 

Preclinical Testing of Total Hip Replacements

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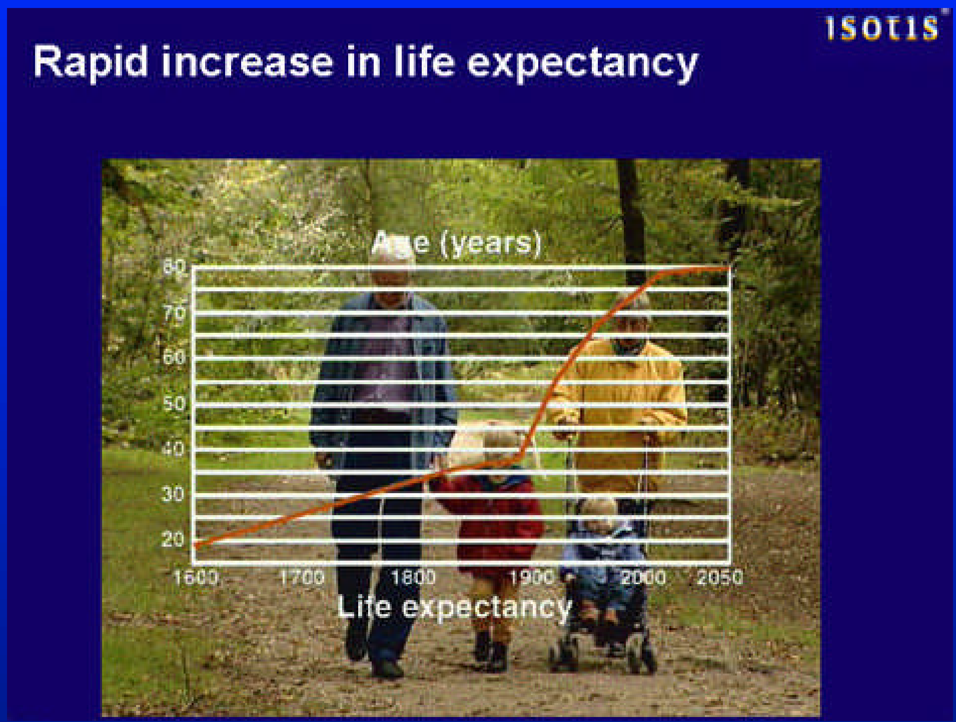
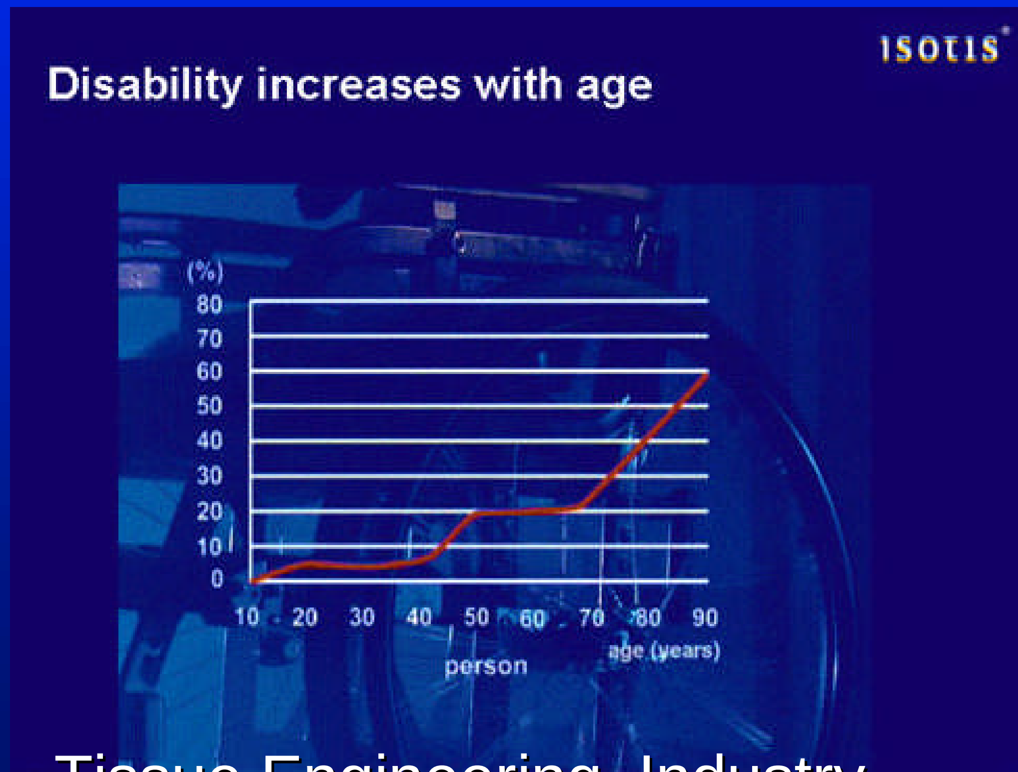
Challenge of the 20th Century
- increased lifespan



Challenge of the 21st Century
- increased healthspan

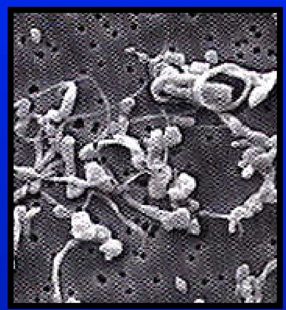


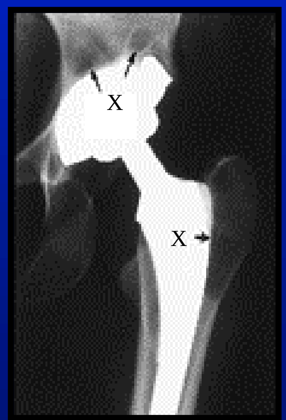
Tissue Engineering Industry
- growth 16% per annum

Total Joint replacement

- Pain due to arthritis, requires total joint replacement
- Increasing number of hip arthroplasties (primary and revision)
  - 13,000 primary hips, Swedish hip register, 2004
- Better success
  - 5 year survival improved from 97 to 97.7% in last two 5 year periods
- Younger patients
  - 81% increase over last 9 years in operations for 45 – 54 year olds (Swedish hip register, 2004)

Clinical Failure of Artificial Joints





<u>**Release of sub-micron or nano sized wear particles**</u>

- Inevitable during use (Malchau *et al* 1993)
- Significant biological problem, PE-on-CoCr - 79% failures
- All materials – small particulates – bioactive (Campbell *et al* 2003)

Osteolysis, cell toxicity, metal ion release

⇩

In vitro **wear testing essential**

provide indication of particle release

Total Joint Replacement

- Metal-on-polymer
- Ceramic-on-polymer
- Metal-on-metal
- Ceramic-on-ceramic
- Ceramic-on- metal
- Metal-on-ceramic

Multi-station Hip Joint Simulation

- 3 Decades of Wear Testing
- Revealed important design information
- Use actual prosthetic components themselves
- Simulate any kinematics & mechanics
- Generates clinically relevant wear particle parameters
- Help to determine **Osteolytic Potential**

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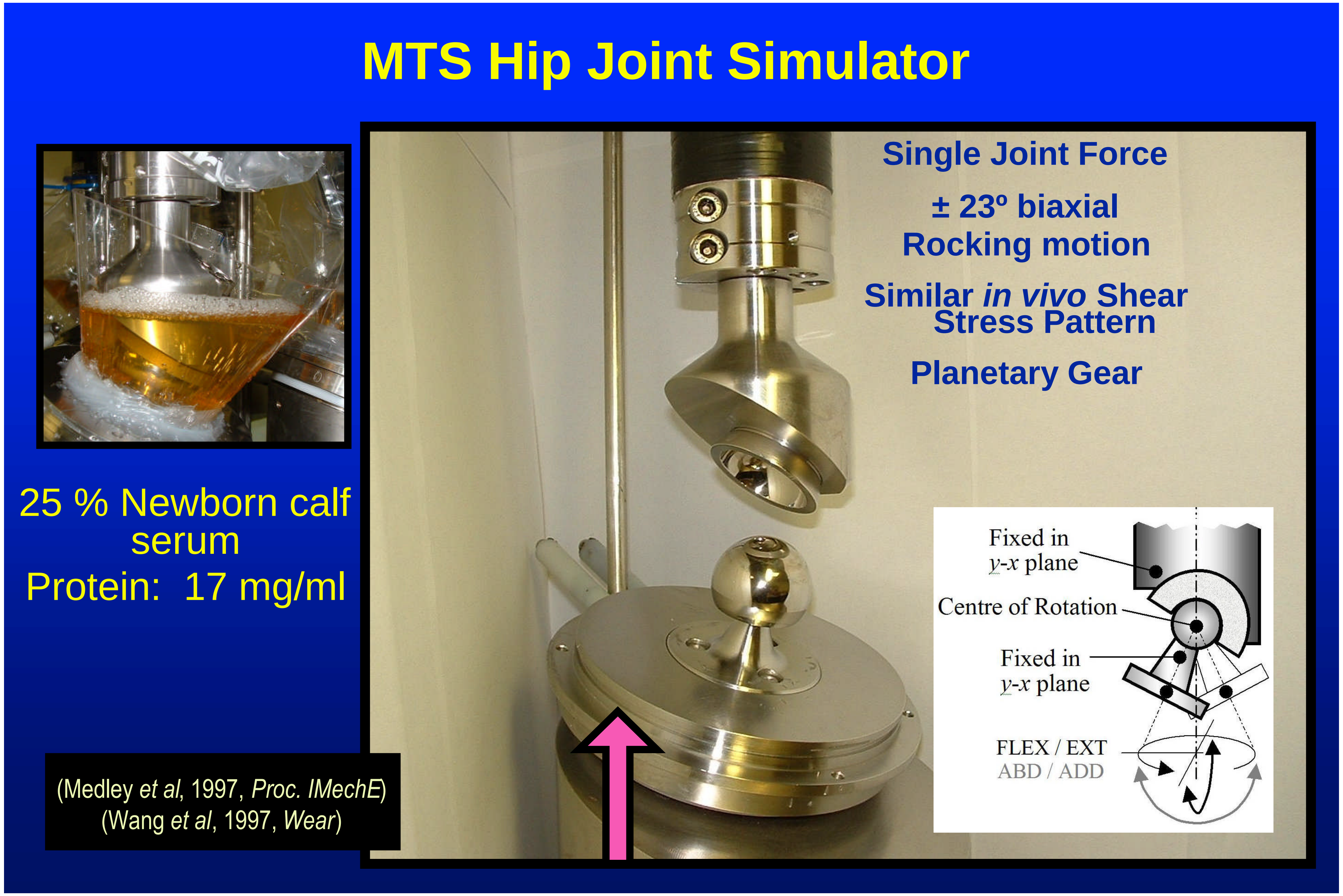
Influence of Particle material, size & concentration using cell culture studies

(Fisher *et al* 2001, *Proc IMechE*)


MTS Hip Joint Simulator
25 % Newborn calf serum
Protein: 17 mg/ml
(Medley et al, 1997, Proc. IMechE)
(Wang et al, 1997, Wear)
Single Joint Force
± 23º biaxial Rocking motion
Similar in vivo Shear Stress Pattern
Planetary Gear
Fixed in y-x plane
Centre of Rotation
Fixed in y-x plane
FLEX / EXT
ABD / ADD

Disadvantages

- Simplistic walking models using virgin heads (ISO/FDIS)
- Continuous motion – more favourable lubrication

→ Wear is always lower compared to clinical data

UHMWPE-on-Metal	**Metal-on-Metal**
Clinical – 35 - 70 mm^3/year	**Clinical – 5 - 10 mm^3/year**
In vitro – 15 - 30 mm^3/year	**In vitro – 0 - 2 mm^3/year**

New Generation of Wear Testing

- Explanted Components (Elfick *et al* 2001, *Wear*)
- Purposely Scratched Components (Fisher *et al* 2001, *Proc IMechE*)
- Adding Third-body Particles (Essner *et al* 2001, *Wear*)
- Swing-Phase Micro-Separation (Nevelos *et al* 2000, *J. Arthroplasty*)
- Intermittent Loading (Roter *et al* 2002, *48^{th} ORS*)

WEAR IS A FUNCTION OF USE

but there has been no severe activity simulation

Why Simulate Adverse Gait ?

- **Increasing aging population**
- Higher expected activity ?
- 2 → 4.5 million cycle / year (Wallbridge and Dowson, 1992, *Eng Med*)

- Hip resurfacing patients – Running London & Boston Marathons
- World competition level – Squash, Badminton, Judo
- Continued clinical success

High activity is deleterious to a hip joint

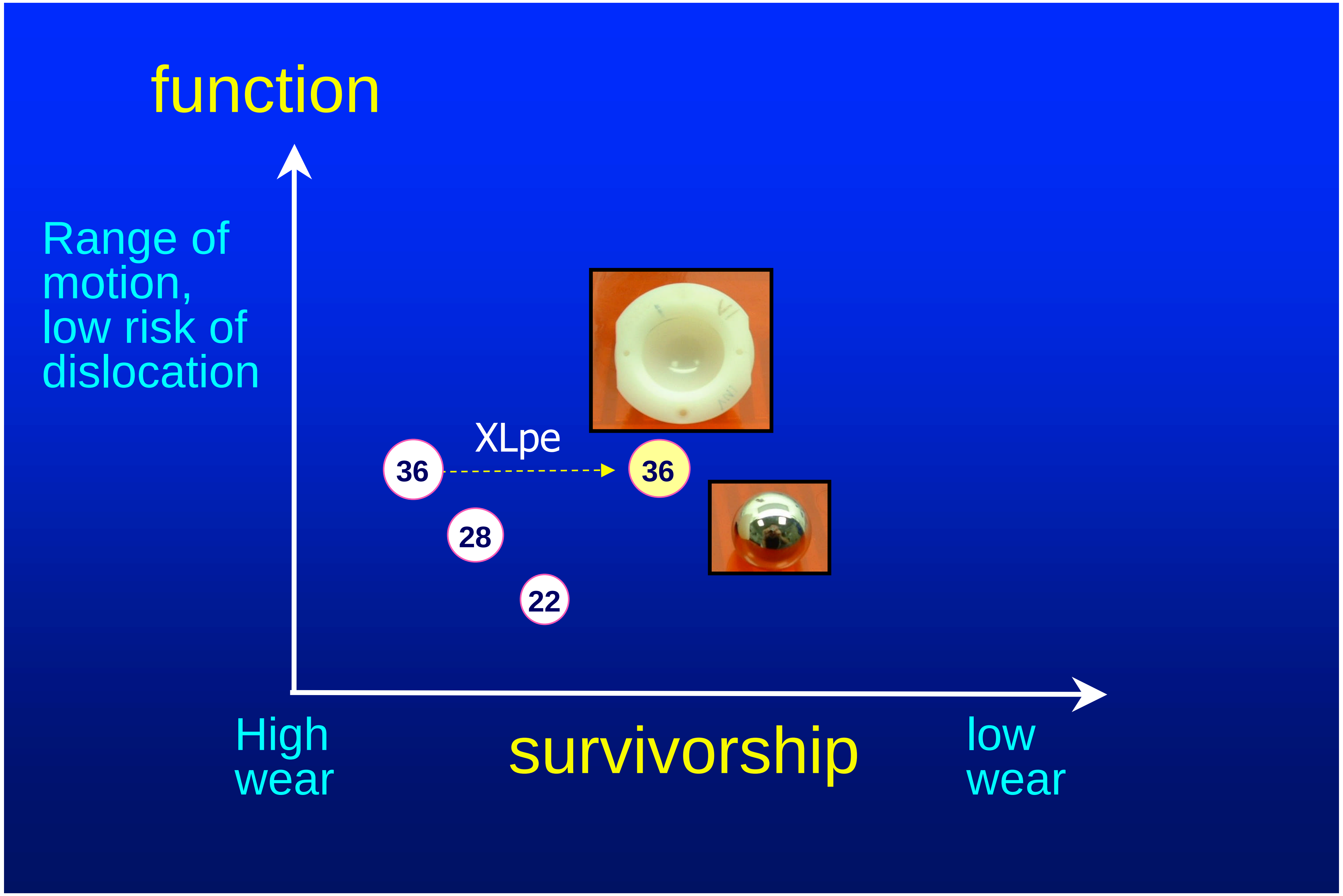
- ♦ How much ?
- ♦ What is the nature of the wear particles ?

Metal-on-polyethylene

- EtO sterilised (non cross-linked)
- 3 Mrad gamma irradiation in air
  - cross-linked
  - oxidation
- 3 – 5 Mrad gamma irradiation in N_2
- High levels gamma irradiation in N_2

Metal-on-polyethylene

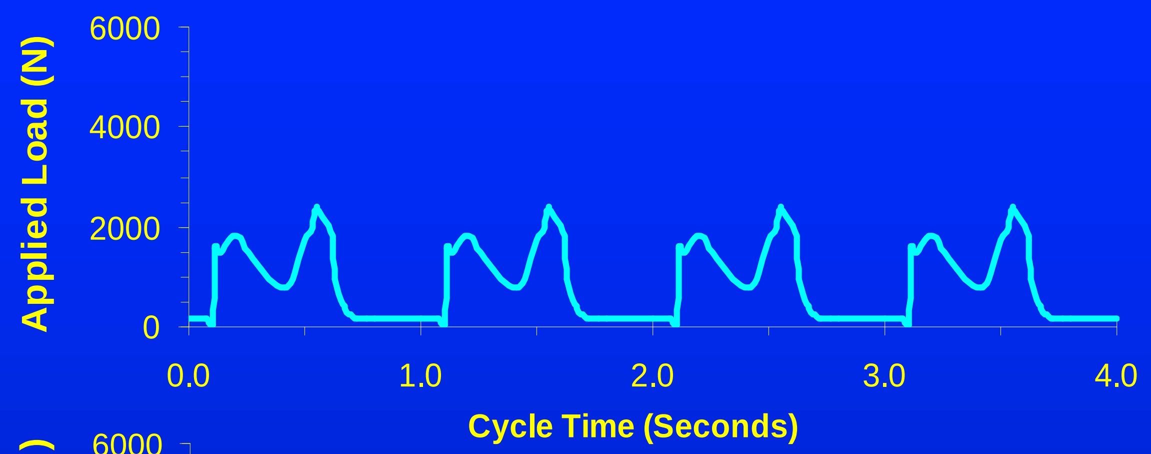
- Head size
  - Diameter 22, 28, 32 mm
  - Wear rate 50, 75, 90 mm^3/year
  - Lancaster wear equation, V = kPx
- Head damage
- Backside wear
- Particles


function
Range of motion, low risk of dislocation
XLpe
36
36
28
22
High wear
survivorship
low wear

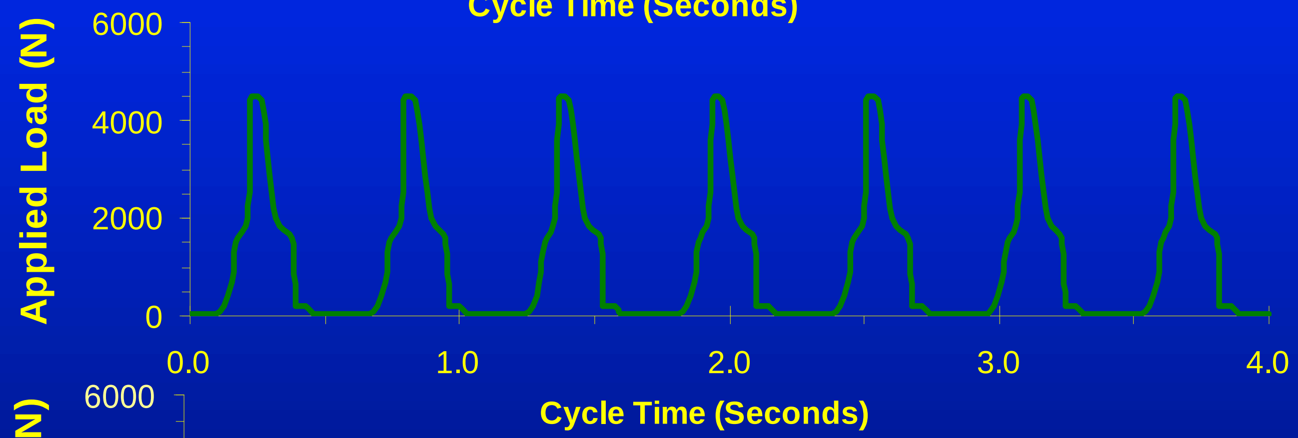
Aims of Studies

- To determine a short term laboratory test to predict the clinical performance of modern generation hip prostheses

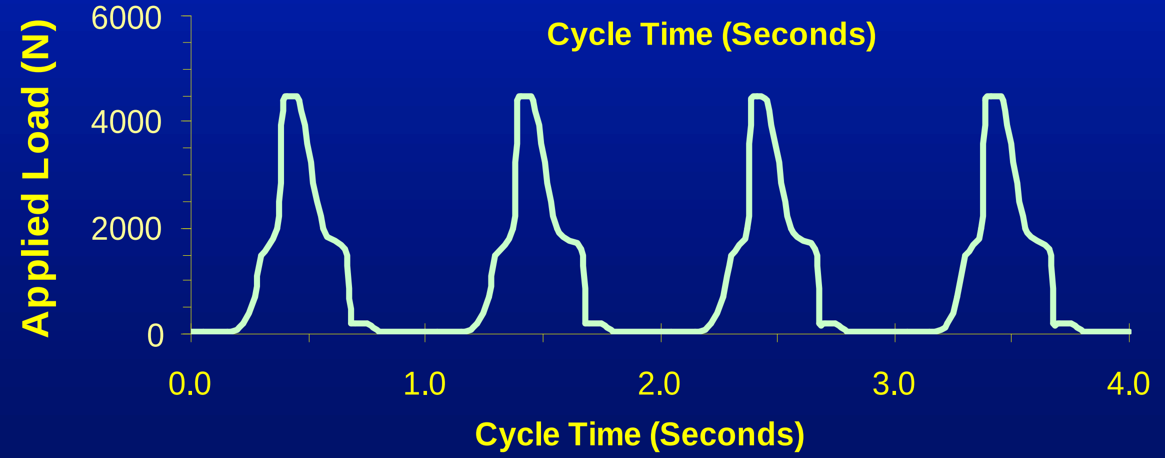
Normal walking



Fast jogging



Slow jogging



XL UHMWPE-on-Metal Hip Bearings

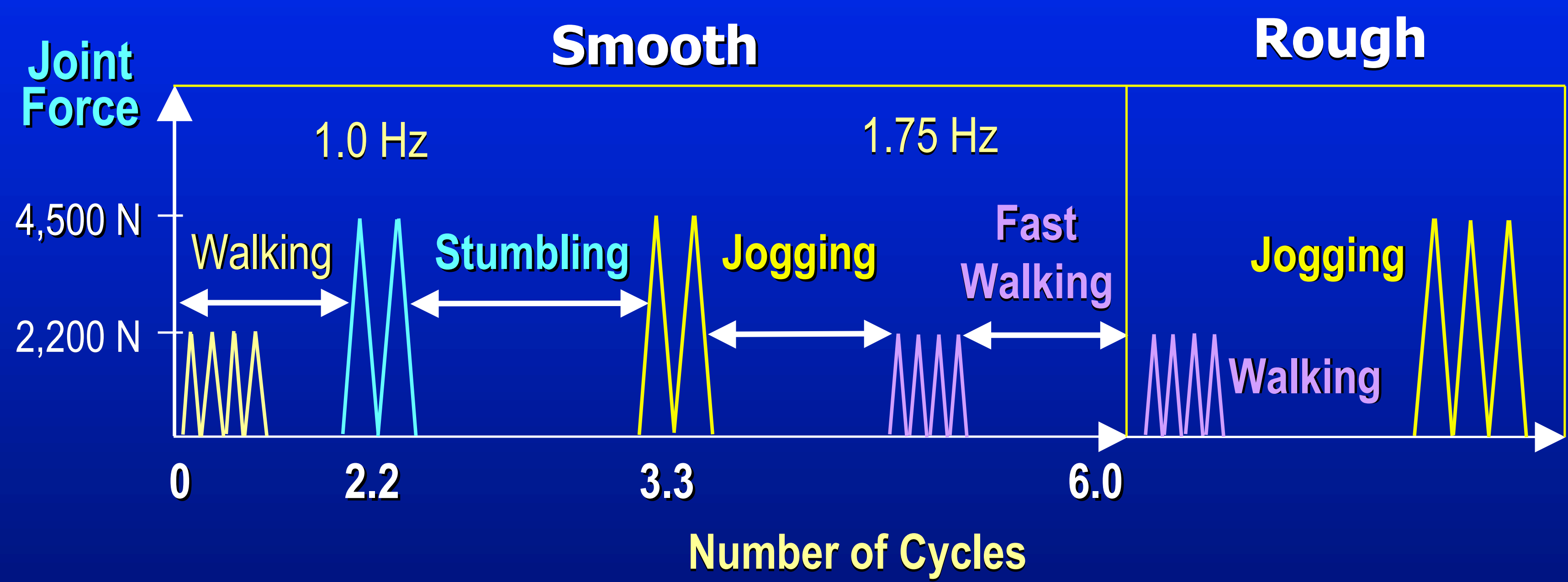
- 14x **28 mm** diameter sockets & CoCrMo femoral heads (DePuy, UK)
- UHMWPE GUR 1020 Gamma Irradiated 5 Mrads (in N_2)

	Median Ra
Smooth Conditions	0.007 µm
Rough Conditions	0.35 µm

∅ 5 mm & ∅ 10 mm Patches

Methods

- Physiological Test Configuration
- Gravimetric wear analysis + controls



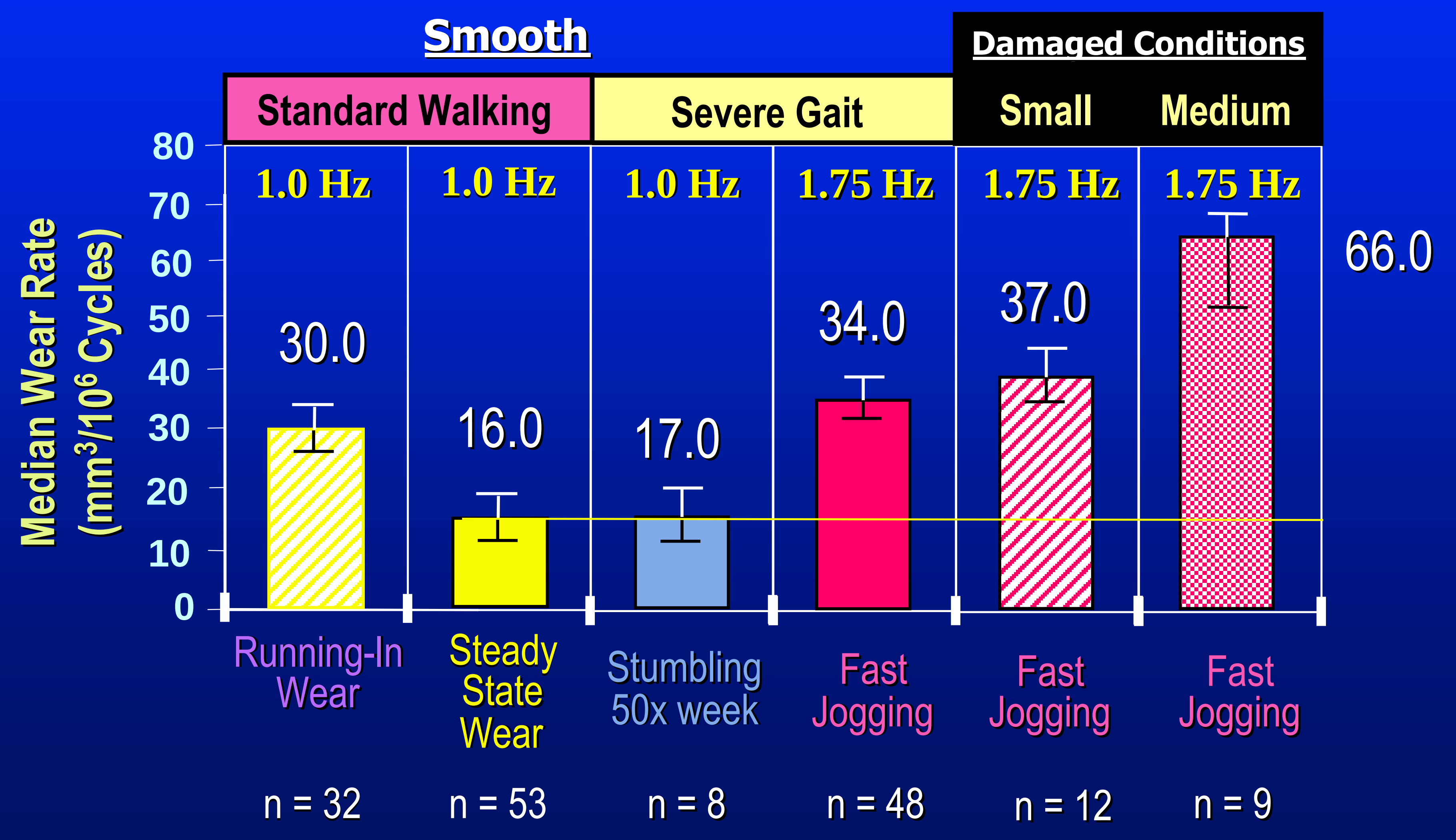
PE Wear Particle Analysis

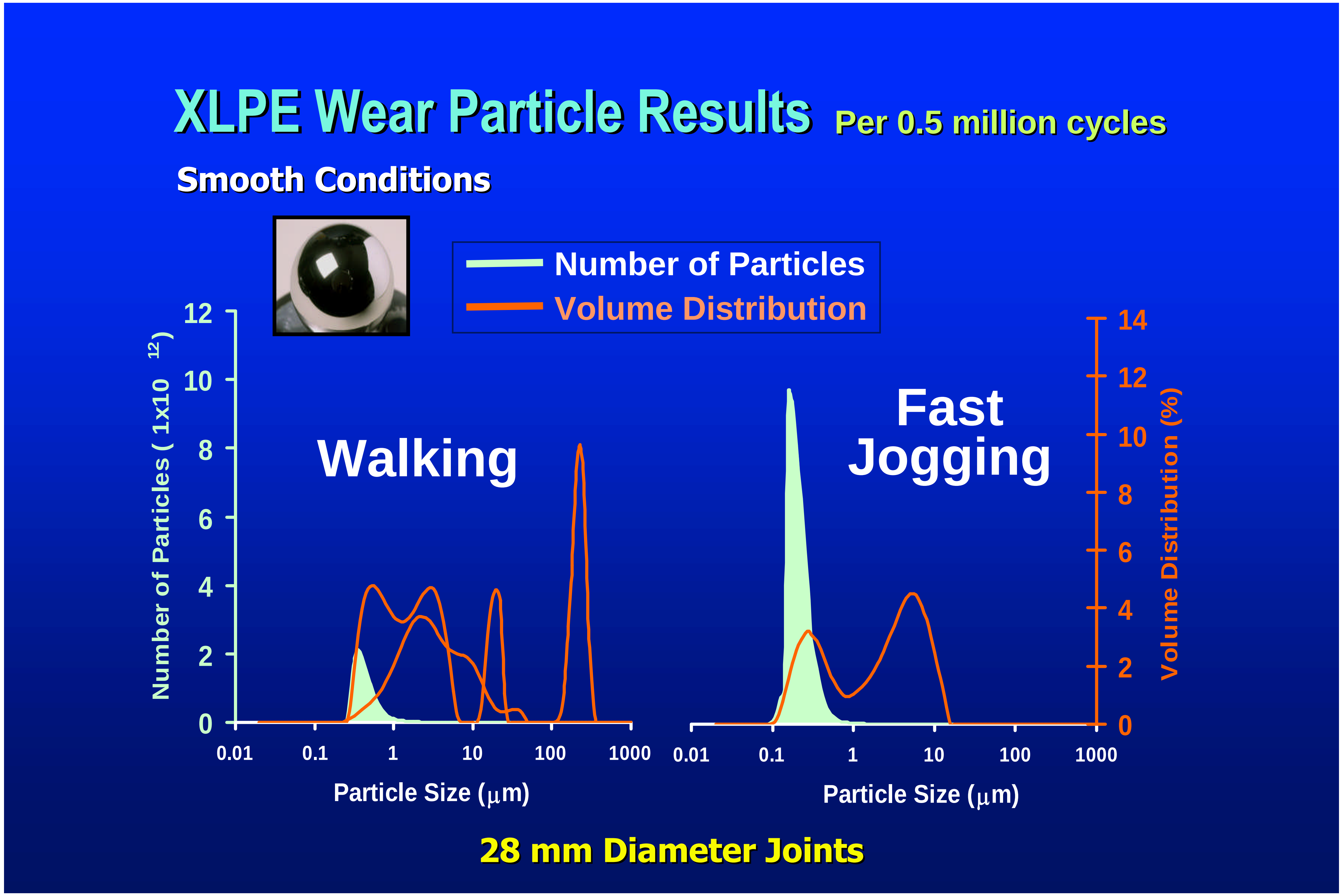
- Mastersizer (Particle Analyser)

(Elfick *et al* 2001, *Wear*)

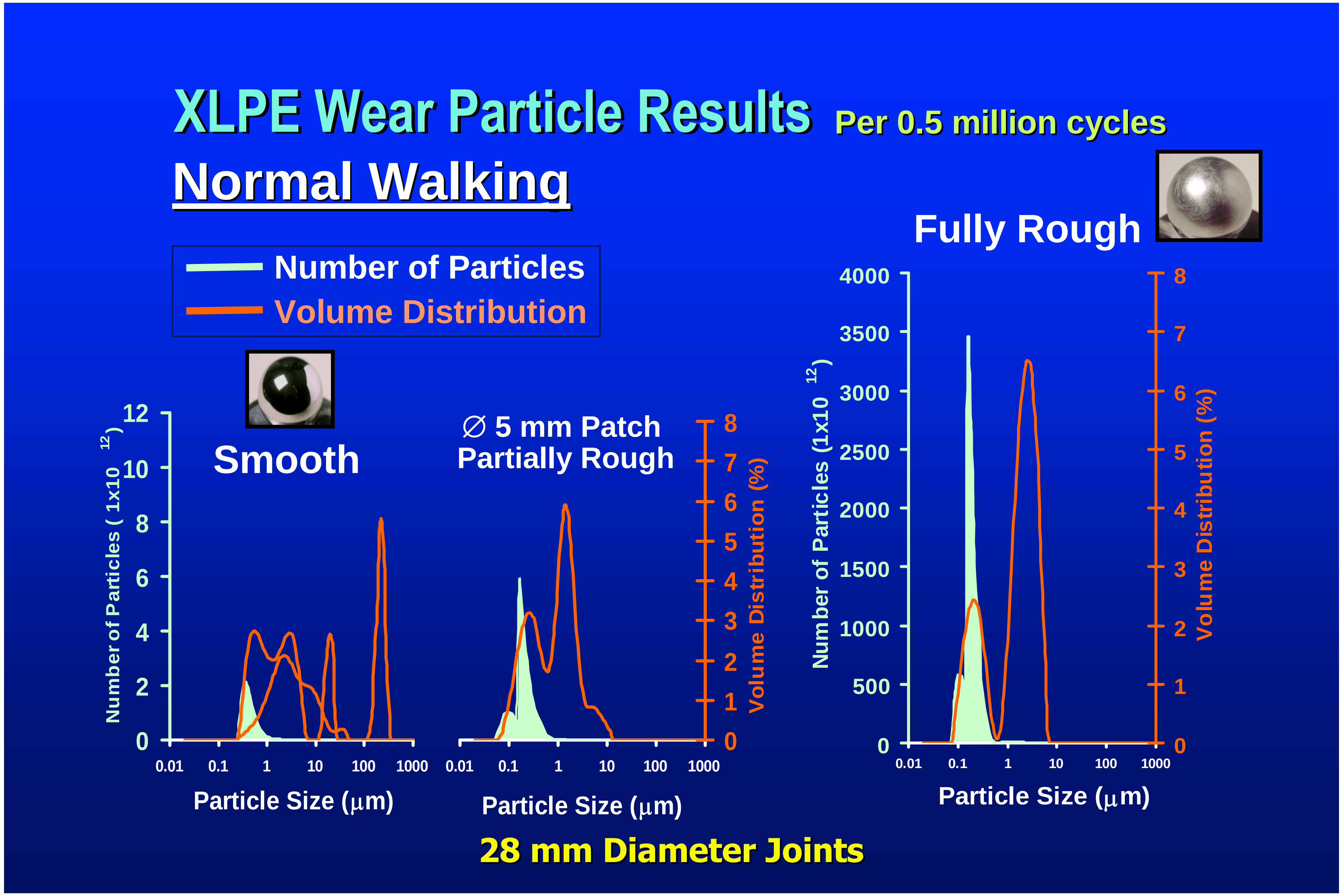
XLPE Volumetric Wear Results

28 mm Diameter Joints





XLPE Wear Particle Results
Per 0.5 million cycles
Smooth Conditions
Number of Particles
Volume Distribution
Walking
Fast Jogging
Number of Particles (1x10 12)
Volume Distribution (%)
0
2
4
6
8
10
12
14
0.01
0.1
1
10
100
1000
Particle Size (μm)
Particle Size (μm)
28 mm Diameter Joints

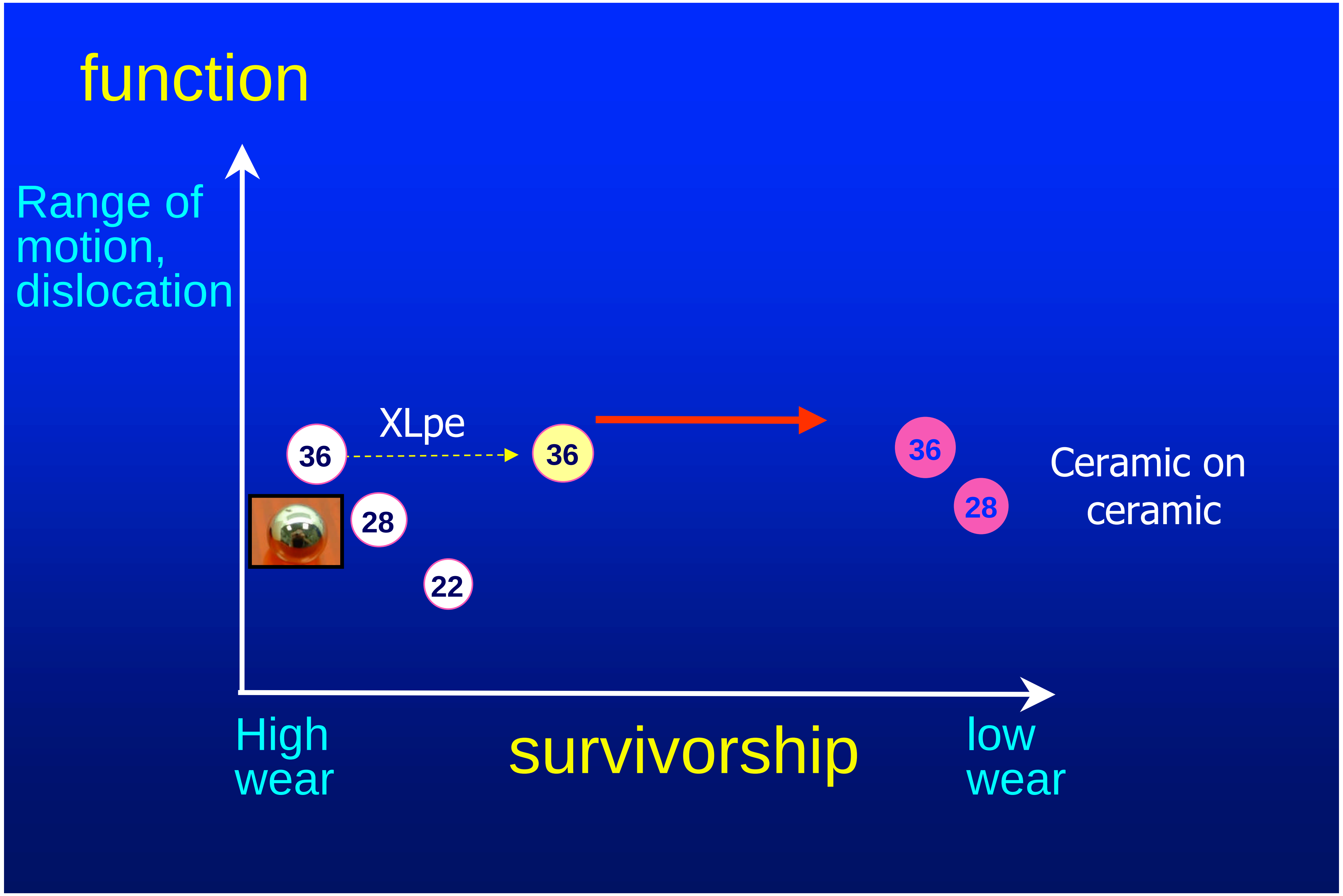

XLPE Wear Particle Results
Per 0.5 million cycles
Normal Walking
Number of Particles
Volume Distribution
Smooth
∅ 5 mm Patch
Partially Rough
Fully Rough
Number of Particles (1x10 12)
Number of Particles (1x10 12)
Volume Distribution (%)
Particle Size (μm)
0.01
0.1
1
10
100
1000
12
10
8
6
4
2
0
4000
3500
3000
2500
2000
1500
1000
500
7
5
3
1
28 mm Diameter Joints

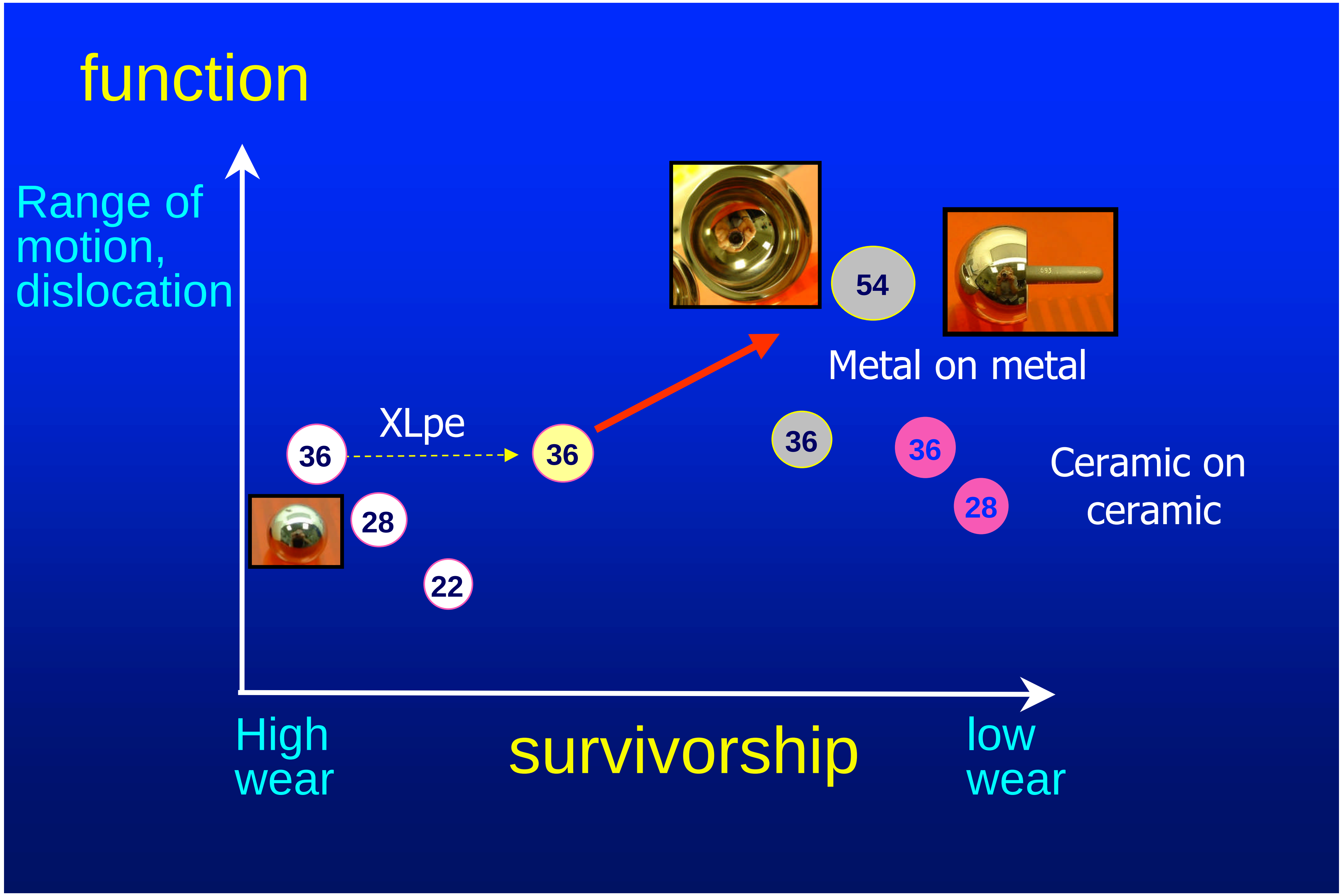
Ceramic-on-polyethylene

- Lower wear rates ~ 30 $mm^3/10^6$ cycles
- High resistance to head damage
- Good clinical results
- Limit on head size
- Particles

Ceramic-on-ceramic

- Very low wear rates
- Good clinical results
- Limit on head size
- Risk of fracture


function
Range of motion, dislocation
XLpe
36
36
28
22
36
28
Ceramic on ceramic
High wear
survivorship
low wear

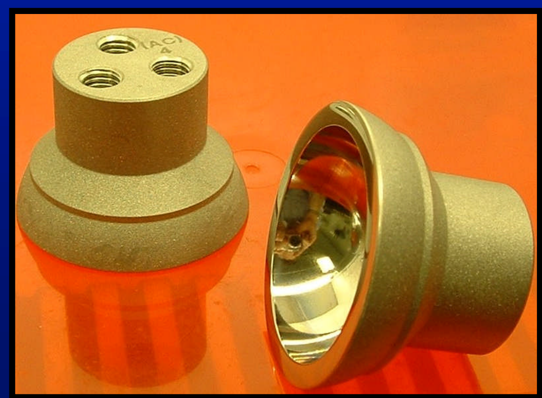

function
Range of motion, dislocation
54
Metal on metal
XLpe
36
36
36
36
28
22
28
Ceramic on ceramic
High wear
survivorship
low wear

Metal-on-metal

- Low wear rates: 0.1 – 4 $mm^3/10^6$ cycles
- Run-in, steady state
- Material parameters
  - high (0.2.- 0.35 wt%) / low (0.07 wt%) carbon
  - heat treatment
- Geometric parameters
  - Head diameter
  - Clearance
- Particles

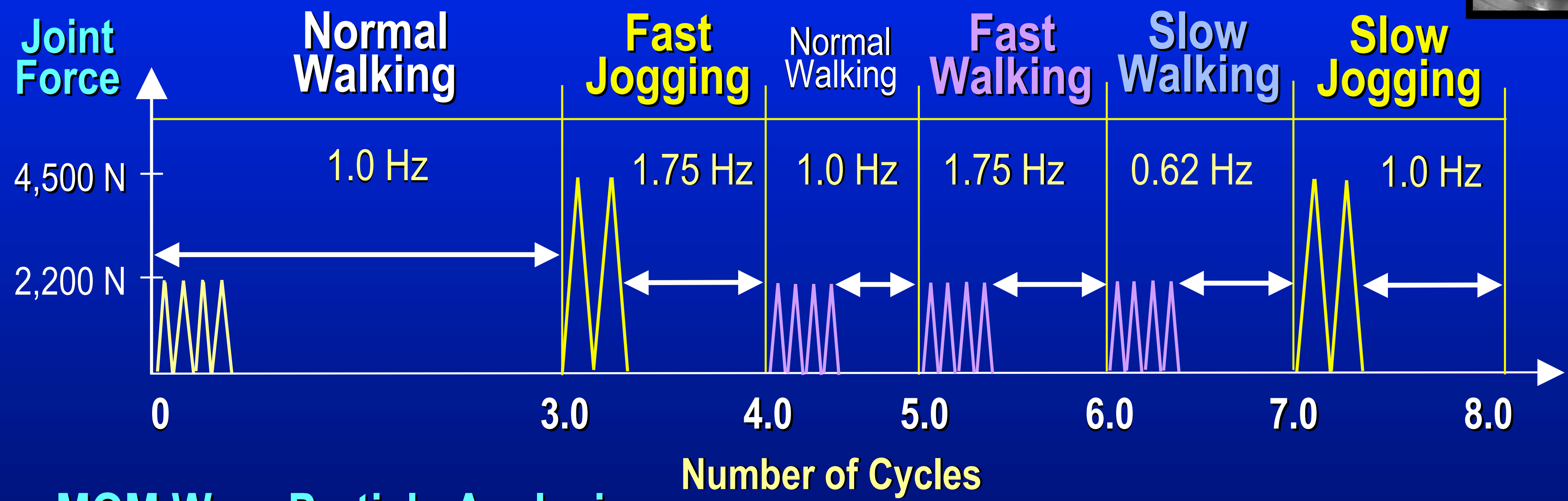
Metal-on-Metal (MoM) Hip Bearings

- 10x **40 mm** diameter, CoCrMo head and socket (Corin Medical, UK)
- High Carbon Cast CoCrMo alloy to BS7252-4, (0.2 – 0.35 % wt)



Methods

- Physiological Configuration
- Gravimetric wear analysis + controls

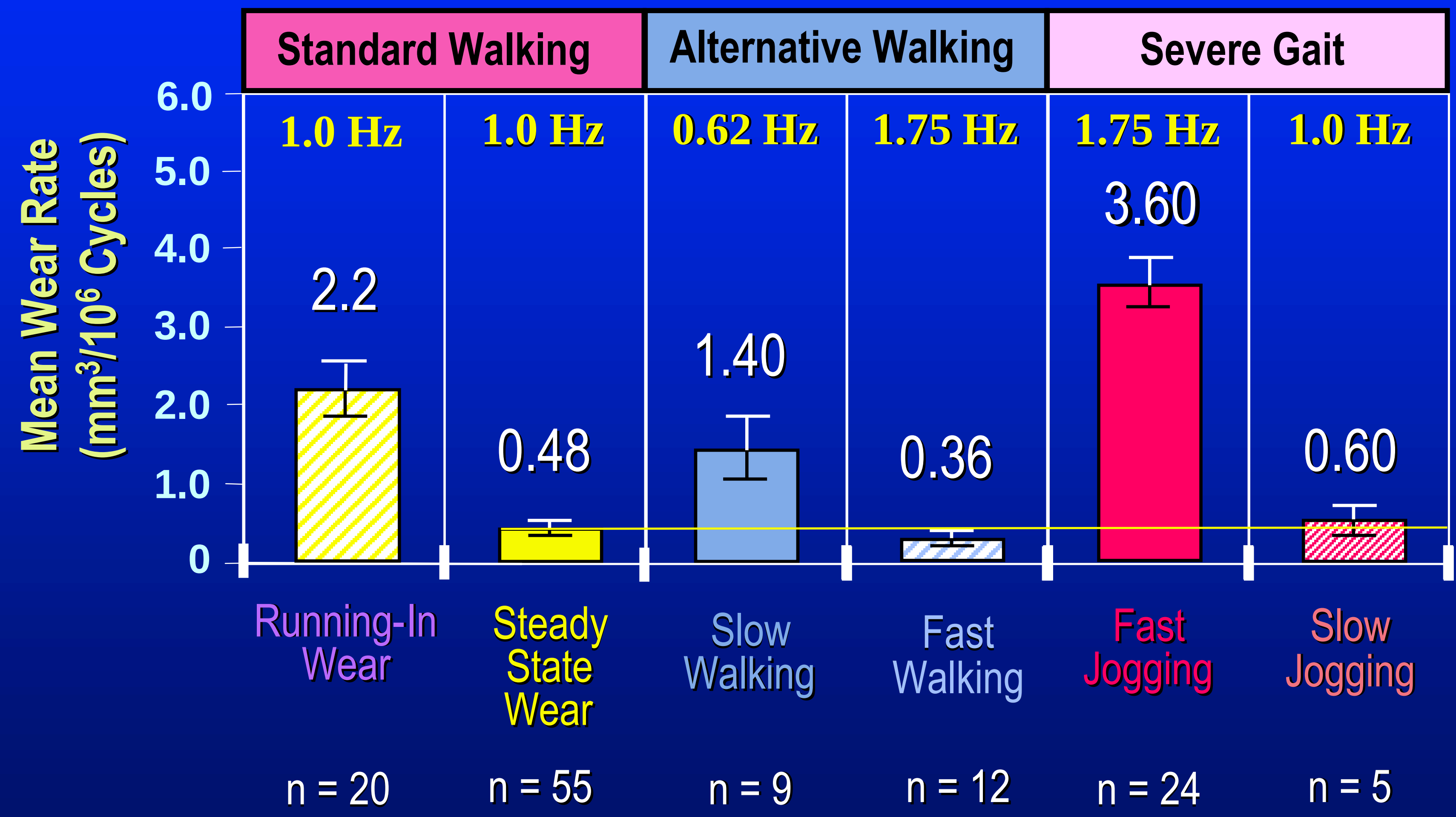


MOM Wear Particle Analysis

- 4-Looped Enzymatic Extraction & Isolation Protocol
- TEM Analysis, Image Pro Plus

MOM Volumetric Wear Results

40 mm Diameter Joints – Smooth Conditions

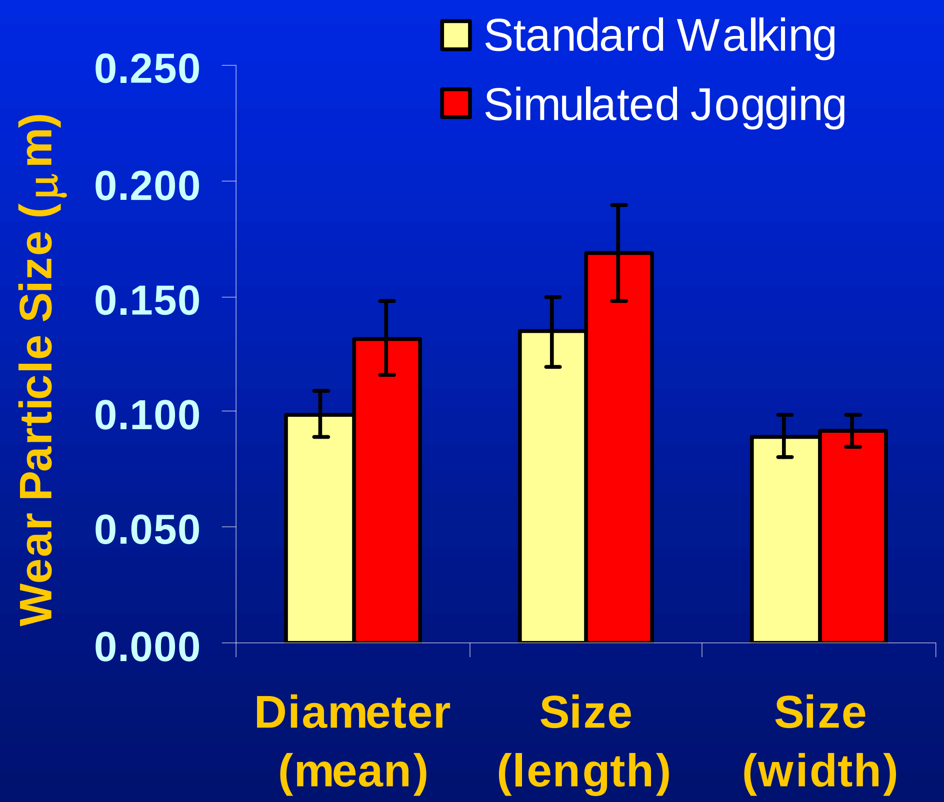


MOM TEM Wear Particle Results

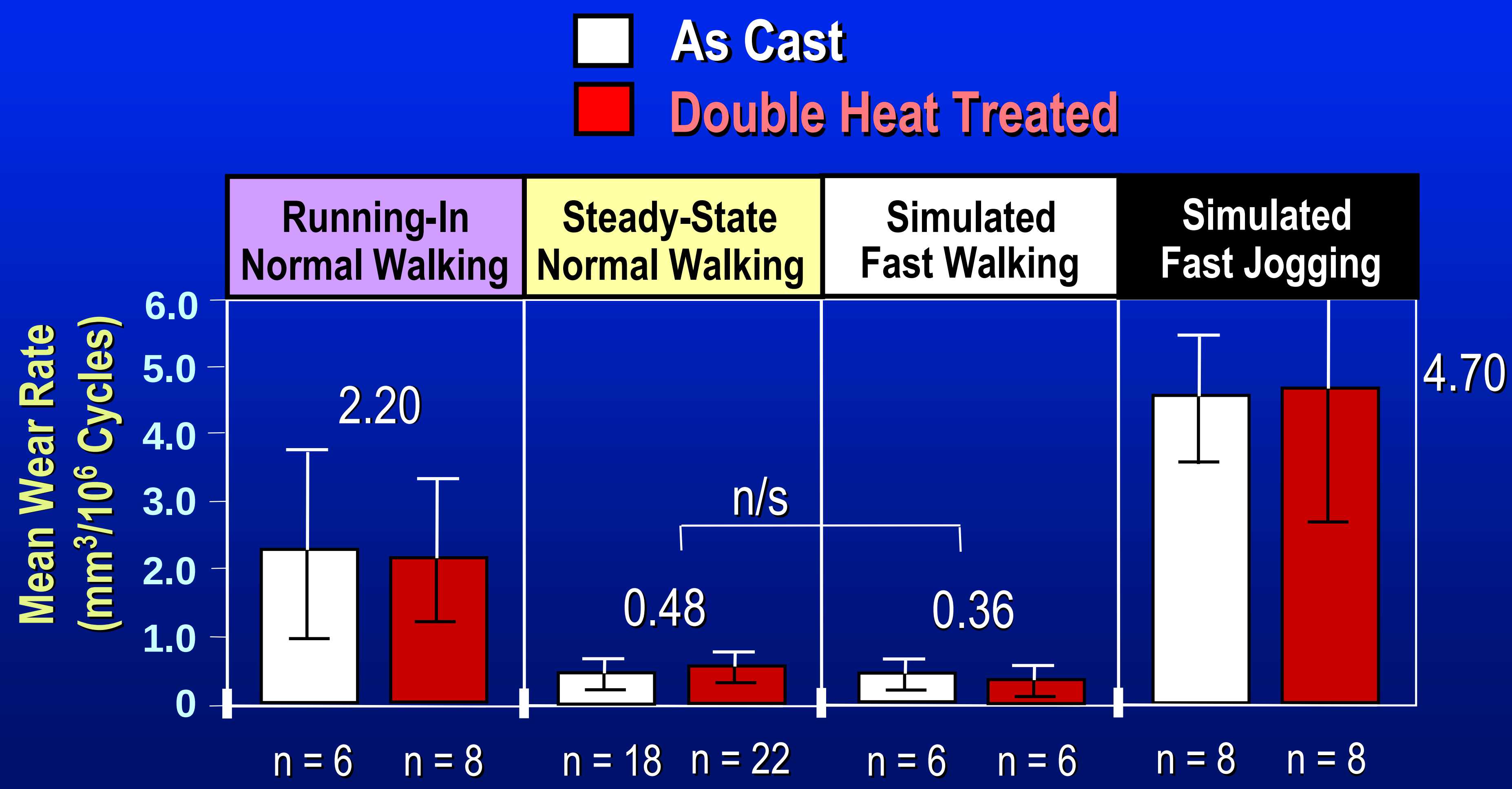
40 mm Diameter Joints - Smooth

Total of 314
CoCrMo Particles

TEM Results



Influence of metallographic treatments and testing geometry



Influence of Bearing Diameter

28mm 4x RC = 40 μm

40mm 10x RC = 110 μm

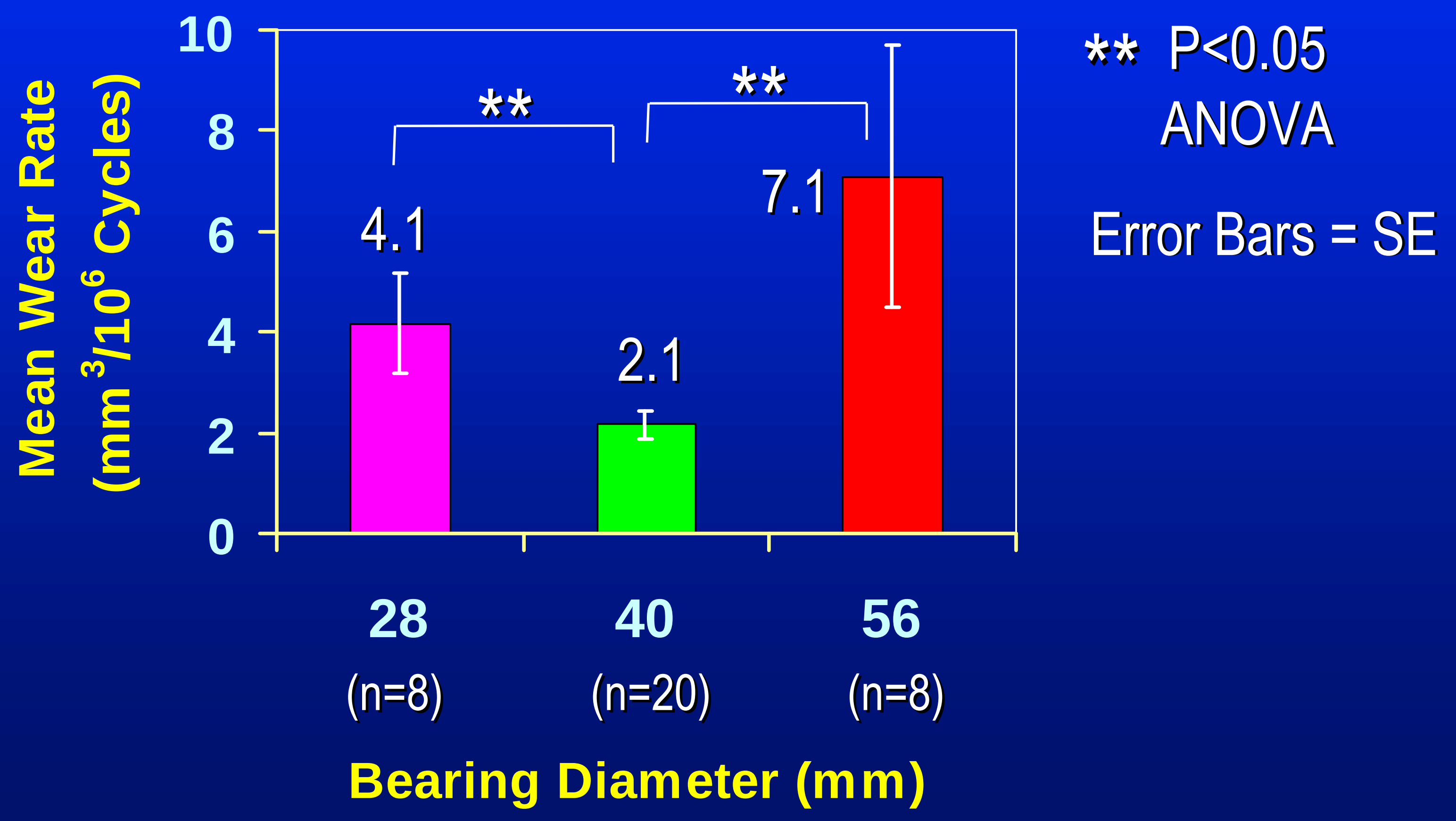
56mm 4x RC = 140 μm

High Carbon CoCrMo

Max dev. of sphericity 4 – 8 μm

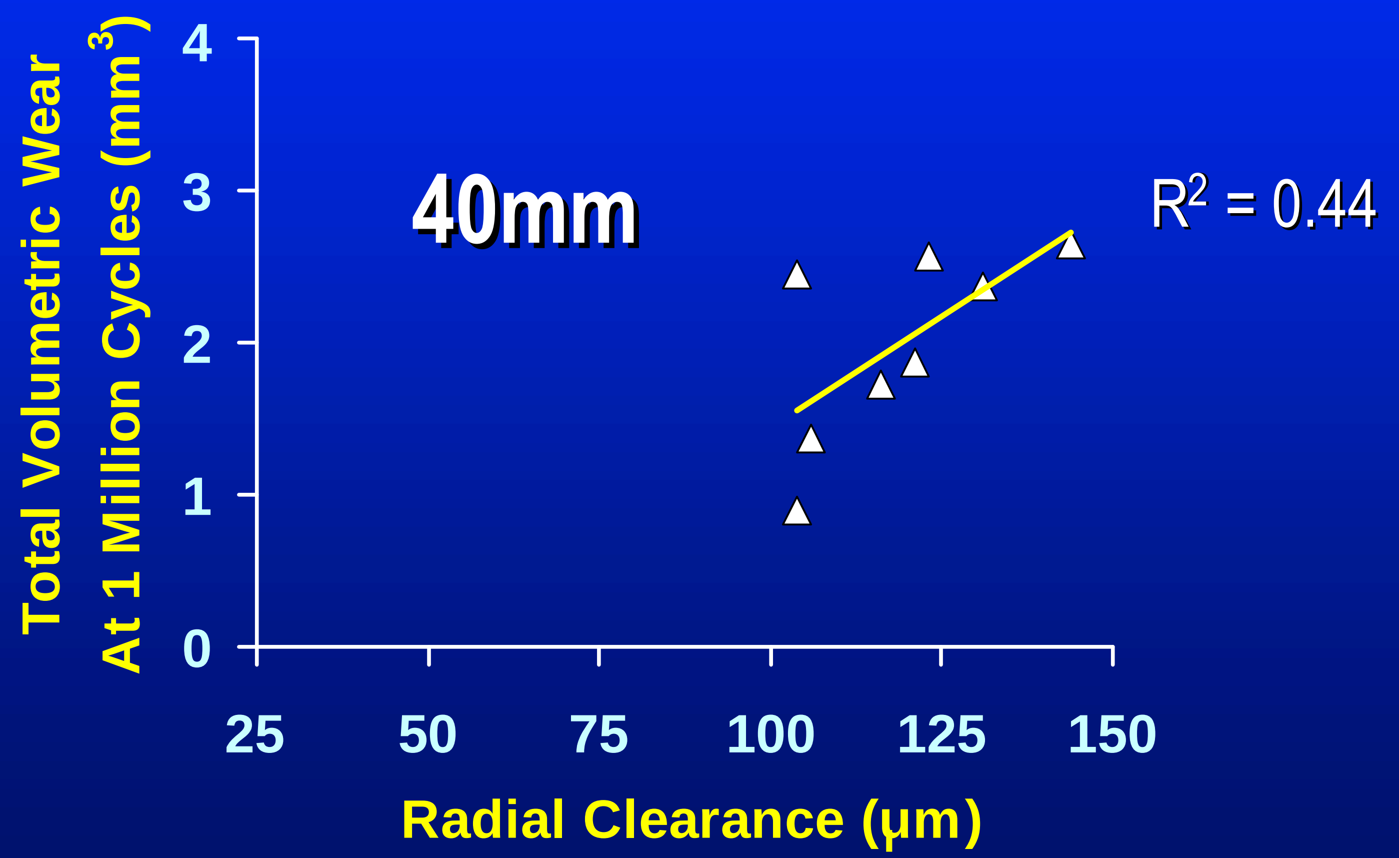
Influence of diameter

Running-In Wear



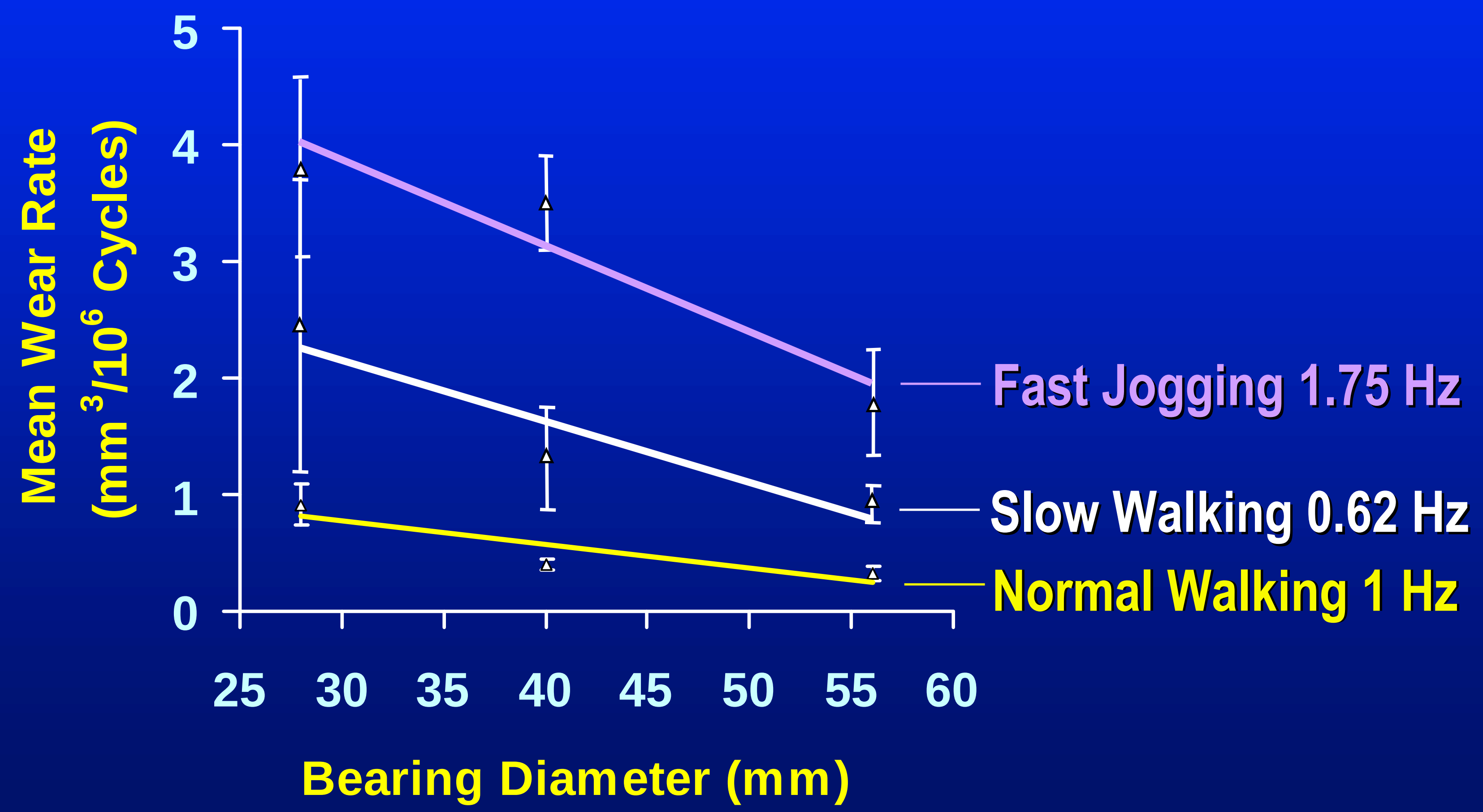
Influence of clearance

Running-In Wear



Influence of activity

Steady-State Wear



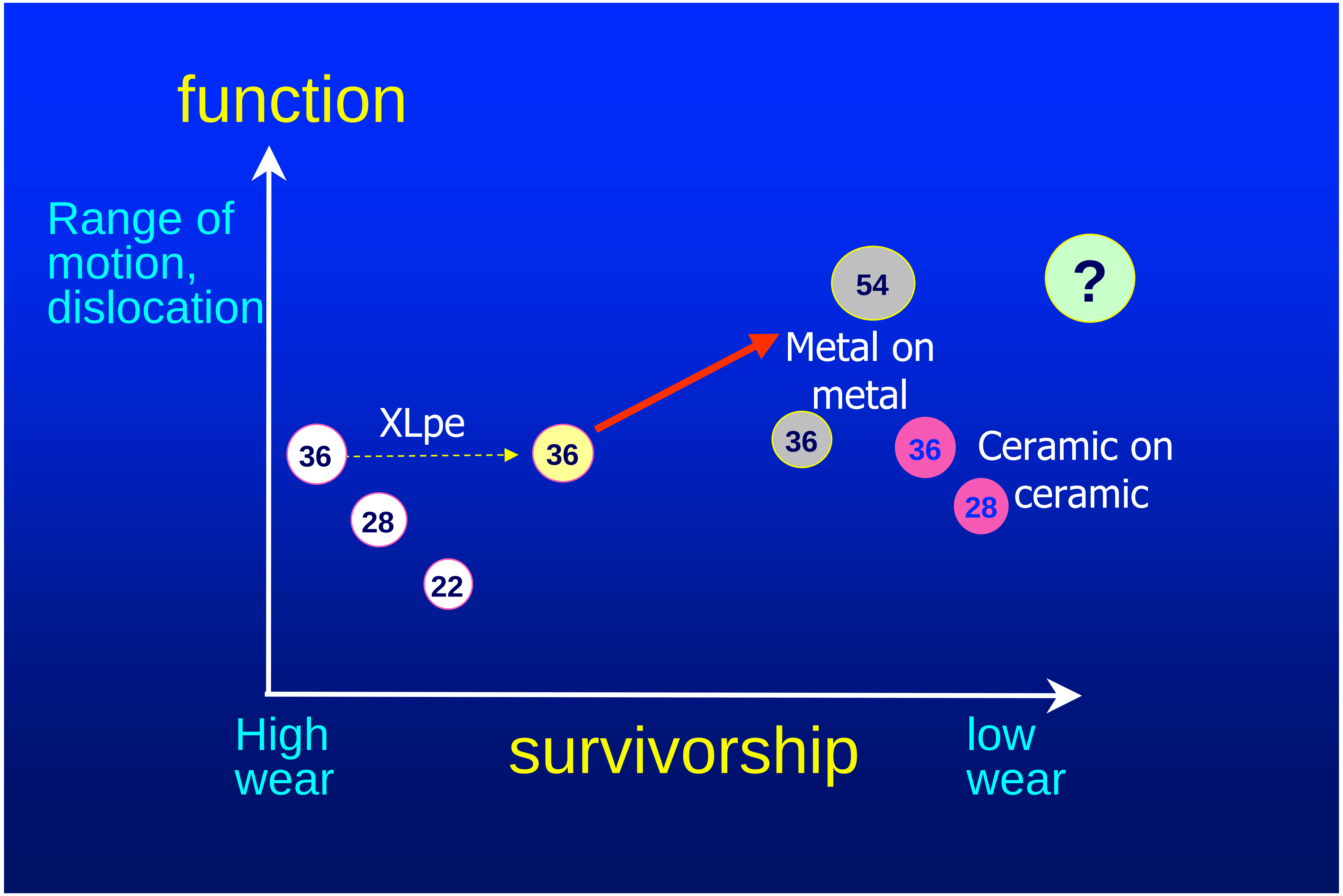
Testing

Any wear testing is better than none

Simplistic wear testing – may underestimate failure

The addition of severe gait simulations

- Can strongly increase volumetric wear & wear particle sizes
- May have the potential to improve appropriate prosthesis selection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