Les registres axés sur les patient-es peuvent améliorer santé, soins et connaissances scientifiques: Expérience du Geneva Arthroplasty Registry

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Introduction

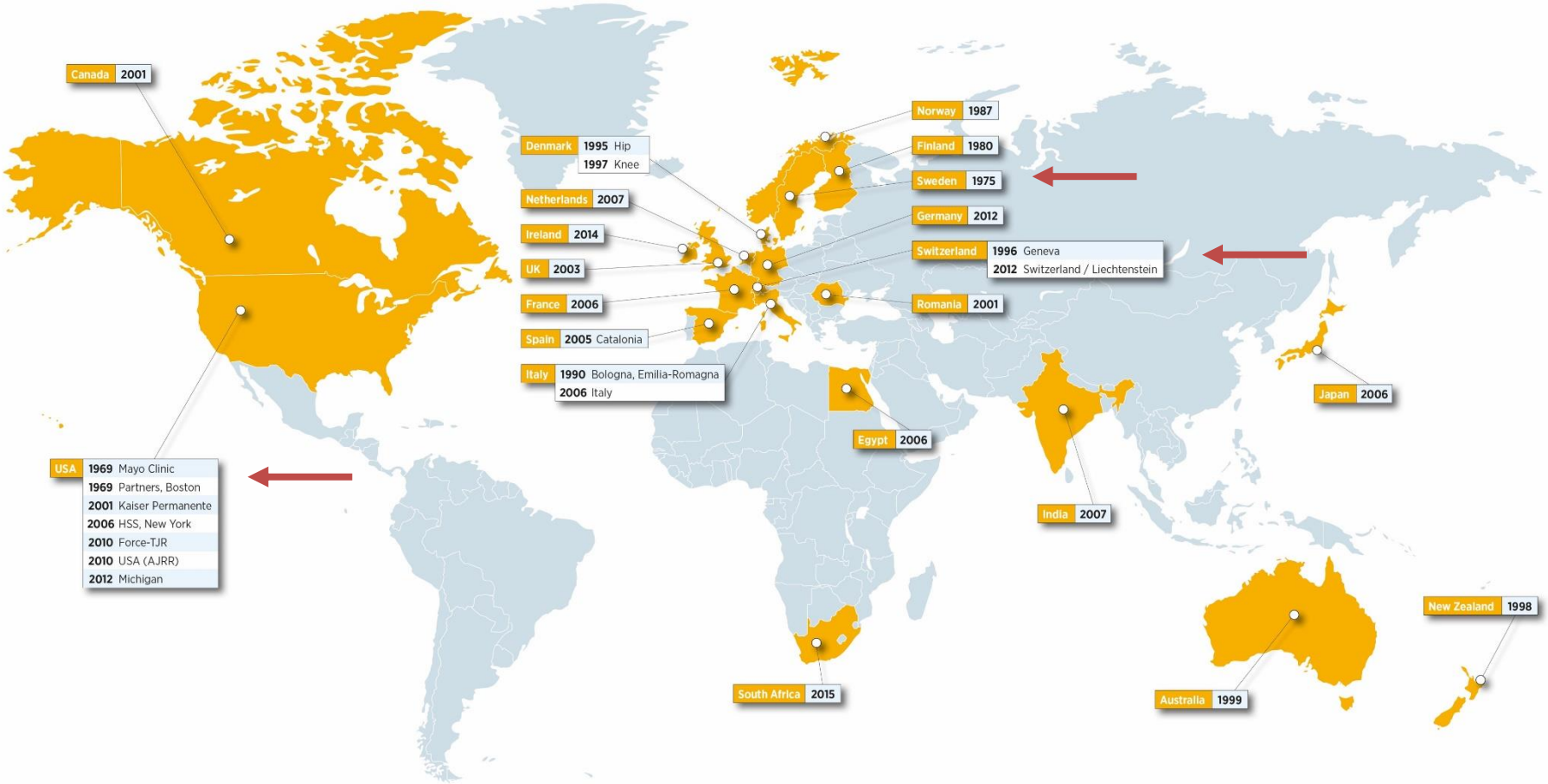
«Les cliniciens aident les patients de trois manières :

- en diagnostiquant ce qui ne va pas,
- en proposant un traitement qui fait plus de bien que de mal,
- et en leur donnant une indication de ce que l'avenir leur réserve.»

Guyatt G et al. User's guide to the medical literature. JAMA Evidence 2002

"This prescription doesn't cure anything, but it has fewer side effects than other drugs."

Registres de prothèses dans le monde



International Society of Arthroplasty Registries (ISAR): Members 2023

Geneva Arthroplasty Registry (GAR)

Prothèses de hanche (PTH) et protheses de genou (PTG)

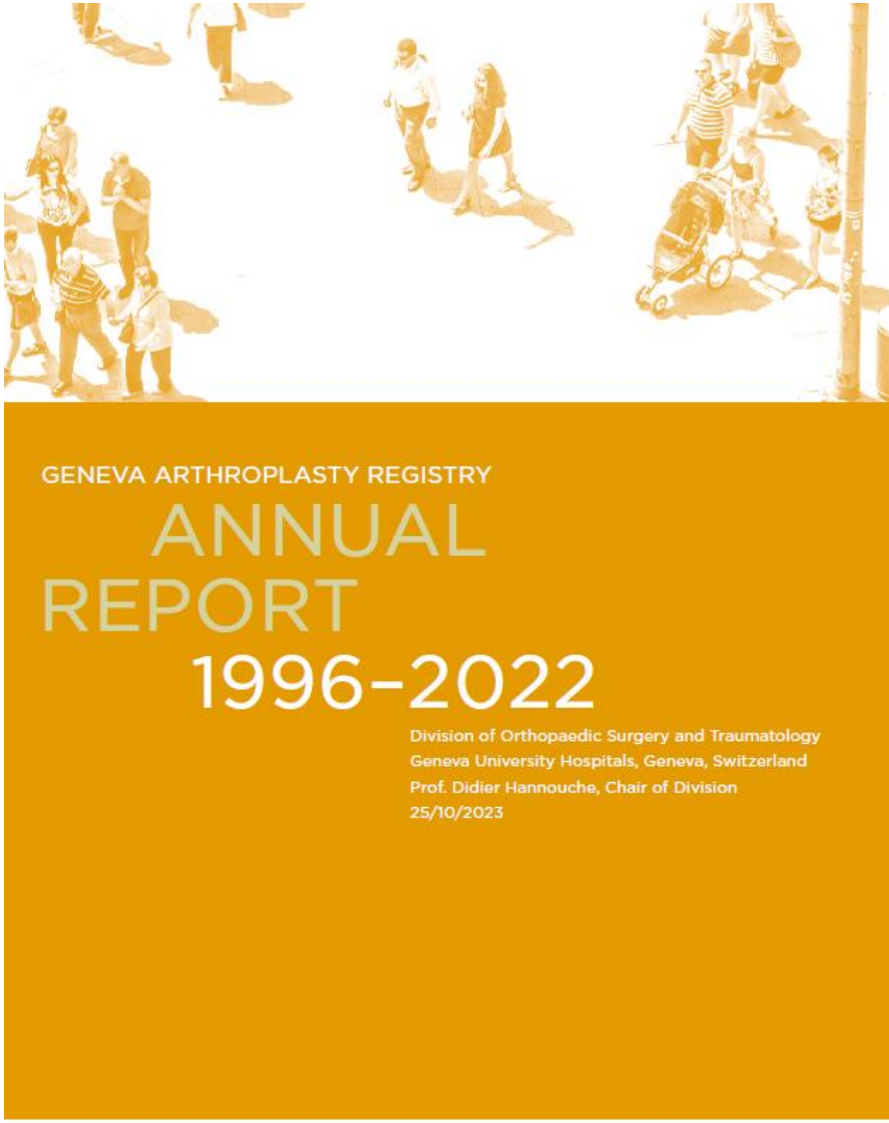
Crée 1996 par

Prof. Pierre Hoffmeyer

Service de chirurgie orthopédique et traumatologie de l'appareil moteur HUG

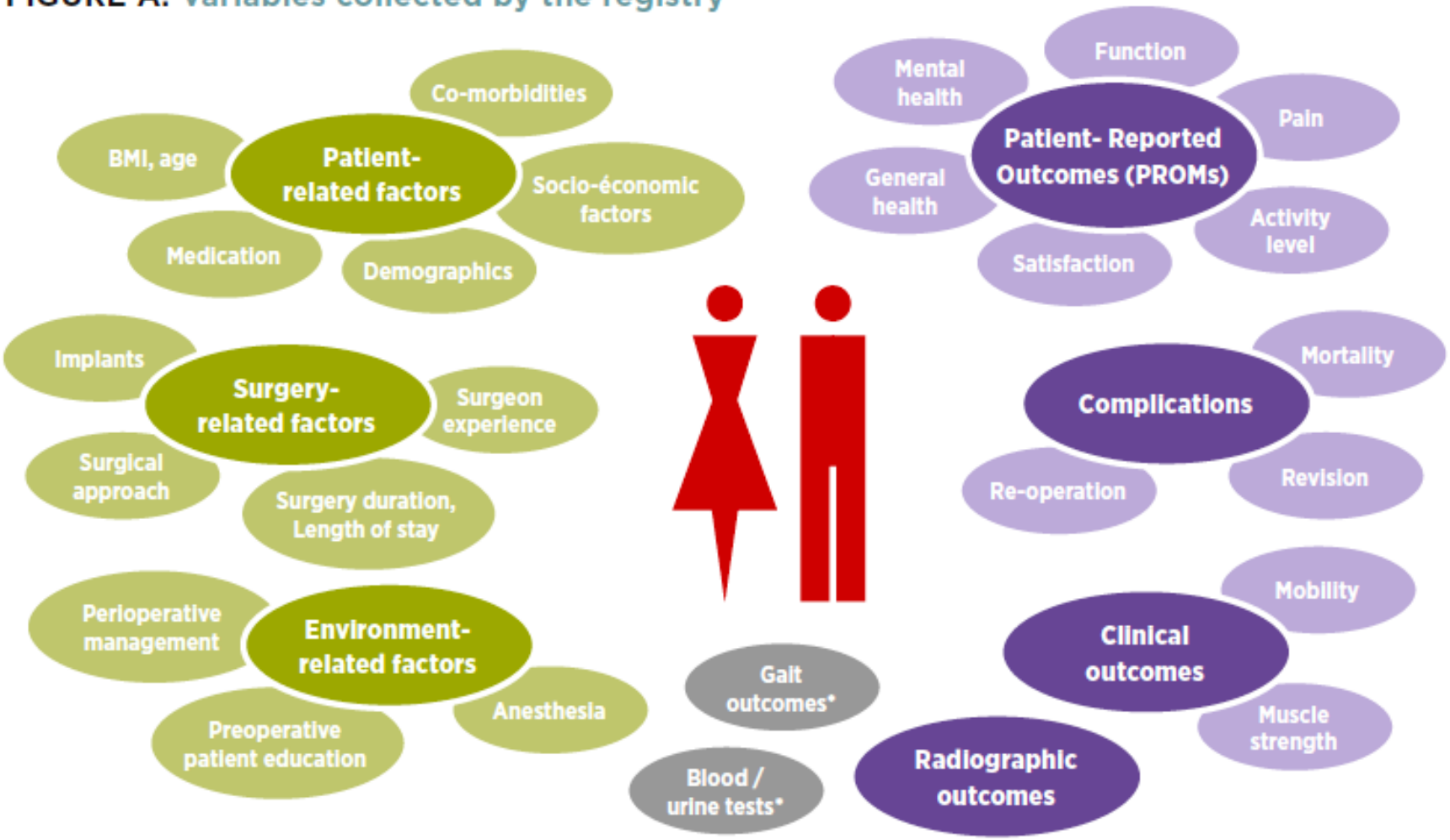
Environ 900 interventions par année

Age moyen patient-es 69 ans



GAR – Domaines des variables

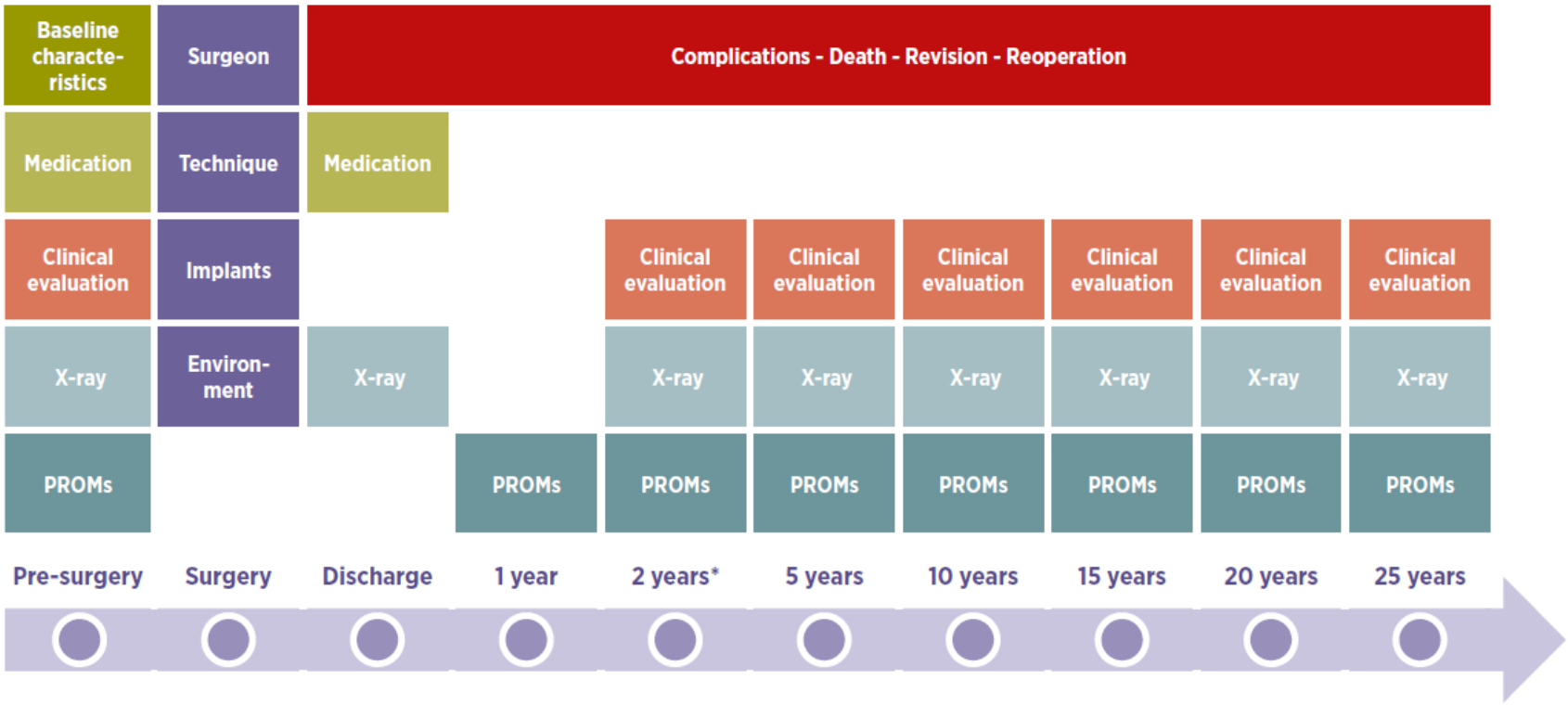
FIGURE A: Variables collected by the registry



* Gait analysis and blood testing (except for metal ion levels in the context of metal-on-metal hip arthroplasty) is not part of the routine follow-up. Gait analysis and/or blood testing are performed for particular study questions – requiring pre-specified study protocols and additional ethics committee approval – nested within the registry.

GAR – Timeline recolte de données

FIGURE B: Timeline data collection total hip arthroplasty



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Objectives registre GAR

☒ Descriptif

☒ Surveillance post-marketing

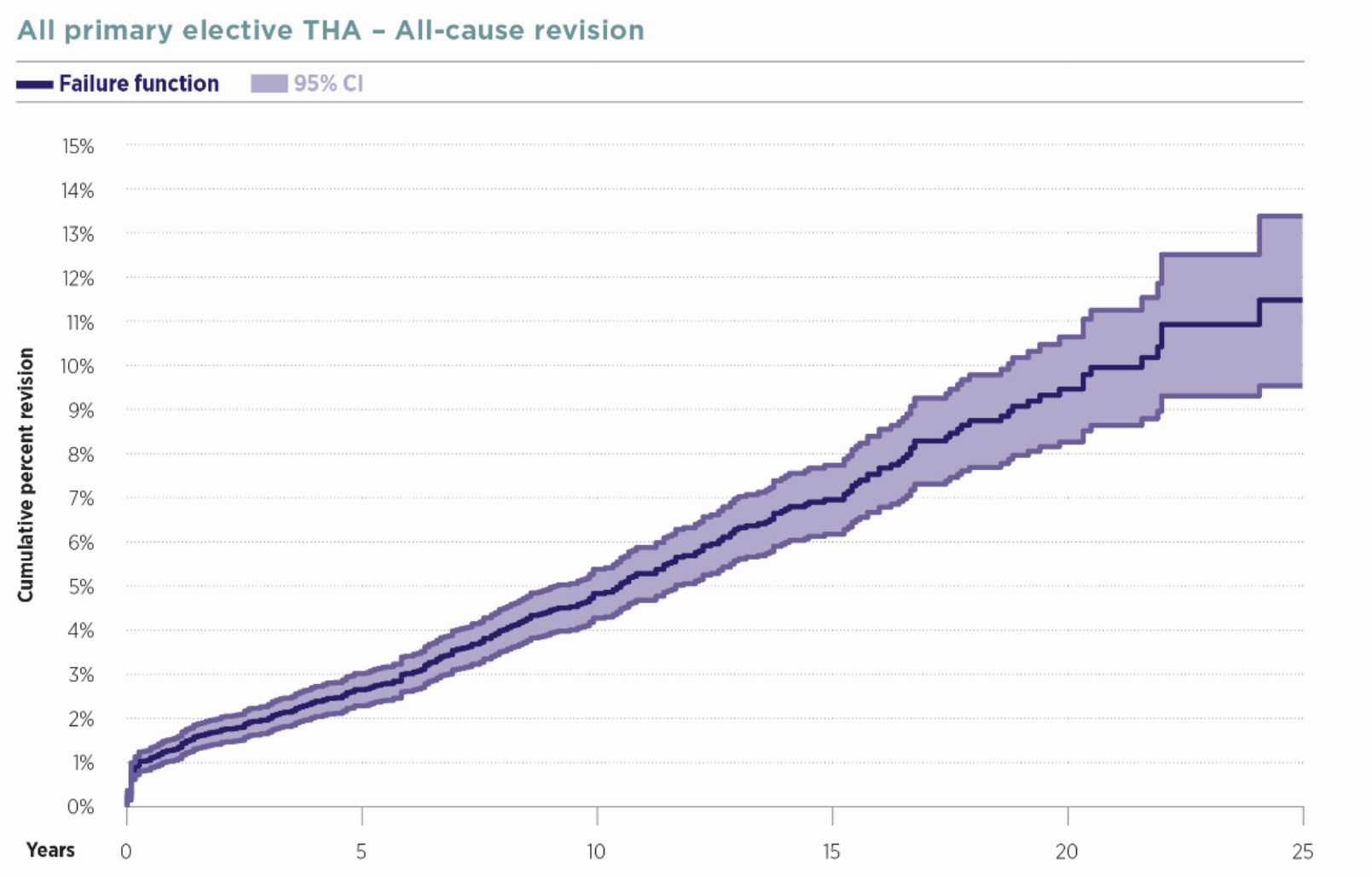
☒ Évaluation comparative interventions/traitements

☒ Amélioration de la qualité, benchmarking

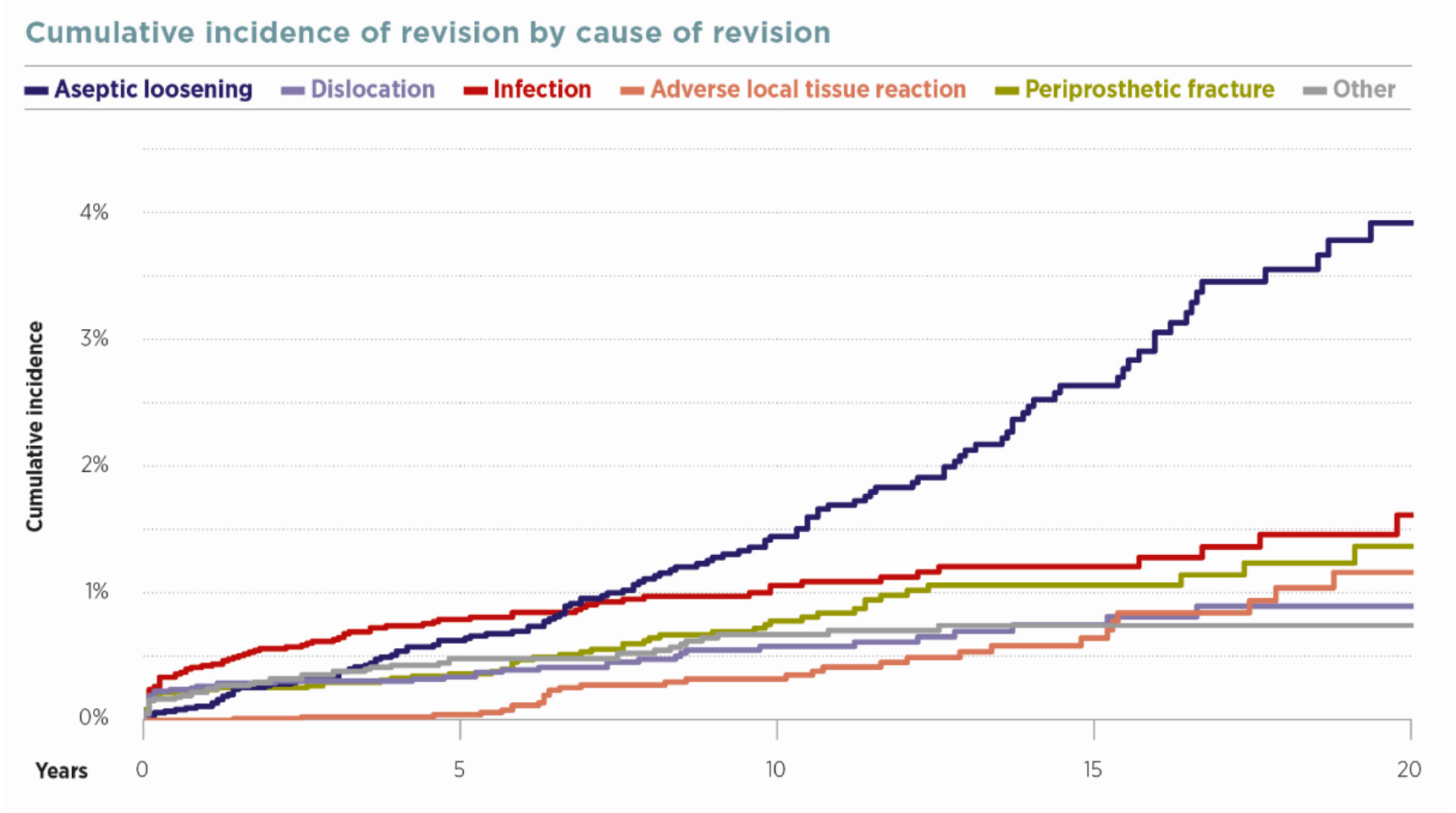
☒ Recherche clinique/translationnelle

☒ Support décisionnel pour cliniciens/patients

Descriptif – Durée de vie d'une PTH



Descriptif – Causes de revision d'une PTH



Surveillance post-marketing

- Mise sur le marché des nouveaux implants et contrôle post-marketing: peu règlementée dans le passé (EU Directive)
- Surveillance via les registres, établie d'une manière volontaire depuis 1969
- EU Medical Device Regulation (MDR) entrée en vigueur mai 2021
- Registres deviennent source d'information reconnue concernant sécurité et performance clinique des implants dans nouvelle loi (MDR)

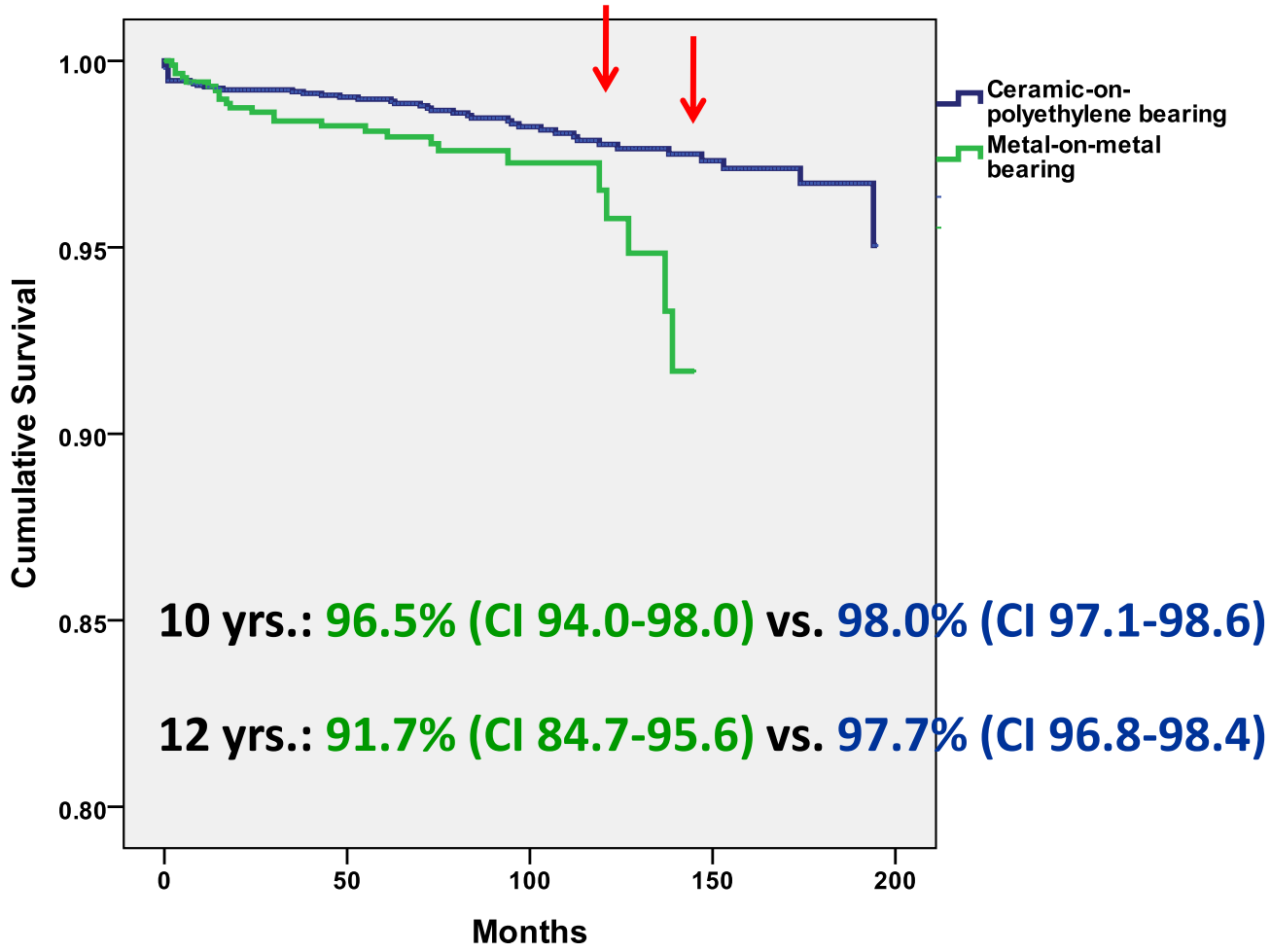
Melvin T et al. New medical device regulations: the regulator's view. EFORT Open Rev. 2019
Lübbeke A et al. The case for an academic discipline of Medical Device Science. EFORT Open Rev. 2021

Surveillance - Evaluation comparative implants

- Garavaglia G et al. 10-year results with the Morscher pressfit Cup. Int Orthop. 2011
- Christofilopoulos P et al. Total Hip Arthroplasty with a large diameter metal-on metal cup (Durom) and a standard stem. Short term results. EFORT 2012
- Berton C et al. Outcomes of cable vs. wire fixation five years after total hip arthroplasty. JBJS Br. 2012
- **Lübbeke A et al. Comparative assessment of metal-on-metal vs. ceramic-on-polyethylene small head total hip arthroplasty. BJJ 2014**
- Gonzalez AI et al. Comparison of dual-mobility cup and unipolar cup for prevention of dislocation after revision total hip arthroplasty. Acta Orthop. 2017
- Garavaglia G et al. Short stem total hip arthroplasty with the direct anterior approach demonstrates suboptimal fixation. Int Orthop. 2021
- Pijls B et al. MoM total hip replacements in Europe: a NORE report. EOR 2019

Prothèses métal-metal (MoM)

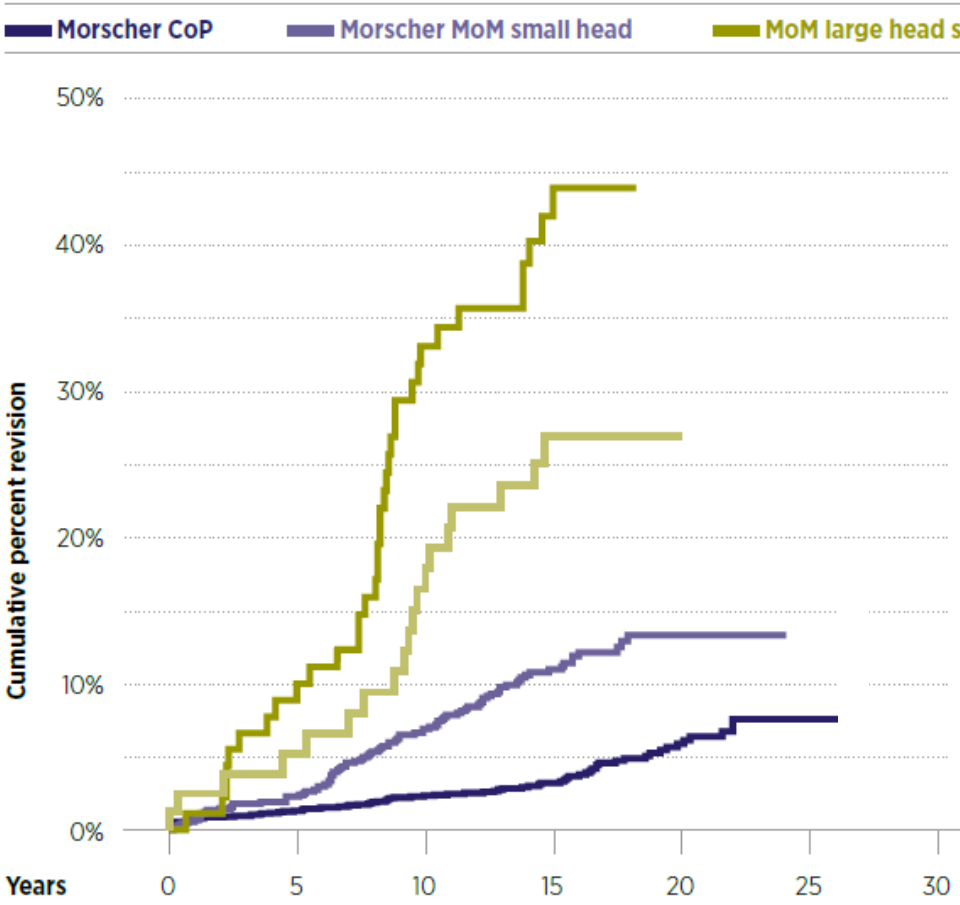
Implant survival according to bearing surface (CoP vs. MoM)



Lübbeke A et al. Comparative assessment of metal-on-metal vs. ceramic-on-polyethylene small head total hip arthroplasty. BJJ 2014

Prothèses MoM: résultats à long-terme

FIGURE 53: All primary elective THA - All cause revision according to types of MoM implants



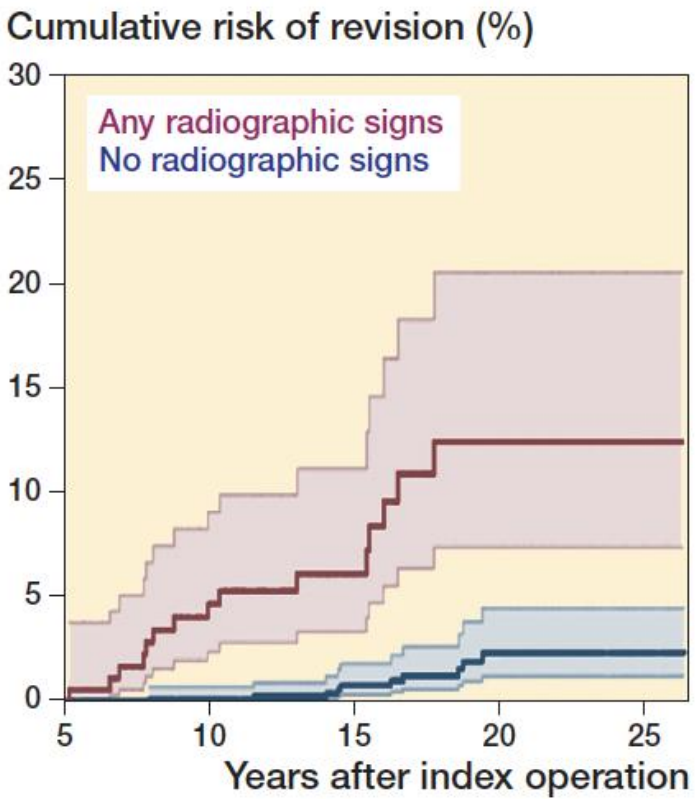
Log Rank test,
p<0.001

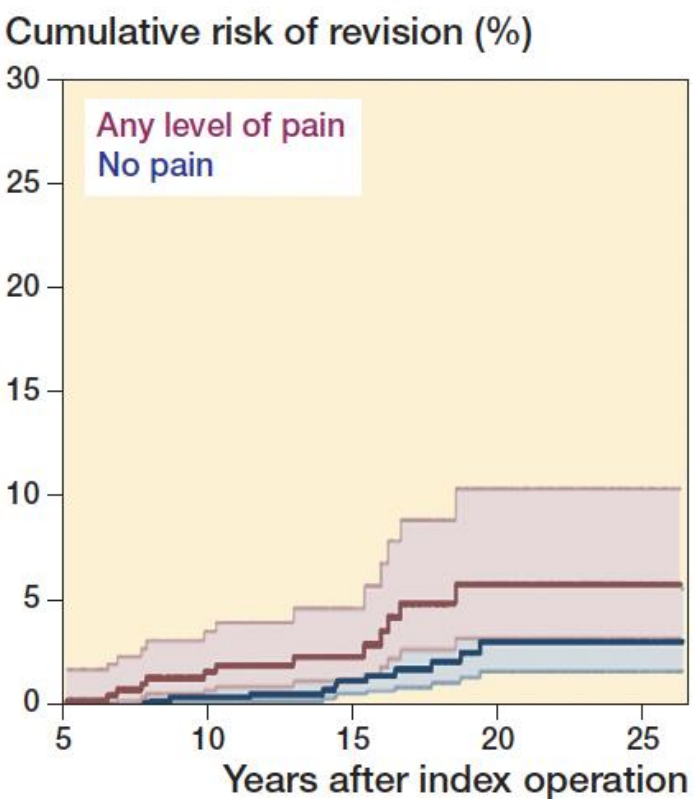
	Total N	N of Events
Morscher CoP*	2497	86
Morscher MoM small head	915	92
MoM large head stemmed	92	35
MoM large head resurfacing	81	19
Overall	**3585**	**232**

Geneva Arthroplasty Registry. Annual report 1996-2022.

Gonzalez A et al. Long-term outcomes of small head metal-on-metal compared to ceramic-on-polyethylene THA.

Surrogate endpoints for revision



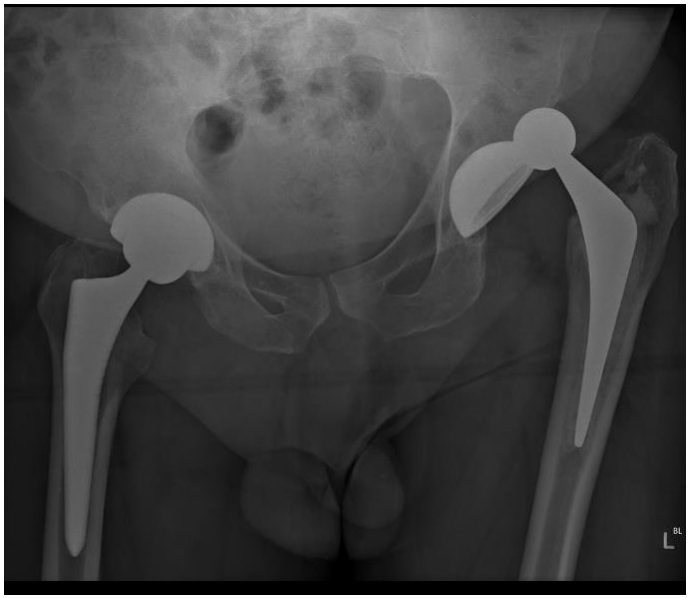


Lübbeke A et al. Radiographic signs and hip pain 5 years after THA with a cemented stem predict future revision for aseptic loosening: a prospective cohort study. Acta Orthop 2024

Amélioration de la qualité

Complications

- Exemple: Luxation



Luxation PTH

II.10.4 Dislocation risk within 6 months postoperative for primary THA

FIGURE 20: Dislocation risk (%) within 6 months for all primary THAs per year

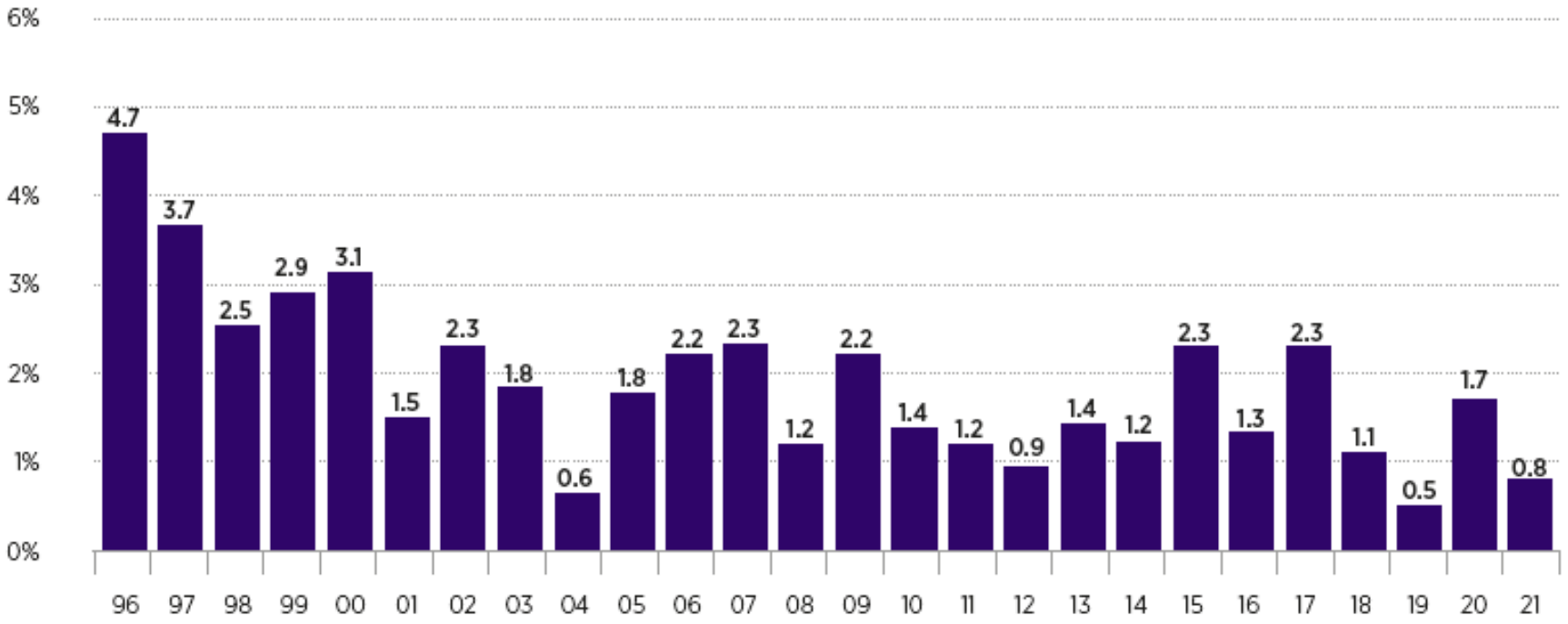


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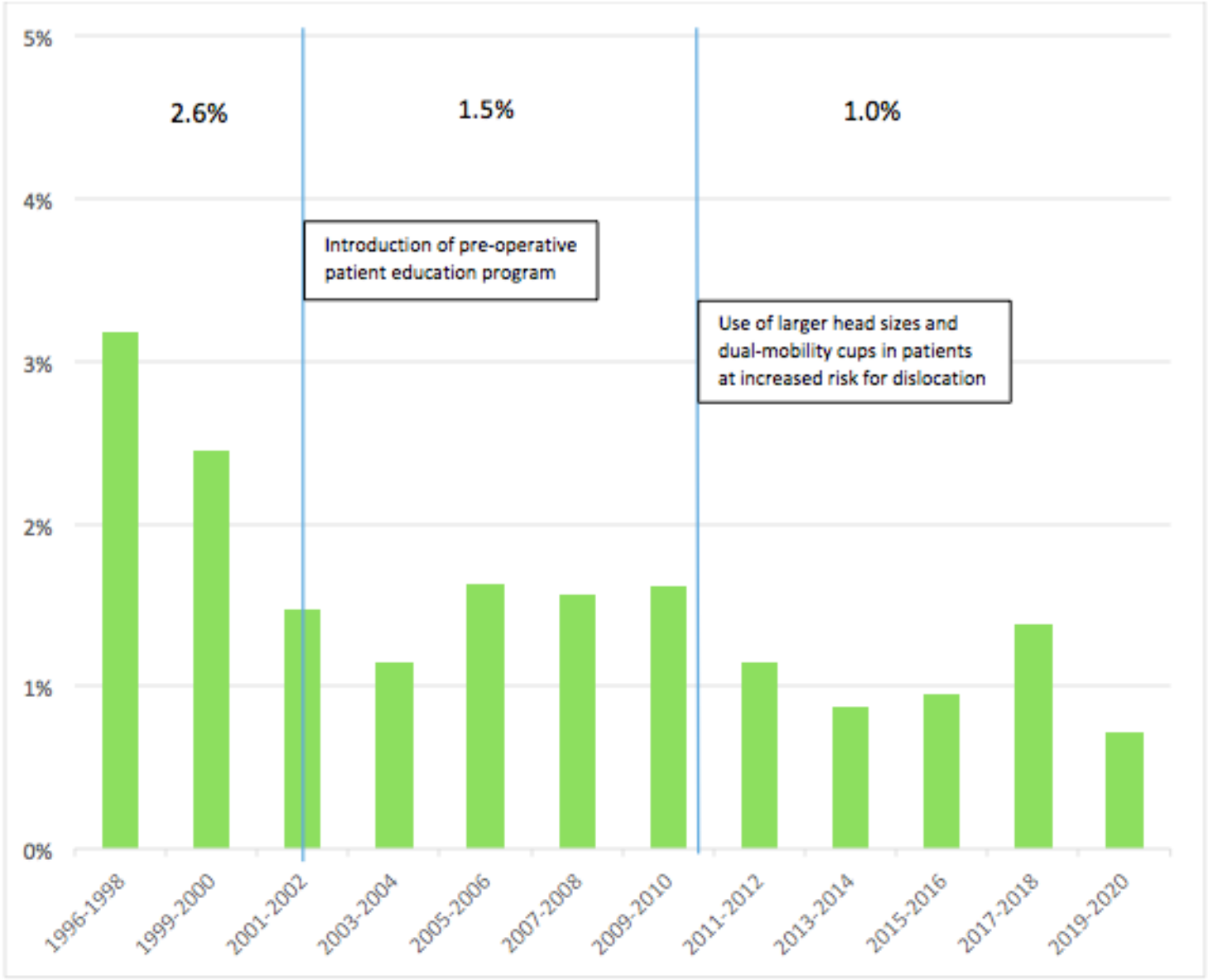
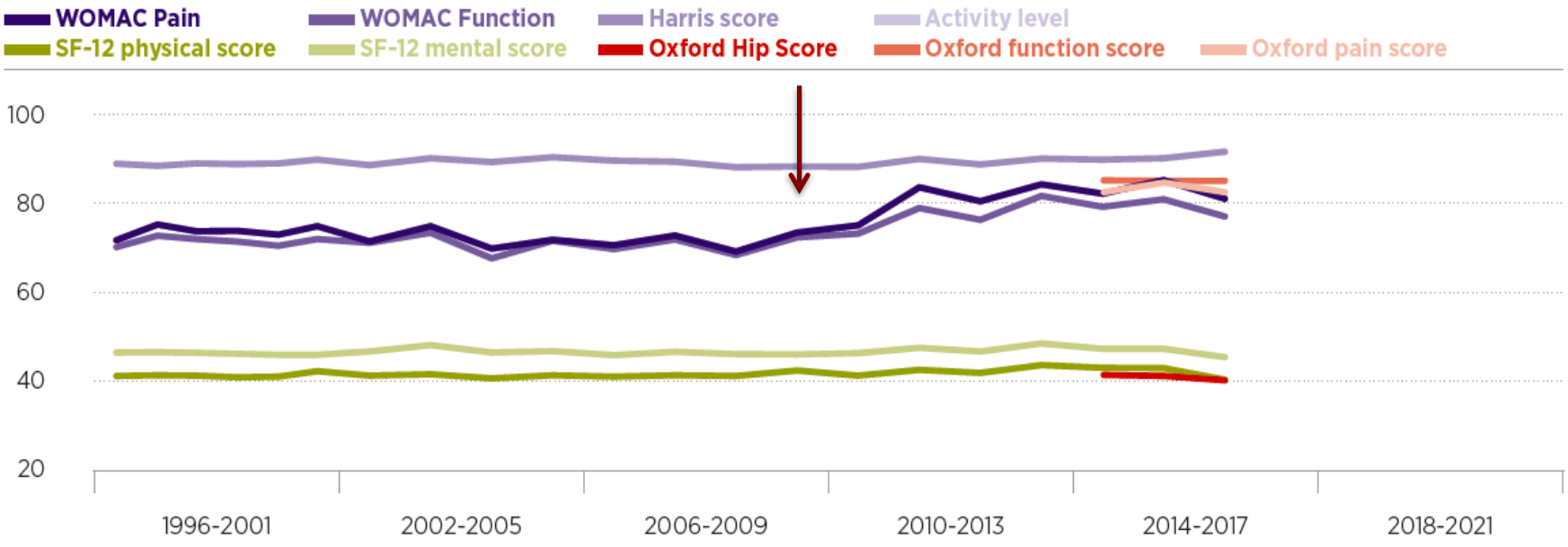
Figure 6. Trend in occurrence of dislocation (%) within 6 months after primary elective THA 1996-2020



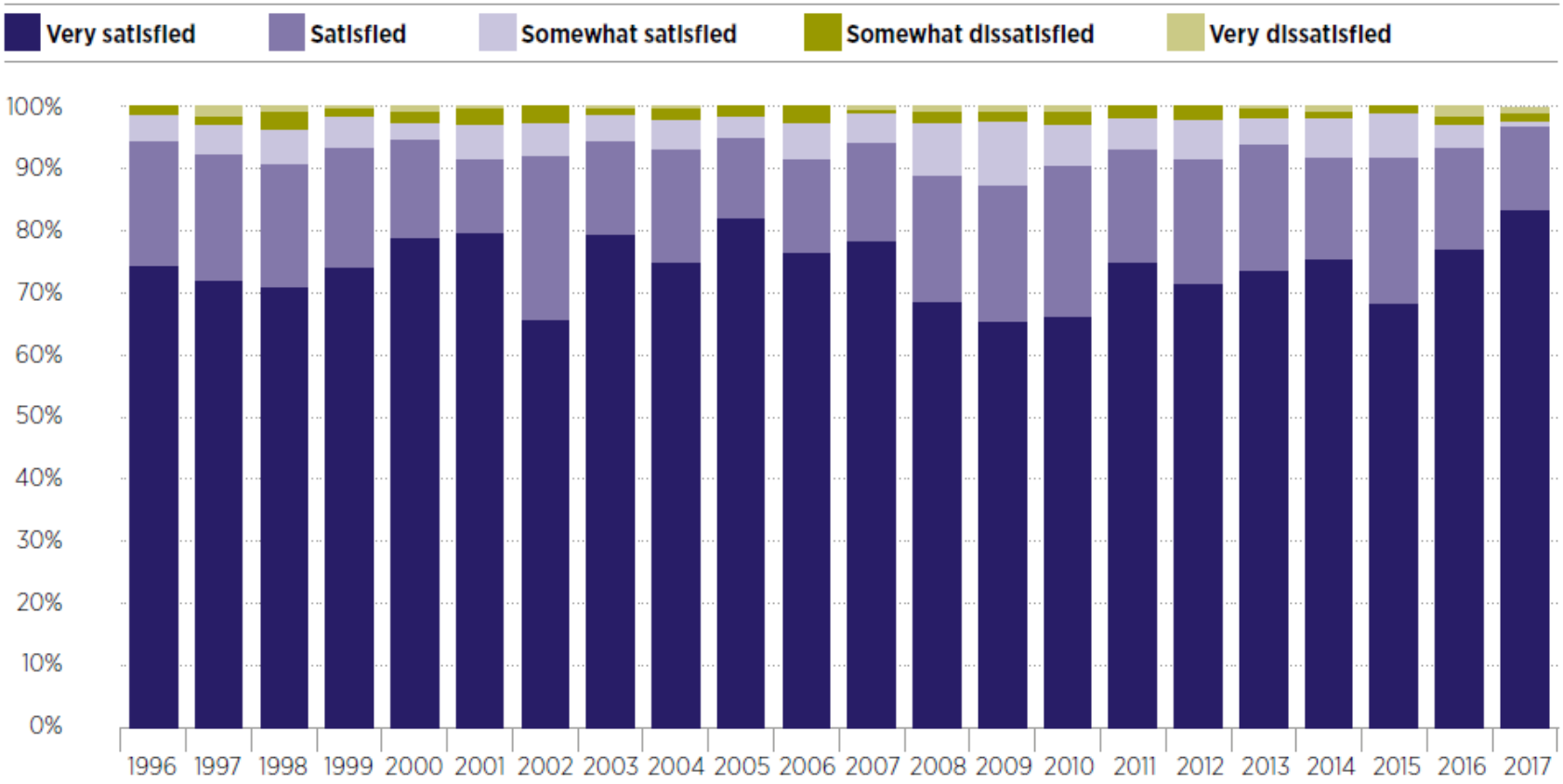
Trends in patient-reported outcomes

FIGURE 75: Trends in PROMs 5 years after surgery for elective THA



Trends in patient satisfaction

FIGURE 62: Trend in patient satisfaction 5 years after primary THA



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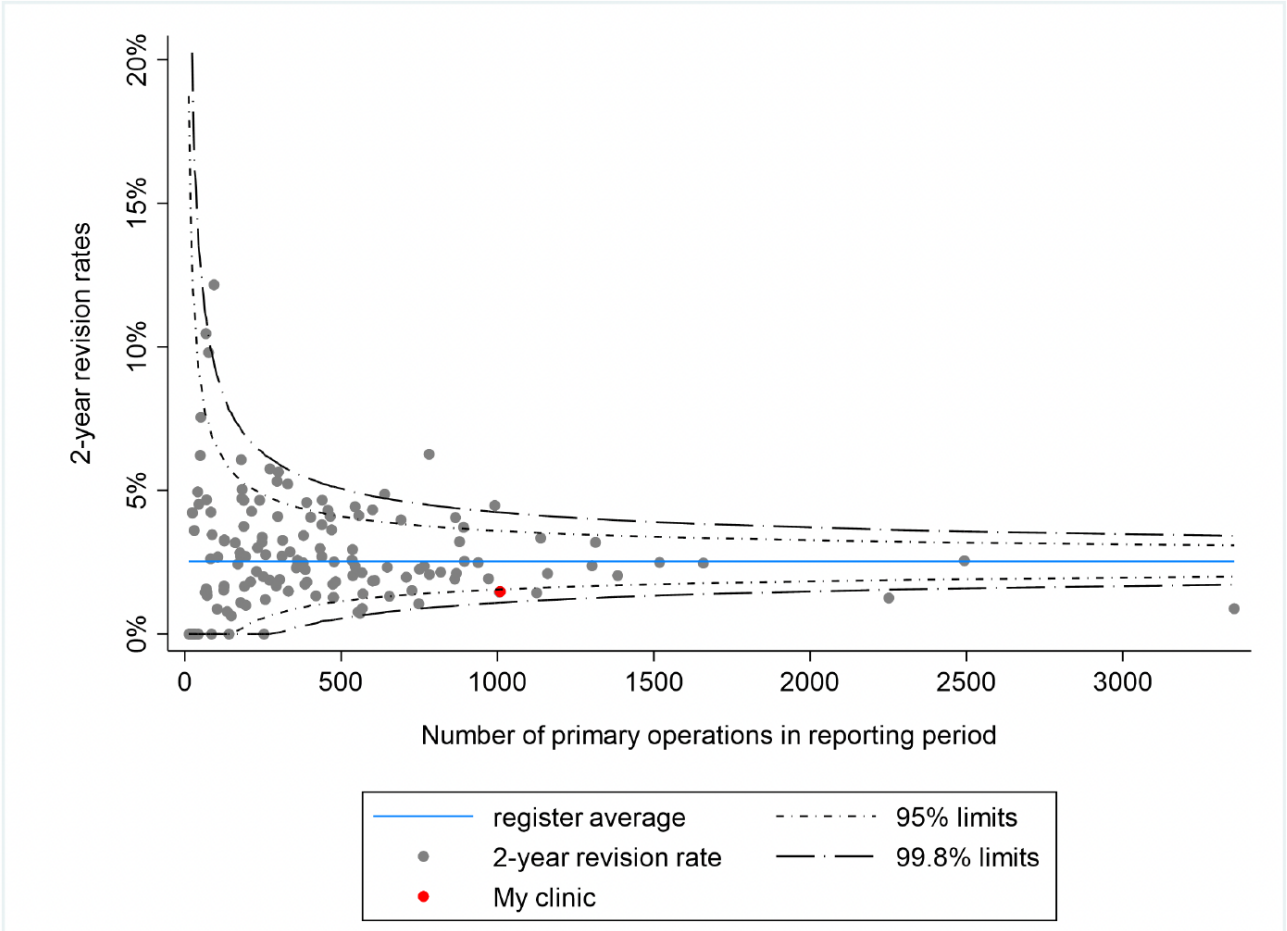
Benchmarking GAR - Registre Suisse (SIRIS)

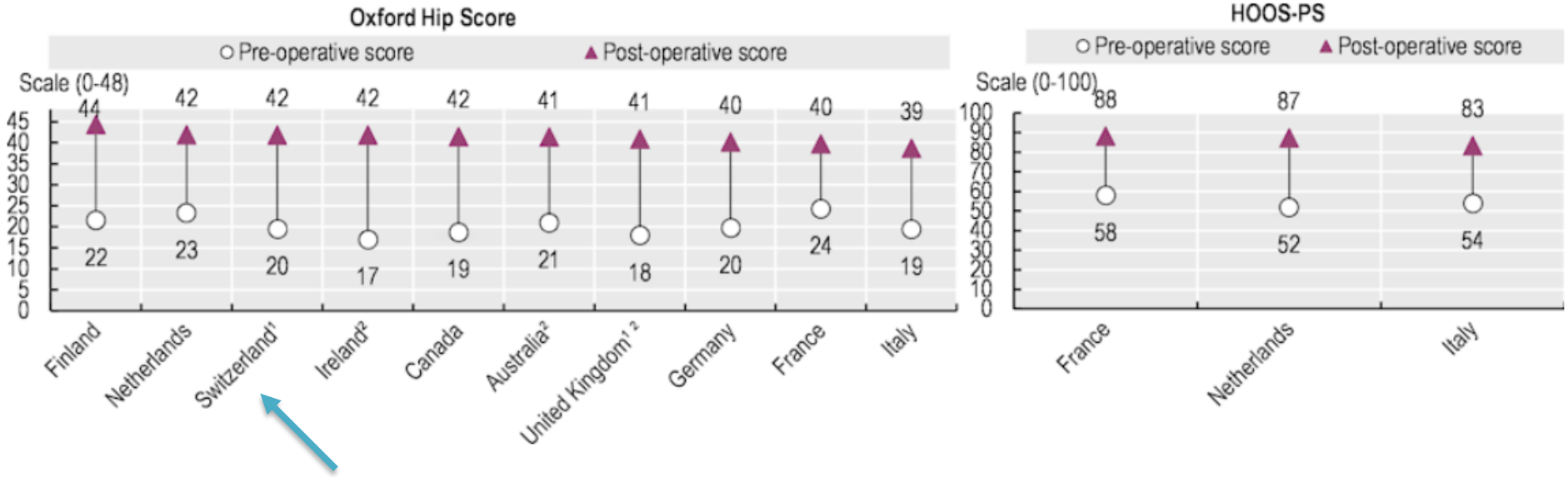
SWISSRDL siris

2.3.6a First Hip revisions (THA, diagnosis primary OA) – funnel plot of risk adjusted* revision rates (4-year moving average)



Benchmarking patient-reported outcomes GAR – OECD countries

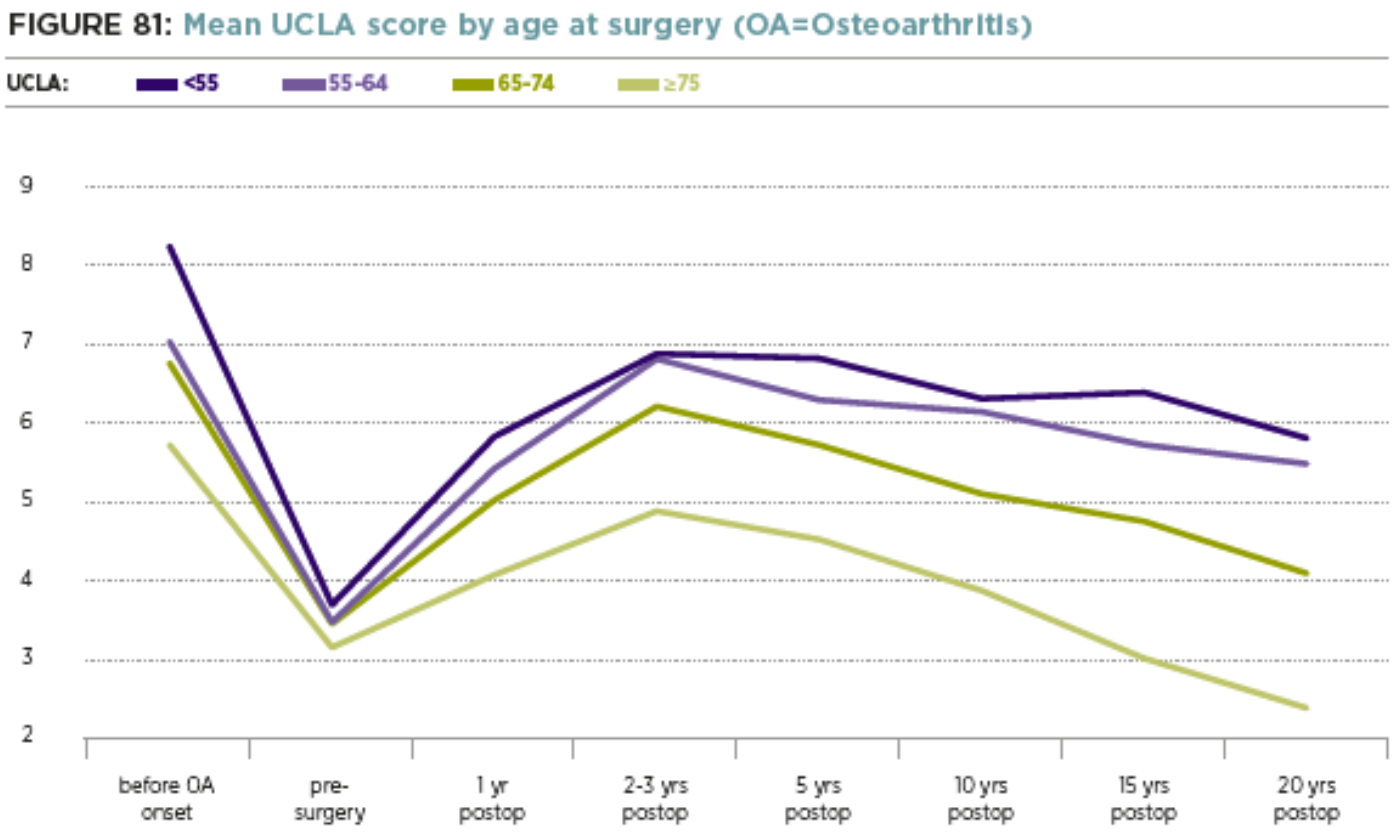
Figure 6.27. **Patient-reported outcomes before and after hip replacement surgery, disease-specific measure, 2023 (or nearest year)**



Source: OECD PaRIS Hip and Knee PROMs Pilot Data Collection

Recherche clinique – Activité physique

III.15 Physical activity (UCLA score) at follow-up by age at surgery



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Recherche clinique – Activité physique

- Descellement aseptique: Cause principale de révision à long terme
- Activité physique: Facteur déterminant de longévité des implants

"… physically demanding jobs may be more difficult to retain if they involve **prolonged standing, kneeling/squatting or handling ≥10 kg**. These work effects … having the most significant impact on those with lower educational attainment and/or income."

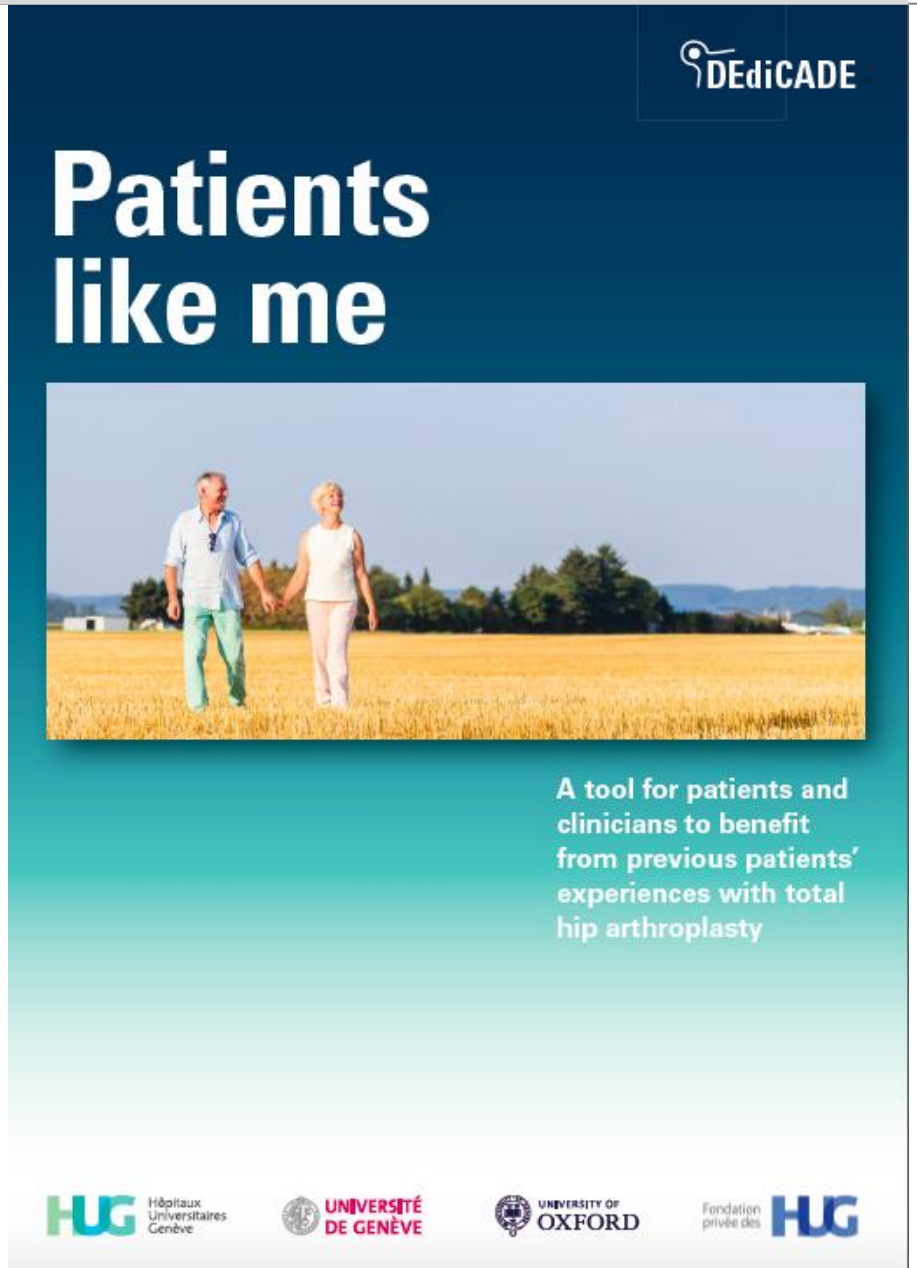
"The overall risk of revision was small but **intensive physical activity** may be associated with an **increased risk of revision**. This needs to be balanced against the importance of PA for mental health, cardiometabolic health, and disability-free survival."

Zaballa E et al. Feasibility and sustainability of working in different types of jobs after THA. Occup Environ Med. 2022
Zaballa E et al. Level of physical activity after total hip arthroplasty and risk of revision surgery in patients aged under 65. Revised version under consideration by Acta Orthopaedica

Support décisionnel pour cliniciens/patients

L'objectif de ce projet était de développer un outil utilisant l'expérience de patients antérieurs pour éclairer la prise de décision clinique centrée sur le patient.

- 6836 PTH primaires electives
- 39 prédicteurs: age, sex, BMI, ASA, Charnley, comorbidity count, diagnosis, previous surgery, smoking, SES, self-rated health, SF12 mcs, WOMAC pain/function, ...
- 20 ans de suivi



“Patients like me”

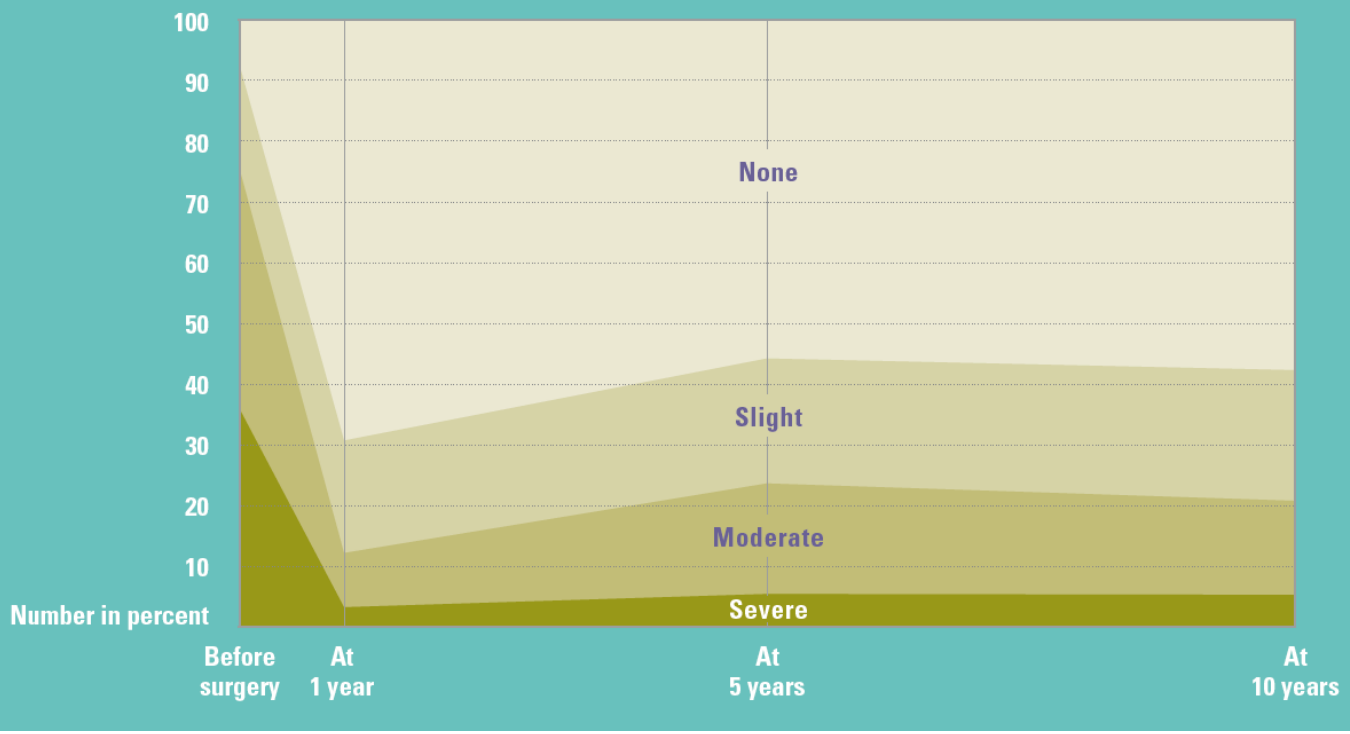
Douleur nocturne – Tous les patients - Trajectoire sur 10 ans

EXAMPLE:
PAIN RELIEF
Night

How much pain do you have at night in bed?

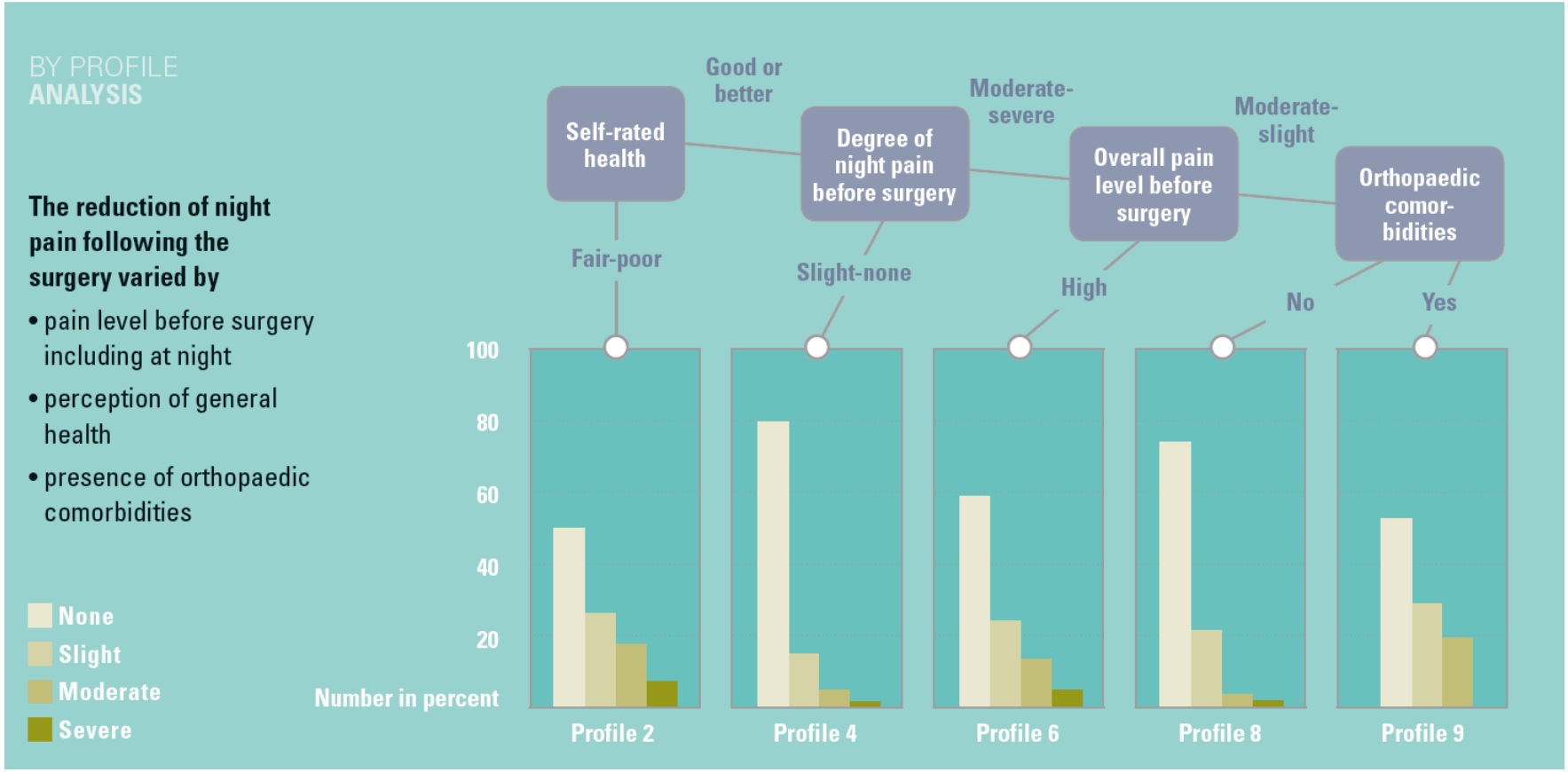
GENERAL
ANALYSIS

On average, patients reported a large reduction in night pain. 75% had moderate to severe night pain prior to surgery compared to 12% 1 year after surgery.



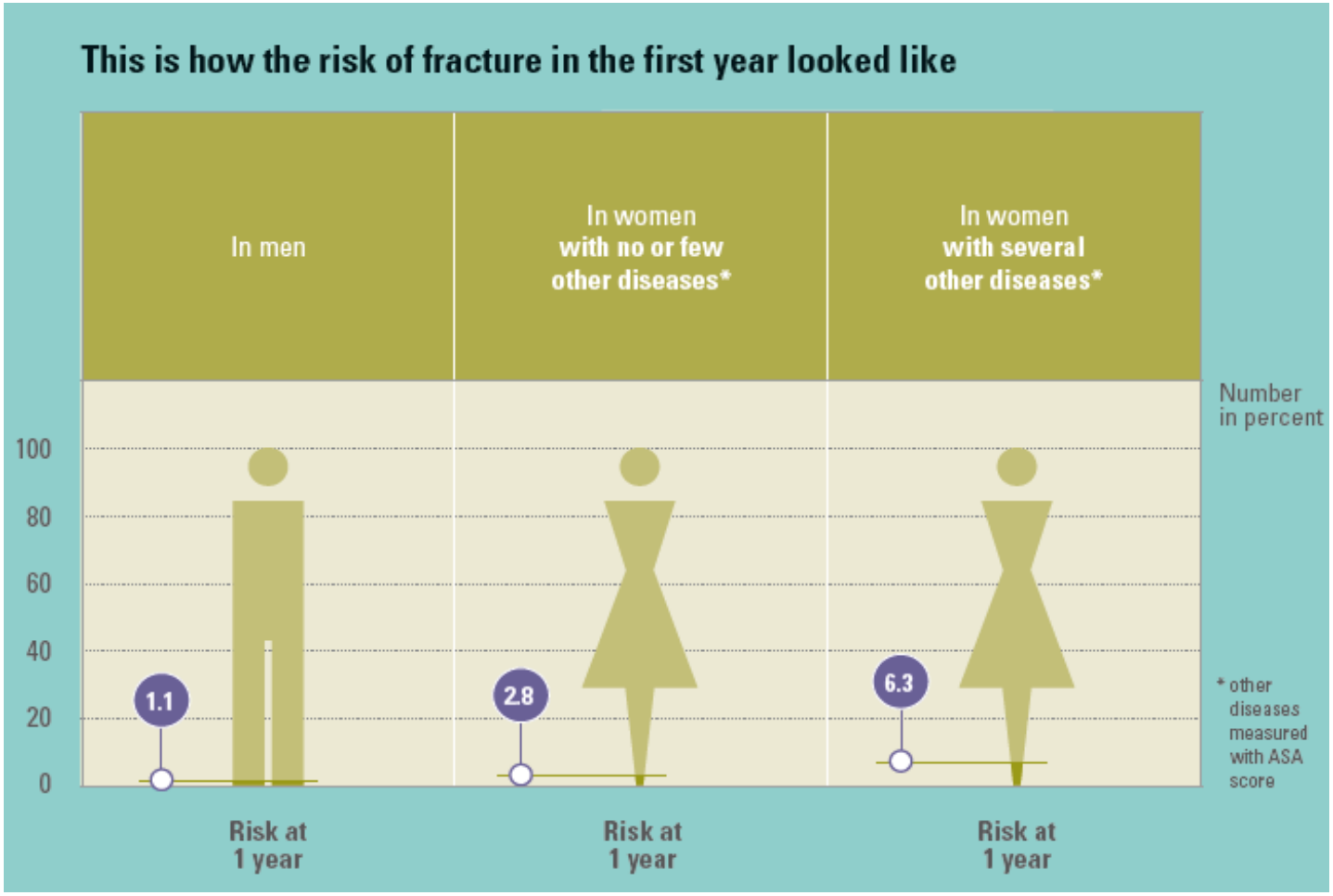
“Patients like me”

Douleur nocturne à 1 an – Par profile patient



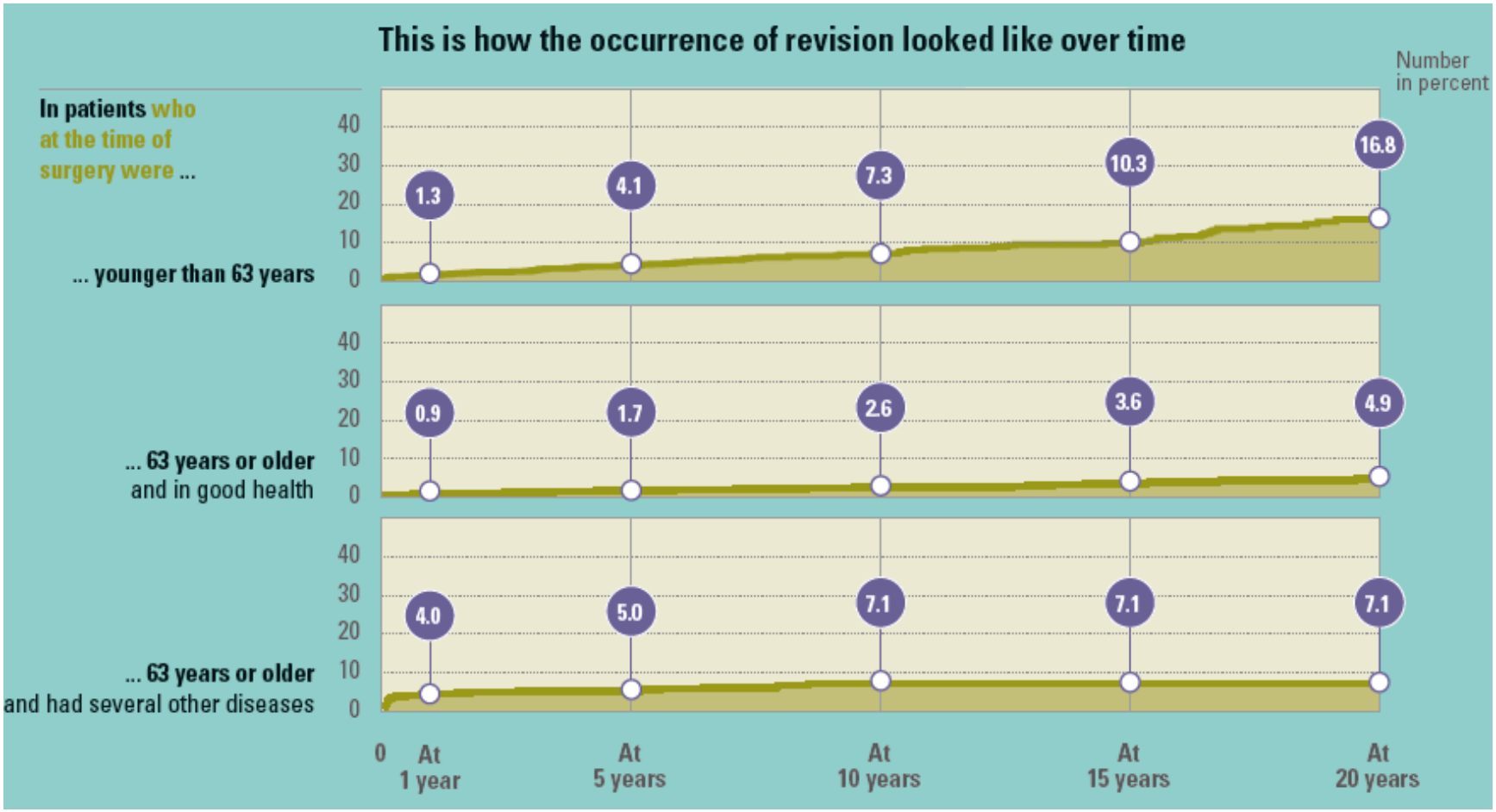
“Patients like me”

Risque de fracture intra-/postoperative 1ère année par profile patient



“Patients like me”

Incidence cumulative d’une révision par profile patient



Conclusion

Richesse

Complexité

Patience

Equipe

Bénéfice exponentiel