23RD INTERNATIONAL EXPERTS SYMPOSIUM

CRITICAL ISSUES in aortic endografting 2019

LIVERPOOL UNITED KINGDOM MAY 23-24

Who picks up the pieces when the balloon of. ”promising” technology bursts?

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KING'S HEALTH PARTNERS

Disclosure

Speaker name: **Rachel Bell**

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I have the following potential conflicts of interest to report:

Consulting

Employment in industry

Shareholder in a healthcare company

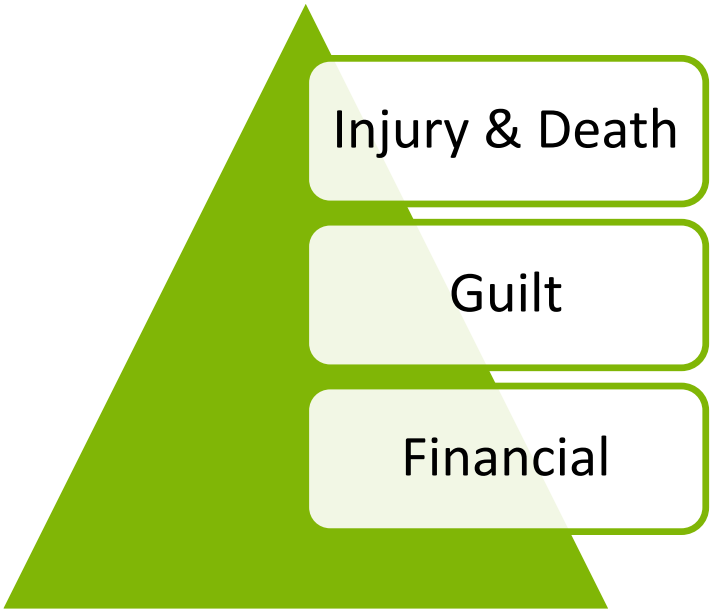
Owner of a healthcare company

Other(s)

I do not have any potential conflict of interest

Introduction

- Medical device failure is not new
- There is an enormous unseen cost
  1. How did it happen?
  2. How do we manage the fall out?
  3. How do we learn from it?
  4. How can we stop it happening again?



Medtronic Recalls Cardiac Resynchronization Therapy and Implantable Cardioverter Defibrillators Due to Manufacturing Error Preventing Electrical Shock Delivery

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The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- Recalled Product(s): Medtronic Cardiac Resynchronization Therapy with Defibrillation (CRT-Ds) and Implantable Cardiovert-Defibrillators (ICDs)
- Product Codes: NIK, LWS

NHS

Health A-Z | Live Well | Care and support

Fears of faulty 'toxic' hip replacement implant

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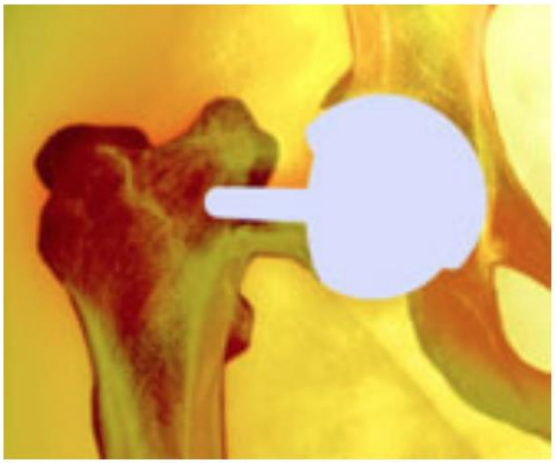
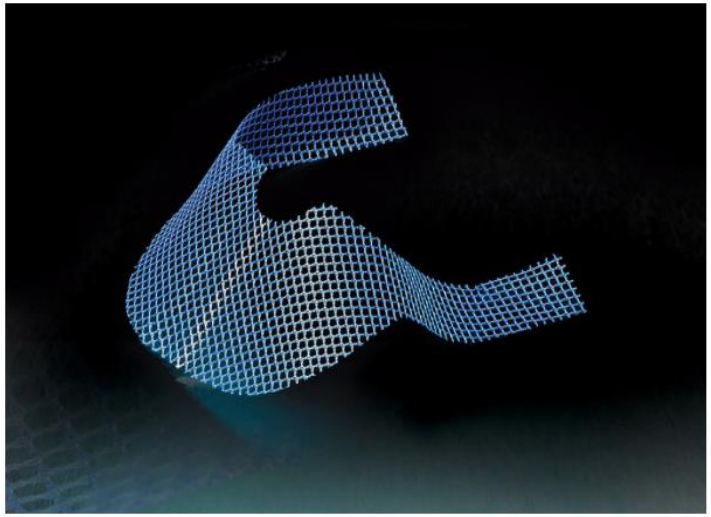
Monday January 30 2012



Faulty 'toxic' DePuy ASR hip implants have been recalled

The New York Times

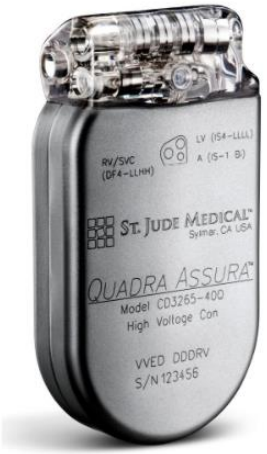
F.D.A. Halts U.S. Sales of Pelvic Mesh, Citing Safety Concerns for Women



The Food and Drug Administration said there was insufficient evidence that mesh worked better than surgery to repair pelvic organ prolapse. Boston Scientific

The New York Times

St. Jude Medical Played Down Defibrillator Failures for Years, F.D.A. Says



One of the nearly 400,000 defibrillators recalled by the F.D.A last fall. St. Jude Medical was ordered by the agency to provide a plan for correcting its reporting on the device problems within 15 days.
St. Jude Medical

By Katie Thomas

April 13, 2017

Nellix failure

GOV.UK

Home > Alerts and recalls for drugs and medical devices

Nellix Endovascular Aneurysm Sealing (EVAS) System - Device recall and enhanced patient surveillance (MDA/2019/002)

Endologix has stopped selling the Nellix EVAS device and is recalling unused stock. MHRA recommends enhanced patient surveillance due to a high risk of graft failure beyond two years after implantation.

Published 25 January 2019
Last updated 29 January 2019 — see all updates
From: Medicines and Healthcare products Regulatory Agency

Issued: **25 January 2019**
Alert type: **Medical device alert**
Medical specialty: **Radiology, Vascular and cardiac surgery**

Eur J Vasc Endovasc Surg (2018) 56, 342–348

Editor's Choice — Mid-term Migration and Device Failure Following Endovascular Aneurysm Sealing with the Nellix Stent Graft System — a Single Centre Experience

Seamus C. Harrison *, **Andrew J. Winterbottom, Patrick A. Coughlin, Paul D. Hayes, Jonathan R. Boyle**

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Objective: Endovascular aneurysm sealing (EVAS) with the Nellix stent graft system is a novel concept in the management of abdominal aortic aneurysm (AAA) that aims to reduce the prevalence of all endoleaks following endovascular repair. There are few data describing the longer-term durability of this approach. The aim was to report the longer-term outcomes following EVAS in a single centre.

Methods: This is a retrospective review of all patients that underwent Nellix at Cambridge University Hospitals Foundation Trust. Factors that are described as device failure include secondary sac rupture, graft explantation, further surgical procedures for Type 1 endoleak, or major migration of the stent grafts with pressurisation of the aortic sac.

Results: A total of 161 patients have been treated with Nellix. The indications included primary AAA ($n = 115$), ruptured AAA ($n = 4$), salvage of other aortic grafts ($n = 18$), primary iliac aneurysm ($n = 6$), and chimney EVAS (ChEVAS) for pararenal AAA ($n = 18$). In total there have been 42 graft failures in patients treated with EVAS for primary AAA. The 4 year freedom from graft failure was 42% in patients treated for primary AAA. Failures mostly occurred more than 2 years post-Nellix implant. There were eight secondary sac ruptures (incidence 2.4 per 100 person years) and there have been 14 graft explants.

Conclusions: Failure of aneurysm sealing following treatment with Nellix has been more common than anticipated and can cause aortic rupture. Post-operative surveillance of Nellix stent grafts is crucial to identify features of failure.

Article history: Received 7 February 2018, Accepted 7 June 2018,

Keywords: Abdominal aortic aneurysm, Endovascular sealing, EVAS, Nellix, Endoleak, Graft failure

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Who picks up the pieces?

Doctors, department & trust

- Notification of the patients
- Notification of Medical Director; Patient Safety Lead; MRHA
- Organisation of enhanced surveillance
- Counselling of patients about the problems with the device; lack of durability; need for enhanced surveillance; redo surgery
- Dealing with aftermath – ruptures; explants; unhappy patients; unhappy colleagues; serious incidents; inquests
-  Bed days; operating capacity; LOS; OP appts; CT scans

Patient & family

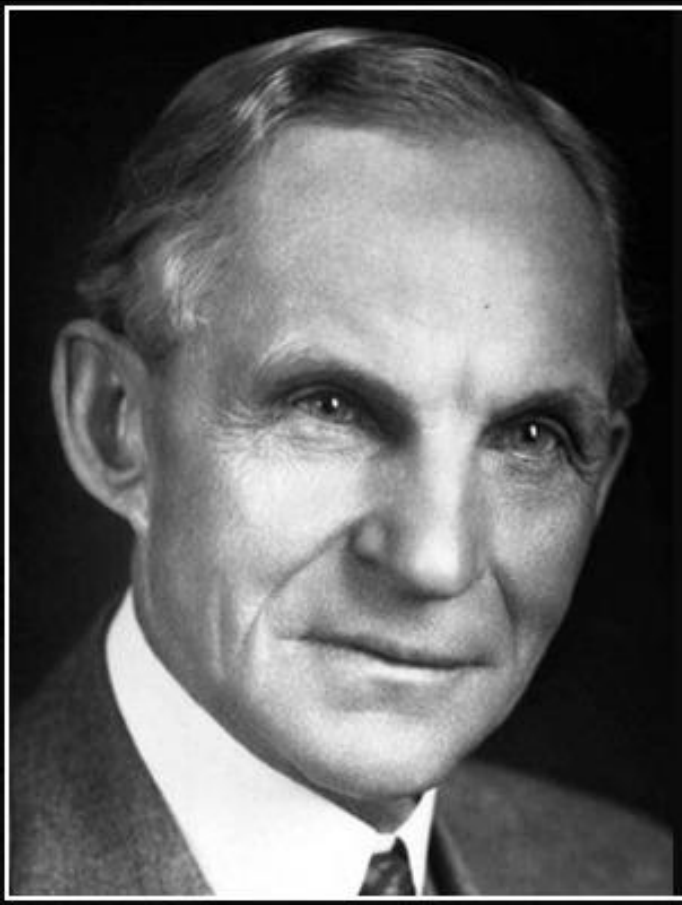
- Often remarkably understanding
- Also remarkably unquestioning
- Maybe the generation & that the Daily Mail has yet to report it
- Anxious about the risk of rupture
- Anxious about the prospect of further surgery

The Surgeon

- Guilt
- Feels responsible
- Feels like you have caused harm
- Never done intentionally
- Burden of disclosure to the patients
- Burden of ongoing care
- Psychological impact
- Reluctance to embrace new technology

Industry relationships

- Huge financial cost
- Doctors become risk averse
- Potential reduction in innovation
- Longer time for new technology to get to market
- Likely to be more rigorous testing for new devices
- There will be an increase need to provide data on longer term follow up



The only real mistake is the one from which we learn nothing.

— Henry Ford —

AZ QUOTES

From tragedy – great learning

Tacoma Narrows Bridge Collapse

Research in bridge aerodynamics & aeroelastics - has changed the way span bridges are built

Sinking of the Titanic

SOLAS - International maritime treaty

What have I learnt

- At GSTT we only performed Nellix in those where there was no other option
- Why were we not concerned by the lack of proximal fixation??
- We were worried by the lack of bail out options
- We are rubbish at assessing fitness for open surgery
  - Patients that had been deemed unfit for open repair have now survived explantation
  - We are better at open surgery now than we were when Vascunet report was published
  - Polymer degrades; Sealing causes devascularization of the arterial wall
- Not all bad
  - Some patient groups are still doing well - 'thrombus-less' AAA's
  - Polymer technology may be useful going forward
- Type II endoleaks are still troublesome

What do we need to do?

- Need more stringent testing of devices
- End practice of ‘grandfathering’
- Strict procedure for introduction of novel devices
- Compulsory data collection and audit of results
- Compulsory reporting of adverse events to the MHRA
- Unique identifier system – allowing quick notification about recalls and safety problems

Summary

- Enormous cost associated with medical device failure
- Questions for us
  - How do we safely introduce novel devices?
  - How should we monitor new devices?
  - How should we recall/safety notify?
- As professionals we have to lead the way
- We have to learn from errors
- We have to be the patient's advocate