Device Survivorship in Hip and Knee Arthroplasty: American Joint Replacement Registry vs. International Data

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Disclosures

AAOS: Board or committee member
AJRR: Board or committee member
AAHKS: Board or committee member
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Biomet: Paid consultant; Research support
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Journal of Arthroplasty: Editorial board
Knee Society: Board or committee member; Research support
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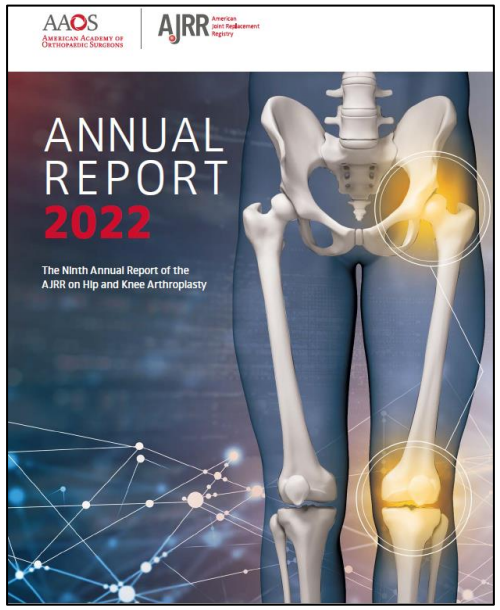
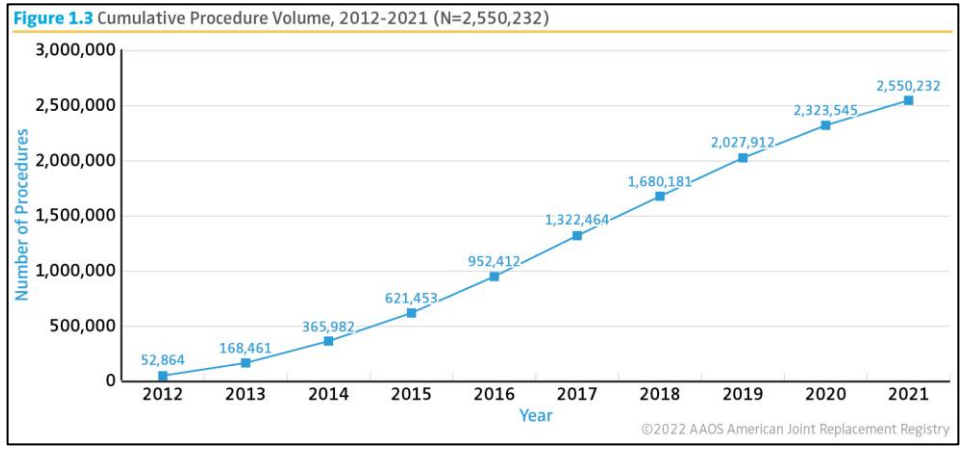
Introduction

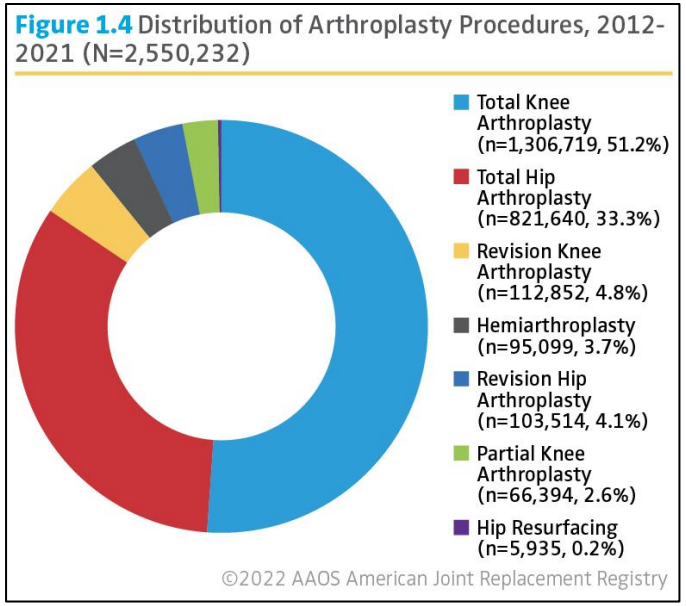


AAOS encompasses five active registries with over ***1,500 submitting institutions*** and 12,700 registered surgeons across all 50 states

To date, the AJRR represents ***over 3.4 million procedures*** *and over 10 years of data collection*

ODEP
Orthopaedic Data Evaluation Panel





AAOS American Academy of Orthopaedic Surgeons | AJRR American Joint Replacement Registry

Introduction:
Is AJRR Data Representative in US?

RESEARCH: RESEARCH ARTICLE

Is American Joint Replacement Registry Data Representative of National Data? A Comparative Analysis

Porter, Kimberly R. PhD, MPH; Illgen, Richard L. MD; Springer, Bryan D. MD; Bozic, Kevin J. MD; Sporer, Scott M. MD; Huddleston, James I. MD; Lewallen, David G. MD; Browne, James A. MD

Orthopaedic Proceedings

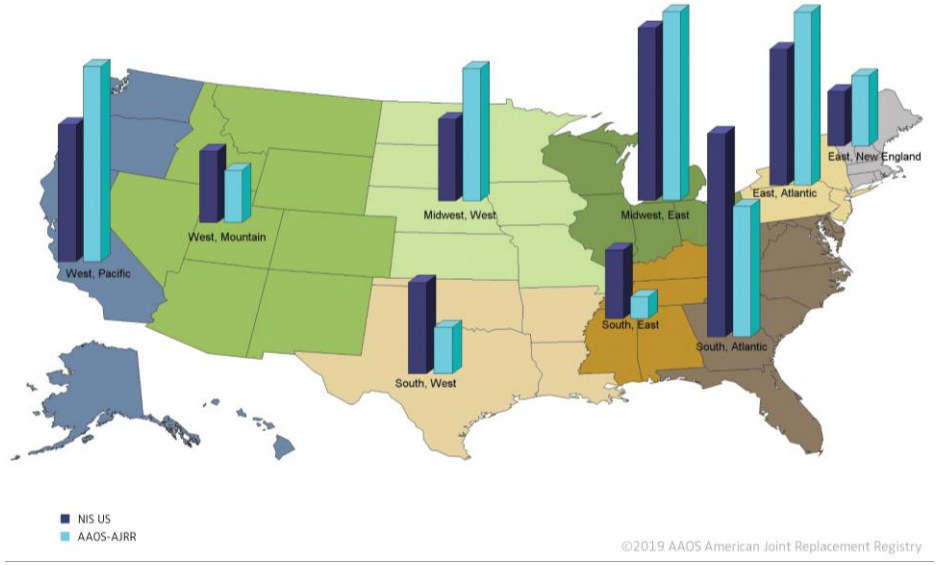
KNEE

FULL ACCESS

IS AMERICAN JOINT REPLACEMENT REGISTRY (AJRR) DATA REPRESENTATIVE OF NATIONAL DATA? A COMPARATIVE ANALYSIS

The Knee Society (TKS) 2020 Members Meeting, held online, 10–12 September 2020.

Richard L. Illgen · Bryan D. Springer · Kevin J. Bozic · Scott M. Sporer · James I. Huddleston · David G. Lewallen · Kimberly Porter · James A. Browne



AJRR: Becoming a National US Joint Registry

E. Anthony Rankin, MD

Orthopedics, 2013;36(3):175–176

Published Online: February 22, 2013 · https://doi.org/10.3928/01477447-20130222-02 · Cited by: 16

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Introduction:
Is AJRR Data Representative Worldwide?

- Implications for international comparisons
  - Benchmarking
  - Regulatory Approval
    - More implants entering US market than anywhere else in the world

- Example: ODEP Ratings

Knee Clinical Reference Data Summary

Criteria - Total Knee Replacement

Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*	15A*
Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of the development centre	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate ‡	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
Criteria - A Ratings	**3A**	**5A**	**7A**	**10A**	**13A**	**15A**
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	66	60	55	51	45	42
Maximum revision rate ‡	5.5%	6.0%	6.5%	7.0%	8.0%	8.5%
‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level						
Criteria - B Ratings	**3B**	**5B**	**7B**	**10B**	**13B**	**15B**
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
Pre-Entry A*	**Pre-Entry**					
Product launched under Beyond Compliance	Product details supplied to ODEP					

Combining data sets:
Please note, that where any combination of volumes across 2 constructs is included in a submission (e.g. for constructs with or without patellae), a minimum number of 100 implants must be available for each construct. In addition, at least one construct must have the minimum volume past the benchmark being applied for.

FOR PUBLIC RELEASE 14 October 2020

ODEP Orthopaedic Data Evaluation Panel

Purpose

- In collaboration with the Orthopaedic Data Evaluation Panel (ODEP), the American Joint Replacement Registry (AJRR) investigated the consistency of both hip and knee arthroplasty survivorship compared to the National Joint Registry of England and Wales (NJR)

- First AJRR device-specific comparison of survivorship against an international registry

- Determine the feasibility of using AJRR data for ODEP Ratings

Methods - Hip

- Three primary hip devices varying in performance and design were selected
  - Cementless socket
  - Fit and fill cementless stem
  - Blade cementless stem
- High-volume implant manufacturers independently submitted Kaplan Meier survivorship to ODEP using NJR data
  - AJRR mirrored methods in independent analysis
- Results were stratified by three age cohorts (all-age,<65, ≥65 years) to facilitate supplementation of AJRR with Medicare claims for all-age and ≥65 age analyses

Methods - Knee

- Three primary knee devices varying in performance and design were selected
  - Posterior stabilized (PS)
  - Cruciate retaining (CR)
  - Unicompartmental knee arthroplasty (UKA)
- High-volume implant manufacturers independently submitted Kaplan Meier survivorship to ODEP using NJR data
  - AJRR mirrored methods in independent analysis
- Results were stratified by three age cohorts (all-age,<65, ≥65 years) to facilitate supplementation of AJRR with Medicare claims for all-age and ≥65 age analyses

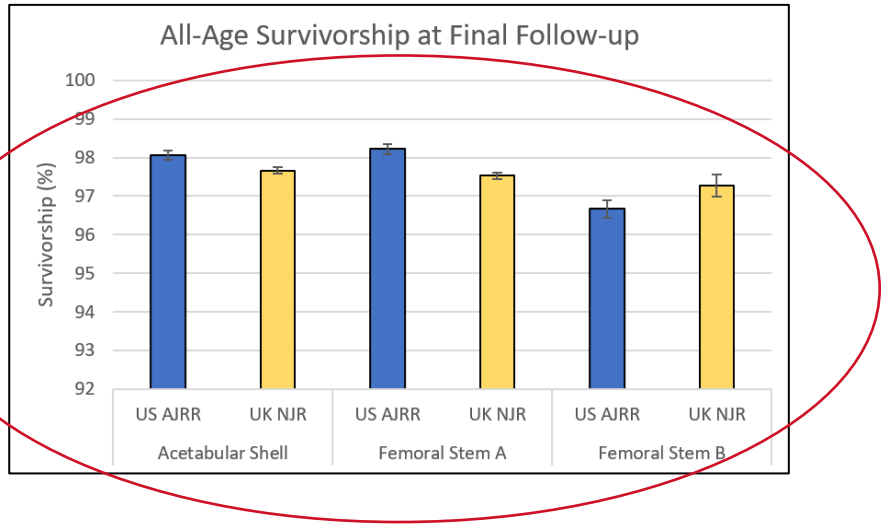
Results- Hip

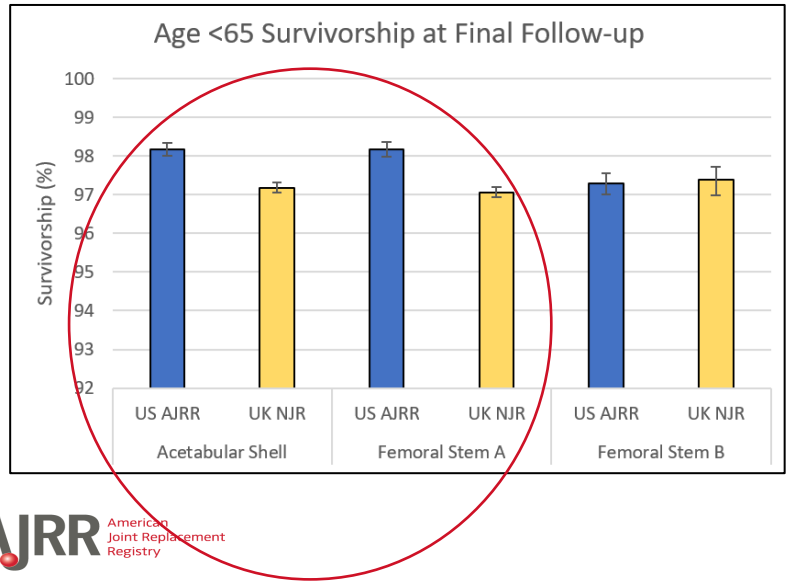
- 210,506 AJRR and 422,657 NJR primary hip cases
- + 65 – AJRR 52% and NJR 58%
- Statistical agreement is indicated by overlapping 95% confidence intervals **for each** survivorship probability between data sources

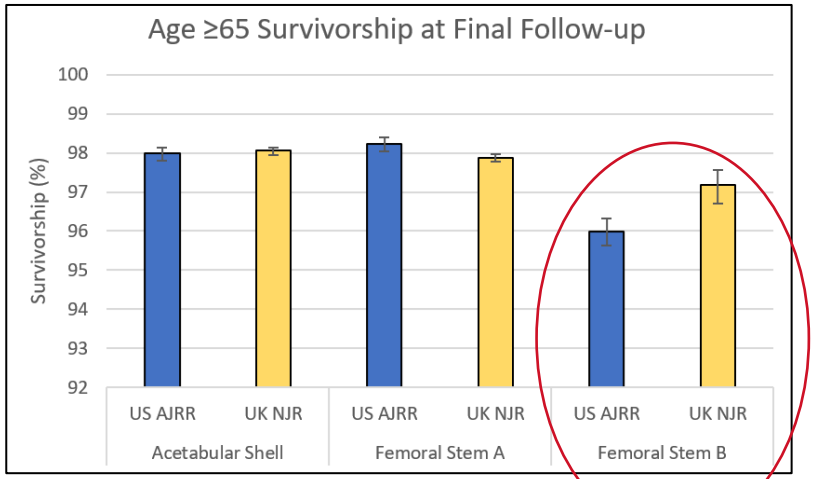
All-Age Cohort	Years	N	1 Year	3 Years	5 Years	7 Years	8 Years
Socket	US AJRR	101,185	99.08 (99.02, 99.13)	98.67 (98.59, 98.74)	98.42 (98.33, 98.5)	98.17 (98.07, 98.27)	98.07 (97.95, 98.19)
	UK NJR	198,449	99.26 (99.22, 99.30)	98.70 (98.65, 98.75)	98.30 (98.24, 98.36)	97.90 (97.83, 97.97)	97.66 (97.58, 97.74)
Fit and Fill Stem	US AJRR	69,077	99.12 (99.05, 99.19)	98.70 (98.61, 98.79)	98.47 (98.37, 98.57)	98.28 (98.16, 98.39)	98.22 (98.08, 98.34)
	UK NJR	207,187	99.25 (99.21, 99.28)	98.66 (98.61, 98.71)	98.22 (98.16, 98.28)	97.77 (97.70, 97.84)	97.53 (97.45, 97.61)
Blade Stem	US AJRR	40,244	98.28 (98.14, 98.4)	97.56 (97.4, 97.71)	97.10 (96.92, 97.27)	96.79 (96.59, 96.98)	96.67 (96.44, 96.88)
	UK NJR	17,021	98.82 (98.65, 98.97)	98.18 (97.96, 98.37)	97.79 (97.55, 98.01)	97.47 (97.19, 97.71)	97.28 (96.99, 97.55)
Age 65+ Cohort	**Years**	**N**	**1 Year**	**3 Years**	**5 Years**	**7 Years**	**8 Years**
Socket	US AJRR	52,727	98.99 (98.9, 99.07)	98.55 (98.44, 98.65)	98.33 (98.2, 98.44)	98.05 (97.9, 98.19)	97.98 (97.8, 98.13)
	UK NJR	115,212	99.25 (99.20, 99.30)	98.82 (98.76, 98.88)	98.53 (98.46, 98.60)	98.24 (98.15, 98.32)	98.05 (97.95, 98.14)
Fit and Fill Stem	US AJRR	36,207	99.09 (98.98, 99.18)	98.70 (98.58, 98.82)	98.51 (98.38, 98.64)	98.31 (98.15, 98.46)	98.22 (98.03, 98.4)
	UK NJR	120,754	99.23 (99.18, 99.28)	98.78 (98.72, 98.84)	98.46 (98.38, 98.53)	98.09 (98.00, 98.17)	97.88 (97.78, 97.97)
Blade Stem	US AJRR	20,422	97.98 (97.78, 98.17)	97.18 (96.93, 97.4)	96.60 (96.32, 96.86)	96.20 (95.88, 96.49)	95.99 (95.62, 96.33)
	UK NJR	7,936	98.67 (98.39, 98.90)	98.06 (97.73, 98.35)	97.69 (97.32, 98.01)	97.40 (96.99, 97.76)	97.17 (96.71, 97.56)
Age <65 Cohort	**Years**	**N**	**1 Year**	**3 Years**	**5 Years**	**7 Years**	**8 Years**
Socket	US AJRR	44,891	99.19 (99.1, 99.27)	98.81 (98.7, 98.91)	98.52 (98.4, 98.64)	98.30 (98.15, 98.44)	98.18 (98, 98.34)
	UK NJR	83,237	99.27 (99.21, 99.33)	98.55 (98.46, 98.62)	97.99 (97.89, 98.09)	97.47 (97.35, 97.58)	97.18 (97.05, 97.31)
Fit and Fill Stem	US AJRR	30,352	99.18 (99.07, 99.28)	98.70 (98.56, 98.82)	98.42 (98.26, 98.56)	98.23 (98.05, 98.39)	98.18 (97.99, 98.36)
	UK NJR	86,433	99.27 (99.21, 99.32)	98.48 (98.40, 98.56)	97.90 (97.80, 98.00)	97.35 (97.24, 97.47)	97.06 (96.93, 97.19)
Blade Stem	US AJRR	18,436	98.58 (98.4, 98.74)	97.94 (97.72, 98.14)	97.59 (97.34, 97.81)	97.35 (97.08, 97.6)	97.29 (97.01, 97.55)
	UK NJR	9,085	98.96 (98.72, 99.15)	98.28 (97.99, 98.53)	97.88 (97.55, 98.17)	97.52 (97.14, 97.85)	97.38 (96.98, 97.73)

Results – Hip

- AJRR and NJR showed similar trends for comparatively high and low performing devices
  - 0.18% average difference in survivorship at eight years (final follow-up)
- Blade stem did not reach statistical agreement for all-age and 65+ cohorts but showed only 0.61% difference in survivorship at eight years
- Socket and fit and fill stem reached statistical agreement at four and five years in all-age and through seven and eight years in the ≥65-year-old cohort.







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Results - Knee

- There were 42,671 AJRR and 60,439 NJR primary knee cases
- Statistical agreement is indicated by overlapping 95% confidence intervals for each survivorship probability between data sources

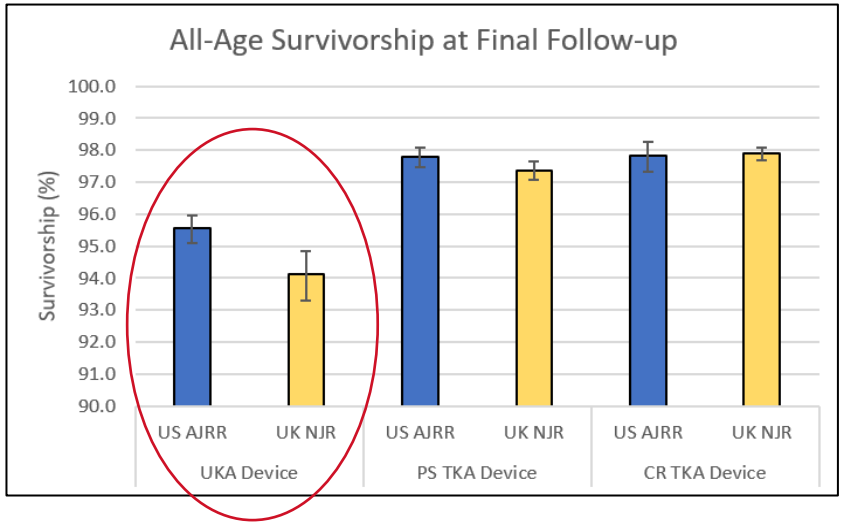
All-Age Cohort	Years	N	1 Year	3 Years	5 Years	7 Years	8 Years
UKA Device	US AJRR	16,525	98.99 (98.83, 99.14)	97.51 (97.24, 97.75)	96.49 (96.15, 96.8)	95.70 (95.28, 96.08)	95.55 (95.11, 95.95)
	UK NJR	6,486	99.17 (98.91, 99.37)	97.59 (97.15, 97.95)	96.32 (95.77, 96.81)	94.78 (94.04, 95.42)	94.11 (93.29, 94.84)
PS TKA Device	US AJRR	20,010	99.33 (99.2, 99.43)	98.65 (98.47, 98.8)	98.26 (98.05, 98.45)	98.04 (97.79, 98.27)	97.80 (97.46, 98.09)
	UK NJR	18,022	99.45 (99.32, 99.55)	98.61 (98.41, 98.78)	97.93 (97.68, 98.15)	97.62 (97.34, 97.87)	97.38 (97.07, 97.66)
CR TKA Device	US AJRR	6,136	99.44 (99.21, 99.6)	98.60 (98.25, 98.89)	98.15 (97.73, 98.49)	98.04 (97.6, 98.4)	97.84 (97.33, 98.25)
	UK NJR	35,931	99.58 (99.51, 99.64)	98.84 (98.71, 98.96)	98.41 (98.25, 98.55)	98.09 (97.90, 98.25)	97.90 (97.70, 98.09)

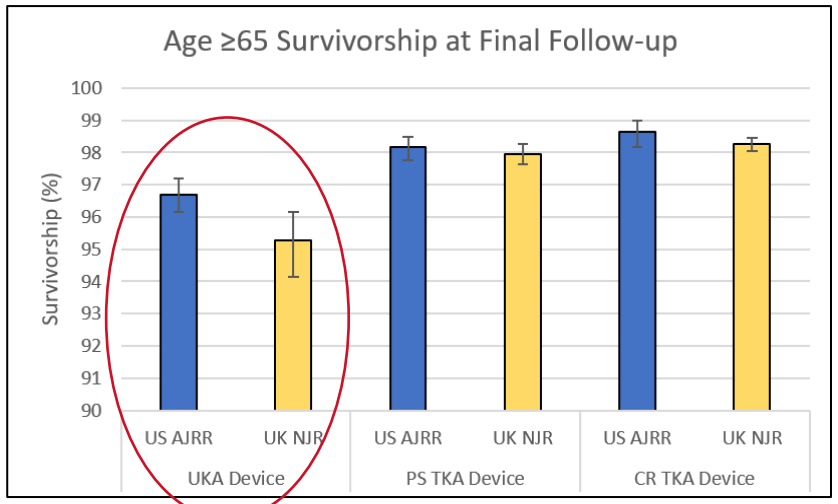
Age ≥65 Cohort	Years	N	1 Year	3 Years	5 Years	7 Years	8 Years
UKA Device	US AJRR	7,718	99.19 (98.96, 99.37)	98.07 (97.72, 98.37)	97.41 (96.98, 97.79)	96.70 (96.14, 97.18)	96.70 (96.14, 97.18)
	UK NJR	3,318	99.16 (98.78, 99.42)	97.89 (97.30, 98.35)	97.01 (96.28, 97.59)	95.91 (94.97, 96.68)	95.26 (94.15, 96.16)
PS TKA Device	US AJRR	12,950	99.39 (99.24, 99.51)	98.82 (98.61, 99)	98.59 (98.35, 98.8)	98.46 (98.18, 98.69)	98.16 (97.76, 98.49)
	UK NJR	12,687	99.43 (99.28, 99.55)	98.89 (98.68, 99.07)	98.37 (98.10, 98.60)	98.14 (97.83, 98.40)	97.96 (97.63, 98.25)
CR TKA Device	US AJRR	4,019	99.49 (99.21, 99.67)	99.06 (98.7, 99.33)	98.68 (98.23, 99.01)	98.63 (98.17, 98.97)	98.63 (98.17, 98.97)
	UK NJR	25,342	99.60 (99.52, 99.68)	99.02 (98.88, 99.14)	98.69 (98.52, 98.85)	98.45 (98.25, 98.62)	98.26 (98.03, 98.46)

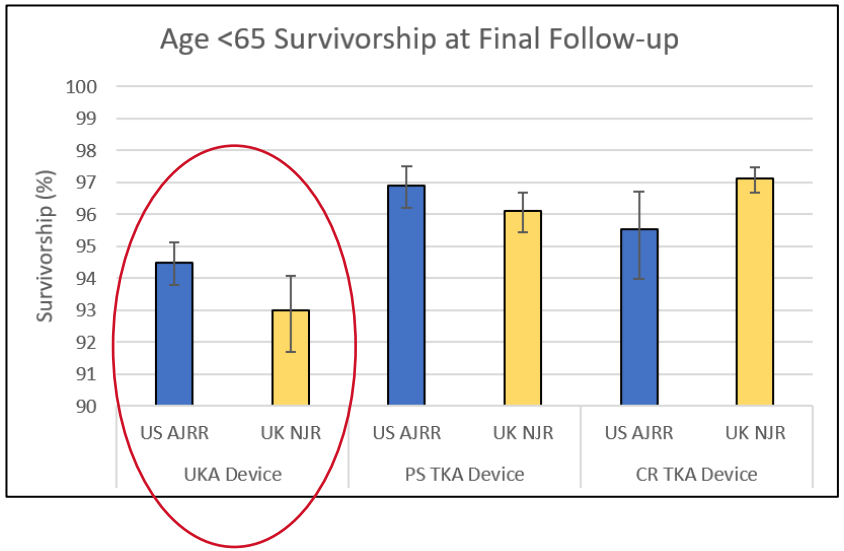
Age <65 Cohort	Years	N	1 Year	3 Years	5 Years	7 Years	8 Years
UKA Device	US AJRR	8,072	98.80 (98.54, 99.02)	96.97 (96.54, 97.34)	95.61 (95.06, 96.1)	94.78 (94.12, 95.36)	94.48 (93.78, 95.11)
	UK NJR	3,168	99.18 (98.79, 99.45)	97.27 (96.60, 97.82)	95.63 (94.75, 96.37)	93.65 (92.47, 94.64)	92.98 (91.70, 94.07)
PS TKA Device	US AJRR	6,284	99.17 (98.91, 99.37)	98.18 (97.8, 98.5)	97.49 (97.02, 97.9)	97.07 (96.47, 97.58)	96.91 (96.2, 97.49)
	UK NJR	5,335	99.47 (99.23, 99.64)	97.95 (97.49, 98.32)	96.93 (96.36, 97.41)	96.47 (95.84, 97.01)	96.11 (95.43, 96.69)
CR TKA Device	US AJRR	1,640	99.16 (98.56, 99.51)	97.23 (96.22, 97.97)	96.57 (95.43, 97.42)	96.31 (95.1, 97.22)	95.54 (93.97, 96.71)
	UK NJR	10,589	99.53 (99.37, 99.64)	98.42 (98.14, 98.66)	97.75 (97.40, 98.05)	97.28 (96.87, 97.63)	97.11 (96.68, 97.48)

Results - Knee

- Similar trends for comparatively high and low performing devices through final follow-up (eight years)
- All three devices showed clinical and statistical agreement in survivorship for all cohorts in early and mid-term follow-up
- UKA device was statistically agreeable up to 7 years in all age cohort but fell outside this range at 8 years







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Conclusion

- AJRR performance hip and knee arthroplasty trends and survivorship were similar to NJR's hip and knee arthroplasty trends and survivorship
- All cohorts were similar with greatest consistency in the age ≥65 cohort
- Encouraging results for reliability of outcome capture in AJRR compared to the highest capture total joint arthroplasty registry in the world
- Implications for global improvement in patient safety
- ODEP Pilot Underway

ODEP Orthopaedic Data Evaluation Panel

AAOS American Academy of Orthopaedic Surgeons

Beyond Compliance

March 2023

To all manufacturers of Total Knee Replacements

Dear Colleague

We would be grateful for your help!

Over the past 2 years ODEP has been working with AJRR to a
AJRR data to be used for ODEP submissions.

There are a lot of gains to be had if this was possible.

- Nowadays more data is being added to the AJRR tha
- With the MDR and UKCA there will be more, new TJ
any other part of the world.
- Without a benchmark these implants will not easily
probably in the EU and many other parts of the wor
- Obviously, having AJRR data to benchmark them wil
purchasers. In Principle this is nothing new; ODEP be
world that are not used in the UK

We realise that this will increase your workload but we reckon that for the future using AJRR data for ODEP will be very advantageous for all manufacturers.

What if we find that the revision rates don't line up satisfactorily? Well we think they probably will but we have a cunning plan if they don't!

You are welcome to contact ODEP or AJRR for further information if you require it

Kind Regards

Keith Tucker FRCS
Chair of ODEP and the
Beyond Compliance Advisory Group

Bryan D. Springer, MD, FAAOS
AJRR Steering Committee Chair

James I. Huddleston, III, MD, FAAOS
AJRR Steering Committee Vice Chair

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Registry Program
Improving Orthopaedic Care Through Data

Thank you!