



# **Shifting paradigms for high-risk devices**

## **lessons learned from the past**

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BMJ

BMJ 2012;345:e7090 doi: 10.1136/bmj.e7090 (Published 24 October 2012)

Page 1 of 5

FEATURE

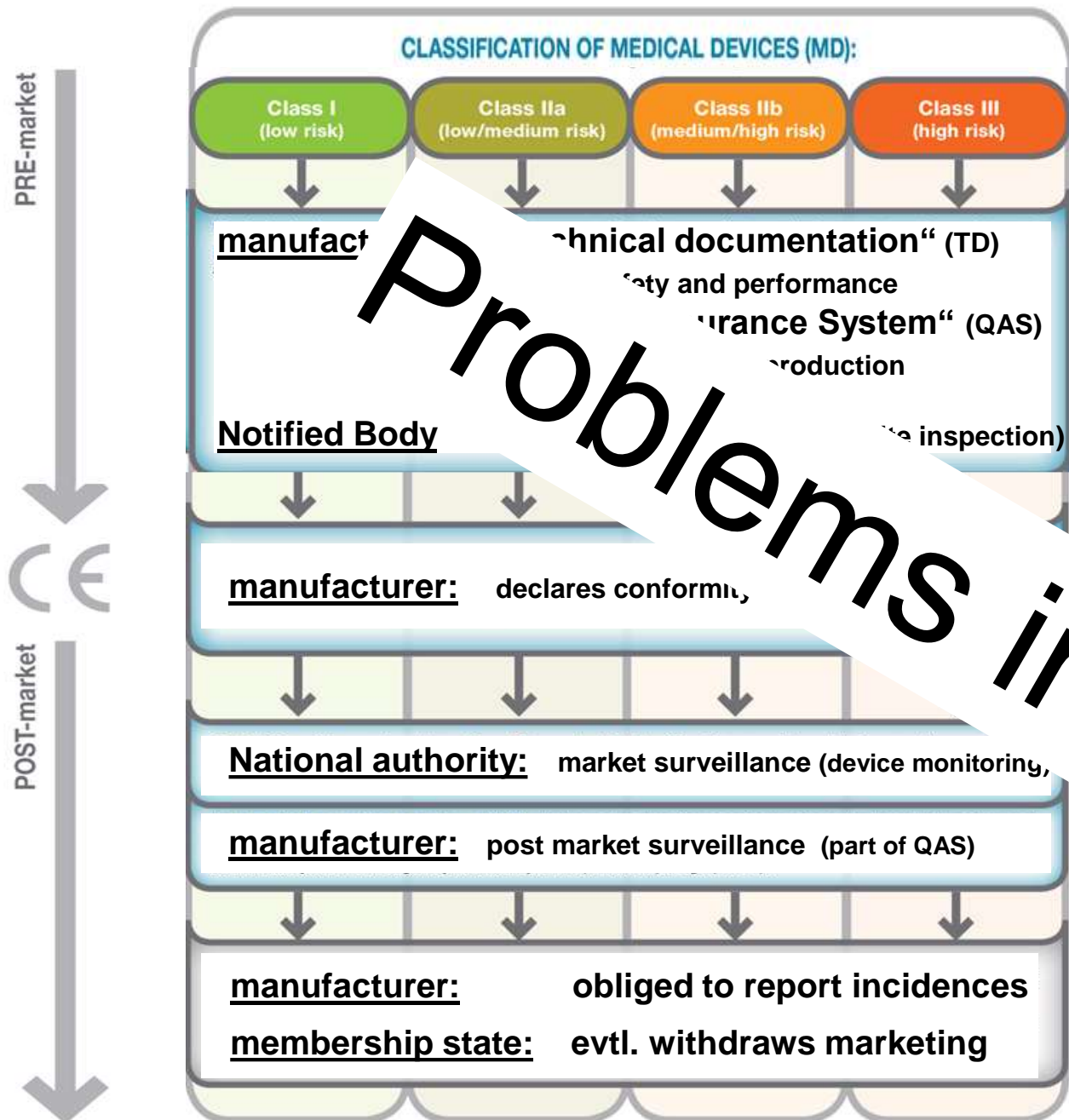
MEDICAL DEVICE REGULATION

## How a fake hip showed up failings in European device regulation

Deborah Cohen investigates how EU authorities would be prepared to allow a fake hip prosthesis with dangerous design flaws onto the market

Deborah Cohen *investigations editor*





**Problems in the past**

**Main problems**

**> 70 (competing) NBs in Europe**

**no governmental licensing agency (like US-FDA)**

**National adoptions (i.e. no EC-wide registry)**

Conformity assessment procedure (art. 11)

Declaration of conformity and CE marking

Vigilance system (in case of incidents):

## Modern MoM



1996



**D. McMinn**  
BHR©

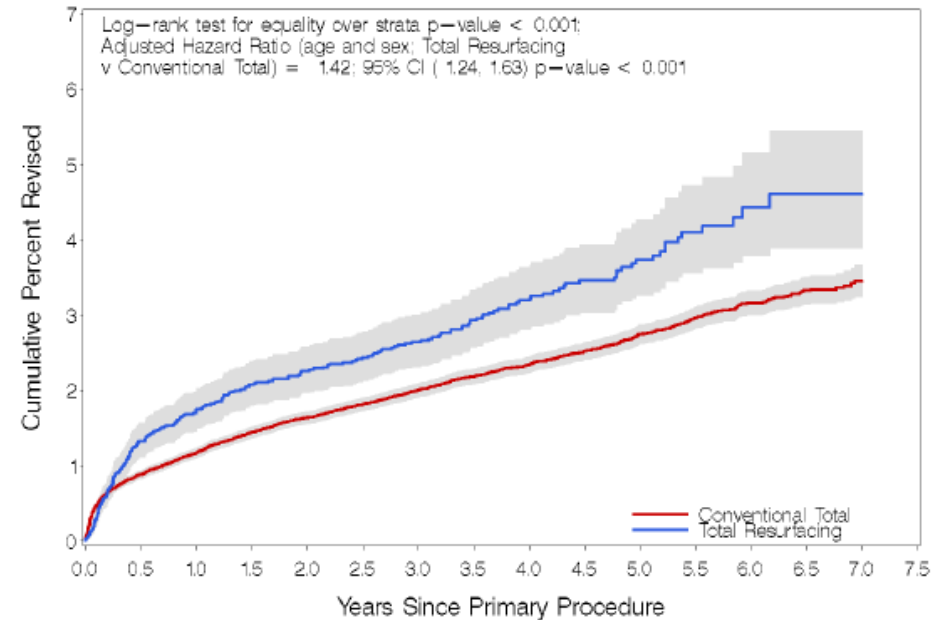
**H. Amstutz**  
Conserve Plus©

**Designer studies:  
promising results**



# ANNUAL REPORT 2008

**Figure HT11: Cumulative Percent Revision of Conventional Total and Total Resurfacing Hip Replacement (Primary Diagnosis OA excluding Infection)**



# Hip resurfacing



## ANNUAL REPORT 2012

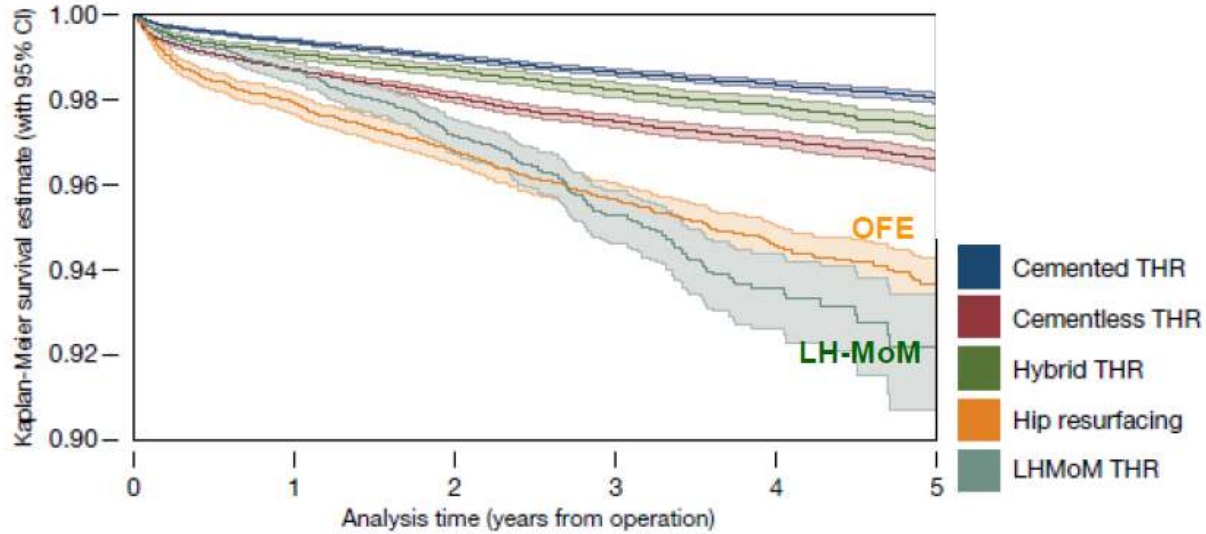
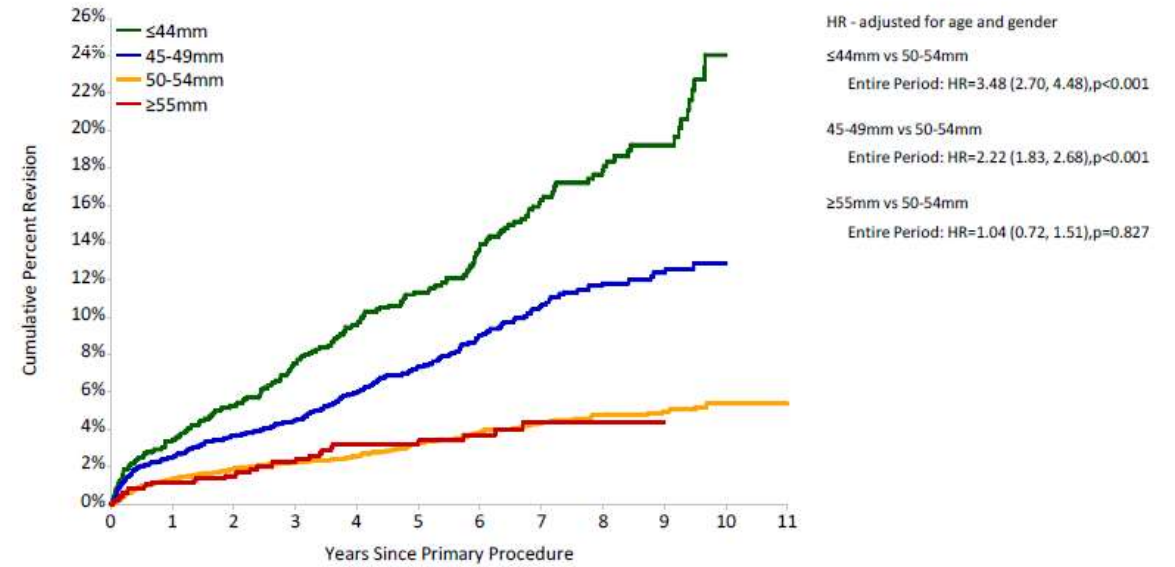


Figure HT42: Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement by Head Size (Primary Diagnosis OA)



# Hip resurfacing



**Designer studies:  
promising results**



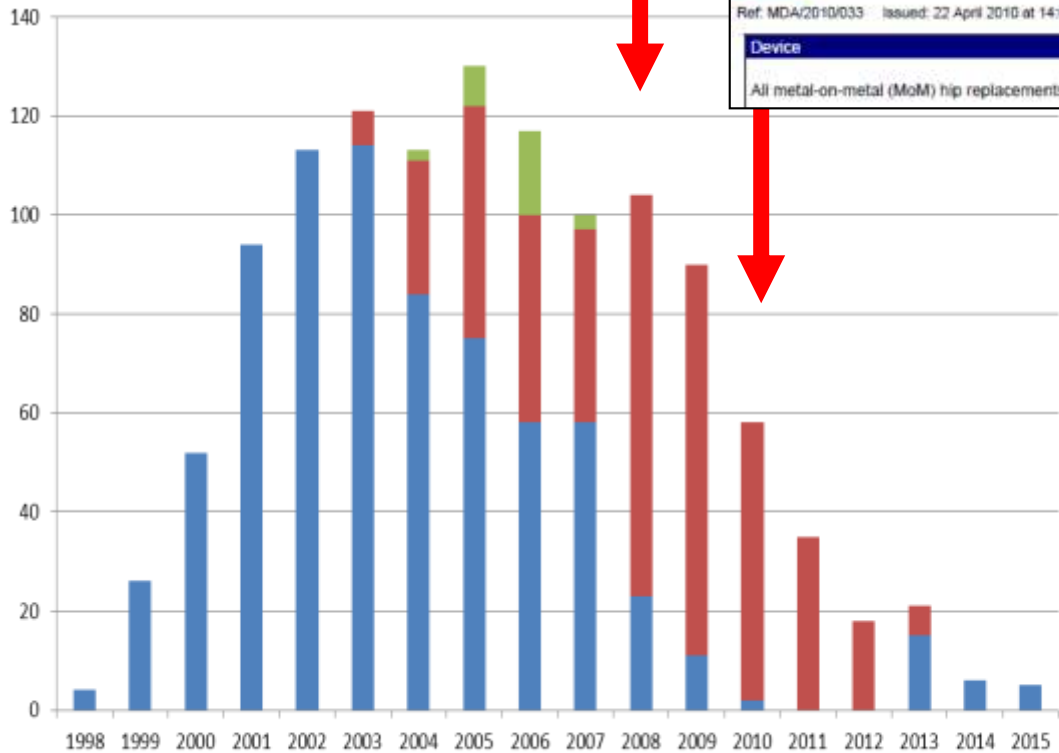
**Medical Device Alert**

**Action**

Ref: MDA/2010/033 Issued: 22 April 2010 at 14:00

**Device**

All metal-on-metal (MoM) hip replacements.

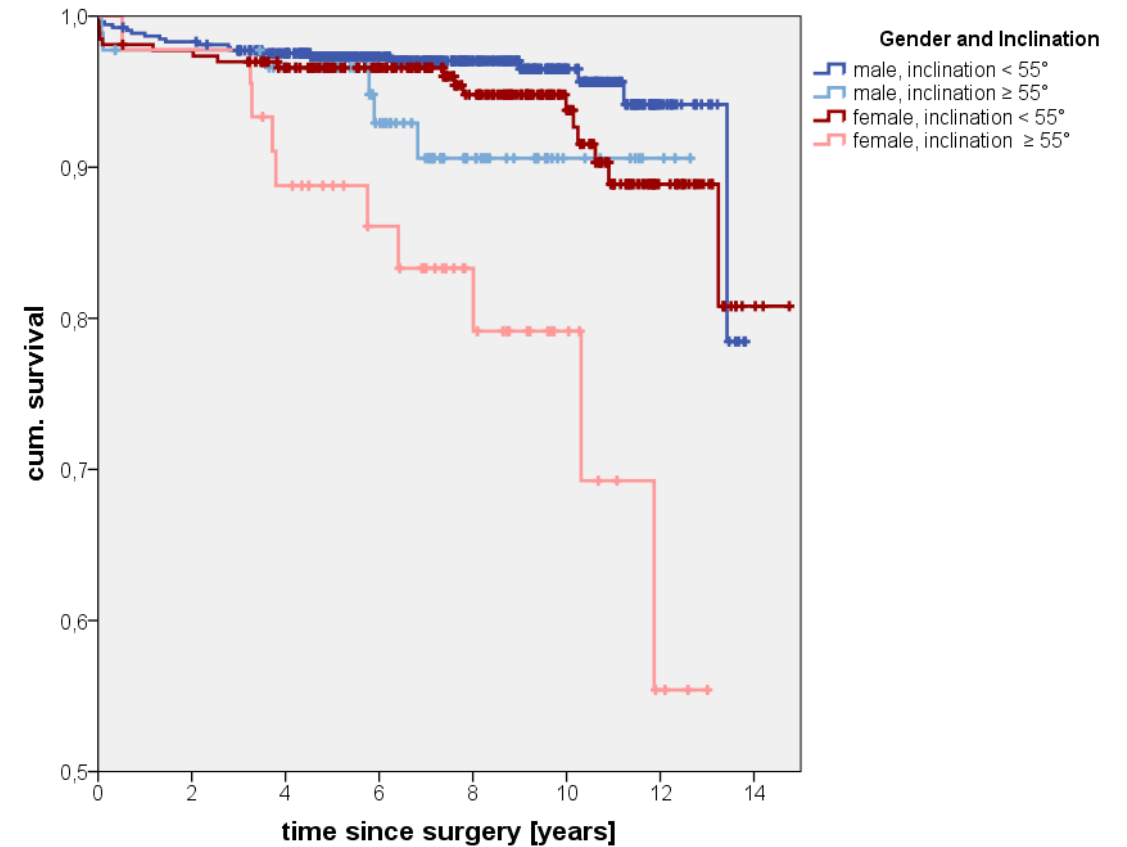


Dresden experience

## Revision Rate and Patient-Reported Outcome After Hip Resurfacing Arthroplasty: A Concise Follow-Up of 1064 Cases

Sonja Bömert, Jörg Lützner, MD, Franziska Beyer, Klaus-Peter Günther, MD, Albrecht Hartmann, MD

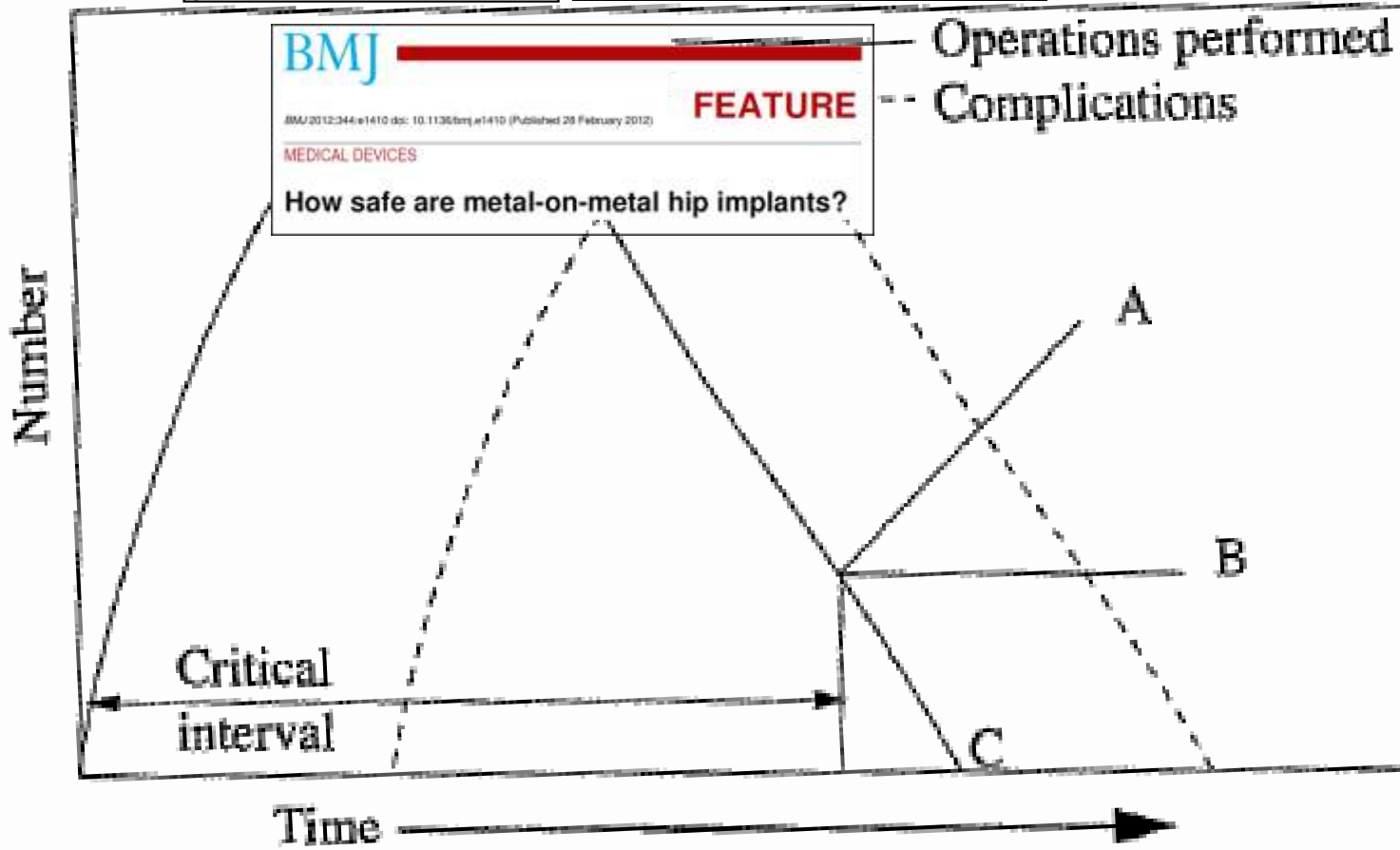
Department for Orthopaedic and Trauma Surgery, University Hospital Carl Gustav Carus, TU Dresden, Dresden, Germany



# Lessons learned



<b>Medical Device Alert</b> <b>Immediate action / update</b> Ref: MDA/2010/069 Issued: 07 September 2010 at 13:00 Device DePuy ASR™ hip replacement implants.	<b>Medical Device Alert</b> Ref: MDA/2012/036 Issued: 25 June 2012 at 11:00 Device All metal-on-metal (MoM) hip replacements
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Innovations in surgery  
Gross (1993)

## Instructional Lecture: Hip

EOR | VOLUME 2 | MAY 2017  
DOI: 10.1302/2058-5241.2.170008  
www.efortopenreviews.org



EFORT open reviews

### Advances in hip arthroplasty surgery: what is justified?

Luigi Zagra

I would conclude the overview of this ICL with this advice from the EFORT Ethical Code: “there should be an end to the haphazard way in which new surgical techniques and products are introduced. Patients may be attracted by the latest trend before it has been properly tried and evaluated. The history of Orthopaedics is littered with widely different procedures which have proved of little value”.<sup>84</sup>

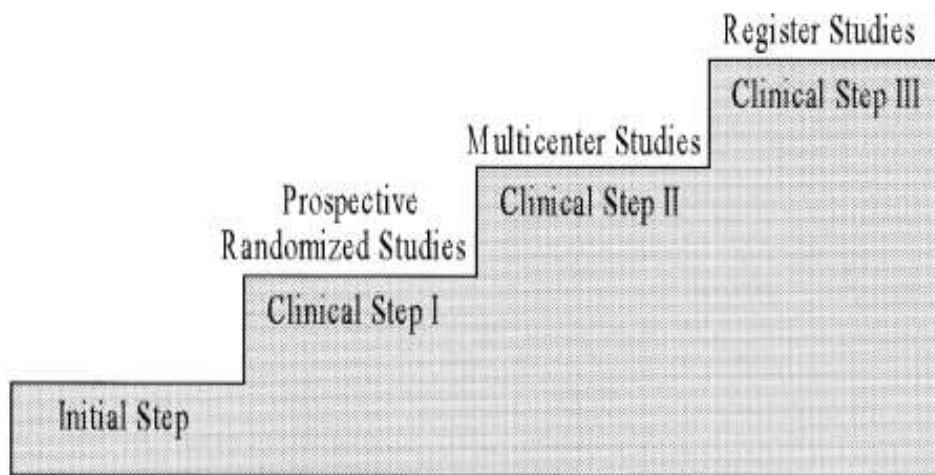


# Lessons learned



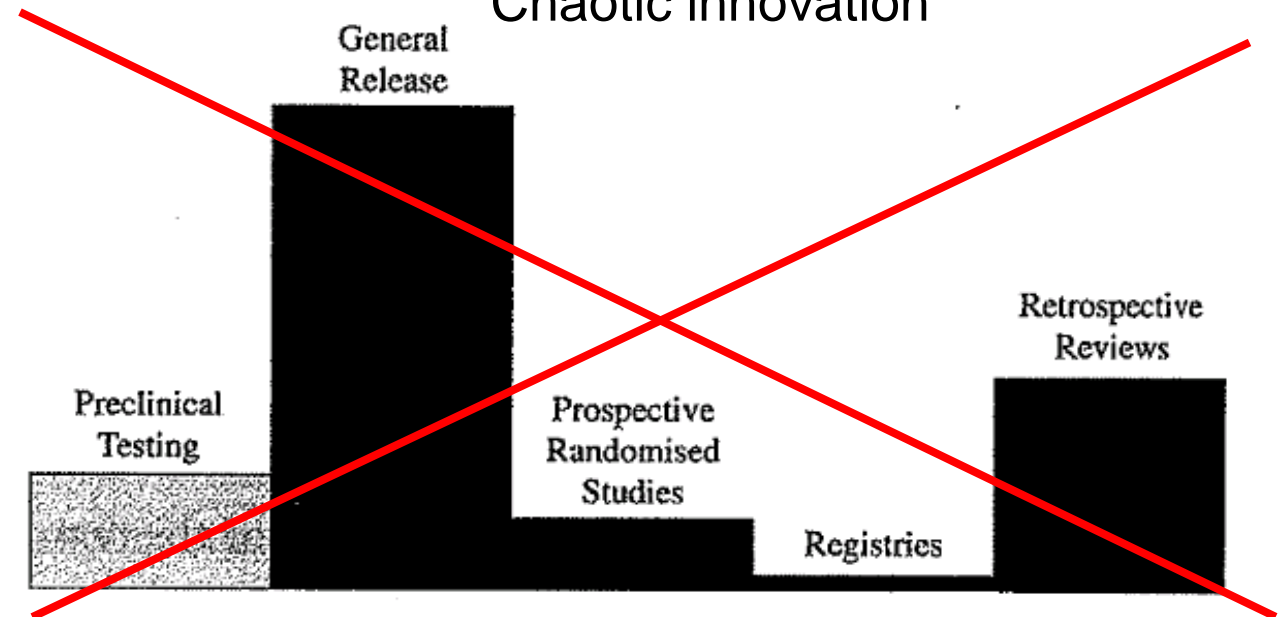
- Registries are effective, but at a late stage
- Response of regulatory authorities is inhomogenous and delayed
- Close surveillance of innovations

Stepwise innovation



Malchau

Chaotic innovation



Dunbar

## European Multicentric Efficacy Study

### Science News

from research organizations

### New hip resurfacing implant could lead to better outcomes for patients

Date: February 7, 2018

Imperial College  
Prof. Justin Cole

Source: Imperial College London

Summary: Surgeons are treating patients with a new type of hip implant that could lead to better outcomes for younger, more active people requiring surgery.

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- > Medical Technology
- > Chemistry

#### FULL STORY

Surgeons are treating patients with a new type of hip implant that could lead to better outcomes for younger, more active people requiring surgery.

Fifteen patients have so far been treated with a novel ceramic hip resurfacing implant in a new trial at Imperial College London. Early results suggest patients can return to physical activities such as swimming and cycling within six weeks of their operation.

The investigation, whose lead site is Charing Cross Hospital, part of Imperial College Healthcare NHS Trust, is the first in the world to resurface patients' hips without using metal implants.

## New hip implant for active patients

Hippocratic Post | 8th February 2018 | AGEING, INNOVATION, MUSCULAR & SKELETAL, NHS, SURGERY | No Comments

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Advertisement at very early stage