



Leiden University
Medical Center



Scientific Evidence and Innovation in the EU

Rob Nelissen

Professor & Chairman Orthopaedics, Leiden University Medical Center

Chairman NORE, a standing committee of EFORT



Disclosures

Institutional Grants

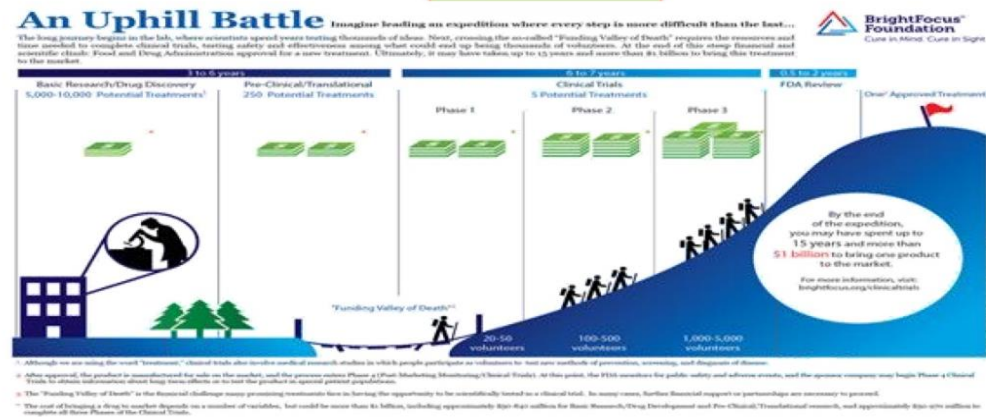
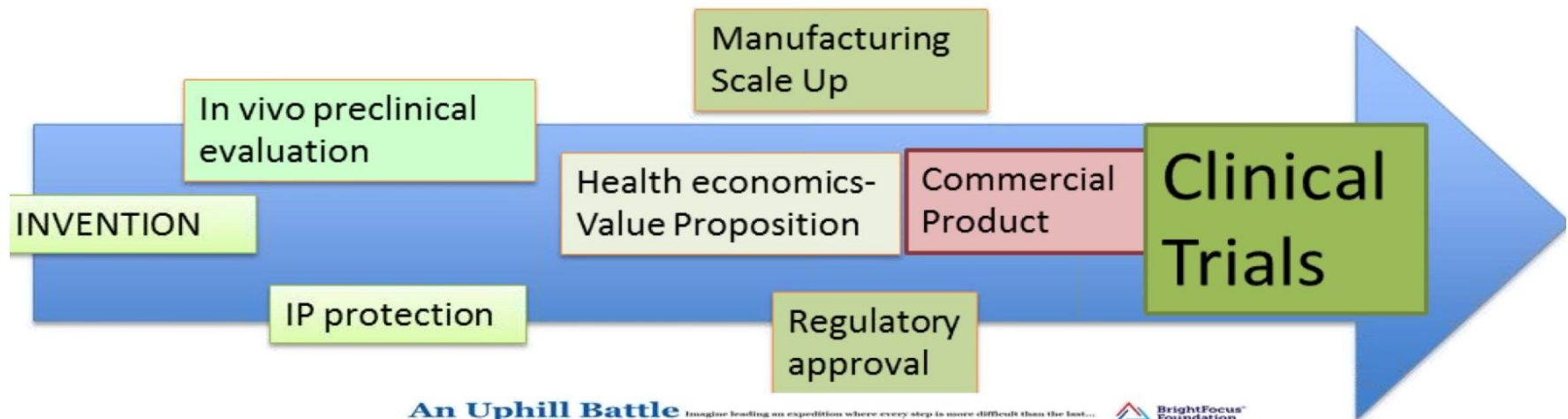
- ZonMW, Dutch Arthritis Foundation, STW, NWO,
- Contract research Stryker, Implantcast, RSACore_LUMC

Professional Boards:

- Chairman Dutch Arthroplasty Register (LROI)
- Chairman Network Orthopaedic Registries of Europe (N.O.R.E.), a standing committee of EFORT
- President RSA Society
- Past President Netherlands Orthopaedic Association (NOV -2018)



Innovation Pathway





THE LANCET Commission on Global Surgery

- Over 235 million operations are performed worldwide per annum
- Less than 1% of surgical patients are recruited into clinical studies

$$\frac{\text{Benefit}}{\text{Risk}} > 1$$

$$\frac{\text{Risk}}{\text{Benefit}} > 1$$

SIGNAL

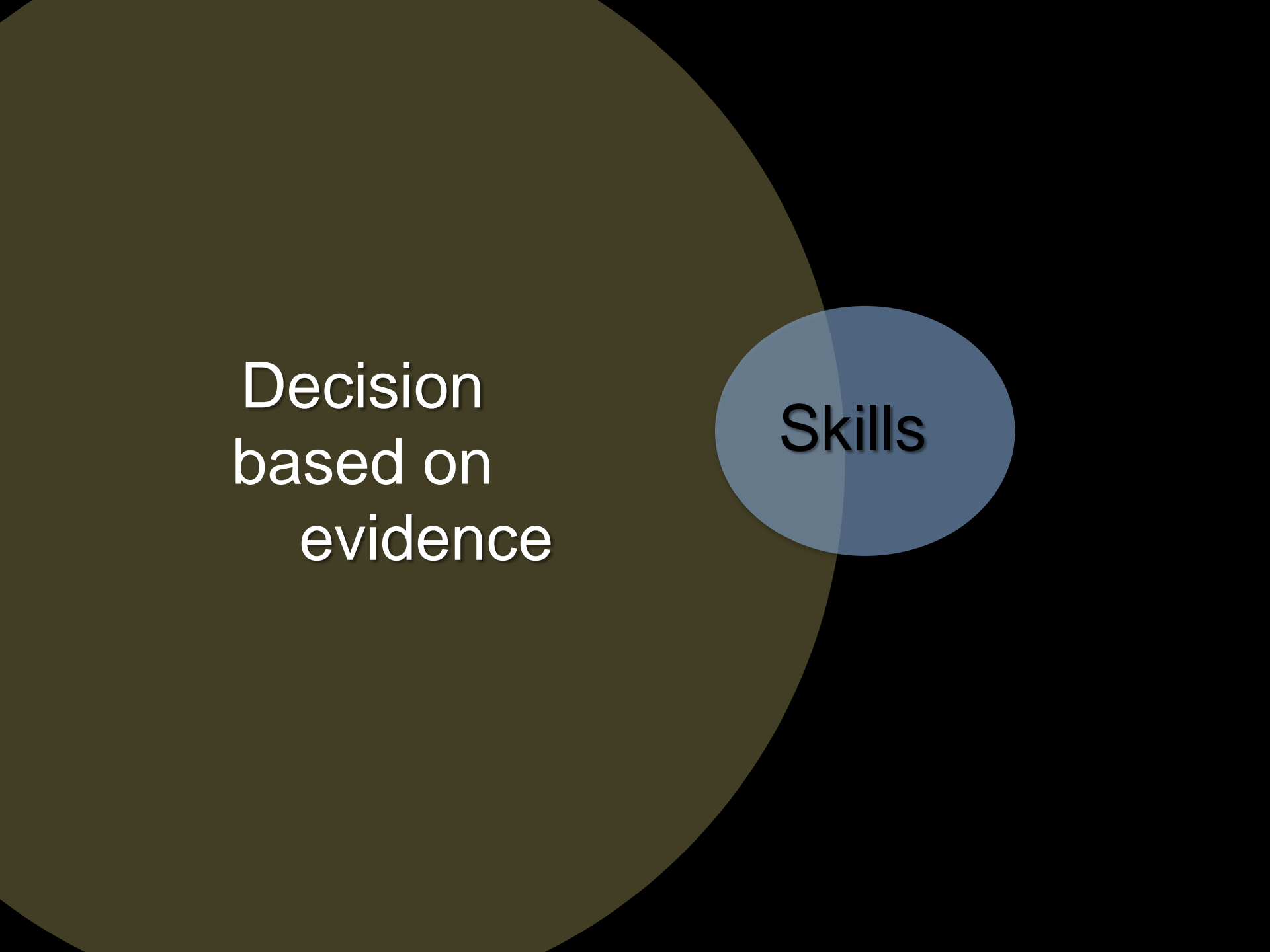
A glowing blue signal waveform, resembling a heartbeat or an audio signal, is centered on a black background. The waveform is composed of many sharp, jagged peaks and valleys, giving it a dynamic and energetic appearance. The word "SIGNAL" is written in a bold, white, sans-serif font, positioned horizontally across the middle of the waveform. The overall effect is one of high-tech or digital communication.

SIGNAL



Decision

Skills

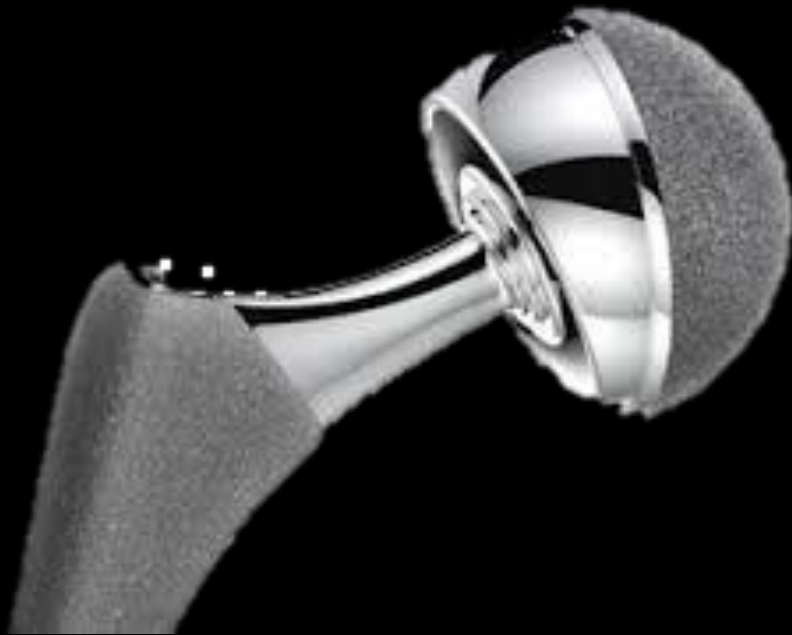


A Venn diagram consisting of two overlapping circles. The larger circle on the left is dark olive green and contains the text 'Decision based on evidence' in white. The smaller circle on the right is blue and contains the text 'Skills' in black. The intersection of the two circles is shaded a darker blue.

Decision
based on
evidence

Skills

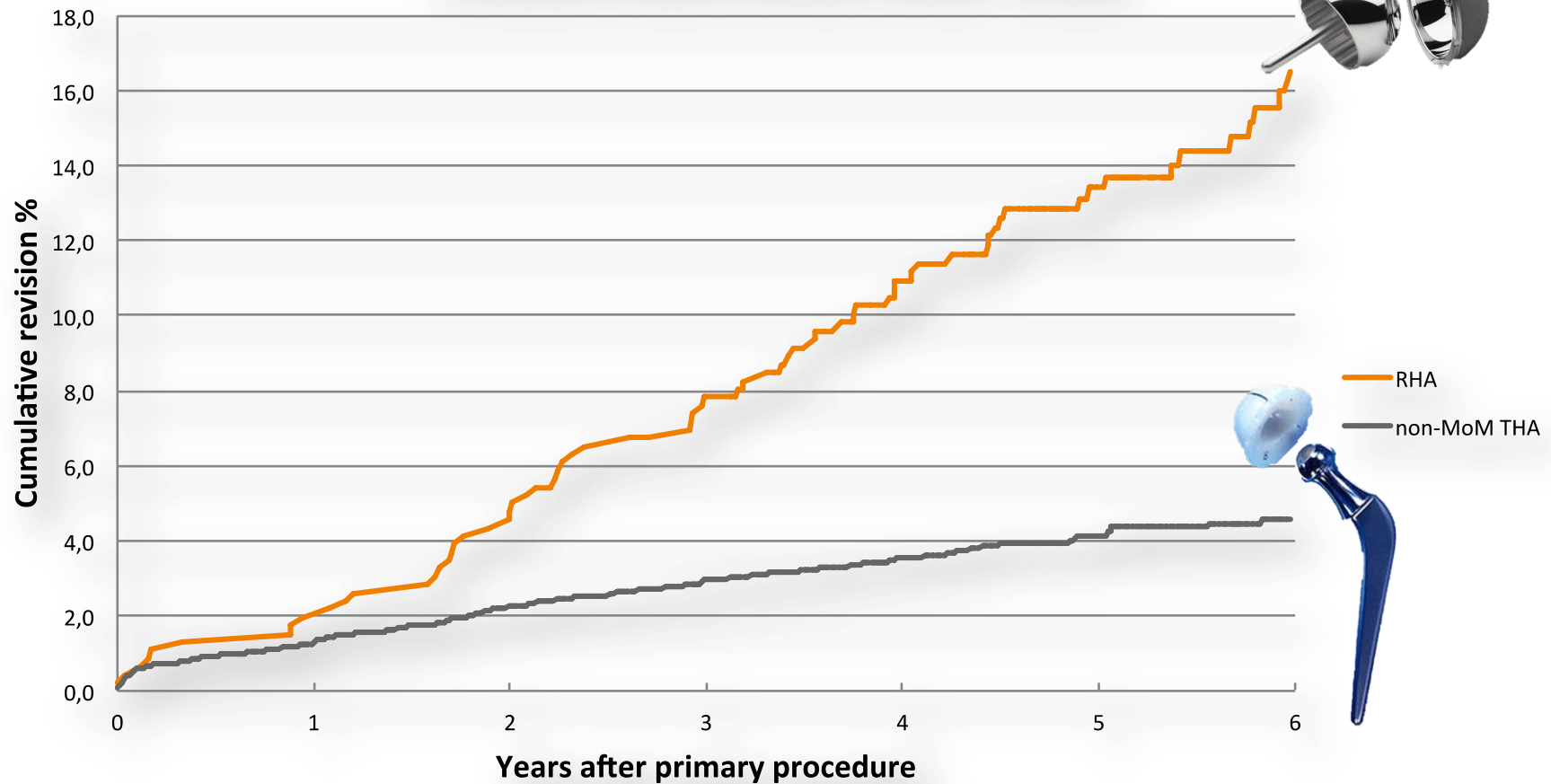




Survival Analysis (end-point revision Implant)



Cumulative incidence Revision, females <55 years



2016

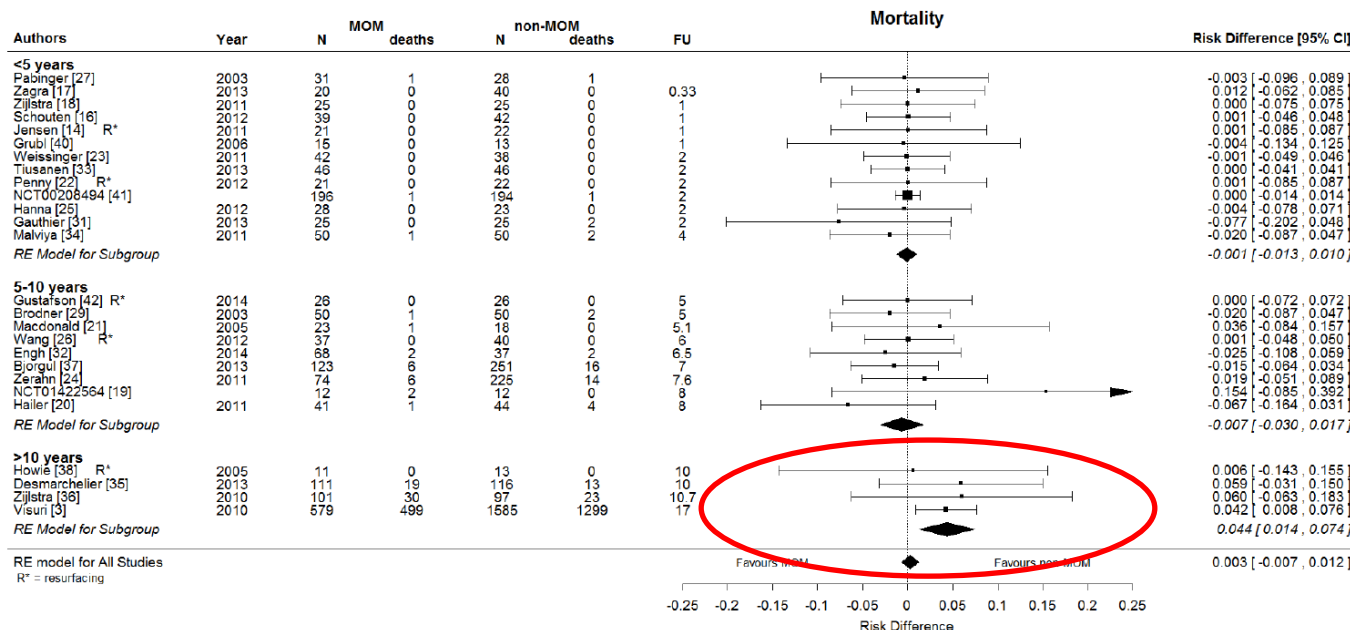
RESEARCH ARTICLE

Increased Mortality in Metal-on-Metal versus Non-Metal-on-Metal Primary Total Hip Arthroplasty at 10 Years and Longer Follow-Up: A Systematic Review and Meta-Analysis

B. G. Pijls^{1*}, J. M. T. A. Meessen¹, J. W. Schoones⁴, M. Fiocco^{2,3}, H. J. L. van der Heide¹, A. Sedrakyan^{5,6}, R. G. H. H. Nelissen¹

ONE

Increased Mortality in Patients with Metal on Metal Total Hip Arthroplasty



RESEARCH

Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies



OPEN ACCESS

Marc J Nieuwenhuijse *research fellow ICOR and FDA*¹²³, R G H H Nelissen *professor*², J W Schoones *information specialist*⁴, A Sedrakyan *associate professor*¹³

1. Gender knee



2. High Flex knee



3. Ceramic – ceramic bearing



4. Modular neck



5. Monoblock acetabulum



Summary

Nieuwenhuijse, Nelissen, Sedrakyan BMJ 2014

Meta analysis 15,384 implants in 13,164 patients

Lower revision

1. Monoblock acetabulum: hazard ratio 0.8 – 1.0

Higher revision

1. modular femoral necks: hazard ratio 1.9
2. ceramic-on-ceramic Hip: hazard ratio 1.0-1.6
3. high flexion knee: hazard ratio 1.0-1.8

Levels of Evidence





The Risk of Small
Studies is

BIG

To read this article in full, please review your options for gaining access at the bottom of the page.


Electric Morcellation-related Reoperations After Laparoscopic Myomectomy and Nonmyomectomy Procedures

Presented at the AAGL 41st Global Congress of Minimally Invasive Gynecology, Las Vegas, NV, November 5-9, 2012.

[Nigel Pereira](#), MD  , [Tommy R. Buchanan](#), MD, [Kayla M. Wishall](#), MD, [Sarah H. Kim](#), BS, [Irene Grias](#), DO, [Scott D. Richard](#), MD, [Carl R. Della Badia](#), DO



DOI: <https://doi.org/10.1016/j.jmig.2014.09.006> |  CrossMark

 Article Info

Abstract

Full Text

Images

References

Abstract

Study Objective

To identify, collate, and summarize the most common causes and pathologies of electric morcellation-related reoperations after laparoscopic myomectomy and nonmyomectomy procedures.

Design

A systematic review of published medical literature from January 1990 to February 2014 reporting morcellation-

2015

Systematic review

32 articles
66 patients

J&J Begins Settlement of Power Morcellator Cancer Lawsuits

🏠 > News > J&J Begins Settlement of Power Morcellator Cancer Lawsuits

March 30, 2016

Johnson & Johnson is making a move to settle lawsuits filed by women who say the company's surgical devices called power morcellators spread undetected uterine cancer, *The Wall Street Journal* reported.

As of March 15, 2016, there are about 31 morcellator lawsuits pending in federal court against J&J's Ethicon unit before Judge Kathryn H. Vratil in Kansas, according to the Judicial Panel on Multidistrict Litigation. These cases combined with





Dilemma: Randomised controlled Trial (RCT)



Patients in **Your Practice**

REAL World Data = Registry data



Dutch Arthroplasty Register

De LROI is een register voor gewrichtsprothesen (heup, knie, enkel, schouder, elleboog, pols, vinger en duim) die in Nederland geplaatst zijn.

[Inloggen?](#)

Aantal registraties op dit moment



Totaal 600.305



Heup 332.394



Knie 256.488



Enkel 495



Schouder 10.131



Elleboog 636



Pols 50



Vinger/duim 111



<https://www.lroi.nl/kalender/2018/01#cal20>

**15
JAN**



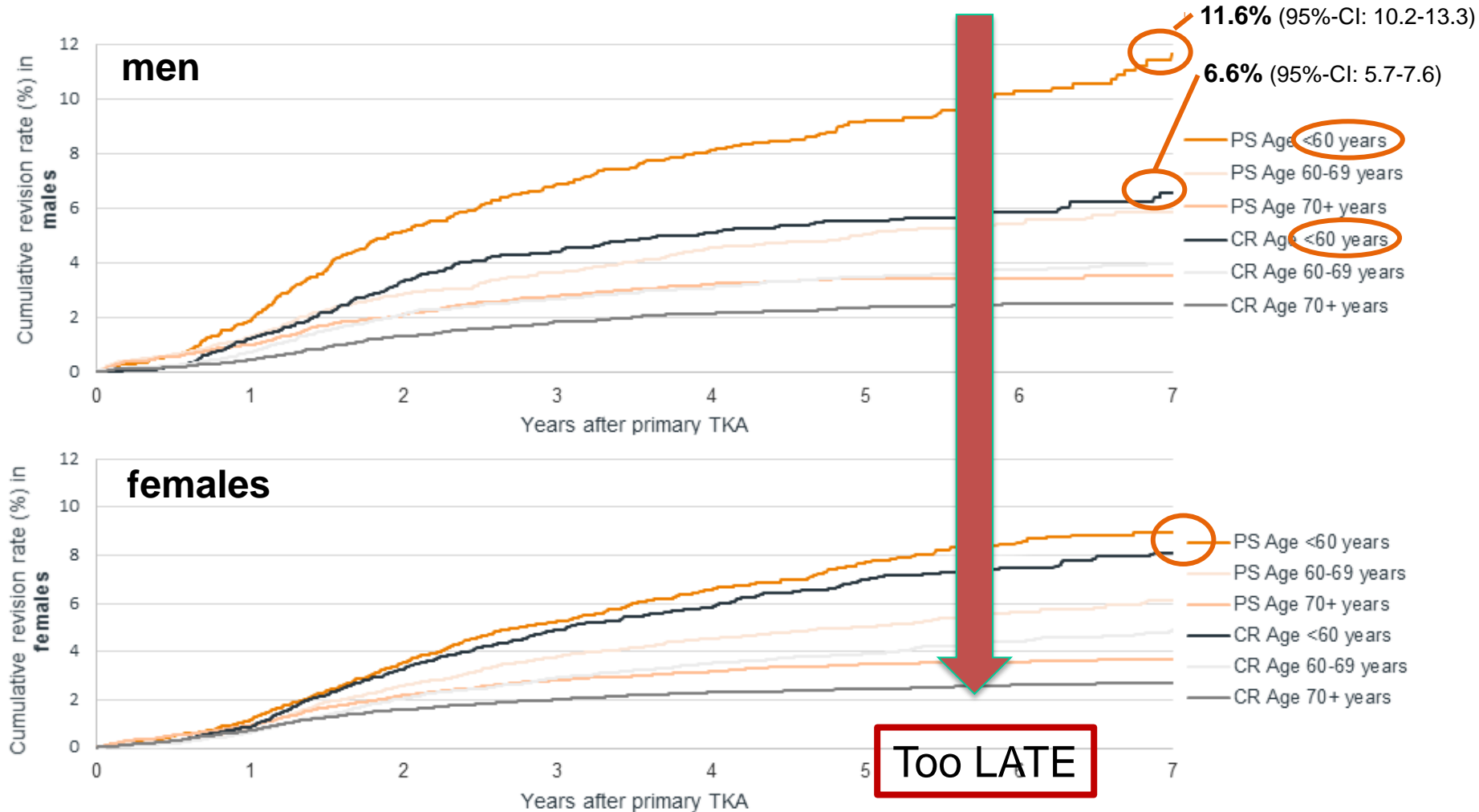
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[LEES MEER →](#)

**Deadline indienen abstracts
ISAR congres (IJsland)**

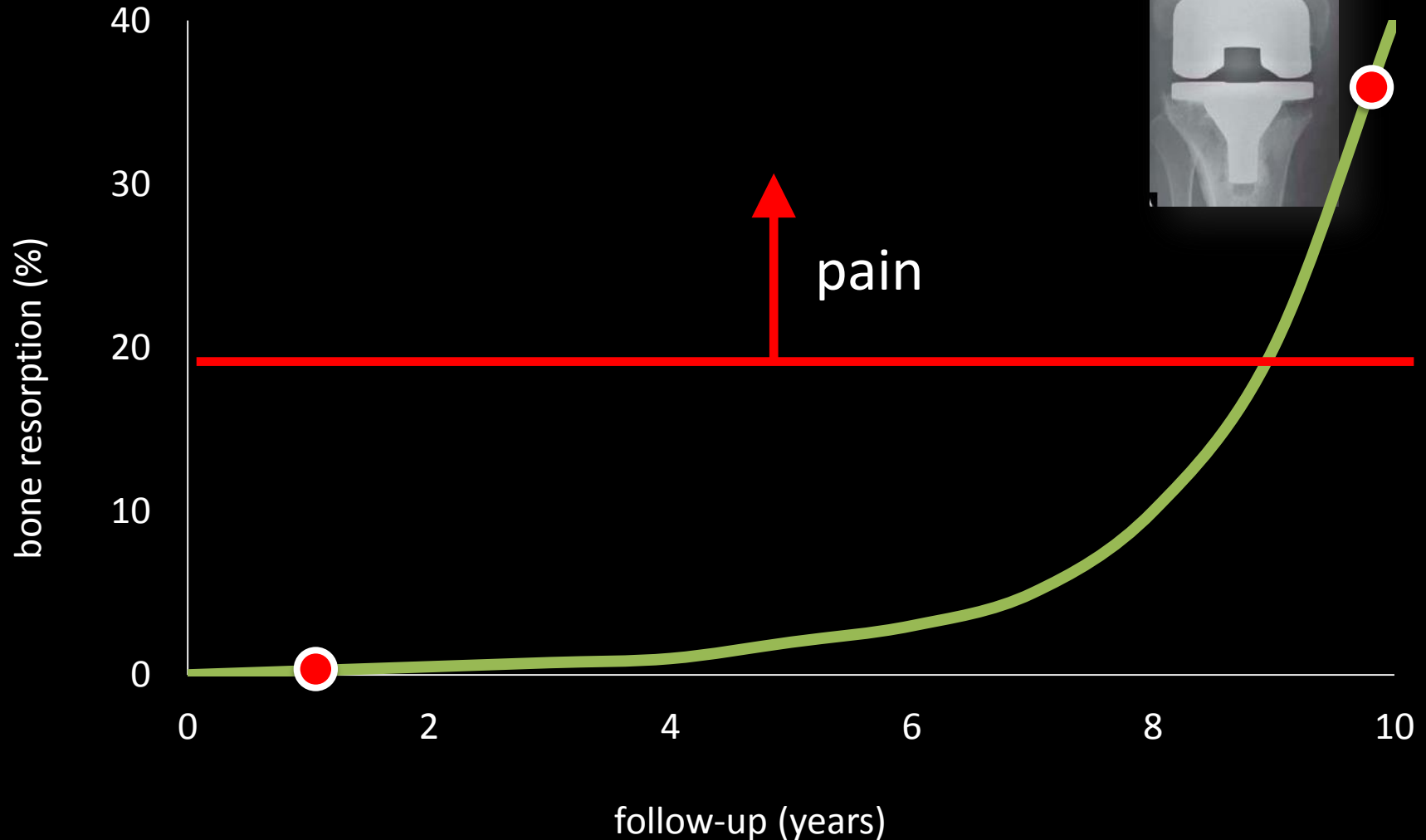
**LROI**

Results 7-year revision rate PS vs CR TKA



Detection implant failure

Registries slow



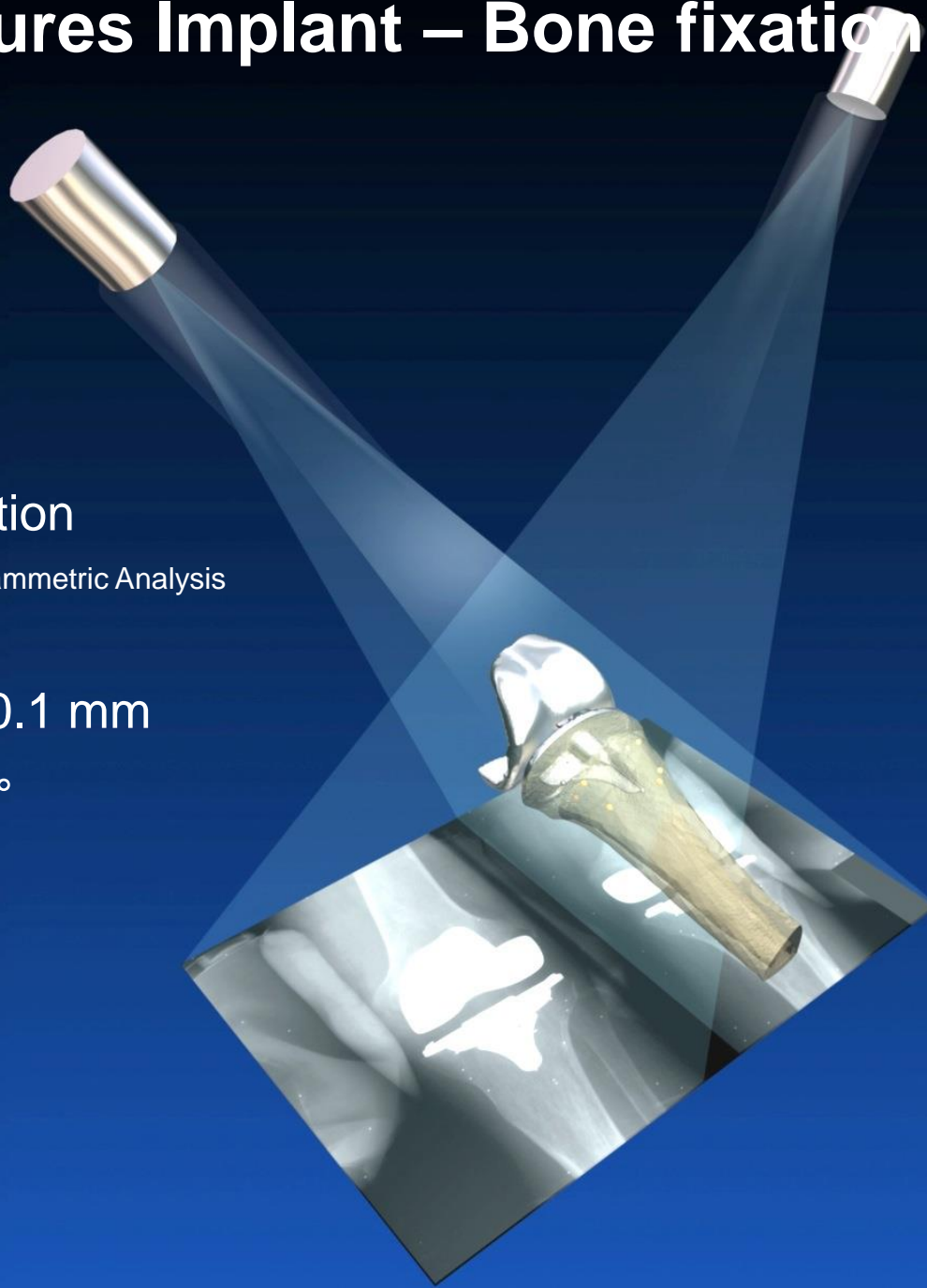


RSA measures Implant – Bone fixation

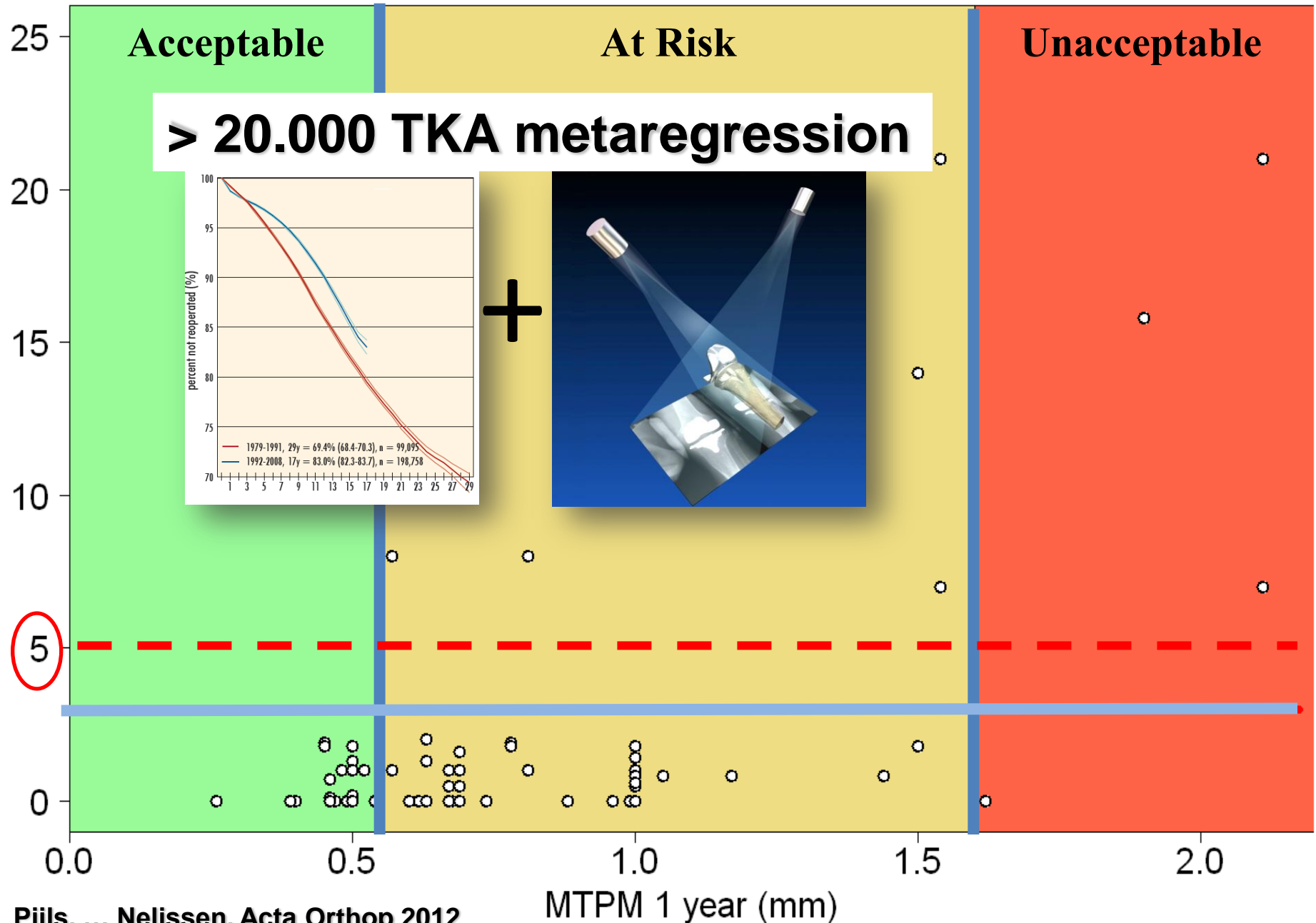
RSA: 3D migration

Roentgen Stereophotogrammetric Analysis

- Translation 0.1 mm
- Rotation 0.1°

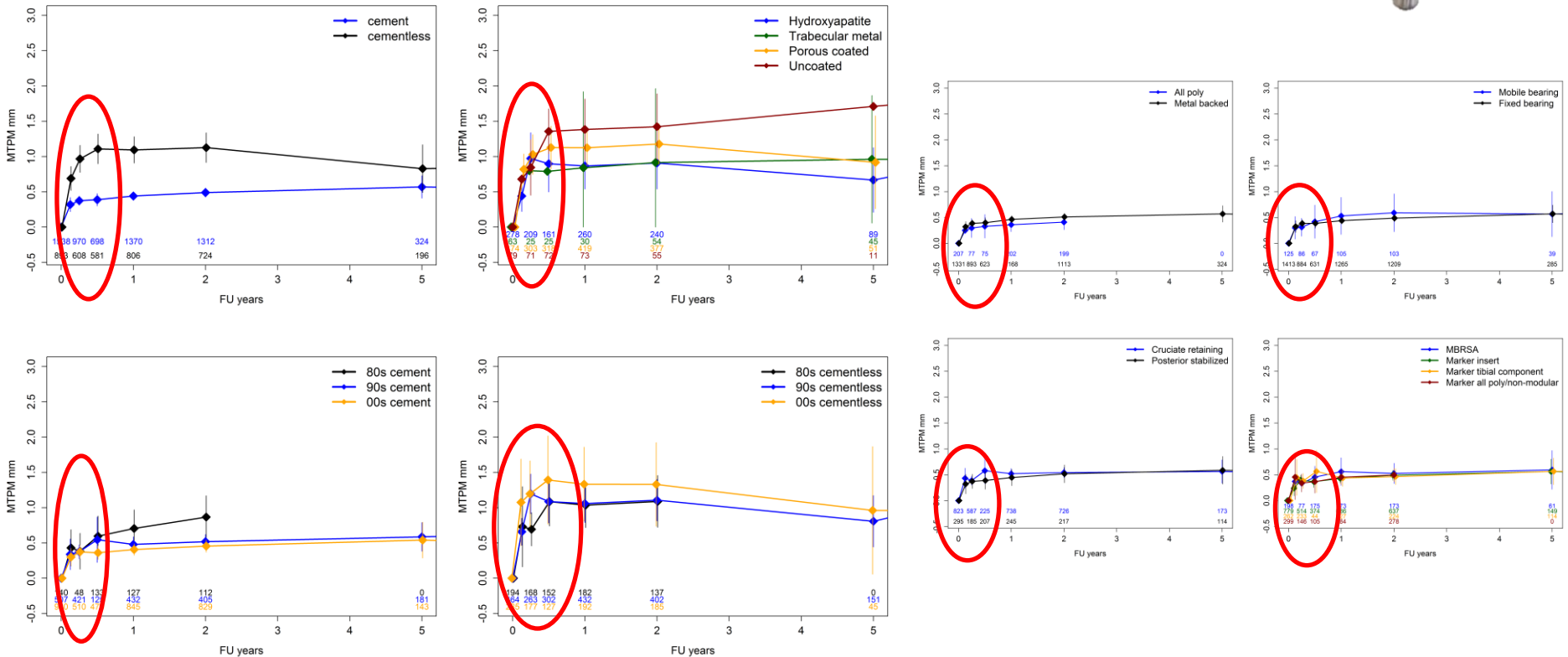


Revision (%) at 10 yrs and MTPM in similar TKP



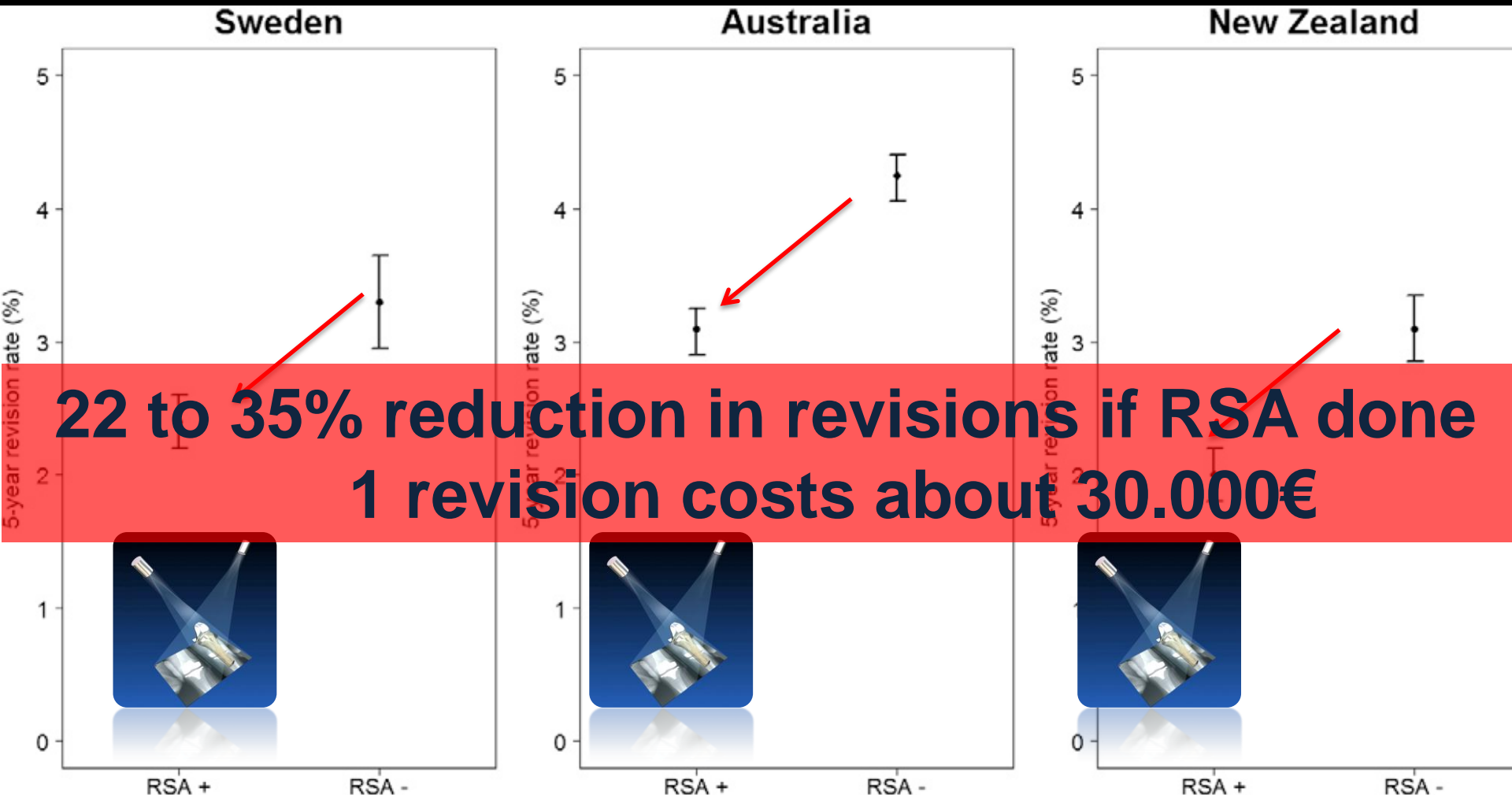


0-6 months Prognostic Feasible...



Effect RSA:

less performing implant earlier taken off market

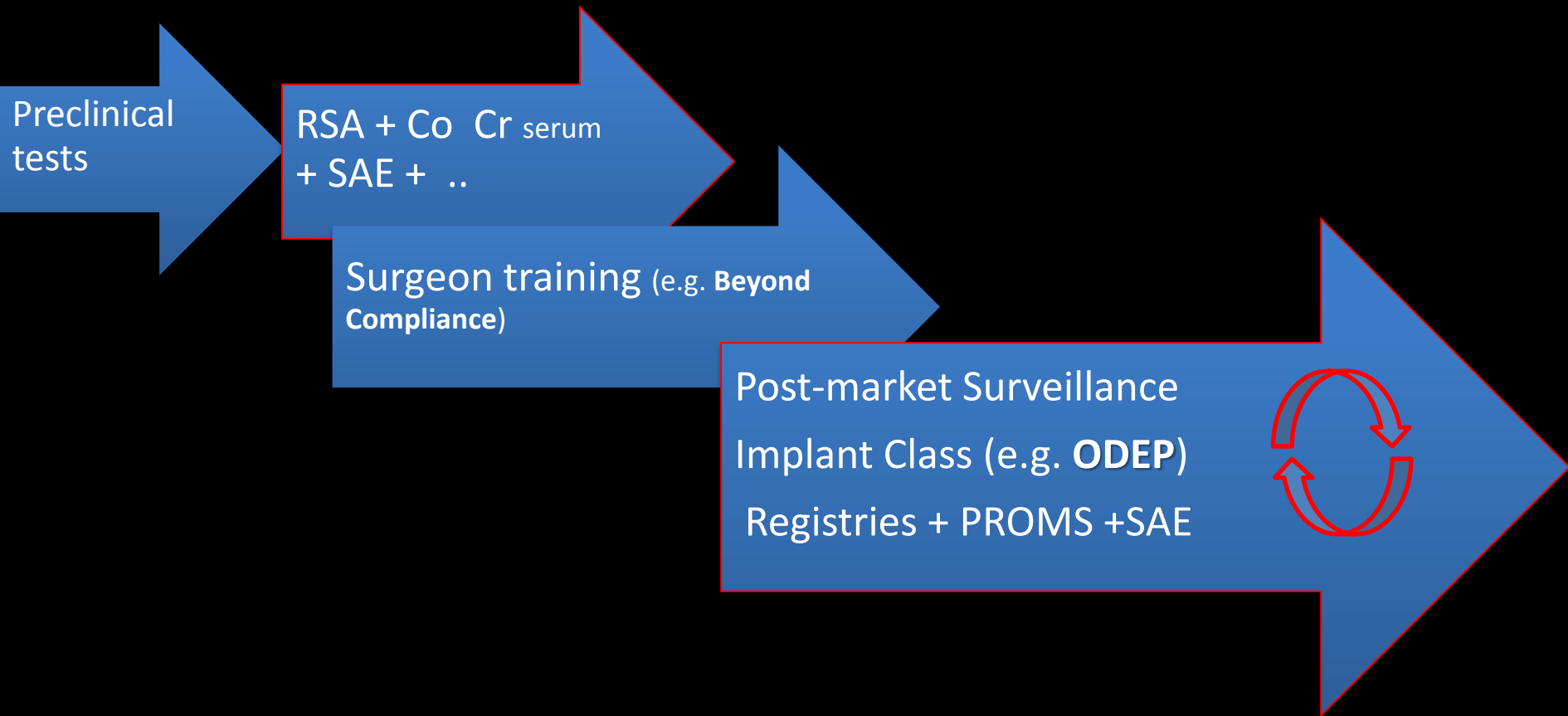


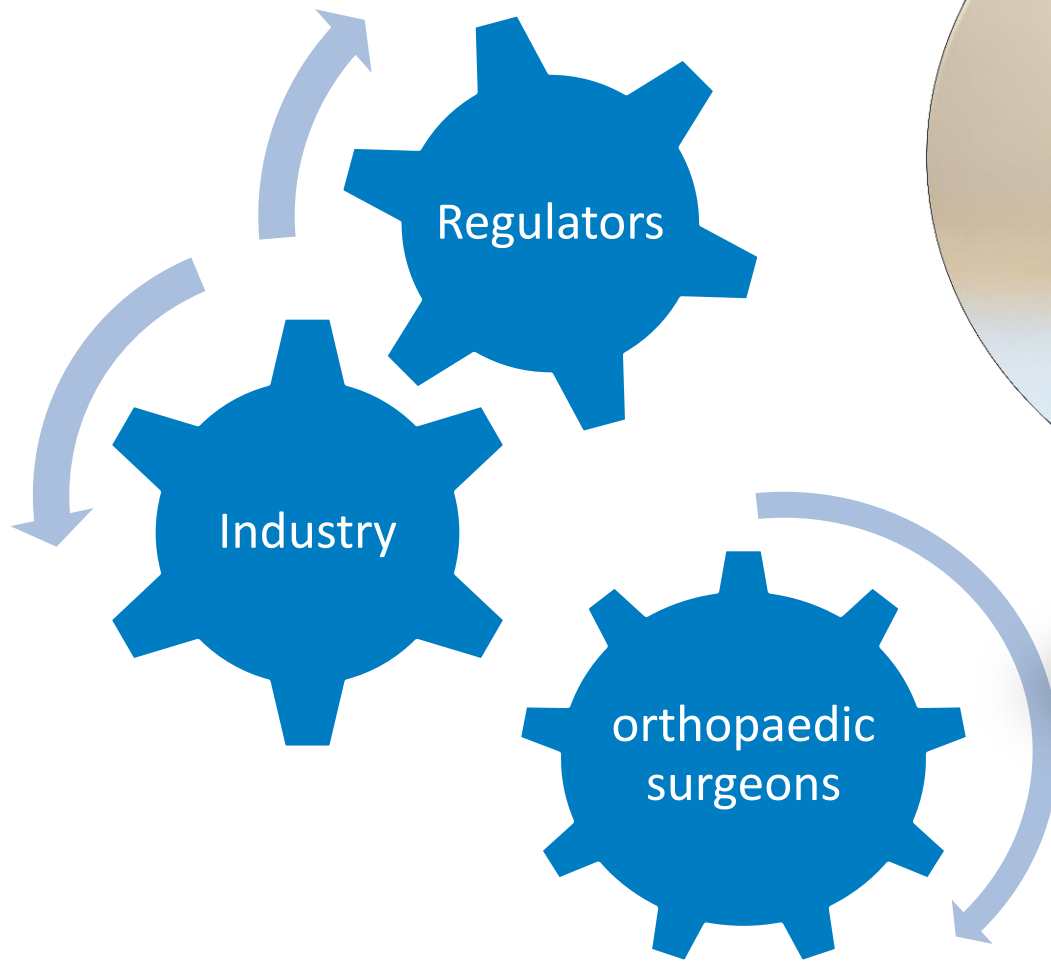
Decision
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Skills

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Evaluation Toolbox New Implants







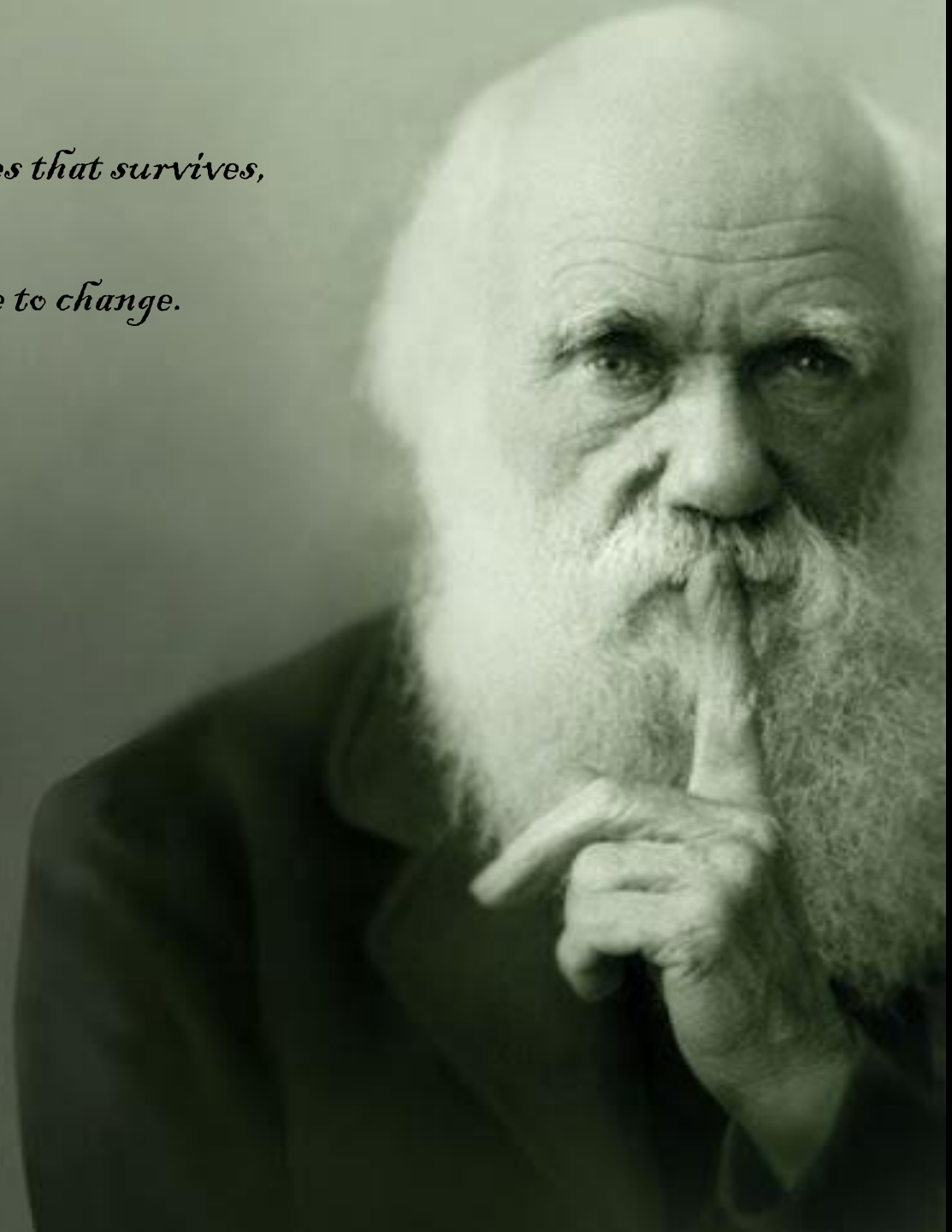
“Don't let your
patient become a
fashion victim”

Bulstrode BMJ 1993

*It is not the strongest of the species that survives,
nor the most intelligent.*

It is the one that is most adaptable to change.

Charles Darwin



Evidence:

An Ally for Patients, an Asset for Surgeons

