

National Joint Replacement Registry

The Role and Benefits of National Arthroplasty Registries.

Orthopaedic Surgeon Perspective

Presenter SE Graves
Director AOANJRR



AOANJRR Background

- Fully owned by the Australian Orthopaedic Association
- Data collection commenced in 1999 with full national implementation in 2002
- Funded by the Federal Government (Federal legislation 2009 to ensure cost recovery process updated in 2015)
- Listed as a Federal Quality Assurance Activity
- Major impact on joint replacement surgery Nationally and Internationally

AOANJRR



AOA Partners with

- South Australia Health and Medical Research Institute
- University of South Australia

AOANJRR Overview

(as of March 2016)

Participation Entirely Voluntary:

- Hospitals – **307** public & private (100%)
- Surgeons – **100 %** participation
- Patients – **34** 'have opted off'
- Data on over **99%** of procedures (Validated)
- Increasing at **5-7%** per year (over **100,000** procedures p.a.)

Currently information on almost **1.2 million** Procedures

- **502,397** hip procedures
- **597,435** knee procedures
- **33,288** shoulder procedures
- Almost **6 million** individual prostheses components

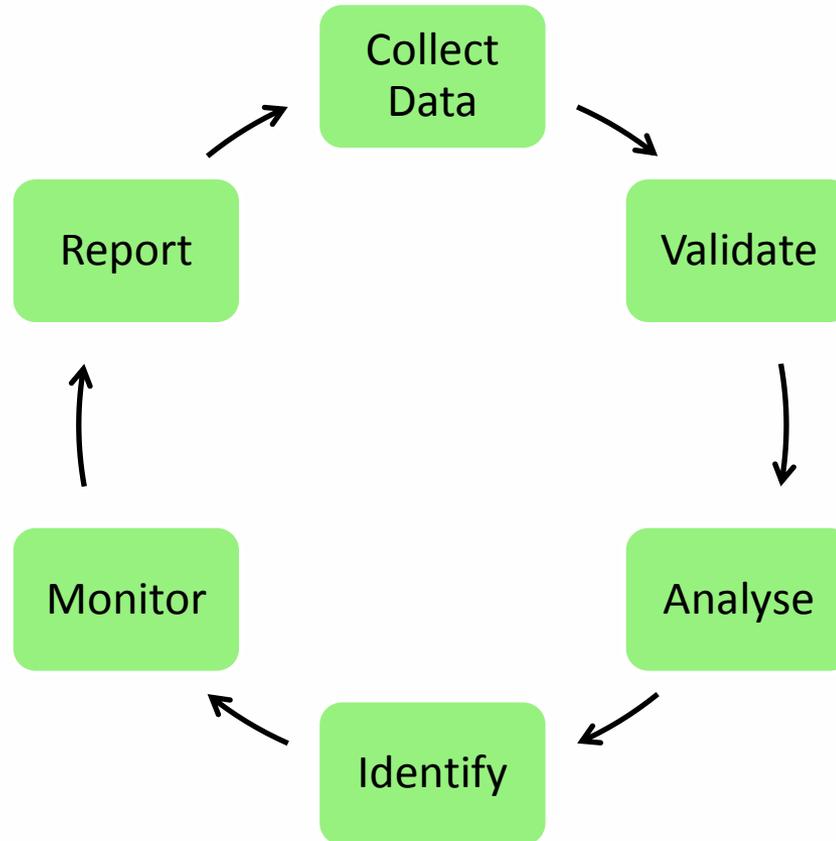
Additional Devices

- Elbow
- Wrist
- Ankle
- Spinal Disc replacement

Purpose

Collect quality clinical evidence that can be used to identify and monitor the effect of factors impacting on the outcome of joint replacement surgery and provide that information to relevant stakeholders to enable action and continuous beneficial change.

Improvement



Factors that Affect Outcomes

- Influenced by patient, surgeon, operative and prosthesis specific factors.
- The final result is a complex interaction between each of these.
- Registries are able to assess the relative importance of each of all relevant factors
- Almost all improvement in joint replacement in the last 10 years has been driven by registry data

Primary outcome measure

- Death
- Revision
- Reasons for revision
- Types of revision
- Patient, surgeon, hospital, and prosthesis factors that impact on revision

Additional Data Collection

- Comorbidity data (BMI ASA or more detailed)
- Adverse events other than revision
- PROM's
- Radiological
- Prostheses Retrieval Data
- Data linkage (EHR, Administrative data sets, others)

Individual Devices

New prostheses 2003-2007

Prostheses	Total	≥ 100
Hips	167	19.8%
Knees	99	28.3%
All	266	22.9%

New Prostheses introduced into Australia 2003-2007

Outcomes

Prosthesis	Total no. of components	Compared to the three best performing prostheses with CPR of 5 or more years		
		Better	Same	Worse
Hip	33	0	24	9 (27.3%)
Knee	28	0	20	8 (28.6%)
All	61	0	44	17 (27.9%)

Worse = p value < 0.05 on two tailed test

Prostheses 2008- 2012

Prostheses	Total	≥ 100
Hips	108	25.0%
Knees	63	31.7%
All	171	27.4%

New Prostheses introduced into Australia 2008-2012

Outcomes

Prosthesis	Total no. of components	Compared to the three best performing prostheses with CPR of 5 or more years		
		Better	Same	Worse
Hip	27	0	17	10 (37.0%)
Knee	20	0	9	11 (55.0%)
All	47	0	26	21 (44.7%)

Worse = p value < 0.05 on two tailed test

New prostheses 2003-2012

- Better outcome - 1 in 500
- Worse outcome - 30% not used in sufficient numbers to tell but of those where outcomes can be assessed then > 40% chance of worse outcome

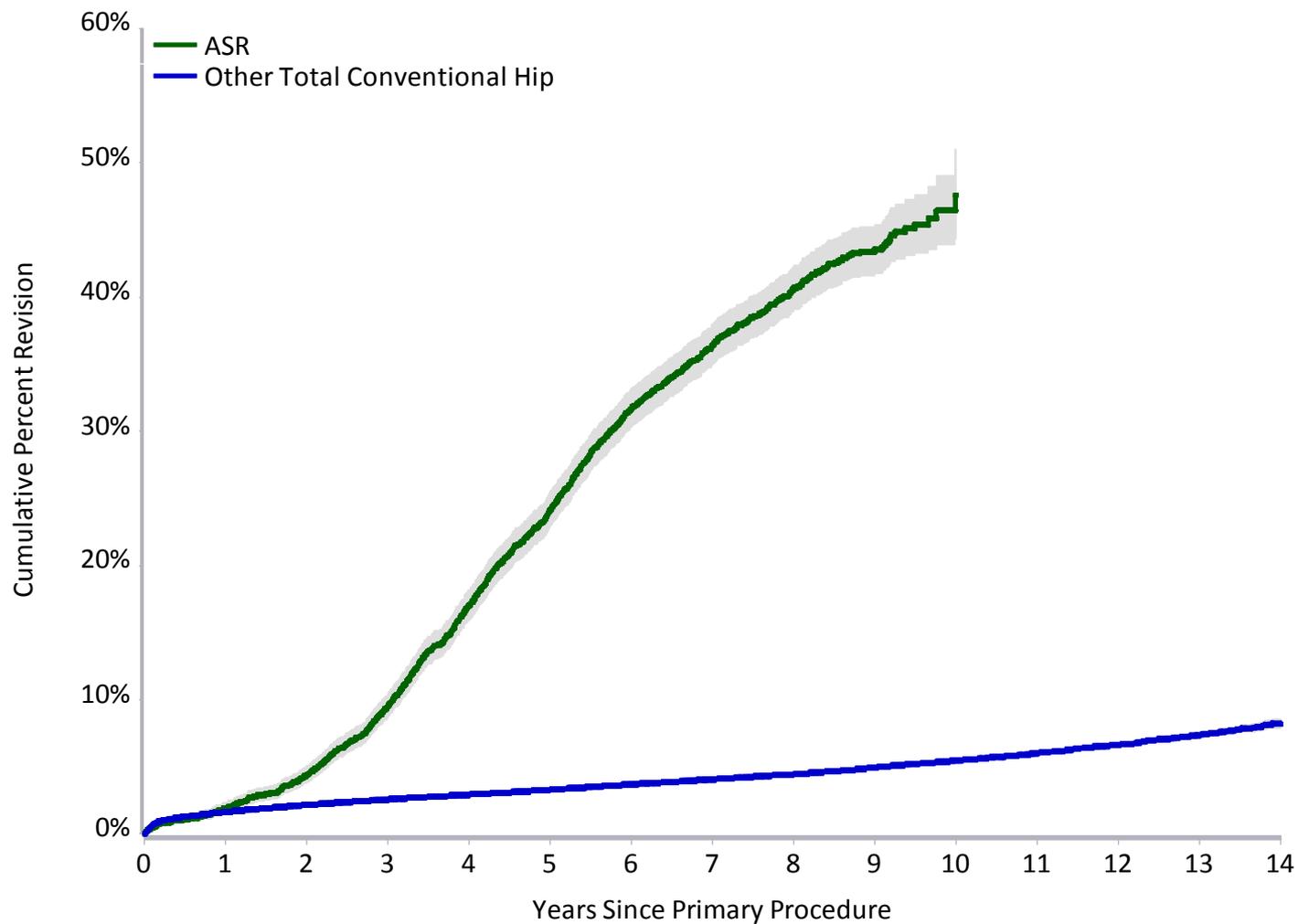
AOANJRR Assessment of Devices

- Simultaneous comparison of all devices within the national setting
- There are differences in outcome individual devices, device specific features and whole classes of devices
- Patient and surgeon factors are always considered and they are important for some devices
- Statistically about 85% of devices perform the same as the best performing device in a particular class
- Of the remaining 15% some of those have a much higher rate of revision (outlier devices)

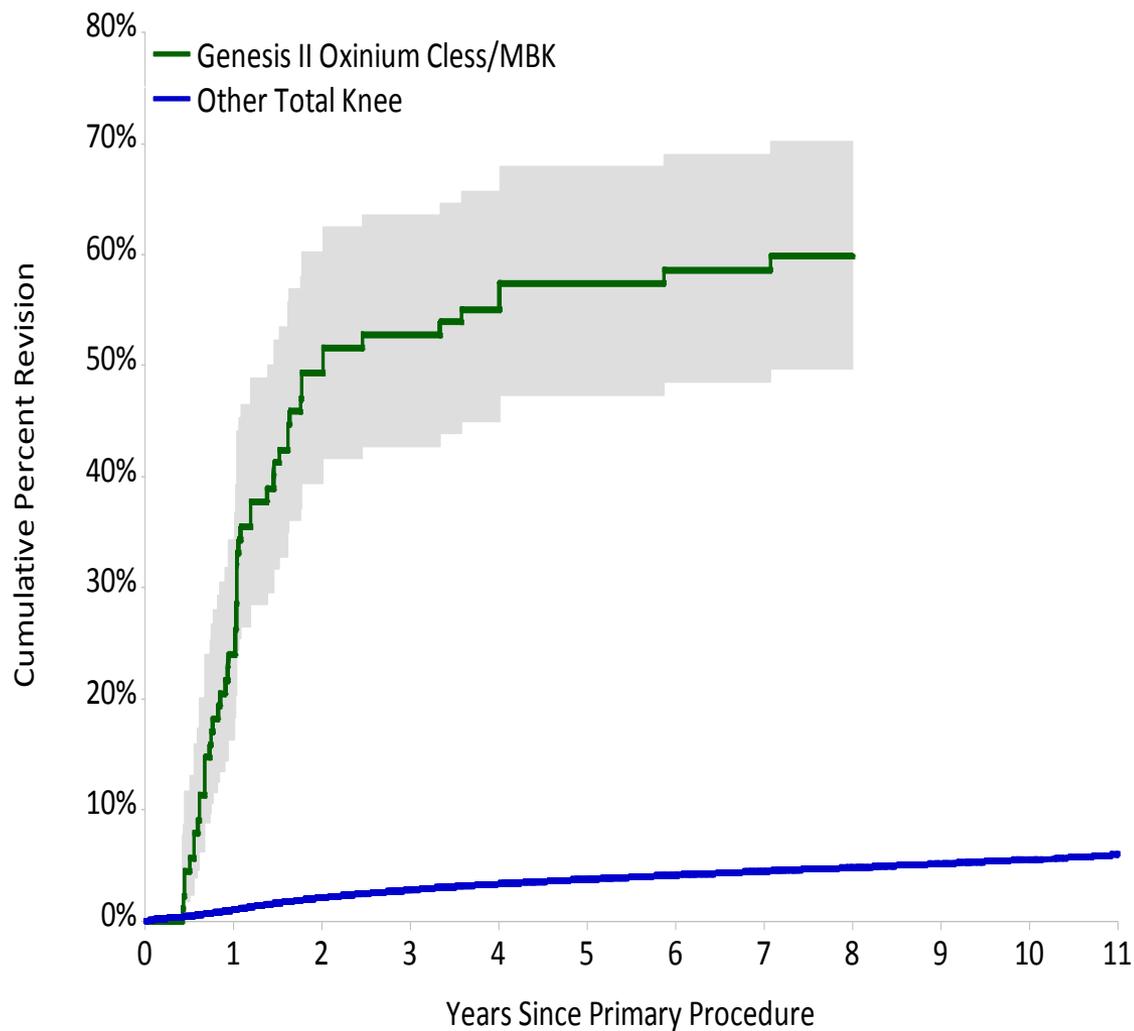
Australian Registry Approach to Identification of Prosthesis Outliers

- Multistage approach
- Stage 1 (screening test 2x the risk of revision)
- Stage 2 (review and further analysis examining impact of confounders)
- Stage 3 Independent Panel Review

ASR XL Current Revision Rate



Cementless Oxinium Genesis TKR

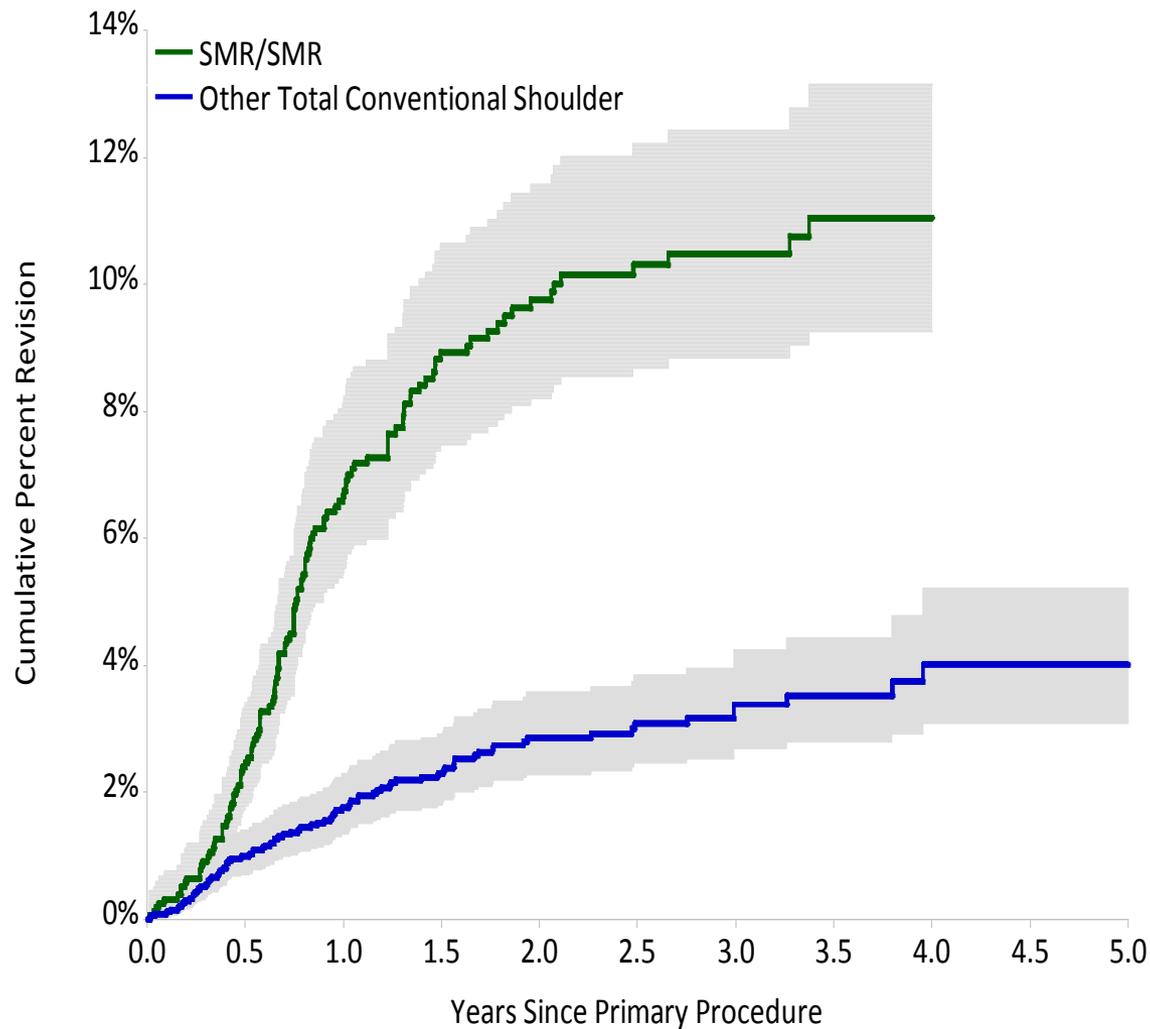


HR - adjusted for age and gender

Genesis II Oxinium Cless/MBK vs Other Total Knee

Entire Period: HR=17.28 (13.19, 22.63), p<0.001

SMR Conventional Shoulder



HR - adjusted for age and gender

SMR/SMR vs Other Total Conventional Shoulder

Entire Period: HR=3.36 (2.55, 4.41), $p < 0.001$

Individual Prostheses Identified

- Between 2004 and 2013 the Registry has identified 117 prostheses or combinations using this approach
 - 58 conventional hip
 - 6 resurfacing
 - 39 total knee
 - 9 Partial Knee
 - 5 conventional and/or reverse shoulder

Best Prostheses

10 year Cumulative Percent Revision (OA, all Patients and all Reasons for Revision)

Hips

MS 30 Stem (n=2000)
 3 different acetabular components **(2.4% - 3.5%)**

Exeter V40 Stem (n=40,000)
 6 different acetabular components **(3.2% - 4.6%)**

Secure Fit & Secure fit Plus Stem (n=10,000)
 With Trident acetabular component **(3.2% - 4.1%)**

Summit Stem (n=3,500)
 Pinnacle acetabular component **(2.9%)**

50% of Hips have less than 5% revision at 10 years

Knees

Nexgen CR (n=10,500)
(3.0%)

Nexgen CR Flex (n=31,000)
(2.9%)

PFC Sigma CR (n=21,500)
(3.7%)

PFC Sigma PS (n=6,500)
(4.5%)

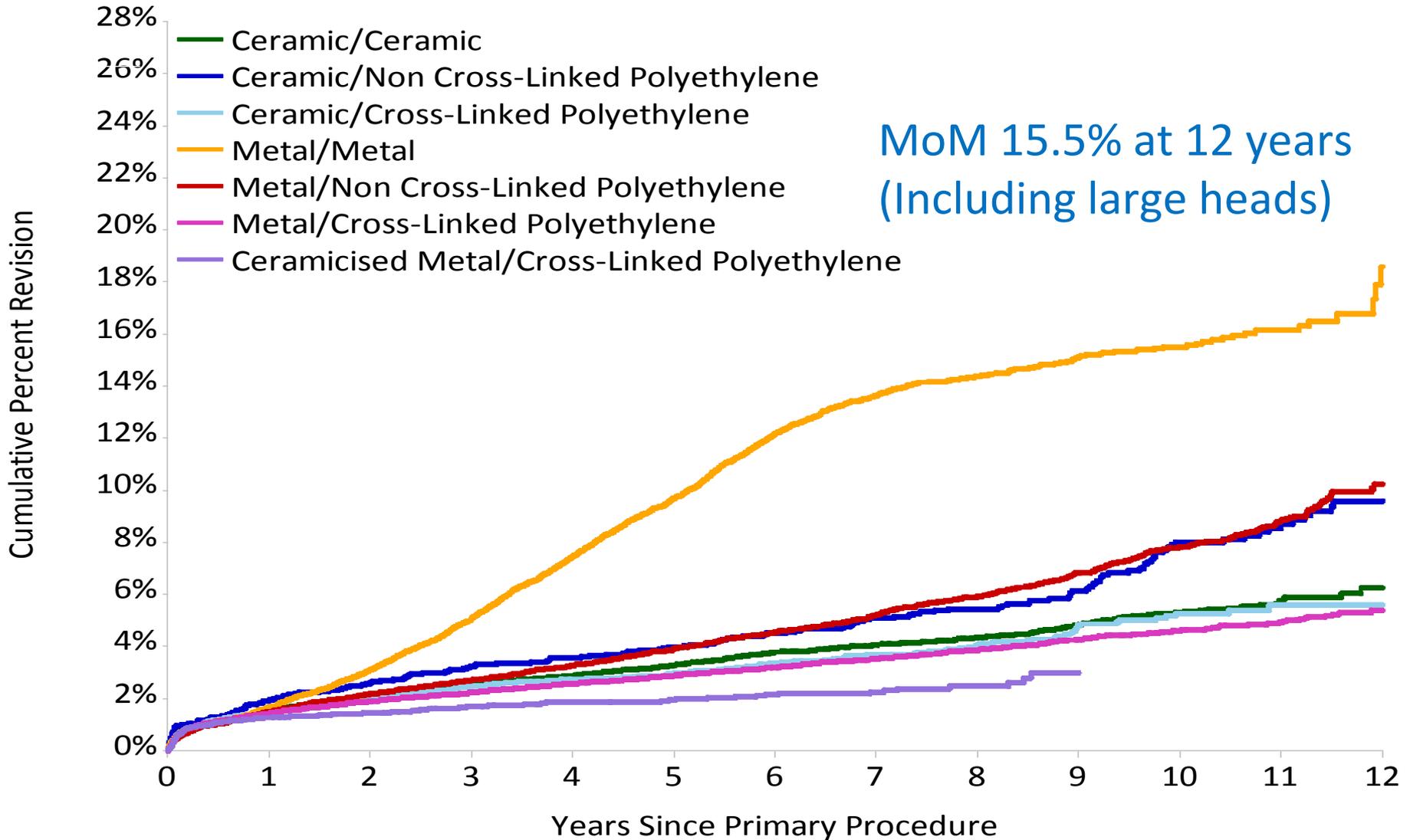
25% of Knees have less than 5% revision at 10 years

Class of Device

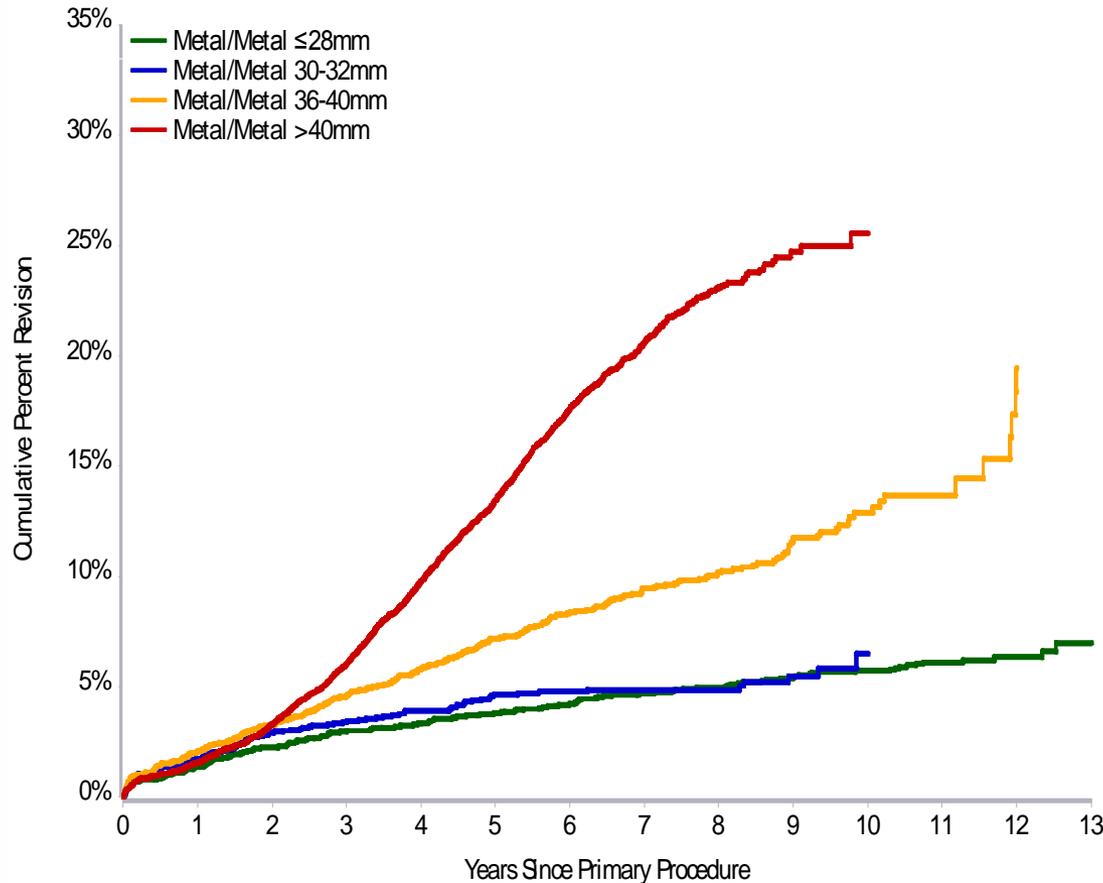
Bearing Surfaces



Cumulative Percent Revision of Primary THR by Bearing Surface (OA)



Cumulative Percent Revision of MoM Primary THR by Head Size (OA)



HR - adjusted for age and gender

Metal/Metal 30-32mm vs Metal/Metal ≤28mm

Entire Period: HR=1.16 (0.90, 1.50), p=0.240

Metal/Metal 36-40mm vs Metal/Metal ≤28mm

0 - 4.5Yr: HR=1.87 (1.51, 2.32), p<0.001

4.5Yr - 5Yr: HR=3.53 (2.18, 5.74), p<0.001

5Yr - 6.5Yr: HR=2.16 (1.47, 3.17), p<0.001

6.5Yr - 9Yr: HR=3.36 (2.27, 4.98), p<0.001

9Yr+: HR=6.90 (3.75, 12.69), p<0.001

Metal/Metal >40mm vs Metal/Metal ≤28mm

0 - 1Yr: HR=1.28 (0.98, 1.67), p=0.068

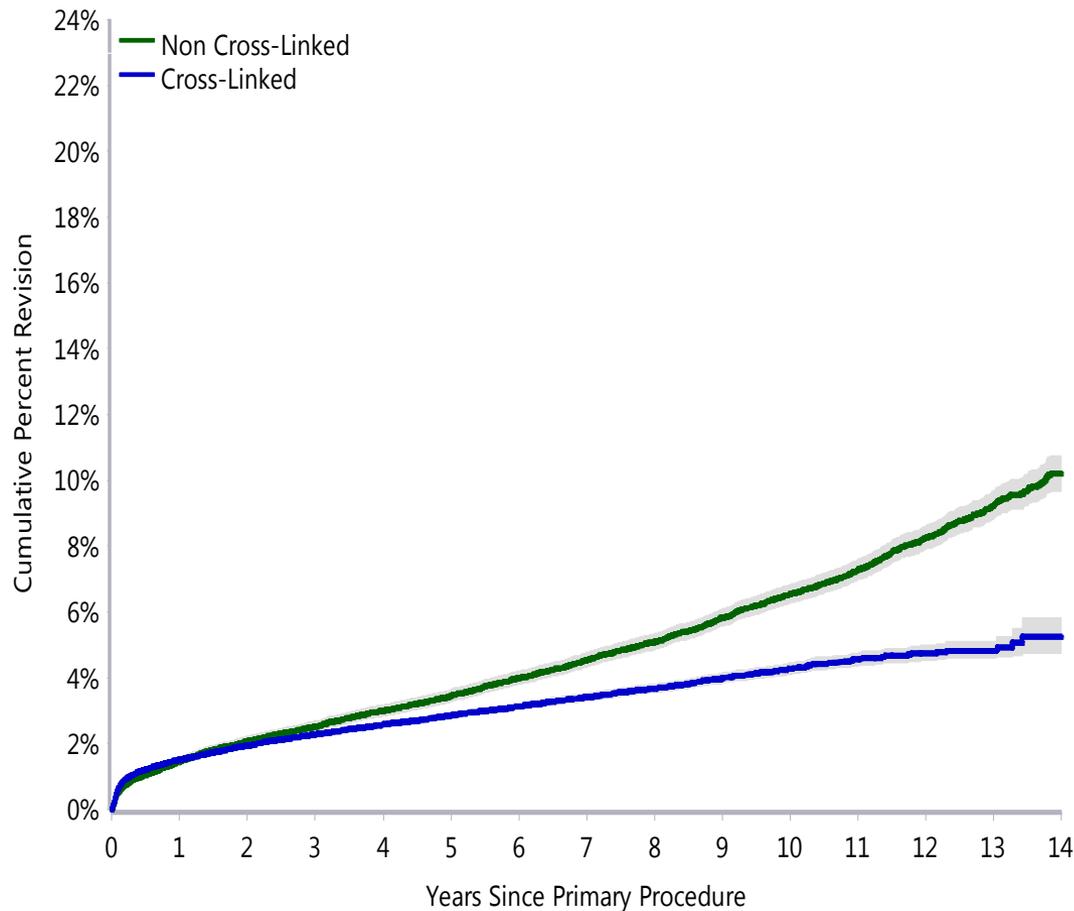
1Yr - 2Yr: HR=2.37 (1.77, 3.17), p<0.001

2Yr - 2.5Yr: HR=4.24 (2.88, 6.23), p<0.001

2.5Yr - 3Yr: HR=4.24 (2.90, 6.18), p<0.001

3Yr+: HR=8.78 (7.17, 10.74), p<0.001

Cross-linked V's Non Cross-linked Polyethylene in THR



HR - adjusted for age and gender

Non Cross-Linked vs
Cross-Linked

0 - 3Mth: HR=0.84 (0.74, 0.95),p=0.004

3Mth - 6Mth: HR=1.04 (0.82, 1.31),p=0.749

6Mth - 1.5Yr: HR=1.49 (1.30, 1.71),p<0.001

1.5Yr - 2.5Yr: HR=1.25 (1.05, 1.49),p=0.011

2.5Yr - 5Yr: HR=1.61 (1.41, 1.83),p<0.001

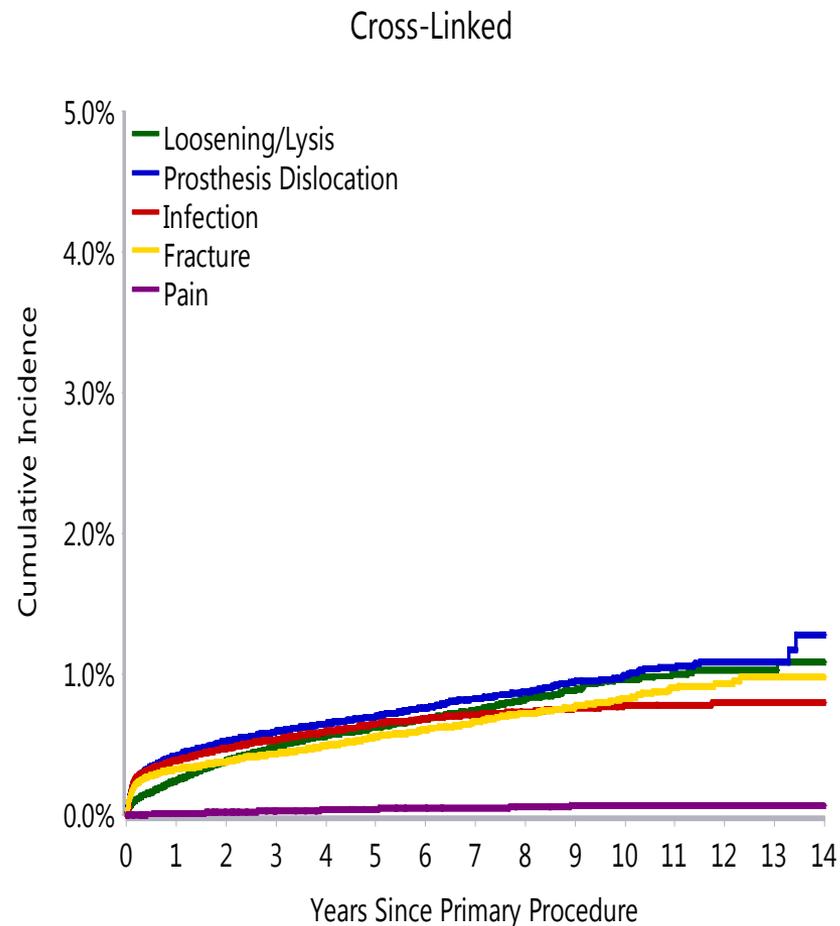
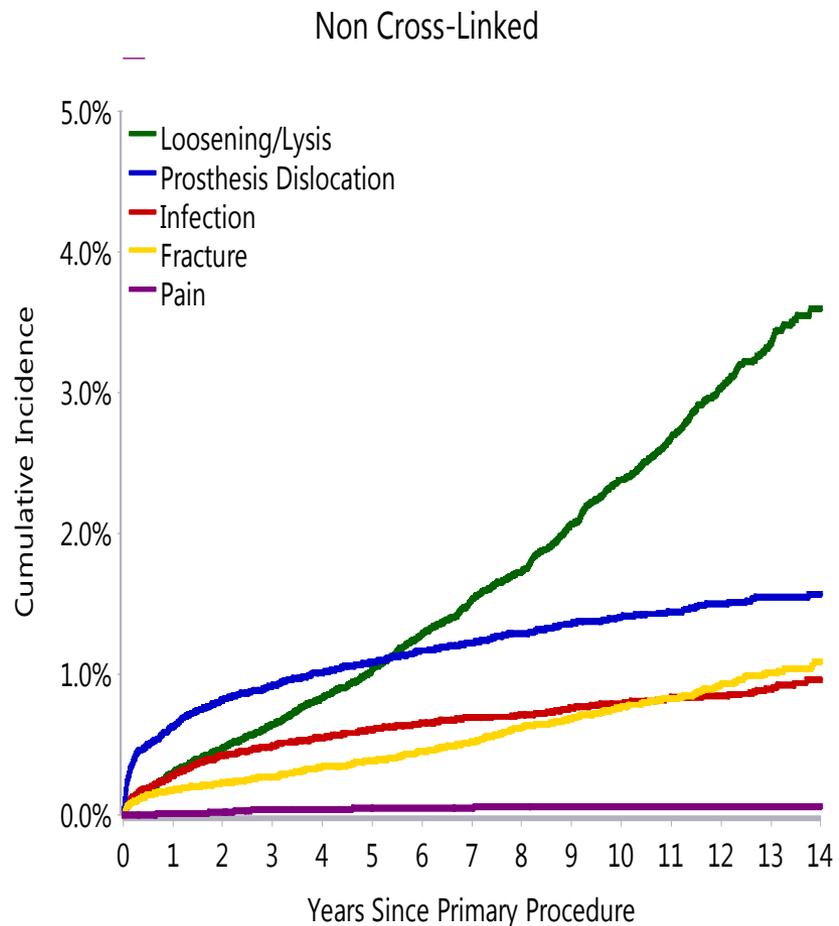
5Yr - 6.5Yr: HR=1.92 (1.59, 2.31),p<0.001

6.5Yr - 9Yr: HR=2.25 (1.90, 2.67),p<0.001

9Yr+: HR=3.10 (2.48, 3.89),p<0.001

Reasons for Revision

Cross-linked V's Non Cross-linked



Excellent Post market surveillance system in an environment of ineffective Global Regulation

Joint replacement is a quality procedure which is being harmed by the current global approach to the introduction of new technology.

Need to change current approach to premarket technology assessment

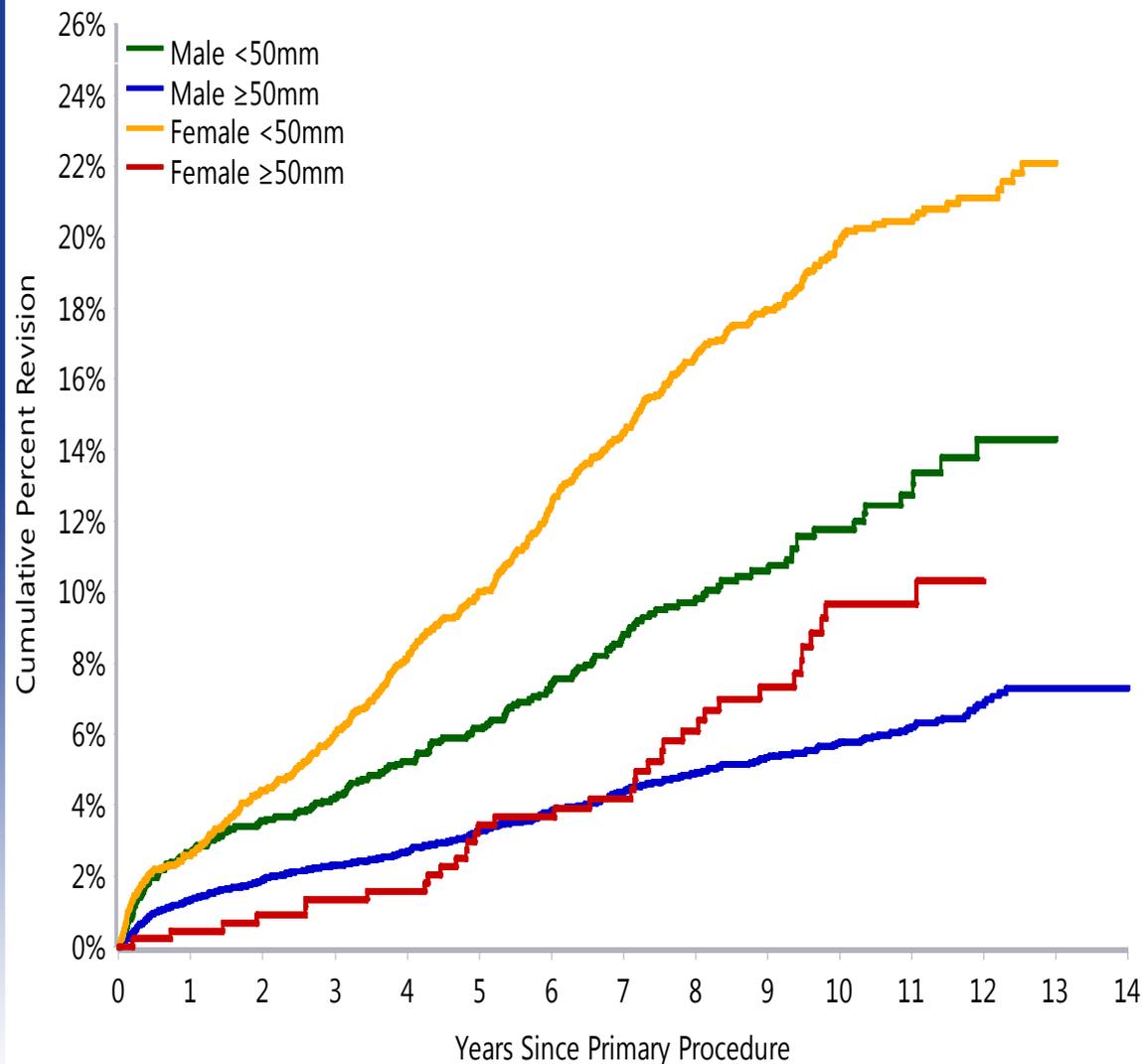
Approaches to Premarket Clinical Evidence

- Mostly none
- Company Sponsored
-
- Beyond Compliance
- Australian Prostheses List
- Harvard Global Program
- FDA US Registries Coordinated Program

- Registries are integral to all the developing programs

Impact of Patient Factors

Resurfacing (Head Size & Gender)



HR - adjusted for age

Male <50mm vs Male ≥50mm

Entire Period: HR=2.06 (1.74, 2.45), p<0.001

Male ≥50mm vs Female ≥50mm

0 - 1.5Yr: HR=1.44 (0.83, 2.50), p=0.197

1.5Yr - 3Yr: HR=0.83 (0.46, 1.50), p=0.532

3Yr - 5Yr: HR=0.67 (0.38, 1.19), p=0.171

5Yr+: HR=0.50 (0.32, 0.79), p=0.003

Male <50mm vs Female <50mm

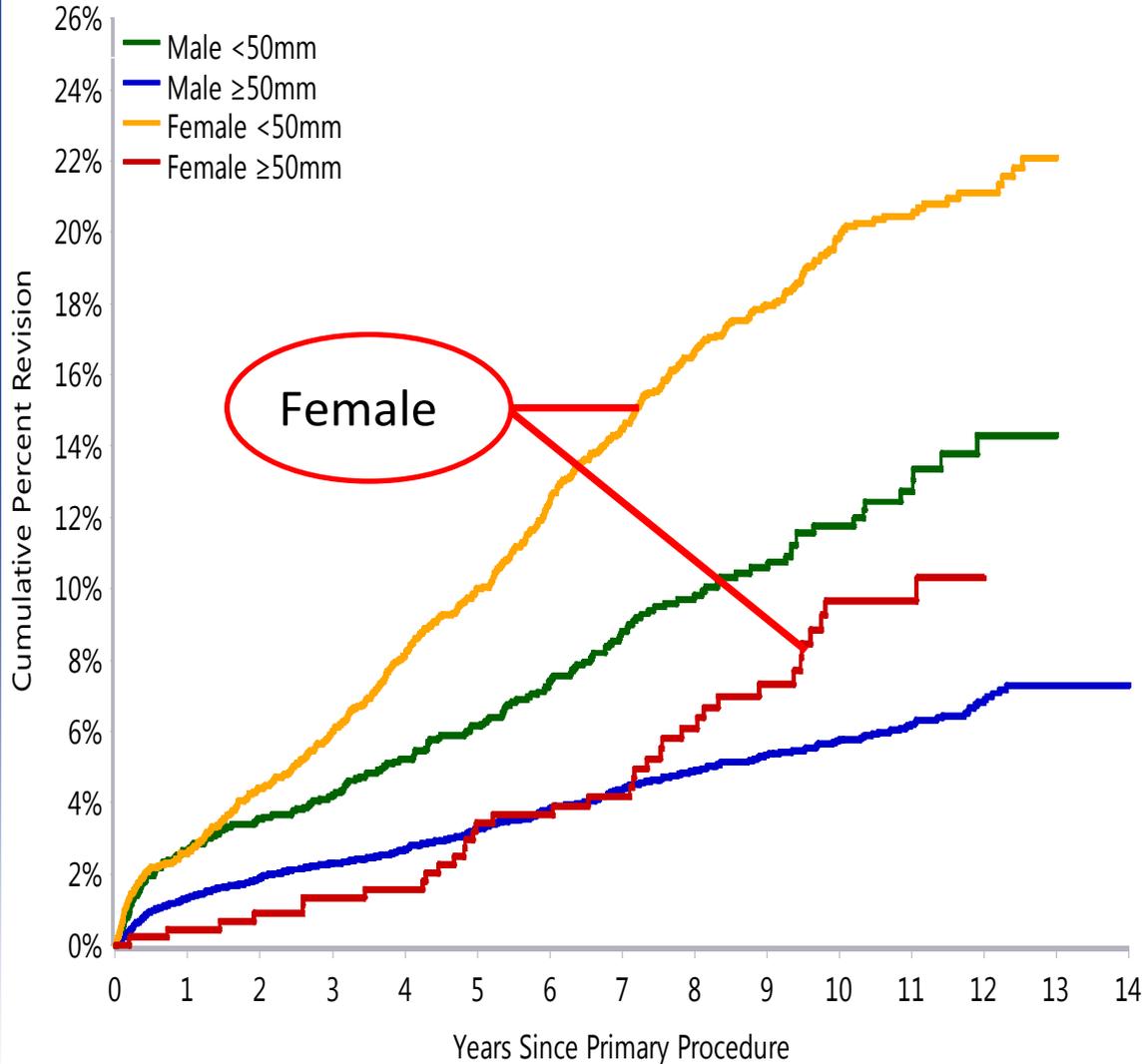
Entire Period: HR=0.60 (0.50, 0.71), p<0.001

Female <50mm vs Female ≥50mm

0 - 5Yr: HR=3.08 (1.83, 5.18), p<0.001

5Yr+: HR=2.05 (1.31, 3.20), p=0.001

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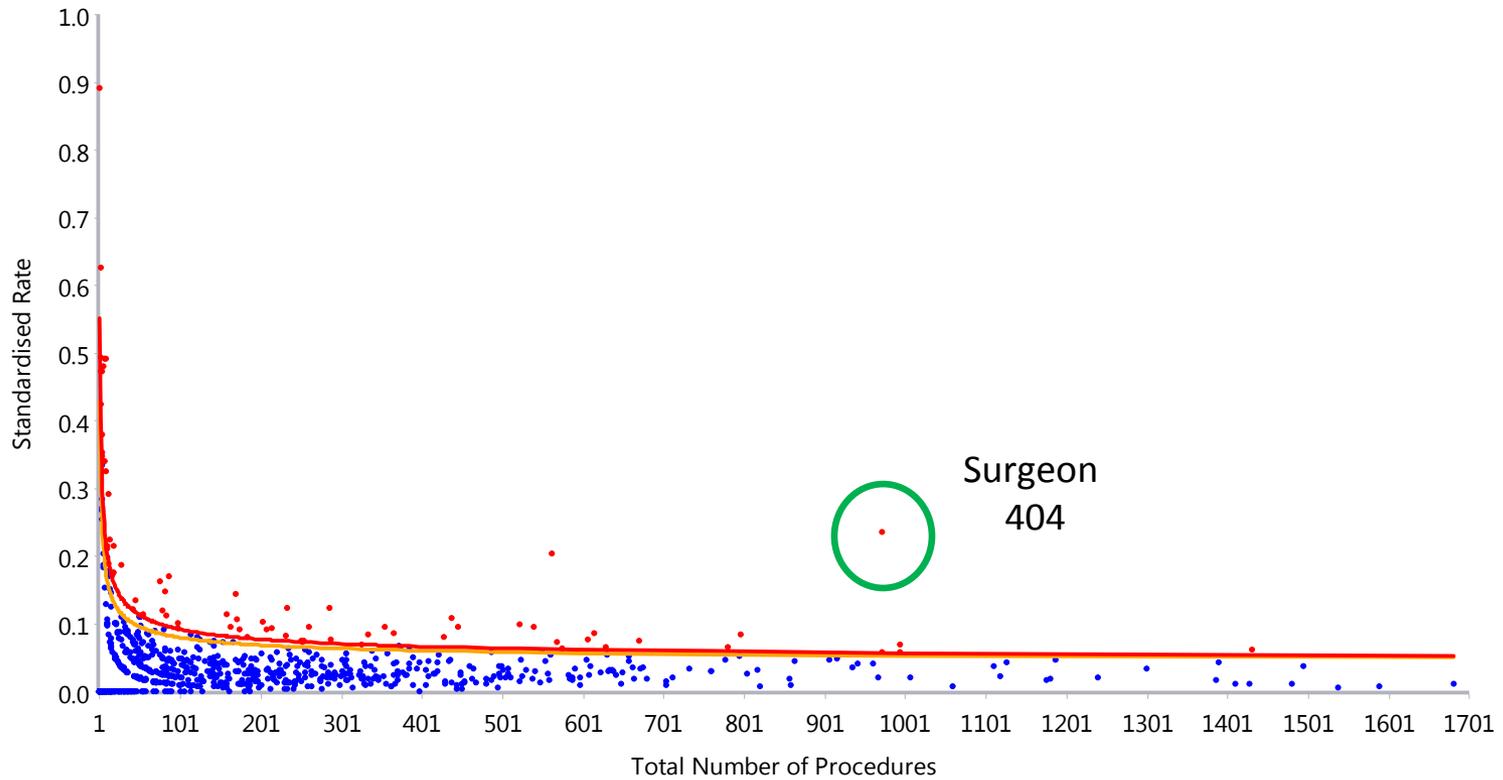
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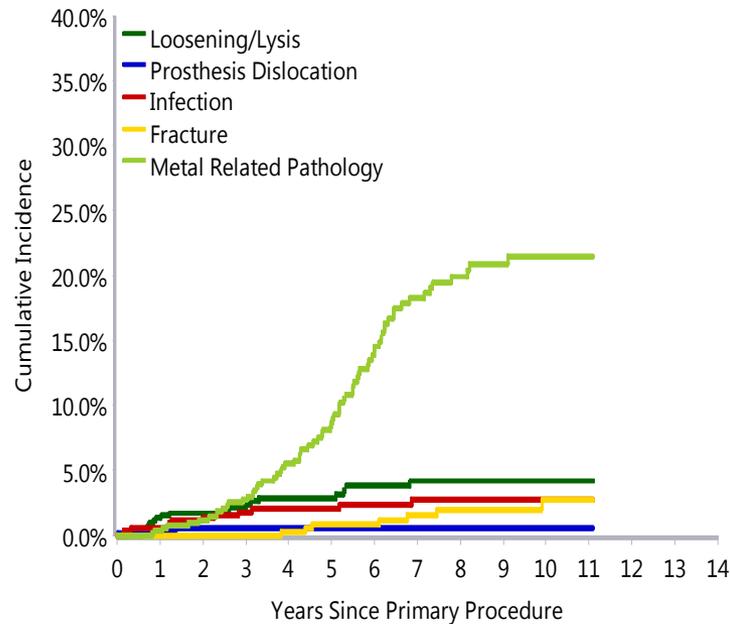
Surgeon and Hospital

Surgeon Performance

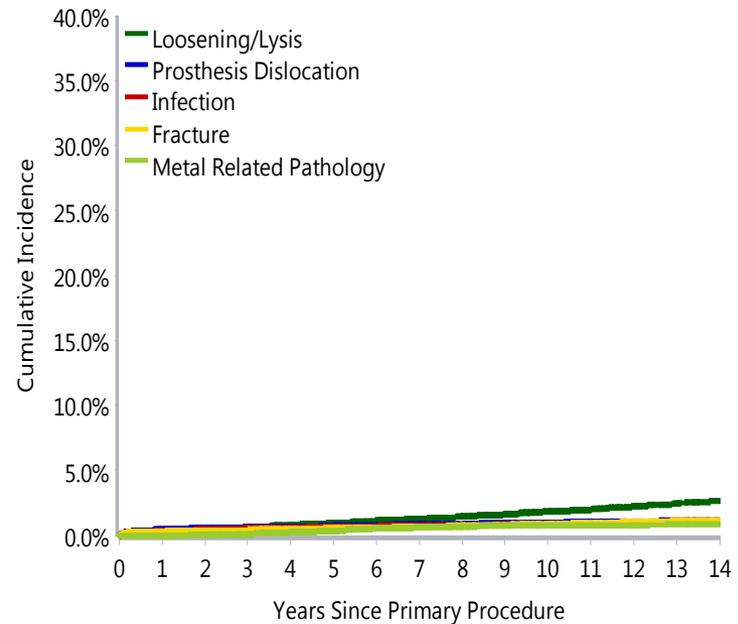


Reasons why a Surgeon is an outlier can be identified

Surgeon 404



Other Surgeons



Enhancing Surgeon Performance

- Surgeons can review their own performance through secure confidential website access
- Privacy of Information protected by Government Legislation
- Many examples of assisting surgeons to improve outcomes
- Registry increasing the information provided
- AOA addressing the issue of surgeons who don't review data
- CPD points for contributing, reviewing and consulting with trusted colleagues about own performance

Hospital performance varies

- Standardised reports to assess hospital performance
- Hospitals use this information to identify problems and areas for improvement
- Develop policies to enhance outcomes based on registry data
- Some hospitals are considering releasing data publically

What makes a quality registry

Optimised to bring about beneficial change

- Governance
- Ownership
- Data Quality
- Availability and delivery of information to all stakeholders
- Integration into the health care system
- International collaboration

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AOANJRR Provides Information to Multiple Stakeholders

- Surgeons
- Consumers
- Government Health Departments
- Government Regulators
- Hospitals and Health Care Systems
- Medical Device Companies
- Health Insurers

Nationally and Globally

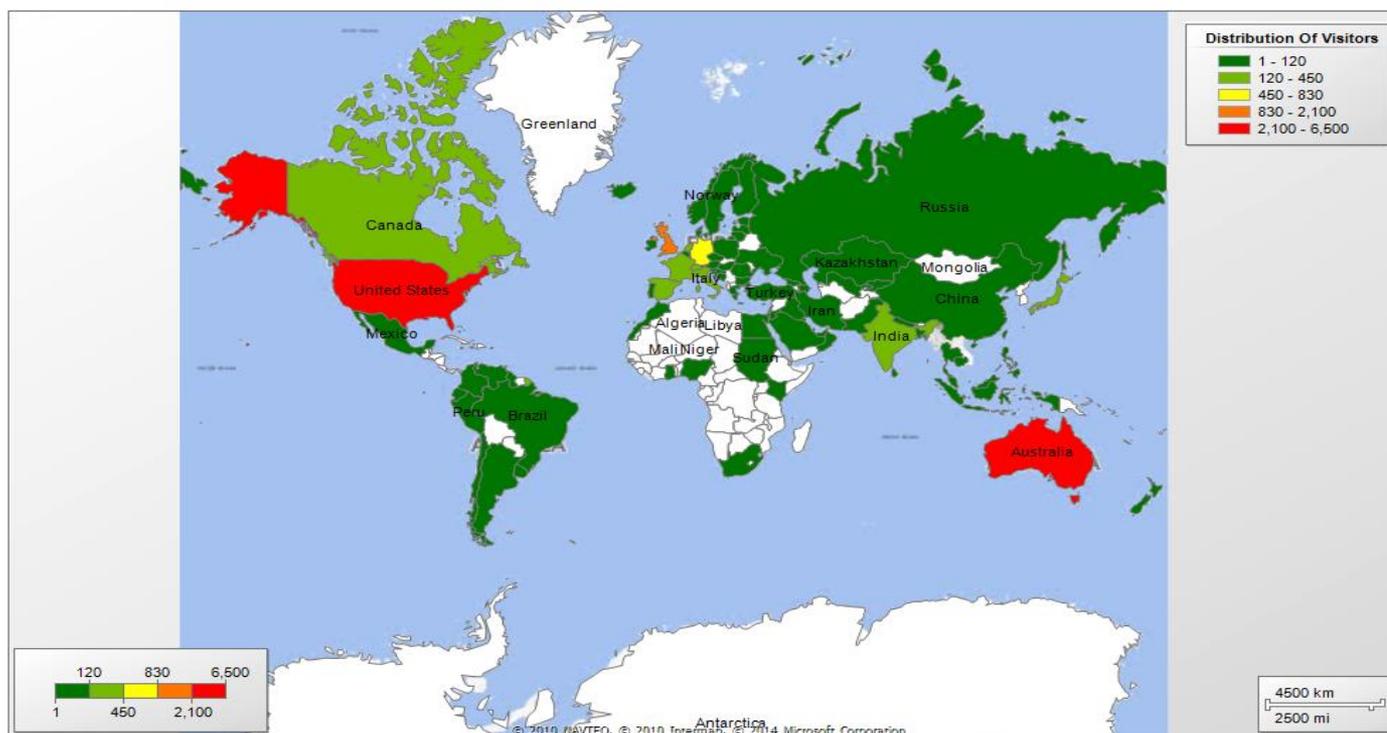


AOANJRR Provides Information to Multiple Stakeholders

- Annual Report (15 separate reports)
- Secure stakeholder specific internet access (surgeons regulators and government and industry)
- Ad hoc reports (300 individual data requests each year) from government, industry, surgeons and research organisations
- Stakeholder specific websites

Global Map of Data Use

214 countries



Integration into Health Care Systems

- Detailed analyses of identified prostheses provided to Regulator on release of annual report
- This is independently reviewed by regulator nominated physicians that provides advice to regulator on required actions.
- Up classification of joint prostheses from Class IIB to Class III
- Department Health uses data used to determine if devices are reimbursed and the level of reimbursement.

International Collaboration

- With other individual registries
- ISAR
- ICOR
- Benchmarking
- Registry nested trials

Are Registries Effective?

- The revision burden is decreasing:
 - *Revision hip procedures* have decreased as a proportion of all hip procedures from **13.1%** in 2002 to **10.2%** in 2014
 - *Revision knee procedures* have decreased as a proportion of all knee procedures from **8.8%** in 2004 to **7.7%** in 2014
- Over \$600 million in savings to the Australian Health Care system in the last ten years
- Flow-on savings internationally

National Joint Replacement Registry

Thank You

