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International Consortium of Orthopedic Registries (ICOR): Methodology and Pilot Study Results

Meeting of the Orthopaedic and Rehabilitation Devices Advisory Panel
June 27-28, 2012

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The ICOR: Mission and Goals

- To advance the research and improve evidence for the safety and effectiveness of orthopedic devices and procedures
  - Harmonize the data among US-based and international orthopedic registries
  - Implement a distributed data analysis system and conduct studies to monitor the safety and effectiveness of orthopedic devices
  - First studies: hip implant bearing surface, fixed vs mobile knees, implant database,

Contract Awarded to Cornell-Kaiser

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Bearing Surface Study

- Data from all ICOR registries is important
- There is no clarity/consensus on what should be the main reference bearing surface category for comparisons
- The evidence is not always consistent and there is a need for robust analyses
- Need more power for evaluating subgroup effects

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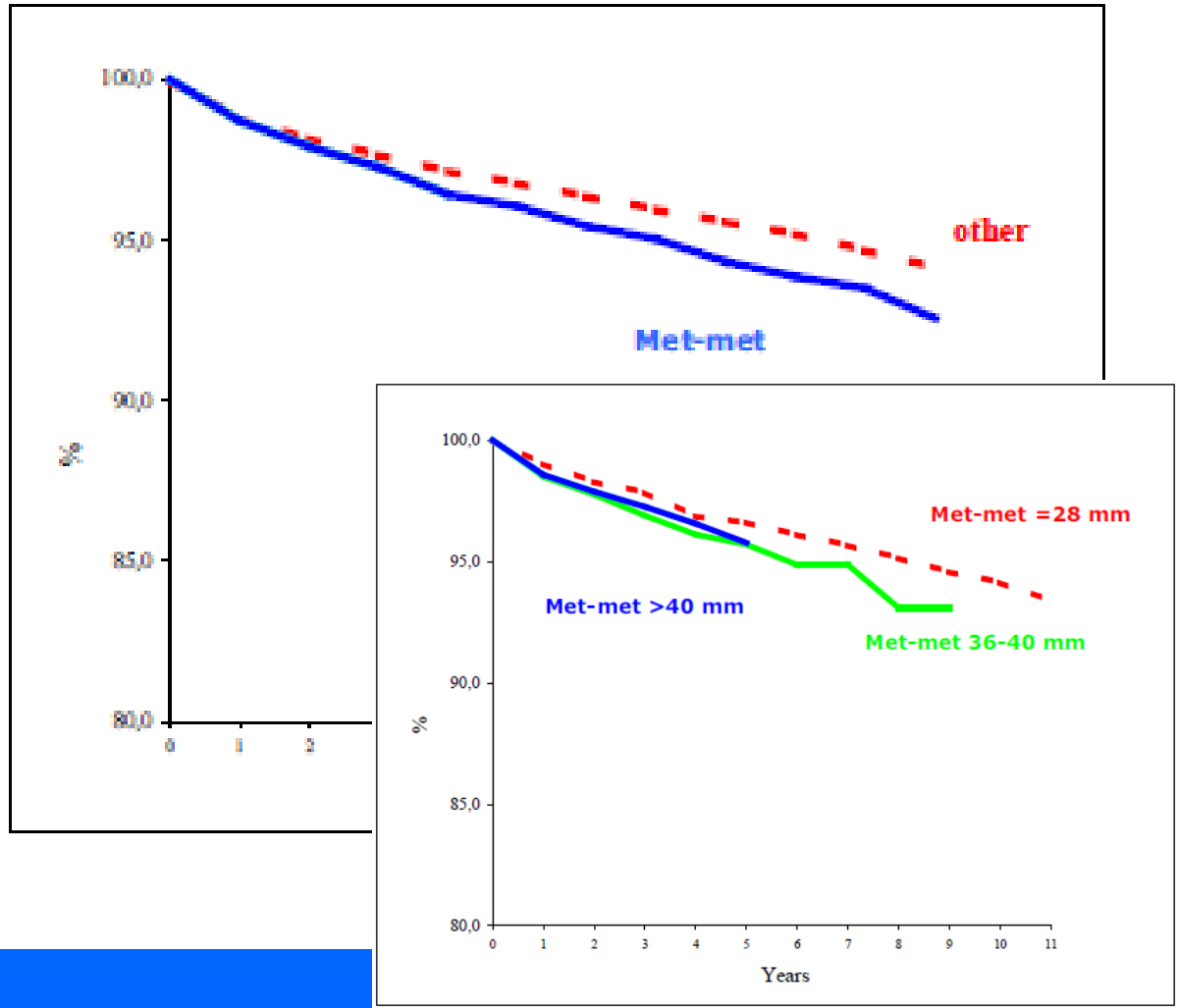
Example: Data from Italy

- Hip surgeries from 2000-2010
- Over 97,000 hip procedures from 72 orthopedic units in 61 hospitals
- Combined THR and resurfacing data
- ASR excluded in analysis presented



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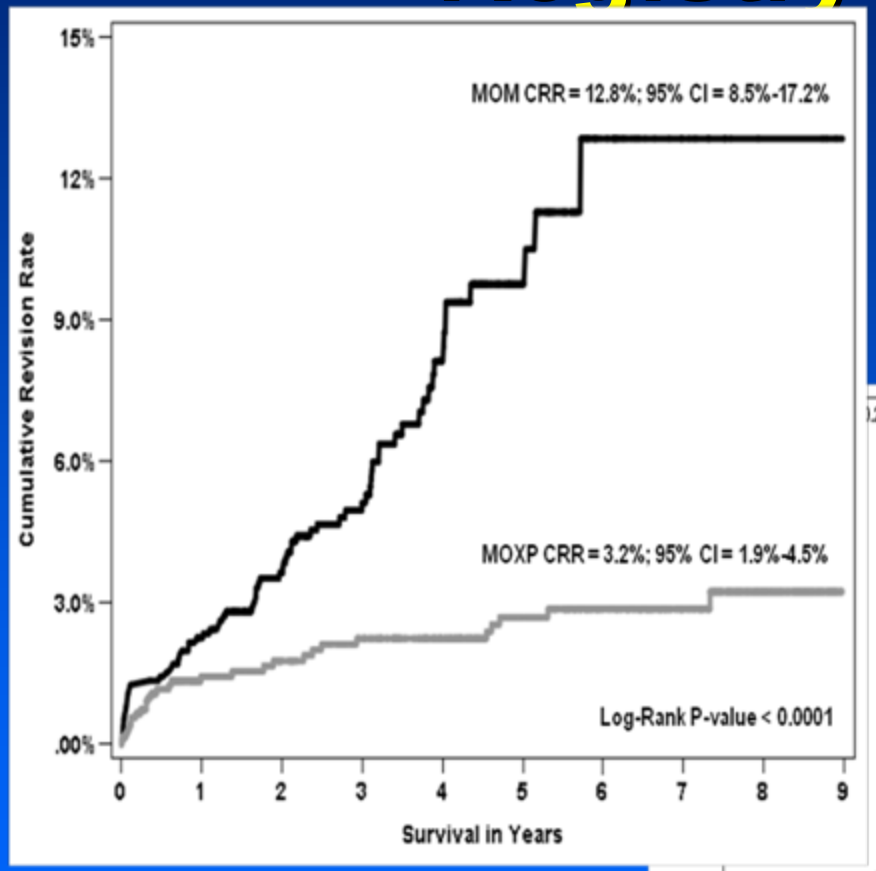
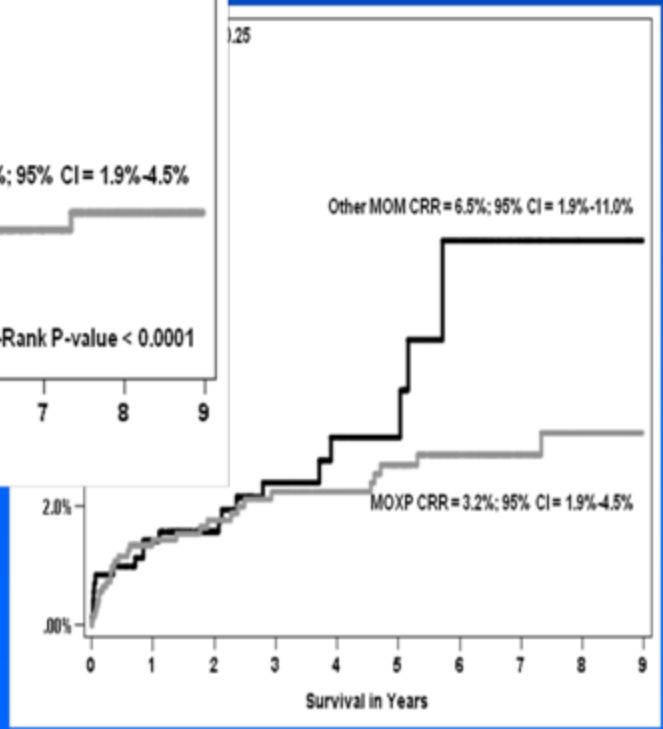
Example: Health East Registry

- Established 1991 and Over 9,000 hip procedures in greater metropolitan St. Paul, MN
- Analysis of matched sample of MoM and modified MoP THR
- 94% osteoarthritis
- 98% 36mm or larger head size





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Example: New Zealand Registry

- Began collecting hip data in January 2000
- Over 80,000 hip procedures
- Less than 10% of procedures include ASR

Size	Surfaces	No. Ops.	Observed comp. Yrs	Number Revised	Rate/100-Component years	Exact 95% confidence interval	
<=28	CP	7973	44316	308	0.70	0.62	0.78
<=28	CM	15	20	0	0.00	0.00	18.88
<=28	MM	2765	20010	119	0.59	0.49	0.71
<=28	MP	37076	209531	1354	0.65	0.52	0.59
29_36	CC	4846	14377	106	0.74	0.60	0.89
29_36	CP	2839	5883	46	0.78	0.57	1.04
29_36	CM	335	407	3	0.74	0.15	2.15
29_36	MM	1421	4880	39	0.80	0.57	1.09
29_36	MP	7776	16359	106	0.65	0.53	0.78
>36	CC	250	192	1	0.52	0.01	2.90
>36	CM	6	7	0	0.00	0.00	51.47
>36	MM	1591	5104	82	1.61	1.28	1.99
>36	MP	13	45	0	0.00	0.00	8.13

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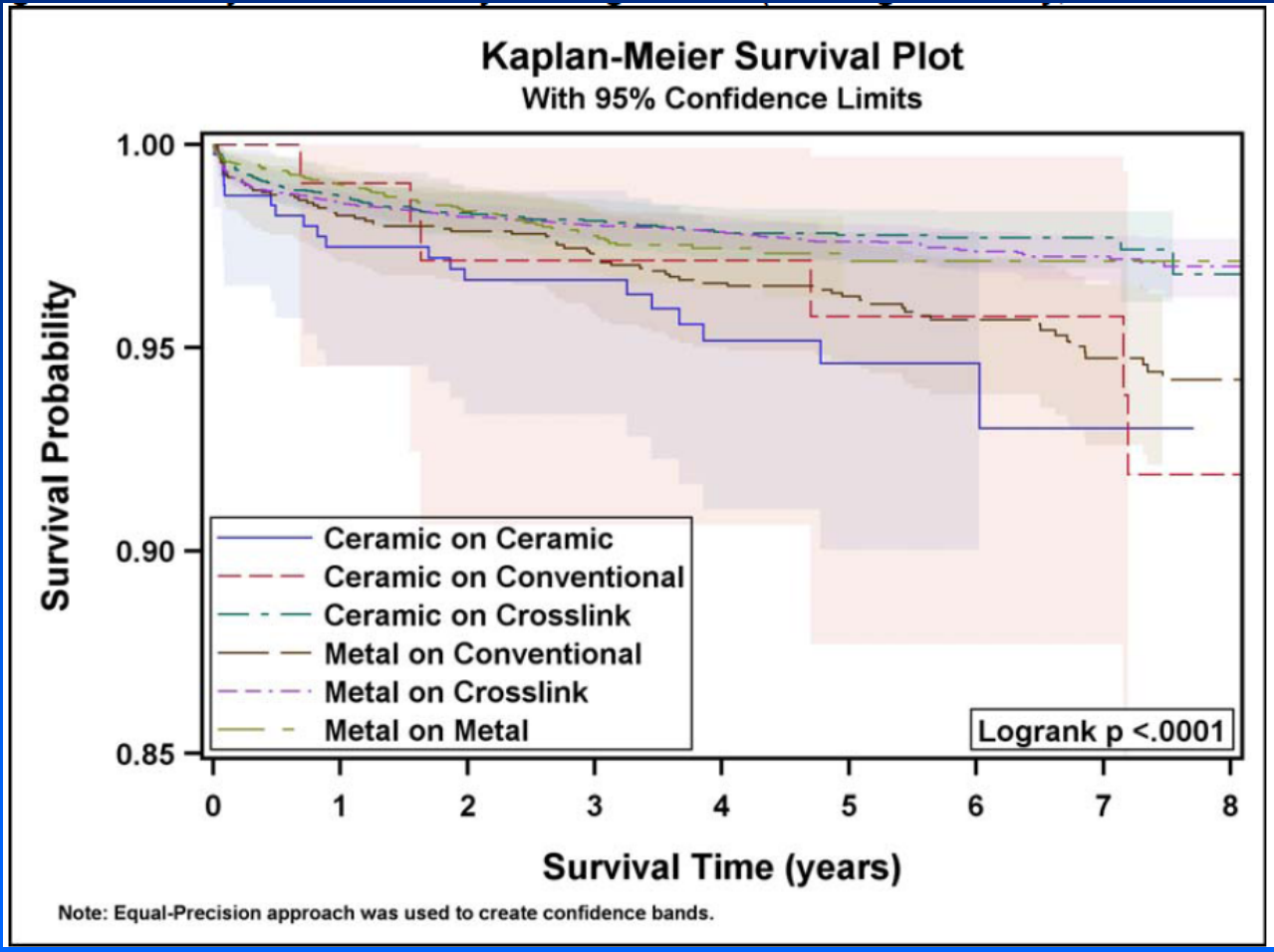
Example: Kaiser Permanente Registry

- Established 2001
- Over 24,000 hip procedures from 350 surgeons
- Analysis includes only osteoarthritis procedures
- About 10% of MoM are ASR



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American Joint Replacement Registry
Austrian Arthroplasty Register
Canadian Joint Replacement Registry
HealthEast Joint Registry
New Zealand Joint Register
OrthoCarolina
Rush University Med. Ctr. Joint Registry
ScFCOT THA Registry
Scottish Arthroplasty Project
Virginia State Registry

Australian Orthopaedic Assoc. Registry
California Joint Replacement Registry
England & Wales National Joint Registry
Hip and Knee Registry of the Netherlands
Norwegian Arthroplasty Register
Portuguese Arthroplasty Register
Slovakian Arthroplasty Register
Swedish Hip and Knee Registers
UMass FORCE Registry
Western Slope Study Group

>3,000,000 Patients Worldwide

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ICOR uses Decentralized Distributed Data Network System

- A system for remotely accessing clinical and other data resources secured and controlled by data owners
  - Reduces security, proprietary, legal, and privacy concerns
  - Minimizes data transfer
  - Eliminates need to create, maintain, and secure access to a central data repository
  - Eliminates disclosure of protected health information
  - Each registry can evaluate, track, and authorize data uses

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ICOR Coordinating Center

- Write & distribute code
- Aggregate findings across
- Support Registry leads

Analytical code

Frequencies, Crosstabs, Cox regression results, survival probabilities

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Analytical Approaches

- Interim Approach
  - Meta-analysis of Cox regression estimates
  - Estimate weighted by a function of the SE of the estimate
- Long-term Approach
  - Multivariable random effects model for analysis of survival probabilities
  - Allows more flexibility in testing interactions (i.e, time-varying effects, interactions among risk factors, and time-varying risk factor interactions)

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Pilot Project: Patients and Methods

- Modern practice centered
- Years from 2001-2010
- THA (not resurfacing)
- Osteoarthritis patients only
- Uncemented THA
- Age 45-64
- Head size (<28, 28, 32, 36 ,>36)
- n=51, 484 **(Australia, Norway and US/Kaiser)**

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Primary Endpoint: Any Revision

- Revisions due to specific causes: wear, aseptic loosening, osteolysis, dislocation, component damage and fracture, metal sensitivity (ALVAL, metalosis, pseudotumor), periprosthetic fracture, infection, squeak and others.
- Revision is defined as removal, exchange or addition of implant parts such as cup, liner, head, neck, stem

Kaiser n=9983	**Ceramic_on_Ceramic**	**Ceramic_on_Conventional**	**Ceramic_on_Crosslink**	**Metal_on_Conventional**	**Metal_on_Crosslink**	**Metal_on_Metal**
head_size<28		1	**1**	5	**8**	
head_size=28	15	18	**508**	139	**834**	**45**
head_size=32	236	5	**863**	25	**1863**	**16**
head_size=36	49	1	**748**	2	**1616**	**1462**
head_size>36			**64**		**207**	**1252**

Norway n=3089	Ceramic_on_Ceramic	Ceramic_on_Conventional	Ceramic_on_Crosslink	Metal_on_Conventional	Metal_on_Crosslink	Metal_on_Metal
head_size<28	**1**	**2**		3		
head_size=28	**304**	**705**	**532**	240	149	8
head_size=32	**542**	**52**	**333**		14	
head_size=36	**121**		**27**		5	1
head_size>36						50

Australia n=38412	Ceramic_on_Ceramic	Ceramic_on_Conventional	Ceramic_on_Crosslink	Metal_on_Conventional	Metal_on_Crosslink	Metal_on_Metal
head_size<28	**3**	**9**	**82**	**266**	**858**	
head_size=28	**2640**	**410**	**884**	**735**	**3713**	**1361**
head_size=32	**7148**	**34**	**1618**	**58**	**2615**	**831**
head_size=36	**5253**	**18**	**1266**	**15**	**1558**	**861**
head_size>36	**655**	**1**	**22**	**8**	**85**	**5540**
Groupings	hs≤28, hs≥32	hs≤28, hs≥32	hs≤28, hs≥32	hs<28, hs≥28	hs≤28, hs=32,hs≥36	hs<36, hs≥36
Data Sources	**Norway & Australia**	**Norway & Australia**	**All three**	**Australia**	**Kaiser & Australia**	**Kaiser & Australia**

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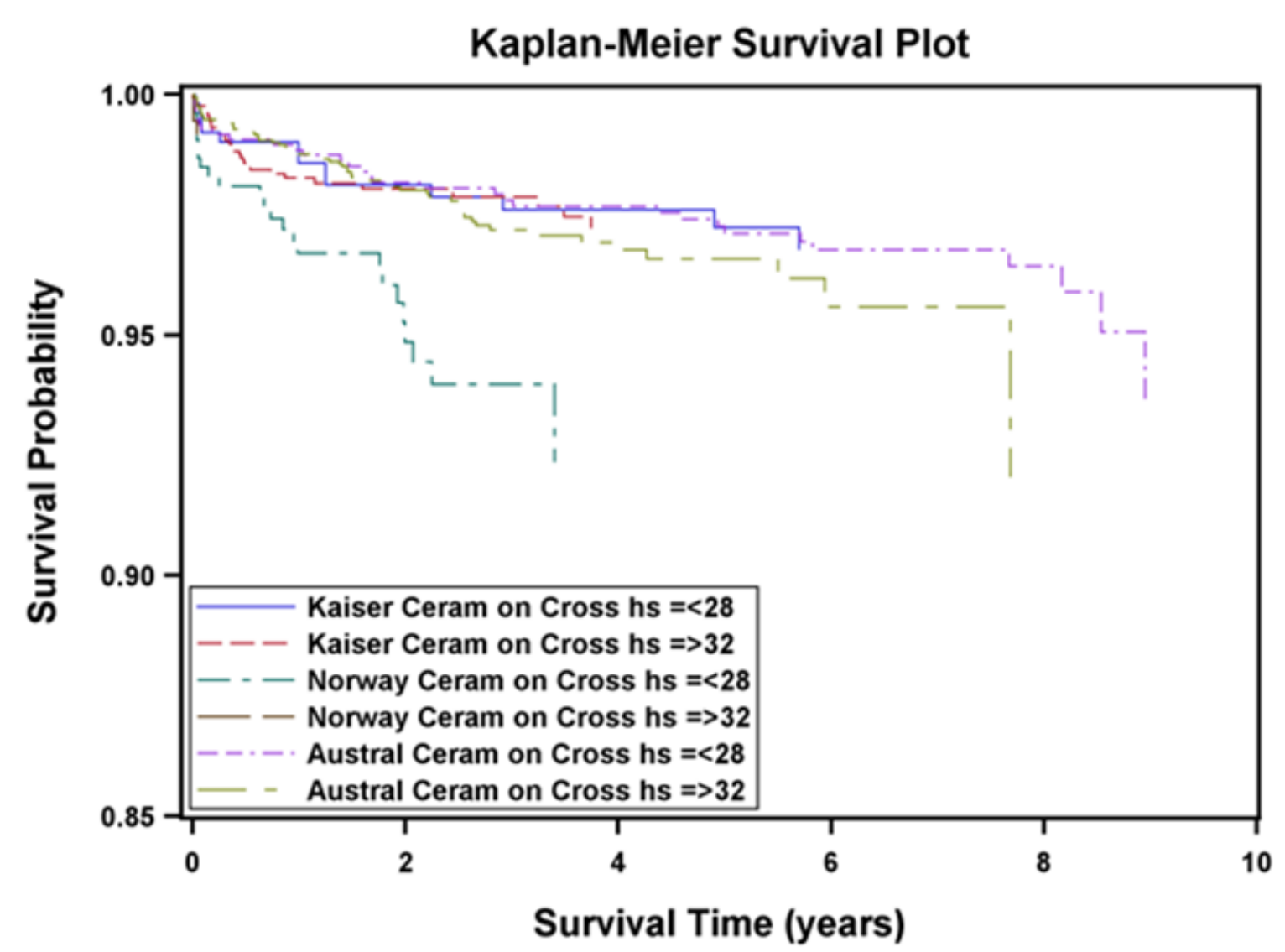
Head Size Effect: Ceramic on Cross-linked Polyethylene



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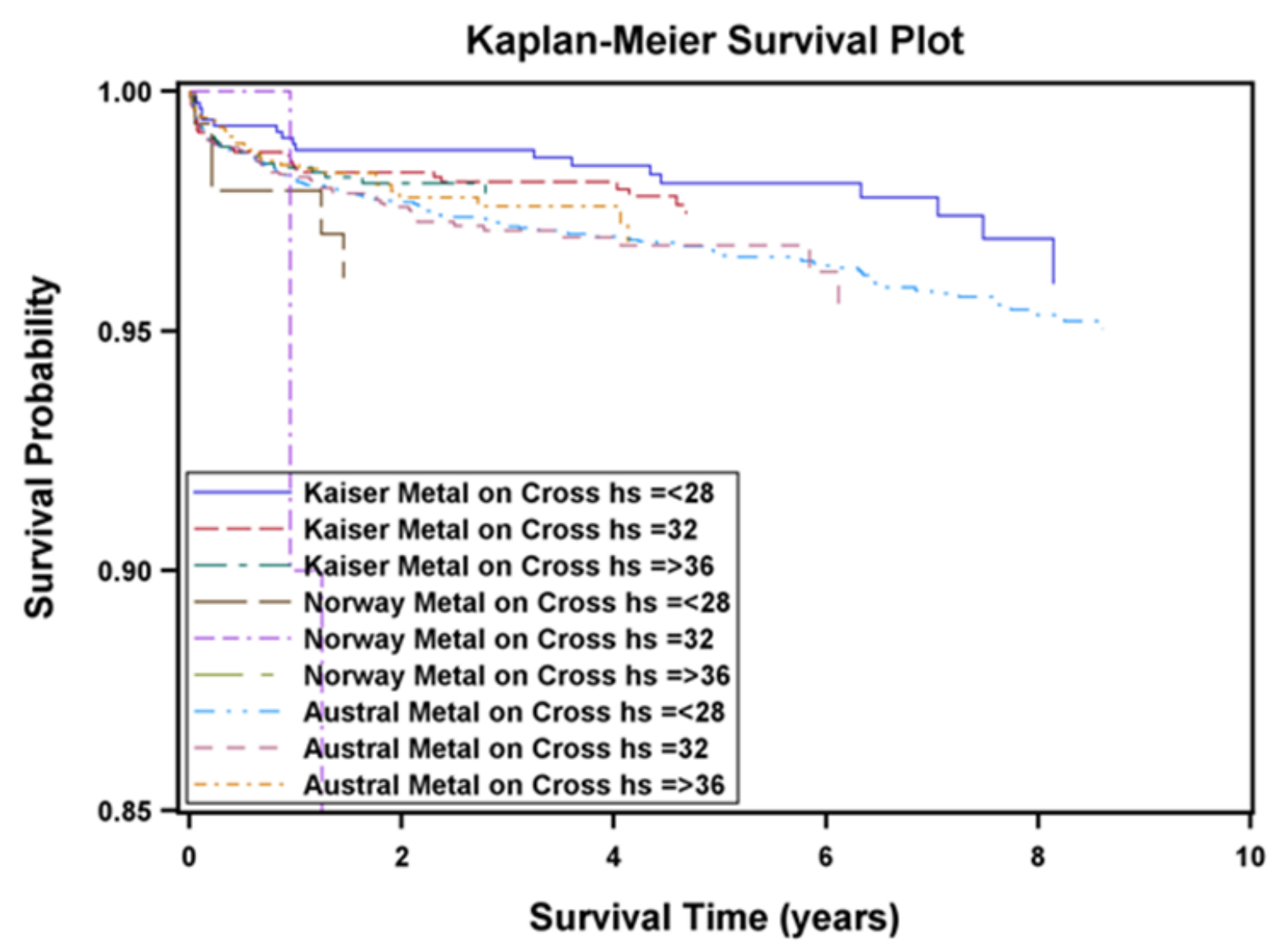
Head Size Effect: Metal on Cross-linked Polyethylene



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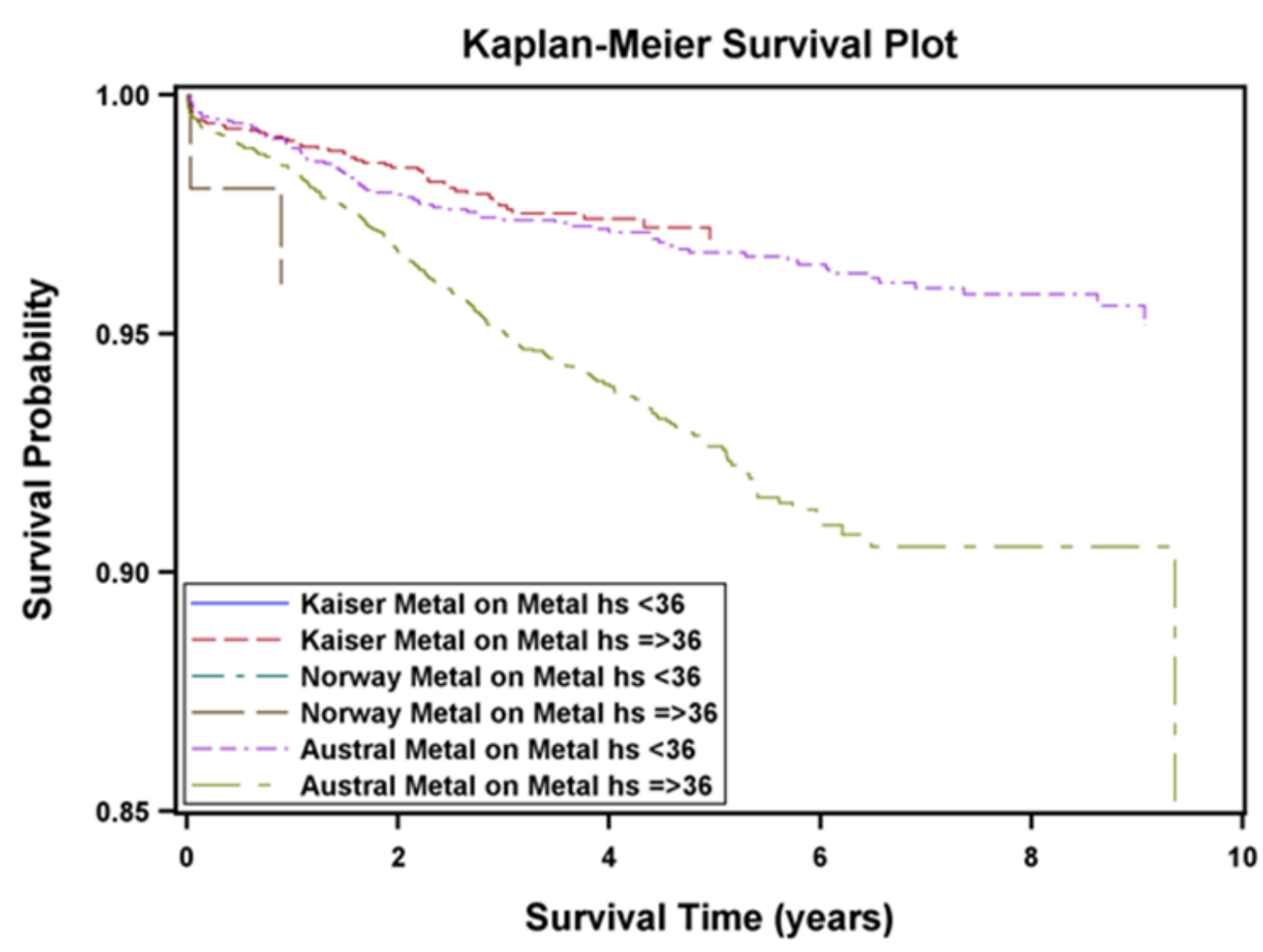
Head Size Effect: Metal on Metal



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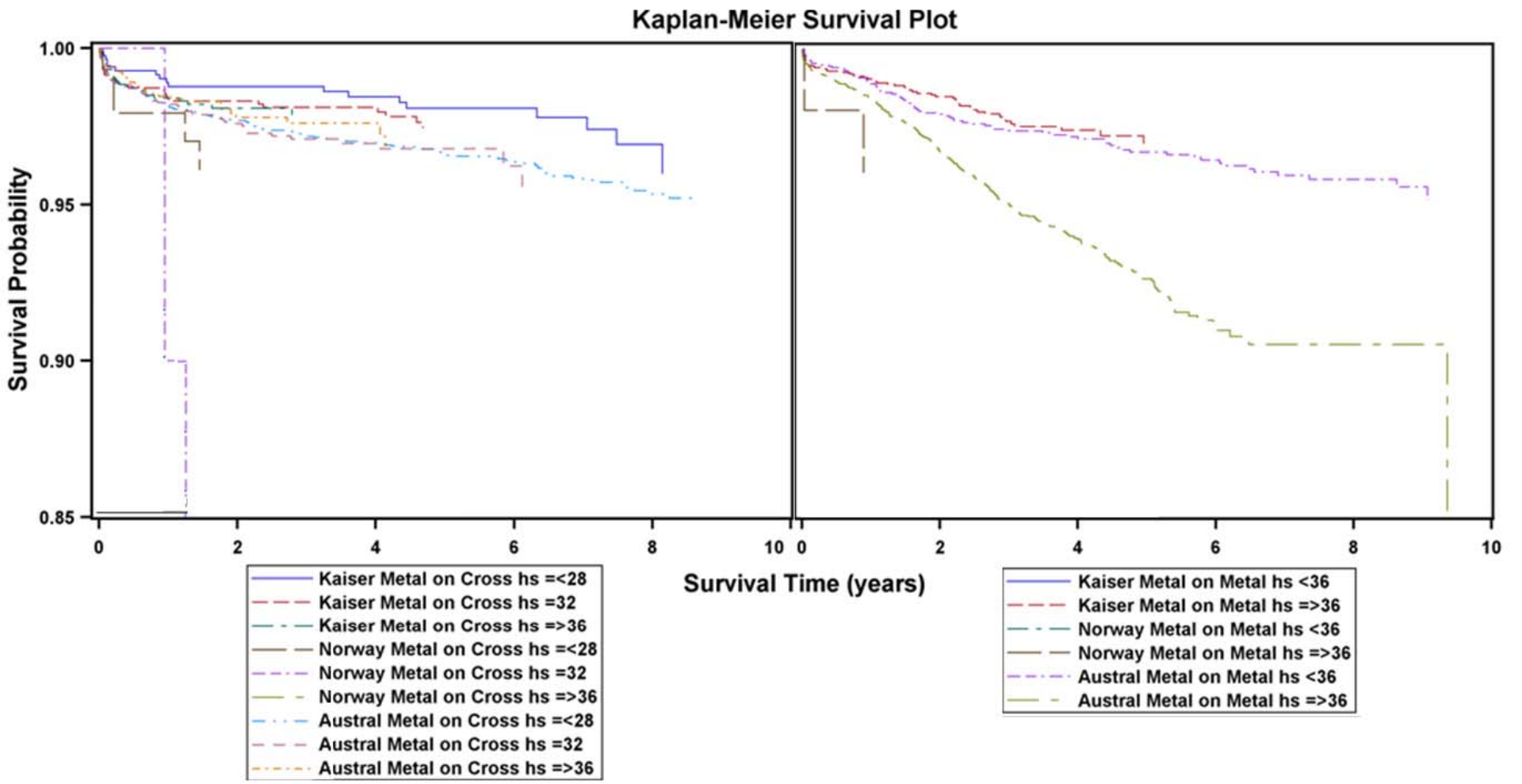
Relative Comparison



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Interim Approach:

Meta-analysis of Cox Regression Estimates

	Overall Estimates Across Regestries				Individual Registry Effects		
Bearing surface	HR	95 % CI		p-value	HR-Australia	HR-Norway	HR-Kaiser
Ceramic on Crosslink w/ hs>=32 vs. <=28 (reference)	0,84	0,57	1,2	0,38	1,3	0,24	0,98
Metal on Crosslink >=32 vs.=<28 (reference)	1,05	0,82	1,4	0,68	1,02	No data	1,18
Metal on Crosslink >=36 vs. <=28 (reference)	0,97	0,69	1,37	0,86	0,85	No data	1,34
Metal on Metal >=36 vs. <36 (reference)	2,34	1,71	3,2	0,001	2,34	No data	tbd

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Thank You!

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