EAR
European Arthroplasty Register

Quality of Datasets

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AKH
www.akh.linz.at

ORTHOPAEDICS
UNIVERSITY OF INNSBRUCK
EFORT – JOINT EFFORTS

E A R

European Arthroplasty Register

QoLA-Project

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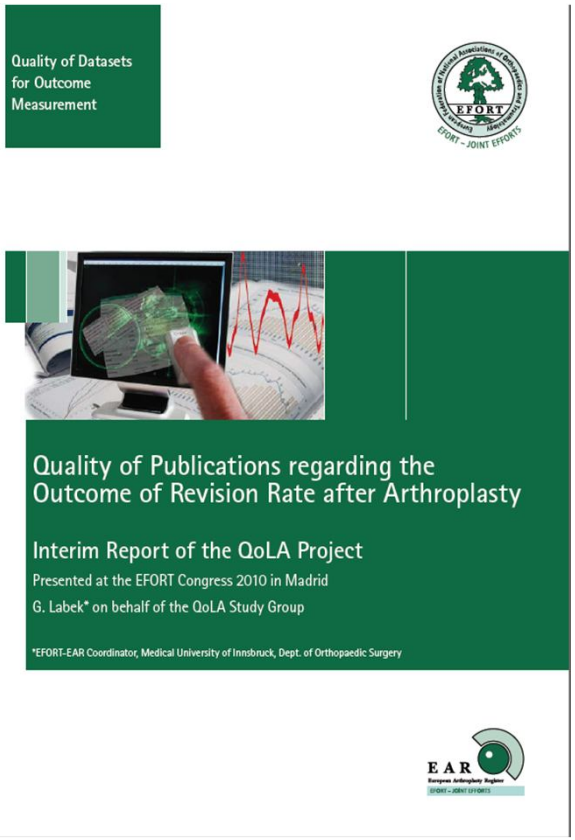
- EU-Commission, EUPHORIC-Project:
  Quality of data presented for
  CE-Licensing, market monitoring,...?

  Development of a methodology

  Test on a sample:
  - about 50% of data from scietific publications not reproducable
  - mainly US-Literature and inventors

  Decision to check the literature of all Implants possible



QoLA-Research Group

- Medical University Innsbruck, Dept. of Orthopaedic Surgery, Austria
- University Kiel, Dept. of Orthopaedic Surgery, Germany
- Hacettepe University, Dept. of Orthopaedic Surgery, Turkey
- University Leiden, Dept. of Orthopaedic Surgery, Nederlands
- Semmelweiss Univ. Budapest, Dept of Orthopaedic Surgery, Hungary
- Endoklinik, Hamburg, Germany
- Sozialmedizinisches Zentrum Ost, Dept of. Orthopaedic Surgery, Vienna, Austria
- South Danish University, Vejle, Denmark
- Haddassah Univ. Hospital, Jewish University Jerusalem, Israel
- University Martin, Dept. of Orthopaedic Surgery, Martin, Slovakia
- University Pleven, Dept. of Orthopaedic Surgery, Pleven, Bulgaria
- University Hospital Geneva, Dept. of Orthopaedic Surgery, Geneva, Switzerland
- Allgemeines Krankenhaus Linz, Dept. of Orthopaedic Surgery, Linz, Austria
- Istituto Galeazzi, Milano, Italy
- University Arad, Dept. of Orthopaedic Surgery, Arad, Romania
- Medical University Salzburg, Dept. of Orthopaedic Surgery, Salzburg, Austria
- Clinica Foisor de Foc, Bucharest, Romania
- Hospital del Mar, Dept. of Orthopaedic Surgery, Barcelona, Spain
- University Lille, Dept. of Orthopaedic Surgery, Lille, France
- Clinique de l´Yvette, Paris, France
- Dr. Günther Ziernhöld, Bolzano, Italy
- Orthopädisches Physiotherapiezentrum, Graz, Austria
- Johanneum Research, Graz, Austria
- Landeskrankenhaus Klagenfurt, Dept. of Orthopaedic Surgery, Klagenfurt, Austria
- Oberschwabenklinik, Wangen, Germany
- **Centro Hospitalar do Nordeste, Macedo de Cavaleiros, Oporto, Portugal**
- **Hospital Curry Cabral, Lisboa, Portugal**
- **Centro Hospitalar do Tâmega e Sousa, Penafiel, Portugal**

Available Datasets

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- Clinical studies
  - sample based
  - Aim is to draw general conclusions
  - Bias Factors and confounders
    (Patient selection, Publication, study design,...)
- Register
  - All operations
    (Primary and Revisions = Failures)
  - Reference for checks concerning confounders

EAR/Europe

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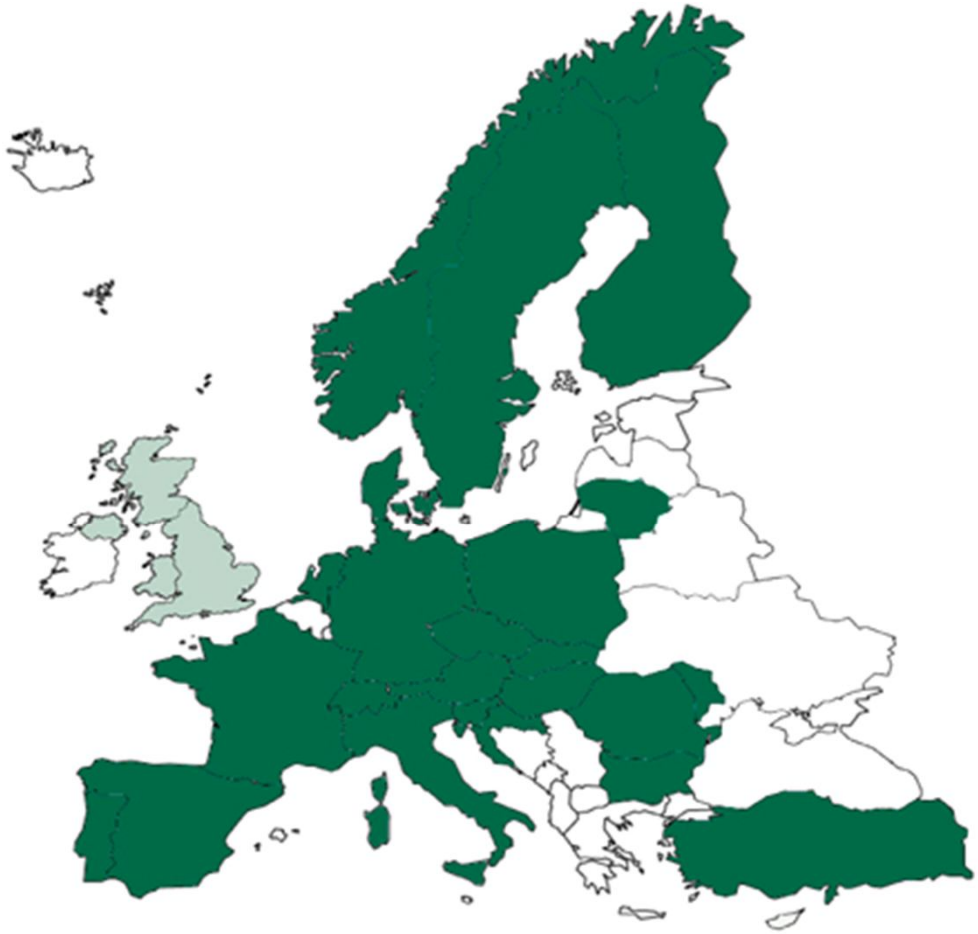

Rational

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Frankfurter Allgemeine
FAZ.NET

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30. Mai 2010 | Reise | Wissen | Auto | Computer | Beruf & Chance | Kunstmarkt | Im

Aktuell › Wirtschaft

Vioxx-Skandal

Artikel-Services

Vioxx wohl für bis zu 140.000 Herzinfarkte verantwortlich

Zuerst verboten, nun doch veröffentlicht: Nach einer Studie des stellvertretenden Leiters der amerikanischen Zulassungsbehörde für Arzneimittel ist das Merck-Medikament wohl für bis zu 140.000 Herzinfarkte verantwortlich.

Stellvertretender Leiter der FDA David Graham

25. Januar 2005 Das Schmerzmittel Vioxx ist nach einer Studie seit seiner Markteinführung 1999 in den Vereinigten Staaten wahrscheinlich für bis zu 140.000 teilweise tödliche Herzinfarkte verantwortlich.

Die britische Medizinzeitschrift „The Lancet" veröffentlichte am Dienstag im Internet eine entsprechende Studie von David Graham, dem stellvertretenden Leiter der Abteilung der amerikanischen Zulassungsbehörde für Medikamente FDA (Food and Drug Administration), die Arzneien auf ihre Unbedenklichkeit prüft. Die Untersuchung ist von der FDA allerdings nicht freigegeben worden.

Anzeige

FDA-Report:
140.000 myocardial infactions due to Vioxx

Are and to what extend are results from sample based studies reproducible in average patient service???

Rational

oplasty Register

The Epoch Times

Sunday, May 30, 2010

Home Nation World China Business Opinion Science & Technology Arts & Entertainment Health

Will Fosamax Be Merck's New Vioxx?

By Martha Rosenberg

Created: Jan 22, 2009
Last Updated: Jan 26, 2009

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Related articles: Health > Western Medicine

(Martha Rosenberg)

For Merck, 1999 was a good year. In its 64-page annual report, Merck predicted arthritis medicine Vioxx—"Our Biggest, Fastest and Best Launch Ever!"—would prevent Alzheimer's disease and colon cancer.

It announced it was seeking approval to market asthma drug Singular to 2-year-olds.

And it predicted 40 million women would take its new osteoporosis drug, the bisphosphonate Fosamax, as it continued to "help educate both physicians and patients" about the bone

Only Pharma?????

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Problem for physicians, manufacturers and authorities:

- Many potential confounders in studies not verfiable
- No overview on the entire market concerning sideeffects
- Detection often by chance
  (Vioxx: side effect in a study not designed for)

Arthroplasty has a reference dataset representing almost all cases treated in a country available by
National Arthroplasty Registers

QoLA-Project

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- 108 Implant systems,
  82 of them (76%) data aquisition and analysis completed
  - 67 Data available
  - 15 systems: no outcome studies published

Implant	Manufacturer	
Natural Hip	DePuy	New
Pinnacle	DePuy	New
RBK	Global Orthopaedics	Small Comp
Option	Kinamend	Small Comp
F2L Multineck	Lima	Small Comp
SPH Blind	Lima	Small Comp
Journey	S&N	New
Citation	Stryker	
ABG Cup	Stryker	
Unix Uni	Stryker	
Anca-Fit	Wright	
Advantim	Wright	
ZCA	Zimmer	
ZUK Uni	Zimmer	New

Material and Methods

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- Review to identify all implants documented in worldwide high level national registers in relevant numbers
  - Clinical studies: English or native language of the partner in Medline-listed Journals
  - Registers: Annual Reports and Journal publications

Material and Methods

- Medline- und manual literature research in several steps
- Publications with sufficiant information to calculate
  „Revisions per 100 observed component years“ (Number of primary and revision cases, FUP-period)
- Detail analyses for potential confounders
  - Implant developer
  - Region of Origin
  - Methodological quality of the Study

Material and Methods

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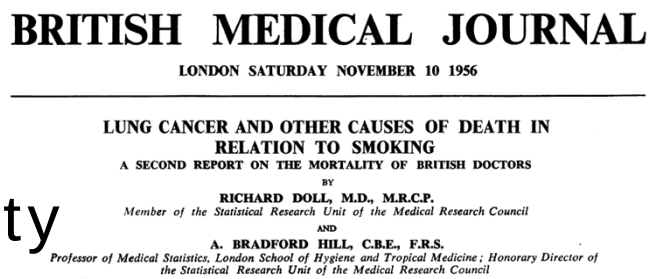
- „Revisions per 100 observed component years“
- Standard procedure for cohort studies
  - 1950-ies: Smoking and Lung cancer
  - years of exposition to a potential risk (smoking)
  - ev. adjusted to qualitiy (how many cigarettes)
  - => Total amount Number of exposition years
  - Number of observed events (lung cancer)
- Adopted for arthroplasty by the Australian Register for Arthroplasty



BRITISH MEDICAL JOURNAL

LONDON SATURDAY NOVEMBER 10 1956

LUNG CANCER AND OTHER CAUSES OF DEATH IN RELATION TO SMOKING

A SECOND REPORT ON THE MORTALITY OF BRITISH DOCTORS

BY

RICHARD DOLL, M.D., M.R.C.P.

Member of the Statistical Research Unit of the Medical Research Council

AND

A. BRADFORD HILL, C.B.E., F.R.S.

Professor of Medical Statistics, London School of Hygiene and Tropical Medicine; Honorary Director of the Statistical Research Unit of the Medical Research Council

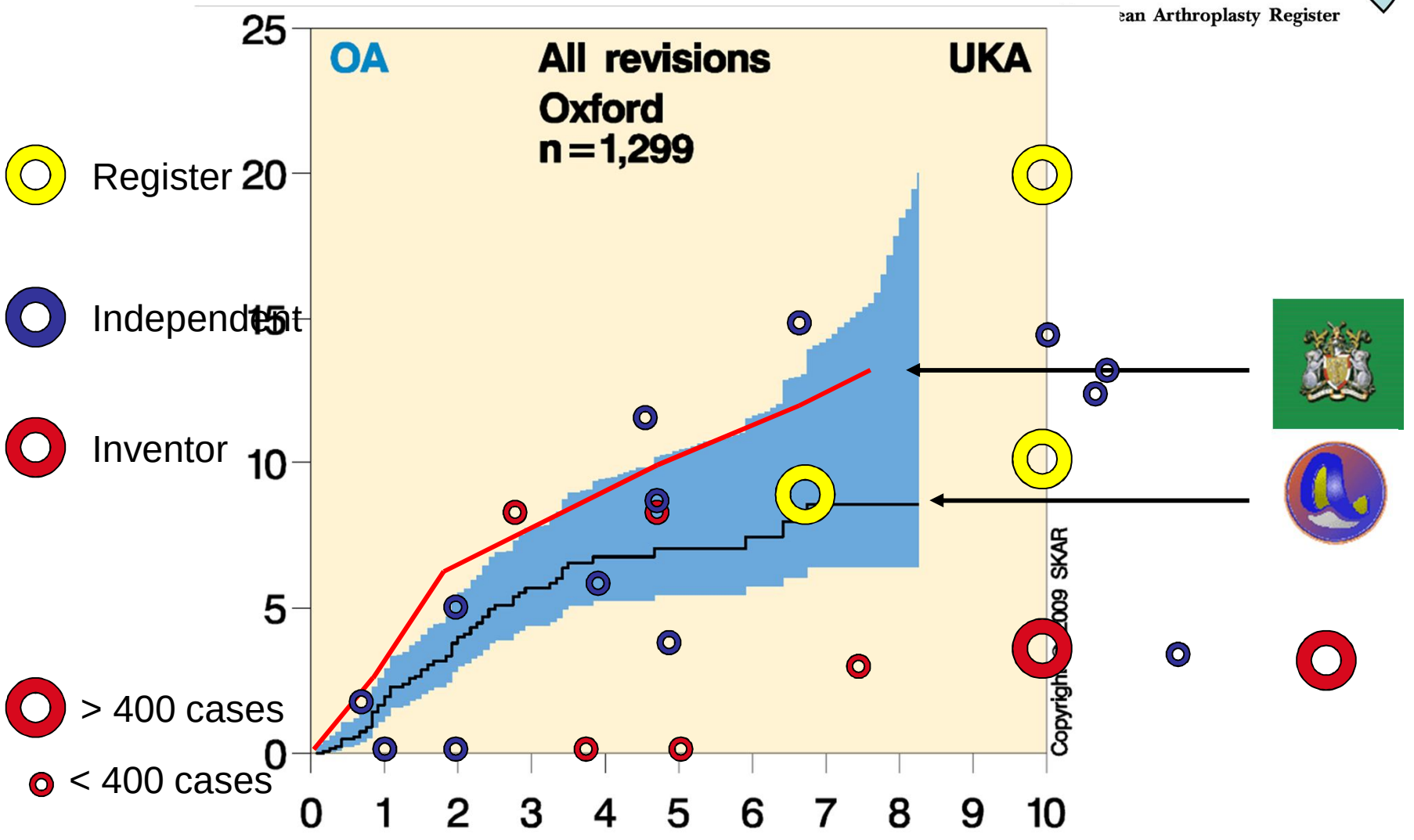
Material and Methods

- Observed component years (= years at risk):
  - Number primary operations x Follow up periode
  - If periode of time was presented: linear function
- Revisions per 100 .... => %
- Value of 1 => 1% Revision rate after 1 year, 10% Revision rate after 10 years
- Competetive Metanalyses of pooled data from clinical studies and Register datasets
- Confidence Intervals

Metaanalysis Oxford Uni

- 23 Publications included
- 20 sample based studies
  - 7 by the inventor´s group, Oxford,Nuffield
  - 13 independent publications
- 3 based on National Arthroplasty Register datasets (2x SF, 1x S)
- 3 Annual Reports (S, SF, AUS)

Metaanalysis Oxford Uni



Metanalyses Oxford Uni

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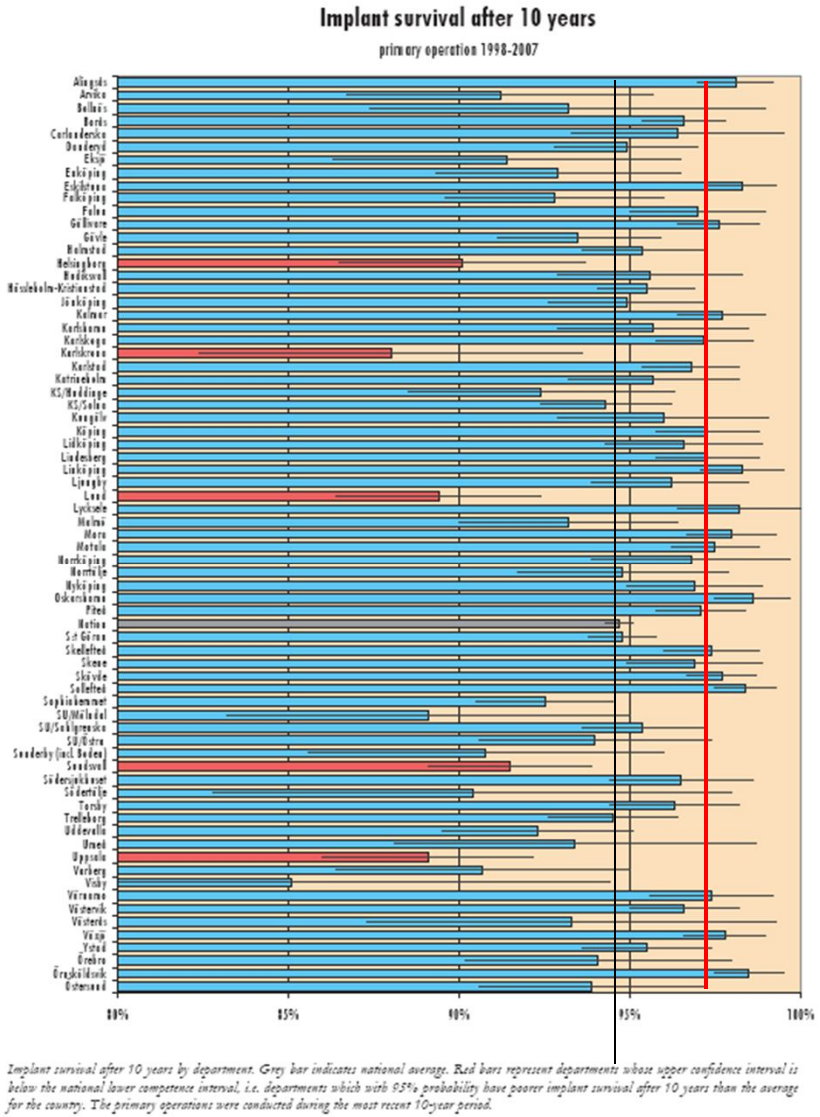
	Number	FUP	Revision Rate [%]	Number primaries	Number Revisions	Observed component years	Revisions per 100 observed component years	CI	Factor Difference to Register
Inventor studies	7	9,64	4,30	**1559**	67	15029	**0,45**	0,35-0,57	**4,40**
Independnt clinical studies	13	4,99	6,09	**1445**	88	7205	**1,22**	0,99-1,50	**1,61**
Total clinical studies	20	7,40	5,16	3004	155	22234	**0,70**	0,60-0,82	**2,82**
Register Journal publications	3	9,04	14,51	1951	283	17638	1,60	1,43-1,80	
Registers Annual Reports	3	3,51	6,88	11985	825	42037	1,96	1,83-2,10	

Difference single departments



Implant survival after 10 years by department. Grey bar indicates national average. Red bars represent departments whose upper confidence interval is below the national lower competence interval, i.e. departments which with 95% probability have poorer implant survival after 10 years than the average for the country. The primary operations were conducted during the most recent 10-year period.

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- Sweden:
  - **Best clinics differ from the average at a factor of about 2 – max. 3**

Differences countries

	S	N	SF	DK	AUS	NZ	GB
AGC	0,94	0,56	0,76	2,39	0,77	0,38	
NexGen	0,37/ 2,71				1,55	1,66	1,27
Oxford Uni	**0,86**		**1,17**		**0,97**		
Duraloc	1,04			1,02	0,86		1,14
PFC	0,91			1,44	1,03	1,02	0,88

Metanalyses Oxford Uni

EAR
European Arthroplasty Register

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Metanalyses Oxford Uni

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- 51.9% of all cases published in clinical studies coming from Oxford
- 65% of all ocy coming from the inventor´s group in Oxford
- In average these data show statistically significant and relevant differences to other datasets

Metanalyses Oxford Uni

- 4.4 times better than in Registers
  22.7 % of the Revision rate

- 2.74 times better than in independent studies
  36.5% of the revision rate

Discussion

- High impact of the developing group from Oxford on the publications of their product

- Inventors
  - High competence due to extensive research and focus on the subject
  - Implants and instrumentations are adjusted to personal preferences and environment
  - More strict follow up of patients and actions for improvement

  - Learning curve during process of development
  - Testing of borders for indications of the product

  - Economic interests

Discussion

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- Outcome published by the Oxford-Group seem not reproducable by the majority of users

- Data coming from Oxford have a certain impact on the users impression


Orthopaedicstoday
EUROPE
Surgeons look to hip tribology to provide better clinical results with THA, new bearing surfaces
Mobile bearing UKA appropriate for one-third of knee replacement patients, surgeon says

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One-third of knee replacement patients are candidates for a mobile bearing UKA, surgeon says

"At least one in three knees that require knee replacement are appropriate for a unicompartmental knee replacement," and would meet all recommended indications and contraindications for it, Murray said at the Knee Society Specialty Day Meeting during the 2010 Annual Meeting of the American Academy of Orthopaedic Surgeons, here.

"Two-thirds of our patients are not ideal and have some of these contraindications, yet there is no difference in the outcome between those who have contraindications and those who do not."

Summary

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- In the Registers used up to 10% Market share for Uni´s
- Prof. Murray recommends 33%, i.e. wider indications
- Oxford Group published in average
  - 4.4 times better revision rate than in Registers
  - 2.74 times better revision rates than other expert users
  - 5.18 times better than the outcome in the British NJR (5th AR, 8260 patients, 6,9% revision rate after 3 years)

Interpretation

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- How to match these findings???????
- Congratulation to the surgical skills of the Oxford Group????
- Is only the Oxford Group able to use the product properly???
- How useful are these data for personal decisions for average users worldwide????
- Shall we all send our patients to Oxford????

Taperloc stem

Follow up period	Number primary cases	Number revision cases	Observed component years	Revisions per 100 observed component years	CI	Factor difference author studies to indepen det studies	Faktor Difference Register
Rothman Institute							
	859	4	6315,3	0,06	0,02-0,16	5,50	10,92
Others							
	1070	32	9799,56	0,33	0,23-0,46		1,99
Total clinical studies							
	1929	36	16114,86	0,22	0,16-0,31		2,93
Register							
Taperloc/M2a (AUS)	319	11	739	1,49	0,34-1,73		0,99
Taperloc/Mallory Head (AUS)	663	14	1805	0,78	0,19-0,8		0,52
Total	982	25	2544	0,98	0,28-0,85 (adjusted)		0,66

AGC

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Data source	Follow up period	Revision Rate [%]	Primary Cases	Revision cases	Observed component years	Revisions per 100 observed component years	CI	Factor difference to Register
US	10,65	1,74	27936	485	297556,95	0,16	0,15-0,18	4,52
Europe	5,07	3,24	2527	82	12806,9	0,64	0,52-0,79	1,15
M.A. Ritter	9,45	1,68	26261	441	248258,15	0,18	0,16-0,19	4,15
Register Publications	6,56	3,33	12869	428	84374	0,51	0,46-0,56	1,45
Total Register	4,79	3,53	35284	1245	169026,5	0,74	0,70-0,78	

Zweymüller- SL - stem

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	Follow up Period	Revision rate [%]	Primary cases	Revsision cases	Observed component years	Revisions per 100 observed component years	CI	Faktor Difference Clinical studies to Register
Independent Studies (all types)	6,97	2,79	9754	272	67947,98	**0,40**	0,36-0,45	1,55
Inventor studies (all types)	6,00	4,28	654	28	3926	**0,71**	0,49-1,03	0,87
Alloclassic Clinical Literature	6,70	2,26	8576	194	57445,74	**0,34**	0,29 - 0,39	1,82
Register Australia		2,34	4620	108	11628	0,93	0,77 - 1,12	
Adjustment					Division by 1,5	**0,62**		
Register Study Norwegen	17,5	1,47	408	6	2536,2	**0,24**	0,11-0,52	1,96

Summary Literature worldwide

Citation stem	Not a single revision published	n.a.	n.a.	n.a.	
Contemporrary cup	Not a single revision published	n.a.	n.a.	n.a.	
SecurFit cup	Not a single revision published	n.a.	n.a.	n.a.	USA
Summit	Not a single revision published	n.a.	n.a.	n.a.	USA
Versys stem	Not a single revision published	n.a.	n.a.	n.a.	USA
Pinnacle cup	Not a single revision published	Nur Entwicklerpublikationen	Nur Entwicklerpublikationen	Nur Entwicklerpublikationen	USA
Vitalock cup	Not a single revision published	n.a.	n.a.	n.a.	USA
Optetrak KTEP	41,10	Not a single revision published	Yes	Yes	USA
Pappas-Büchel OSG-TEP	10,15	14,29	Yes	Yes	USA
C-stem	8,69	n.a.	n.a.	n.a.	USA
Corail stem	7,78	5,24	Yes	Yes	USA
CPT stem	7,33	n.a.	n.a.	n.a.	USA
Synergy	6,79	n.a.	n.a.	n.a.	USA
Charnley cup	5,28	n.a.	n.a.	n.a.	GB
MG Uni	4,5	5,2	Yes	No	USA
Trilogy	4,36	n.a.	n.a.	n.a.	USA
AGC	4,01	4,15	Yes	Yes	USA
Genesis II	3,86	3,70	Yes	Yes	USA
Fitmore cup	3,22	n.a.	n.a.	n.a.	EU
Accolade Trident	3,17	n.a.	n.a.	n.a.	USA
Taperloc	2,90	10,81	Yes	Yes	USA
Bicontact	2,80	2,11	No	No	EU
Oxford Uni	2,71	4,37	Yes	Yes	GB
Link Uni	2,65	11,4	Yes	Yes	EU

Summary Literature worldwide

Allofit	2,34	2,59	No	No	EU
Avon	2,18	2,17	No	No	GB
Charnley stem	2,17	n.a.	n.a.	n.a.	GB
Spotorno CLS cup	2,11	9,05	Yes	No	EU
Cormet Resurfacing	2,1	n.a.	n.a.	n.a.	EU
Definition stem	1,95	n.a.	n.a.	n.a.	
Hintegra	1,94	1,94	No	n.a.	EU
Alloclassic	1,84	0,87	No	No	EU
Durom Resurfacing	1,71	n.a.	n.a.	n.a.	USA
STAR	1,56	4,63	Yes	No	EU
Harris-Galante-Pfanne	1,53	2,22	No	No	USA
ABG I cup	1,50	n.a.	n.a.	n.a.	EU
LCS	1,46	1,17	No	No	USA
NexGen	1,45	n.a.	n.a.	n.a.	USA
Conserve Plus	1,43	1,47	No	No	USA
Profix	1,39	n.a.	n.a.	n.a.	USA
BHR	1,33	4,33	Yes	No	GB
Triathlon TKA	1,29	n.a.	n.a.	n.a.	USA
PFC Uni	1,26	n.a.	n.a.	n.a.	USA
AML cementless stem	1,22	4,74	Yes	No	USA

Summary Literature worldwide

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Duraloc	1,21	n.a.	n.a.	n.a.	USA
Romanus cup	1,15	n.a.	n.a.	n.a.	
Natural Knee	1,12	1,07	No	No	USA
ASR	1,06	n.a.	n.a.	n.a.	USA
Agility	1,02	2,43	No	No	USA
SPII	0,99	n.a.	n.a.	n.a.	EU
Spotorno	0,98	1,84	No	No	EU
Eius Uni	0,89	n.a.	n.a.	n.a.	USA
Kinemax TKA	0,83	n.a.	n.a.	n.a.	USA
PFC	0,70	0,64	No	No	USA
Müller Schaft zem	0,70	0,59	No	No	EU
RM cup	0,62	n.a.	n.a.	n.a.	EU
Lubinus-cup	0,58	n.a.	n.a.	n.a.	EU
ABG Stem	0,27	n.a.	n.a.	n.a.	EU
Durom THA	0,25	n.a.	n.a.	n.a.	USA

Literature USA

Implant	Factor Difference Outcome in Registers and comprehensive publications in peer reviewed journals	Factor Difference Inventor Outcome and Register outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment
SecurFit cup	Not a single revision published	n.a.	n.a.	n.a.
Summit	Not a single revision published	n.a.	n.a.	n.a.
Versys stem	Not a single revision published	n.a.	n.a.	n.a.
Pinnacle cup	Not a single revision published	Nur Entwicklerpublikationen	Nur Entwicklerpublikationen	Nur Entwicklerpublikationen
Vitalock cup	Not a single revision published	n.a.	n.a.	n.a.
Citation stem	Not a single revision published	n.a.	n.a.	n.a.
Contemporary cup	Not a single revision published	n.a.	n.a.	n.a.
Optetrak KTEP	41,10	Not a single revision published	Yes	Yes
Pappas-Büchel OSG-TEP	10,15	14,29	Yes	Yes
C-stem	8,69	n.a.	n.a.	n.a.
Corail stem	7,78	5,24	Yes	Yes
CPT stem	7,33	n.a.	n.a.	n.a.
Synergy	6,79	n.a.	n.a.	n.a.
MG Uni	4,5	5,2	Yes	No
Trilogy	4,36	n.a.	n.a.	n.a.
AGC	4,01	4,15	Yes	Yes
Genesis II	3,86	3,70	Yes	Yes
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Literature USA

Taperloc	2,90	10,81	Yes	Yes
Durom Resurfacing	1,71	n.a.	n.a.	n.a.
Harris-Galante-Pfanne	1,53	2,22	No	No
LCS	1,46	1,17	No	No
NexGen	1,45	n.a.	n.a.	n.a.
Conserve Plus	1,43	1,47	No	No
Profix	1,39	n.a.	n.a.	n.a.
Triathlon TKA	1,29	n.a.	n.a.	n.a.
PFC Uni	1,26	n.a.	n.a.	n.a.
AML cementless stem	1,22	4,74	Yes	No
Duraloc	1,21	n.a.	n.a.	n.a.
Natural Knee	1,12	1,07	No	No
ASR	1,06	n.a.	n.a.	n.a.
Agility	1,02	2,43	No	No
Eius Uni	0,89	n.a.	n.a.	n.a.
Kinemax TKA	0,83	n.a.	n.a.	n.a.
PFC	0,70	0,64	No	No
Durom THA	0,25	n.a.	n.a.	n.a.

18 Implants too positive, 1 too negative, 2 Inventor Bias

= 58,6% not reproducable

Literature GB

EAR
European Arthroplasty Register

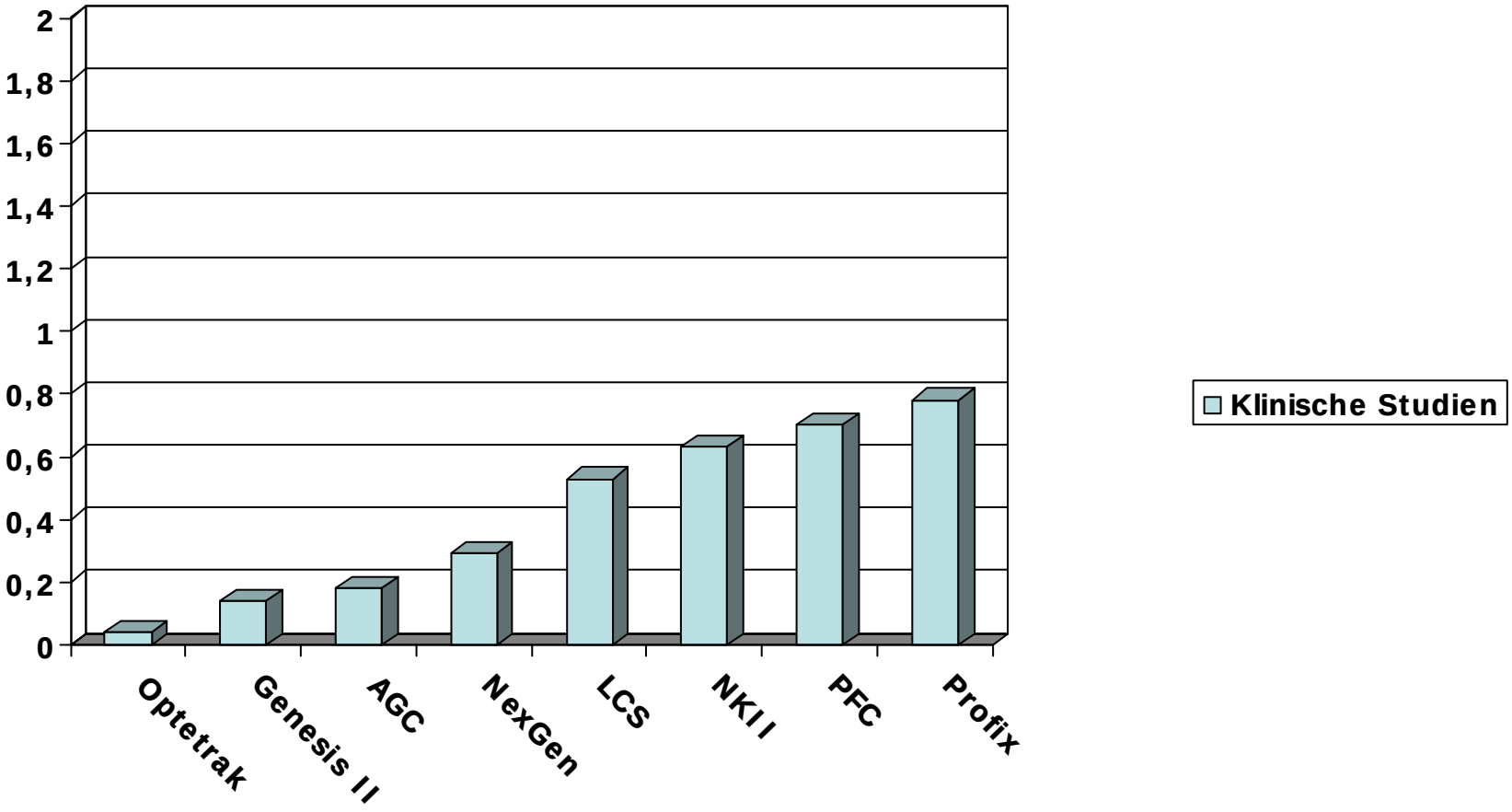
Implant	Factor Difference Outcome in Registers and comprehensive publications in peer reviewed journals	Factor Difference Inventor Outcome and Register outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment
Charnley cup	5,28	n.a.	n.a.	n.a.
Oxford Uni	2,71	4,37	Yes	Yes
Avon	2,18	2,17	No	No
Charnley stem	2,17	n.a.	n.a.	n.a.
BHR	1,33	4,33	Yes	No

Literature Continental Europe

Implant	Factor Difference Outcome in Registers and comprehensive publications in peer reviewed journals	Factor Difference Inventor Outcome and Register outcome	Inventor Bias	Inventor Bias leading to Bias in aggregated Assessment
Fitmore cup	3,22	n.a.	n.a.	n.a.
Bicontact	2,80	2,11	No	No
Link Uni	2,65	11,4	Yes	Yes
Allofit	2,34	2,59	No	No
Spotorno CLS cup	2,11	9,05	Yes	No
Cormet Resurfacing	2,1	n.a.	n.a.	n.a.
Hintegra	1,94	1,94	No	n.a.
Alloclassic	1,84	0,87	No	No
STAR	1,56	4,63	Yes	Yes
ABG I cup	1,50	n.a.	n.a.	n.a.
SPII	0,99	n.a.	n.a.	n.a.
Spotorno	0,98	1,84	No	No
Müller Schaft zem	0,70	0,59	No	No
RM cup	0,62	n.a.	n.a.	n.a.
Lubinus-cup	0,58	n.a.	n.a.	n.a.
ABG Stem	0,27	n.a.	n.a.	n.a.

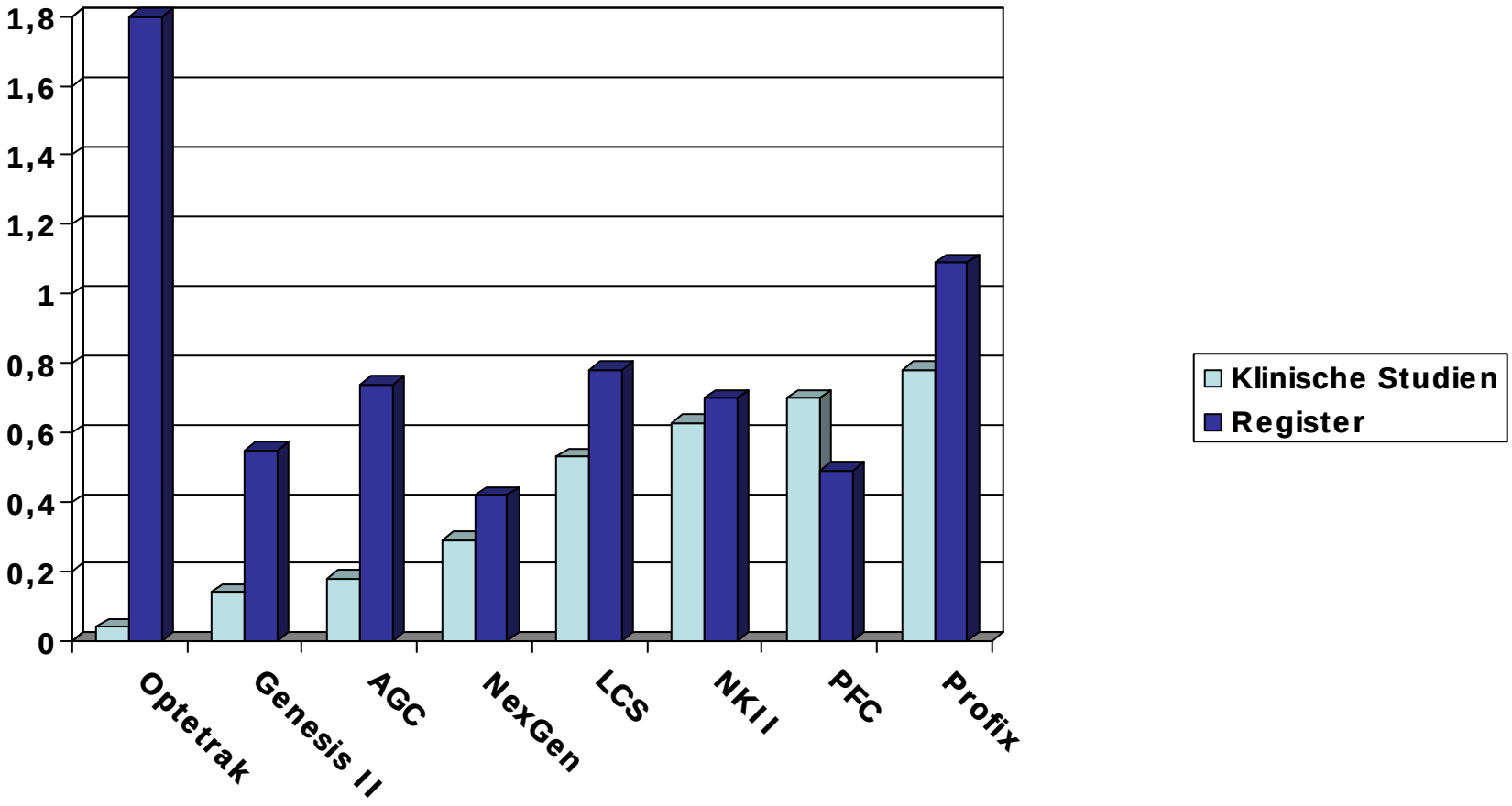
Impact on daily decisions

E A R
European Arthroplasty Register



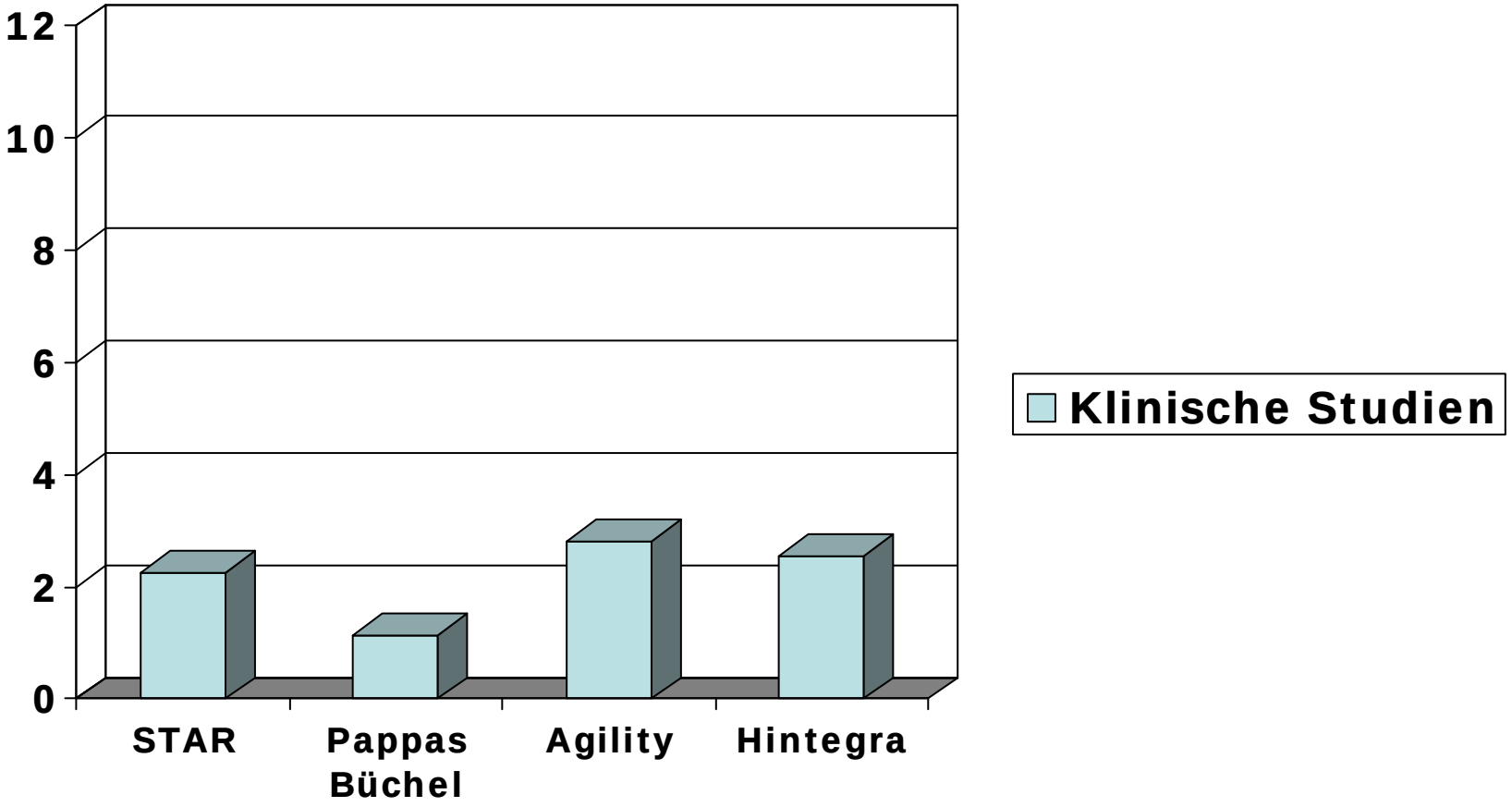
Impact on daily decisions

EAR
European Arthroplasty Register



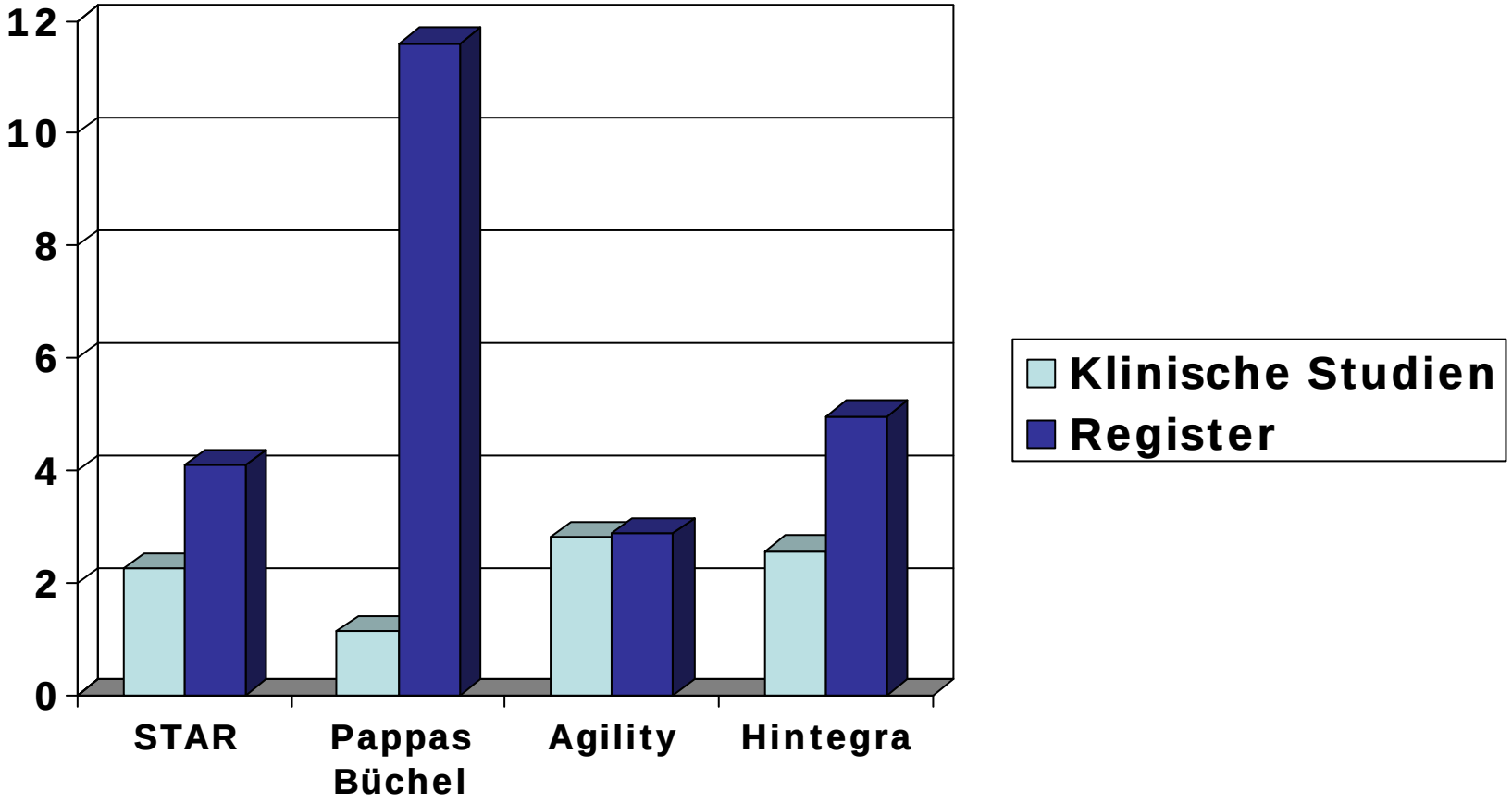
Impact on daily decisions

E A R
European Arthroplasty Register



Impact on daily decisions

EAR
European Arthroplasty Register



Literature Inventor

Optetrak TKA	Not a single revision published	Yes	Yes	USA
Pappas-Büchel TAA	14,29	Yes	Yes	USA
Taperloc stem	10,81	Yes	Yes	USA
Spotorno CLS cup	9,05	Yes	No	EU
AML cementless stem	4,74	Yes	No	USA
STAR TAA	4,63	Yes	Yes	EU
Oxford Uni	4,37	Yes	Yes	GB
BHR Resurfacing	4,33	Yes	No	GB
AGC TKA	4,15	Yes	Yes	USA
Genesis II TKA	3,70	Yes	Yes	US, Can
Agility TAA	2,43	No	No	USA
Harris-Galante cup	2,22	No	No	US
Avon retropatellar KA	2,17	No	No	GB
Bicontact stem	2,11	No	No	EU
Hintegra TAA	1,94	No	No	EU
Spotorno stem	1,84	No	No	EU
Conserve Plus Resurfacing	1,47	No	No	USA
LCS TKA	1,17	No	No	USA
Natural Knee TKA	1,07	No	No	USA
Alloclassic stem	0,87	No	No	EU
PFC TKA	0,64	No	No	USA
Müller stem cem.	0,59	No	No	EU

Inventor USA

Implant	Factor Difference Outcome in Registers and comprehensive publications in peer reviewed journals	Factor Difference Inventor Outcome and Register outcome	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Pinnacle cup	Not a single revision published	Only Inventorpublications	Only Inventorpublications	Only Inventorpublications
Optetrak KTEP	41,10	Not a single revision published	Yes	Yes
Pappas-Büchel OSG-TEP	10,15	14,29	Yes	Yes
Taperloc	2,90	10,81	Yes	Yes
Corail stem	7,78	5,24	Yes	Yes
MG Uni	4,5	5,2	Yes	No
AML cementless stem	1,22	4,74	Yes	No
AGC	4,01	4,15	Yes	Yes
Genesis II	3,86	3,70	Yes	Yes
Agility	1,02	2,43	No	No
Harris-Galante-Pfanne	1,53	2,22	No	No
Conserve Plus	1,43	1,47	No	No
LCS	1,46	1,17	No	No
Natural Knee	1,12	1,07	No	No
PFC	0,70	0,64	No	No

- 9 out of 15 not reproducible (=60%)

Inventor GB

EAR
European Arthroplasty Register

Implant	Factor Difference Outcome in Registers and comprehensive publications in peer reviewed journals	Factor Difference Inventor Outcome and Register outcome	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Oxford Uni	2,71	4,37	Yes	GB
Avon	2,18	2,17	No	GB
BHR	1,33	4,33	No	GB

Inventor Continental Europe

EAR
European Arthroplasty Register

Implant	Factor Difference Outcome in Registers and comprehensive publications in peer reviewed journals	Factor Difference Inventor Outcome and Register outcome	Inventor Bias leading to Bias in aggregated Assessment	Region of Origin
Link Uni	2,65	11,4	Yes	Yes
Spotorno CLS cup	2,11	9,05	Yes	No
STAR	1,56	4,63	Yes	Yes
Allofit	2,34	2,59	No	No
Bicontact	2,80	2,11	No	No
Hintegra	1,94	1,94	No	n.a.
Spotorno	0,98	1,84	No	No
Alloclassic	1,84	0,87	No	No
Müller Schaft zem	0,70	0,59	No	No

Impact Inventor USA

EAR
European Arthroplasty Register

Implantat	Nachuntersuchungszeit	Fallzahl Primär gesamt	Fallzahlen Revision gesamt	Observed component years	Revisions per 100 observed component years	Entwickler Faktor Differenz unabh. klin. Studie	Entwickler Faktor Differenz Register	Alle Studien Faktor Differenz Register	% Primärfälle durch Entwickler	% Revisionsfälle durch Entwickler	% observed component years durch Entwickler
Optetrak KTEP	5,10	448	1	2283,50	0,04	evisions by Deve	visions by Dev	41,10	74,78	0,00	81,43
Pinnacle cup	5,90	42	0	247,80	0,00	y one designer st	Revision publis	evision publi	100,00	n.a.	100,00
Pappas-Büchel OSG-TEP	6,10	517	36	3152,60	1,14	1,92	14,29	10,15	57,25	41,67	58,63
Taperloc	8,35	1929	36	16114,86	0,22	5,50	10,81	2,90	44,53	11,11	39,19
Corail stem	11,72	214	2	2507,50	0,08	5,24	5,24	7,78	68,69	100,00	67,42
AML cementless stem	10,39	577	23	5992,17	0,38	9,92	4,74	1,22	62,43	17,39	67,61
AGC	8,67	30596	571	310872,85	0,18	2,38	4,15	4,01	85,83	77,23	79,86
Genesis II	6,34	15049	136	95433,36	0,14	1,15	3,70	3,86	47,51	47,79	45,89
Agility	4,28	682	82	2917,33	2,81	4,03	2,43	1,02	31,96	23,17	54,87
Harris-Galante-Pfanne	9,31	7352	393	68481,41	0,57	1,60	2,22	1,53	31,46	16,79	24,37
Conserve Plus	5,00	2023	140	10134,00	1,40	1,42	1,47	1,43	96,24	95,82	96,95
LCS	11,43	14196	863,00	162271,22	0,53	0,79	1,17	1,46	5,67	6,95	5,56
MG Uni	8,10	449	29	3639,00	0,80	5,20	1,16	1,44	27,17	6,90	24,98
Natural Knee	7,16	1514	68	10847,70	0,63		1,12	1,12	91,88	100,00	97,17
PFC	6,13	14363	617	88090	0,70	0,92	0,64	0,70	7,21	4,38	4,03

Impact Inventor USA

EAR
European Arthroplasty Register

- 60% of Implants show significant and relevant too positive outcome
- Outlier Implants have predominantly inventor groups, which have a dominating position in publications concerning their implants
- Frequently few cases

- Exeptions
  - Spezial implants (Resurfacing hips, Ankle Arthroplasty)
- Well reproducible Outcome:
  - <25% proportion of inventors of the total numbers published

Impact Inventors Europe

EAR
European Arthroplasty Register

Implantat	Nachuntersuchungszeit	Fallzahl Primär gesamt	Fallzahlen Revision gesamt	Observed component years	Revisions per 100 observed component years	Entwickler Faktor Differenz Register	Alle Studien Faktor Differenz Register	% Primärfälle durch Entwickler	% Revisionsfälle durch Entwickler	% observed component years durch Entwickler
Link Uni	14,29	3276	171	46823,70	0,37	11,40	2,65	39,50	12,87	55,27
Spotorno CLS cup	8,19	3833	90	31387,80	0,29	9,05	2,11	7,80	1,11	4,76
STAR	4,60	1233	149	5676,61	2,62	4,63	1,56	14,92	6,04	17,94
Allofit	5,30	467	5	2473,24	0,20	2,59	2,34	17,56	40,00	33,49
Bicontact	8,54	1264	17	10790	0,16	2,11	2,80	43,20	88,24	66,49
Hintegra	2,42	403	25	975,90	2,56	1,94	1,94	100,00	100,00	100,00
Spotorno	5,24	9233	133	48361,53	0,28	1,84	0,98	3,25	2,26	4,24
Alloclassic	6,70	8576	194	57445,74	0,34	0,87	1,84	7,63	14,43	6,83
Müller Schaft zem	6,92	6551	266	45315,50	0,59	0,59	0,70	1,88	3,01	2,55

Impact Inventors Europe

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- In general well reproducible outcome

- Link Uni: 1 publications by Nieder from 1991 in a German Journal (Orthopäde)
- Sportorno: 1 small study (5% ocy)
- Outlier STAR (Kofoed)
- Reproducible results even in cases when the inventor dominates publications

Subanalysis Literature Regions

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- USA:
  - All Implants:
  - 51,3% of all primary cases by the inventor
  - 49,2% of all observed component years
  - Implants with Inventors:
  - 58,8% of all primary cases by the inventor
  - 52,5 of all observed component years (i.e. shorter FUP than average)

Subanalysis Literature Regions

- Contiental Europe:
  - All Implants :
  - 10,2% of all primary cases by the inventor
  - 15,9% of all observed component years
  - Implants with Inventors :
  - 13,8% of all primary cases by the inventor
  - 20,6 of all observed component years (i.e. longer FUP than average)

Number cases/implant published

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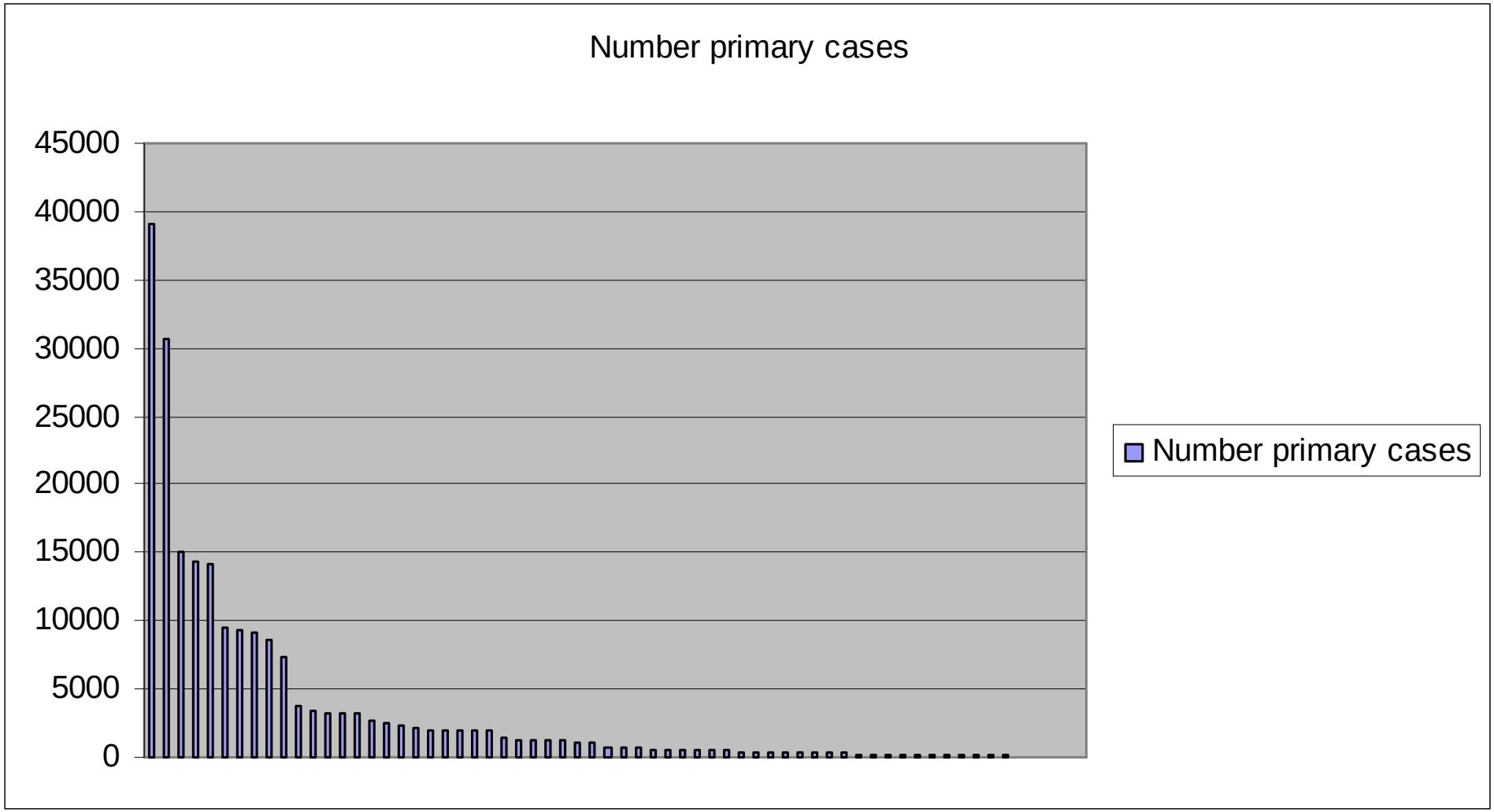
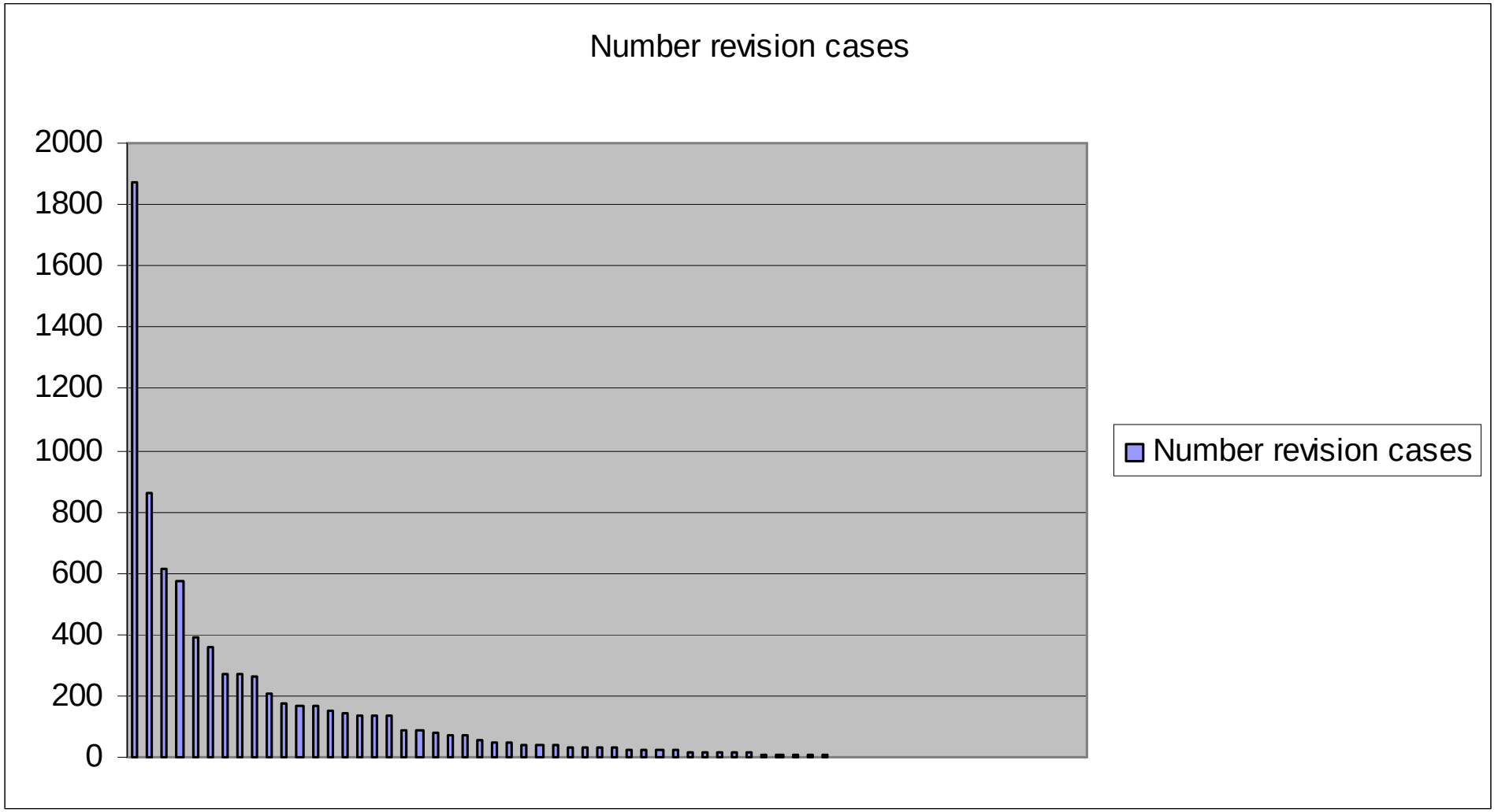


Number cases/implant published

EAR
European Arthroplasty Register



Summary number cases published

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- 18 of 82 Implant systems (=22%) have published > 100 revisions (for any reason)
- 1/3 of them not reproducible results
- => 15% sufficiant and correct
- Registers: 44,6% > 100 Revisions

Charnley-stem
LCS TKA
PFC TKA
AGC TKA
Harris-Galante cup
ABG stem
Alloclassic stem
Bi-metric
Müller stem
ABG I cup
Oxford Uni
Link Uni
RM-cup
STAR TAA
Conserve Plus
Genesis II TKA
Spotorno stem
Kinemax TKA

Summary number cases published

EAR
European Arthroplasty Register

USA	LCS TKA
	PFC TKA
	AGC TKA
	Harris-Galante cup
	Conserve Plus
	Genesis II TKA
	Kinemax TKA
Europa	Charnley-stem
	ABG stem
	Alloclassic stem
	Bi-metric
	Müller stem
	ABG I cup
	Oxford Uni
	Link Uni
	RM-cup
	STAR TAA
	Spotorno stem

Summary and Discussion

- More than 50% of peer reviewed published datasets show results, which are statistically significant and relevant not reproducible in average patient care.

- Problems mainly at
  - Implant developers
  - Publications from USA

- In the USA also independent literature affected in relevant amount

Summary and Discussion

- Significant differences between USA and Europe

- USA (journals, Congresses, Current concept, guidelines,..) dominated by implant inventors, pressure groups and special interest groups
- Lack of independent reference data => difficult to identify inplausible outcome

- In Europe such reference data are available
- Research groups/persons with questionable published outcome (McMinn, Oxford) can be identified by a critical assessment even in a regular metanalysis

Summary and Discussion

- Even large number of published cases is no guarantee for valid data
- System in research and data handling?
  - Special interests?
  - Influence of stakeholders
    - Manufacturers
    - Marketing for persons and clinics?
  - USA: legal issues?

Summary and Discussion

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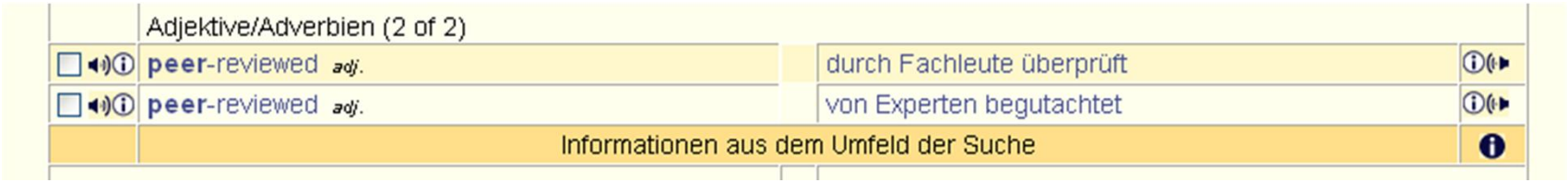
- Basic Aim of Research:
  - Independent exchange of knowledge for improvement of patient care
  - Peer review:



	Adjektive/Adverbien (2 of 2)	
	peer-reviewed *adj.*	durch Fachleute überprüft
	peer-reviewed *adj.*	von Experten begutachtet
	Informationen aus dem Umfeld der Suche	

  - independent?
  - particular interests?
  - legal interests? (guidelines)

Summary

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- Outcome published in clinical studies are frequently not reprodubibla in avarege patient care
- Careful assessment
- Register data are more reliable
- The best quality of information is from the own Register
  - reflects the own circumstances
  - most relevant benchmarks

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European Arthroplasty Register

European Federation of National Associations of Orthopedics and Traumatology
EFORT

Final Report EFORT-Congress 2011 Copenhagen