Shifting paradigms for high-risk devices
lessons learned from the past

Jörg Lützner

University Center for Orthopaedics & Traumatology
University Medicine Carl Gustav Carus Dresden, Germany
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
Main problems

> 70 (competing) NBs in Europe

no governmental licensing agency (like US-FDA)

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

Problems in the past

Vigilance system (in case of incidents):

Declaration of conformity and CE marking

Notified Body: Auditing TD & QAS (on-site inspection)

manufacturer: declares conformity and affixes CE-marking

National authority: market surveillance (device monitoring)

manufacturer: post market surveillance (part of QAS)

manufacturer: obliged to report incidences

membership state: evtl. withdraws marketing

Conformity assessment procedure (art. 11)

Technical documentation (TD)

safety and performance

Quality Assurance System (QAS)

standards of production

manufacturer: declaration of conformity

Notified Body: Auditing TD & QAS (on-site inspection)
Hip resurfacing

Modern MoM

1996

Designer studies: promising results

D. McMinn

BHR©

H. Amstutz

Conserve Plus©

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

Log-rank test for equality over strata: p-value < 0.001
Adjusted Hazard Ratio (age and sex: Total Resurfacing vs. Conventional Total) = 1.42, 95% CI (1.24, 1.63), p-value < 0.001
Figure H742: Cumulative Percent Revision of Primary Total Resurfacing Hip Replacement by Head Size (Primary Diagnosis OA)

- HR: adjusted for age and gender
- 54mm vs 50-54mm
  - Entire Period: HR=3.48 (2.70, 4.48) p<0.001
- 45-49mm vs 50-54mm
  - Entire Period: HR=2.22 (1.81, 2.68) p<0.001
- 255mm vs 50-54mm
  - Entire Period: HR=1.04 (0.72, 1.51) p=0.827
Hip resurfacing

Designer studies: promising results

Medical Device Alert

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

Gender and Inclination
- male, inclination < 55°
- male, inclination ≥ 55°
- female, inclination < 55°
- female, inclination ≥ 55°

Dresden experience
Lessons learned

Innovations in surgery

Gross (1993)
Advances in hip arthroplasty surgery: what is justified?

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”.

Luigi Zagra
Lessons learned

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

Stepwise innovation

Chaotic innovation

Malchau

Dunbar
European Multicentric Efficacy Study

Science News

New hip resurfacing implant could lead to better outcomes for patients

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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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.