

# Storia dei fallimenti in chirurgia protesica. *Le scelte dei clinici fra ragione e passione.*

Emilio Romanini (Roma)  
Gabriele Potalivo (Perugia)

GRUPPO DI LAVORO ORTOPEDIA BASATA SULLE



# Storia dei fallimenti in chirurgia protesica. *Le scelte dei clinici fra ragione e passione.*



- EBM
- Ricerca
- Editoria
- Conflitti di interesse
- Economia sanitaria
- Cittadini
- Comitati etici



 **SIOT2012**



97° CONGRESSO NAZIONALE  
DELLA SOCIETÀ ITALIANA DI ORTOPEDIA E TRAUMATOLOGIA

Lesioni capsulo-legamentose acute | Le protesi dolorose



novembre 1962 → novembre 2012



*Sir John Charnley*  
*Low friction arthroplasty*

# Storia dei fallimenti in chirurgia protesica.

*Le scelte dei clinici fra ragione e passione.*



## Storia dei fallimenti

Fase concezionale (<1960)

Fase adolescenziale (<1980)

Fase adulta (<2000)

Fase della (im)maturità (<oggi)

Passione (ingenuità/conflitti di interesse)

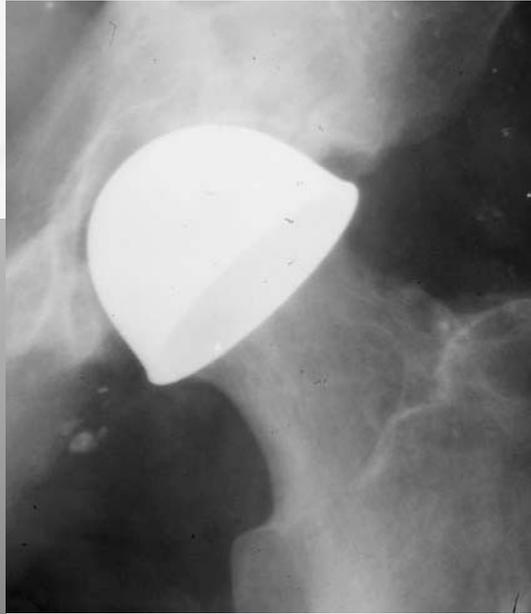
Ragione (informazione/ricerca)

Fase concezionale (<1960)



*La dolce vita, 1960*

# Smith Petersen



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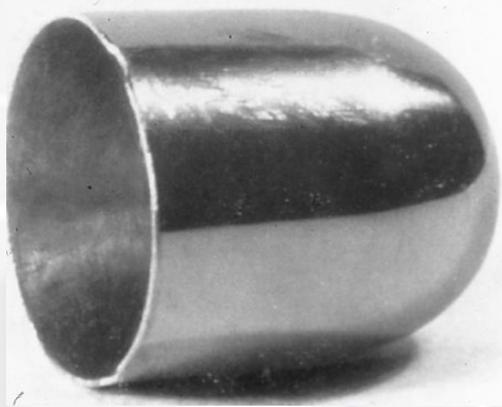
**AUSTENAL<sup>®</sup> LABORATORIES, INC.**  
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224 EAST 39th STREET • NEW YORK 18, N.Y.



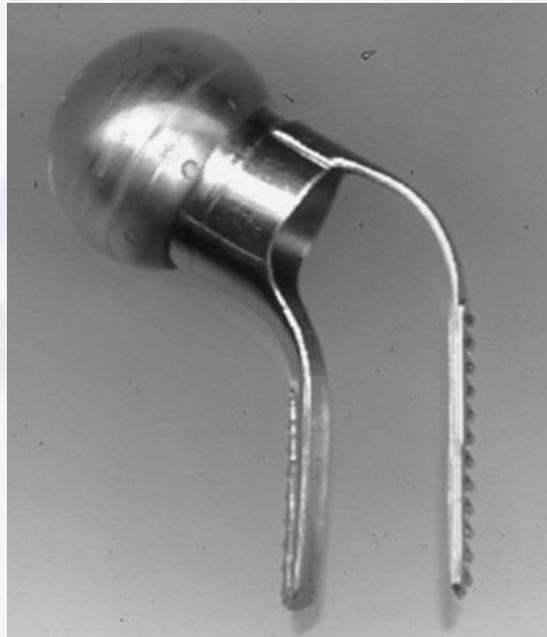
# Artroplastica modellante a "cupola" femorale

Pais

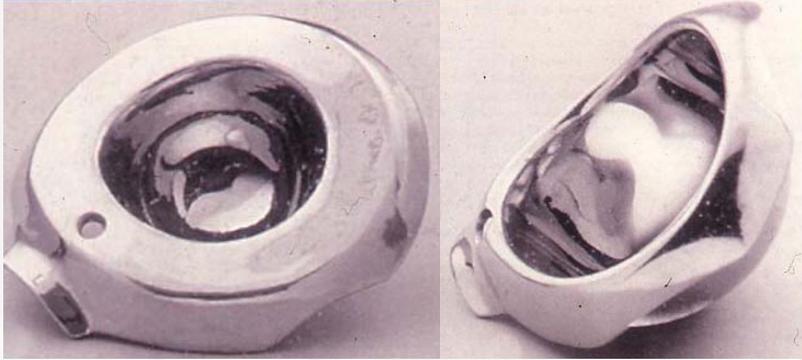


Scaglietti

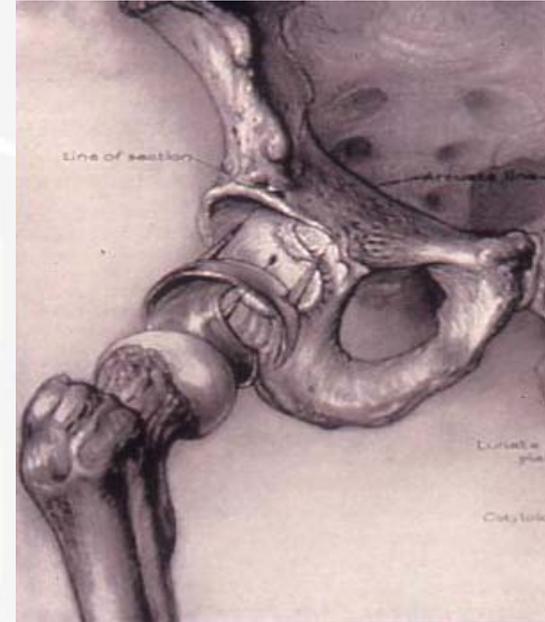
Marino-Zuco



# Artroplastica modellante a "cupola" acetabolare

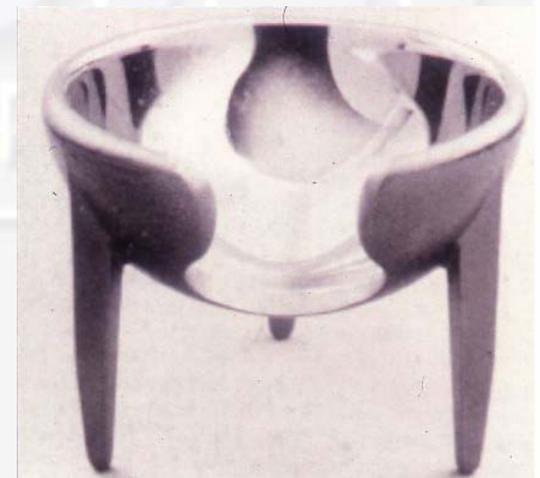
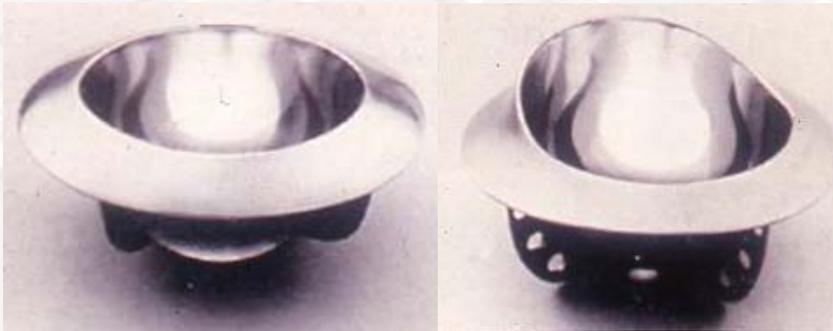


Albee-Pearson



Urist

McBride



# Endoprotesi a stelo corto



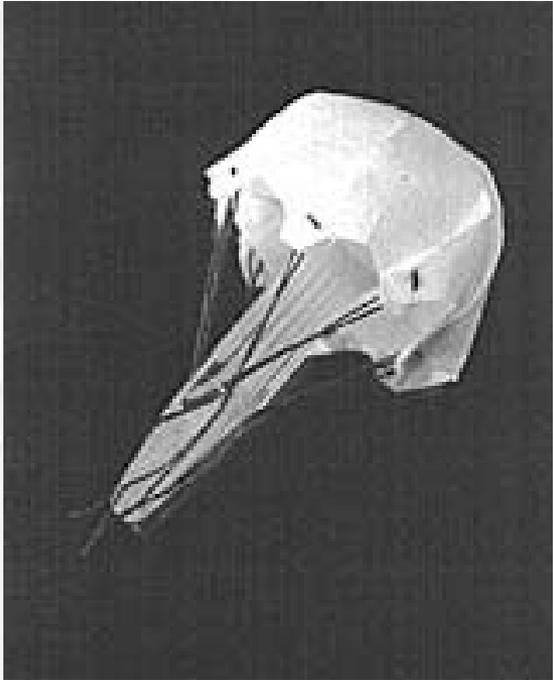
Bohlman



Thomson



Zanoli



Judet

# Judet



**HIP ARTHROPLASTY**  
with  
**PROSTHETIC HEADS**  
•  
**TECHNIQUE**  
of  
Doctors  
**R. and J. JUDET**

Patent Pending

**Reinforced Monobloc and Grooved**  
**Drs JUDET'S MODEL**  
is made of

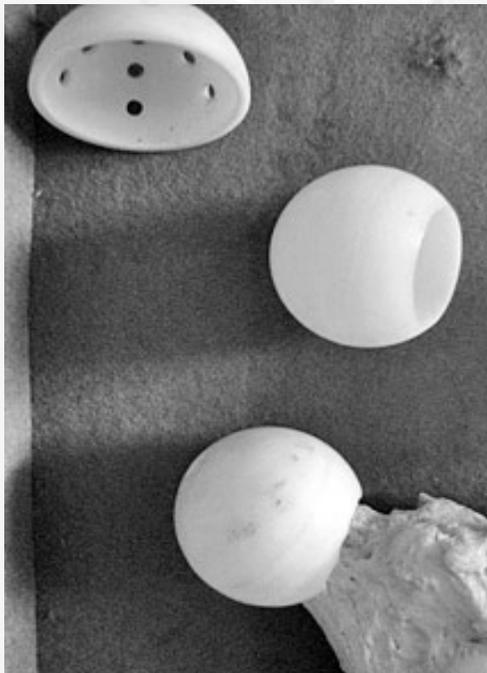
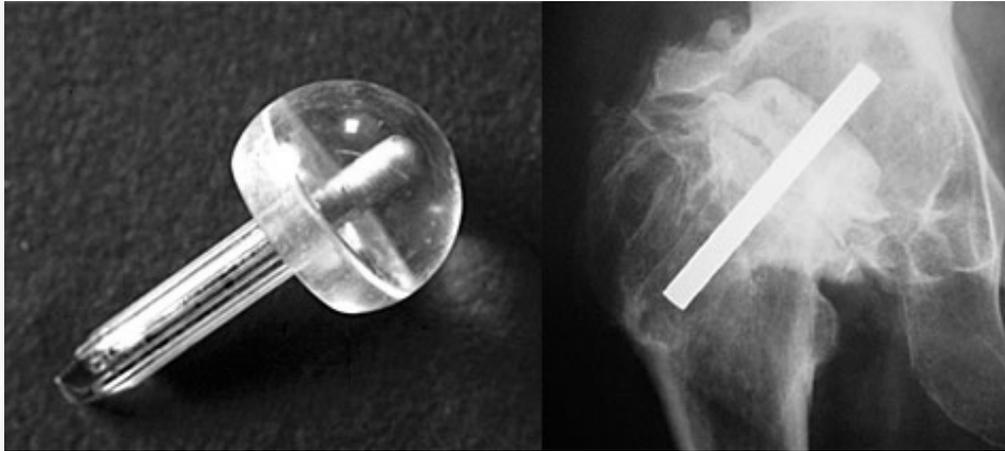
- 1 Stainless Steel Armature of high breaking strength embedded before polymerisation. (By this process no plugs or cement are used in inserting of the armature.)
- 2 Grooves preventing the risk of rotation.
- 3 Grooves specially ended to prevent risk of extraction.

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# Charnley



**Charnley  
PROSTHESIS**  
for low-friction Arthroplasty of the Hip-joint.

Diagram illustrating the components of the Charnley Prosthesis:

- ACETABULAR CUP
- CEMENT RESTRICTOR  
*Patent applied for*
- FEMORAL PROSTHESIS
- FEMORAL NECK PUNCH
- SOCKET HOLDER

SOLE AUTHORISED MANUFACTURER

*"The cart has been put before the horse.  
The artificial joint has been made and used, and  
now we are trying to find out how and why it fails"*

John Charnley 1955



Le varie artroplastiche mi hanno subito disilluso e credo di esser stato uno dei primi a prevederne i molti insuccessi. E le mie previsioni si sono avverate molto prima di quel che avrei creduto.

Alle Giornate Scientifiche Mediterranee del 1955, al collega che qualche anno prima, a proposito delle mie sfavorevoli opinioni, scherzosamente mi aveva detto "crepi l'astrologo!", io potevo dire, pure scherzosamente "l'astrologo non è crepato, ma sono crepate molte anche!"

Ugo Camera 1960



*Trial and error*



*Charnley 1962*

*Serendipity*



*Ling (Exeter) 1969*

Fase adolescenziale (<1980)



*Il tempo delle mele, 1980*

Prosthesis type	1960s	1970s	1980s	1990s
<b>Cemented</b>				
<b>1st generation</b> Finger packing	1960s			
<b>2nd generation</b> Intramedullary femoral plug, cement gun, superalloys for stems		mid-1970s		
<b>3rd generation</b> (some still regarded as experimental) Pressurisation, porosity reduction, precoating, rough surface, centrisation			mid-to late 1980s	
<b>Ceramic (heads/cups)</b>		late 1970s		
<b>Uncoated press-fit cementless</b>		late 1970s		
<b>Porous-coated cementless</b>			early 1980s	
<b>Hybrid (cemented stem/ uncemented cup)</b>			early 1980s	
<b>HA-coated cementless</b>			late 1980s	
<b>Fully modular</b>			late 1980s/	early 1990s

1. Protesi cementate
2. Protesi non cementate
3. Protesi di rivestimento

# Cementate: *Christiansen* (1974)

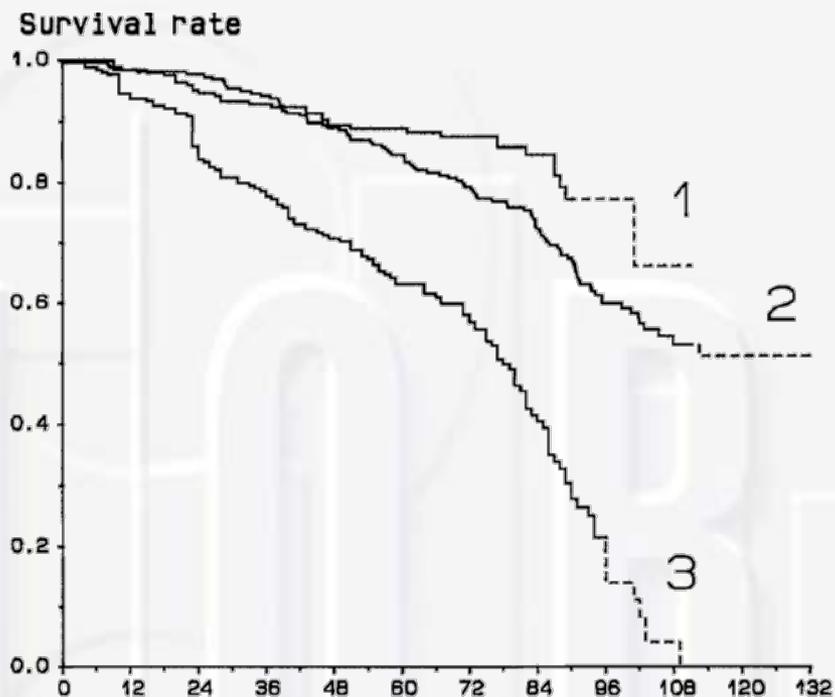
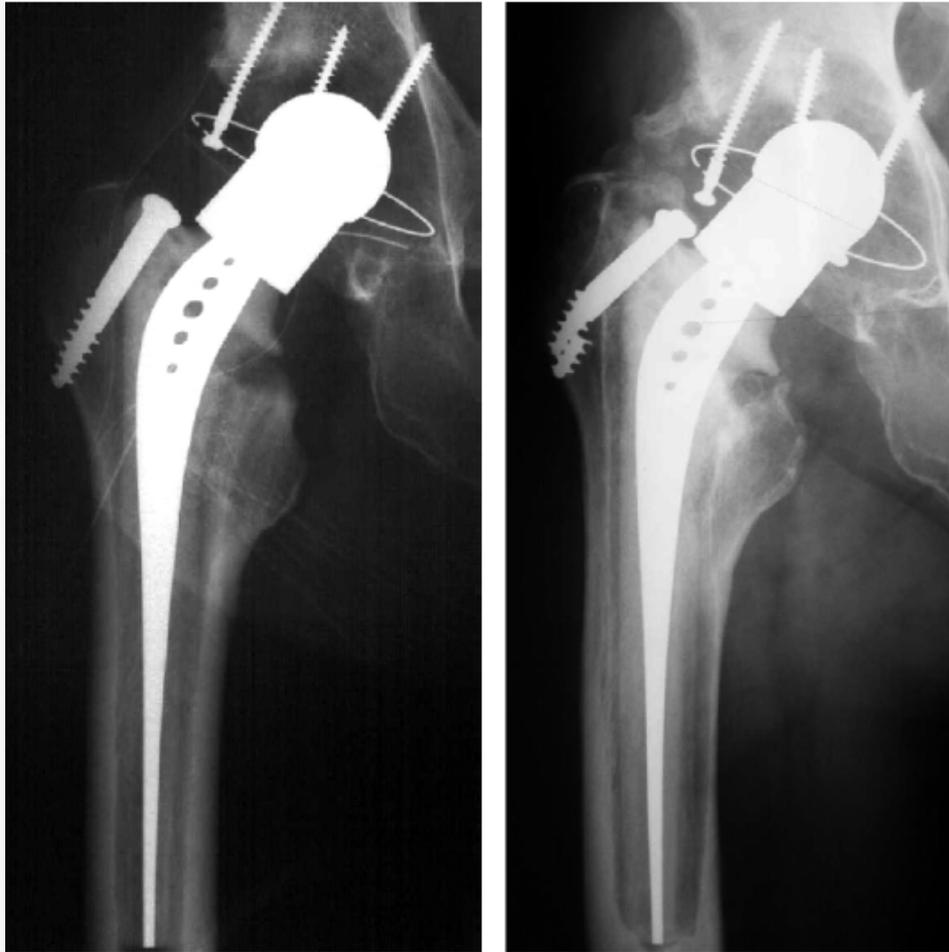


Table 4. Failures of THA at follow-up\*

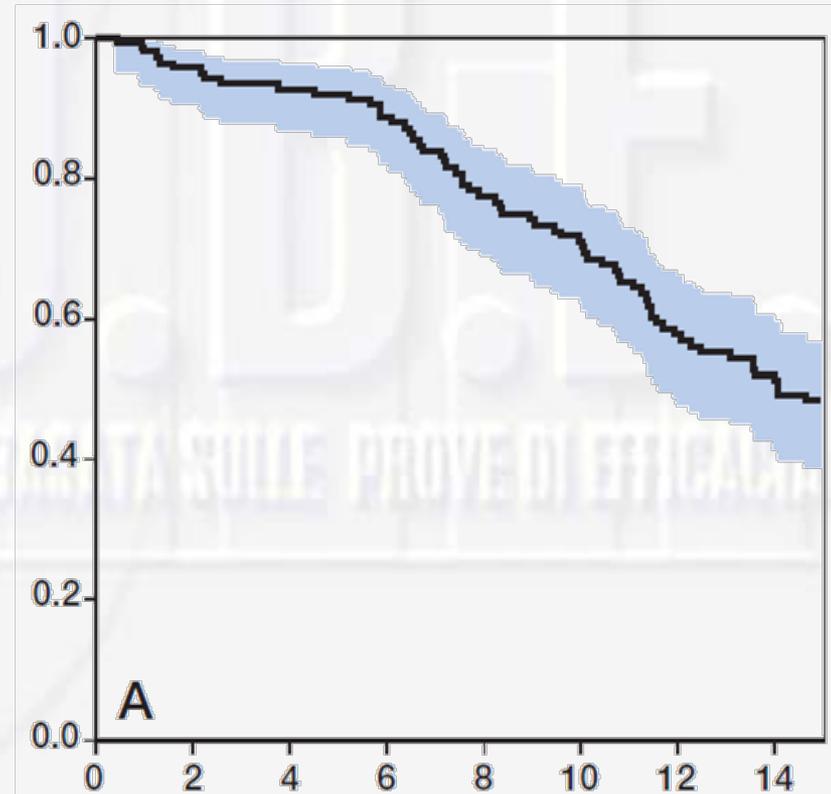
Group (No. of patients)	No failure (per cent)	No. of loosened (failed) (per cent)			Sum hips
		Cups	Stems**	Both	
Charnley (75)	95 (96%)	1 (1%)	3 (3%)	0	99
Christiansen (61)	47 (69%)	13 (19%)	3 (4%)	5 (7%)	68

# Non cementate: *RM Isoelastic* (1973)



theses (5, 8, 12). *E. Morscher* in Basle implanted the first isoelastic endoprosthesis in 1973. Later, it was primarily *R. Bombelli* and *G. Hierholzer* who studied the isoelastic approach both theoretically and clinically (2). By February 1990, *R. Bombelli* alone had implanted 2953 isoelastic hip endoprostheses. Worldwide, a total of 92000 cups and 37000 shafts has been implanted to date.

Niinimaki JBJS 1994  
Trebse Acta Orthop 2005  
Nagi Acta Orthop. Belg., 2006



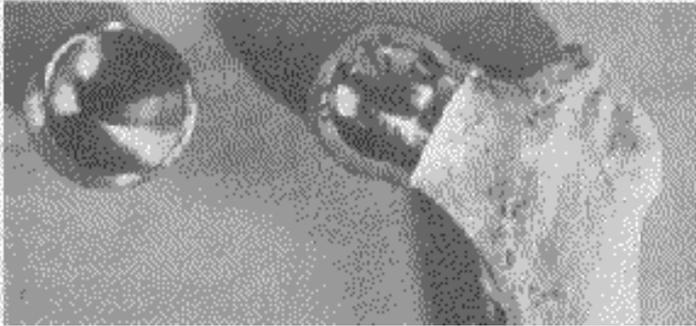
# Protesi di rivestimento 1/2

## Paltrinieri & Trentani 1971

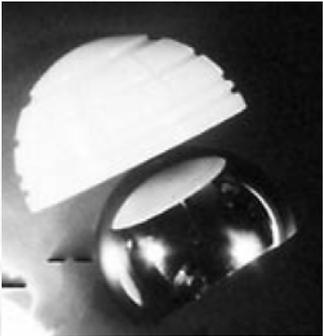
### Complications in Surface Replacement Arthroplasty of the Hip: Experience with the Paltrinieri – Trentani Prosthesis

C. Trentani<sup>1</sup> and F. Vaccarino<sup>2</sup>

<sup>1</sup> Rizzoli Institute, University of Bologna, Italy  
<sup>2</sup> Catholic Medical Center of Brooklyn – Queens, New York, USA



## Freeman 1972



Arch. Orthop. Traumat. Surg. 92, 191–198 (1978)

Archives of Orthopaedic and Traumatic Surgery

### ICLH Cemented Double Cup Hip Replacement

M. A. R. Freeman and G. C. Brown

The London Hospital, Whitechapel, London E1 1BB, Great Britain

## Capello & Eicher 1973



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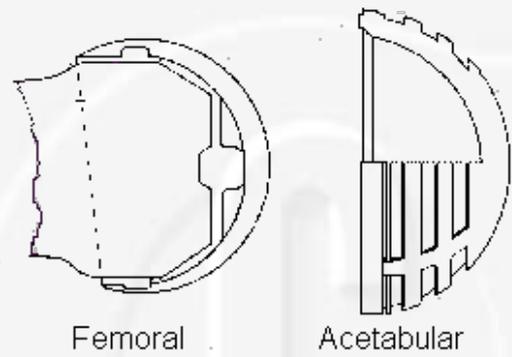
### The Indiana Conservative (Surface-Replacement) Hip Arthroplasty

BY WILLIAM N. CAPELLO, M.D.\*, GARY W. MISAMORE, M.D.\*, AND THOMAS M. TRANCIK, M.D.\*  
INDIANAPOLIS, INDIANA



# Protesi di rivestimento 2/2

## Amstutz 1975



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**Surface Replacement of the Hip  
with the Tharies System**

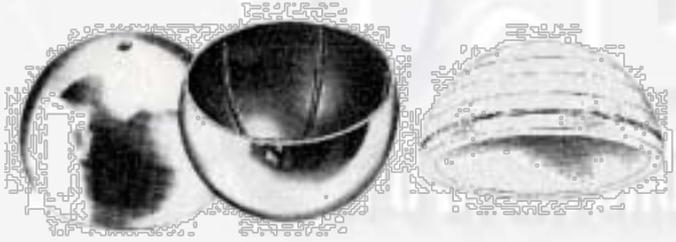
TWO TO FIVE-YEAR RESULTS

BY H. C. AMSTUTZ, M.D.\*, A. GRAFF-RADFORD, M.D.\*, L. L. MAI, PH.D.\*, AND  
B. J. THOMAS, M.D.\*, LOS ANGELES, CALIFORNIA

*From the University of California at Los Angeles School of Medicine, Los Angeles*



## Wagner 1975



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**Wagner Surface Replacement Arthroplasty of the Hip**

ANALYSIS OF FOURTEEN FAILURES IN FORTY-ONE HIPs

BY WILLIAM C. HEAD, M.D.\*, DALLAS, TEXAS



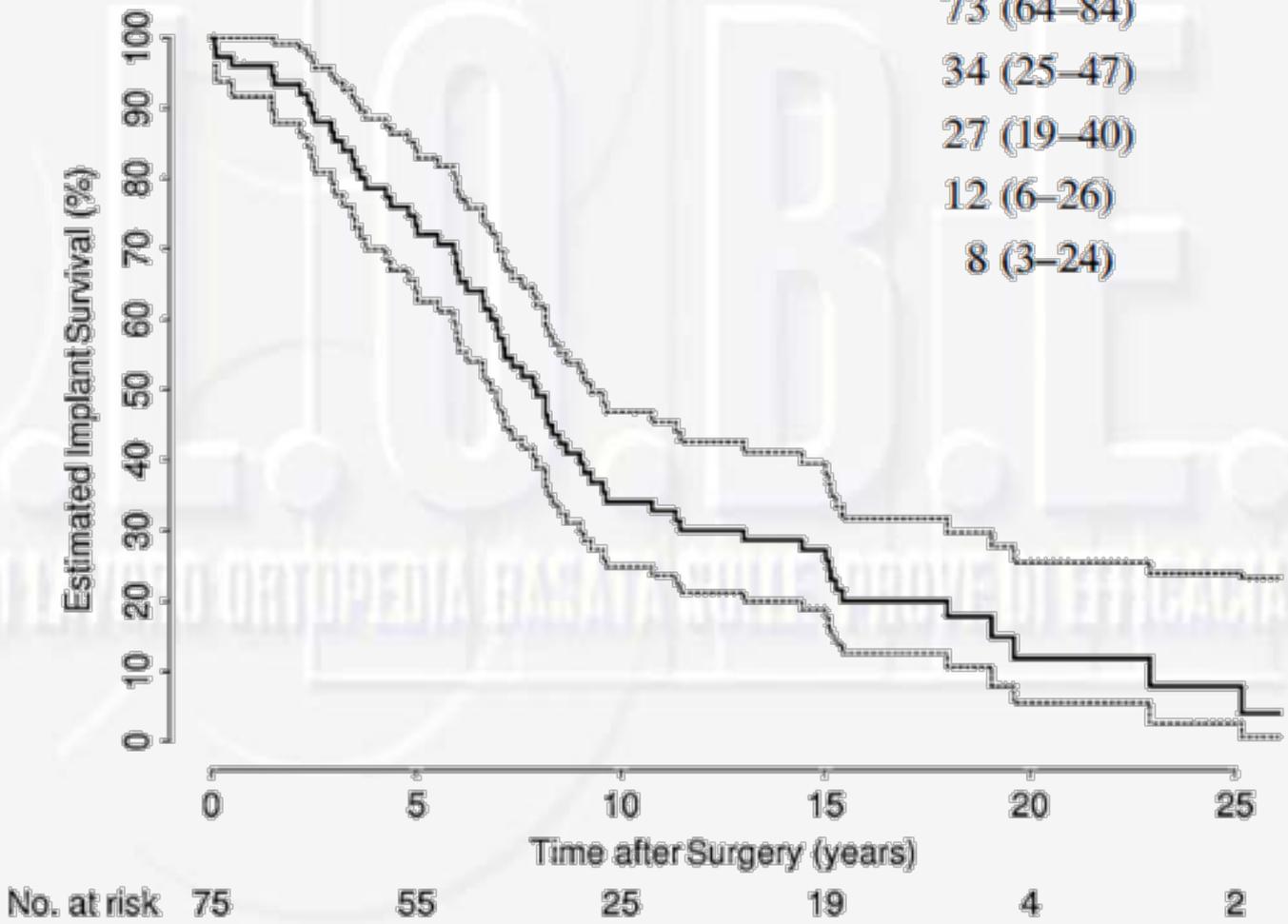
# Hip Resurfacing Arthroplasty

## Risk Factors for Failure Over 25 Years

Eric J. Yue MD, Miguel E. Cabanela MD,  
Gavan P. Duffy MD, Michael G. Heckman MS,  
Mary I. O'Connor MD

Estimated implant survival (95% CI; %)\*

- 96 (92–100)
- 93 (88–99)
- 85 (78–94)
- 79 (70–89)
- 73 (64–84)
- 34 (25–47)
- 27 (19–40)
- 12 (6–26)
- 8 (3–24)



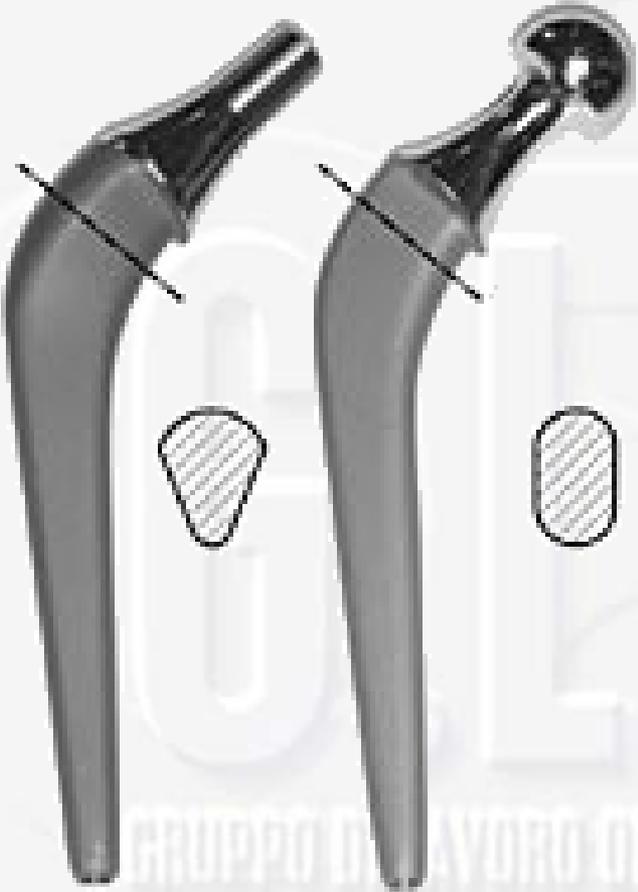
THARIES n=62  
Indiana n=28  
15 bilaterali

Fase adult(er)a (<2000)



L'ultimo bacio (2000)

# Protesi cementate: 3M Capital Hip



**Flanged**

**Roundback**

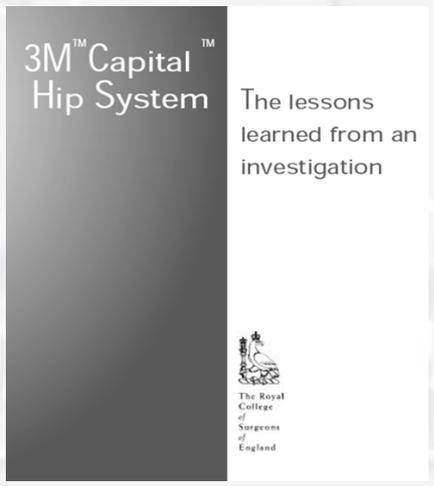
## Health Service Circular



Series number: HSC 1998/088  
Issue date: 1st May 1998  
Review date: 31st March 1999  
Category: Finance  
Status: Action

*sets out a specific action on the part of the recipient with a deadline where appropriate*

## 3M CAPITAL HIP SYSTEM - SECOND UPDATE



Royal College of Surgeons of England. 2001  
McGrath J Bone Joint Surg Br. 2001  
Janssen ORS, 2005

## The history of the Capital Hip

1991	Capital Hip used in UK hospitals until 1997
1992	
1993	First reports of problems with Capital Hip
1994	
1995	Questions raised at an orthopaedic conference about the performance of the Capital Hip
1996	Performance monitored by the Medical Devices Agency until 1998
1997	Capital Hips withdrawn from the market for commercial reasons
1998	Hazard Notice issued by Medical Devices Agency in February 1998
	Capital Hip Care Centre 24-hour free helpline immediately set up for patients
	Capital Hip investigation commissioned in June 1998
1999	
2000	Guidance on Total Hip Replacement published by National Institute for Clinical Excellence
	End of follow-up for the Capital Hip investigation
2001	Report on findings of the Capital Hip investigation and recommendations published

primi  
900 impianti



altri  
3700 impianti  
(sic)

IN THIS SITE...

- [+ About the NJR](#)
- [+ Patients](#)
- [+ Healthcare providers](#)
- [+ Research](#)
- [+ Implant suppliers](#)
- [+ News and Events](#)
- [+ Reports, Publications and Minutes](#)
- [+ Metal-on-Metal Hip Implants](#)

Home

## Welcome

**to the National Joint Registry (NJR) website.**

Hip, knee, ankle, elbow and shoulder joint replacements are common and highly successful operations that bring many patients relief from pain and improved mobility. Thousands of these joint replacement operations take place in the UK every year.

The National Joint Registry (NJR) was set up by the Department of Health and Welsh Government to collect information on all hip, knee, ankle, elbow and shoulder replacement operations and to monitor the performance of joint replacement implants.



### NJR website - three minute survey



The NJR is looking to refresh its website and we'd like to get your thoughts on the current site. Please take just three minutes to answer a quick survey - all responses are completely confidential. Thank you in advance for your time.

[> Click here to take the survey](#)

### NJR News and Events: Latest headlines

### NJR 9th Annual Report 2012



Read the report and see the highlights [here](#). Data from more than 1.2 million procedures are now registered on the NJR, with 2011-12 the first year for reporting hospital-level data.

[> Click here to go to the Report](#)

### StatsOnline



View and download NJR statistics.

[>StatsOnline](#)

### NJR Data Entry System



Enter data into the NJR

[> Data Entry](#)

System

### Quick links

- [> MHRA Device Alerts](#)
- [> Patient consent](#)
- [> NJR clinician feedback](#)
- [> Data collection forms](#)
- [> Data security and confidentiality](#)

# Cemento Boneloc



## *Promesse*

Ridotta tossicità

Bassa temperatura

Sistema chiuso

## *Fatti*

Fallimento precoce



1991 Lancio sul mercato

1993 Ritiro della pistola

1995 Ritiro del prodotto

>4500 pazienti (sic)

Linder Acta Orthop Scand 1995

Thanner Acta Orthop Scand 1995

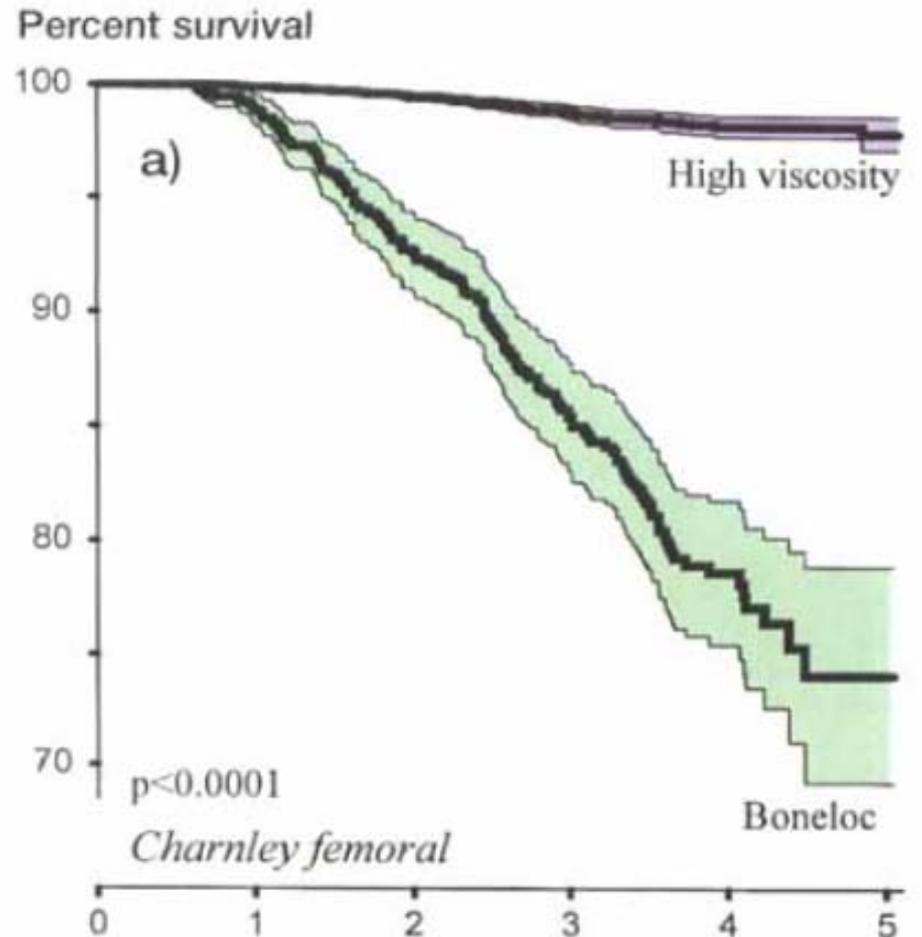
Gebuhr Acta Orthop Belg 2000

Walczac J Arthroplasty 2000

## Exeter and Charnley arthroplasties with Boneloc or high viscosity cement

Comparison of 1,127 arthroplasties followed for 5 years in the Norwegian Arthroplasty Register

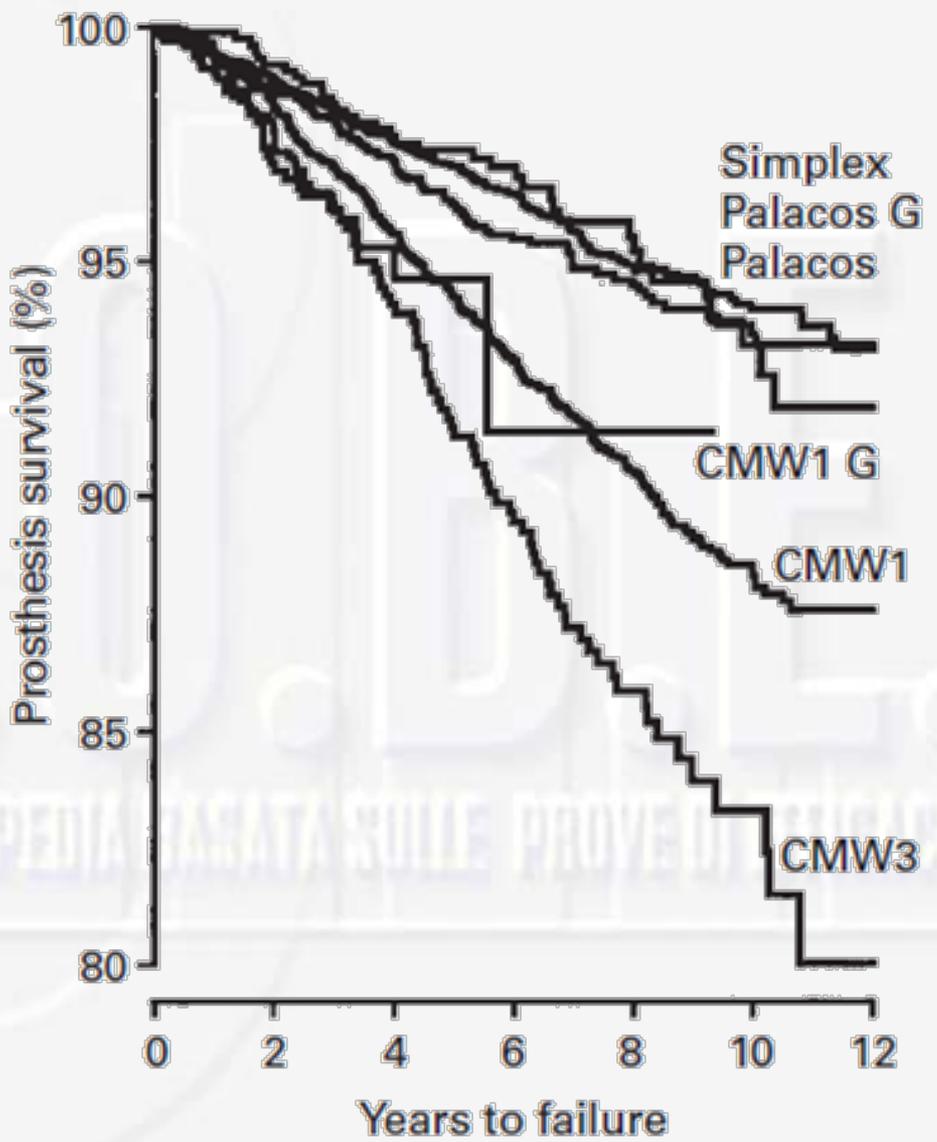
Ove Furnes<sup>1</sup>, Stein Atle Lie<sup>1,2</sup>, Leif Ivar Havelin<sup>1</sup>, Stein Emil Vollset<sup>2</sup> and Lars Birger Engesaeter<sup>1</sup>



# Protesi cementate: tipo di cemento e fallimento



*Protesi tipo Charnley fissata con diversi tipi di cemento*



# Mercato dei dispositivi impiantabili (fine anni '90)

Over 60 hip prostheses from 19 companies

Health Technology Assessment 1998, Vol. 2: No. 20

Review

**Primary total hip replacement surgery:  
a systematic review of outcomes and  
modelling of cost-effectiveness  
associated with different prostheses**

R Fitzpatrick  
E Shortall  
M Sculpher  
D Murray  
R Morris

M Lodge  
J Dawson  
A Carr  
A Britton  
A Briggs

- the commercial interest of manufacturing companies active in supplying the orthopaedic profession
- orthopaedic surgeons' creativity and ingenuity

Health Technology Assessment  
NHS R&D HTA Programme



# 1993

*Acta Orthop Scand* 1993; 64 (6): 699–716

## **Failed innovation in total hip replacement**

Diagnosis and proposals for a cure

Rik Huiskes

*Acta Orthop Scand* 1993; 64 (5): 497–506

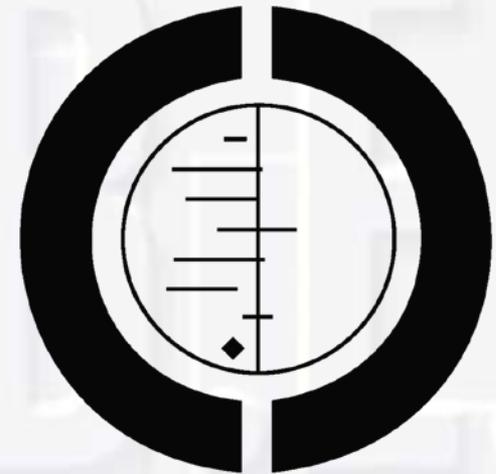
## **Prognosis of total hip replacement in Sweden**

Follow-up of 92,675 operations performed 1978–1990

Henrik Malchau, Peter Herberts and Lennart Ahnfelt

## **Designer hips**

*Don't let your patient become a fashion victim*

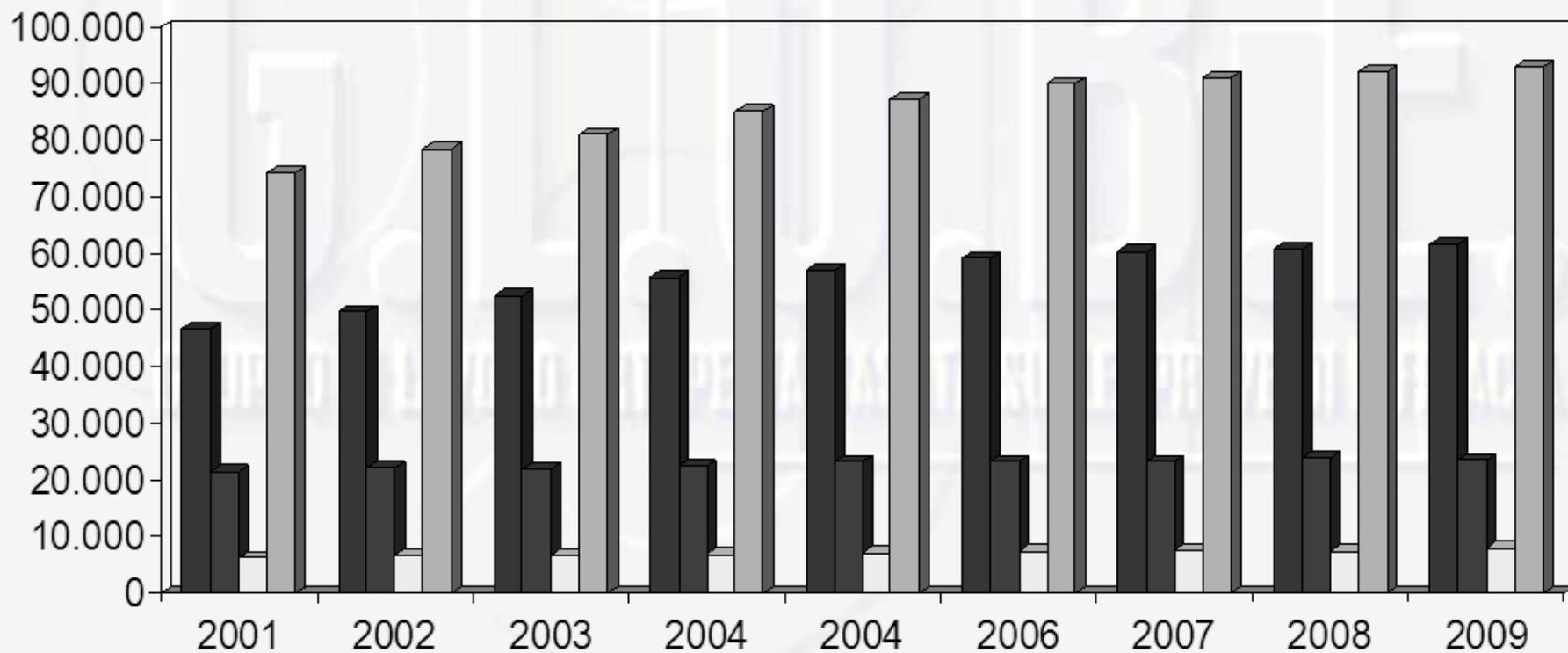


**THE COCHRANE  
COLLABORATION®**

*Fase della (im)maturità (<oggi)*



*Immaturi, 2011*



Guidance on  
the Selection of  
Prostheses for  
Primary Total Hip  
Replacement

April 2000

2000

# National Institute for Clinical Excellence Guidance on the Selection of Prostheses for Primary Total Hip replacement

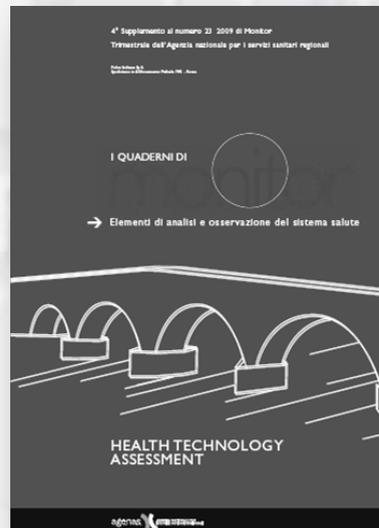
- Benchmark: 90% survival rate at 10 years
- Data from a number of centers
- Adequately sized studies
- RCT or observational (*consecutive non selected*)
- Available for peer-review

# EBM ed Health Technology Assessment in chirurgia protesica



1. Analisi epidemiologica
  2. RS (RCT)
- Oltre 200 sistemi

## G.L.O.B.E.



2007

1. Analisi epidemiologica
2. RS (RCT + registri)
3. Analisi costo-efficacia



- stelo Exeter Matt
- coppa Sulzer Inter-Op
- inserti Hylamer
- stelo Centralign
- teste in zirconia
- coppa Durom
- steli modulari (vari)
- **coppa ASR**

# Il caso ASR/XL

- 2003 introduzione sul mercato (FDA 2005)
- 2005 prime segnalazioni di fallimenti precoci
- 2007 registro australiano: RR a 2 anni 5.2% vs 2%
- 2008 FDA: 400 segnalazioni
- 2010 registro inglese: RR a 7 anni 12% vs 3%
- 2010 richiamo volontario dell'azienda (93.000 pz, sic)
- 2011 segnalazione del Ministero alle ASL
- 2012 *striscia la notizia*



# PROTESI DELL' ANCA: PERICOLO COBALTO



**Dott. FRANCESCO BIZZARRI**

**SPECIALISTA IN ORTOPEDIA E TRAUMATOLOGIA**

**STRASCIA**

**TABLE 1**

**Revision Rate of Primary Total Conventional Hip Replacement**

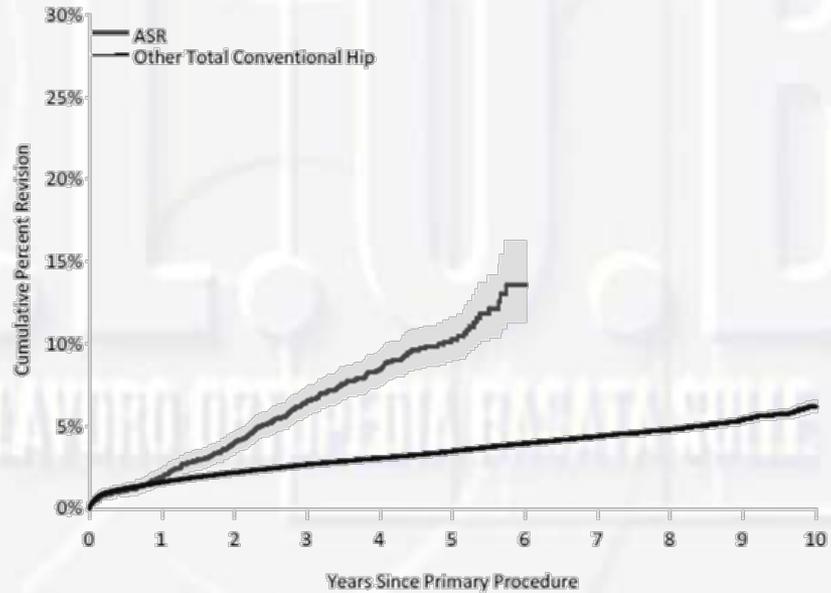
The **Revision Rate** of the ASR Total Conventional Hip Acetabular Prosthesis is compared to all Other Total Conventional Hip prostheses.



**Table 1: Revision Rates of Primary Total Conventional Hip Replacement**

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
ASR	329	4410	14826	2.22 (1.99, 2.47)
Other Total Conventional Hip	5992	192172	797892	0.75 (0.73, 0.77)
<b>TOTAL</b>	<b>6321</b>	<b>196582</b>	<b>812718</b>	<b>0.78 (0.76, 0.80)</b>

**Figure 1: Cumulative Percent Revision of Primary Total Conventional Hip Replacement**



HR - adjusted for age and gender  
 ASR vs Other Total Conventional Hip  
 0 - 2Wk: HR=1.37 (0.84, 2.26), p=0.210  
 2Wk - 1Mth: HR=0.27 (0.10, 0.72), p=0.009  
 1Mth - 9Mth: HR=1.14 (0.83, 1.55), p=0.418  
 9Mth - 1.5Yr: HR=3.03 (2.36, 3.90), p<0.001  
 1.5Yr+: HR=4.92 (4.25, 5.70), p<0.001

Number at Risk	0 Yr	1 Yrs	3 Yrs	5 Yrs	7 Yrs	10 Yrs
ASR	4410	4286	2565	567	0	0
Other Total Conventional Hip	192172	161406	112450	72956	38336	2803

**Table 3.11** Estimated revision rates following primary hip replacement for metal-on-metal prostheses (95% confidence intervals).

	Metal-on-metal type				
	Small head with conventional modular cup	Large head with conventional modular cup	Large head with resurfacing cup (excl. ASR)	Large head with ASR cup	All metal-on-metal stemmed prostheses
Year 1	1.23% (0.84%-1.79%)	1.38% (1.17%-1.63%)	1.18% (0.95%-1.48%)	1.24% (0.85%-1.82%)	1.29% (1.15%-1.45%)
Year 2	1.92% (1.41%-2.62%)	2.32% (2.03%-2.66%)	2.53% (2.15%-2.97%)	4.03% (3.23%-5.01%)	2.55% (2.33%-2.79%)
Year 3	2.92% (2.24%-3.82%)	3.47% (3.06%-3.93%)	4.10% (3.56%-4.71%)	7.50% (6.30%-8.92%)	4.10% (3.79%-4.44%)
Year 4	3.72% (2.87%-4.82%)	4.49% (3.94%-5.12%)	5.85% (5.08%-6.73%)	10.79% (9.16%-12.72%)	5.62% (5.19%-6.08%)
Year 5	4.74% (3.66%-6.15%)	5.17% (4.47%-5.96%)	7.48% (6.35%-8.81%)	17.16% (14.08%-21.00%)	7.26% (6.64%-7.94%)
Year 6	6.91% (5.20%-9.18%)	6.86% (5.25%-8.95%)	8.63% (6.78%-10.99%)	28.96% (17.80%-47.14%)	9.50% (8.34%-10.83%)
Base	2,250 (10.3%)	10,857 (49.5%)	6,694 (30.5%)	2,116 (9.7%)	21,917 (100%)

Note: numbers in the smaller sub-groups are too small to reliably estimate Year 7 revision rates. Small head refers to head diameter of less than 36mm. Large head refers to head diameter of 36mm or more.

1. **Innovazione**  
benefici vs rischi
2. **Formazione**  
chirurgica e metodologica
3. **Ricerca**  
*universal dilemma*
4. **Informazione**  
... o promozione?
5. **Regolamentazione**  
*marchio CE?*



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

Rajan Anand, MBBS, Stephen E. Graves, MBBS, DPhil, FAOrthA, Richard N. de Steiger, MBBS, Dip Biomech, FRACS(Orth), David C. Davidson, MBBS, FRCSEd, FAOrthA, Philip Ryan, MBBS, BSc, FAFPHM, Lisa N. Miller, BSc Hons (Math), and Kara Cashman, BSc Hons (O&G), Grad Dip Math Sc

*Investigation performed at the Australian Orthopaedic Association National Joint Replacement Registry, Adelaide, Australia*

**TABLE I Summary of Performance of New Hip Prostheses Used in More Than 100 Procedures**

Hip Prosthesis	Total No. of Components	Compared with the Three Best Performing Prostheses with Follow-up of $\geq 5$ Years		
		Better	Same	Worse
Cementless femoral	11	0	9	2
Cementless acetabular	12	0	9	3
Cemented femoral	1	0	0	1
Cemented acetabular	0	0	0	0
Resurfacing femoral	5	0	3	2
Resurfacing acetabular	4	0	2	2
<b>Total</b>	<b>33</b>	<b>0</b>	<b>23</b>	<b>10</b>

The current approach to the introduction of new prostheses does not appear to be either clinically efficacious or cost-effective

# Formazione (chirurgica)

## *Curva di apprendimento/learning curve*

Using innovative implants possibly exposes a patient to risks due to the **surgeon's inexperience** introducing the new surgical technique, perhaps leading to an increase of complication.

Huiskes R. Acta Orthop Scand 1993  
van Oldenrijk BMC Musculoskeletal Disorders 2008

The Journal of Arthroplasty Vol. 26 No. 6 2011

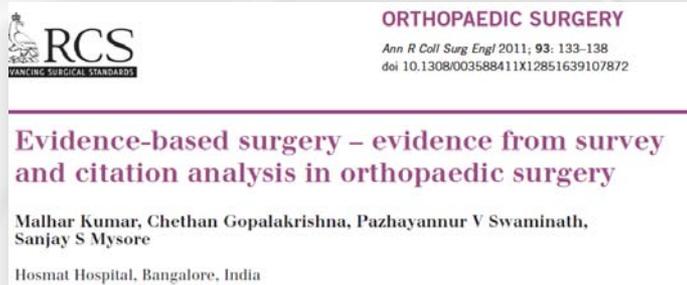
### **High-Flexion vs Conventional Prostheses Total Knee Arthroplasty: A Meta-Analysis**

Shi-xing Luo, MD, Wei Su, MD, Jin-min Zhao, MD, PhD, Ke Sha, MD,  
Qing-jun Wei, MD, and Xiao-feng Li, MD



# Formazione (metodologica)

Scarsa (ma crescente) conoscenza dell'EBM



*Kumar Ann R Coll Surg 2011*  
*Wallace BMJ Open. 2012*  
*J Can Surg 2012*



Bon augurio  
di buona lettura  
e di "Tever duro" selto  
i rischi di stanchezza  
Alessandro  
Liberati

# Ricerca in chirurgia protesica

The Journal of Arthroplasty Vol. 26 No. 6 2011

## **The Stepwise Introduction of Innovation into Orthopedic Surgery**

The Next Level of Dilemmas

Henrik Malchau, MD, PhD, Charles R. Bragdon, PhD, and Orhun K. Muratoglu, PhD

The **universal dilemma** is that unavoidable “gap” that always exists between the limits of *nonhuman research* and *what will actually occur in humans* after large-scale long-duration application of the new technology.

Malchau J Arthroplasty 2011

# Regolamentazione

The methods of device regulation seem to be more from the 1950s than the 21st century.”



**Medical Devices — Balancing Regulation and Innovation**

Gregory D. Curfman, M.D., and Rita F. Redberg, M.D.

# Informazione o promozione?

## Chirurgia di artroplastica di rivestimento dell'anca e del ginocchio

*"La protesi non è più una soluzione obbligata nelle patologie dell'anca. L'alternativa preferibile prevede la conservazione della testa del femore, che viene rivestita e difesa con sottili cupole metalliche. L'intervento è possibile a tutte le età"*



il Giornale • Sabato 8 settembre 2007

Una innovativa metodica mininvasiva, sviluppata in Inghilterra da McMinn, presenta notevoli vantaggi

## Protesi d'anca anche per gli sportivi

### Testimonianze



### Video dei risultati di pazienti operati di artroplastica di rivestimento dell'anca

Judoka: Paziente di 56 anni. Video eseguito 1 anno dall'intervento

Judoka: Paziente di 49 anni. Video eseguito 1 anno dall'intervento

Maratoneta: Paziente di 59 anni. Video eseguito 7 mesi dall'intervento

Maratoneta: Paziente di 37 anni. Video eseguito 6 mesi dall'intervento

Tennista: Paziente di 52 anni. Video eseguito 1 anno dall'intervento

# Conclusioni

- Know and understand the **evolution** of hip arthroplasty
- Selection of the prosthesis must be carefully made from sound clinical and **scientific data**
- **Before** embarking on a prosthesis program, establish an immediate and a prospective protocol for the operation during the neosurgical period and for an indefinite long-term follow-up
- Establish a **data bank** for easy and complete retrieval
- A surgeon should never lose the ability to review his or her own experience with **unbiased, objective scrutiny**

Mark B. Coventry

*Lessons learned in 30 years of THA, CORR 1992*

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chirurgia ortopedica

G.L.O.B.E.  


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[www.artrogruppo.it](http://www.artrogruppo.it) [www.globeweb.org](http://www.globeweb.org) [www.iss.it/riap](http://www.iss.it/riap)



# LA SANITÀ TRA RAGIONE E PASSIONE

Da Alessandro Liberati, sei lezioni per i prossimi anni



**PROGRAMMA PRELIMINARE**

BOLOGNA  
14 dicembre 2012

**LIB**  
TALKS

