The Value and Limitations of Registry Data

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Jing Xie, PhD
Vice President, Global Clinical Research
Biomet, Inc.

Topics

- **Biomet supports Appropriate Use of Registry Data**

- **Advantages and Limitations of Registry Data**
  - Revision is a crude endpoint as multiple, non-device-related factors contribute to revision
  - Analysis of registry data should be device-specific not on the basis of an entire device class.

- **Appropriate Interpretation of Registry Revision Data**
  - Should be interpreted with caution while mindful of limitations

Biomet Supports Appropriate Use of Registry Data

Biomet strongly supports

- development of orthopedic registries,
- appropriate use of registry data, and
- efforts to standardize data collection, analysis and reporting among registries such as FDA support of the International Consortium of Orthopaedic Registries (ICOR)

Revision is a Crude Endpoint

- "**While device design can impact implant survival, other factors, such as surgical technique, surgeon, hospital, patient factors, and even country, may have far more impact on revision rate than implant design.**" *Barrack, Orthopedics 2011 Sep 9;34(9)*

- "**…quite clearly the reasons for a revision may not be directly related to the performance of the prosthesis.** " *Foreword to the 7th Annual Report, National Joint Registry for England and Wales; Mr. Martyn Porter, Chairman*

Data Analysis should be Product Specific not as Device Class

Smith et al, Failure Rates of Stemmed metal-on-metal Hip Replacement: Analysis of Data from the National Joint Registry of England and Wales, march 13, 2012, Lancet

- Analyzed the National Joint Registry of England and Wales for primary hip replacements undertaken between 2003 and 2011.
- Analysis and findings are based on the MoM THA Class

Biomet Analysis

- Case level data extract on Biomet MoM THAs from the England and Wales NJR via supplier feedback.
- Same database mined and analyzed to reduce variability of patient baseline and other variables.
- Analysis and findings are based on each individual MoM THA

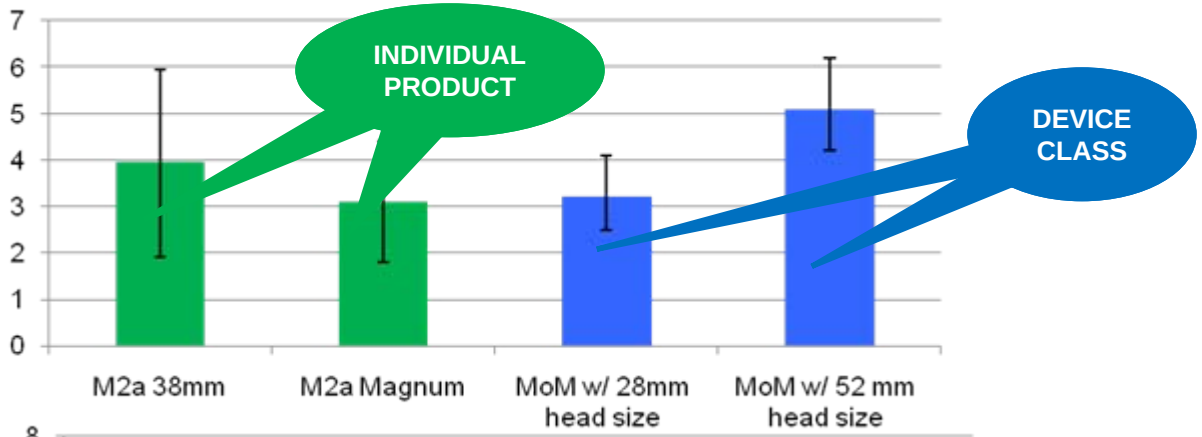
Findings on MoM THA Class by Smith et al. NOT observed with Biomet MoM THAs in same database

Findings on DEVICE CLASS (Smith et al, Lancet)

Findings on PRODUCT SPECIFIC (Biomet MoM)

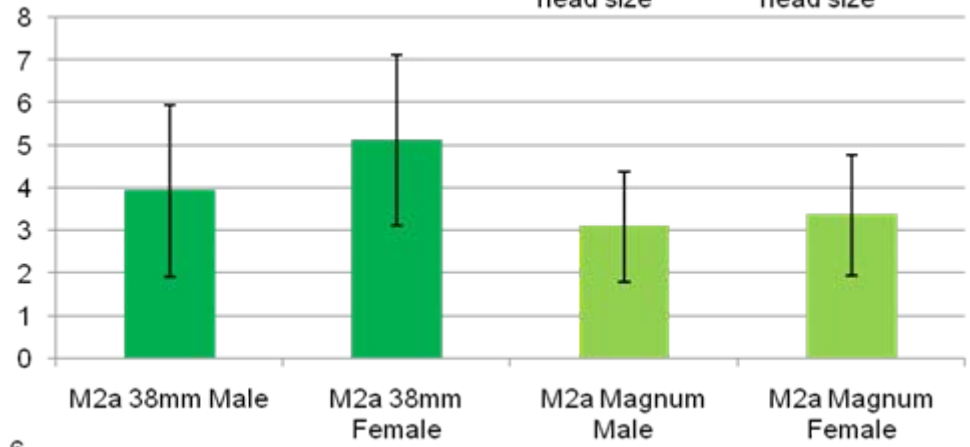
Head size was an independent predictor of revision

Not found with Biomet products



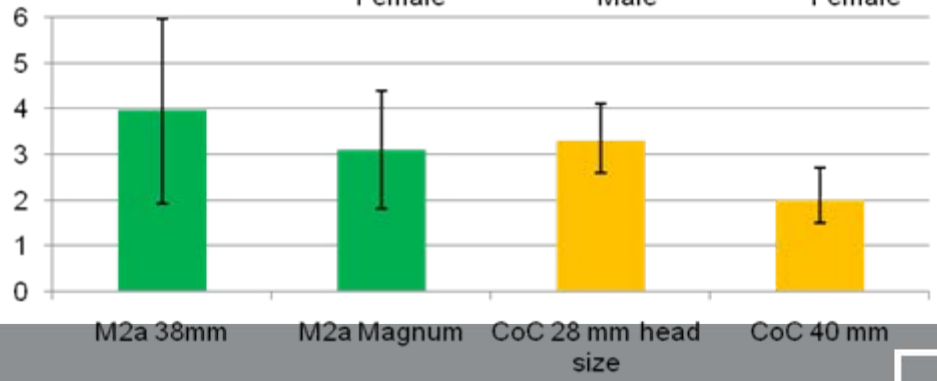
MoM revision rates for women were higher than for men

Not found with Biomet products

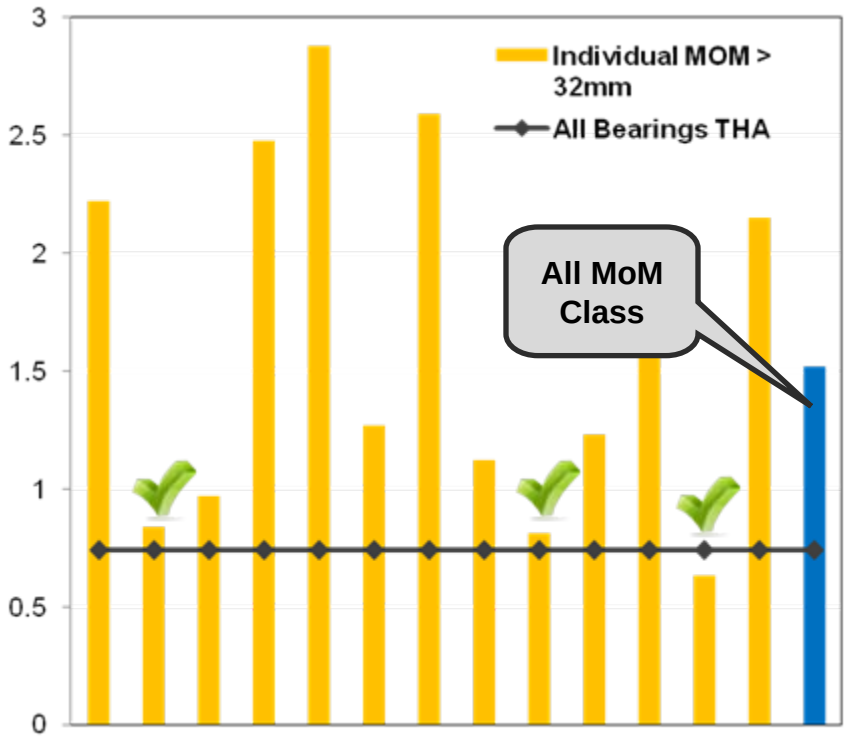


Higher failure rates in MoM compared with other bearing surfaces

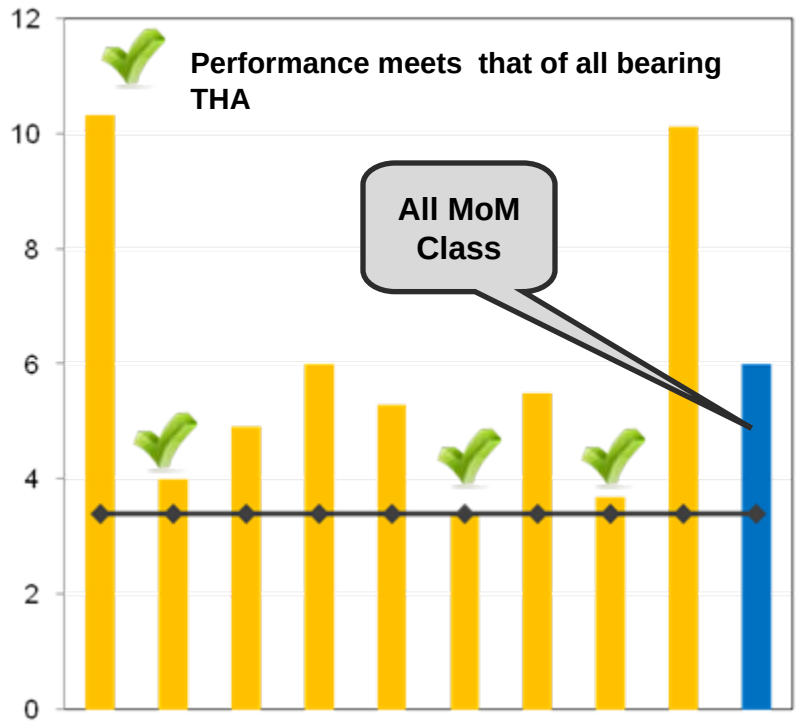
Not found with Biomet products



Data Analysis should be Product Specific not as Device Class



Revision per 100 OCY



Cumulative Revision Rate at 5 yrs

- Performance of Individual MoM THAs varies significantly
- Performance of MoM THA Class may not reflect that of Individual Products
- Registry Data is useful for establishing benchmarks (e.g. all bearing THA) against which to compare specific designs

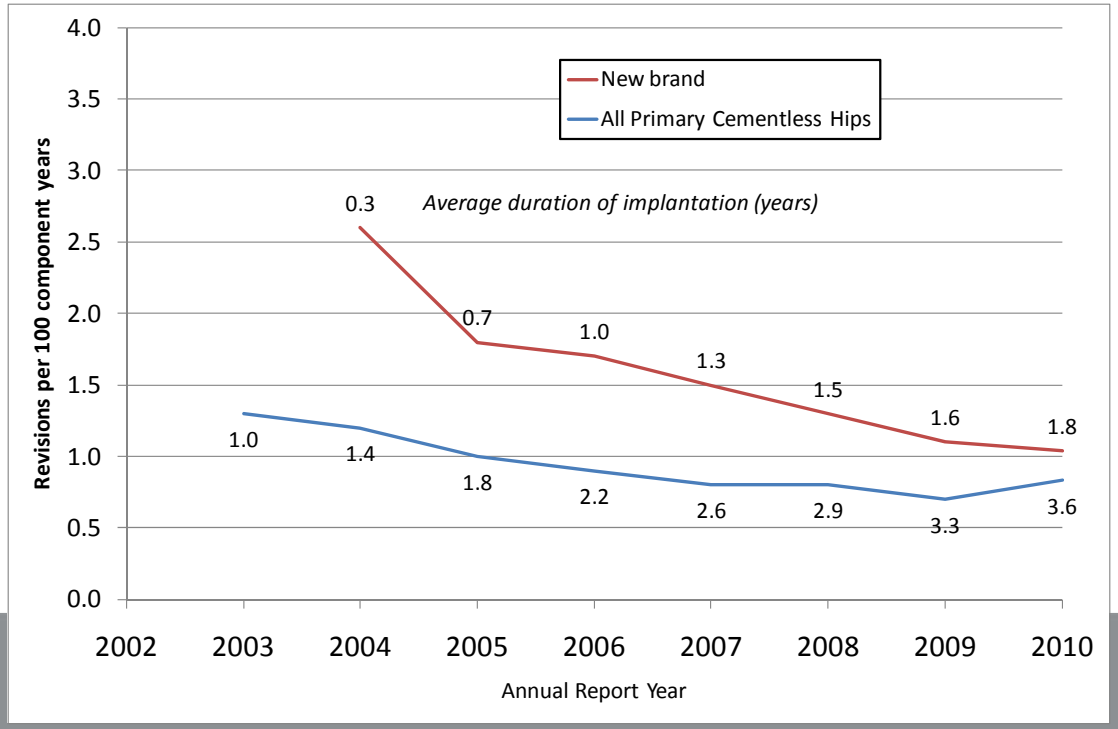
Data based on Australian National Joint Registry 2011 annual report

Advantages and Limitations of Registry Data

Advantages	Limitations
➢ Reflect "real-world" experience with devices based on diverse patient population, surgeon and hospital settings ➢ Potential earlier safety signals ➢ Large number of cases with long-term follow-up ⬇ **Registry Data is useful for establishing benchmarks against which to compare specific designs**	➢Lack of detail regarding reasons for revision ➢Lack of controlled patient and surgeon factors: surgeon training, learning curve, preoperative factors, co-morbidities, etc ➢No endpoints other than survivorship (with level 1 data) ⬇ **Revision is a Crude Endpoint!** ➢Disproportional contribution of various implants (No. of cases and length of follow-up)

Comparative Effectiveness & New Implant Evaluation

- Potential Difference in Time Horizon of Data Collection
  - Improvement in device performance with time is well documented in Registry
  - Learning Curve more prominent impact on new implants
- Comparison should be time period-specific
  - *Change in revision profile with time is seen - especially in New Implants*
- Imbalance in Number of Cases
  - *More significant impact of one revision on New Implant cohort*



One Surgeon. One Patient.

Standardized Approach in Data Analysis and Reporting Among Registries

Difficult to assess device revision based on multiple Registries due to:

- Lack of Standard Device Identification
- Lack of Standard Analytical Methods
- Lack of Standard Reporting Format – e.g. MoM head size break down (32 mm vs. 36 mm)

Table HT36: Yearly Cumulative Percent Revision of Metal/Metal Primary Total Conventional Hip Replacement by Head Size (Primary Diagnosis OA)

Bearing Surface	Head Size	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs
Metal/Metal	≤28mm	1.4 (1.0, 1.9)	2.9 (2.4, 3.6)	3.7 (3.1, 4.5)	4.5 (3.7, 5.3)	5.1 (4.2, 6.2)
	30-32mm	1.6 (1.1, 2.3)	3.2 (2.4, 4.1)	4.2 (3.2, 5.3)	4.3 (3.4, 5.6)	
	36-40mm	2.0 (1.6, 2.5)	4.1 (3.4, 4.8)	6.1 (5.2, 7.1)	8.0 (6.8, 9.3)	
	>40mm	1.6 (1.3, 1.8)	4.8 (4.4, 5.3)	7.5 (6.8, 8.3)	10.4 (9.0, 12.0)	

Lack of Standard Reporting Format – Head size, Modularity in MoM THA

Table 3.11 Estimated revision rates following primary hip replacement for metal-on-metal prostheses (95% confidence intervals).

	Metal-on-metal type				
	Small head with conventional modular cup	Large head with conventional modular cup	Large head with resurfacing cup (excl. ASR)	Large head with ASR cup	All metal-on-metal stemmed prostheses
Year 1	1.23% (0.84%-1.79%)	1.38% (1.17%-1.63%)	1.18% (0.95%-1.48%)	1.24% (0.85%-1.82%)	1.29% (1.15%-1.45%)
Year 2	1.92% (1.41%-2.62%)	2.32% (2.03%-2.66%)	2.53% (2.15%-2.97%)	4.03% (3.23%-5.01%)	2.55% (2.33%-2.79%)
Year 3	2.92% (2.24%-3.82%)	3.47% (3.06%-3.93%)	4.10% (3.56%-4.71%)	7.50% (6.30%-8.92%)	4.10% (3.79%-4.44%)
Year 4	3.72% (2.87%-4.82%)	4.49% (3.94%-5.12%)	5.85% (5.08%-6.73%)	10.79% (9.16%-12.72%)	5.62% (5.19%-6.08%)
Year 5	4.74% (3.66%-6.15%)	5.17% (4.47%-5.96%)	7.48% (6.35%-8.81%)	17.16% (14.03%-21.00%)	7.26% (6.64%-7.94%)
Year 6	6.91% (5.20%-9.18%)	6.86% (5.25%-8.95%)	8.63% (6.78%-10.99%)	28.96% (17.80%-47.14%)	9.50% (8.34%-10.83%)
Base	2,250 (10.3%)	10,857 (49.5%)	6,694 (30.5%)	2,116 (9.7%)	21,917 (100%)

Summary

- Registry is a viable tool to monitor device performance and provide benchmarks for comparison
- Other factors beyond revision should be taken into consideration
- Registry data should be interpreted with caution and good understanding of its limitations