



Registro Italiano
ArtroProtesi (RIAP)

**EPIDEMIOLOGIA
DI QUALITÀ AL SERVIZIO
DELL'ORTOPEDICO**

7 LUGLIO 2016
Aula Pocchiarri

ISTITUTO SUPERIORE DI SANITÀ
Viale Regina Elena, 299, Roma

Registri protesici: uno strumento per migliorare i propri risultati clinici

Luigi Zagra



ISTITUTO ORTOPEDICO GALEAZZI
ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO
Milan, Italy



Evidence Based Medicine

Potenza del disegno dello studio

- 
- » Revisioni sistematiche e Metanalisi
 - » Studi clinici controllati e randomizzati
 - » Studi di coorte
 - » Studi caso-controllo
 - » Studi osservazionali - **REGISTRI**
 - » Case reports
 - » (parere autorevole)

Cos'è un registro?

Archivio che raccoglie
un certo numero di parametri
della **totalità** degli eventi in esame
in scala :

- Ospedaliera (personale)
- Regionale
- Nazionale
- Sovranazionale

Cos'è un registro?

Attraverso un data set “minimo”,
su base volontaria
(al massimo ospedaliero in Italia)

ASL SOLV.

Paziente: _____

Cartella Clinica: _____

Operatore: _____

Caposala: _____

Strum: _____

Data _____

Firma del chirurgo _____

Lateralità: Dx Sx

Componente acetabolare - Cemento: Si No

Componente acetabolare - Viti: Si No

Componente femorale - Cemento: Si No

Modularità stelo: Si No

Diagnosi (solo in caso di primo impianto)

- Artrosi Primaria
- Artrosi post-traumatica
- Artriti reumatiche
- Neoplasia
- Necrosi asettica testa femorale
- Esiti di displasia o lussazione congenita
- Esiti di malattia di Perthes o epifisiolisi
- Frattura del collo e/o della testa del femore
- Altro

Causa del fallimento (solo in caso di revisione)

- Protesi dolorosa
- Osteolisi da detriti
- Usura dei materiali
- Rottura dell'impianto
- Lussazione
- Frattura periprotetica
- Infezione
- Esiti rimozione impianto
- Mobilizzazione asettica della coppa
- Mobilizzazione asettica dello stelo
- Mobilizzazione asettica totale
- Altro

Intervento precedente (sulla stessa anca)

- Nessuno
- Osteosintesi
- Osteotomia
- Protesi totale
- Reimpianto di protesi
- Spaziatore o rimozione impianto (Girdlestone)
- Artrodesi
- Protesi cefalica o bipolare
- Altro

Via di accesso

- Anteriore
- Antero-laterale
- Laterale
- Postero-laterale
- Altro

Osso di banca Si No

Fattori di crescita Si No

Sostituti dell'osso Si No

Frattura intraoperatoria Si No

| | Ditta | Prezzo |
|---------------------|-------|--------|
| Codice Coppa | | |
| Componente Insetto | | |
| Codice Testa | | |
| Codice Stelo | | |
| Osso di banca | | |
| Sostituti dell'osso | | |
| Fattori di crescita | | |
| Mezzi di sintesi | | |

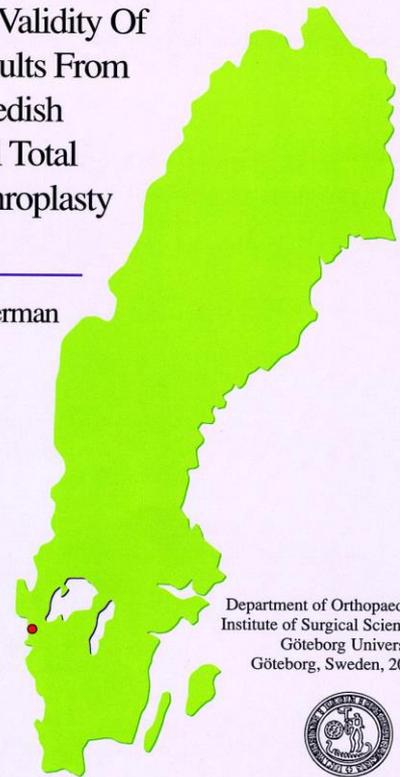
Consente di dare valutazioni
sulla efficacia e sulla efficienza:
di un impianto,
di una struttura (di un operatore),
sui fattori di rischio di una procedura (paziente).

Cos'è un registro?

Secondo il “modello svedese”, l'end-point è la revisione con sostituzione di almeno un componente della protesi.

On The Validity Of
The Results From
The Swedish
National Total
Hip Arthroplasty
Register

Peter Söderman



Department of Orthopaedics
Institute of Surgical Sciences
Göteborg University
Göteborg, Sweden, 2000



ASL SOLV.

Paziente: _____

Cartella Clinica: _____

Operatore: _____

Caposala: _____

Strum: _____

Data _____

Firma del chirurgo _____

Lateralità: Dx Sx

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Componente acetabolare - Viti: Si No

Componente femorale - Cemento: Si No

Modularità stelo: Si No

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- Osteolisi da detriti
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- Rottura dell'impianto
- Lussazione
- Frattura periprotetica
- Infezione
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- Mobilizzazione asettica della coppa
- Mobilizzazione asettica dello stelo
- Mobilizzazione asettica totale
- Altro

Intervento precedente (sulla stessa anca)

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- Osteotomia
- Protesi totale
- Reimpianto di protesi
- Spaziatore o rimozione impianto (Girdlestone)
- Artrodesi
- Protesi cefalica o bipolare
- Altro

Via di accesso

- Anteriore
- Antero-laterale
- Laterale
- Postero-laterale
- Altro

Osso di banca Si No

Fattori di crescita Si No

Sostituti dell'osso Si No

Frattura intraoperatoria Si No

| | Ditta | Prezzo |
|---------------------|-------|--------|
| Codice Coppa | | |
| Componente Insetto | | |
| Codice Testa | | |
| Codice Stelo | | |
| Osso di banca | | |
| Sostituti dell'osso | | |
| Fattori di crescita | | |
| Mezzi di sintesi | | |

Cos'è un registro ?

Curve di sopravvivenza degli impianti, aggiustate per età, sesso, diagnosi, ecc.

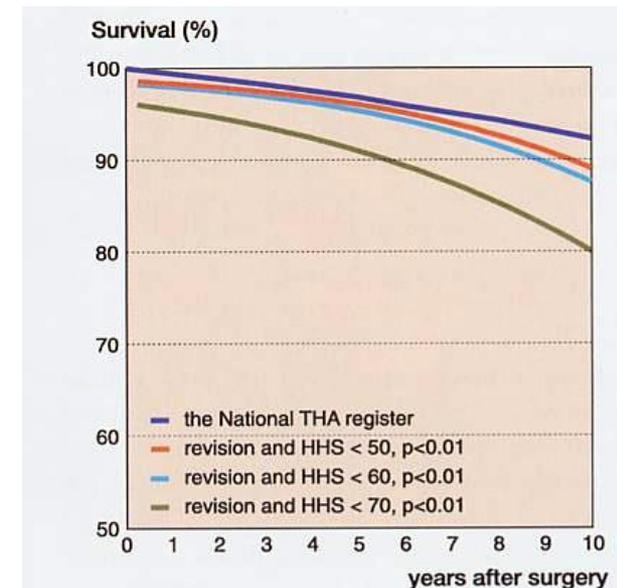
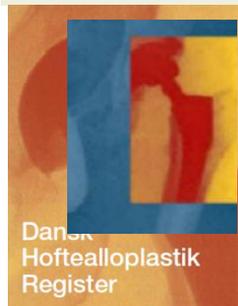


Figure 1. 10-years survival for all THA in the Swedish National Total Hip Arthroplasty Register (n=93,852) compared to the results of the clinical investigation due to Harris Hip Score (n=287).

Registri nazionali

- Scandinavi (NARA): Svezia ('78-'79), Finlandia ('80), Norvegia ('87), Danimarca ('95)
- Europa: Inghilterra e Galles ('02)
- Australia ('99)



Migliorare i risultati?

Prima ancora dei risultati...,
la pratica clinica.

Predicting Dissatisfaction After Total Hip Arthroplasty: A Study of 850 Patients

Raymond E. Anakwe, MRCS Ed, Paul J. Jenkins, MRCS Ed, and
Matthew Moran, MSc, FRCSEd (Tr & Orth)

- A major complication was not a predictor of dissatisfaction
- Postoperative functional scores, pain relief, and restoration of function
- Meeting patient's expectations

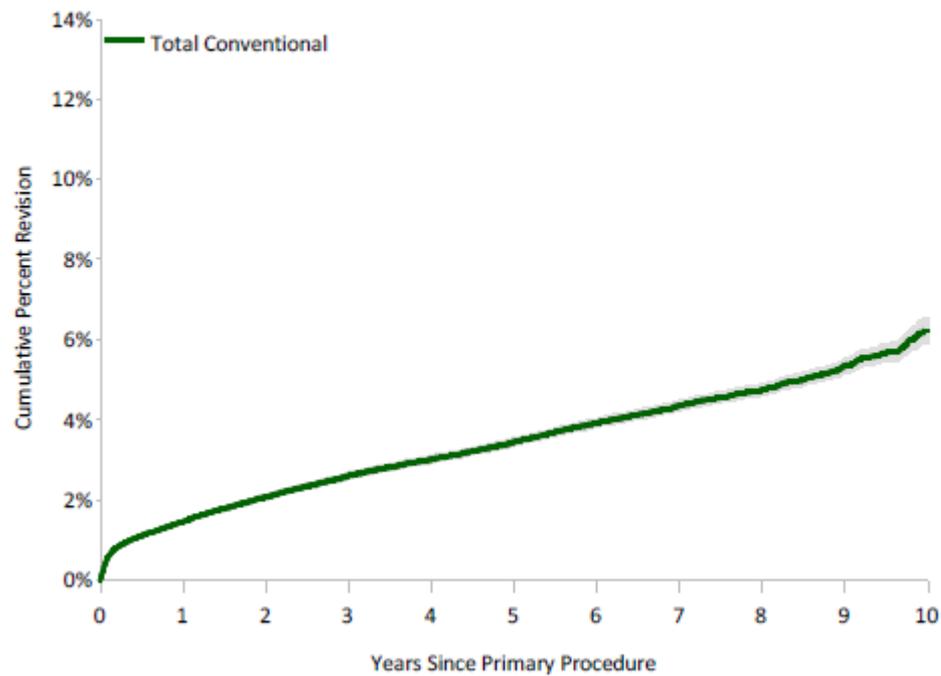
Patient Expectations and Health-Related Quality of Life Outcomes Following Total Joint Replacement

Marta Gonzalez Sáenz de Tejada, BS,¹ Antonio Escobar, PhD,¹ Carmen Herrera, PhD,² Lidia García, BS,³ Felipe Aizpuru, MD,⁴ Cristina Sarasqueta, MD⁵

- Unrealistic expectations are the main cause of dissatisfaction

Informazioni al paziente: Durata

Cumulative Percent Revision of Primary Total Conventional Hip Replacement (Primary Diagnosis OA)



Pazienti con meno di 40 anni

- **1984-1999: 1.1%**

Età media **66** (min 20 - max 93)

- **2000-2010: 4.2%**

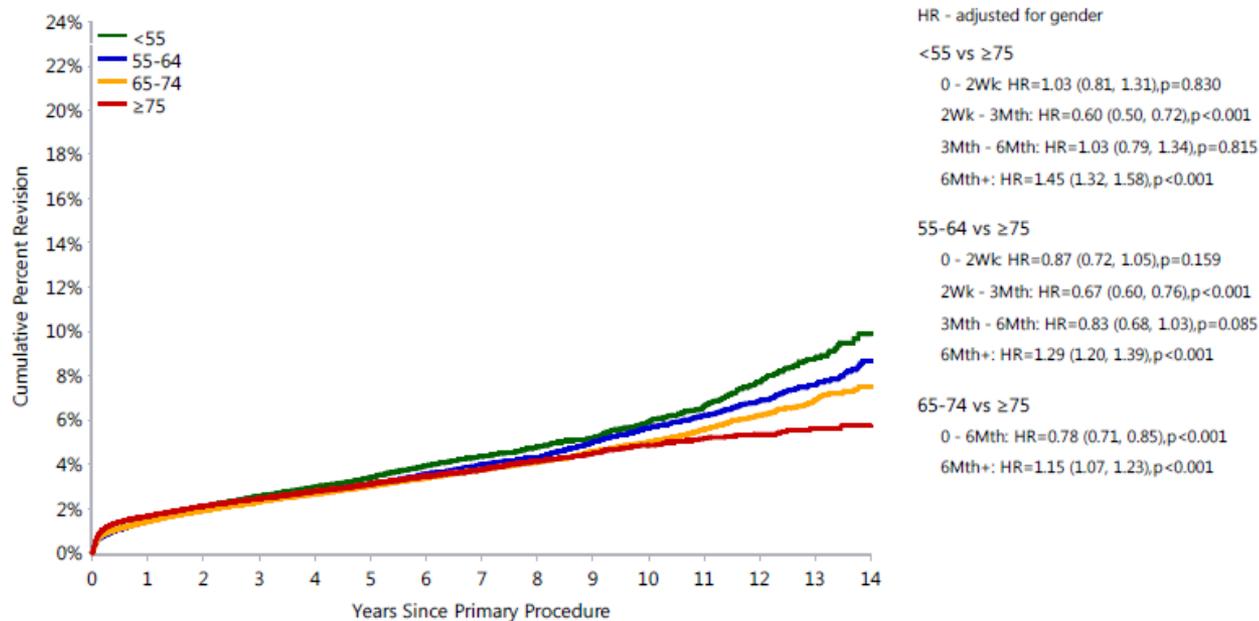
Età media **66** (min 18 - max 89)

- **2010-2015: 5.4%**

Età media **64** (min 16 - max 91)

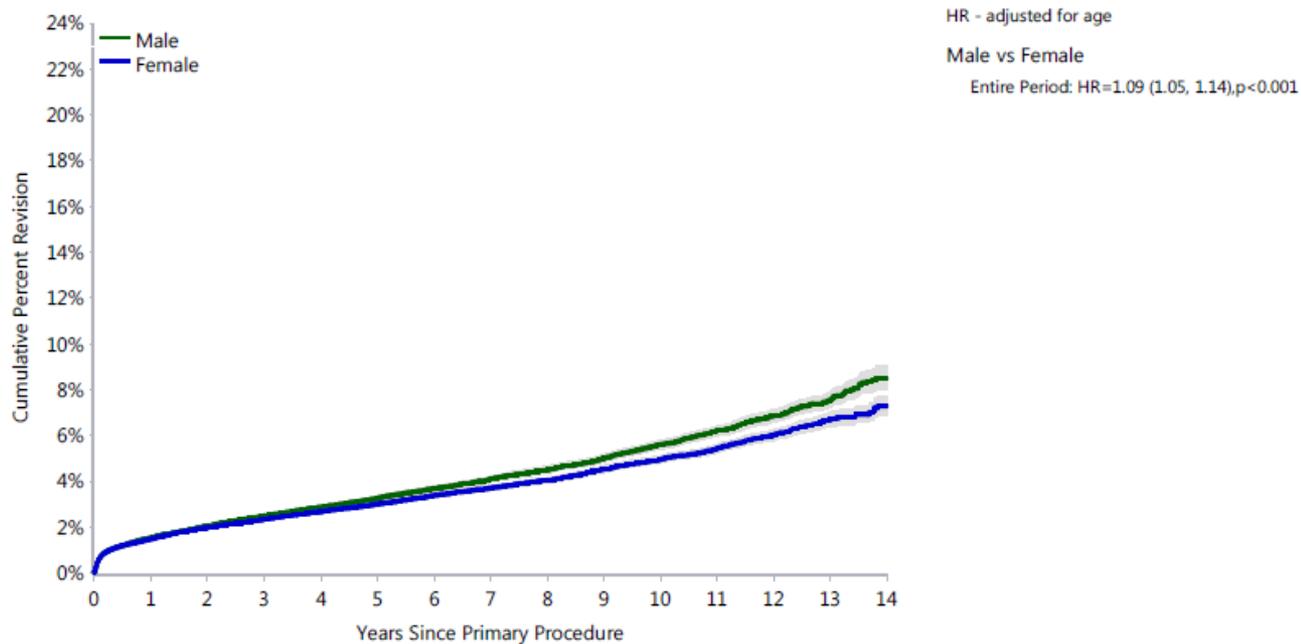
Informazioni al paziente: Età

Figure HT7 Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Age (Primary Diagnosis OA)



Informazioni al paziente: Sesso

Figure HT8 Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Gender (Primary Diagnosis OA)

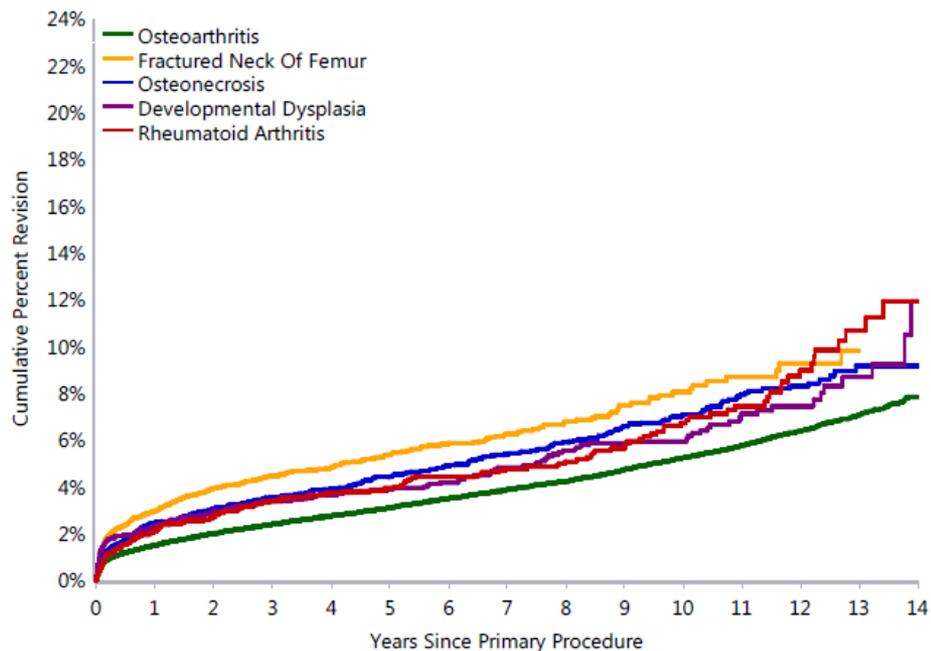


Migliorare i risultati?

Identificare i pazienti a rischio
(prevenzione delle complicanze).

Fattori di rischio: Diagnosi

Figure HT4 Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Primary Diagnosis



HR - adjusted for age and gender

Fractured Neck Of Femur vs Osteoarthritis
Entire Period: HR=1.82 (1.67, 1.98), p<0.001

Osteonecrosis vs Osteoarthritis

0 - 6Mth: HR=1.43 (1.23, 1.67), p<0.001

6Mth - 9Mth: HR=2.65 (1.94, 3.63), p<0.001

9Mth+: HR=1.24 (1.09, 1.40), p<0.001

Developmental Dysplasia vs Osteoarthritis

0 - 2Wk: HR=2.54 (1.69, 3.82), p<0.001

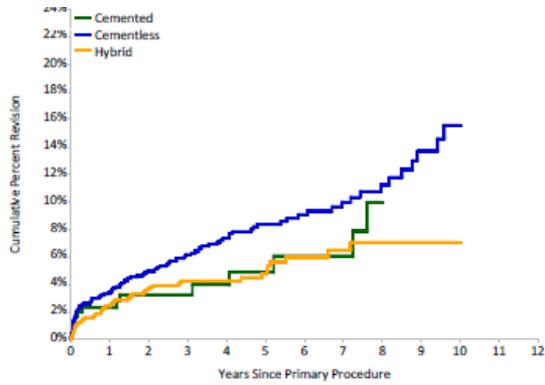
2Wk - 1Mth: HR=1.87 (1.24, 2.80), p=0.002

1Mth - 3Mth: HR=1.20 (0.74, 1.95), p=0.450

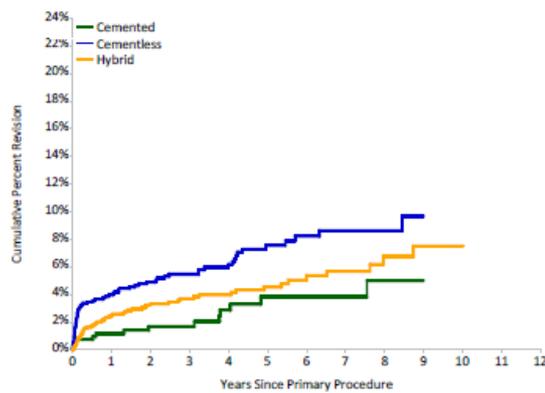
3Mth+: HR=1.05 (0.87, 1.27), p=0.623

Rheumatoid Arthritis vs Osteoarthritis

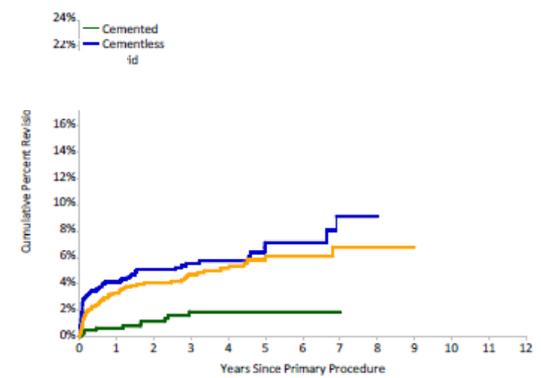
Entire Period: HR=1.33 (1.14, 1.55), p<0.001



< 70 years



70 - 79

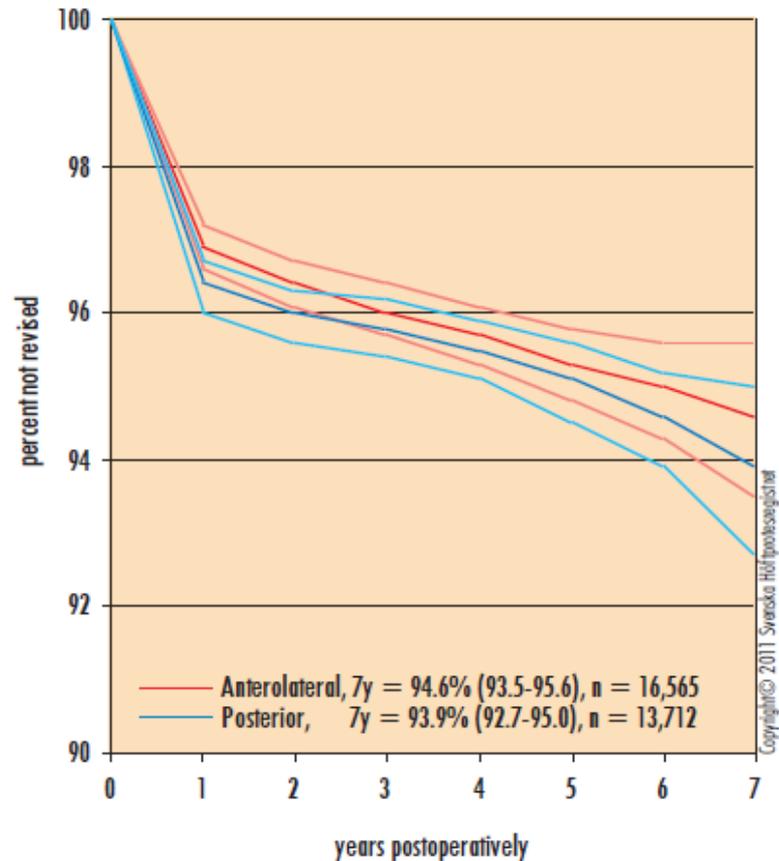


> 80 years

“Cement fixation of the stem has the lowest rate of revision in the younger than 70 and 70-79 year age groups. In the 80 or older cementing both the stem and the cup has the lowest rate of revision”.

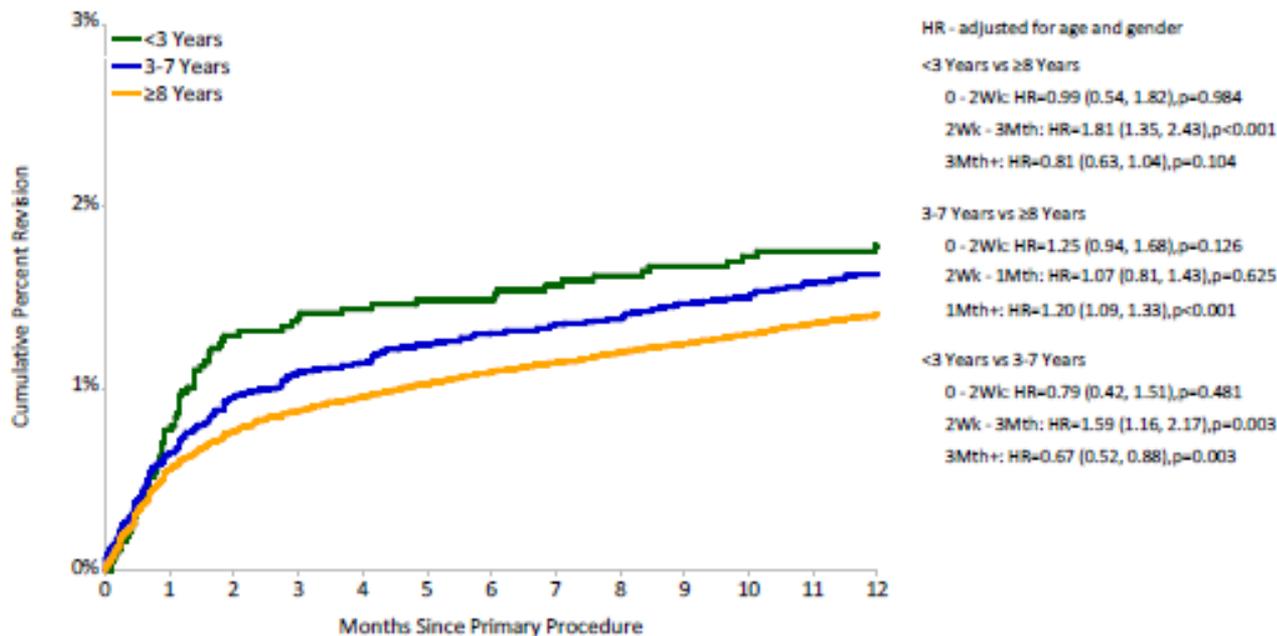


Type of approach
2005-2011



“Posterior approaches continue to lead to an increased risk for dislocation-related operation, but not for reoperation in general”.

Fattori di rischio: L'esperienza del chirurgo

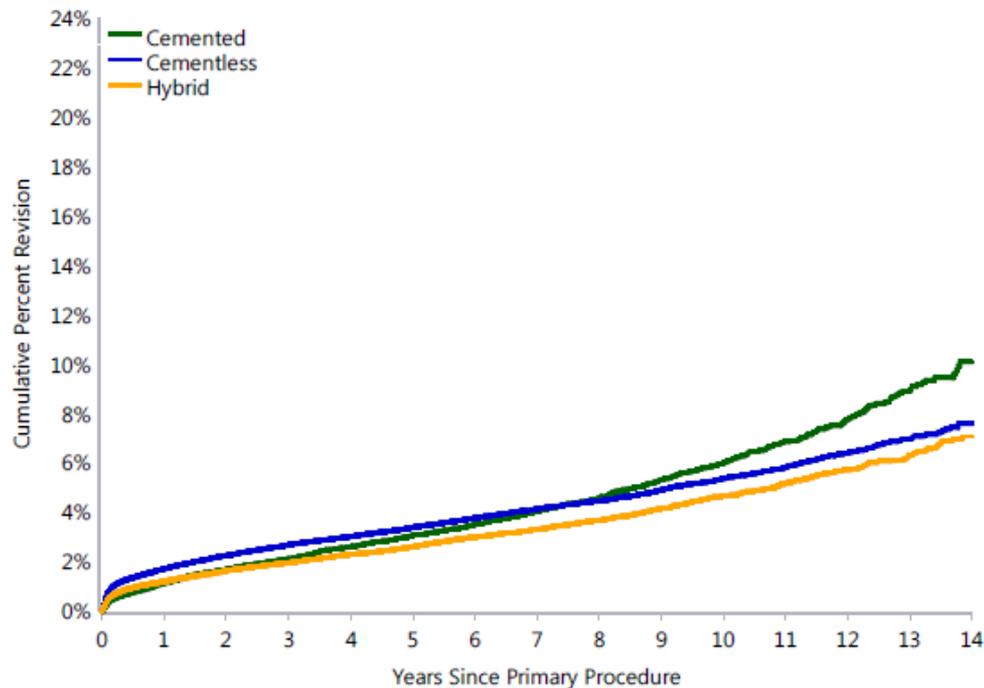


Migliorare i risultati?

La scelta dell'impianto....

Tipo di fissazione

Figure HT11 Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Fixation (Primary Diagnosis OA)



HR - adjusted for age and gender

Cemented vs Hybrid

0 - 1Mth: HR=0.62 (0.47, 0.81), p<0.001
 1Mth - 6Mth: HR=0.97 (0.78, 1.20), p=0.784
 6Mth - 1.5Yr: HR=1.49 (1.24, 1.80), p<0.001
 1.5Yr+: HR=1.44 (1.32, 1.59), p<0.001

Cementless vs Hybrid

0 - 2Wk: HR=1.77 (1.48, 2.11), p<0.001
 2Wk - 3Mth: HR=1.37 (1.24, 1.52), p<0.001
 3Mth - 6Mth: HR=1.14 (0.95, 1.36), p=0.156
 6Mth - 3Yr: HR=1.33 (1.22, 1.45), p<0.001
 3Yr+: HR=0.98 (0.91, 1.06), p=0.636

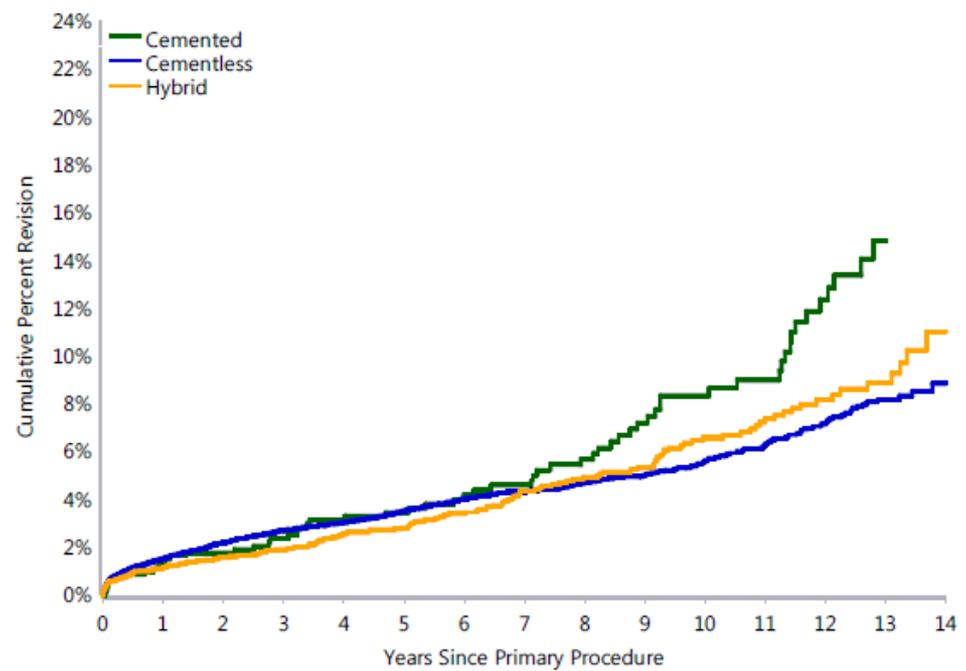
Cementless vs Cemented

0 - 1Mth: HR=2.48 (1.90, 3.23), p<0.001
 1Mth - 3Mth: HR=1.27 (1.04, 1.54), p=0.017
 3Mth - 1.5Yr: HR=0.99 (0.86, 1.15), p=0.931
 1.5Yr - 3Yr: HR=0.93 (0.81, 1.06), p=0.258
 3Yr - 3.5Yr: HR=0.64 (0.51, 0.81), p<0.001
 3.5Yr - 5Yr: HR=0.76 (0.65, 0.89), p<0.001
 5Yr - 5.5Yr: HR=0.71 (0.54, 0.92), p=0.009
 5.5Yr - 6.5Yr: HR=0.79 (0.64, 0.97), p=0.025
 6.5Yr+: HR=0.62 (0.55, 0.70), p<0.001

Tipo di fissazione

Età minore di 55 anni

Figure HT12 Cumulative Percent Revision of Primary Total Conventional Hip Replacement for Patients Aged <55 Years by Fixation (Primary Diagnosis OA)



HR - adjusted for age and gender

Cemented vs Hybrid
 Entire Period: HR=1.40 (1.05, 1.88), p=0.022

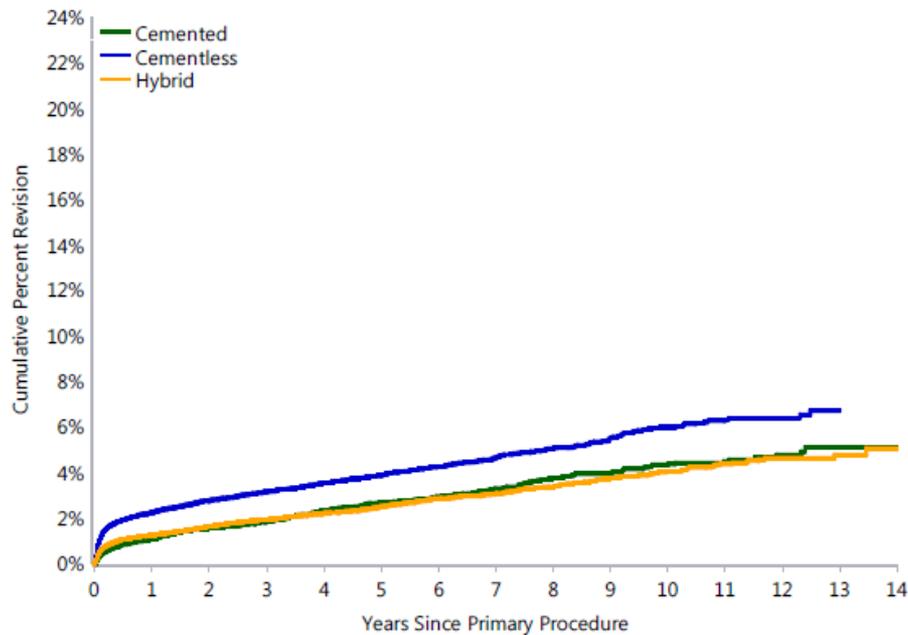
Cementless vs Hybrid
 0 - 3Mth: HR=1.37 (0.95, 1.96), p=0.089
 3Mth - 6Mth: HR=1.22 (0.65, 2.29), p=0.528
 6Mth - 1.5Yr: HR=1.44 (0.94, 2.19), p=0.094
 1.5Yr - 2.5Yr: HR=2.45 (1.31, 4.57), p=0.005
 2.5Yr+: HR=0.70 (0.57, 0.87), p=0.001

Cementless vs Cemented
 0 - 3Mth: HR=0.98 (0.64, 1.49), p=0.912
 3Mth - 2.5Yr: HR=1.15 (0.79, 1.68), p=0.472
 2.5Yr+: HR=0.50 (0.38, 0.67), p<0.001

Tipo di fissazione

Età maggiore di 75 anni

Figure HT15 Cumulative Percent Revision of Primary Total Conventional Hip Replacement for Patients Aged ≥ 75 Years by Fixation (Primary Diagnosis OA)



HR - adjusted for age and gender

Cementless vs Cemented

0 - 2Wk: HR=5.11 (2.51, 10.41), p<0.001

2Wk - 3Mth: HR=1.82 (1.52, 2.19), p<0.001

3Mth+: HR=1.19 (1.04, 1.37), p=0.012

Hybrid vs Cemented

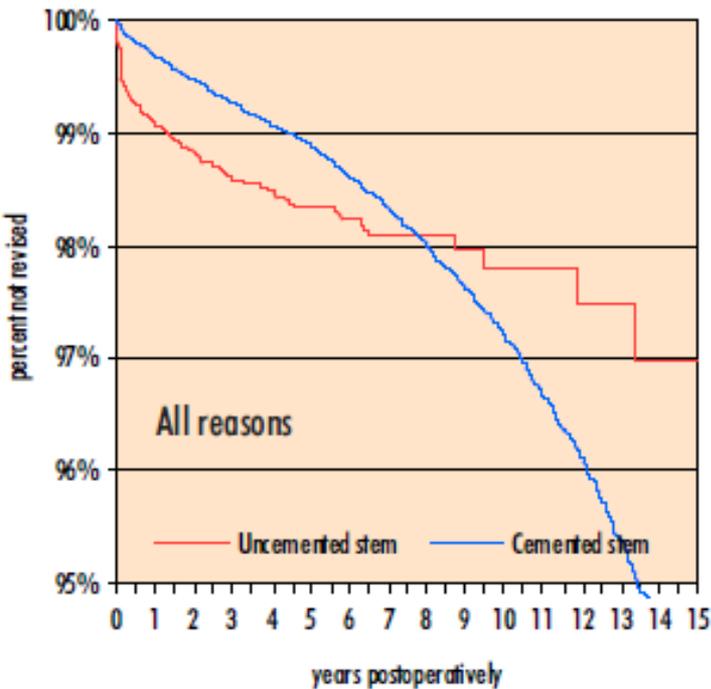
0 - 2Wk: HR=2.74 (1.32, 5.66), p=0.006

2Wk+: HR=0.91 (0.80, 1.04), p=0.155

Cementless vs Hybrid

0 - 3Mth: HR=1.89 (1.64, 2.18), p<0.001

3Mth+: HR=1.34 (1.20, 1.49), p<0.001



In summary we find no clear differences between cemented and uncemented fixation regarding risk of revision irrespective of cause. The different ways of fixing an implant are associated with different types of complications. When choosing fixation, many factors are involved such as the patient's individual bone quality, the surgeon's normal practice and the risk of general influences in the use of bone cement in seriously ill patients. However the data indicate extra caution and careful weighing of these factors one against another if one consider uncemented fixation an older patient. The data also indicate that uncemented stems are preferable in men under 50 years of age.

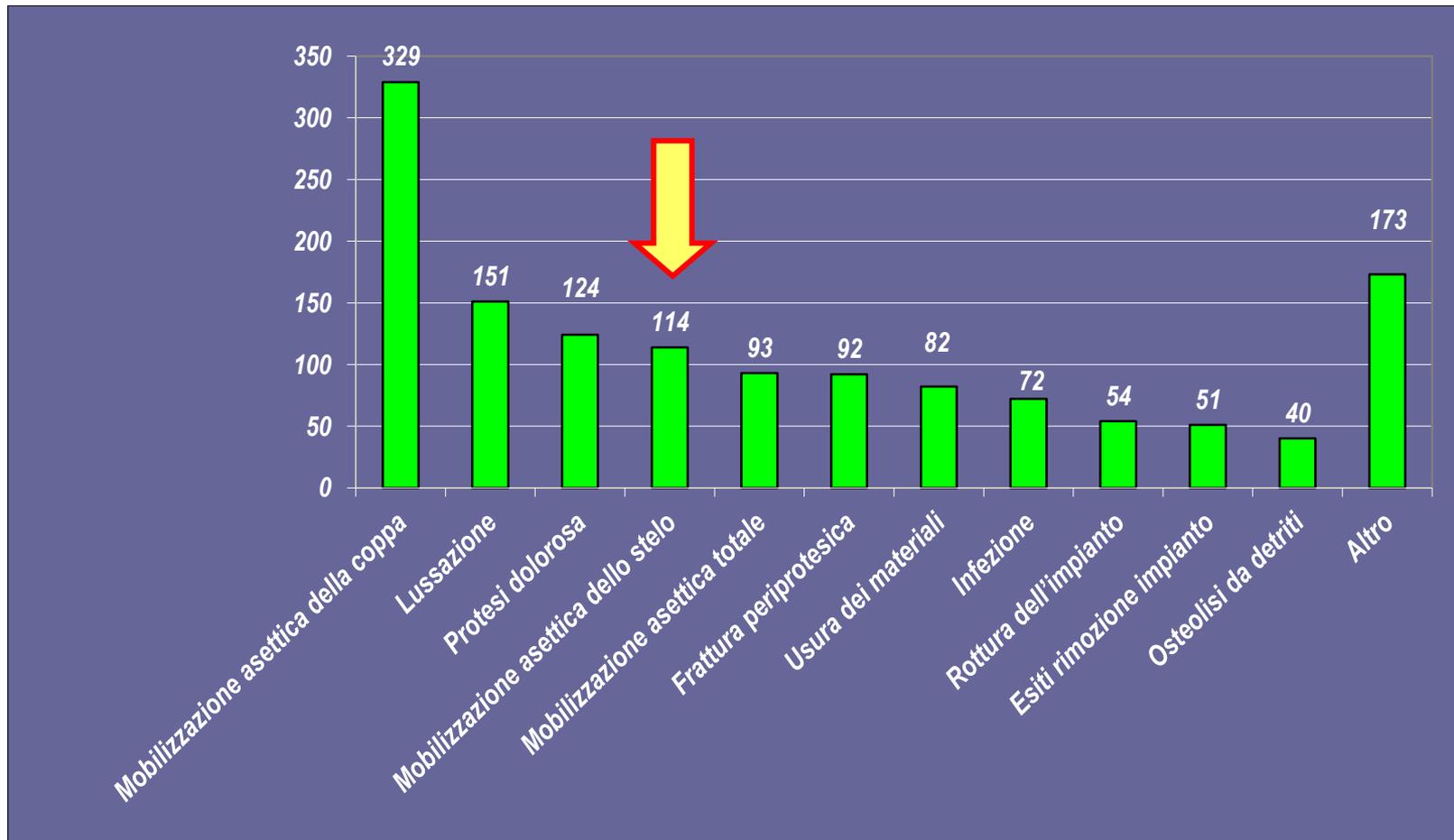
Steli corti

Conclusion

In analysed Arthroplasty Register datasets
all short stems included in this analysis
have

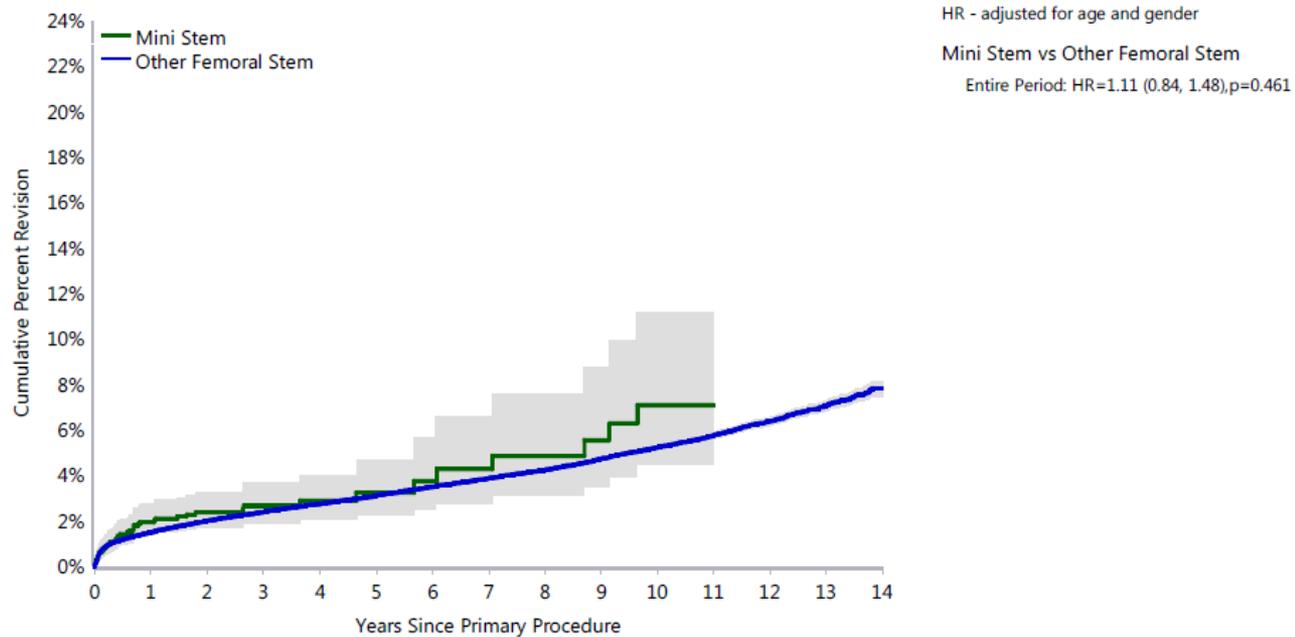
- NOT shown higher revision rates in the first years after surgery,
 - which could be considered as an indicator for improper primary stability.
- Mid term revision rates are similar to conventional total hip arthroplasty.

Il fallimento dello stelo è “solo” la quarta ragione di revisione



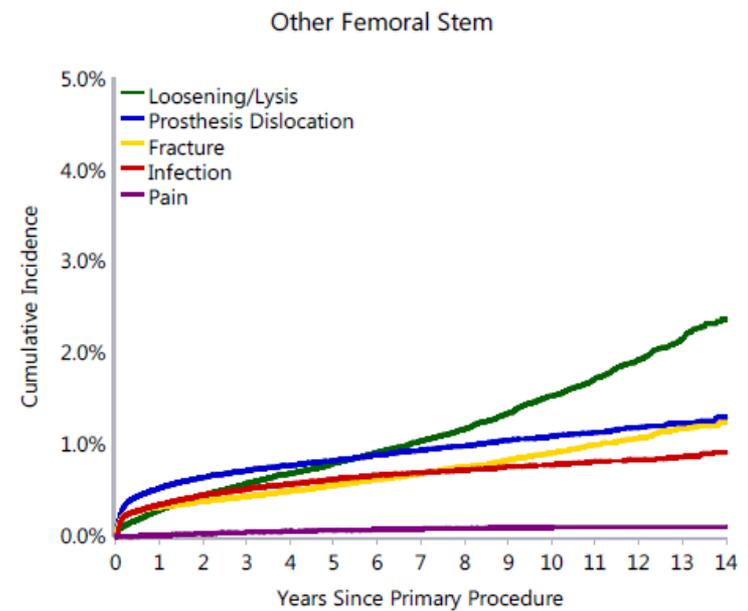
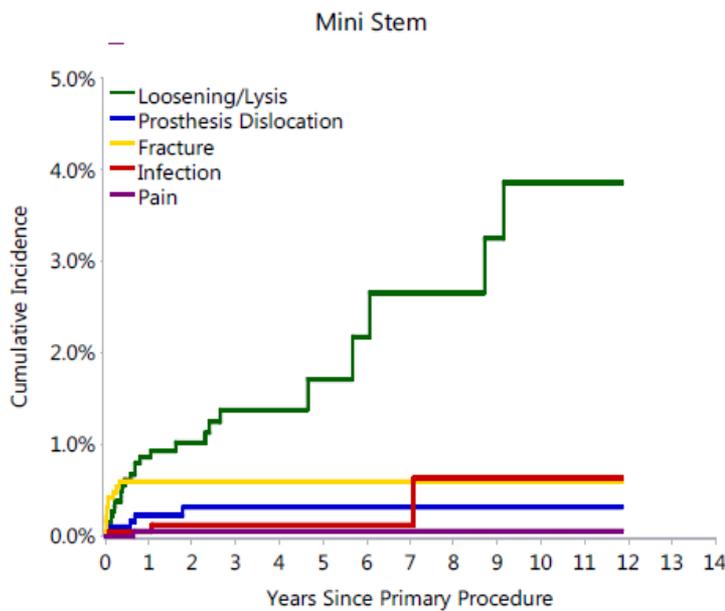
Steli corti

Figure HT16 Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Stem Type (Primary Diagnosis OA)

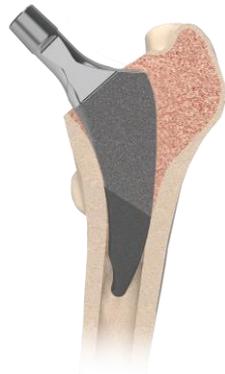


Steli corti

Figure HT17 Cumulative Incidence Revision Diagnosis of Primary Total Conventional Hip Replacement by Stem Type (Primary Diagnosis OA)



Studi clinici controllati

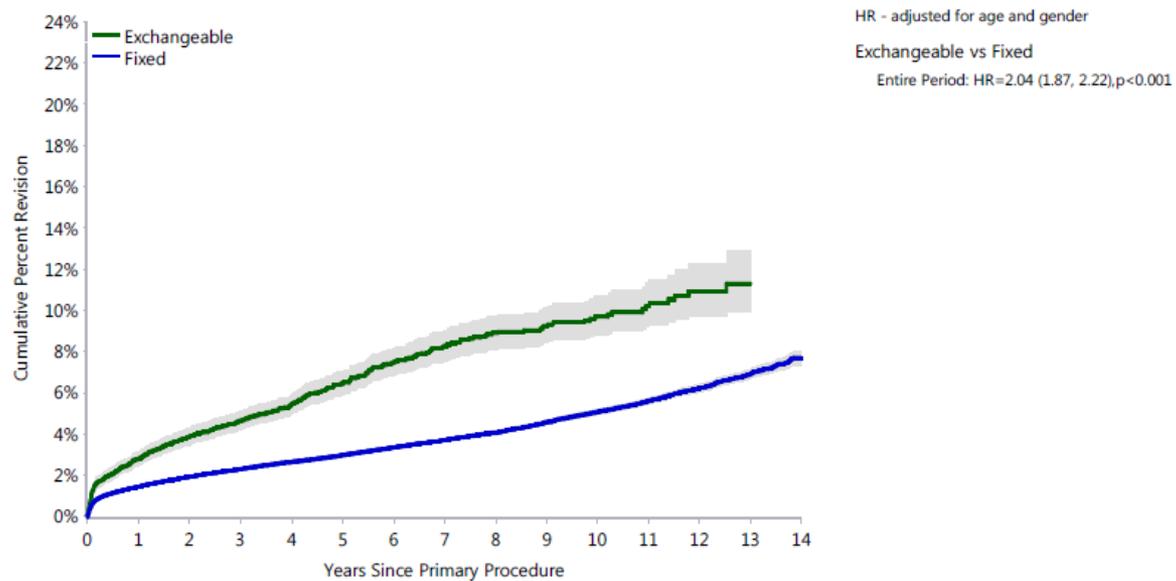


Study activities

| | Preop | Intraop | Discharge | 6 wks. | 6 mo. | 1 yr. | 2 yr. | 5 yr. |
|--------------------------|-------|---------|-----------|--------|-------|-------|-------|-------|
| Radiographic evaluations | x | | x | X | | x | x | x |
| VAS | x | | | X | x | x | x | x |
| TUG | x | | | X | x | x | x | x |
| HOOS | x | | | X | x | x | x | x |
| UCLA | x | | | X | x | x | x | x |
| HHS | x | | | x | x | x | x | x |
| Surgery and implant data | | x | | | | | | |

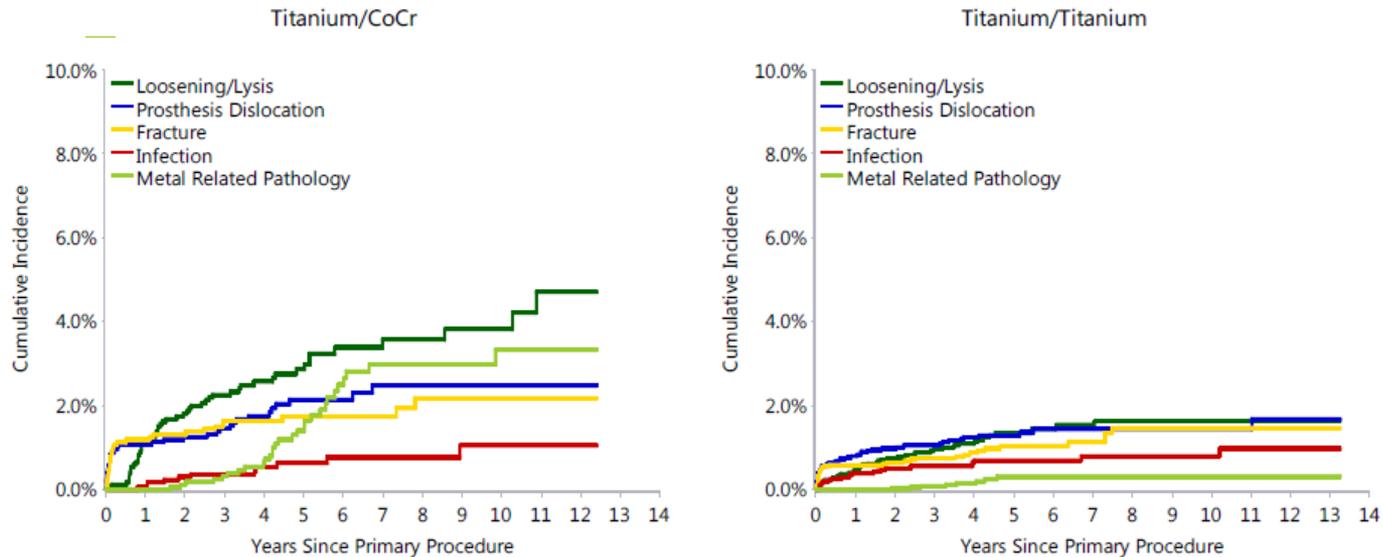
Colli modulari

Figure HT18 Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Type of Femoral Neck (Primary Diagnosis OA)



Colli modulari

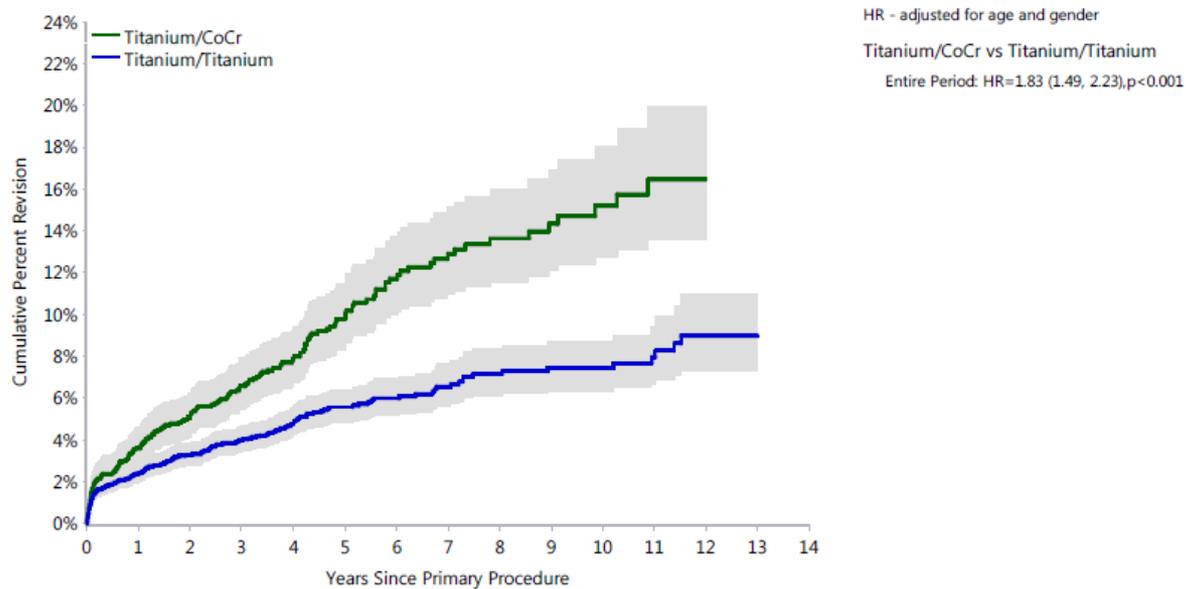
Figure HT22 Cumulative Incidence Revision Diagnosis of Primary Total Conventional Hip Replacement by Stem/Neck Material (Primary Diagnosis OA)



Doppio rischio di revisione per qualsiasi causa

Colli modulari

Figure HT21 Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Stem/Neck Material (Primary Diagnosis OA)



Migliorare i risultati?

Risultati..., cosa funziona, ma soprattutto cosa **NON** funziona.

Guest Editorial

H Malchau, S Graves, M Porter, WH Harris, A Troelsen

The next critical role of orthopedic registries

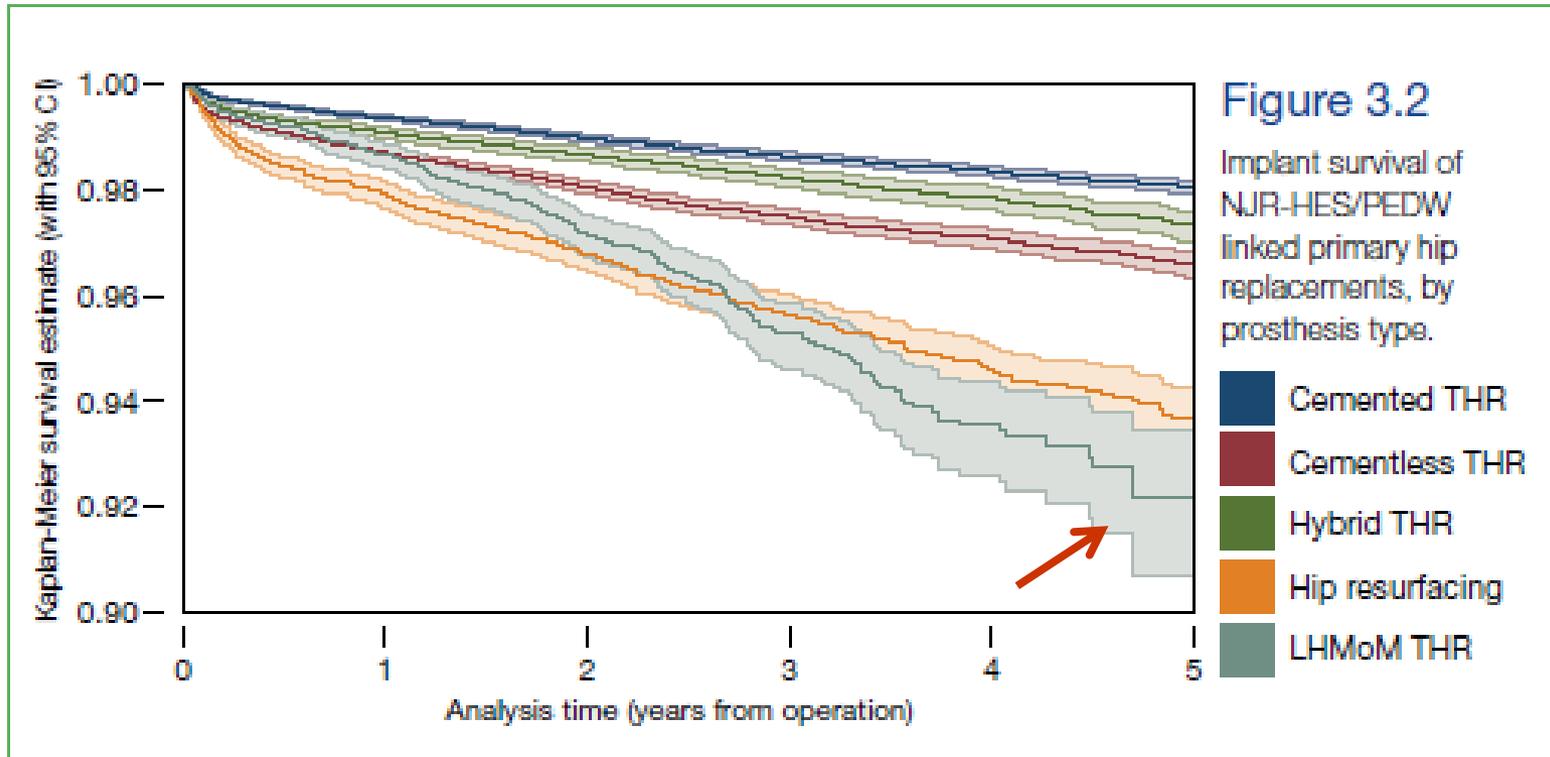
“Registry post-market surveillance has proven to be a powerful method for detection of increased risk of implant failure”.

Il “caso” metallo-metallo



Un esempio

Tasso maggiore di revisioni con met-met



© National Joint Registry 2010



National Joint Registry
www.njrcentre.org.uk



BHS statements on Large Diameter Metal on Metal bearing Total Hip Replacements

- The BHS advises that stemmed, large diameter metal-on-metal primary total hip replacements using bearings of 36 mm or above **should no longer be performed** until more evidence is available, except in properly conducted and ethically approved research studies.
- **This advice does not apply to hip resurfacing**



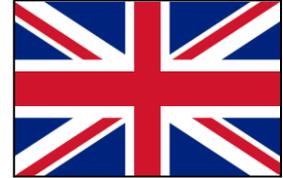
NEDERLANDSE
ORTHOPAEDISCHE
VERENIGING | NOV

Dutch Orthopaedic Association/Nederlandse Orthopaedische Vereniging (NOV)
Bruistensingel 128, 5232 AC 's Hertogenbosch, The Netherlands, E: nov@orthopeden.org

THE USE OF METAL-ON-METAL HIP REPLACEMENTS:
MORE STRICT ADVICE TO NOV MEMBERS, 17 JANUARY 2012

- **The utilization of all MoM with large heads (>36mm) must be suspended**

2012



Medical Device Alert

Ref: MDA/2012/008 Issued: 28 February 2012 at 11:00

Device

All metal-on-metal (MoM) hip replacements

Problem

The MHRA is issuing updated information and advice about the management and monitoring of patients implanted with metal-on-metal (MoM) hip replacements.

Action by

- Medical directors.
- Orthopaedic departments.
- Orthopaedic surgeons.
- Staff involved in the management of patients with joint replacement implants.

CAS deadlines

Action underway: 28 March 2012

Action complete: 30 April 2012

Action

Put updated systems in place for the follow-up and investigation of patients implanted with MoM hip (see appendix).

Note: The recommendations in this Medical Device Alert (MDA) replace the advice previously given in MDA/2010/033 and MDA/2010/069.

2013



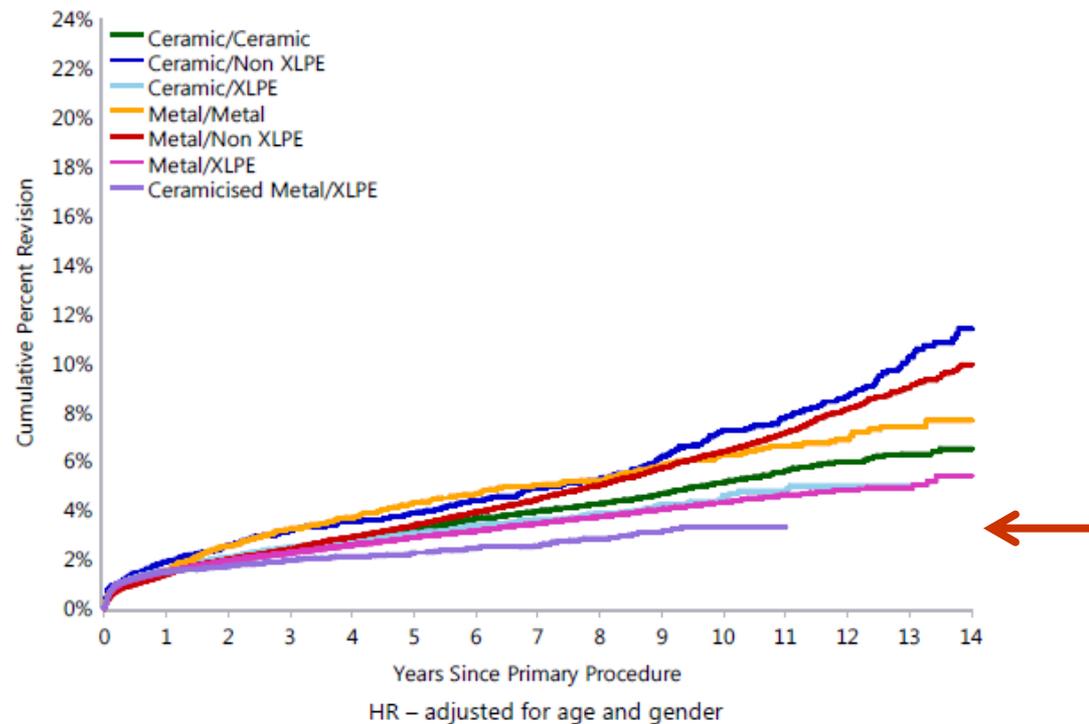
SCENIHR

Scientific Committee on Emerging and Newly Identified Health Risks

The safety of metal-on-metal joint replacements with a particular focus on hip implants

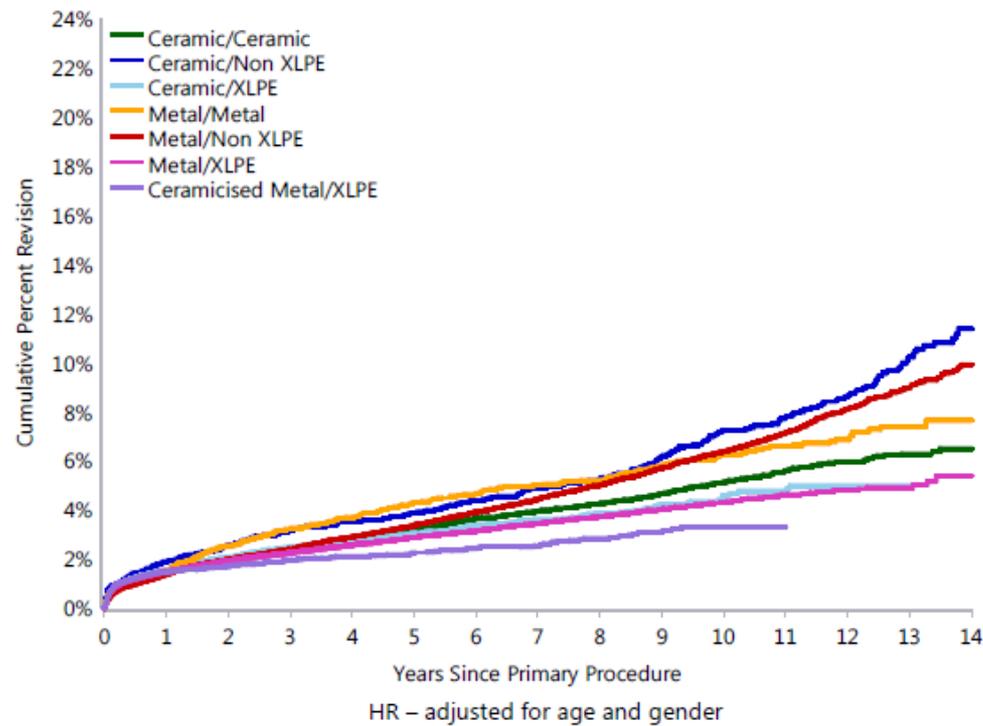
Sopravvivenza accoppiamenti (Oxinium)

Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Bearing Surface (Primary Diagnosis OA)



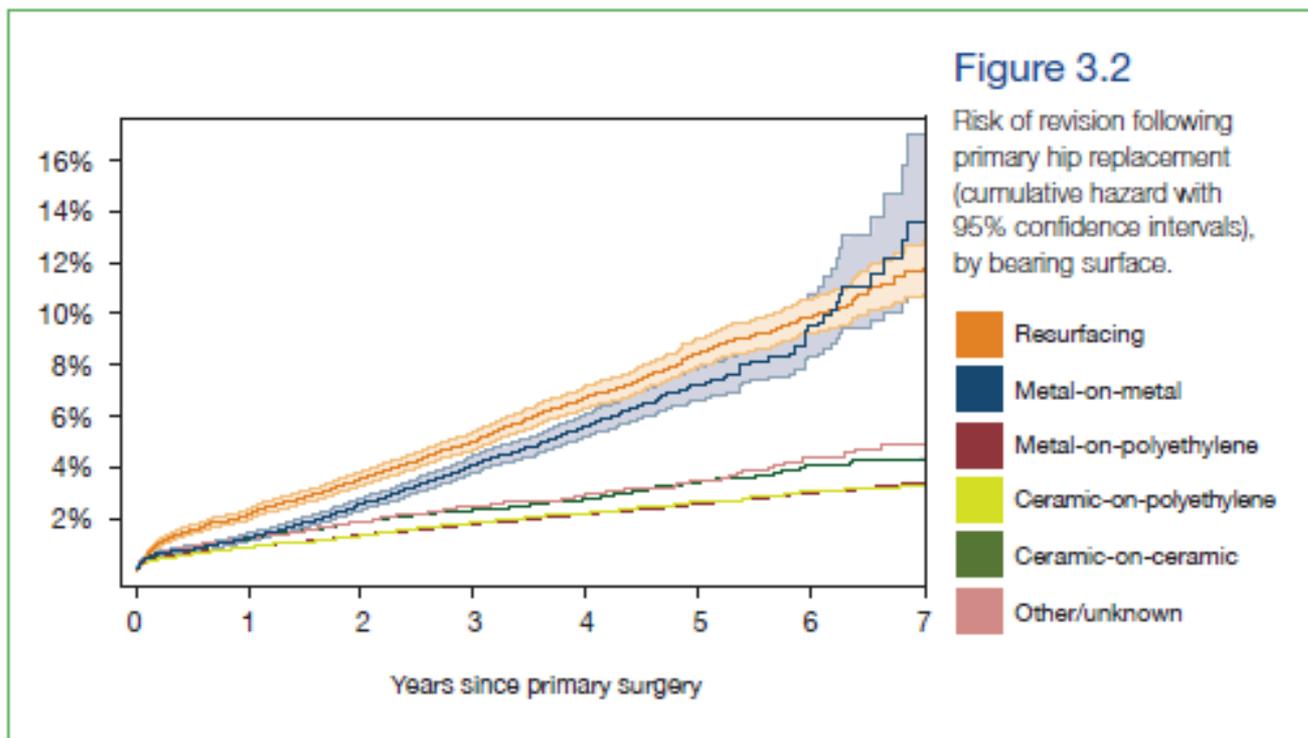
Sopravvivenza accoppiamenti

Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Bearing Surface (Primary Diagnosis OA)



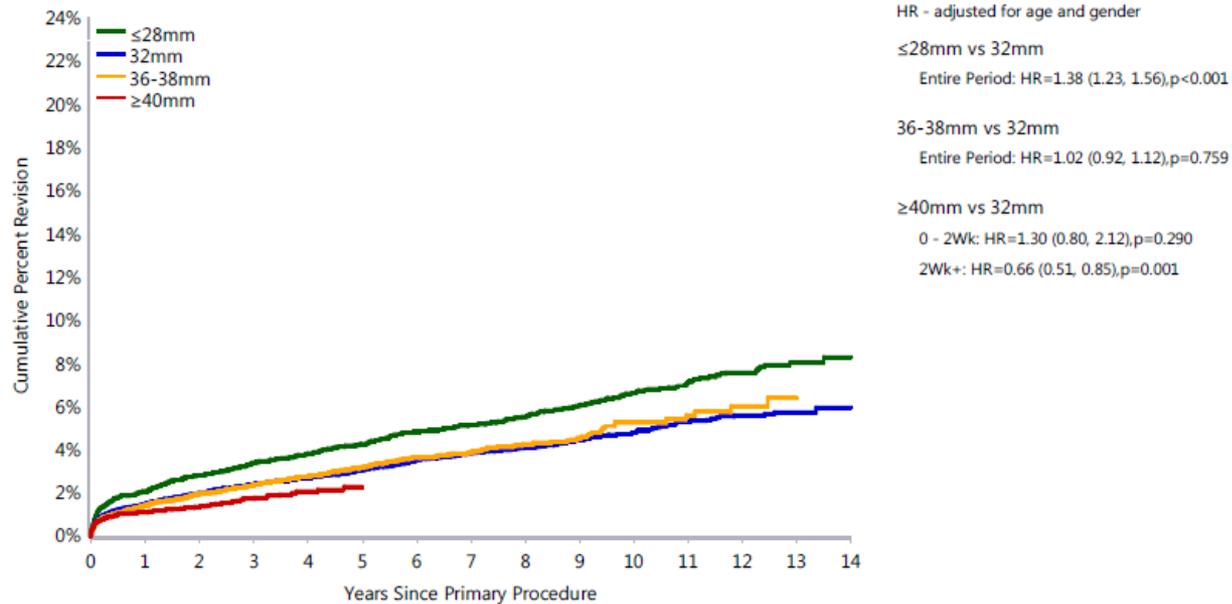


Sopravvivenza accoppiamenti



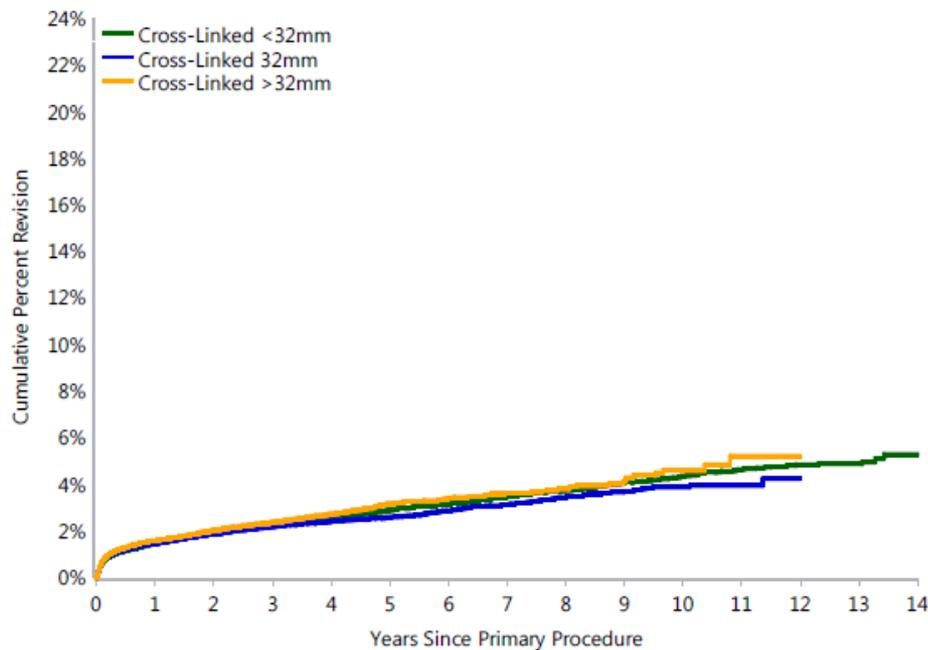
Ceramica-ceramica (diametro testa 32-36mm ...)

Figure HT44 Cumulative Percent Revision of Ceramic/Ceramic Primary Total Conventional Hip Replacement by Head Size (Primary Diagnosis OA)



Cross-linked Poly (diametro testa 32-36mm)

Figure HT27 Cumulative Percent Revision of Primary Total Conventional Hip Replacement using Cross-linked Polyethylene by Head Size (Primary Diagnosis OA)



HR - adjusted for age and gender

Cross-Linked <32mm vs

Cross-Linked 32mm

0 - 1Mth: HR=0.95 (0.82, 1.10),p=0.503

1Mth+: HR=1.12 (1.03, 1.21),p=0.009

Cross-Linked >32mm vs

Cross-Linked 32mm

Entire Period: HR=1.12 (1.03, 1.21),p=0.006

Cross-Linked >32mm vs

Cross-Linked <32mm

Entire Period: HR=1.04 (0.96, 1.13),p=0.324

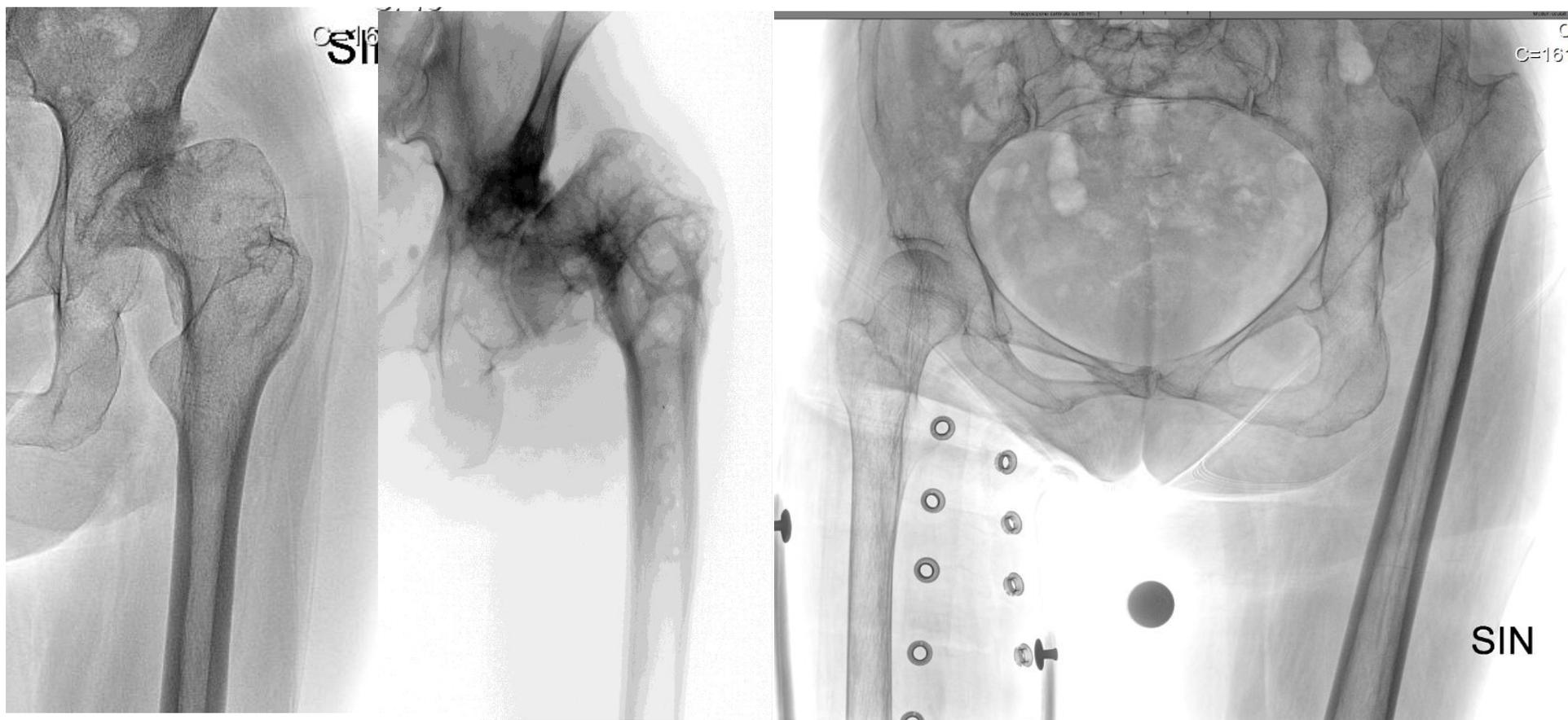
Indicazioni e tecnica

Dipendono dalla qualità dell'osso, dalla morfologia e dalle dimensioni (artrosi primaria)



Indicazioni e tecnica

Dipendono dalla qualità dell'osso, dalla morfologia e dalle dimensioni (LCA)



Guest Editorial

H Malchau, S Graves, M Porter, WH Harris, A Troelsen

The next critical role of orthopedic registries

“Implant performance is potentially confounded by the technical difficulty of inserting the implant, the knowledge and abilities of the surgeon inserting them, and the complexity of the cases.

Many registries monitor performance at the surgeon level.

This together with continuous education and training in how to use new implants should be an integral part of the process”.

Conclusioni

- Ruolo crescente dei registri come strumento primario di valutazione dell'outcome (safety e security dei dispositivi)

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- Strumento imprescindibile per le indicazioni e la comunicazione con i pazienti

Conclusioni

- Ruolo crescente dei registri come strumento primario di valutazione dell'outcome (safety e security dei dispositivi)
- Strumento imprescindibile per le indicazioni e la comunicazione con i pazienti
- I dati vanno interpretati, per questo è necessaria l'attiva collaborazione di tutta la comunità scientifica

Grazie!

