Clinical evaluation of implants

Medical Device Regulation (MDR)

- Supposed to regulate the European Market regarding all medical devices
- In effect since May 26, 2021
- But, there is an exemption for devices already on the market until May 26, 2024 or 2025, depending on the state of EU-certification
- This is the context of spinal implants

As I understand the regulation regarding spinal implants,
it includes two demands/expectations :

They are directed to the manufacturers
Both apply to medical perfomance and safety

1. ***Traceability***
   Every individual device – pedicle screw, connector, washer,
   rod, plate etc. is expected to be traced in case of patient safety or
   material issues

   Because registries are indeed registries, we can foresee discussions
   with manufacturers on cooperation

The Swedish horizon?

- Pedicle screw systems are delivered to clinics unsterilized
- They do not have a UDI (unique device identification = bar code)
- Devices are manually recorded according to brand/type/size
- We need to consider:

  use of implant library,

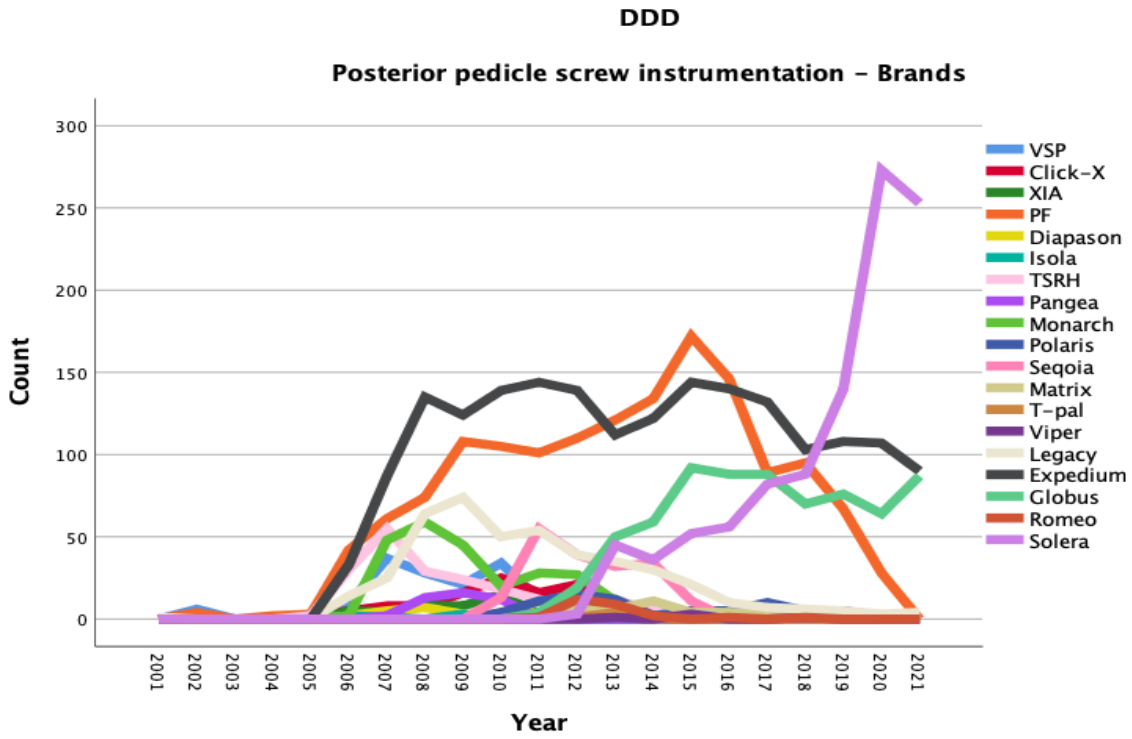
  granularity (i.e. details) of registration

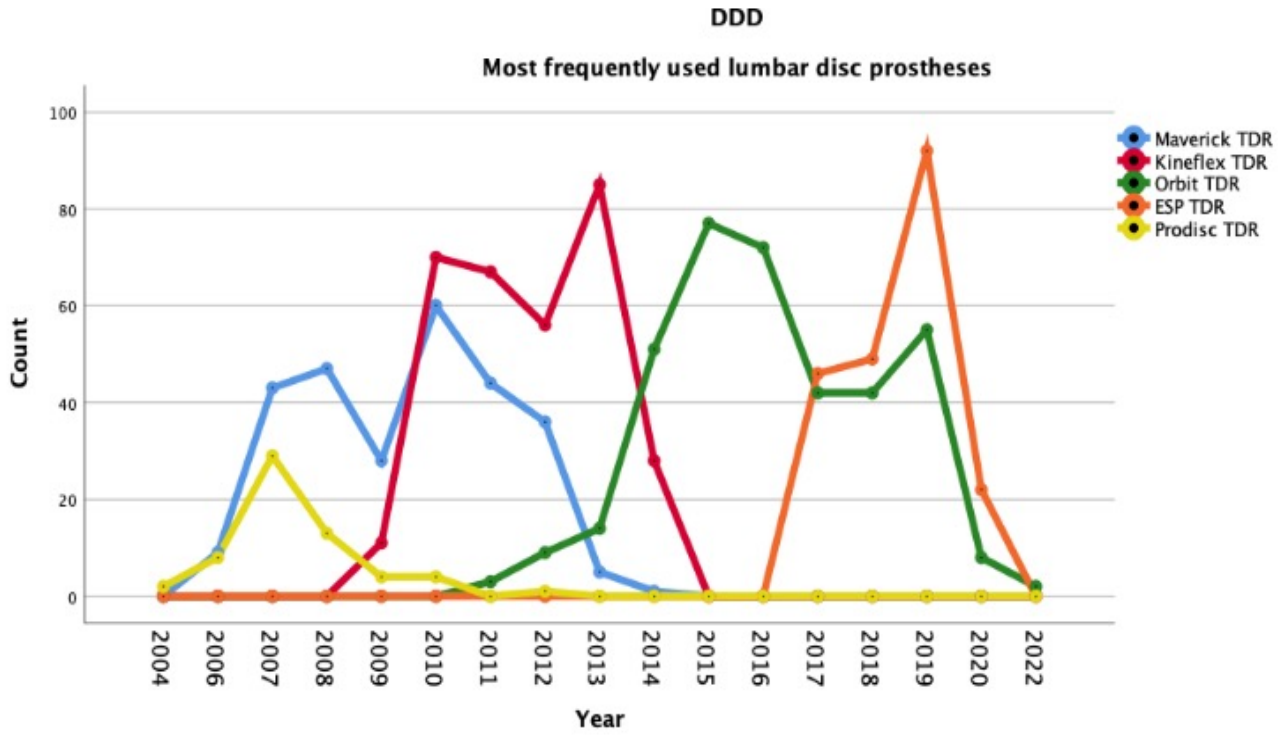
  role of UDI and bar code scanning

- Discussion with manufacturer representatives in Sweden

Swespine

Registration of implant brands since 2006





2. Clinical evaluation

MDR expects that the manufacturer delivers:

"*clinical evidence*" on "*clinical performance*" and "*clinical benefit*"

which means

"*the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis*"

and

"*the magnitude (extent, amount, intensity) of this should be measurable and patient specific*"

This rather demanding expectation will be an obvious request to registries

How do PROMs relate to the success of an implant?

To answer the question we need to contemplate the background of spinal implants

The idea to use implants in spine surgery is based on the assumption that a non-biological device

1. replaces a biological function
2. enhances a biological process

1. Replacement of a biological function

TDR is comparable to THR (or TKR) to a certain degree

Disc and hip prostheses are designed to preserve motion and give pain relief.

Basically the hip is one large motion joint with one disease

In THR there is a strong correlation between radiology, motion and pain relief/functional outcome

X-ray is a rather good “objective” measure of outcome together with a PROM

The disc is more of a large compression joint and connected with two small motion joints – multileveled and a multitude of diagnoses

What is a success of TDR?

Does it require preserved motion?

Obviously there can be preserved motion with remaining pain

Or an eccentrically placed prosthesis in a fused and pain free segment

The relation between PROM and intended implant function is dubious

Contrary to THR, replacement of the biological function is not necessary for success

It could be a failure in success or a success in failure

2. ***Enhancement of a biological process***

The typical pedicle screw based construct

a. *Correction of deformity*

The purpose of the implant is reduction and retainment of alignment until fusion is healed

b. *Stabilization of fractures*

While fracture heals

c. *Neutralization of intervertebral motion*

While graft integrates

Basically the implant has the same purpose:

- a temporary stabilizer while the graft is integrated
- No construct without grafting, or were pseudarthrosis develops, will stay in place – it will loosen or break

What is an implant failure?

Typical description:

An implant failure can manifest as breakage of the implants, fracture of the body or pedicle, extrusion of the screws, or progressive kyphosis or lordosis without bony fusion

Surgical Complications in Neurosurgery
Anil Nanda, Devi Prasad Patra, 2019

A rather cloudy definition

- What is implant failure?
- What is surgeon failure?

Complications in Neurosurgery

- Is a pseudarthrosis an implant failure?

  How do you role out insufficient bed preparation and volume of graft?
- Is loosening of a screw an implant failure?
- Has preparation and insertion been done properly?

  Bone quality – osteoporosis?

  Are sufficient levels instrumented?
- Loosening of a connector?

  Was it applied and tightened correctly?

  Was the rod long enough?

  Was the rod curved properly?

What is an undisputable implant failure?

- Breakage of screw/rod/plate - Yes
- Connector or set screw loosening – possibly
- Screw pull out or loosening – No

- Breakage was a problem in the -80s and -90s

  René Louis, Roy-Camille etc - Steffee turning point

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- Today material breakage is a rarity

Exceptions in special conditions

Early onset scoliosis - Rod distraction systems

- Not a temporary stabilizer
- No fusion

- 15-29% of 2021 cases in recent meta analysis "unplanned reoperations"

Kim G et al. Comparison of surgical interventions for the treatment of early-onset scoliosis: a systematic review and meta-analysis. J Neurosurg Pediatr. 2022 Sep 23;31(4):342-357. doi: 10.3171/2022.8.PEDS22156. Erratum in: J Neurosurg Pediatr. 2023 Jan 13;31(4):388. PMID: 36152334

Correction of idiopathic scoliosis

Optimal biological conditions

Strong forces on instrumentation

The ultimate real life test of implant material quality

Recent reports:

- 0,2-0,6% of 934 cases
  “Implant failure” unspecified

Jamnik AA, et al Repeat surgical interventions following "definitive" instrumentation and fusion for idiopathic scoliosis: a 30-year update. Spine Deform. 2023 Aug 12. doi: 10.1007/s43390-023-00742-6. Epub ahead of print. PMID: 37572225.

- 1,0% of 1816 cases
  “malpostion of implant/implant failure”
  “failed internal fixation”

Dong Y et al. Revision Surgery After Spinal Fusion in Adolescent Idiopathic Scoliosis. Global Spine J. 2022 Jul 21:21925682221117130. doi: 10.1177/21925682221117130. Epub ahead of print. PMID: 35862230

In all other conditions – degenerative, trauma, malignancy:

Implant failure is a possibility

But if not breakage:

You first need to sort out bone quality, surgical technique, the right indication, sufficient number of instrumented levels, proper grafting etc

- All in all, in my view, it will be very difficult to relate implants to PROMs, except in very rare circumstances

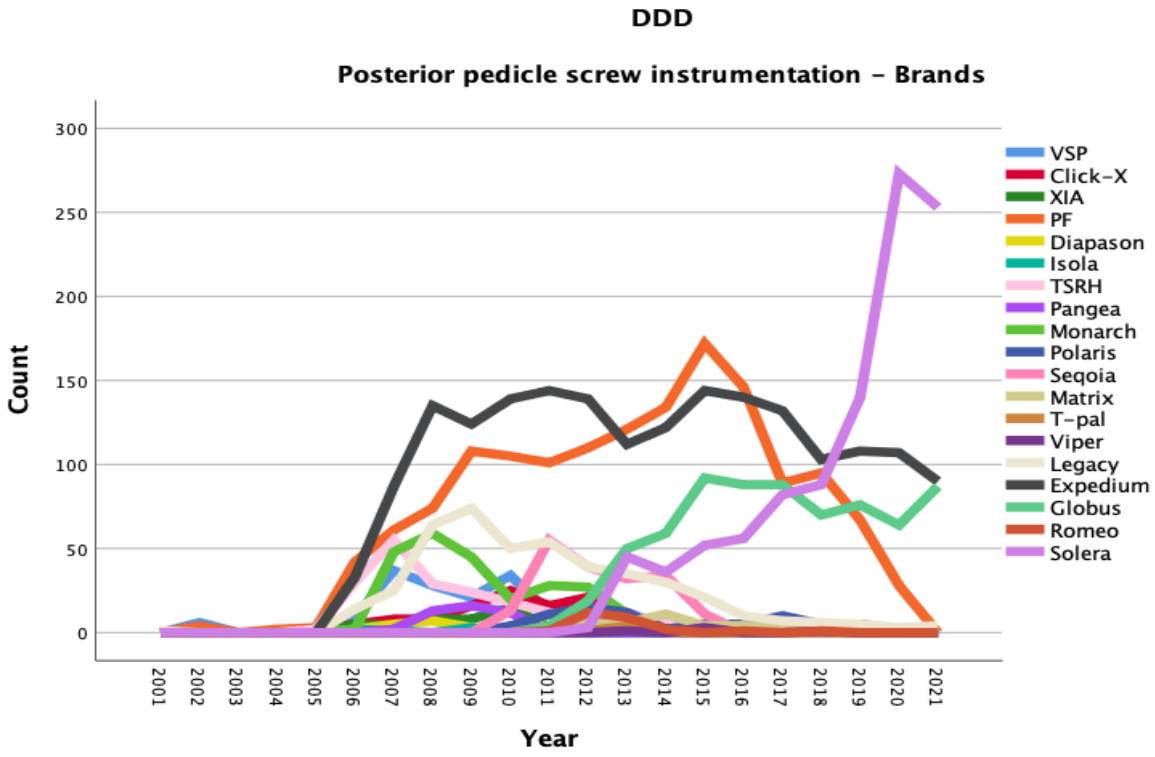
- A legal case would probably end with a failed surgeon

The idea to register every screw, washer, connector etc as a means of quality improvement is probably a delusion.

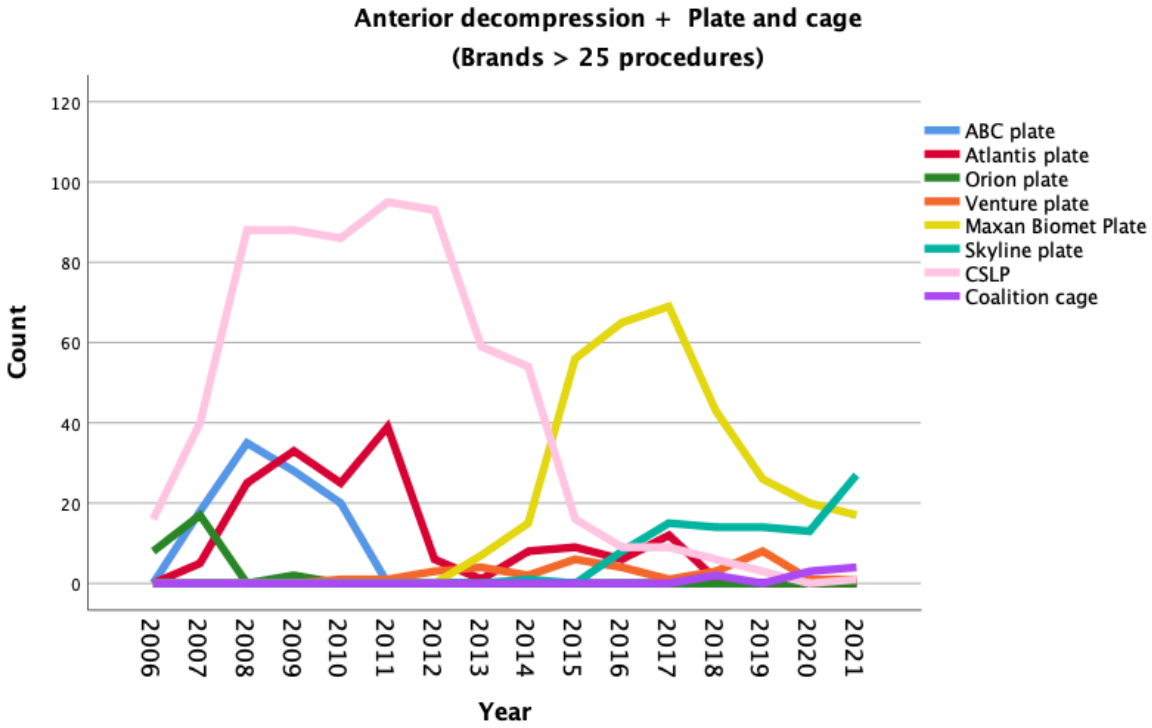
- I can not see its clinical relevance.
- I think the construct brand is enough
- I also think that it is more important to discuss the indications of instrumentation rather than benchmarking of construct brands

Why do we change instrumentation?

Lumbar



CDH



- Manual handling properties
- Economy

Conclusion

We have to adjust to legal demands

Assistance in implant registration is an option to consider

I doubt the feasibility of benchmarking implants by outcome