EAR
European Arthroplasty Register

The European Arthroplasty Registers and National Arthroplasty Registers

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Medical University Innsbruck
Austria

ORTHOPAEDICS
UNIVERSITY OF INNSBRUCK

Register Development

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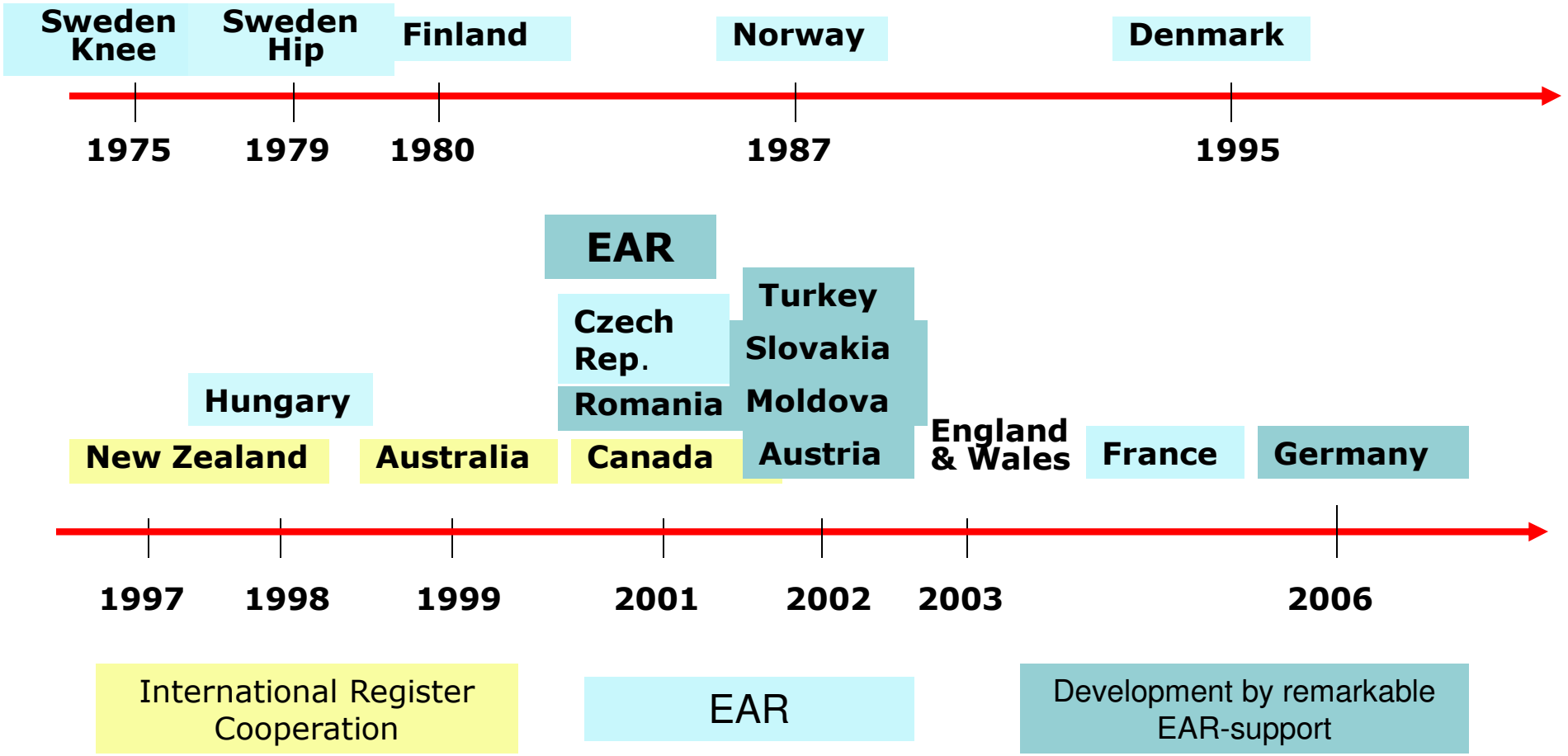
European Arthroplasty Register



Register Development

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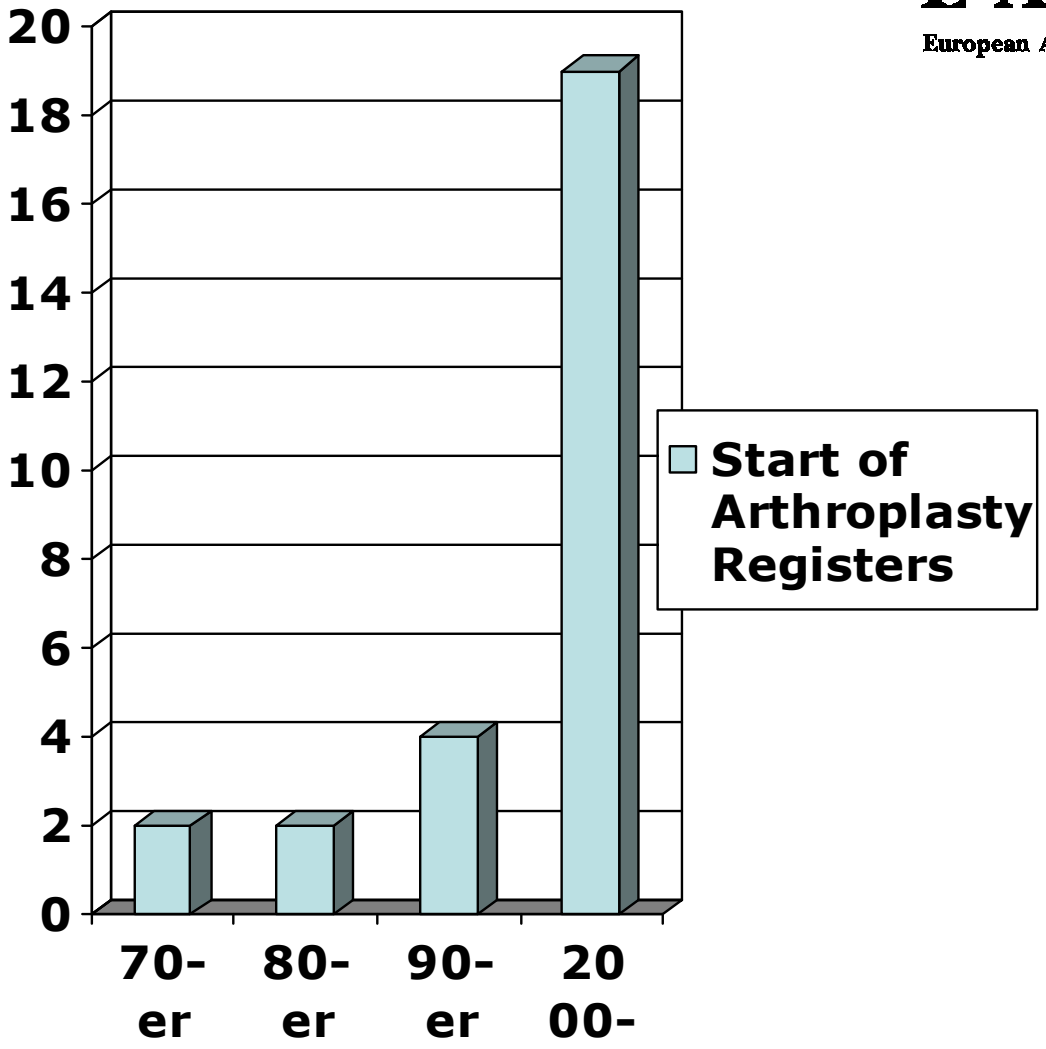
European Arthroplasty Register



Register activities in Europe

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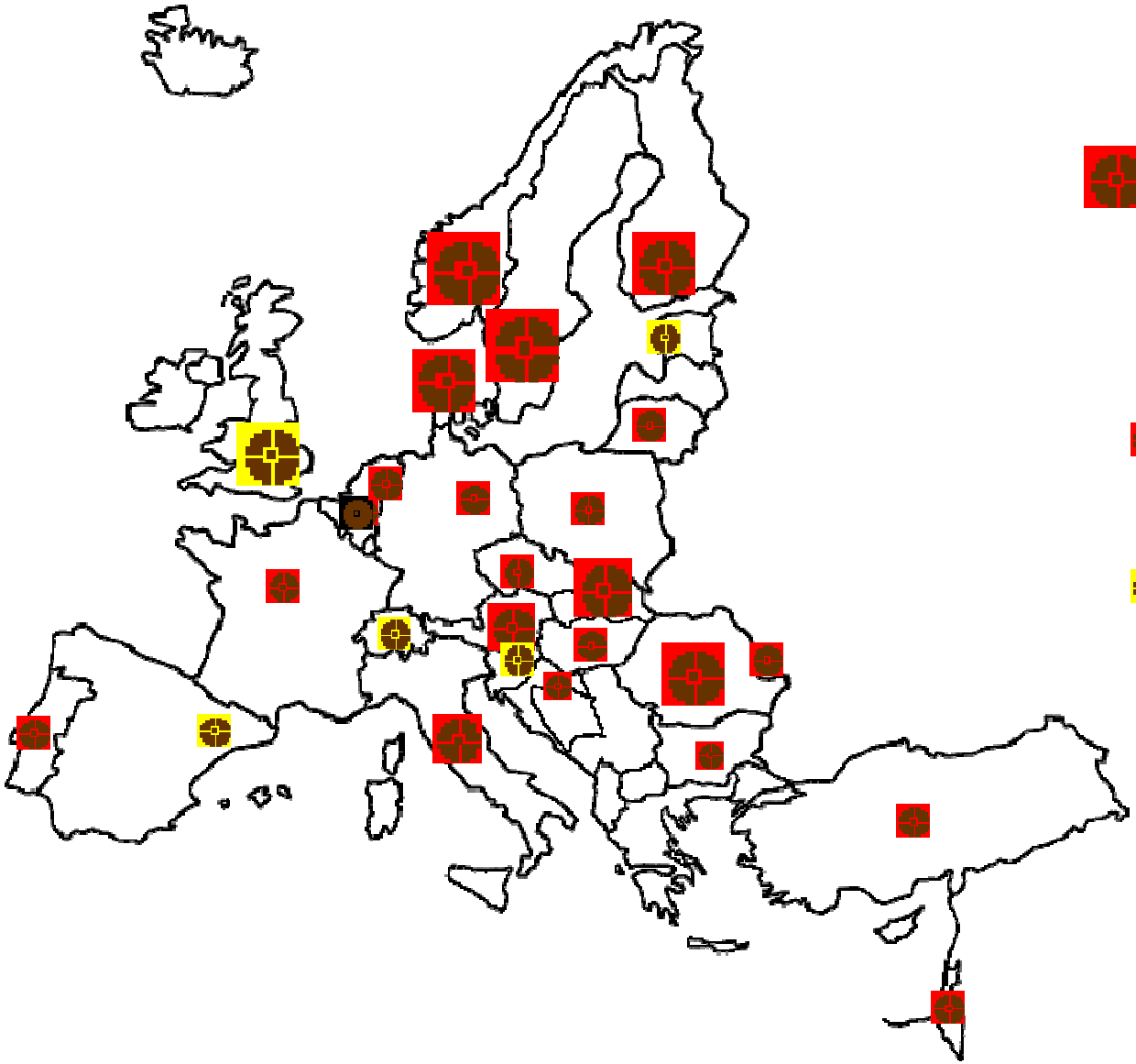

Annual Reports available

EAR Members

Projects and Negotiations

Initiatives

Arthroplasty Registers.....

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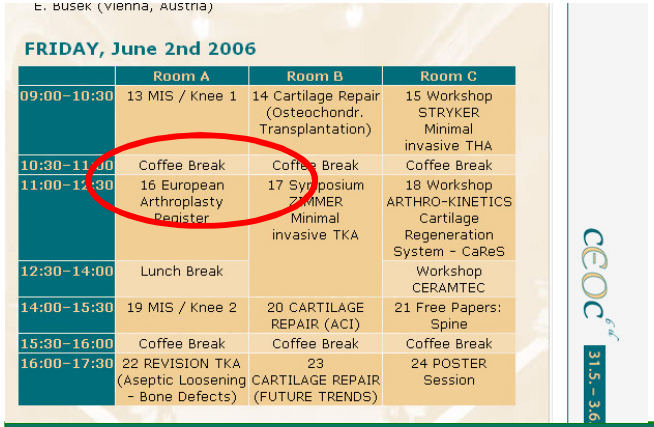
- Are successful and recognised data sources in science and literature
- Successful in Scandinavia
- no general definition of „Register“


E. Busek (Vienna, Austria)

FRIDAY, June 2nd 2006

	Room A	Room B	Room C
09:00–10:30	13 MIS / Knee 1	14 Cartilage Repair (Osteochondr. Transplantation)	15 Workshop STRYKER Minimal invasive THA
10:30–11:00	Coffee Break	Coffee Break	Coffee Break
11:00–12:30	16 European Arthroplasty Register	17 Symposium ZIMMER Minimal invasive TKA	18 Workshop ARTHRO-KINETICS Cartilage Regeneration System - CaReS
12:30–14:00	Lunch Break		Workshop CERAMTEC
14:00–15:30	19 MIS / Knee 2	20 CARTILAGE REPAIR (ACI)	21 Free Papers: Spine
15:30–16:00	Coffee Break	Coffee Break	Coffee Break
16:00–17:30	22 REVISION TKA (Aseptic Loosening - Bone Defects)	23 CARTILAGE REPAIR (FUTURE TRENDS)	24 POSTER Session

Definition of Arthroplasty Registers (EFORT-EAR)

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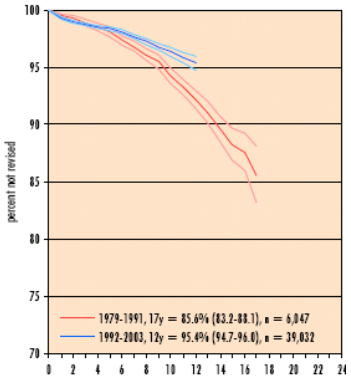
- Registration of ALL primary and revision operations in a country in a central database
- Follow the Patient/Implant until it has to be revised or the patient dies or emigrates
- Definition of Revision (= Failure):
  At least a part of the implant has to be revised
- Focus on survival rate in the reports



Why to start an Arthoplasty Register?

Christiansen hip-prosthesis

69% survival after 6 years
Sudmann et al 1983

More than 10.000 prosthesis used in Scandinavia before the difference between Charnley and Christiansen prosthesis in single hospitals could be shown

Impact of Registers

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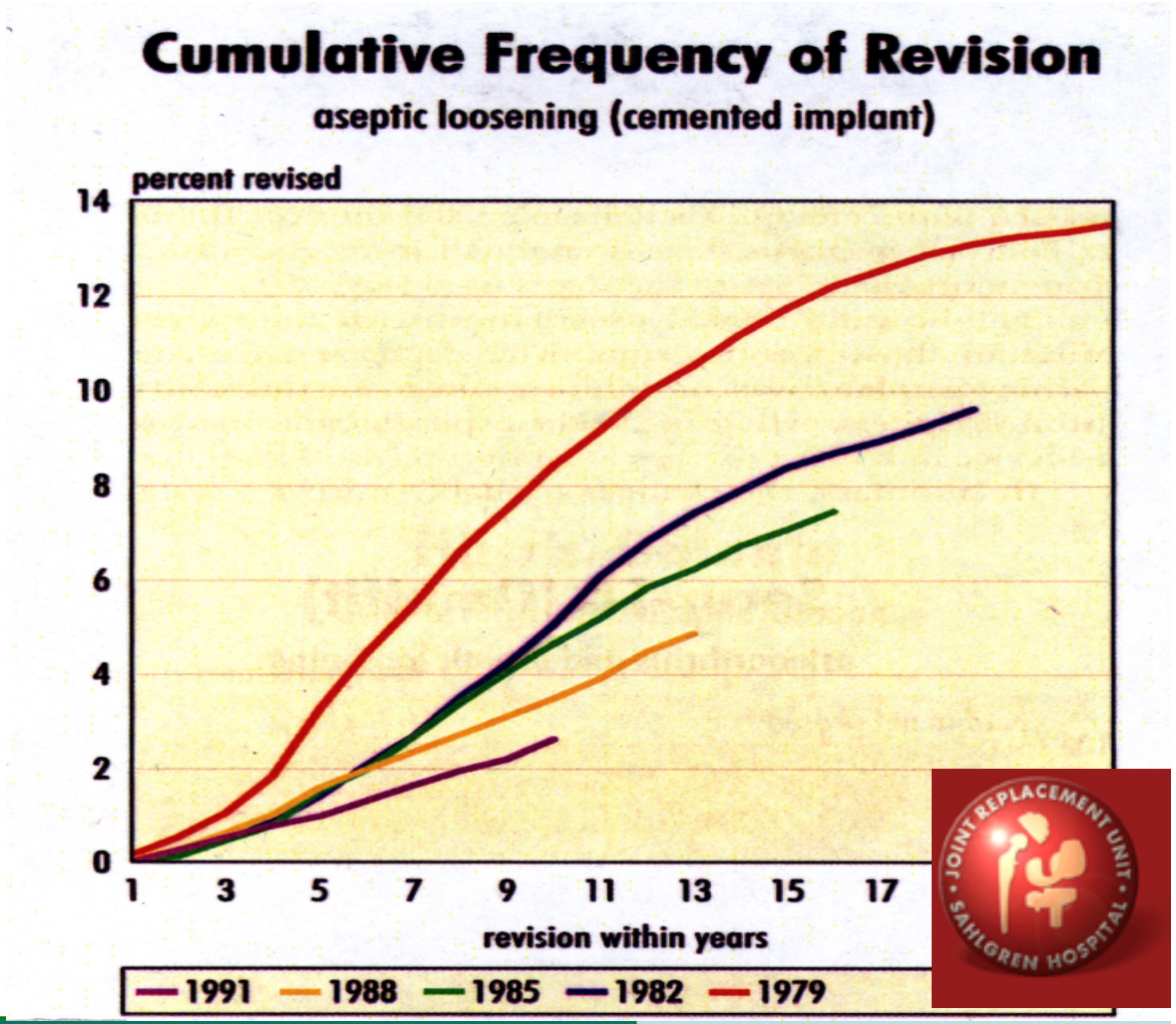
Revision burden

- Sweden:
  - 1979: 18%
  - 2006: 7,7%
- USA (AAOS)
  - Revision burden: 1992-2002: 17,5%



Impact of Registers

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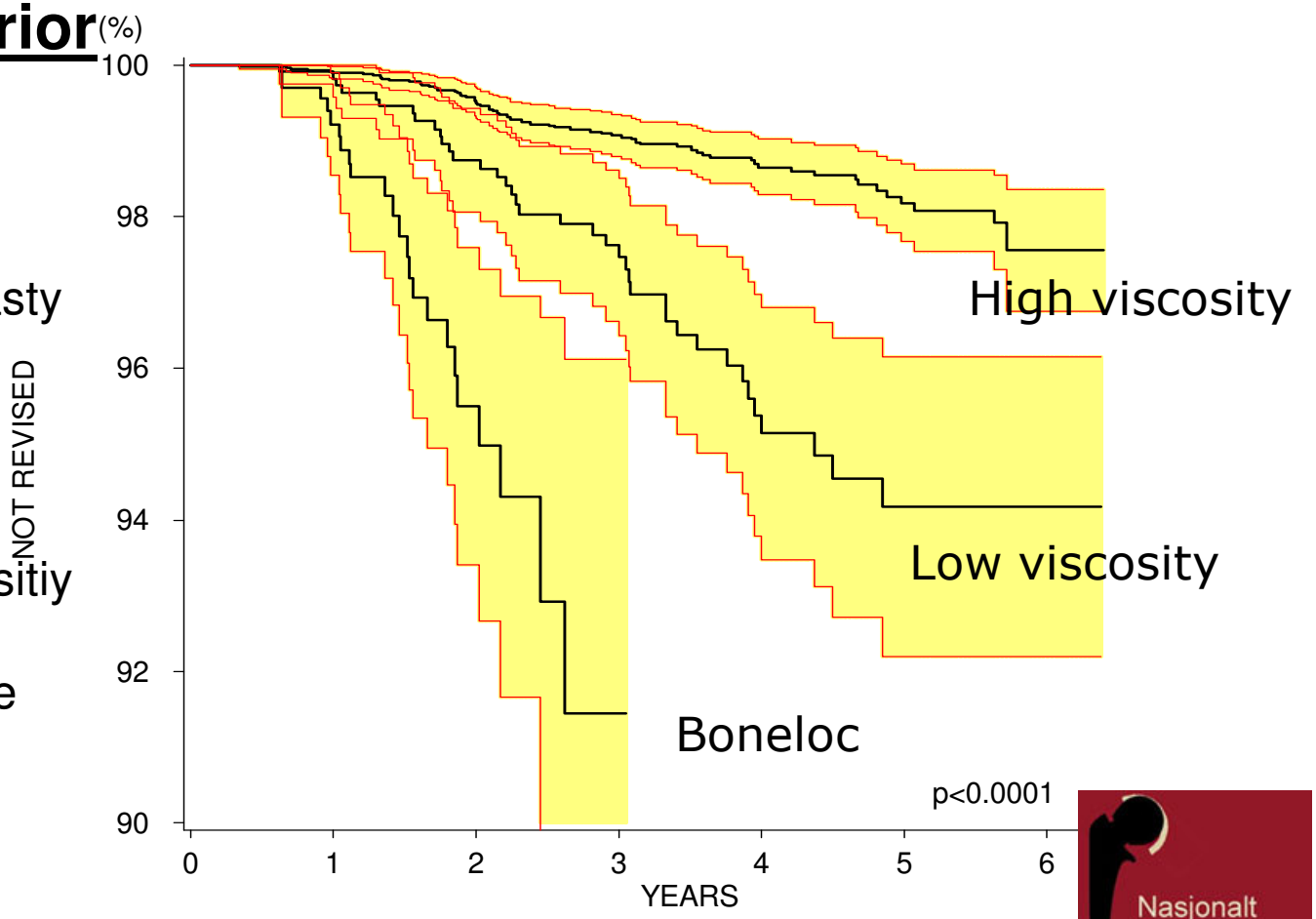
Detection of inferior products

Bone-Cement:
Norwegian Arthroplasty Register

Boneloc and Low Viscositiy Cement brands disappeared from the market



Nasjonalt Register for Leddproteser

Impact of Registers

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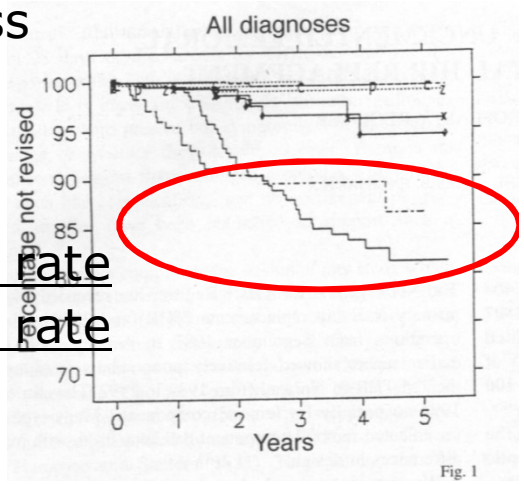
- **<u>Early detection major implant failure:</u>**

- Norway:
  Data from 1987 – 1993
  - 24.408 Implants, 2907 (13%) of them cementless
  - 8 different systems with > 100 Operations / Year
  - 4,5 Years FUP

  - Bio-Fit-stem: <u>n=210; 18,6% Revision rate</u>
  - Femora-stem: <u>n=173; 13,6% Revision rate</u>
  - PM-stem: 5,6% Revision rate
  - Harris-Galante: 3,6% Revision rate
  - Die 4 best performing stems <1% Revision rate



Early aseptic loosening of uncemented femoral components in primary total hip replacement
A review based on the Norwegian Arthroplasty Register
Havelin, Espehaug, Volleat, Engeseter, JBJS Br 1995, Jan 77(1): 11-17

Nasjonalt Register for Leddproteser

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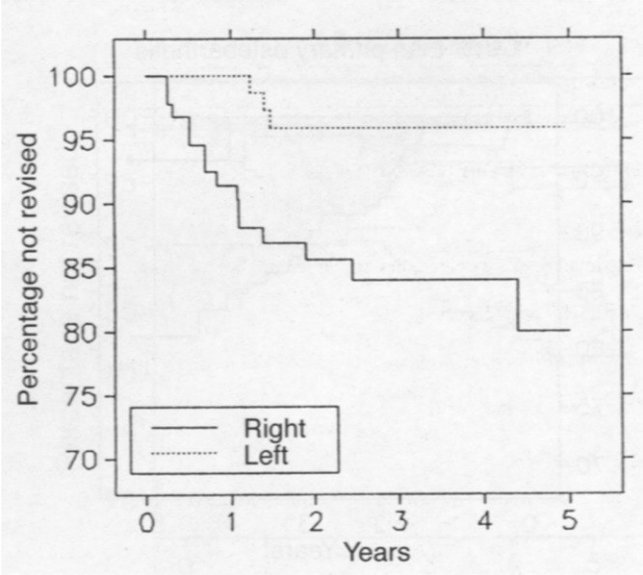
- Rough estimation for reason of failure



Femora-stem Right-Left

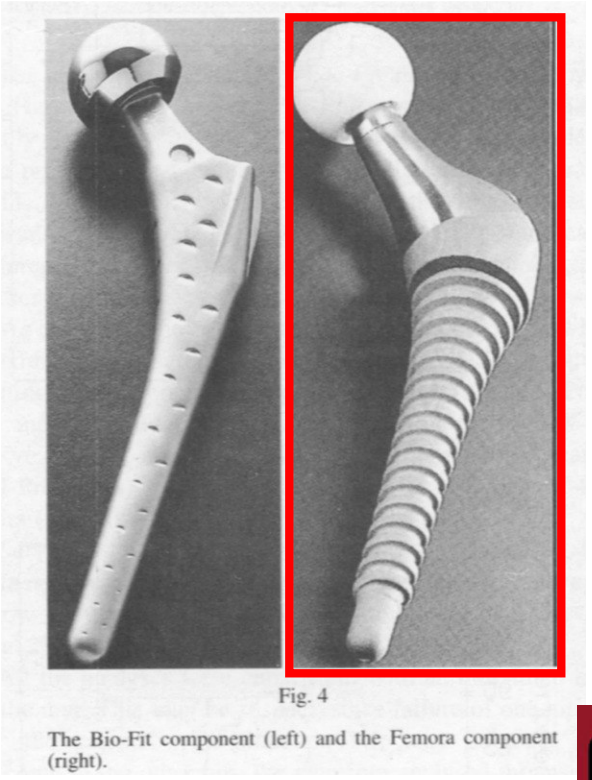


Fig. 4

The Bio-Fit component (left) and the Femora component (right).

Nasjonalt Register for Leddproteser

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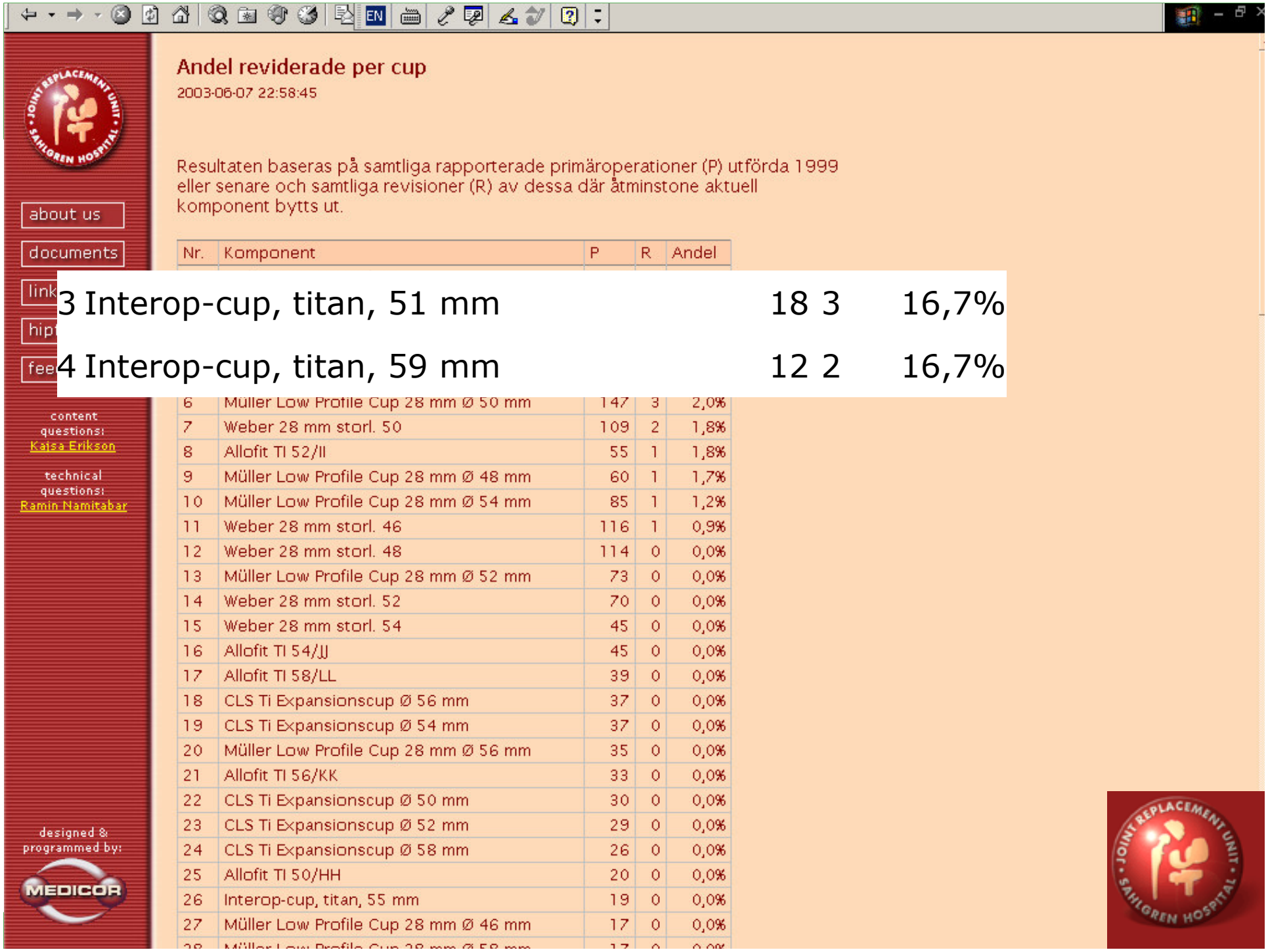
Early detection major implant failure (production process):

- Example: Inter-OP-Cup event in the USA (Sulzer)

  2000: Recall due to Lubricant residues on the surface
  => decreased Osteointegration
  17.000 implants sold; exspected revisions about 4000
  725 Mio $ for reparation by the manufacturer

  A small number of implants were sold in Europe (sweden); after 30 primary implants and 5 revisions after 1,5 years => statistically significant results



about us
documents
link
hip
fee
content questions: Kajsa Erikson
technical questions: Ramin Namitabar
designed & programmed by: MEDICOR

Andel reviderade per cup

2003-06-07 22:58:45

Resultaten baseras på samtliga rapporterade primäroperationer (P) utförda 1999 eller senare och samtliga revisioner (R) av dessa där åtminstone aktuell komponent bytts ut.

Nr.	Komponent	P	R	Andel
3	Interop-cup, titan, 51 mm	18	3	16,7%
4	Interop-cup, titan, 59 mm	12	2	16,7%
6	Müller Low Profile Cup 28 mm Ø 50 mm	147	3	2,0%
7	Weber 28 mm storl. 50	109	2	1,8%
8	Allofit TI 52/II	55	1	1,8%
9	Müller Low Profile Cup 28 mm Ø 48 mm	60	1	1,7%
10	Müller Low Profile Cup 28 mm Ø 54 mm	85	1	1,2%
11	Weber 28 mm storl. 46	116	1	0,9%
12	Weber 28 mm storl. 48	114	0	0,0%
13	Müller Low Profile Cup 28 mm Ø 52 mm	73	0	0,0%
14	Weber 28 mm storl. 52	70	0	0,0%
15	Weber 28 mm storl. 54	45	0	0,0%
16	Allofit TI 54/JJ	45	0	0,0%
17	Allofit TI 58/LL	39	0	0,0%
18	CLS Ti Expansionscup Ø 56 mm	37	0	0,0%
19	CLS Ti Expansionscup Ø 54 mm	37	0	0,0%
20	Müller Low Profile Cup 28 mm Ø 56 mm	35	0	0,0%
21	Allofit TI 56/KK	33	0	0,0%
22	CLS Ti Expansionscup Ø 50 mm	30	0	0,0%
23	CLS Ti Expansionscup Ø 52 mm	29	0	0,0%
24	CLS Ti Expansionscup Ø 58 mm	26	0	0,0%
25	Allofit TI 50/HH	20	0	0,0%
26	Interop-cup, titan, 55 mm	19	0	0,0%
27	Müller Low Profile Cup 28 mm Ø 46 mm	17	0	0,0%

Impact of Registers

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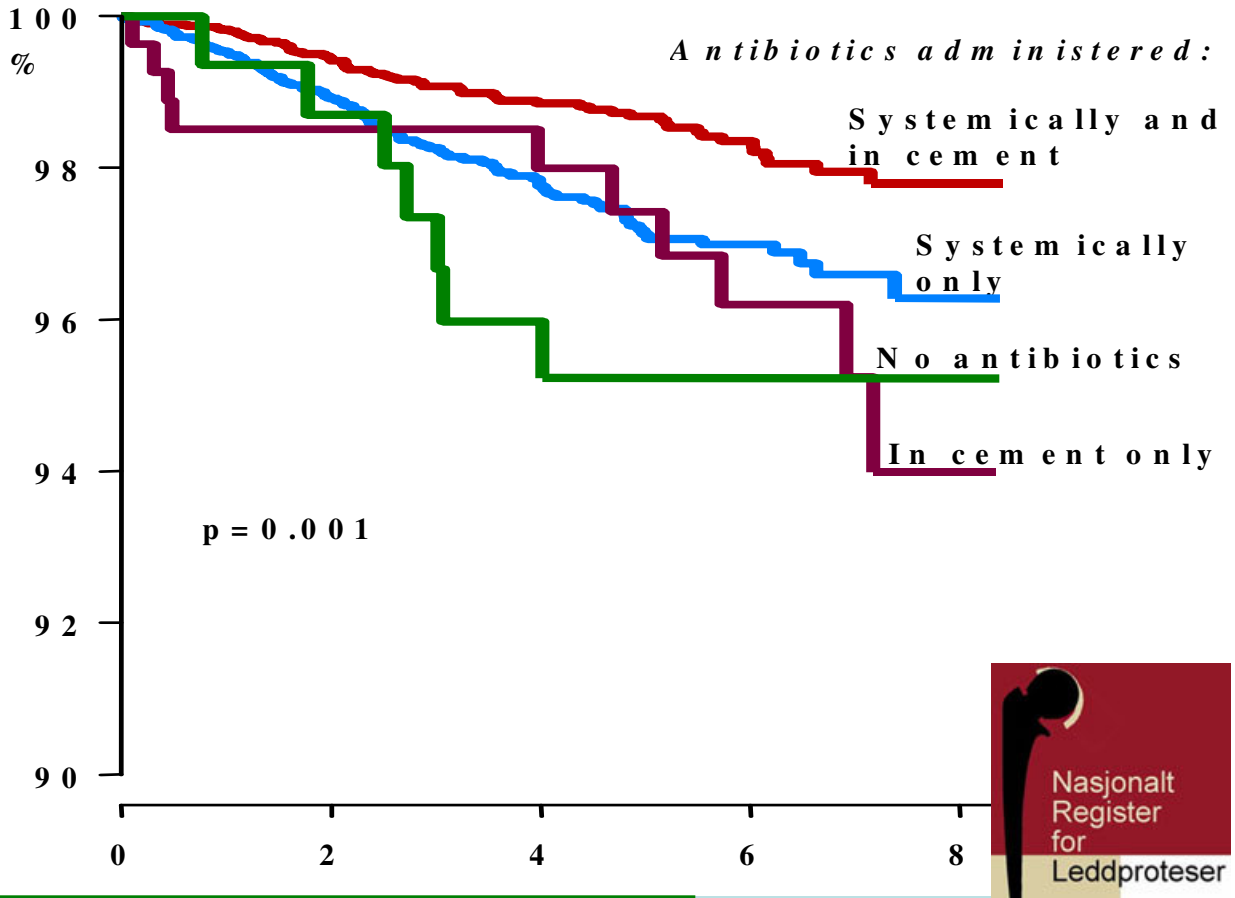
- **Reference for surgical procedures**:

Revision rate referring to antibiotic prophylaxis regimes



Nasjonalt Register for Leddproteser

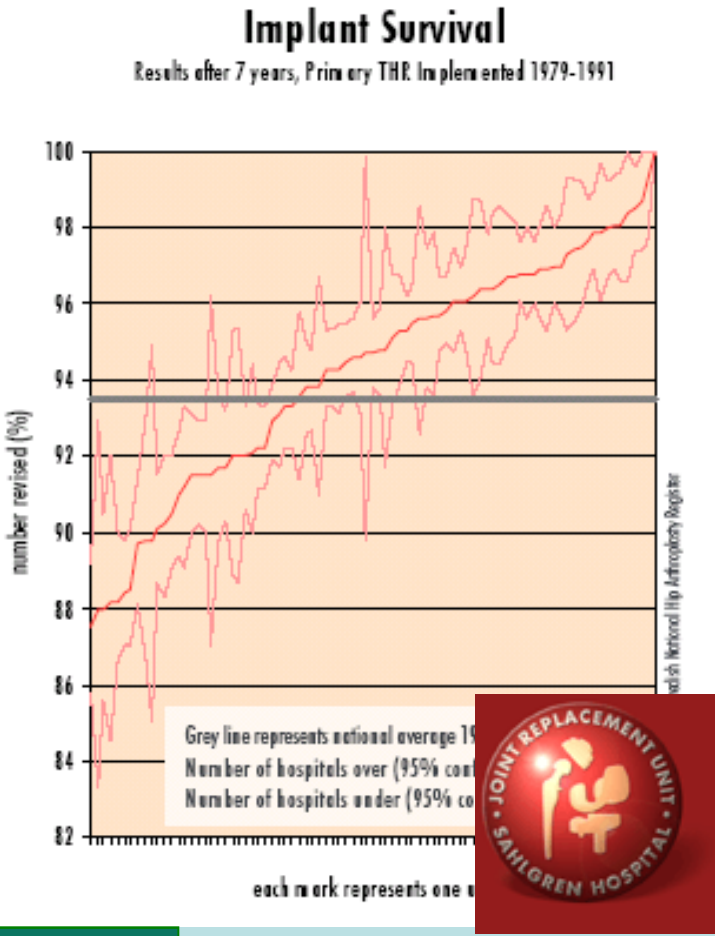
Impact of Registers

- **<u>Decrease of the range between individual departments concerning revision rate</u>**:

<u>Results for individual Units 1979 – 1991:</u>

National average:
93,5% survival rate after 7 years

- 45% of the units above
- 30% at the average
- 25% below the average



Impact of Registers

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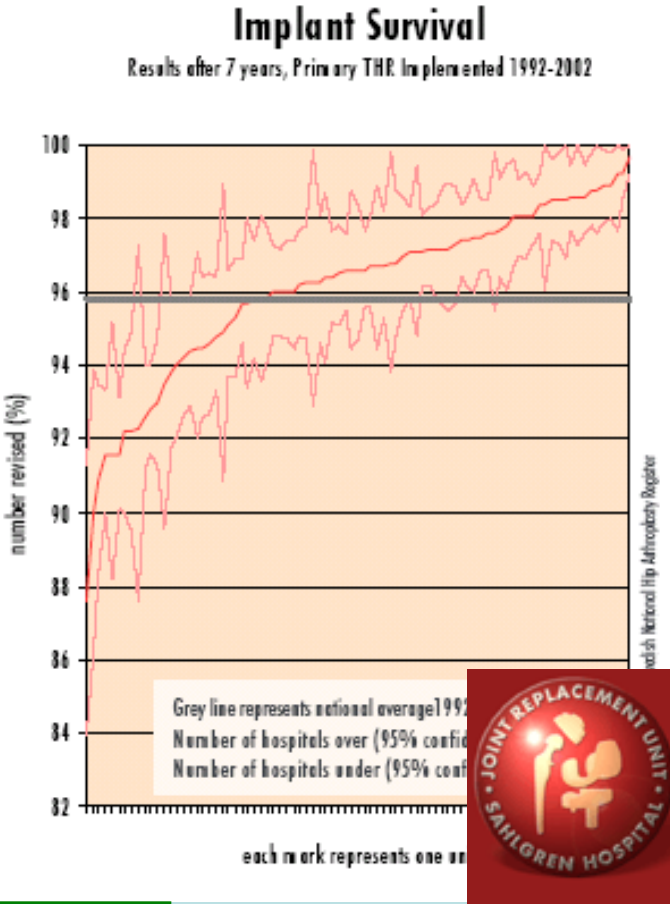
- **<u>Decrease of the range between individual departments concerning revision rate</u>**:

<u>Results for individual Units 1992 - 2002:</u>

National average:
95,8% survival rate at 7 years

- 33% of the units above
- 54% at the average
- 13% below the average



Impact of Registers

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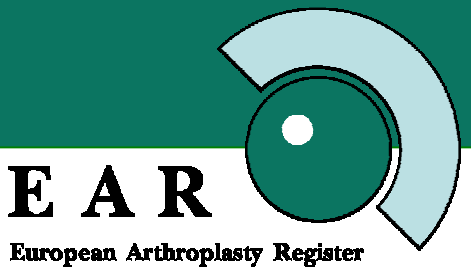
- How it was possible to achieve the reduction in revision rate?
  - Surgeons focused on the best implants
    - 1979: 60 different implants on the swedish market
    - 2001: 3 Implant (stems) have > 90% of the market´share and all of them are in the top performer group
  - Improvement of surgical techniques by feedback
  - Autonomous by the surgeons without regulatory influence by the Public Health System

Financial Impact by a Register

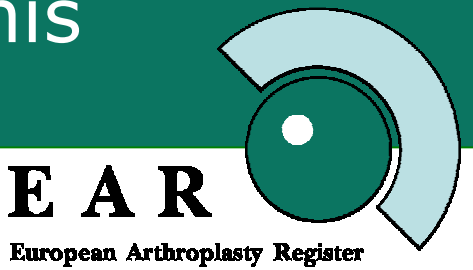


- Compared to the Expenses for Revisions:

- Sweden:
  - if 40 Revisions can be „saved" by a register it is cost effective.
  - The Register has reduced the revision burden by more than 50%
  - This is an equivalent of saving 11.630 revisions in the last 10 years
  - Direct (intrahospital) costs: 139.560.000$

= 14.000.000 $ annually for the Swedish Health Care System

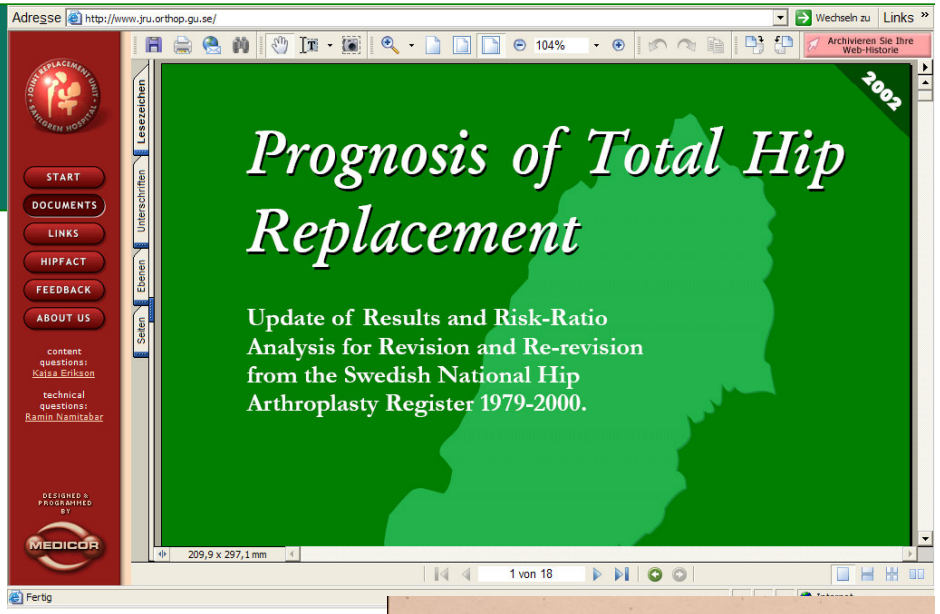
How the scandinavian achieved this tremendous success?



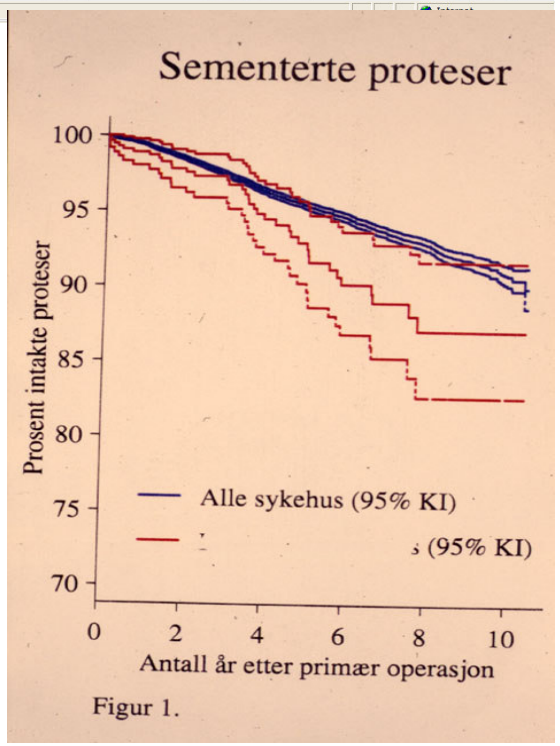
- Active Publication of the results
- Selective Presentations to the different groups of interest.
  - Surgeons
  - Public Health System
  - Scientific Societies, Patients,..
- Assure a fair use of the figures and discussion

Reports

- General Reports published at scientific meetings,..:



- Reports referring to the national situation and (not public) reports to the single departments presenting their situation in comparison to the national average



Copyright: Norwegian Register

Interpretation of Register data

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- Register data are observations
- Reflect local standards
  - might lead to missinterpretation by generalisation of foreign Reports.
  - Only portuguese Register data really fit to the portuguese background
- What to do in the meantime until the Register is producing results??

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Adjustement of Information from Arthroplasty Register Reports

What can i use for myself from foreign Register reports?

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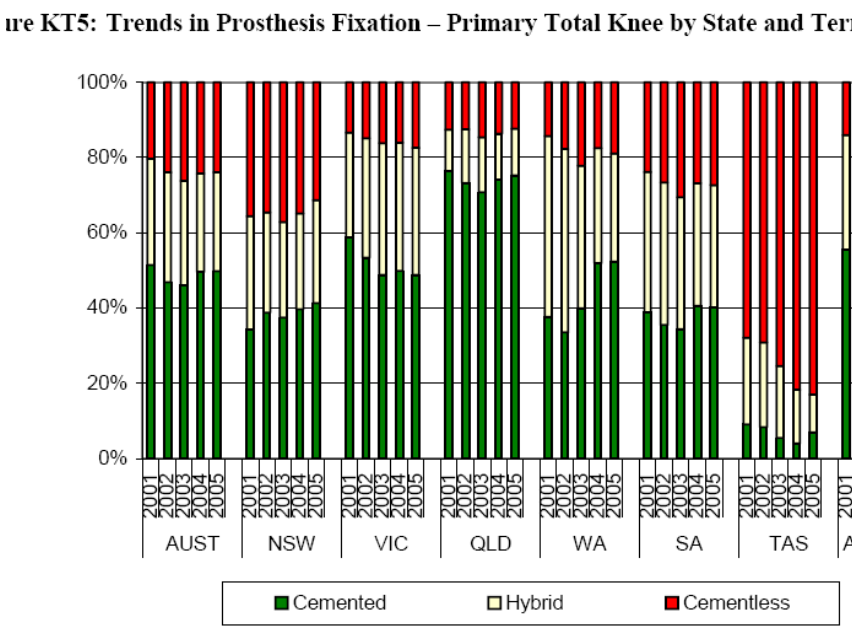

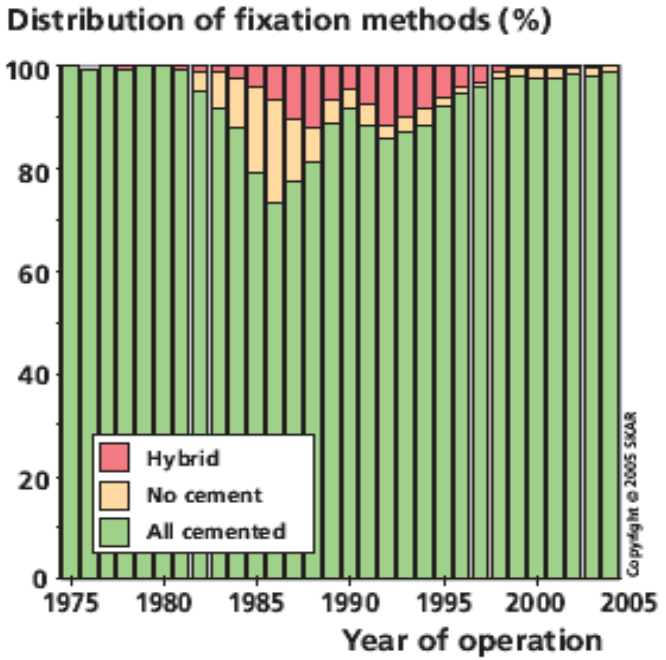

The figure shows the yearly distribution for cemented, uncemented and hybrid fixation of components.

Alloclassic

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Table HT33: Primary Conventional Total Hip where the Femoral and Acetabular components were used with Cementless Fixation requiring Revision

Femoral Component	*Acetabular Component*	*Number Revised*	*Total Number*	*% Revised*	*Observed 'component' years*	*Revisions per 100 observed 'component' years*	*Exact 95%CI*
ABGII	ABGII	69	2396	2.9	6193	1.1	(0.87, 1.41)
ABGII	ABGII (shell & insert)	7	544	1.3	915	0.8	(0.31, 1.58)
ABGII	Trident	23	876	2.6	1756	1.3	(0.83, 1.96)
Accolade	Trident	39	1765	2.2	2343	1.7	(1.18, 2.28)
Alloclassic	Allofit	20	848	2.4	1209	1.7	(1.01, 2.56)
Alloclassic	Fitmore	16	482	3.3	701	2.3	(1.30, 3.71)
Alloclassic SL	Allofit	18	1285	1.4	2996	0.6	(0.36, 0.95)
Alloclassic SL	Fitmore	12	538	2.2	1465	0.8	(0.42, 1.43)
Alloclassic SL	Morscher	7	313	2.2	1018	0.7	(0.28, 1.42)
CLS	Allofit	5	381	1.3	818	0.6	(0.20, 1.43)
CLS	Fitmore	12	404	3.0	1168	1.0	(0.53
Citation	Trident	12	518	2.3	956	1.3	(0.65
Citation	Vitaloc	10	530	1.9	1597	0.6	(0.30

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Table HT39: Individual Primary Conventional Total Hip Prostheses with higher than anticipated revision rates either alone or in combination

Femoral Component	*Acetabular Component*	*Hazard Ratio*	*P Value*	*Total Number*	*% Revised*	*Observed 'component' years*	*Revisions per 100 observed 'component' years*	*Exact 95%CI*
Cementless								
Alloclassic	Fitmore	2.16	0.004	482	3.3	701	2.3	(1.2, 3.4)
Esop	Altas	2.93	0.020	81	4.9	96	4.2	(0.1, 8.2)
Margron	*	3.01	<0.001	563	7.3	1289	3.2	(2.2.4.2)
Profemur	*	7.39	<0.001	134	6.0	103	7.8	(2.4,13.2)
Revitan	*	2.57	0.048	83	6.0	184	2.7	(0.3, 5.1)
**	Artek	3.40	<0.001	158	15.2	667	3.6	(2.2,5.0)
**	Delta	4.78	0.011	136	2.9	79	5.0	(0.1, 10.0)
**	EDF-Plus	2.00	0.020	560	2.1	567	2.1	(0.9, 3.3)
**	Inter-Op	5.13	0.001	27	22.2	111	5.4	(1.1,9.8)
**	Lineage	2.50	0.003	276	4.7	492	2.6	(1.2,4.1)
**	SPH Blind	2.12	<0.001	714	5.3	1897	2.0	(1.42, 2.75)
Cemented								
Elite Plus	Apollo	3.58	0.014	52	9.6	193	2.6	(0.3,4
Elite Plus	Charnley LPW	3.09	0.009	89	7.9	313	2.2	(0.6,3
H Moos	Mueller	14.62	<0.001	19	36.8	66	10.6	(2.7,1

15 4 6 7

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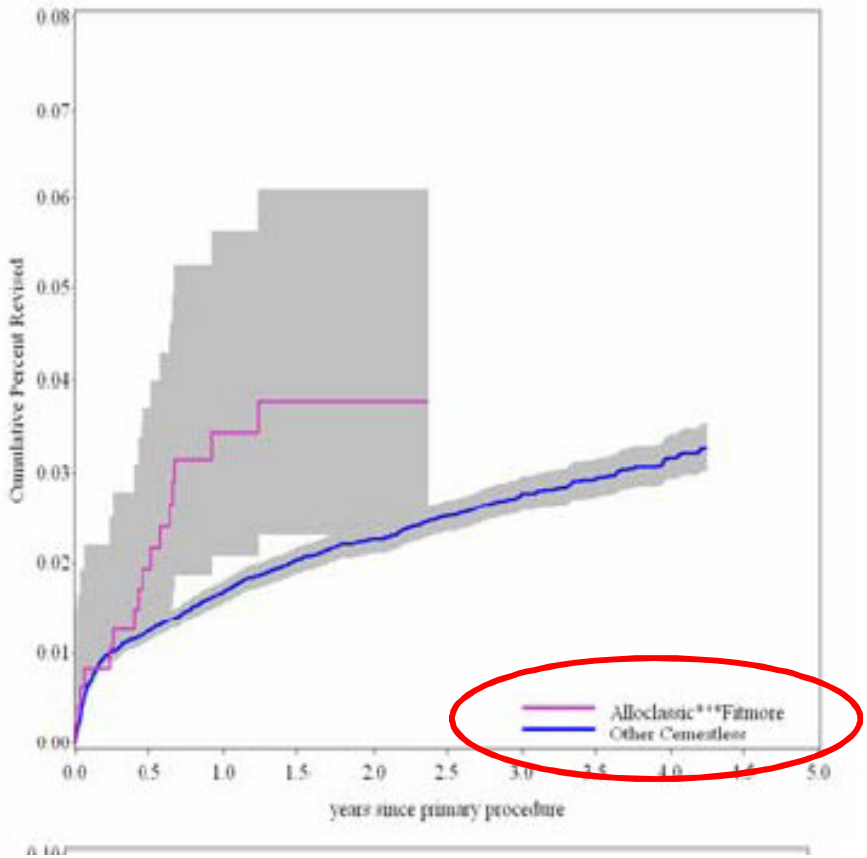
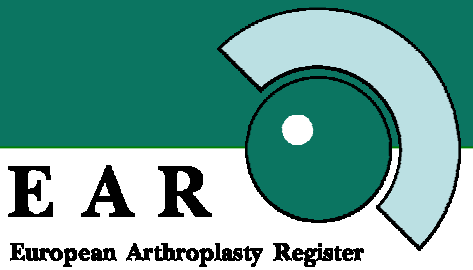
gures HT21-28: Cumulative percentage revisio
prostheses that have been identifie



Detail Evaluation Alloclassic



- Group Alloclassic consists of a mixture of Alloclassic SLO und SLL (- at primary Operations!!!!)
- Relatively small sampe, 15 Revisions
- Almost all Revisions within the first year

Detail Evaluation Alloclassic

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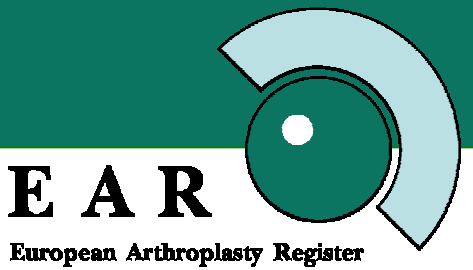
- Questions:
  - Case mix Faktor?
  - Surgical influence?
- Implant related problem????????
- Not everything what´s significant is relevent
- Accurate Analyses by Register staff is recommended and essential to gice the „customer surgeon“ the possibility for proper consequences

Implant tracking - Example



- Omnifit-Cup in Romania:
  Most Popular Implant in Romania

- Omnifit-Cup in Sweden:
  Release from the Market due to poor performance (62% survival rate at 10 years)

- ???????? What´s this?

Omnifit-Cup

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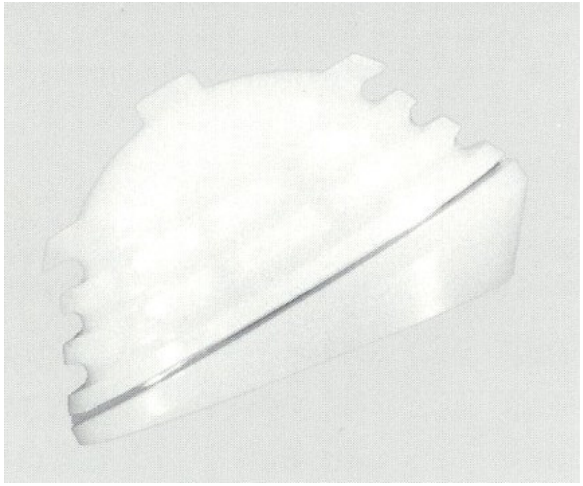
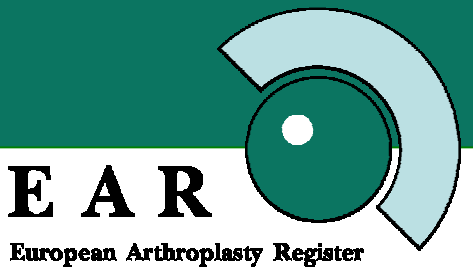
- Sweden

- Romania



Omnifit-Cup



- 6 different versions of this cup
- Not possible to specify simply by the product name
- Dilution in Studies, assessment and scientific discussions?
- Sufficiant information and lack of specification might lead to unsecure feeling by surgeons and/or patients

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Value of Datasets

EUPHORIC-Project

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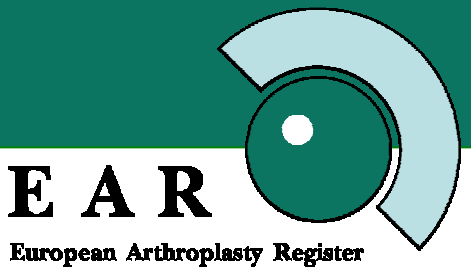
- EUPHORIC: (**EU**ropean **P**ublic **H**ealth **O**utcome **R**esearch and **I**ndicators **C**ollection)
- Methodological Research project by the Euopean Commission (DG SANCO)

Health & Consumer Protection
Directorate-General

EUPHORIC



- Comparison Register and Metaanalyses of peer reviewed literature.
- Revision Rate (Revisions per 100 observed component years)
- Implants with sufficiant publications in both datasets

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Ankle Replacement

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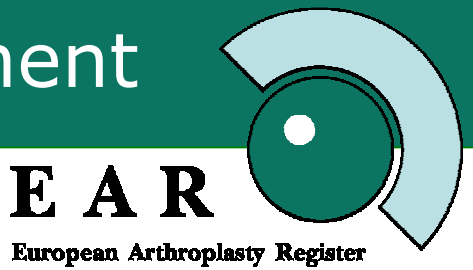
STAR

Metaanalysis STAR Ankle Replacement



- 42 Publications (Medline)
- 23 with survival rate data (1187 Cases)

of these

- 6 Studies from Author´s group (>25%) (212 Cases)
- 17 Independent Studies (975 Cases)

STAR Ankle Replacement

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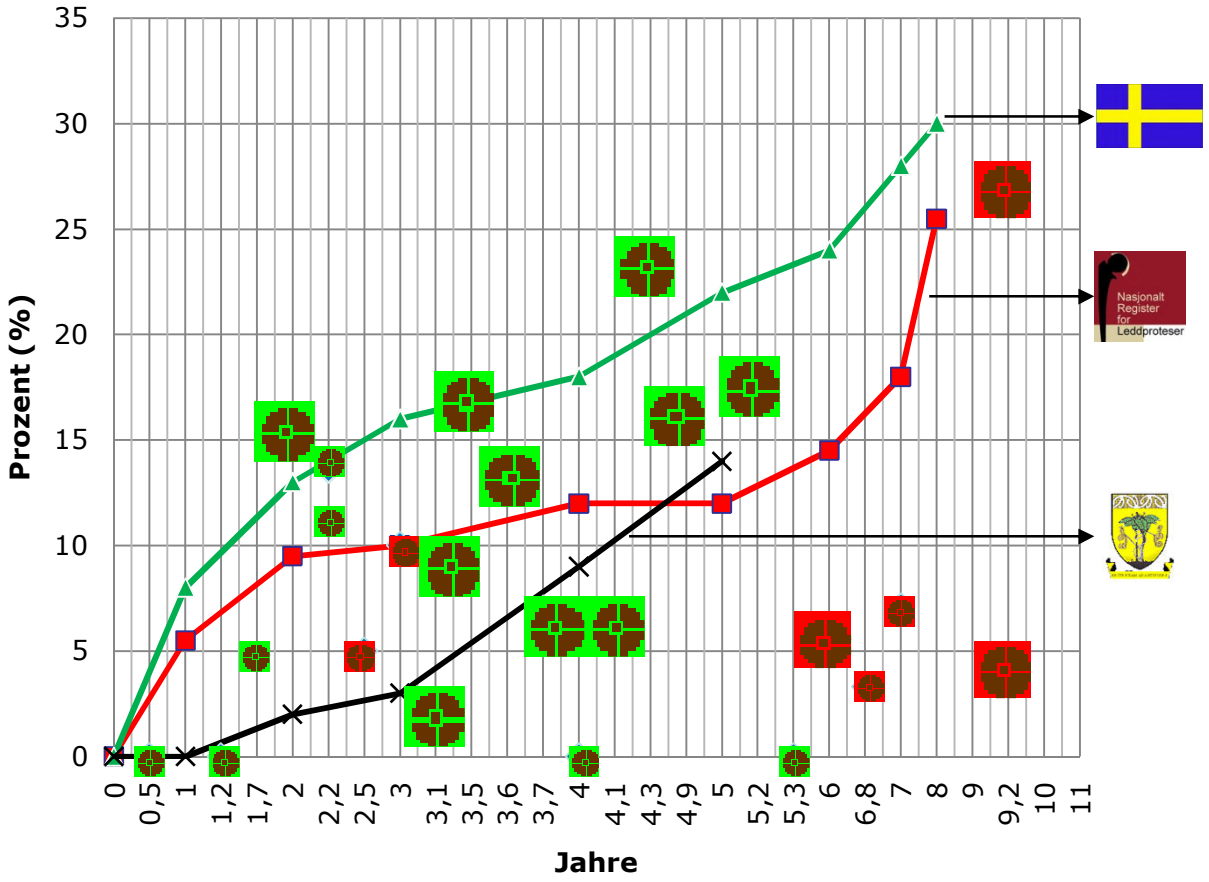
Revisionsraten
Studien vs. Register



N= 531
1993 - 2005
Revisions:
101 (22%)

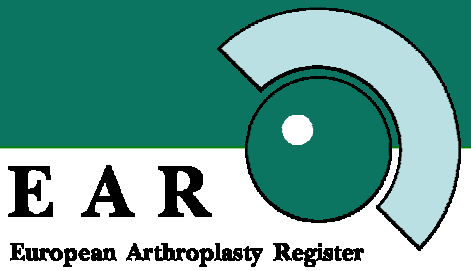
N= 259
1994 - 2004
Revisions:
40 (15,4%)

N= 202
2002 - 2005
Revisions:
14 (7%)

Studies from the author´s group

Studies > 30 Cases

STAR Ankle Replacement



	FUP	Revision Rate	Primary cases	Revision cases	Observed component years	Revisions per 100 observed component years	CI	Factor Difference Register-Studies
Author	5,54	4,89	184	9	1018,50	0,88	0,47-1,67	4,63
Independet Studies	4,44	13,35	1049	140	4658,11	3,01	2,55-3,54	1,36
Pooled clinical studies	4,60	12,08	1233	149	5677	2,62	2,24-3,07	1,56
Pooled Register Data	4,01	16,41	579	95	2321,2	4,09	3,36-4,98	

Other Ankle Replacements

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- Pappas-Büchel:
  - Author is underestimating the Register revision rate by a factor of 14,31
  - Clinical studies (from the US) are underestimating the revision rate by a factor of 7,45

- Agility:
  - Author is underestimating the Register Revision rate by a factor of 2,43
  - Independent Studies are overestimating the benchmark by a factor of 1,66
  - Pooled data near to the Register Benchmark

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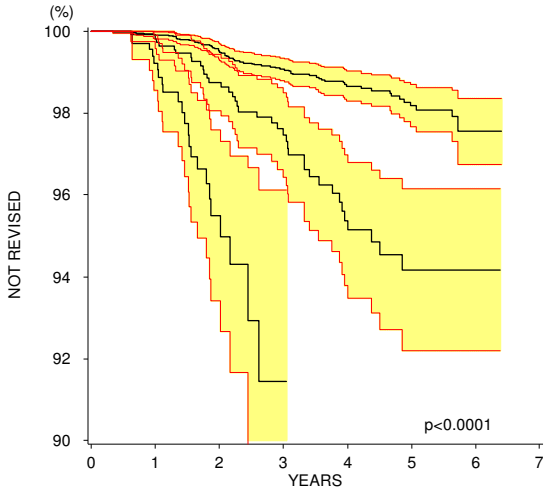
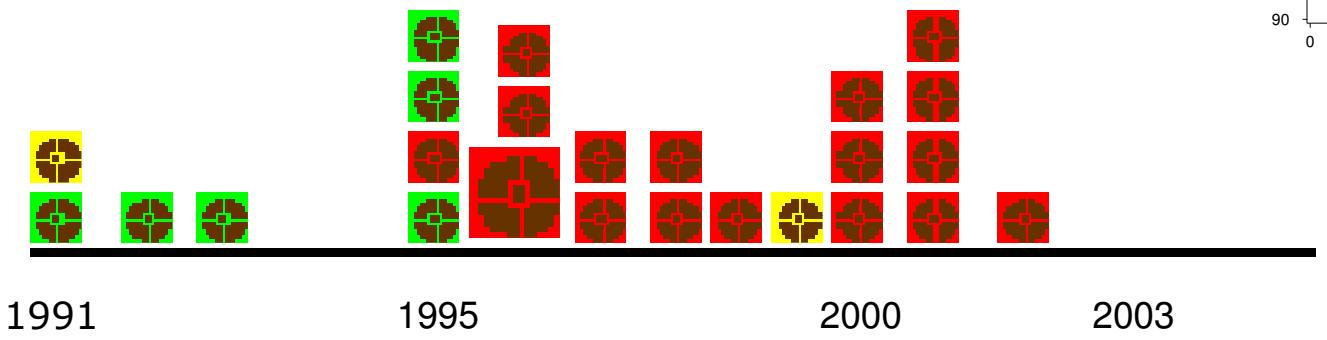
In favour of the product

technical studies or no statment

negative to the product





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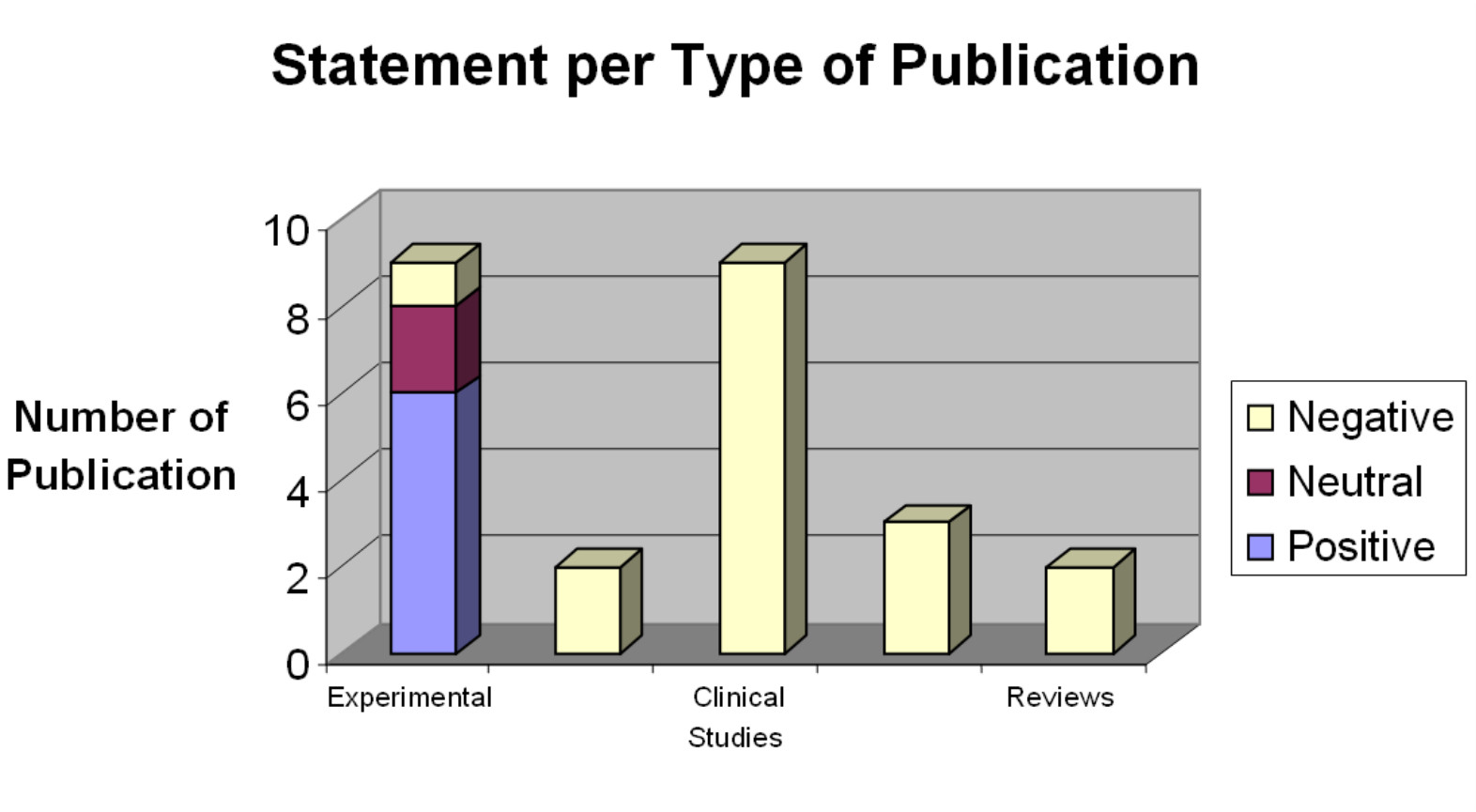

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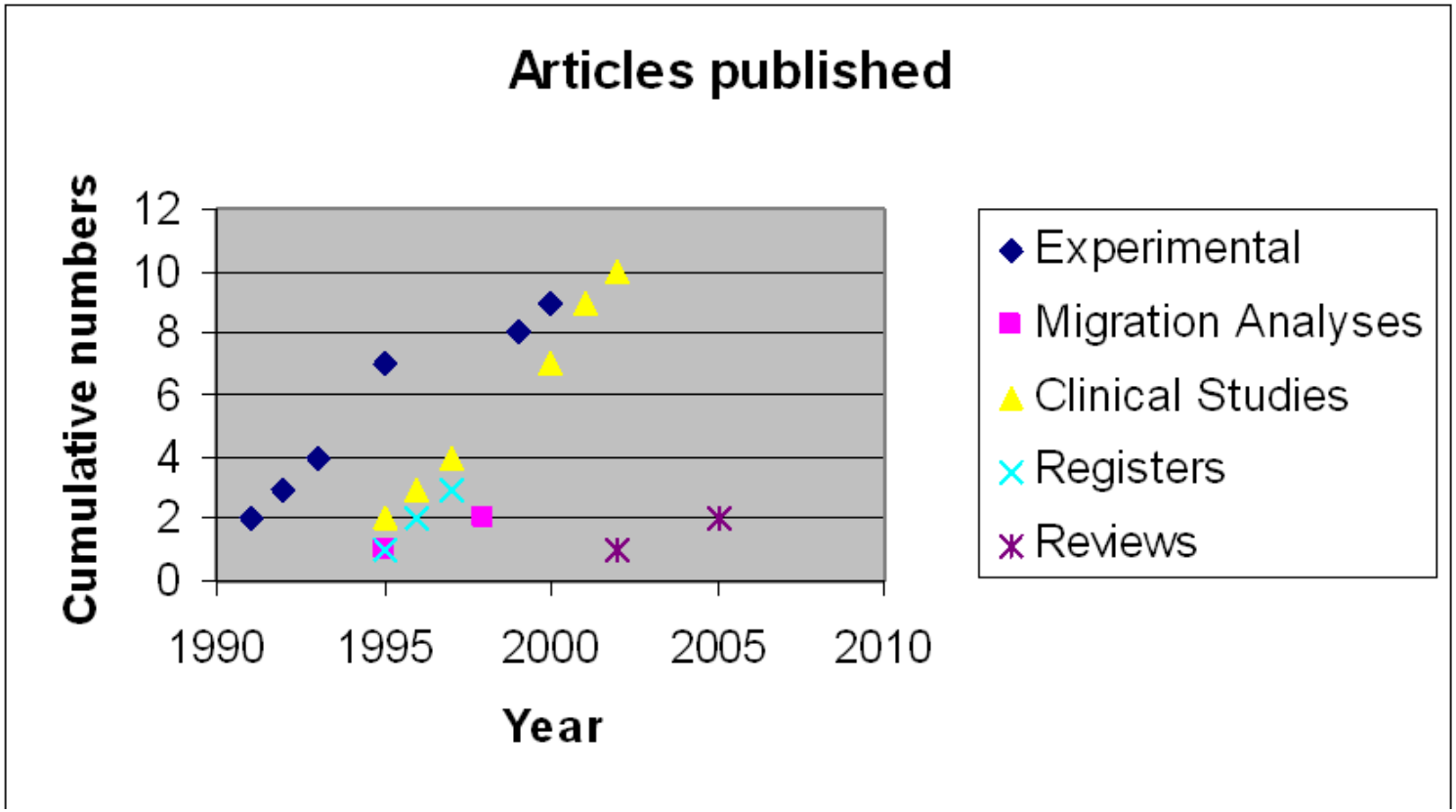

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	FUP-Periode (years	Reoperation Rate [%]	Number primary cases	Observed Componenet years	Number revision cases	Revisions per 100 observed componeht years	Factor Differenc e
Register	3,37	3,48	3338	5618,00	166	2,96	
Clinical Studies	3,43	37,80	627	1091,48	237	21,71	7,33

- Clinical Studies were published at a time where the failure of the product was obvious
- Clinical Studies overestimate the real revision rate by a factor of 7,33

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Patella Replacement at TKA

Patella Resurfacing Clincal Literature

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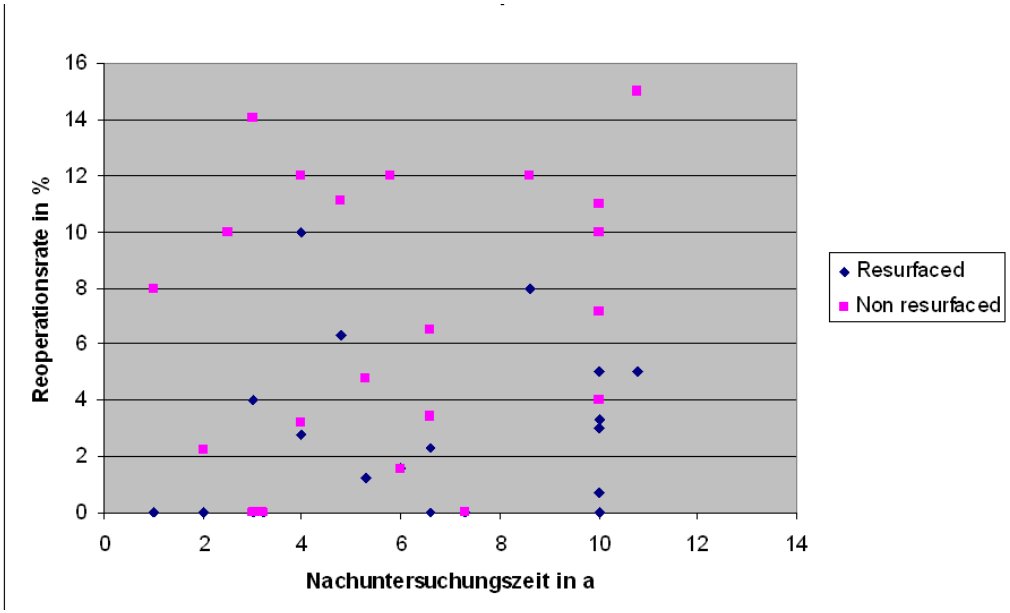

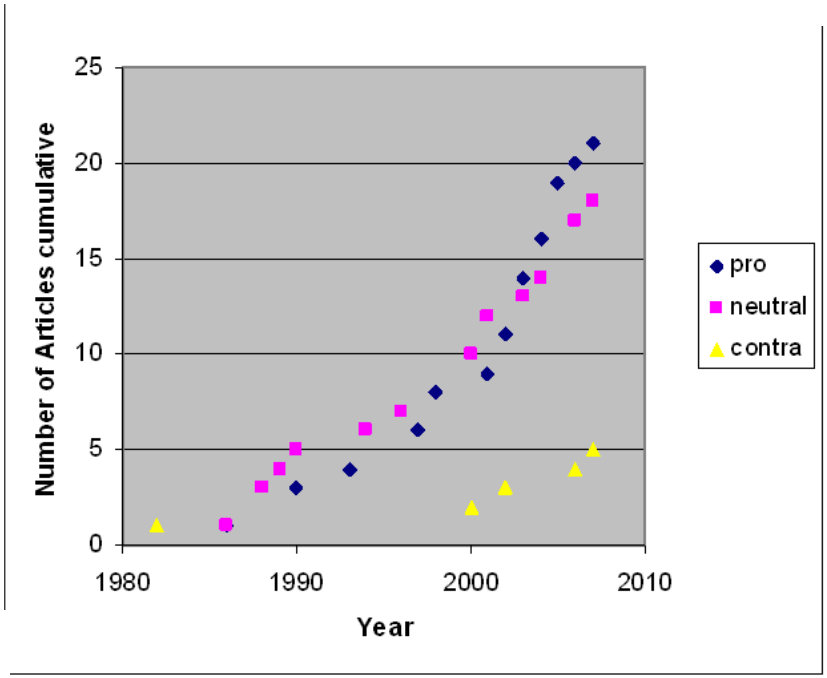

Literature Overview incl. Register

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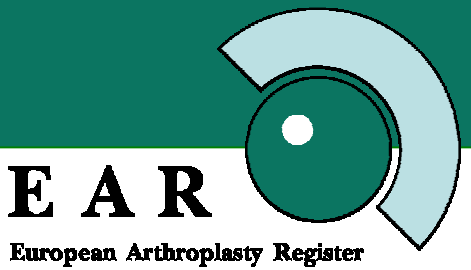
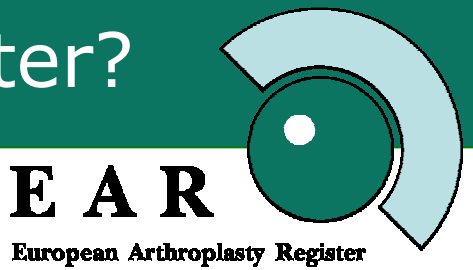
Resurfaced	Follow up periode	Revision rate [%]	Primary cases	Revision cases	Observed component years	Revisions per 100 observed component years	CI	Factor Difference to Register	Factor Difference Resurfacing/ non Resurfacing
Register	3,37	1,98	7578	150	12773,7	1,17	1,0 -1,38		0,99
Clinical Studies	4,28	2,23	527	12	1128,065	1,04	0,61-1,85	1,13	0,58
RCT	5,95	2,80	581	16	1727,15	0,94	0,57-1,5	1,24	0,38
Reviews	4,43	2,03	888	18	1964,7	0,92	0,58-1,44	1,28	0,28
Total clinical studies		**2,31**	**1996**	**46**	**4819,92**	**0,96**	0,72-1,27		
non resurfaced	Follow up periode	Revision rate [%]	Primary cases	Revision cases	Observed component years				
Register	3,38	2,01	15476	311	26173,4	1,19	1,06-1,33		1,01
Clinical Studies	5,73	5,16	625	32	1791,62	1,80	1,27-2,51	0,66	1,73
RCT	5,88	7,37	609	45	1789,75	2,51	1,88-3,35	0,47	2,66
Reviews	4,42	7,24	908	66	2006,4	3,27	2,59-4,16	0,36	3,57
Summe clinical studies		**6,67**	**2142**	**143**	**5587,77**	**2,56**	2,18-3,01		

Summary



- Statistically significant Bias in Clinical Literature
- Authors and Publications from the US have higher Bias factors
- Clinical Literature reviews can not eliminate this bias without reference to Register data

How to organise a National Register?



- Require a professional and solid data collection and evaluation centre
- Results have to be published, discussed and findings have to be considered in daily decisions
- National Orthopaedic Societies are the only forum which can achieve this.
- Registers are just as effective as the surgeons support them

Effects of Registers

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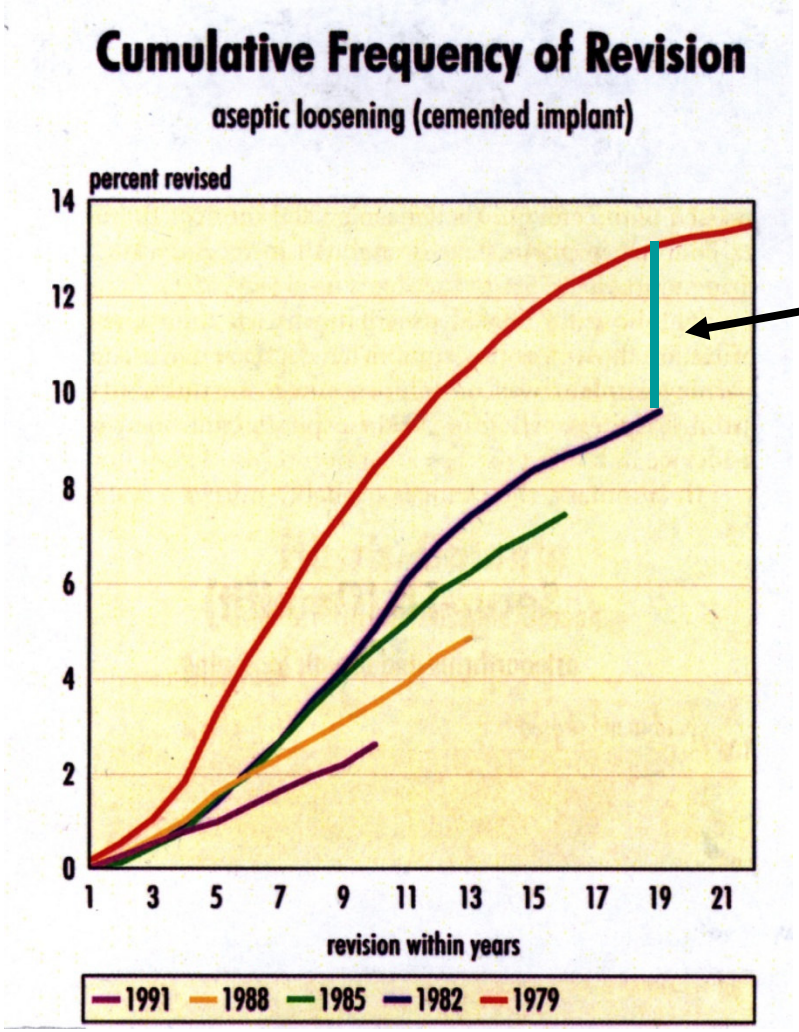

3 Years,
25% Risk reduction

Effects of Registers

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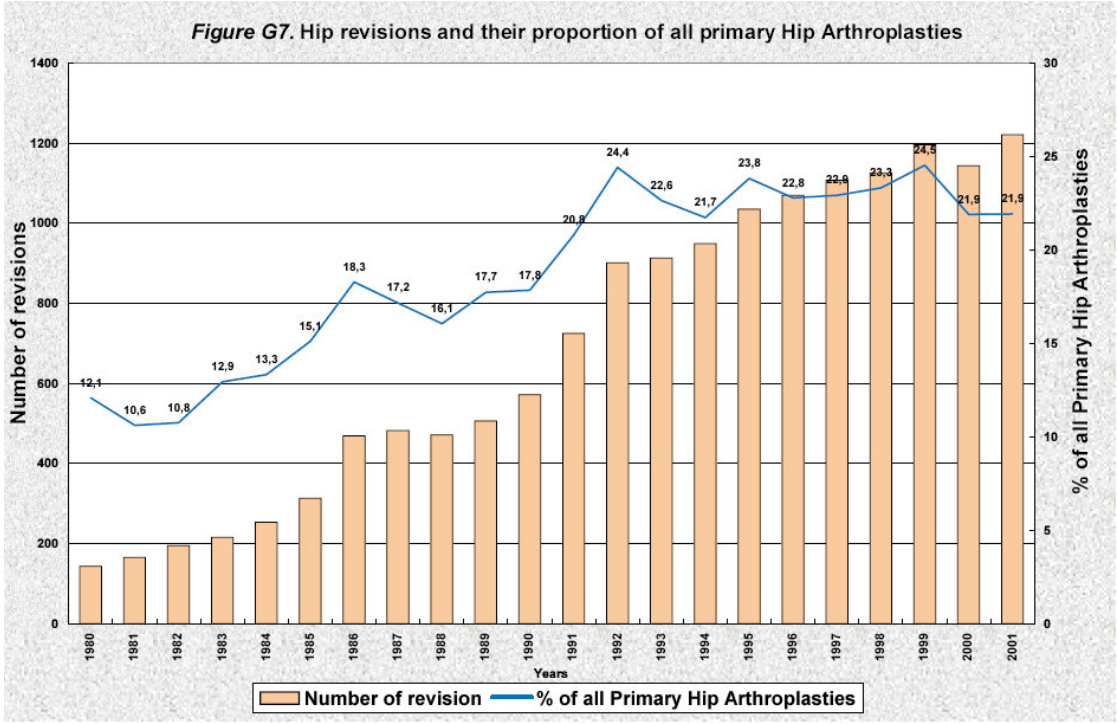
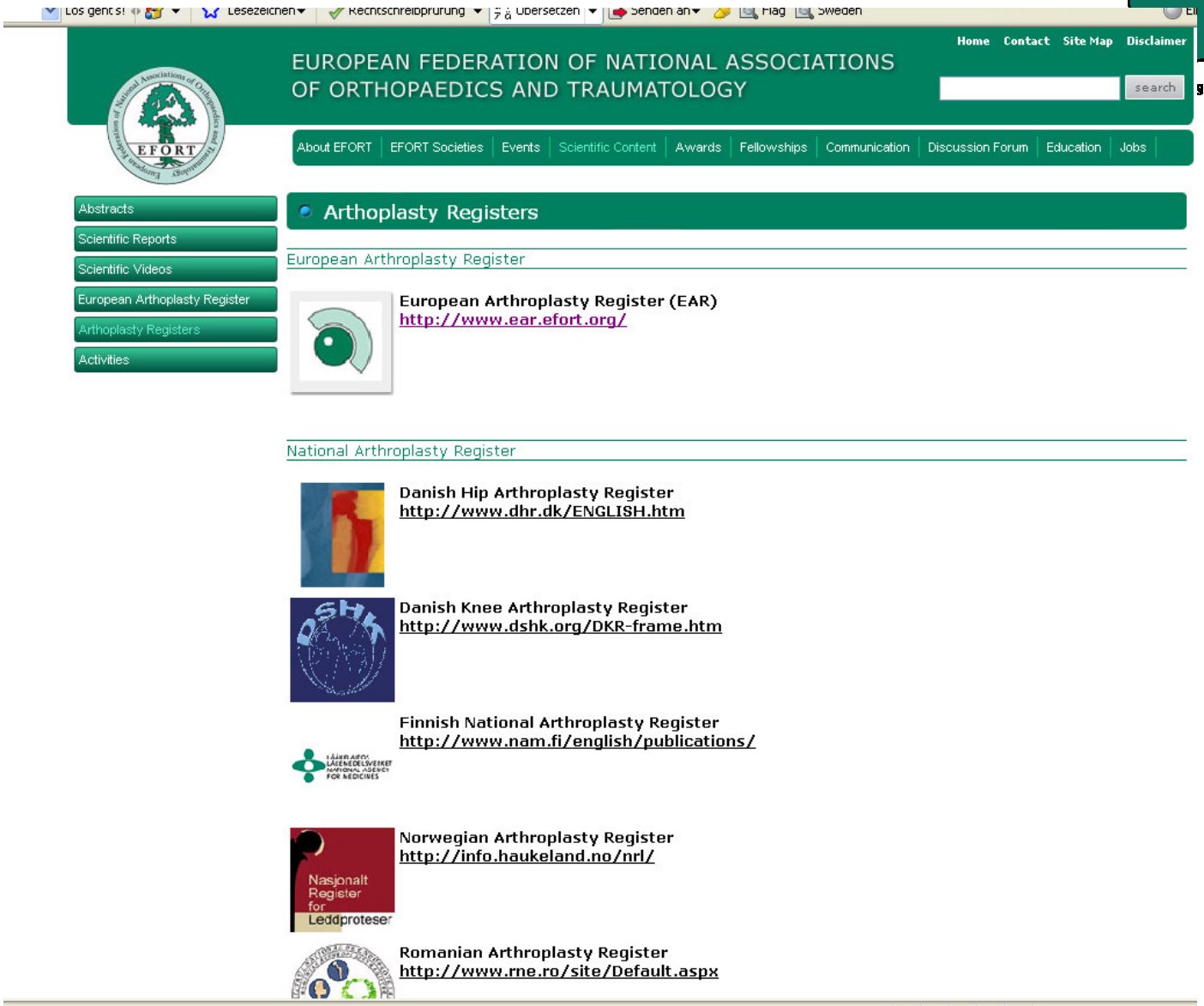


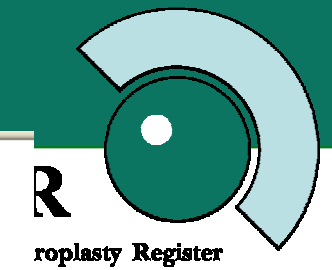
- 1980-1992:
  Rev. Burden:
  12,1 -> 24,4 %
- 1992-2000:
  Stable
- Since 2000:
  Decrease

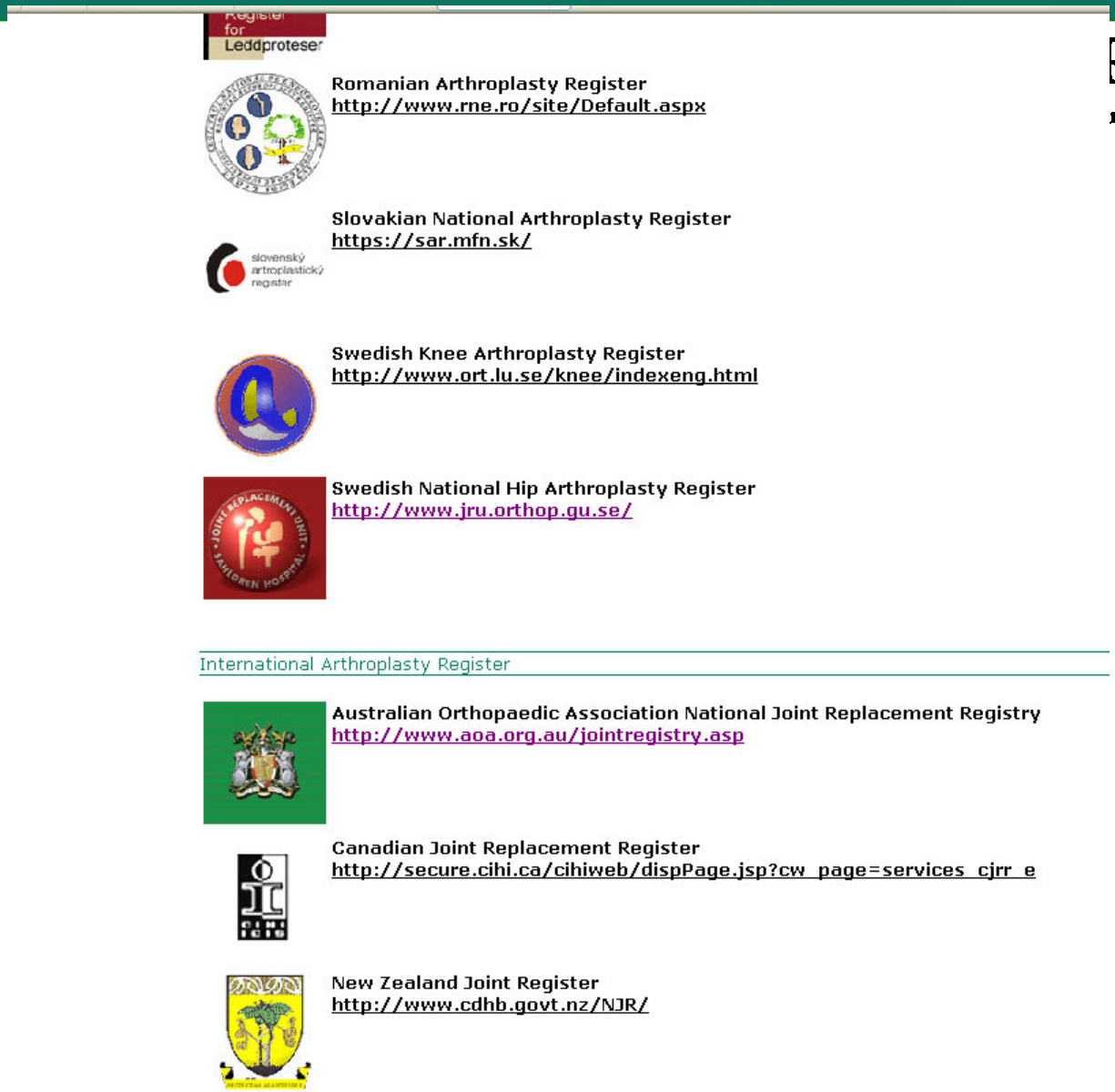
LÄÄKELAITOS
LÄKEMEDELSVERKET
NATIONAL AGENCY
FOR MEDICINES

Register-section at EFORT-Portal



Register-section at EFORT-Portal





EAR-Homepage

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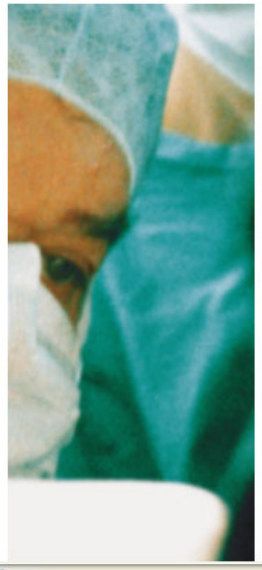
EFORT Associated Activity

- Home
- About EAR
- Research & Publications
- News
- Events
- Extranet Intern. Register
- Extranet EAR-Board



EUROPEAN ARTHROPLASTY REGISTER

Last update: January, 25th 2005

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NEWS

April 12th, 2005 Organised by EAR an Arthroplasty Register section at the EFORT-Portal was launched. Aim is to collect and present worldwide Arthroplasty Register information in a user friendly way.
http://www.efort.org/E/05/01-50.asp

Feedback to this page is welcome.
Please post your message to the EAR-Office by e-mail

The development of an International Register Society was decided at a meeting at the AAOS in February 2005.
EFORT-EAR supports this initiative.

EVENTS

June 6th, 2005 On Monday, 6th of June, 8.00 - 10.00 a European Arthroplasty Register Symposium will be presented at the EFORT-Congress in Lisbon.

EAR will organise a not public meeting concerning innovative documentation systems and techniques for national large scale documentation systems at the EFORT congress. Interested colleagues are invited to order information at the EAR-Coordinator.

EAR REPORTS

- Basic Statements concerning Arthroplasty Registers (7711 KB)
- Development of the Romanian Register (3806 KB)
- New Regulatory Requirements and related challenges in the European Union for orthopaedic medical devices (157 KB)

NATIONAL REGISTERS

- National Registers

RECOMMENDED PUBLICATIONS

- EFORT Minimal Dataset
- Basics about Arthroplasty Registers

CONTACT

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Fertig Internet

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EUPHORIC Results will be Published at the EFORT-Congress 2009 in Vienna

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