Afspejler vores kliniske praksis den bedste nuværende evidens?

Hvilken evidens har vi? - hvad praktiserer vi?

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Disclosures

• **Related to present study:**
  • Nothing

• **Outside present study:**
  Research support from Zimmer, Smith & Nephew, DePuy and Biomet
  Educational and advisory consultant for Smith & Nephew, MAKO and Biomet
  Royalty from Smith & Nephew
  Board member and share holder in RSA Biomedical Inc.
The world scene for orthopedic registries

- It has become a movement - 8 countries with full coverage
- We have an international society for arthroplasty registries - ISAR
- We have been asked to perform post market surveillance for the US population – ICOR
- We have NARA, the first established multi national registry collaboration.
- We can replace most of the pre- and post market approval process when new technology is introduced
This presentation is based on the Swedish experience on introduction of new hip implant technology.

“1995”
The system we propose is based on a stepwise principle.

“1995”
Our patients have the right to be protected from unexpected hazards.
Quality assurance of joint replacement. Legal regulation and medical judgment.

...we have no quarrel with surgeons engaged in prosthetic development...But the question of how and when to market innovations should not entirely be their own decision...
Henrik Malchau  
Ph.D. Thesis 1995

On the importance of Stepwise Introduction of New Implant Technology.

Assessment of Total Hip Replacement using Clinical scoring, Radiostereometry, Digitized Radiography and a National Hip Registry.
Stepwise

Preclinical Testing

Initial Step

Prospective Randomized Studies

Multicenter Studies

Clinical Step I

Clinical Step II

Clinical Step III

Register Studies


retrieval and explant analysis
Evidence-based introduction

The hypothesis

A more precise and careful evaluation when new implant technology is introduced will reduce the number of patients at risk for unexpected failures.

“1995”
Stepwise introduction
Clinical step I

• Prospective, randomized trials.
  RSA, DEXA.
• Evaluation by clinical score systems.
Clinical step I study

Evaluation of Boneloc®
Chemical and mechanical properties, and a randomized clinical study of 30 total hip arthroplasties.

J. Thanner et al.
Acta Orthop Scand 1995;
“1995”

Subsidence stem-bone
Boneloc® vs. Palacos® (mean and SE)

manova: p=0.009
"1995"
Norwegian Registry
Havelin et al, JBJS 77-A, 1995

The Effect of the Type of Cement on Early Revision of Charnley Total Hip Prostheses.

"...The relative risk for stem revision was 8.7 times higher for Boneloc® compared to high viscosity cements..."
Step I studies that should have been performed

• Option precoat stem, The Capital Hip, MIS, carbon reinforced poly, hylamer, HG1 Stem, M-o-M articulations and several other uncemented/cemented systems.
“1995”
Stepwise introduction
Clinical step II

• Open prospective trials and prospective, multicenter trials.
  - Conventional radiography
  - Clinical score systems
“1995”

Stepwise introduction
Clinical step II

• Multicenter study
  - facilitates collection of patients
  - expose the implants to multiple surgeons
  - has potentially a complete registration of complications
“1995”

Stepwise introduction
Clinical step III

• Register studies
  - Observational
  - Regional or nationwide
Malchau, H., Bragdon, C., Muratoglu, O.

The Stepwise Introduction of Innovation into Orthopaedic Surgery: The Next Level of Dilemmas

The “stepwise concept” of introduction could be a major advance if applied appropriate and not delaying important innovations to reach the marketplace in due time.
Compromises in the introduction process are driven by

- The magnitude of the problem addressed (incidence and severity)
- The advantages and risks of the proposed solution
Compromises in the introduction process are driven by

- The “universal dilemma,” meaning the inherent “gap” between all the non-human supporting data versus the unknowns of both efficacy and long-term safety in large human usage over many years.
Three examples

- The first generation highly cross-linked polyethylene
- The recent disaster with metal-on-metal large head THA.
- The general increase in use of uncemented THA in the elderly population
Polyethylene

• How should the risks of late appearance of periprosthetic osteolysis, be balanced against the known risk of continuing to use conventional polyethylene until final proof is evident that the new material actually does decrease the incidence of lysis?
The John Charnley Award 2012:

Clinical Multi-centric Studies of the Wear Performance of Highly Cross-linked Re-melted Polyethylene in THR

1Charles R. Bragdon PhD, 1Michael Doerner BA, 1Harry E. Rubash MD, 1Young-Min Kwon MD, PhD, 2John Martell MD, 3John Clohisy MD, 4Richard White MD, 5Craig Della Valle MD, 6Daniel Berry MD, 1Bryan Jarrett BS, 7Paul Lachiewicz MD, 8Kim Bertin MD, 9Per-Erik Johanson MD, 10 Henrik Palm MD, 1W.H.Harris MD
1Henrik Malchau MD

1Massachusetts General Hospital, Boston, MA, 2University of Chicago Medical Center, Chicago, IL, 3Washington University in St. Louis, St. Louis, MO, 4Presbyterian Hospital, Albuquerque, NM, 5Rush University Medical Center, Chicago, IL, 6Mayo Medical School, Rochester, MN, 7Chapel Hill Orthopedics, Chapel Hill, NC, 8Utah Bone & Joint Center, Salt Lake City, UT, 9Sahlgrenska University Hospital, Gothenburg, Sweden, 10Hvidovre Copenhagen University, Denmark
• How many patients will suffer from osteolysis complications due to late acceptance of the “new” highly cross-linked technology?
The Metal-on-Metal disaster

• How should the increasing incidence of revision due to recurrent dislocation after THA be addressed?
  • Larger head sizes

• As a consequence we got a fast acceptance and high usage of large head resurfacing M-o-M and the concept was expanded to conventional stemmed THA.
The Metal-on-Metal disaster

- The different implant systems got CE and FDA clearance mainly based on similarity (510K) with existing implants.
- The soft-tissue adverse reactions in some patients had given us a new and completely “man made” disease.
- The problem identified through registries
Ban metal-on-metal hip replacements, experts urge
Research published in the Lancet finds 'unequivocal
evidence' of high failure rates of implants, particularly
among women
Number of stemmed metal-on-metal implants by head size - NJR 2003–11
Risk of revision by bearing surface
A review of current fixation usage and registry outcomes in THA
The Uncemented Paradox
Question/purposes

• To investigate trends for usage of uncemented fixation in national registries
• To analyze age stratified risk of revision comparing cemented, hybrid, and uncemented fixation by inquiry to national hip arthroplasty registries.
Uncemented fixation of all primary total hip replacements
Sweden and Australia reporting the least increase (5% increase)
Denmark the greatest increase (21% increase)
Outcome on cemented, uncemented and hybrid THR in patients >75 years

- DK, Aus, Eng, NZ: Significant lower risk of revision following cemented vs. uncemented fixation
Uncemented fixation of all total hip replacements performed in patients >75 years

Data could not be extracted for DK in 2006
Who is to blame, why don’t we follow best practice guidelines as identified in the registries?

- The physicians or the industry?
What motivates the surgeon to adopt new technology?

I want to do the best I can for my patients.

temptations
Motivators for Physicians to Adopt New Technology

• Clinical Benefit - the most noble

• Competition – to be the “latest and greatest”

• Consumer Demand –“I’ll have what she’s having”

• Manufactures ( advertising or other incentives)
Famous People’s Hip

Jack

"Get your life back like I did."

Jimmy

Mary Lou Retton

Biomet Total Joint Replacement Recipient

Floyd
Why has the concept of stepwise introduction not been more generally applied?

• A particularly complex feature of this dilemma is the interaction between the inventors and the orthopaedic implant manufacturing industry.
• The motivations of the inventor and industry may not necessarily be completely aligned.
• An appropriate interplay between inventor and industry is essential for the advancement of the field.
The solution?
ISAR
International Society of Arthroplasty Registries
(www.isarhome.org)

Aim
1. Support network for established and developing registries
2. Encourage cooperation and sharing of information
3. Encourage collaborative activities
4. President: Göran Garellick, Sweden
5. First International Congress in Norway May, 2012
Nordic Arthroplasty Register Association
• improved facilities for post market surveillance
• faster system for early warnings?
Post marked surveillance for orthopedic implants in US

- Post marked surveillance will in part be done based on aggregated data from Regional US Registries and National Registries outside of US
ICOR
International Consortium of Orthopedic Registries

• Establish the Consortium to:
  • leverage data from existing registries
• Advance methods to study device performance and patient outcomes
• Help enhance and harmonize the registry data worldwide
• Improve research collaboration
• FDA Public Workshop - held May 9, 2011
  • 35 registries present
  • All major stakeholders
• How can we prevent the M-o-M to happen in the future?
• Premarket approval process (510K) seems insufficient.
• IDE studies have not been efficient either
“The regulatory framework for implants varies worldwide, but has been generally much less rigorous than for drugs. Widespread surveillance of existing implants is urgently needed.”

Carr et al. Lancet 2012
Resolution of the issues
Go back to Stepwise

• Premarket approval studies could be performed through small scale multi-national randomized studies.

• Post-market surveillance could be established through multi-centric, non-inventor studies.

• Both models, with level I-IV data, should be monitored by the established national registries.
Resolution of the issues
Go back to Stepwise

- Governance Structure (world-wide representation)
  - Orthopedic surgeons, Health care payers, Regulatory bodies, Hospital representatives, lay/public members
What have we learned in the past 30 years with respect to primary THA?

- That registries can
  - Facilitate outcome improvement when the orthopedic community is compliant (Sweden, Norway, Denmark, Australia, England/Wales and several more under way)
  - Provide critical information on outcome.
  - Identify clinical problems but not solutions.
  - Identify best practice.
What have we learned in the past 30 years with respect to primary THA?

- That we need more registries
- And that we should be very critical and skeptical when new technology is introduced
- The Stepwise concept deserve more focus in the future.
FRIENDS, COLLEAGUES, COUNTRYMEN.

2nd International Congress of Arthroplasty Registries

1st - 3rd June 2013

ONLINE REGISTRATION OPENS
22nd OCTOBER 2012

www.isarhome.org
Stratford-upon-Avon, UK

Improving outcome of joint replacement surgery - How can arthroplasty registries contribute?
TO BE OR NOT TO BE A REGISTRY NERD
- THAT IS THE QUESTION!
Thank You!

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