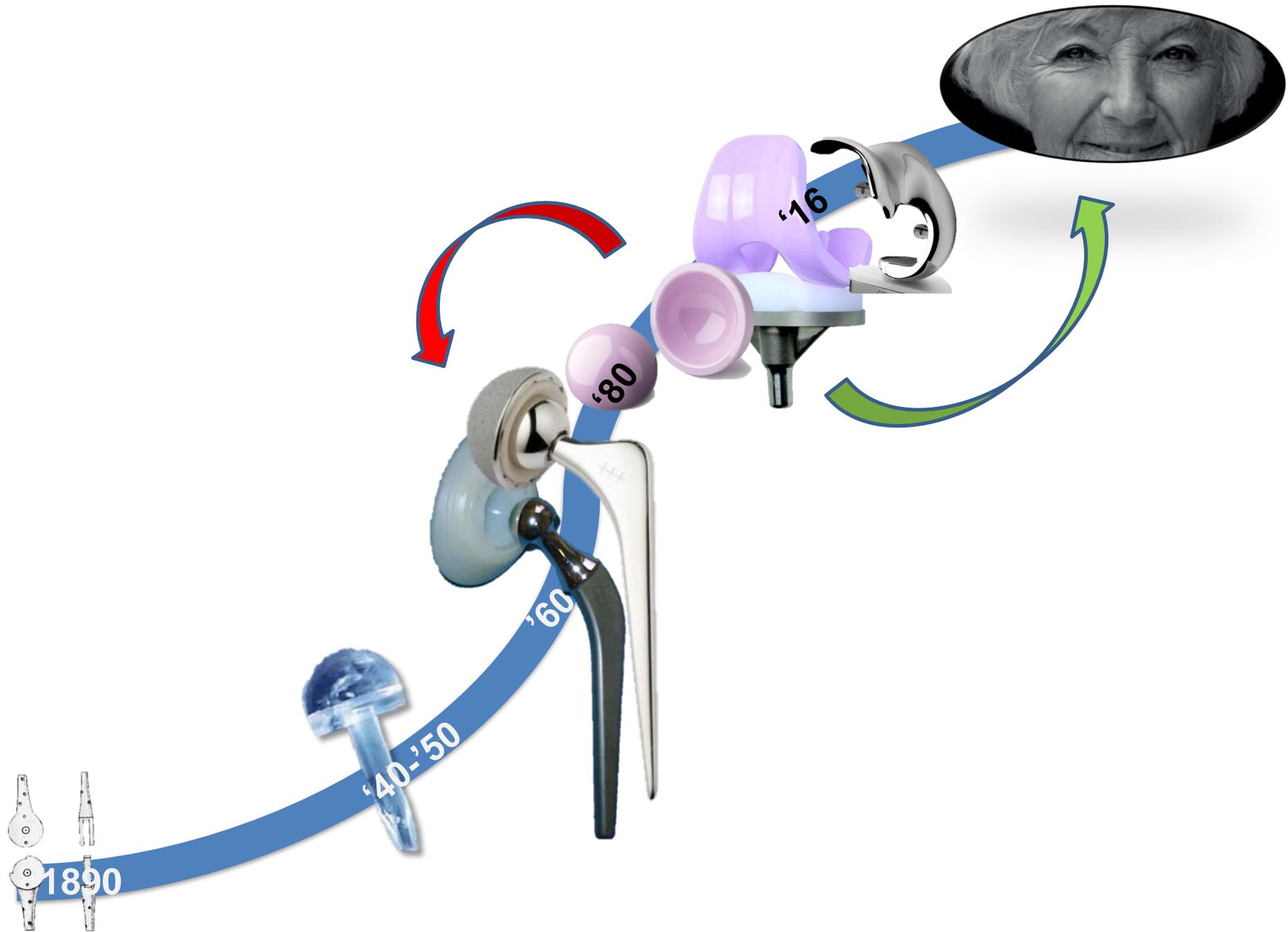# Survelliance & Vigilance

What Surgeons can contribute

Rob Nelissen, MD, PhD

Professor & Chairman Orthopaedics, Leiden University Medical Center

Chairman NORE, an EFORT committee

1890

'40-'50

'60

'80

'16

Sufficient Clinical Evidence **?**

Clinical benefit: *the positive impact of a device on the health of an individual, expressed in terms of meaningful, measurable, patient relevant clinical outcome, including outcome(s) related to diagnosis, or a positive impact on patient management or public health.* *(MDR art 2 (53))*

Risk: *the combination of the probablity of occurence of harm and the severity of that harm* *(MDR art 2 (23))*

$$\frac{\text{Benefit}}{\text{Risk}} > 1$$

$$\frac{\text{Risk}}{\text{Benefit}} > 1$$

Complications Primary Total Hip

Registry studies > 300.000 patients NJR

- Mortality

- Walking difficulty

- Moderate - severe pain

Williams et al 2002; Berstock et al 2014; Hunt et al 2013

Complications Primary Total Hip

- Mortality   0.7%

- Walking difficulty   22%

- Moderate - severe pain   11%

Williams et al 2002;   Berstock et al 2014;   Hunt et al 2013

What Is the Benefit of Introducing
New Hip and Knee Prostheses?

Which Implant Should We Use for Primary
Total Hip Replacement?

ONLY 20-40 % of total hips/knees good clinical evidence

RESEARCH

Appraisal of evidence base for introduction of new
implants in hip and knee replacement: a systematic
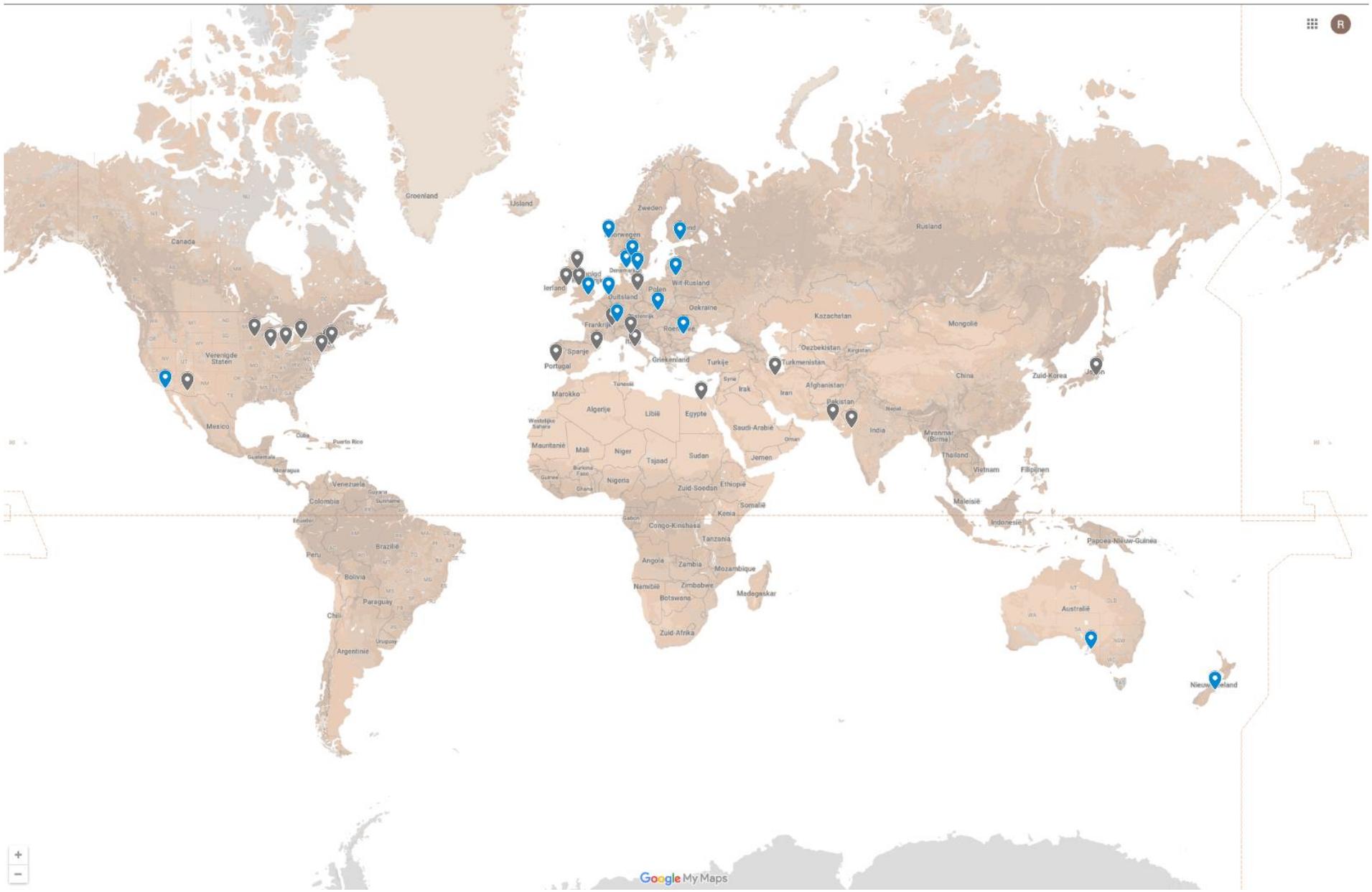review of five widely used device technologies

Marc J Nieuwenhuijse research fellow ICOR and FDA[123], R G H H Nelissen professor[2], J W
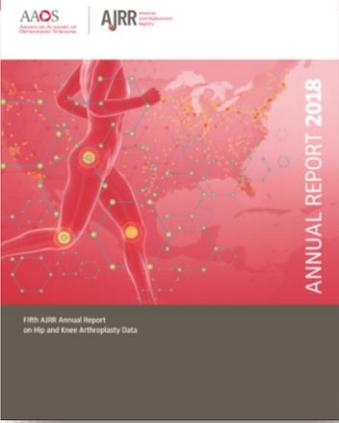... specialist[4], A Sedrakyan associate professor[13]

Selection of implants **performance** in real world
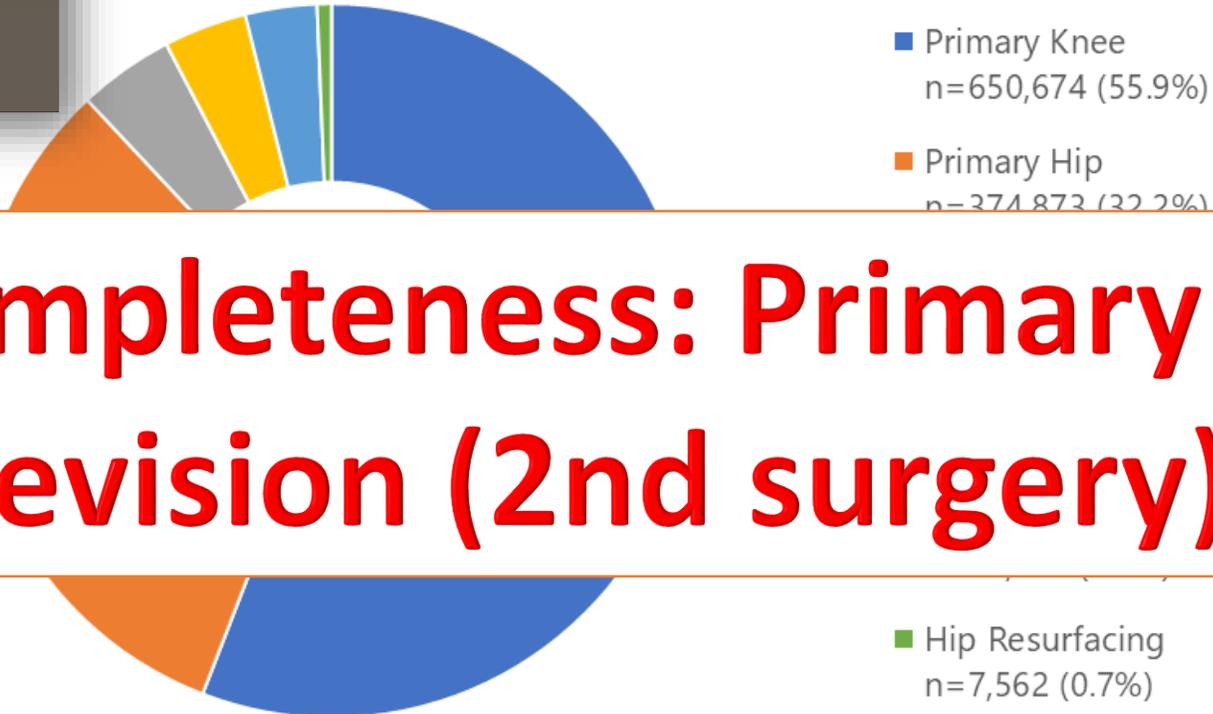

©Swedish Hip Arthroplasty Register

blue: full members >80% data: national registries + KaiserPermanente Inc. (USA)
black: associate members < 80% data completeness

: Distribution of Procedures (N=1,164,814)

- Primary Knee
  n=650,674 (55.9%)

- Primary Hip
  n=374,873 (32.2%)

- Hip Resurfacing
  n=7,562 (0.7%)

Completeness: Primary 29% Revision (2nd surgery) ??

© 2018 AAOS American Joint Replacement Registry

Primary 99% completeness
Revision 97% completeness
like **Sweden, Norway, Denmark, Finland, UK&Wales**, *Germany runner-up;*

Outcome in Registries:

Survival analysis: *end-point* : **Loosening of Implant in bone**

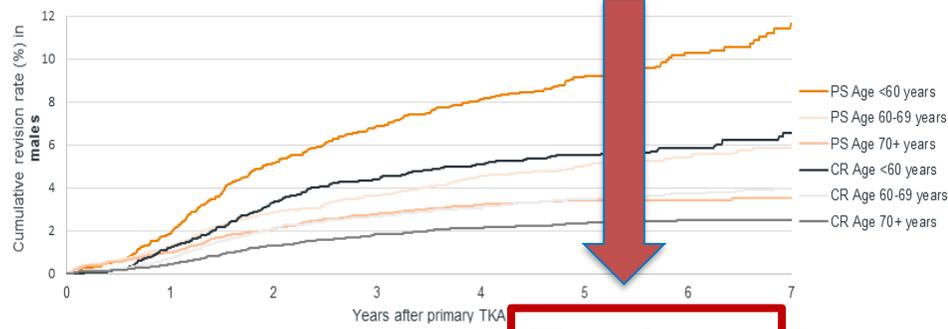# Revision of cemented Total Knee in OA patient
2007-2018 (n=204.702)

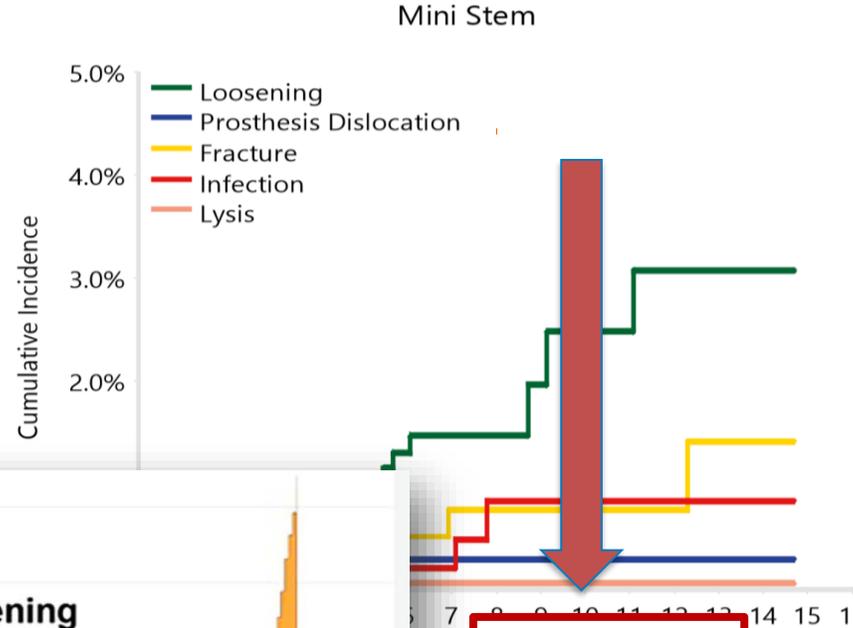| Femur component	Tibia component	Total primary TKAs (n)	Median (IQR) age (yr)	Major revision[1] arthroplasties (n)	Cumulative revision percentage (95% CI)				
					1yr	3yr	5yr	7yr	10yr
All cemented TKAs for osteoarthritis		204,702	69 (62-75)	3,762	0.4 (0.4-0.5)	1.6 (1.6-1.7)	2.2 (2.1-2.3)	2.6 (2.6-2.7)	3.2 (3.0-3.3)
Genesis II	Genesis II	45,521	69 (62-75)	794	0.5 (0.4-0.6)	1.8 (1.6-1.9)	2.3 (2.1-2.4)	2.5 (2.3-2.7)	2.8 (2.5-3.0)
NexGen	NexGen	43,788	69 (62-75)	864	0.4 (0.4-0.5)	1.6 (1.4-1.7)	2.4 (2.2-2.5)	3.1 (2.9-3.3)	3.9 (3.6-4.2)
Vanguard Complete Knee	Vanguard Complete Knee	33,637	69 (62-75)	499	0.4 (0.3-0.5)	1.5 (1.3-1.6)	1.9 (1.8-2.1)	2.2 (2.0-2.4)	2.7 (2.3-3.0)
PFC / Sigma	PFC / Sigma	25,06	70 (63-76)	340	0.4 (0.3-0.5)	1.3 (1.1-1.4)	1.6 (1.4-1.8)	1.9 (1.7-2.1)	2.1 (1.8-2.3)
LCS	LCS	14,353	70 (63-76)	412	0.5 (0.4-0.6)	2.6 (2.3-2.8)	3.5 (3.1-3.9)	4.1 (3.7-4.5)	4.6 (4.1-5.0)
Triathlon	Triathlon	4,675	70 (64-76)	58	0.5 (0.3-0.7)	1.6 (1.2-2.0)	1.8 (1.3-2.3)	2.3 (1.6-3.0)	n.a.
AGC V2	AGC V2	4,419*	71 (65-77)	76	0.2 (0.1-0.3)	1.1 (0.8-1.4)	1.4 (1.2-1.8)	1.8 (1.4-2.2)	2.2 (1.7-2.7)
Optetrak	Optetrak	3,059	70 (62-76)	158	0.7 (0.4-1.0)	3.1 (2.5-3.7)	4.2 (3.5-4.9)	5.3 (4.5-6.2)	7.1 (5.9-8.4)
TC Plus	TC Plus	2,827	70 (63-76)	46	0.5 (0.2-0.8)	1.3 (0.9-1.8)	1.9 (1.4-2.5)	2.2 (1.5-2.8)	2.4 (1.6-3.1)
ACS	ACS	2,645	67 (60-73)	47	0.4 (0.1-0.6)	1.6 (1.1-2.1)	2.1 (1.5-2.7)	2.2 (1.6-2.8)	n.a.

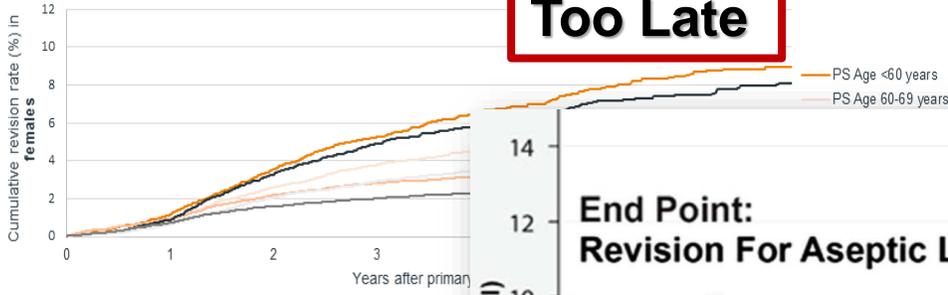[1] Revision of at least the femur or tibia component.
* Denotes prosthesis combinations with no reported use in primary TKAs in 2018.
Please note: n.a. if <50 cases were at risk; TKA: total knee arthroplasty; CI: confidence interval; IQR: interquartile range.

LROI

Evidence from Registries: *the Holy Grail?*

Too Late

Too Late

End Point: Revision For Aseptic Loosening

Too Late

Mini Stem
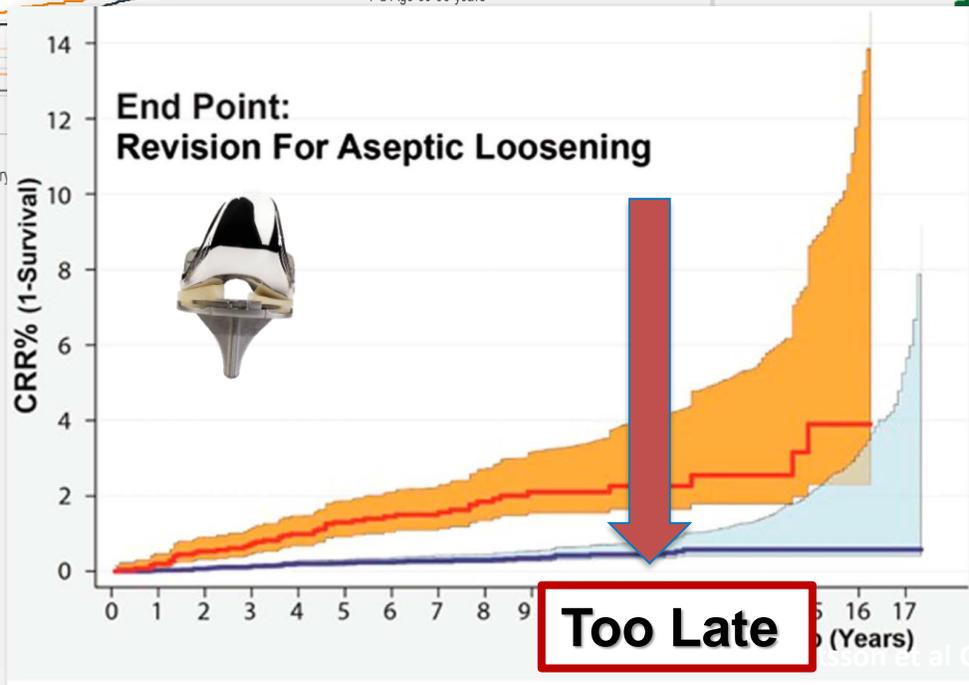
Detection implant failure
Registries slow

Early detection =
Less patients have *bad* new implants
Stimulates *Safe* Innovation

40

30

0

0   2   4   6   8   10

follow-up (years)

Accuracy RSA: Translation 0.1 mm   Rotation 0.1°   x.y.z-axis

2 Years
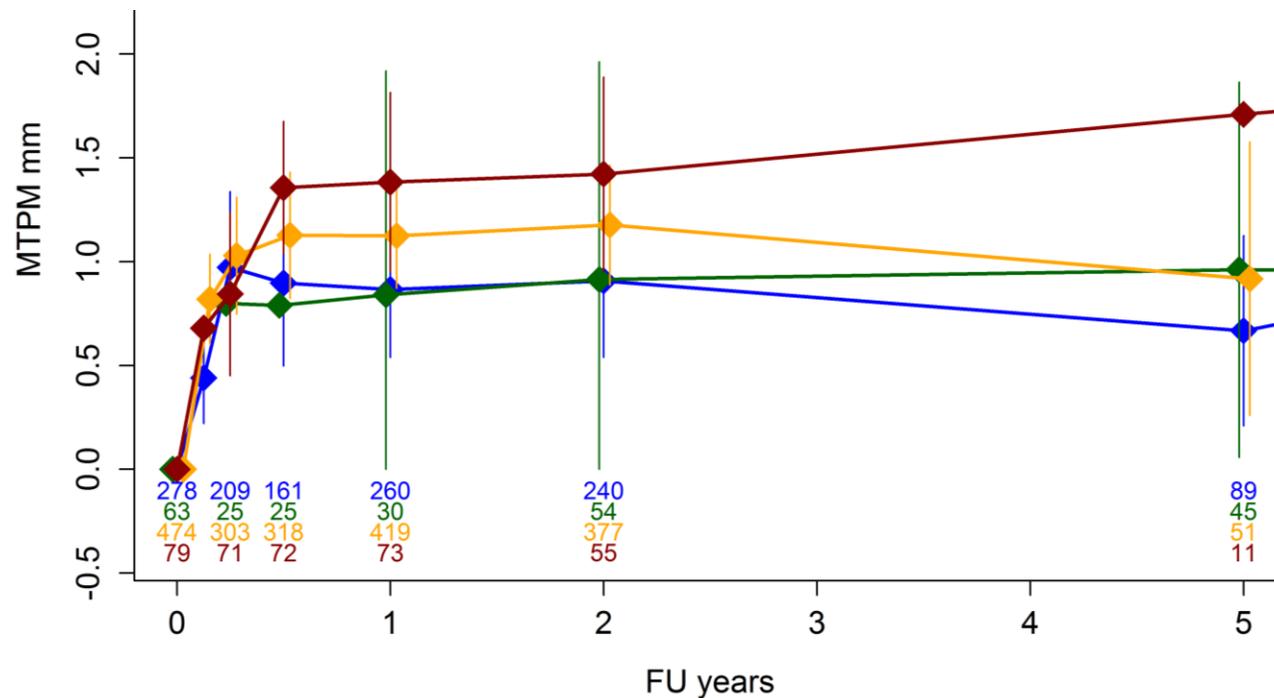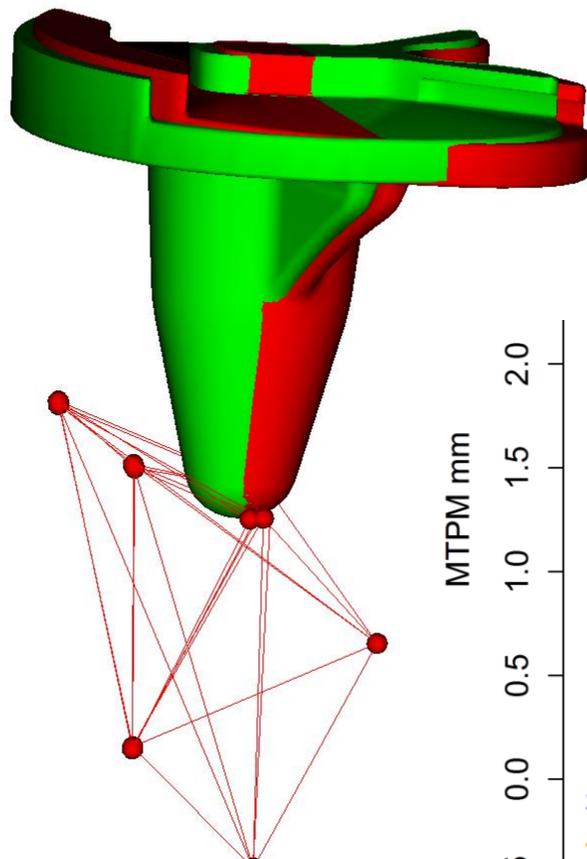
RSA yes   **RSA no**
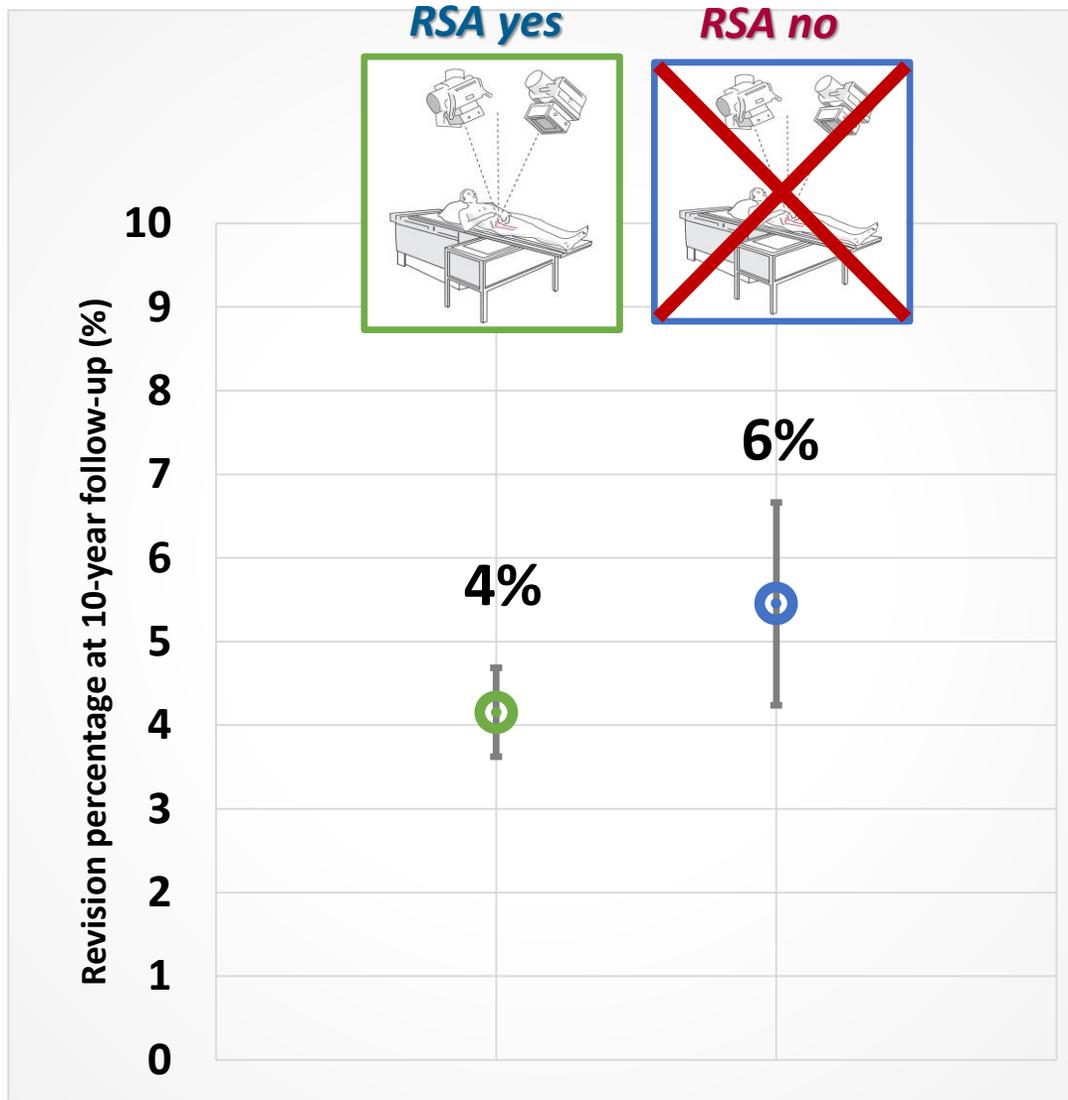
451 different TKA types from 9 Registries

113 RSA TKA

259 Non-RSA TKA

Overall: 1.990.439 TKA

Costs 1 revision: 30.000 €

+ Patient

Revision percentage at 10-year follow-up (%)

4%   6%

Nelissen et al JBJS Am, 2011; Hasan, Nelissen et al, CORR 2020

Survelliance & Vigilance of Surgeons

Criteria - Total Hip Replacement

| Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*
Minimum number of centres outside development centre(s)	3	3	3	3	3
Minium number of surgeons outside of development centre(s)	3	3	3	3	3
Minimum total cohort	150	250	350	500	500
Minimum at risk at benchmark time	150	225	300	400	400
Maximum revision rate ‡	3.0%	3.5%	4.0%	5.0%	6.5%

Criteria - A Ratings				10A	13A
Minimum number of centres and surgeons				3	3
Minimum total cohort				500	500
Minimum at risk at benchmark time				51	42
Maximum revision rate ‡				7.0%	8.5%
‡ The upper 95% confidence interval for KM revision rate (1 - Survival)					

Criteria - B Ratings				10B	13B
Minimum number of centres and surgeons				1	1
Minimum total cohort				100	100
Minimum at risk at benchmark time				40	40
Maximum value of 95% lower confidence limit for revision rate				5.0%	6.5%

Criteria - Pre-Entry A*
Product launched under Beyond Compliance

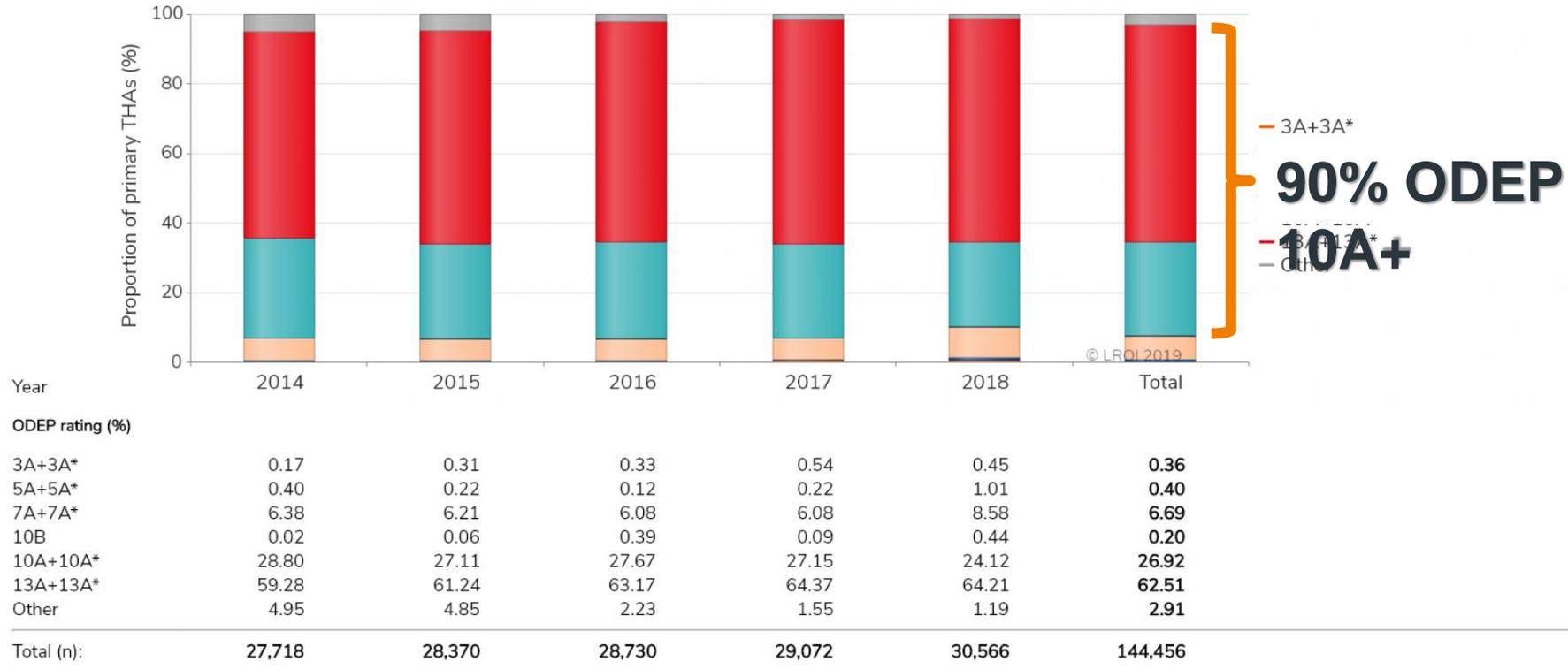| Pre-Entry |
|---|
| Products registered with NJR.
All primaries and revisions monitored via supplier feedback. |
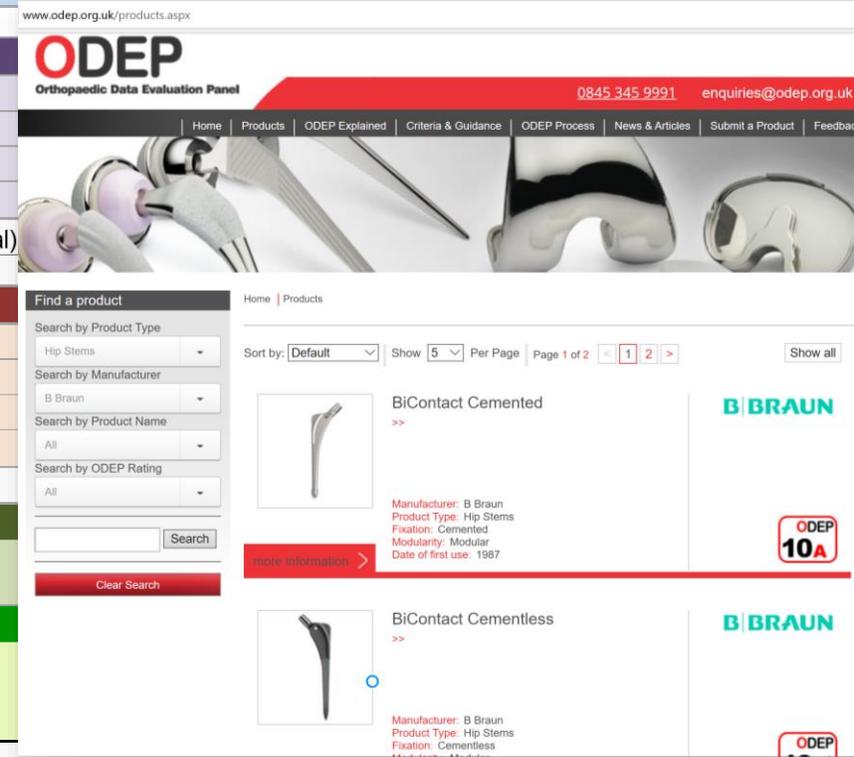
Benchmark: Hipstem Netherlands

FIGURE TREND (PROPORTION [%] PER YEAR) IN ODEP RATING FEMUR COMPONENT IN PRIMARY TOTAL HIP ARTHROPLASTIES IN THE NETHERLANDS IN 2014-2018.

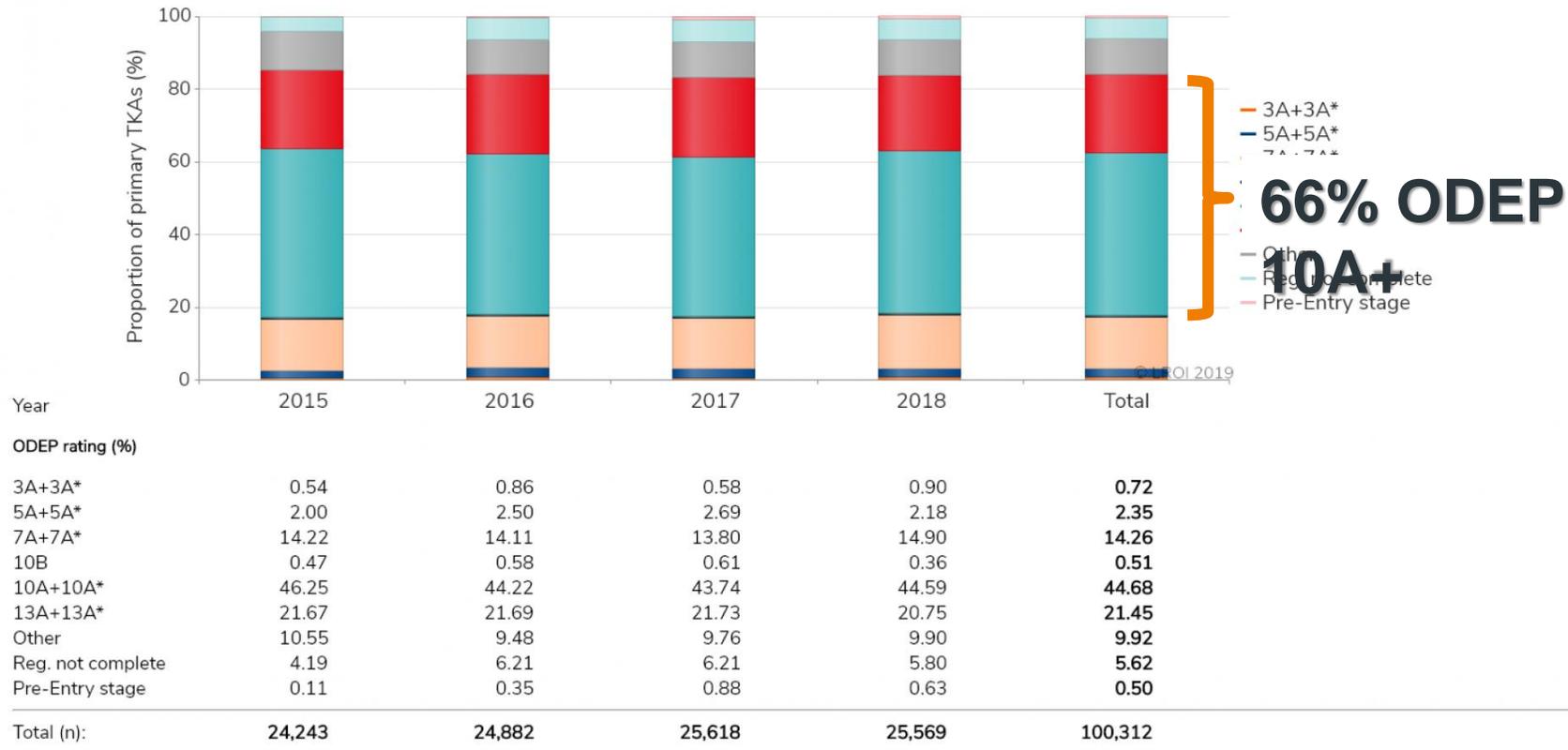| Year	2014	2015	2016	2017	2018	Total
ODEP rating (%)						
3A+3A*	0.17	0.31	0.33	0.54	0.45	0.36
5A+5A*	0.40	0.22	0.12	0.22	1.01	0.40
7A+7A*	6.38	6.21	6.08	6.08	8.58	6.69
10B	0.02	0.06	0.39	0.09	0.44	0.20
10A+10A*	28.80	27.11	27.67	27.15	24.12	26.92
13A+13A*	59.28	61.24	63.17	64.37	64.21	62.51
Other	4.95	4.85	2.23	1.55	1.19	2.91
Total (n):	27,718	28,370	28,730	29,072	30,566	144,456

Please note: More information on ODEP rating can be found on www.odep.org.uk.
Other: All total hip femoral stems of which no ODEP rating is available.
THA: total hip arthroplasty.

ODEP: Orthopaedic Data Evaluation Panel. www.ODEP.org.uk **ODEP 10A* 5% revision at 10 years**

Benchmark Total Knees Netherlands
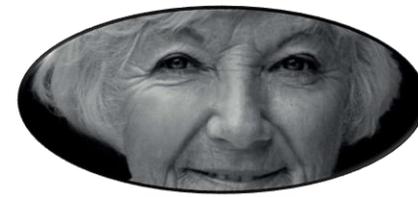
FIGURE TREND (PROPORTION [%] PER YEAR) IN ODEP RATING IN PRIMARY TOTAL KNEE ARTHROPLASTIES IN THE NETHERLANDS IN 2015-2018.
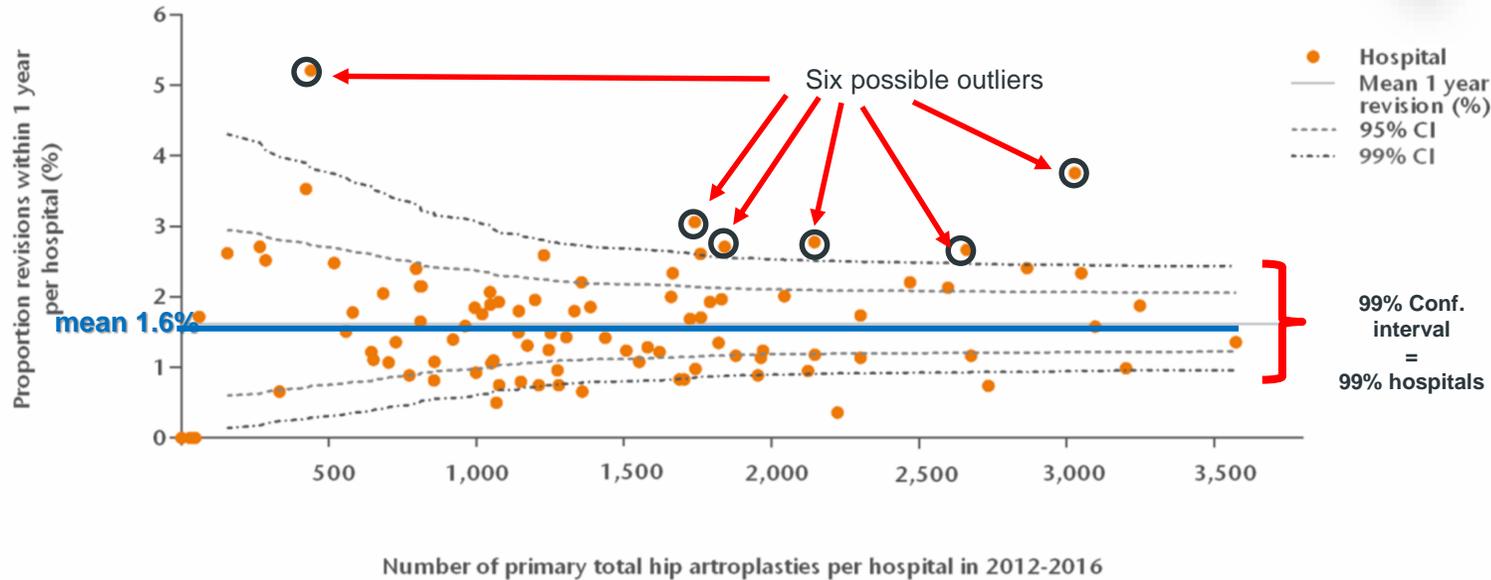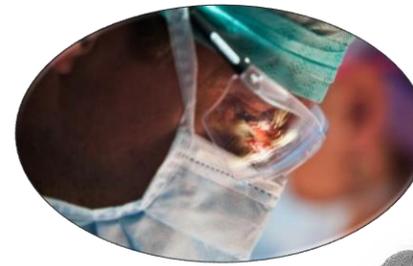

66% ODEP 10A+

Legend:
- 3A+3A*
- 5A+5A*
- 7A+7A*
- Other
- Reg. not complete
- Pre-Entry stage

ODEP rating (%)	2015	2016	2017	2018	Total
3A+3A*	0.54	0.86	0.58	0.90	0.72
5A+5A*	2.00	2.50	2.69	2.18	2.35
7A+7A*	14.22	14.11	13.80	14.90	14.26
10B	0.47	0.58	0.61	0.36	0.51
10A+10A*	46.25	44.22	43.74	44.59	44.68
13A+13A*	21.67	21.69	21.73	20.75	21.45
Other	10.55	9.48	9.76	9.90	9.92
Reg. not complete	4.19	6.21	6.21	5.80	5.62
Pre-Entry stage	0.11	0.35	0.88	0.63	0.50
Total (n):	24,243	24,882	25,618	25,569	100,312

Please note: More information on ODEP rating can be found on www.odep.org.uk
Other: All TKAs of which no ODEP rating is available.

ODEP: Orthopaedic Data Evaluation Panel. www.ODEP.org.uk **ODEP 10A* 5% revision at 10 years**

Outliers: Benchmark performance

mean **1-year revision primary Total Hip per hospital: 1.6%**
THA 2012-2016 n=137.725

Six possible outliers

	Hospital
	Mean 1 year revision (%)
	95% CI
	99% CI

mean 1.6%

99% Conf. interval = 99% hospitals

Proportion revisions within 1 year per hospital (%)

Number of primary total hip artroplasties per hospital in 2012-2016
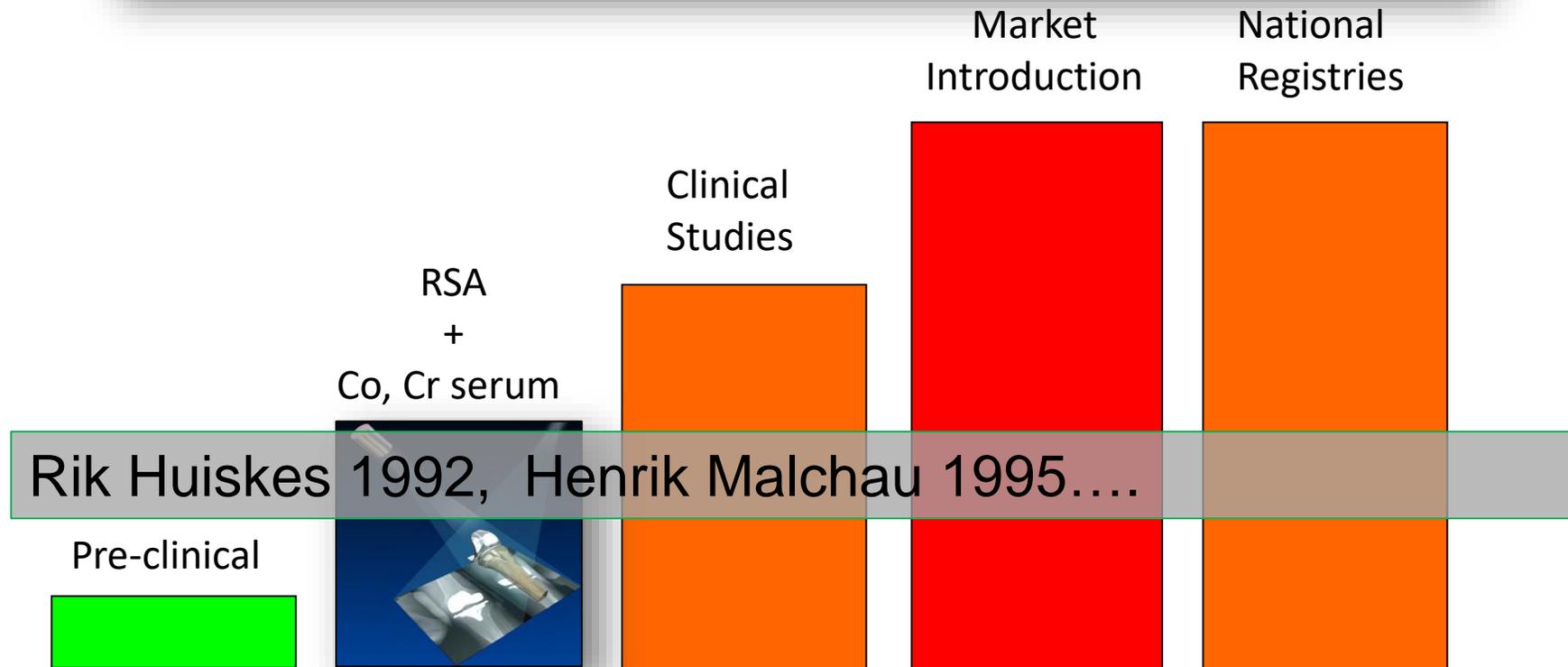
LROI

- *non-designer* Surgeons discuss the new implant (instrumentation, implant handling..)

- Collecting data within NJR (Implant Registry UK&Wales)

- Data on complications

- Pre-entry ODEP rating

RSA and Registries: The Quest for Phased Introduction of New Implants

Rob G.H.H. Nelissen, MD, PhD, Bart G. Pijls, MD, Johan Kärrholm, MD, PhD, Henrik Malchau, MD, PhD, Marc J. Nieuwenhuijse, MD, and Edward R. Valstar, MSc, PhD

Investigation performed at Leiden University Medical Center, Leiden, The Netherlands

Market Introduction

National Registries

Clinical Studies

RSA
+
Co, Cr serum

Rik Huiskes 1992, Henrik Malchau 1995….

Pre-clinical

EQI:

EFORT Quality assessment Implants:

95% survival Total Hip @ 10 yrs in 2 national /regional registries

Innovation

ODEP

2RSA

Approved by

ODEP

10EFORT

Am I the right Surgeon with

the right instruments & Implant and

staff, to do this surgery

for this Patient?

"Do not let your patient become
a fashion victim"

Bulstrode BMJ 1993