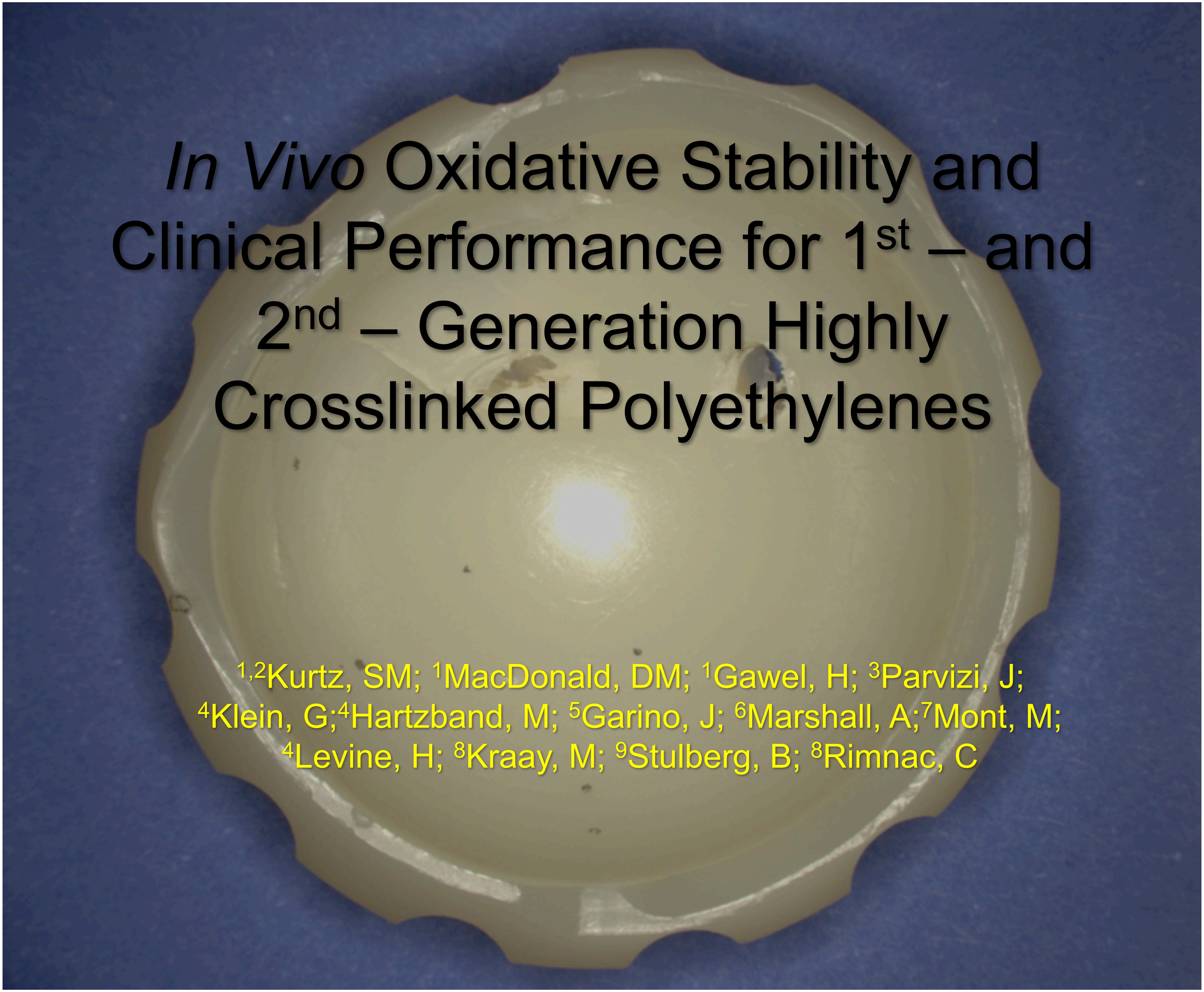

In Vivo Oxidative Stability and Clinical Performance for 1st – and 2nd – Generation Highly Crosslinked Polyethylenes

[1,2]Kurtz, SM; [1]MacDonald, DM; [1]Gawel, H; [3]Parvizi, J; [4]Klein, G;[4]Hartzband, M; [5]Garino, J; [6]Marshall, A;[7]Mont, M; [4]Levine, H; [8]Kraay, M; [9]Stulberg, B; [8]Rimnac, C

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National Institutes of Health

NIAMS
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Background

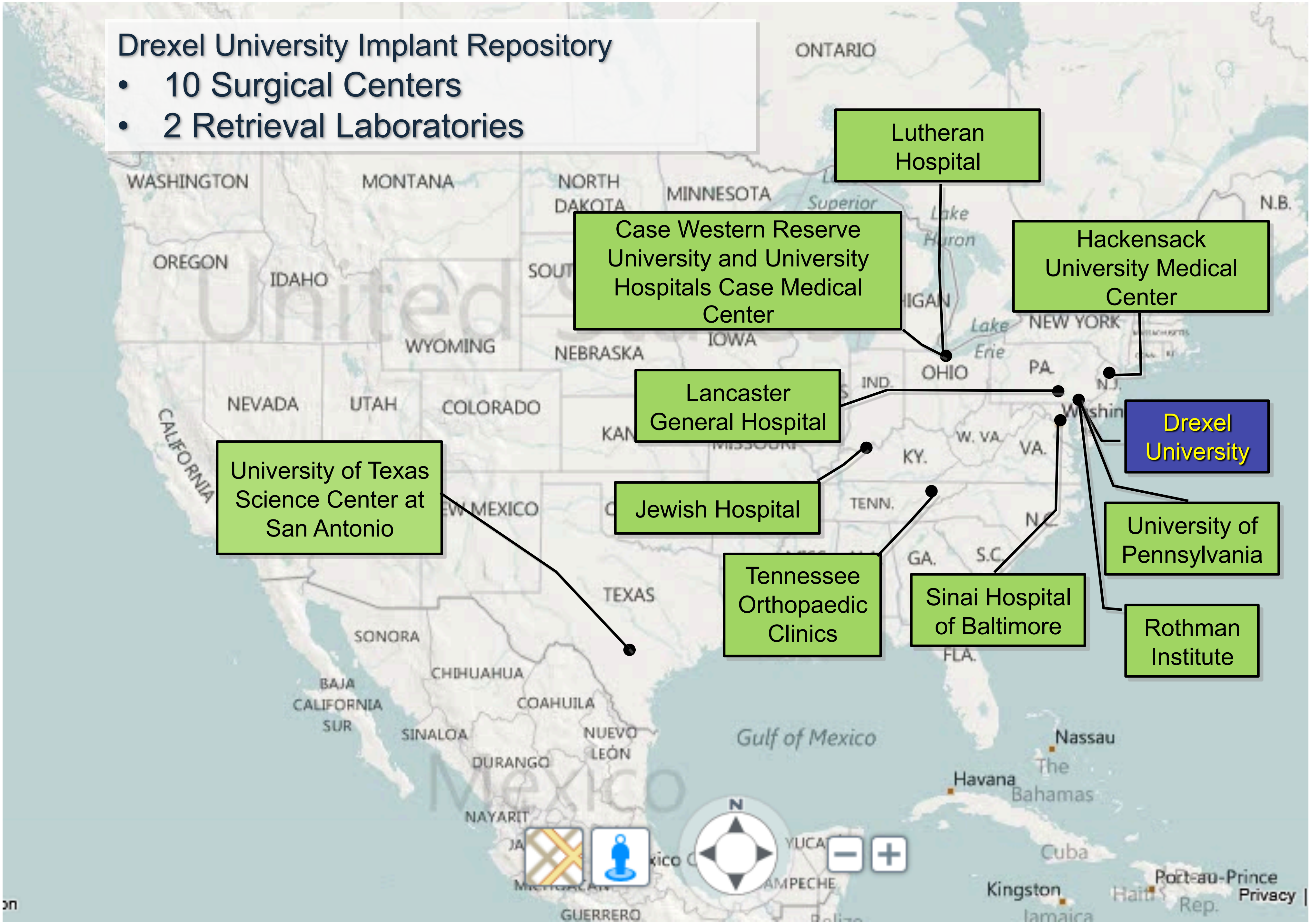
- Highly crosslinked polyethylenes have shown improved *in vivo* wear performance.
  - Significantly reduced osteolysis rates
- 1st Generation HXLPEs Concerns
  - Annealed → Oxidative Stability
  - Remelted → Reduced Mechanical Properties

2^{nd} Generation HXLPE

	Crosslinking Dose	Post-irradiation stabilization	Sterilization Modality	Total Irradiation Dose
Sequentially Annealed	30 kGy in 3 steps	Annealing after each crosslinking dose	Gas Plasma	90 kGy
Vitamin E	100 kGy	Vitamin E doping with subsequent annealing	Gamma in argon	130 kGy

Study Objective

The purpose of this multicenter study was to assess the oxidative, mechanical behavior, wear, and reasons for revision of 1st and 2nd generation highly crosslinked polyethylenes.


Drexel University Implant Repository
• 10 Surgical Centers
• 2 Retrieval Laboratories
Lutheran Hospital
Case Western Reserve University and University Hospitals Case Medical Center
Hackensack University Medical Center
Lancaster General Hospital
Drexel University
University of Texas Science Center at San Antonio
Jewish Hospital
University of Pennsylvania
Tennessee Orthopaedic Clinics
Sinai Hospital of Baltimore
Rothman Institute
ONTARIO
WASHINGTON
MONTANA
NORTH DAKOTA
MINNESOTA
OREGON
IDAHO
WYOMING
NEBRASKA
IOWA
NEVADA
UTAH
COLORADO
CALIFORNIA
TEXAS
OHIO
PA.
NEW YORK
N.B.
IND.
KY.
W. VA.
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S.C.
GA.
FLA.
SONORA
CHIHUAHUA
BAJA CALIFORNIA SUR
COAHUILA
SINALOA
DURANGO
NUEVO LEÓN
NAYARIT
Gulf of Mexico
Nassau
The Bahamas
Havana
Cuba
Kingston
Port-au-Prince
Privacy

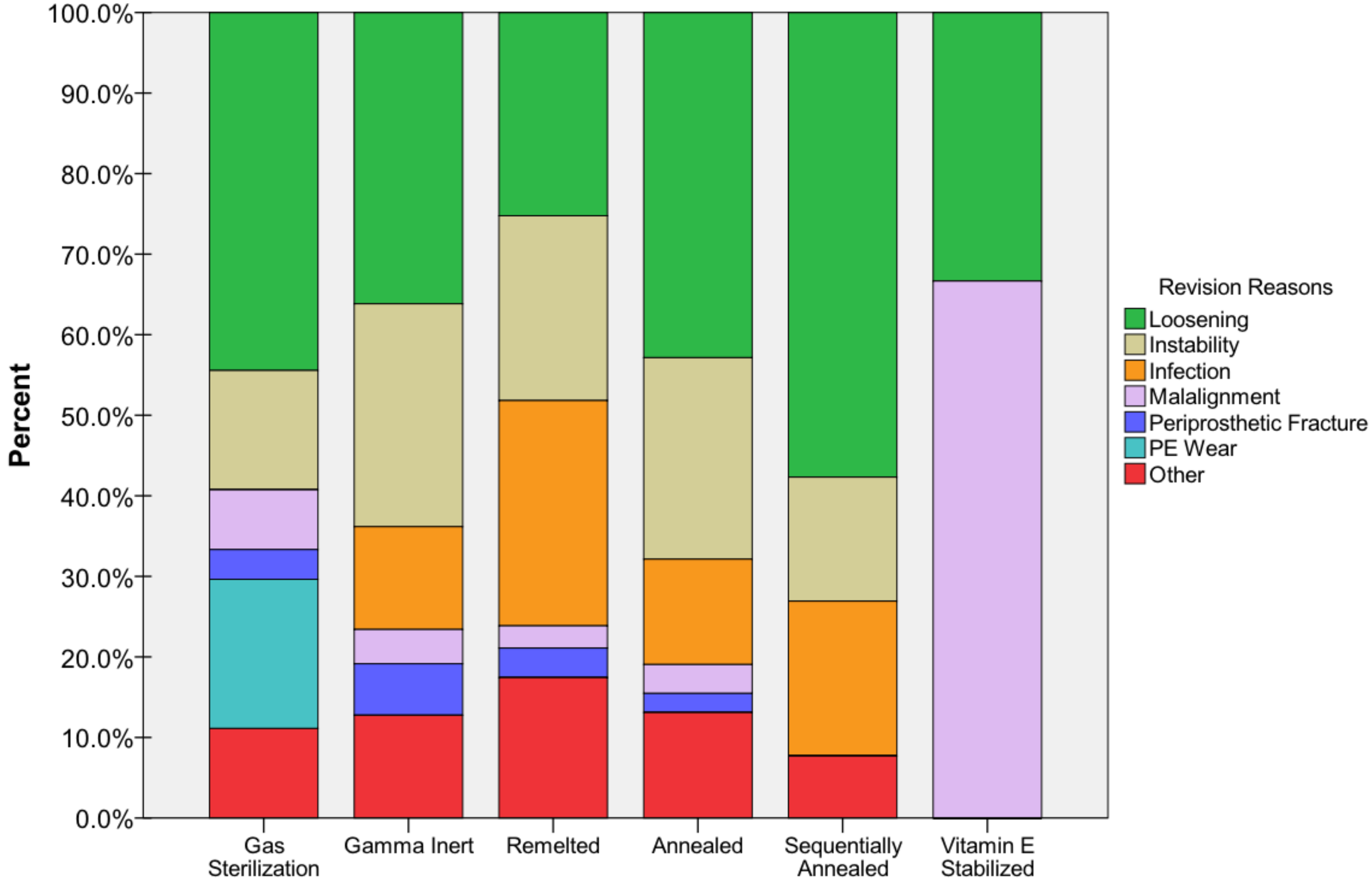
Cohorts (n = 431)

Cohort	n	Manufacturer	Polyethylene Trade name	Terminal Sterilization	Total Irradiation Dose (kGy)
Gas Sterilization	27	Depuy S&N	N/A	Gas Plasma EtO	0
Gamma Inert	47	Depuy Zimmer	N/A	Gamma in inert environment	~35
Remelted	218	Wright Medical Zimmer Zimmer Depuy Smith & Nephew	A-Class Durasul Longevity Marathon XLPE	Gas Plasma or EtO	50 – 100
Annealed	84	Stryker	Crossfire	Gamma in Nitrogen	105
Sequentially Annealed	52	Stryker	X3	Gas Plasma	95
Vitamin E	3	Biomet	E1	Gamma in Argon	130

Patient Demographics

Cohort	n	Age (years)	Gender (%F)	BMI (kg/m^2)	Implantation Time (y)	Max UCLA Score (Range)
Gas Sterilization	27	49 ± 17	56%	32.4 ± 6.9	8.4 ± 3.7	7 (2 – 10)
Gamma Inert	47	59 ± 15	55%	29.4 ± 7.1	6.2 ± 3.8	6 (1 – 9)
Remelted	218	61 ± 13	54%	29.3 ± 7.2	1.9 ± 2.3	5 (1 – 10)
Annealed	84	62 ±12	54%	28.4 ± 6.2	3.8 ± 2.9	5 (2 – 10)
Sequentially Annealed	52	58 ± 15	53%	31.7 ± 6.5	1.2 ± 0.9	5 (1 – 8)
Vitamin E	3	48 ± 25	0%	31.8 ± 2.8	1.2 ± 0.7	4 (3 – 5)

Reasons for Revision

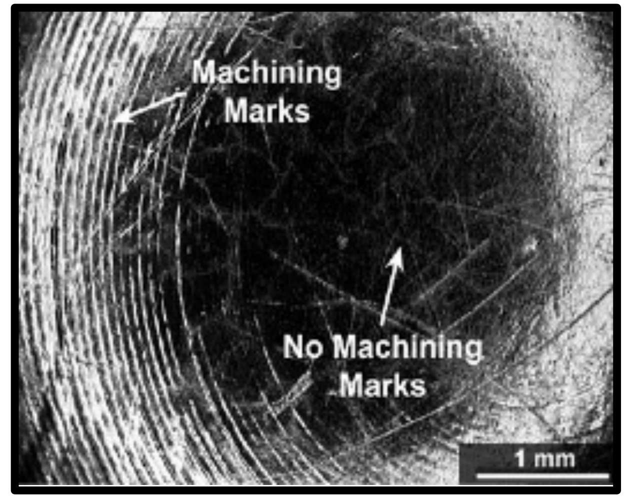


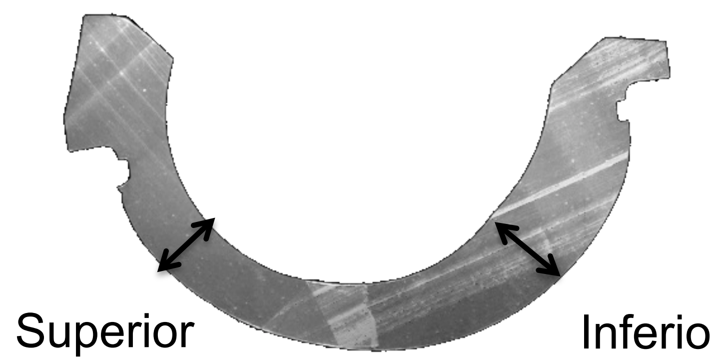
Methods
Penetration Measurement

- Designate superior and inferior sides
- Measure thickness of superior and inferior regions
  - Point-tipped micrometer
    - Accuracy (0.001)

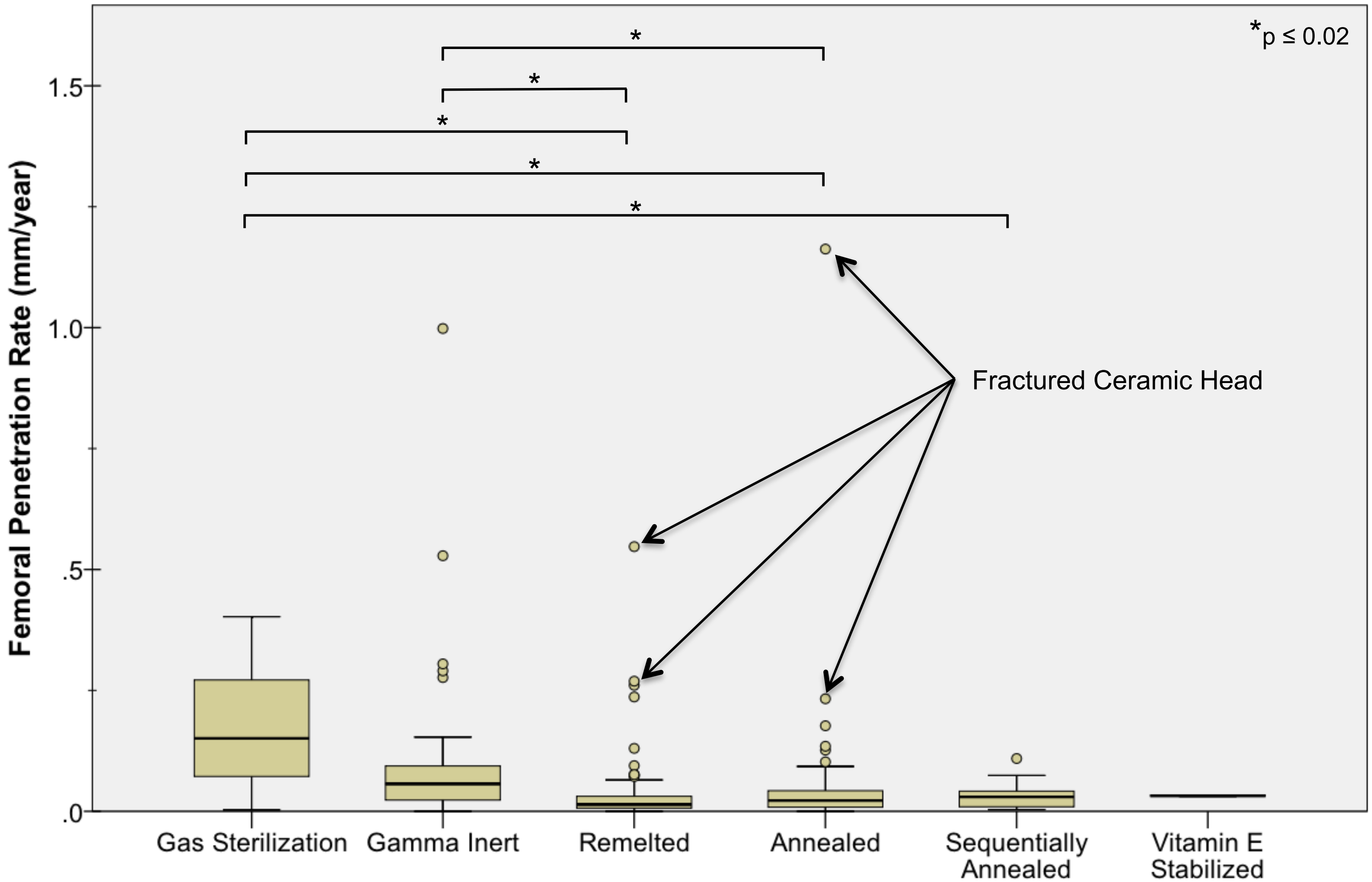
$$\frac{\text{Inferior Thickness} - \text{Superior Thickness}}{\text{Implantation Time}}$$

Linear Penetration Rate





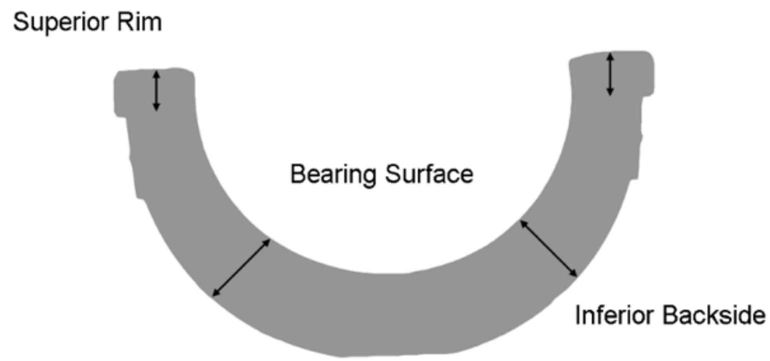
Results
Penetration Rates



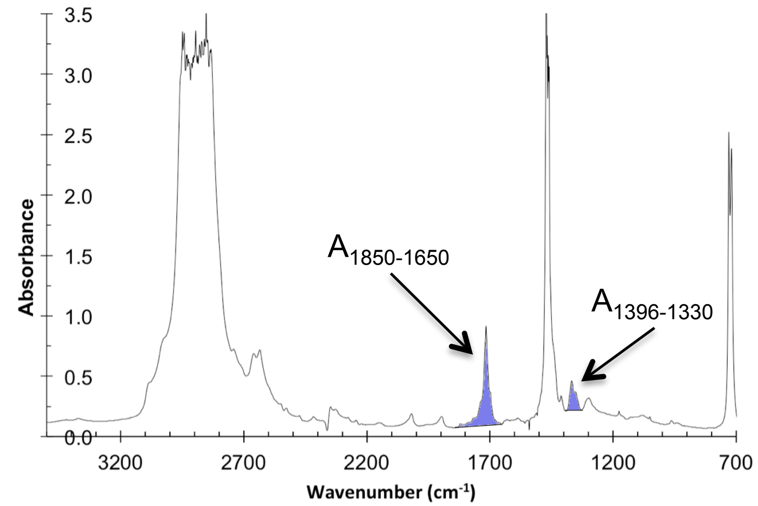
Methods
Oxidation Analysis

- 200 μm sections taken:
  - From superior to inferior cross-section
- Boiled for 6h in heptane to avoid interference of absorbed lipids
- Scanned at 0.1 mm increments
  - 32 repeat scans per location
- Maximum Oxidation Index in accordance with ASTM F2102-01

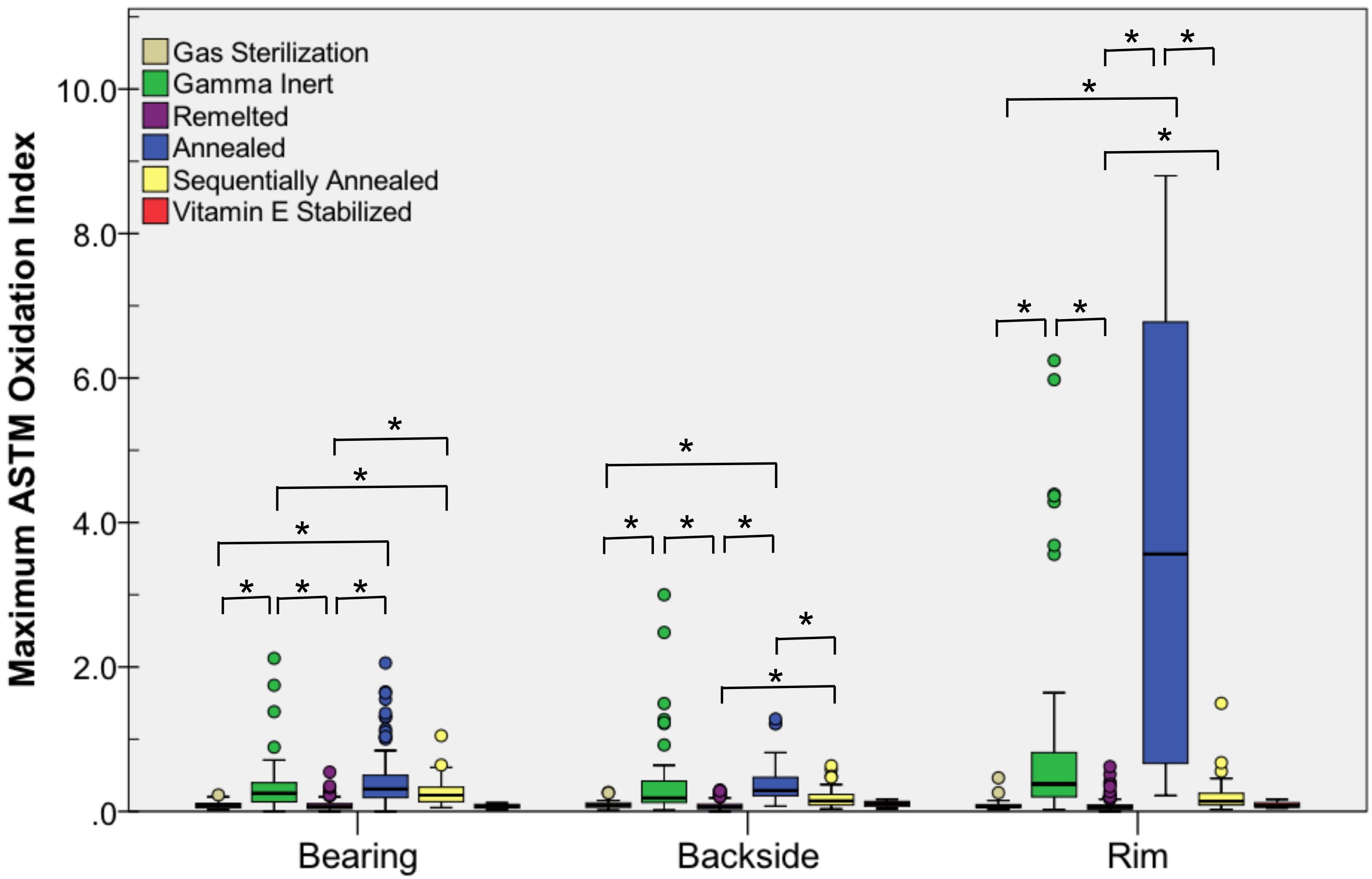
$$OI = \frac{A_{1850-1650}}{A_{1396-1330}}$$



Regions of Interest

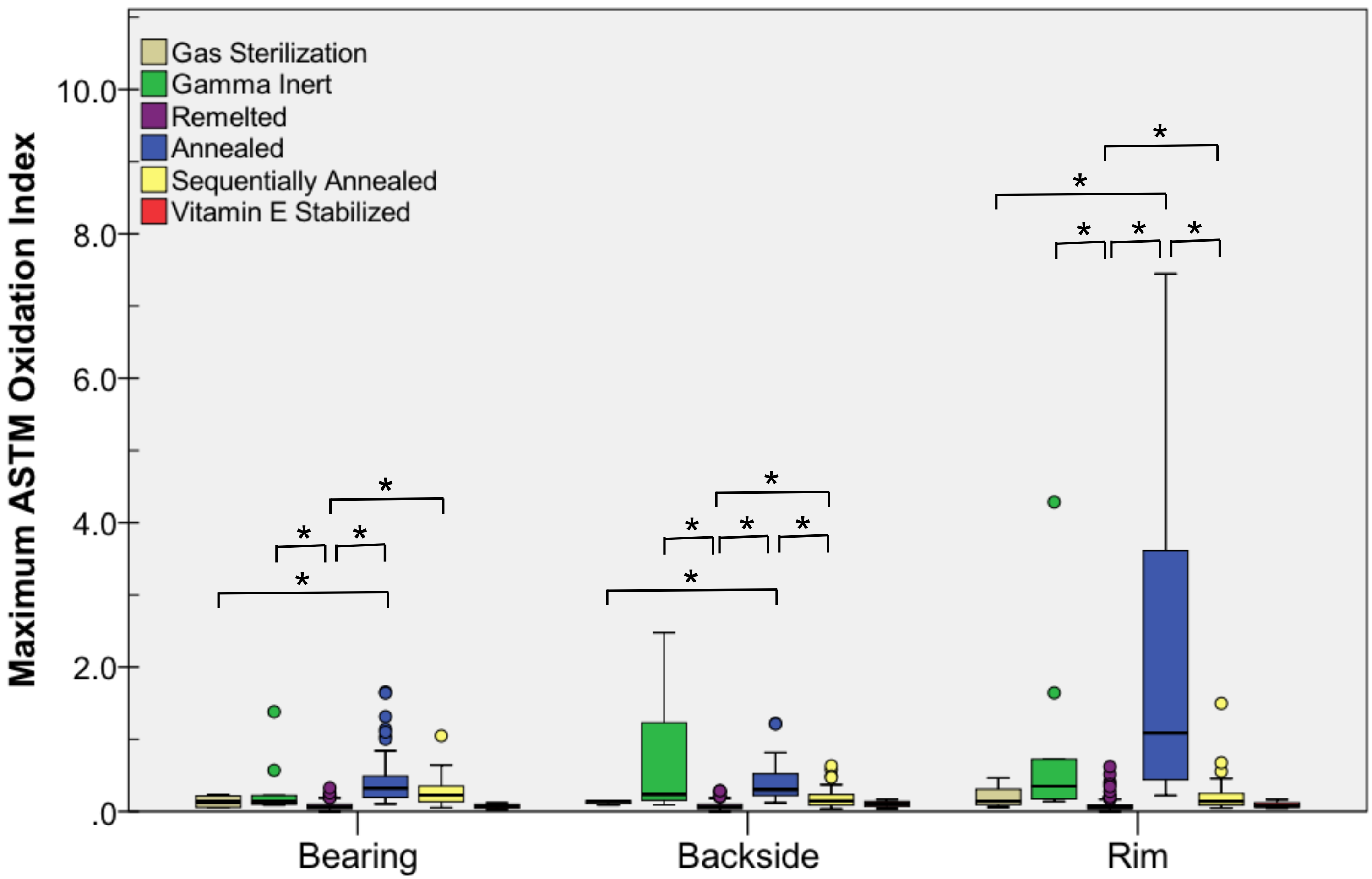


Results
Oxidation (All Liners)



*p ≤ 0.001; Kruskal – Wallis with post-hoc Dunn Test

Results
Oxidation (*in vivo* ≤ 3.4y)

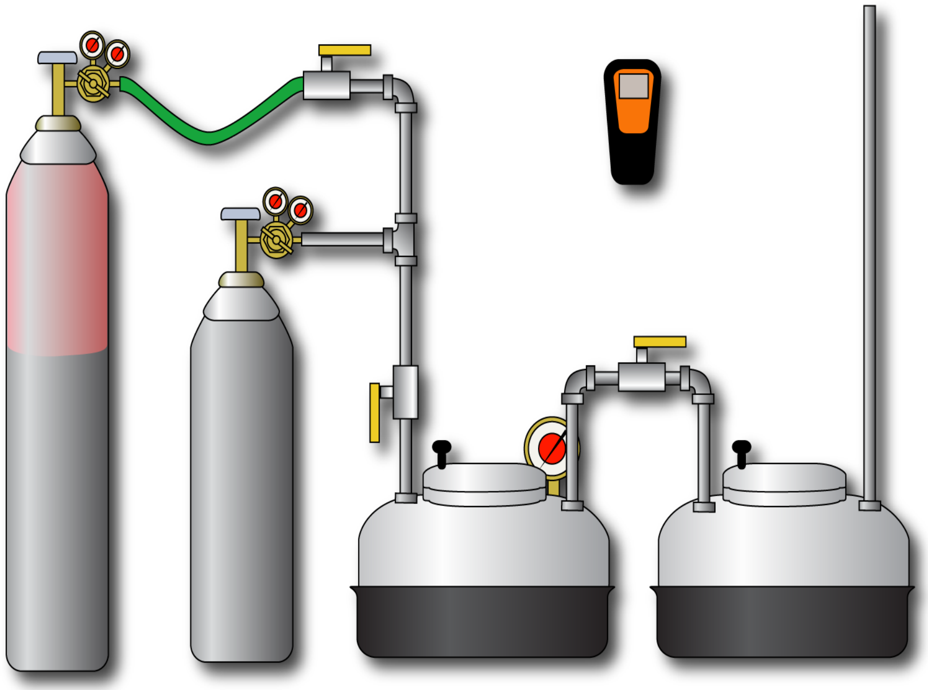


*p ≤ 0.05; Kruskal – Wallis with post-hoc Dunn Test

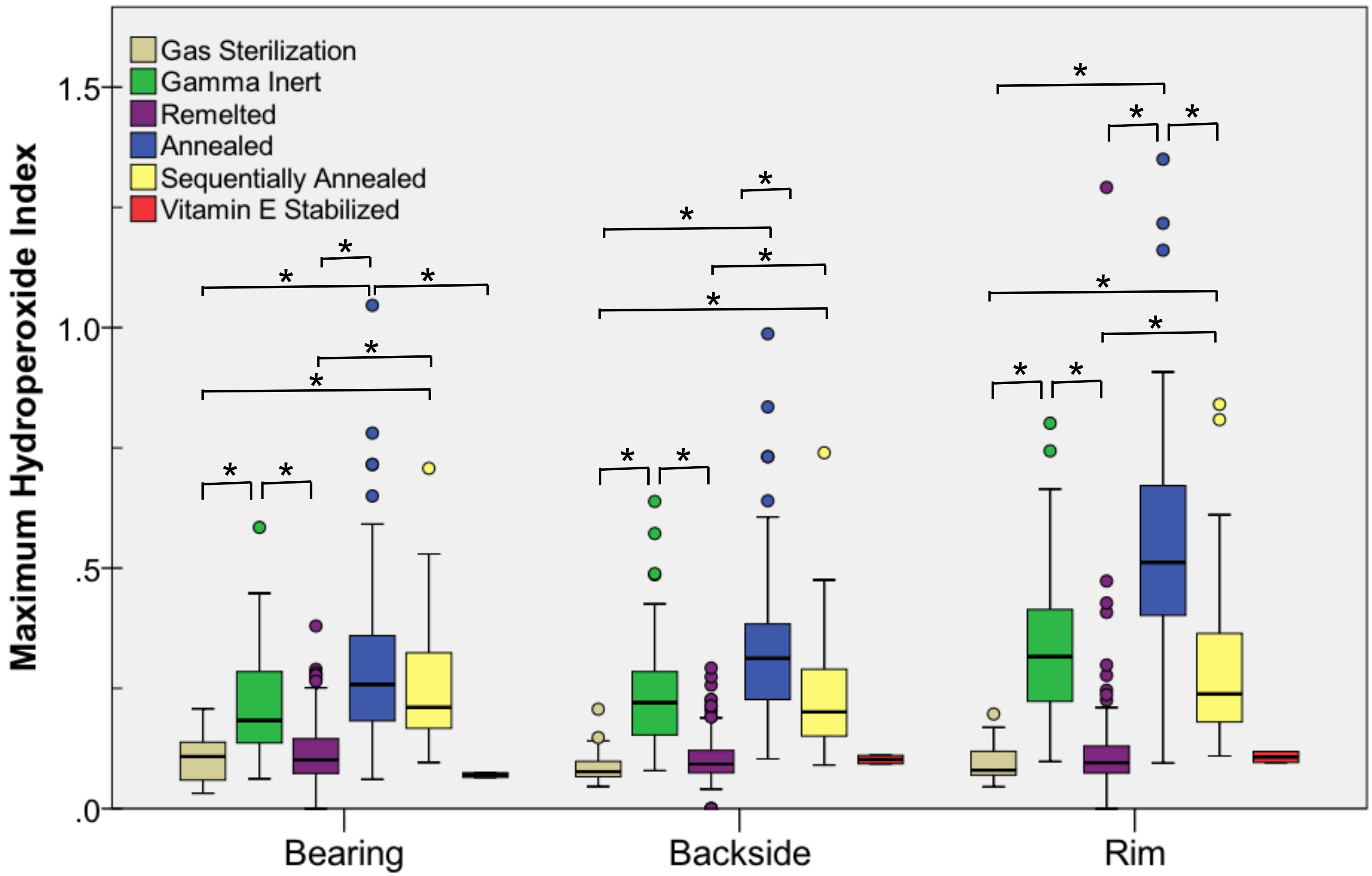
Methods
Hydroperoxide Analysis

- Expose UHMWPE to nitric oxide (NO) gas in the absence of oxygen
  – Hydroperoxides → nitrates
  – Alcohols → nitrites
- Hydroperoxide index measured using FTIR
  – Represents oxidation potential for PE

$$HI = \frac{A_{1670-1600}}{A_{1396-1330}}$$

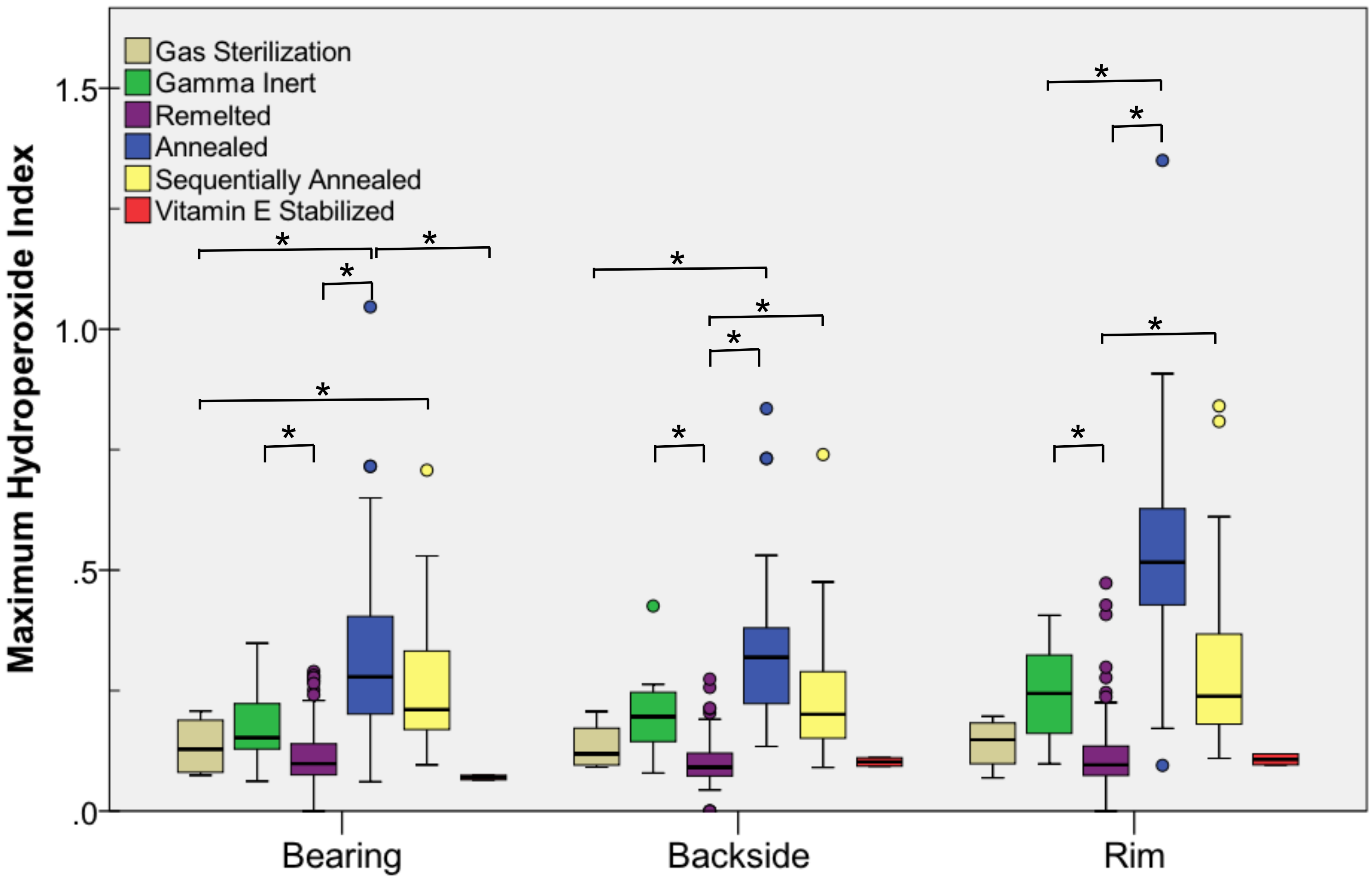


Results
Hydroperoxides (All Liners)



*p ≤ 0.05; Kruskal – Wallis with post-hoc Dunn Test

Results
Hydroperoxides (≤ 3.4y)

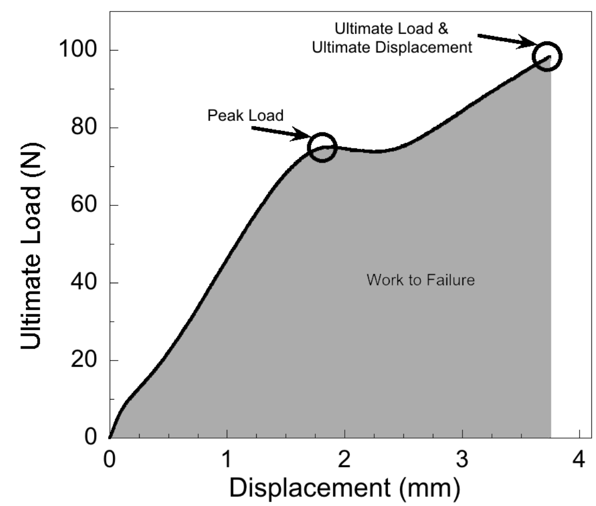


*p ≤ 0.05; Kruskal – Wallis with post-hoc Dunn Test

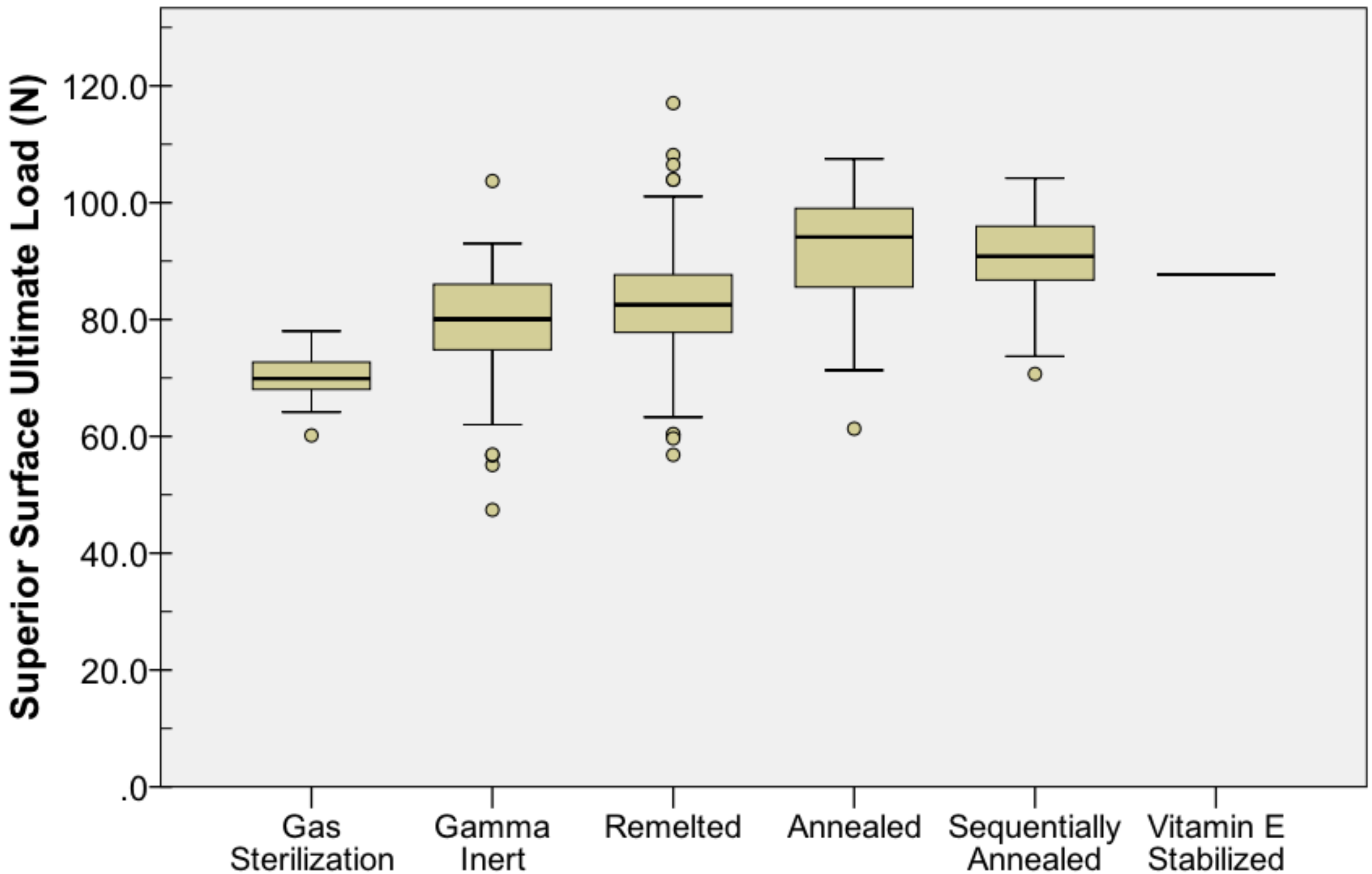
Methods
Small Punch Test

- Cores taken from Inferior and Superior portions of the liner
- Miniature Disks machined from cores (Surface and subsurface specimens)
  - 6.4mm in diameter
  - 0.5mm in thickness
- Testing conducted in accordance with ASTM F2183
  - 4 Metrics Calculated
    - Peak Load
    - Ultimate Load
    - Ultimate Displacement
    - Work to Failure

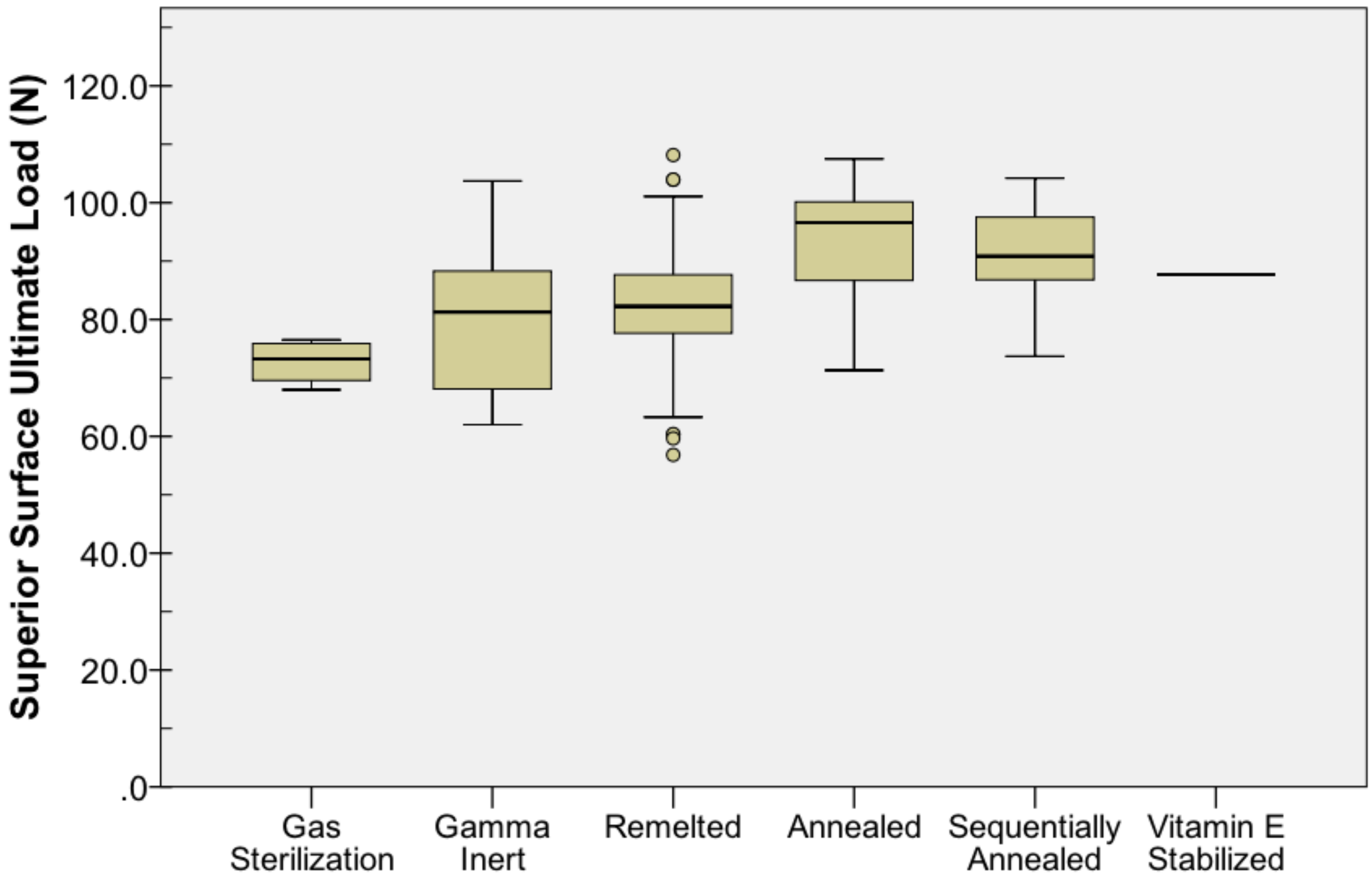
Mechanical characterization



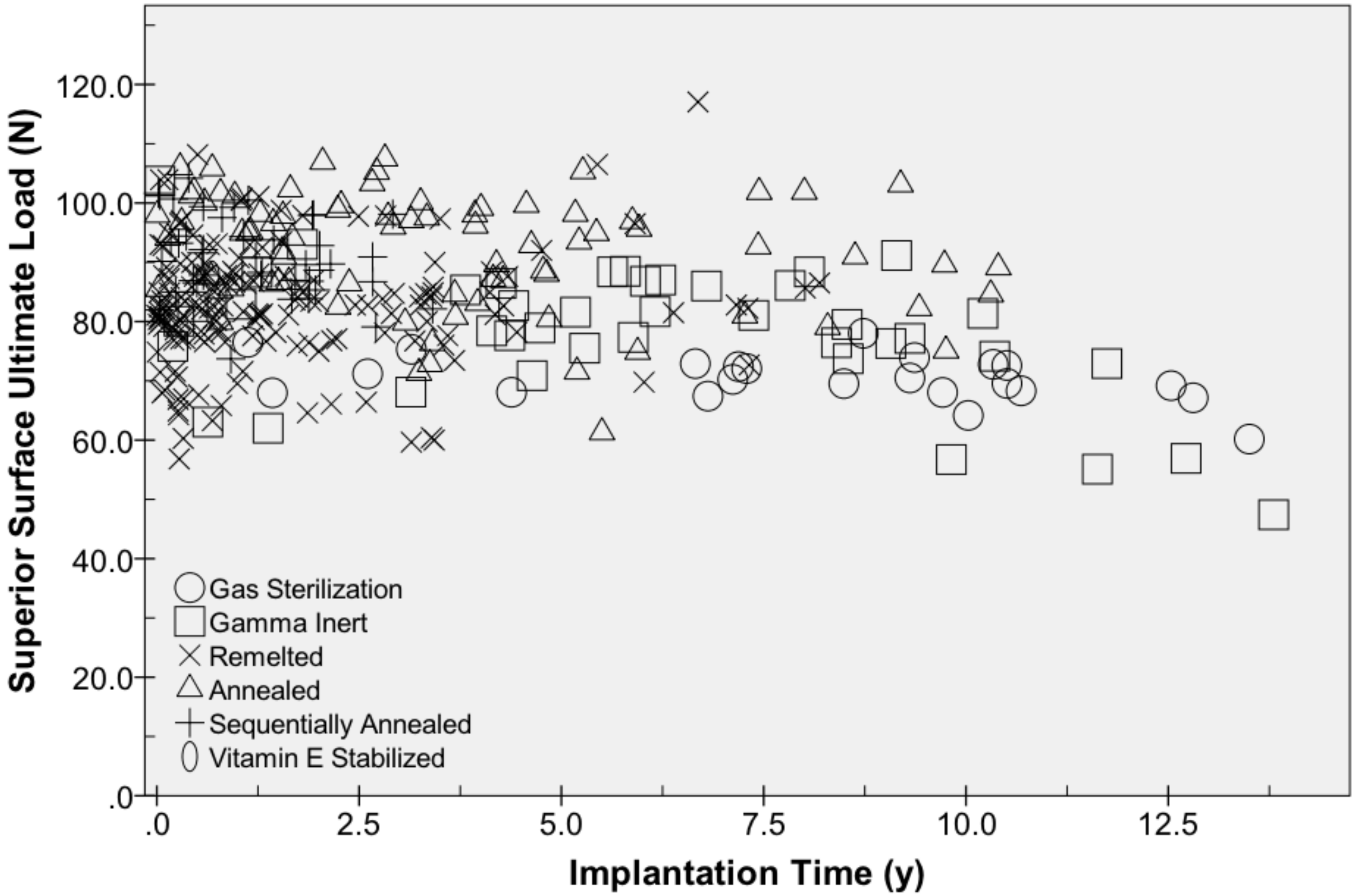
Results
Ultimate Load (All Liners)



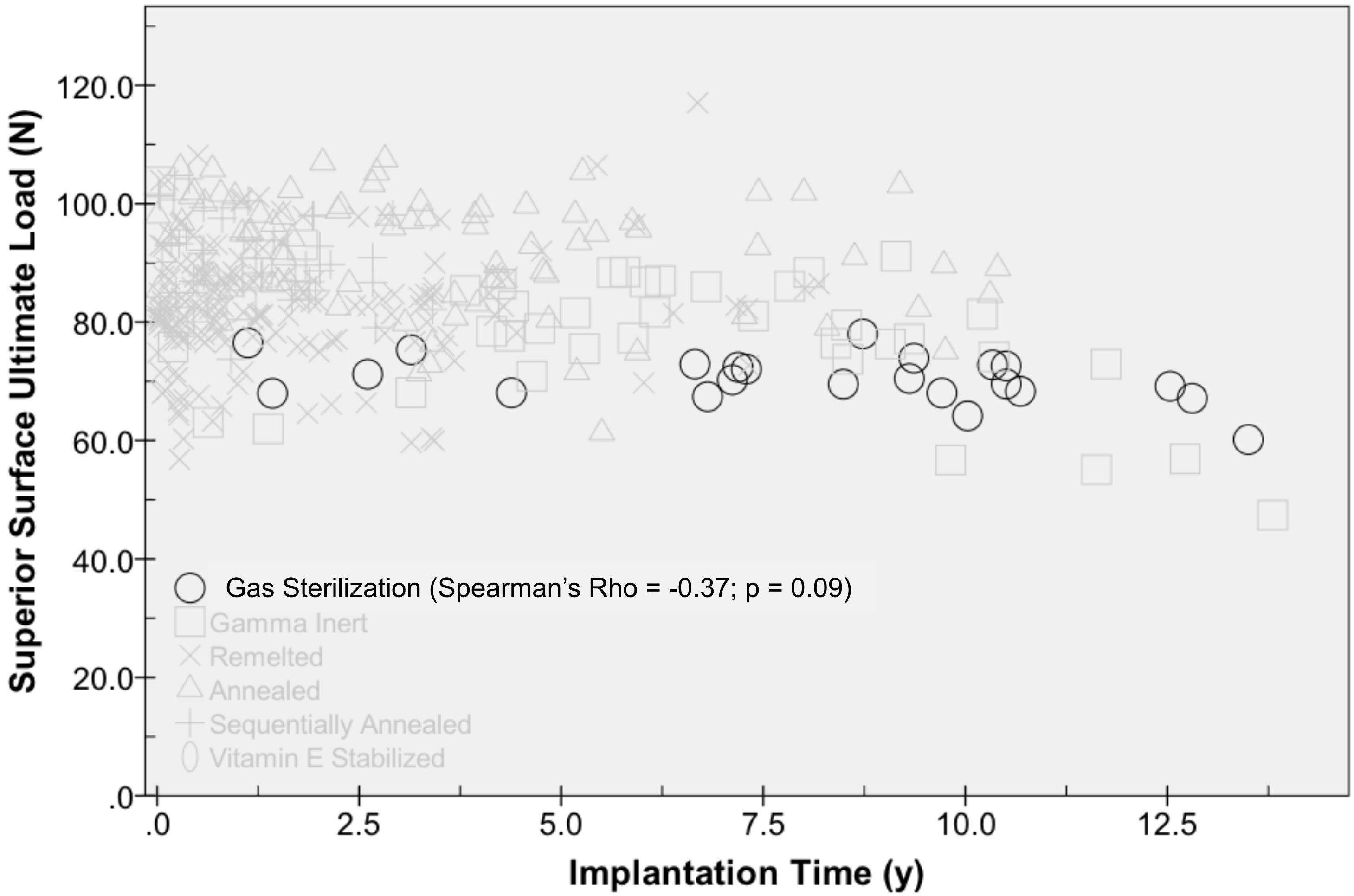
Results
Ultimate Load (Liners ≤ 3.4y)



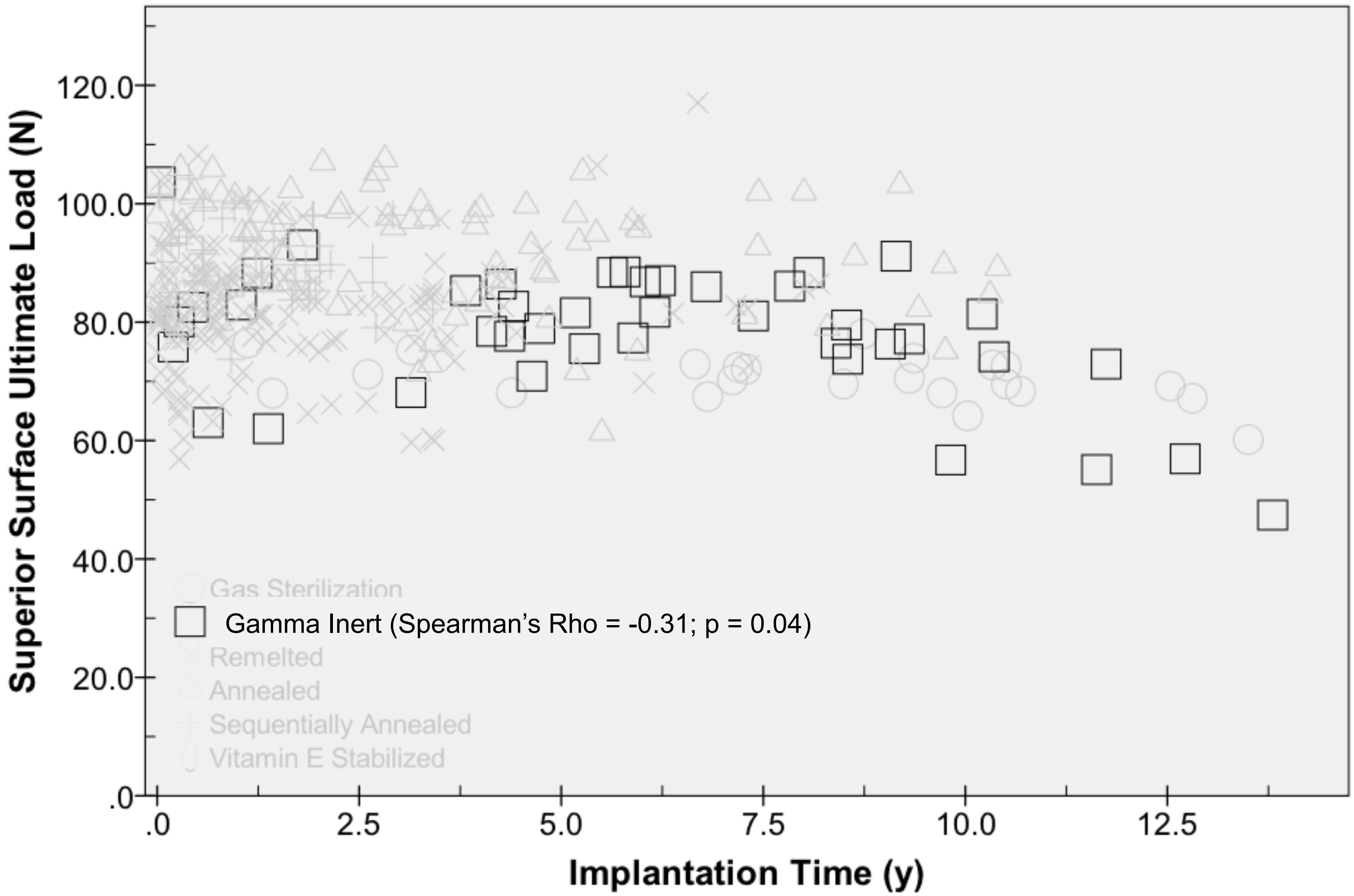
Results
Ultimate Load



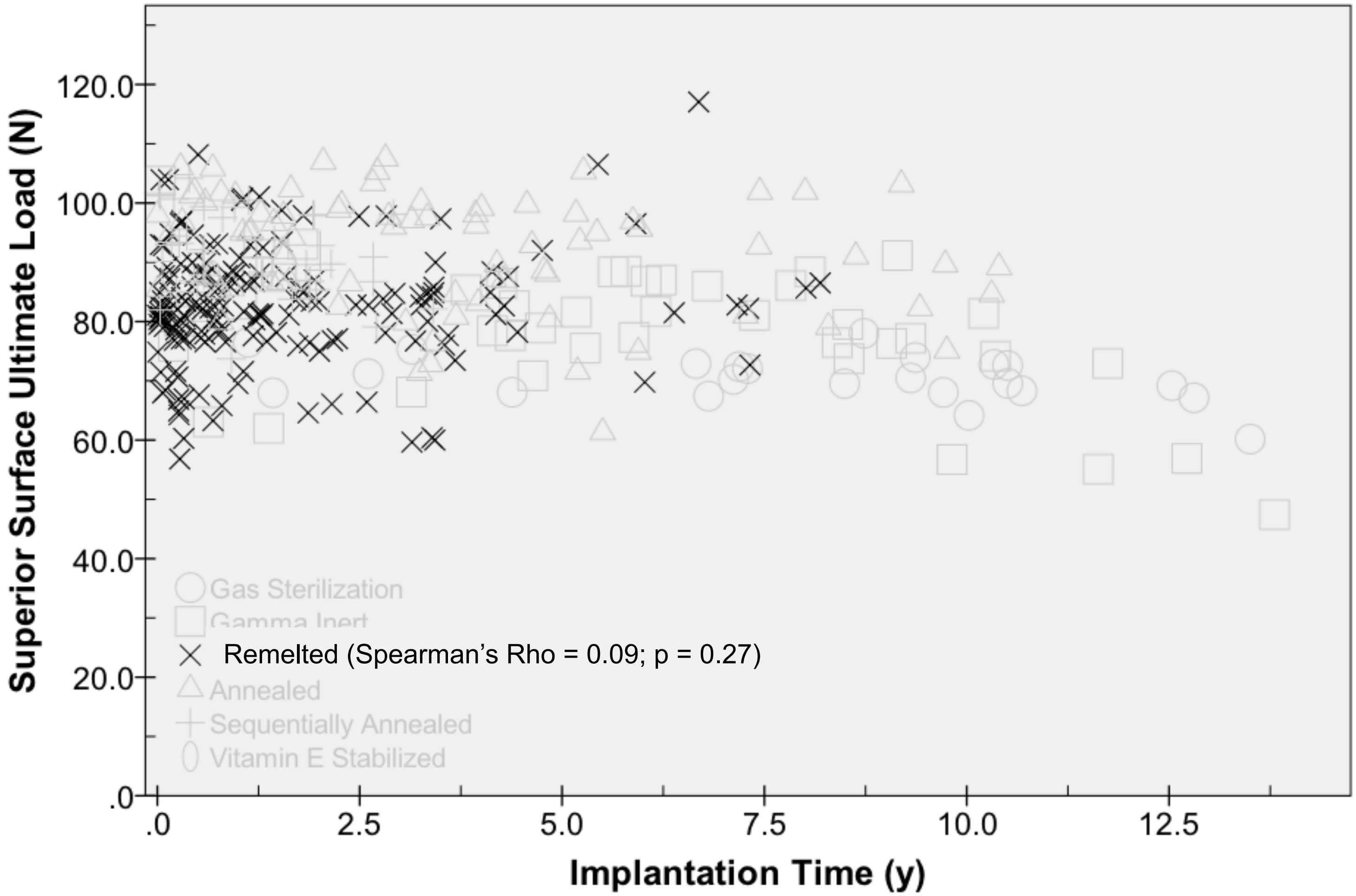
Results
Ultimate Load



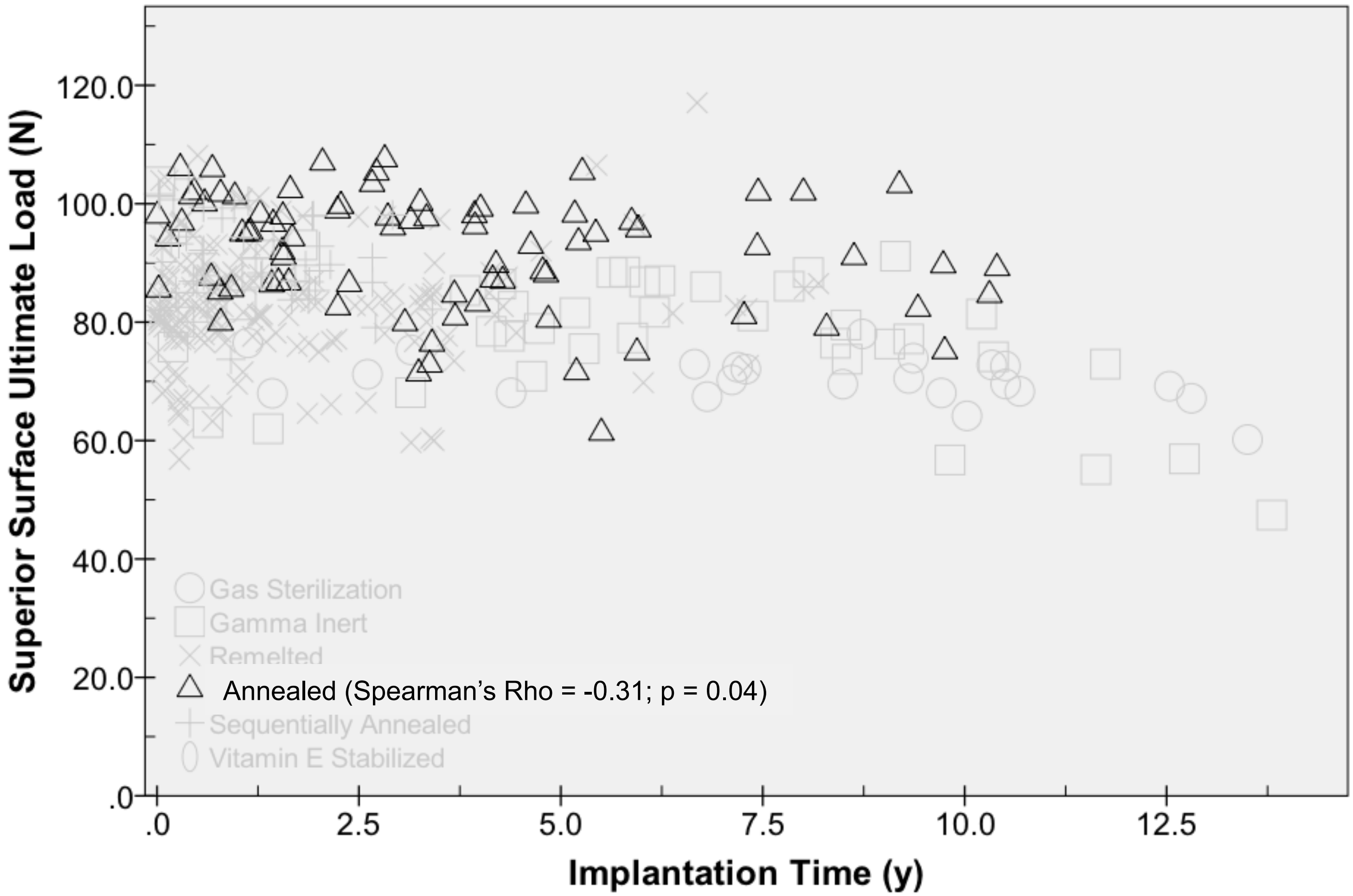
Results
Ultimate Load



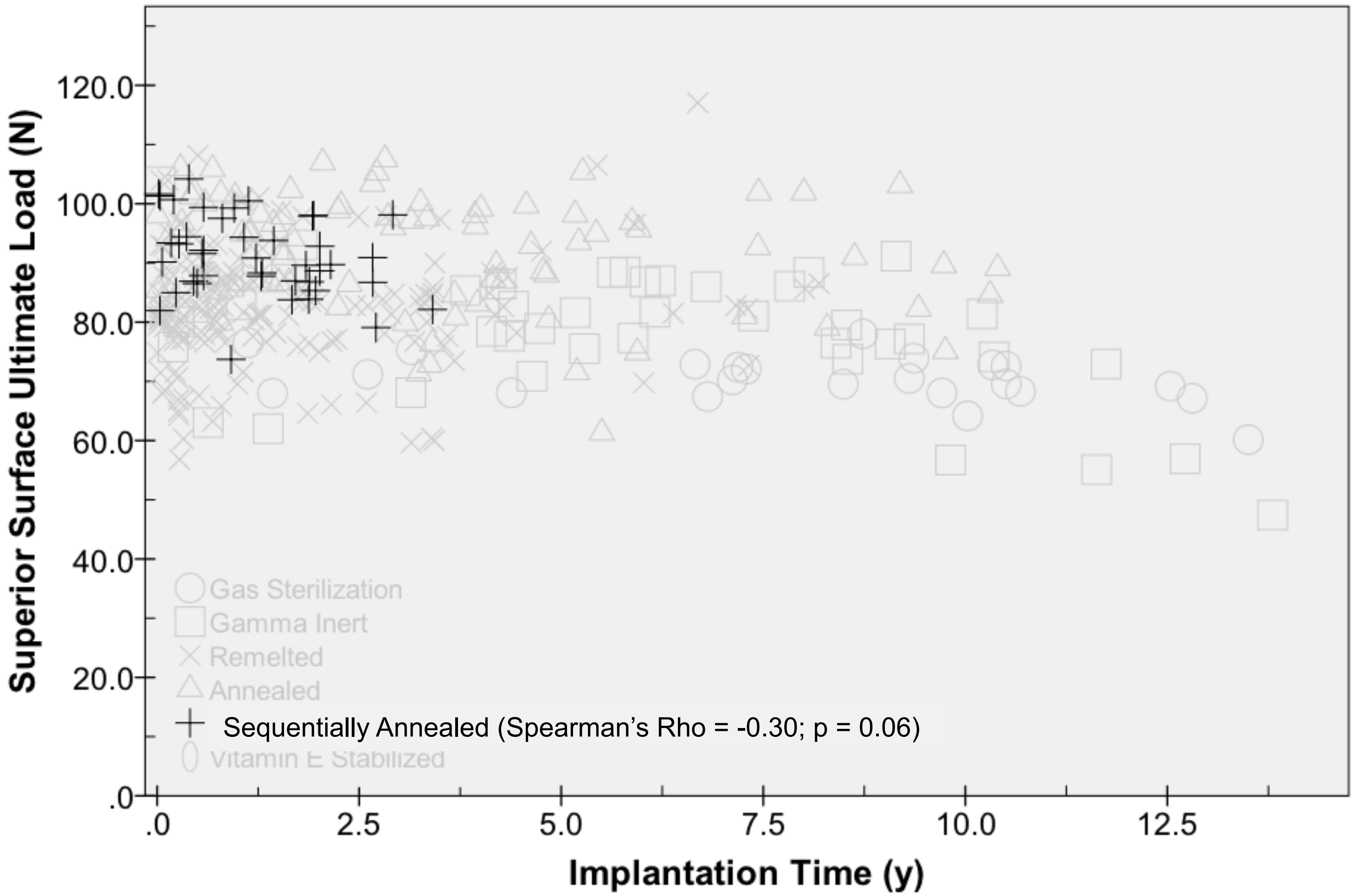
Results
Ultimate Load



Results
Ultimate Load



Results
Ultimate Load

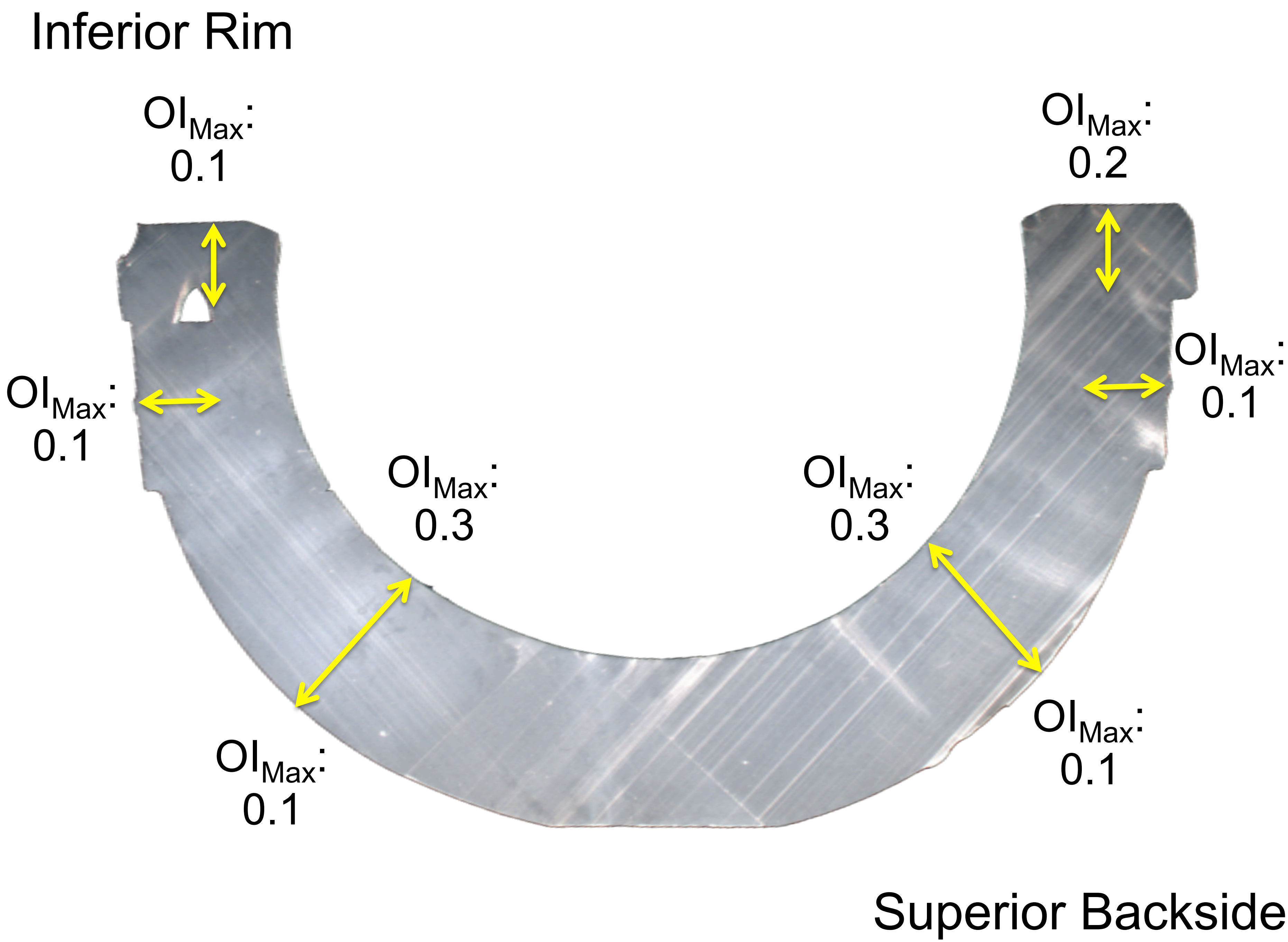


Case Study
Sequentially Annealed

- Male, 59y
  - Black
  - BMI : 28
- Implanted 2006
  - DJD
- Revised 2010
  - Max UCLA Score: 6
  - Revised for Femoral Loosening

In vivo 3.4 y

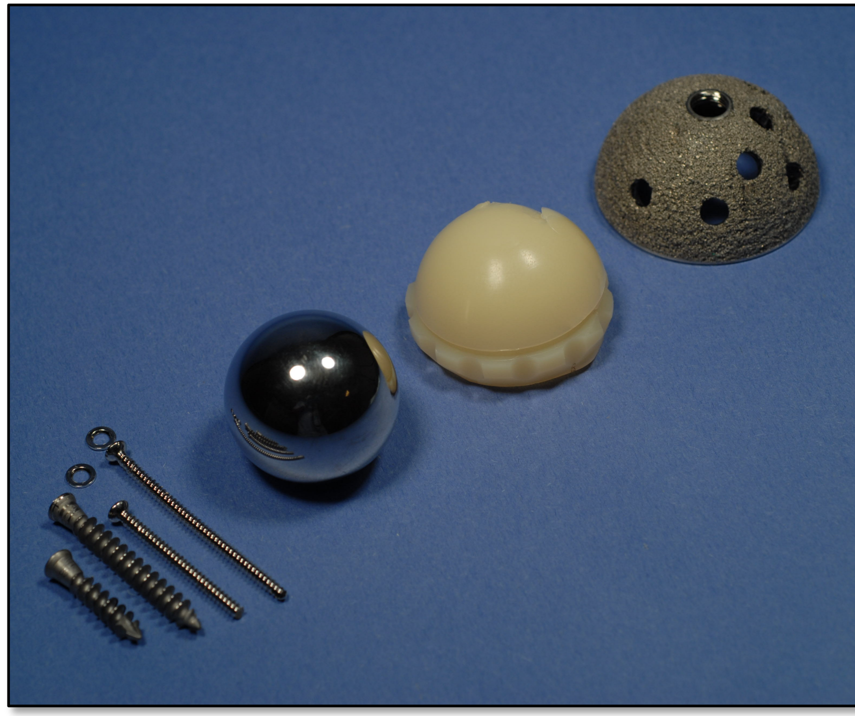

R



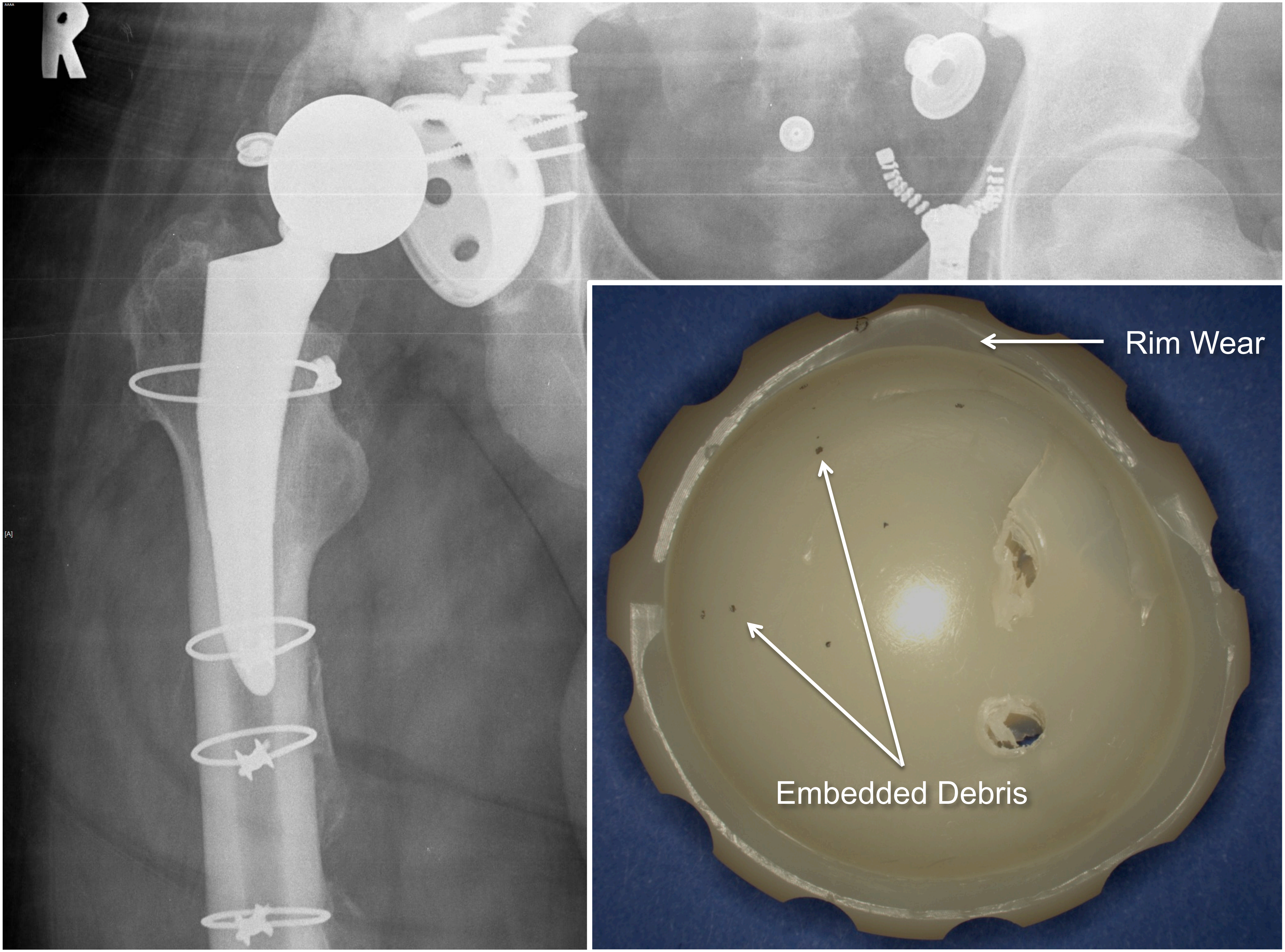
Inferior Rim
OI_{Max}: 0.1
OI_{Max}: 0.2
OI_{Max}: 0.1
OI_{Max}: 0.1
OI_{Max}: 0.3
OI_{Max}: 0.3
OI_{Max}: 0.1
OI_{Max}: 0.1
Superior Backside

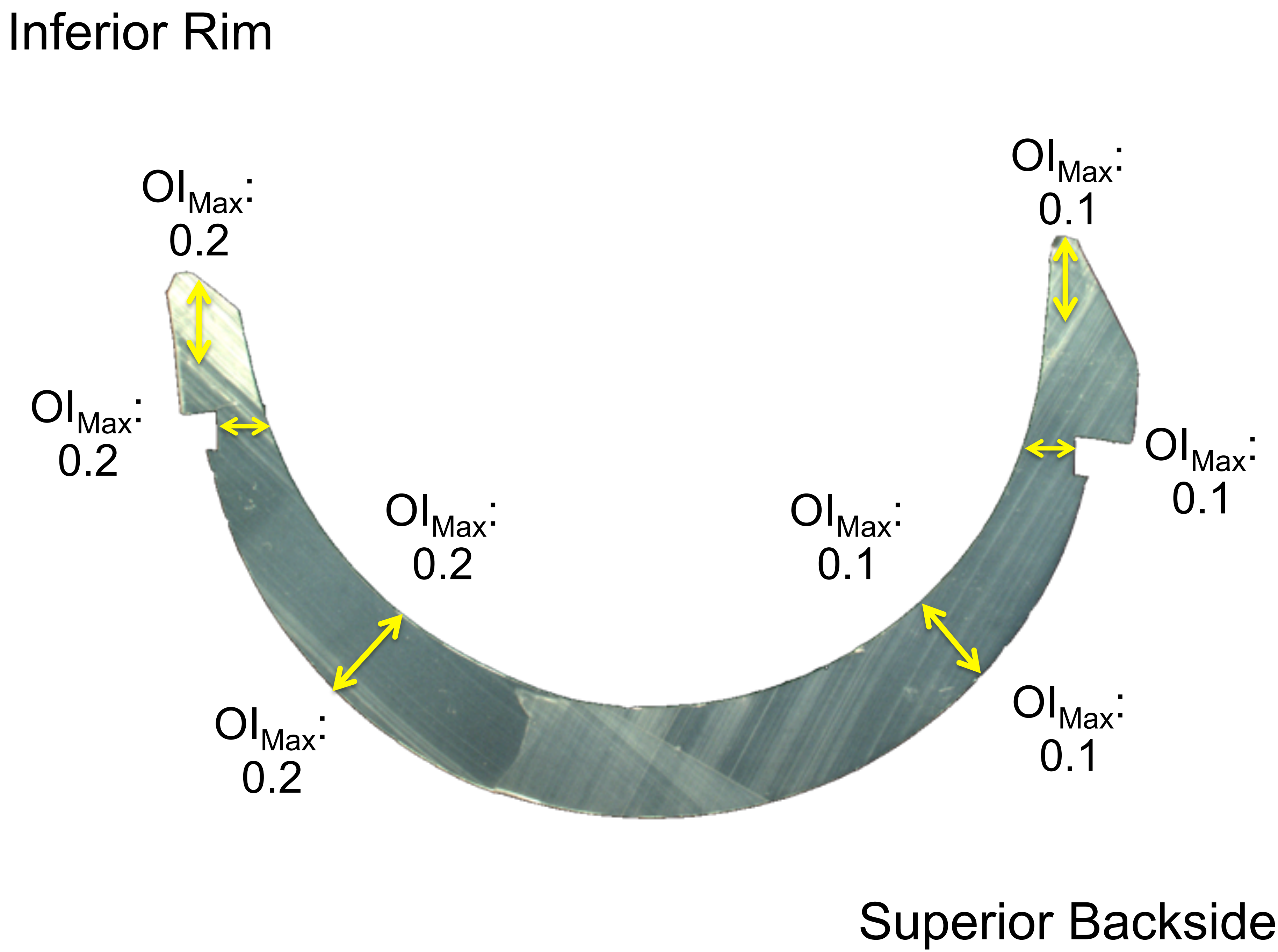
Case Study
Vitamin E Stabilized

- Male, 21y
  - BMI : 34
- Implanted 2009
- Revised 2010
  - Max UCLA Score: 3
  - Revised for Malalignment and Instability



In vivo 0.8 y


R
Rim Wear
Embedded Debris


Inferior Rim
OI$_{Max}$: 0.2
OI$_{Max}$: 0.1
OI$_{Max}$: 0.2
OI$_{Max}$: 0.1
OI$_{Max}$: 0.2
OI$_{Max}$: 0.1
OI$_{Max}$: 0.2
OI$_{Max}$: 0.1
Superior Backside

Discussion

- All HXLPE materials in this study effectively reduced wear as compared to control.
- Oxidative stability is formulation dependent
  - Sequential annealing (X3™)reduces oxidation as compared with 1st generation annealing
  - Vitamin E (E1™) oxidation levels were low and uniform
    - Short implantation time

Discussion

- Mechanical properties also formulation dependent
  - Only Gamma Inert and Sequentially Annealed groups negatively correlated with implantation time
- Additional Vitamin E retrievals necessary to fully characterize their *in vivo* behavior.

Questions