



EUROPEAN ORTHOPAEDIC
RESEARCH SOCIETY

EORS 2025
33rd Annual Meeting

AO ORTHOPAEDIC RESEARCH SUMMIT

June 16–19, 2025
Davos, Switzerland



EUROPEAN ORTHOPAEDIC
RESEARCH SOCIETY



Improvement through Innovation - How much evidence do you need to adopt?

PD Dr. med. Thomas M Randau

Krankenhaus der Augustinerinnen Köln

Klinik für Orthopädie, Spezielle Orthopädische Chirurgie und Sportorthopädie

Conflicts of interest

- Advisor / Speaker / Consultant
 - implantcast GmbH
 - Peter Brehm GmbH
 - Heraeus medical GmbH
 - Lima Corporate SpA / Enovis
 - AE Deutsche Gesellschaft für Endoprothetik

Need for innovation?



The operation of the century: total hip replacement

Ian D Learmonth, Claire Young, Cecil Rorabeck

Lancet 2007; 370: 1508–19

Published Online

March 29, 2007

DOI:10.1016/S0140-

6736(07)60457-7

Department of Orthopaedics,

Bristol Royal Infirmary,

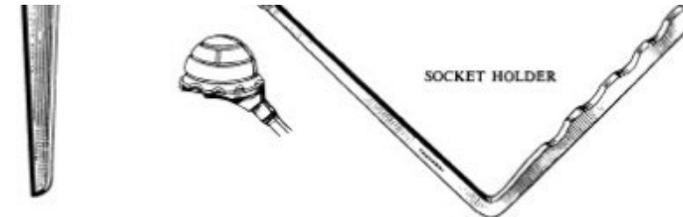
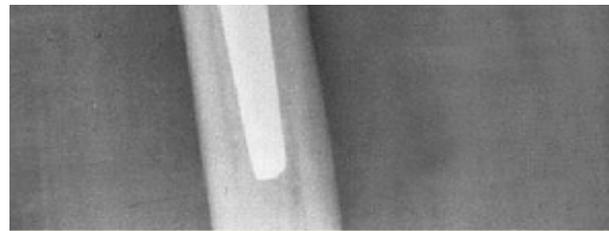
Bristol BS2 8HW, UK

(Prof I D Learmonth FRCS);

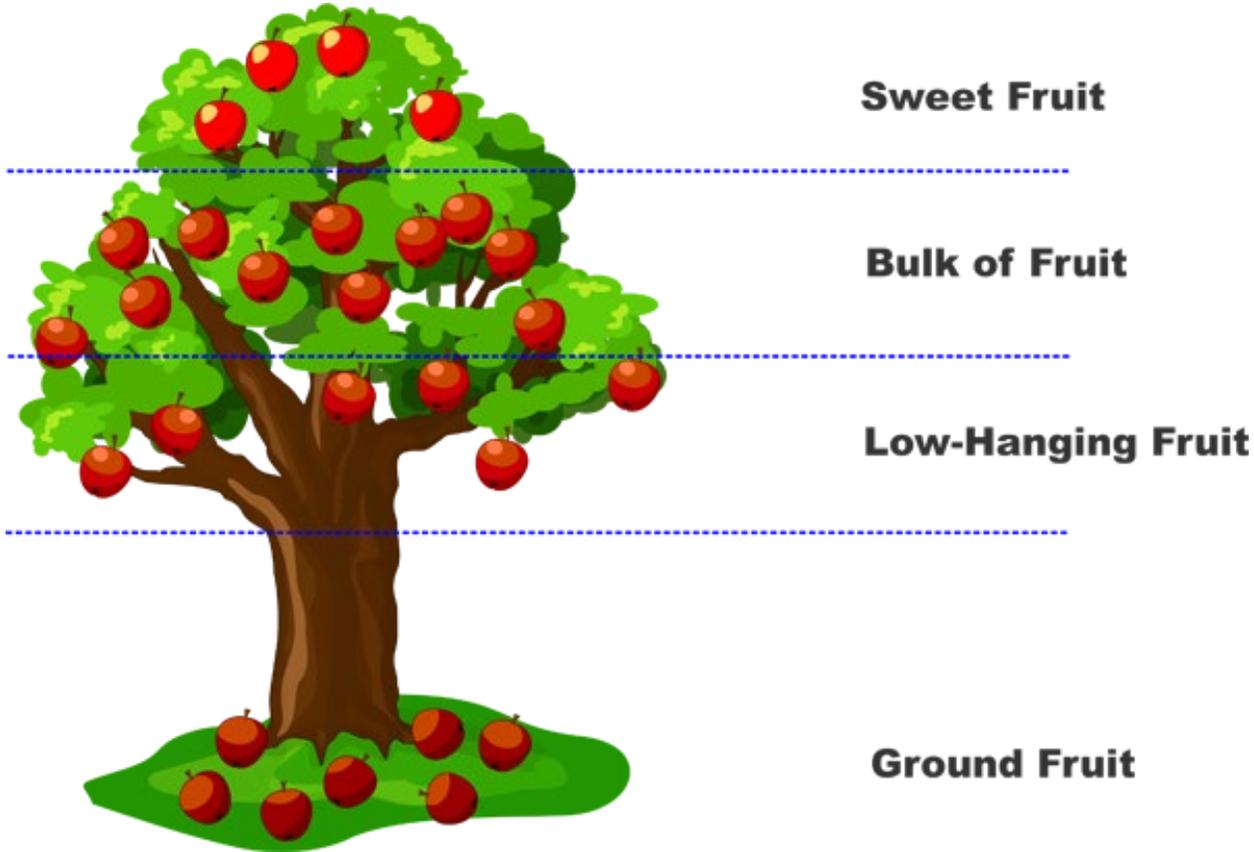
Cumberland Infirmary,

Carlisle CA2 7HY, UK

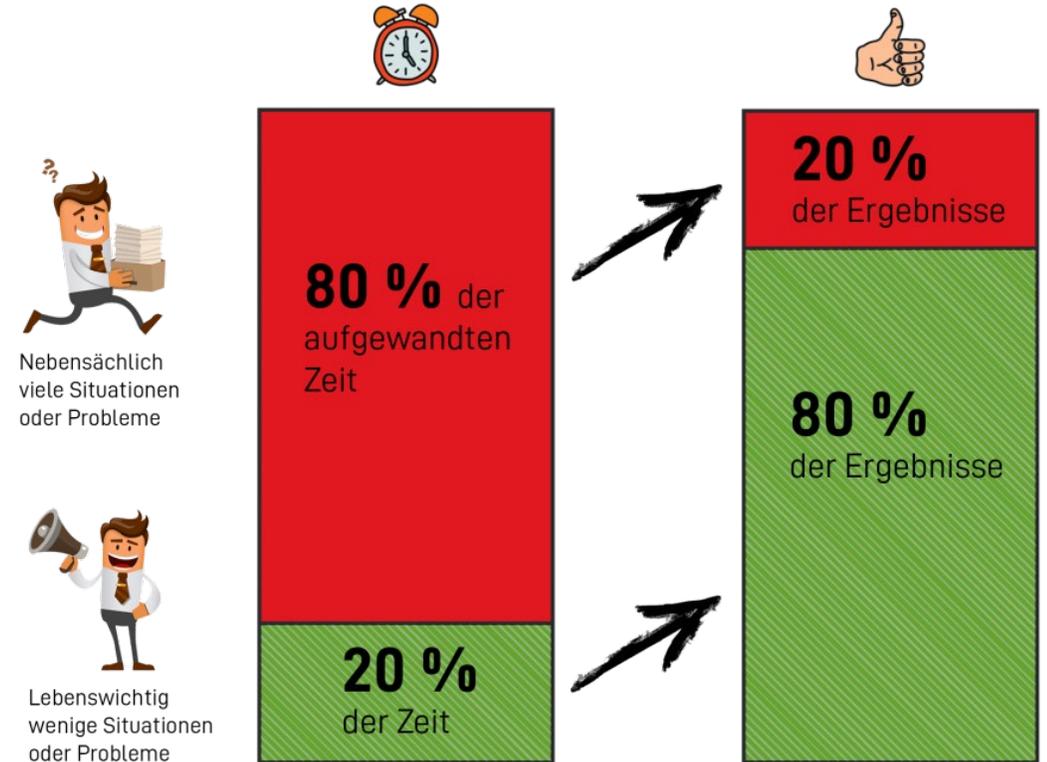
In the 1960s, total hip replacement revolutionised management of elderly patients crippled with arthritis, with very good long-term results. Today, young patients present for hip-replacement surgery hoping to restore their quality of life, which typically includes physically demanding activities. Advances in bioengineering technology have driven development of hip prostheses. Both cemented and uncemented hips can provide durable fixation. Better materials and design have allowed use of large-bore bearings, which provide an increased range of motion with enhanced stability and very low wear. Minimally invasive surgery limits soft-tissue damage and facilitates accelerated discharge and rehabilitation. Short-term objectives must not compromise long-term performance. Computer-assisted surgery will contribute to reproducible and accurate placement of implants. Universal economic constraints in healthcare services dictate that further developments in total hip replacement will be governed by their cost-effectiveness.



Low-Hanging Fruits & Marginal Gains?



Das Pareto-Zeitprinzip

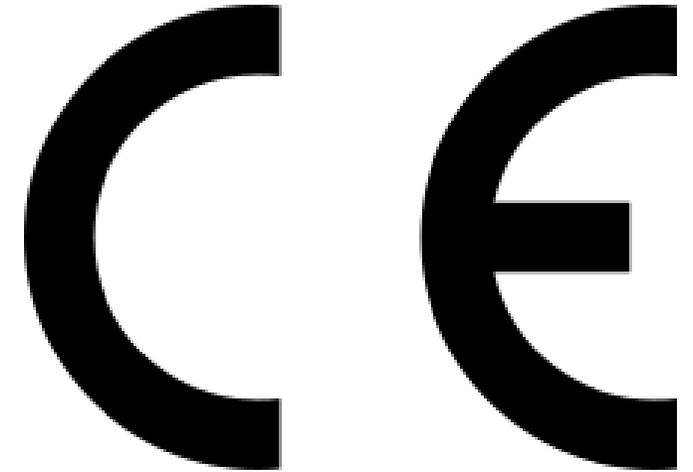


All CE rtified..

- Former Guideline 93/42/EWG

„Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer“

- Changed to EU MDR: „Medical Device Regulation (EU) 2017/745“ on 25.05.2017



Those were the days..

- e.g. MUTARS Tumor Hip Arthroplasty: Designed 1992 (Winkelmann, Gosheger, UKMünster)
- Classical „Napkin Design“ – scribbled drawing on a coaster
- Short ways, direct cooperation
- Pragmatic Solutions



- 2005 Erstimplantation MUTARS® Xpand
- 2004 Die erste MUTARS® Silber Prothese wird implantiert
- 2002 Der MUTARS® proximale Humerus kommt auf den Markt
- 2000 Die 1000. MUTARS® Implantation wird durchgeführt
- 1998 Markteinführung des MUTARS® Revisionssystems
- 1995 Erstimplantation der MUTARS® proximalen Tibia
- 1993 Das erste MUTARS® distale Femur wird implantiert
- 1992 Implantation der ersten MUTARS® Prothese



This article is more than 13 years old

Ban metal-on-metal hip replacements, experts urge

Research published in the Lancet finds 'unequivocal evidence' of high failure rates of implants, particularly among women

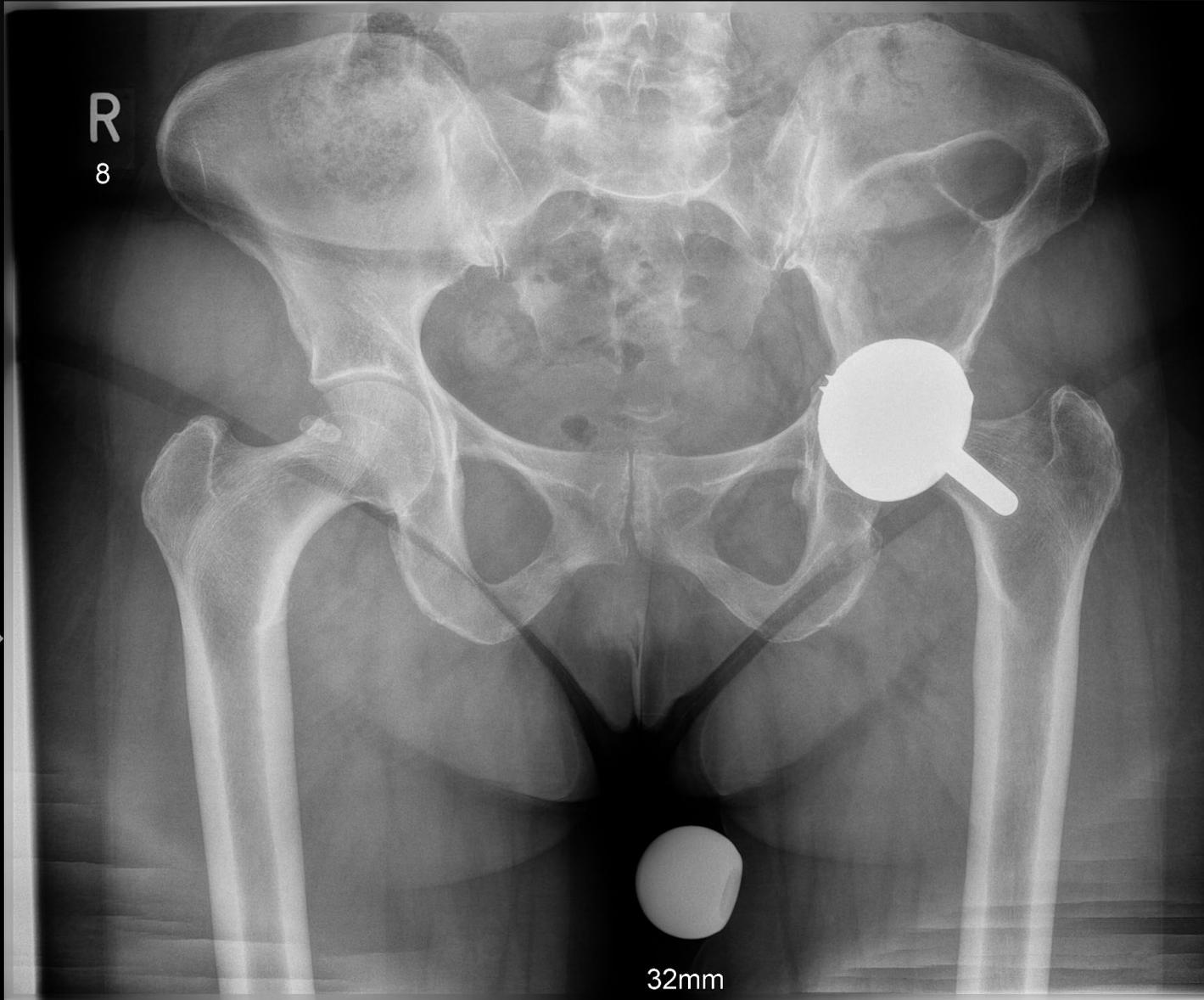
Blood metal ion thresholds to identify patients with metal-on-metal hip implants at risk of reactions to metal debris



Advertisement



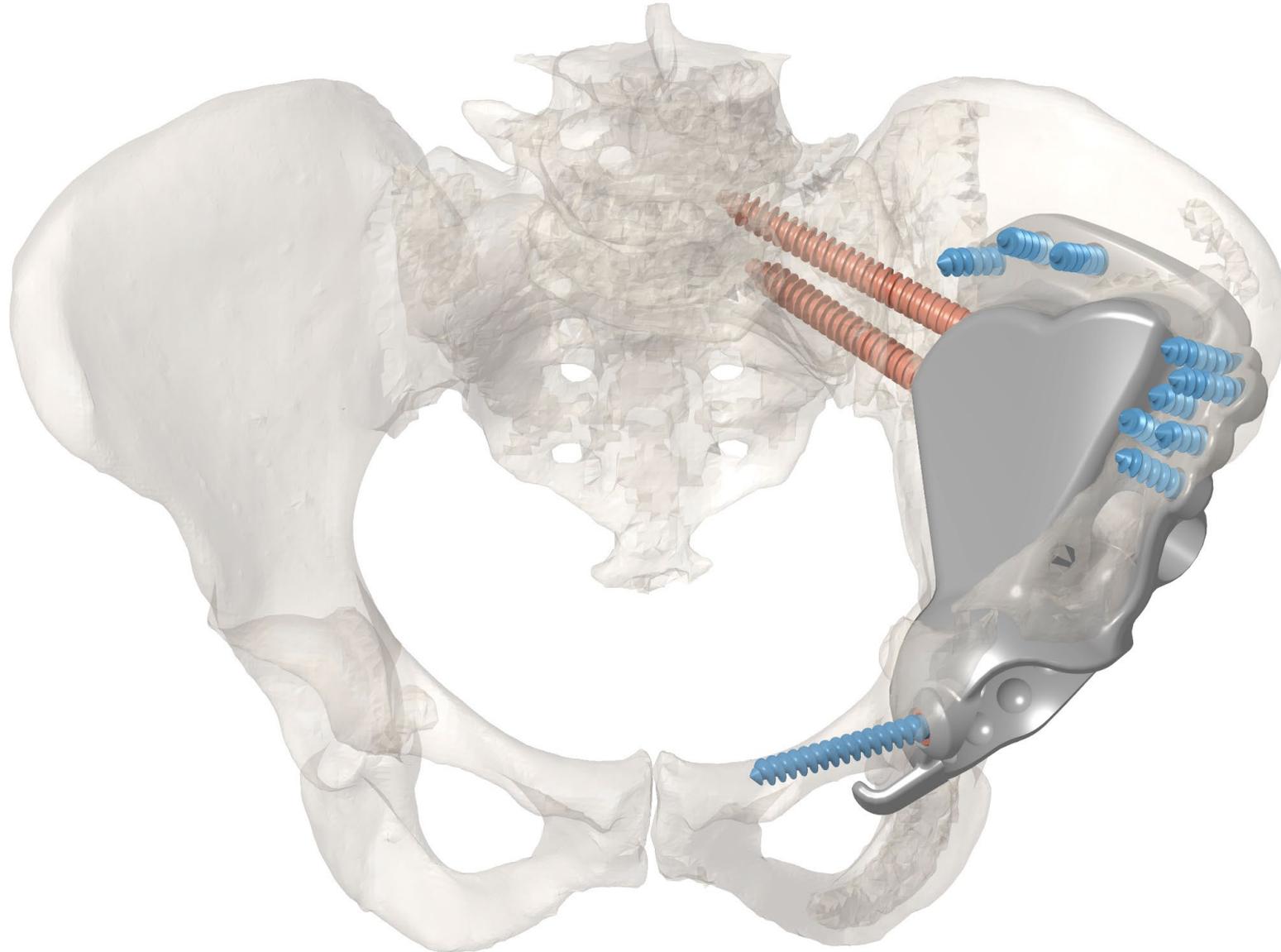
Rx. Pre-OP



Rx. Post Explant



PMI Planning



Rx. Post-OP Outlet / Inlet



Rx. Post-OP Obturator / Ala



Yet still..

PRIMARY HIP · Volume 39, Issue 11, P2800-2806, November 2024 · [Open Access](#)

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Two-Year Results of Ceramic-on-Ceramic Hip Resurfacing in an International Multicenter Cohort

[David Lin, MBBS^a](#) · [Joshua Xu, MD^a](#) · [Patrick Weinrauch, MBBS^b](#) · ... · [Andrew Manktelow, MBBS^e](#) · [Paul E. Beaulé, MD^f](#) · [William L. Walter, MBBS^{a,g}](#) ... [Show more](#)

[Affiliations & Notes](#) ▾ [Article Info](#) ▾

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Resurfacing Head



Acetabular Cup



Orthopaedics & Traumatology: Surgery & Research

Available online 4 April 2025, 104239

In Press, Corrected Proof [What's this?](#)



Review article

Hip resurfacing arthroplasty reduces dislocation and infection rates without differences in clinical outcomes compared to short and standard stems: A Network Meta-Analysis

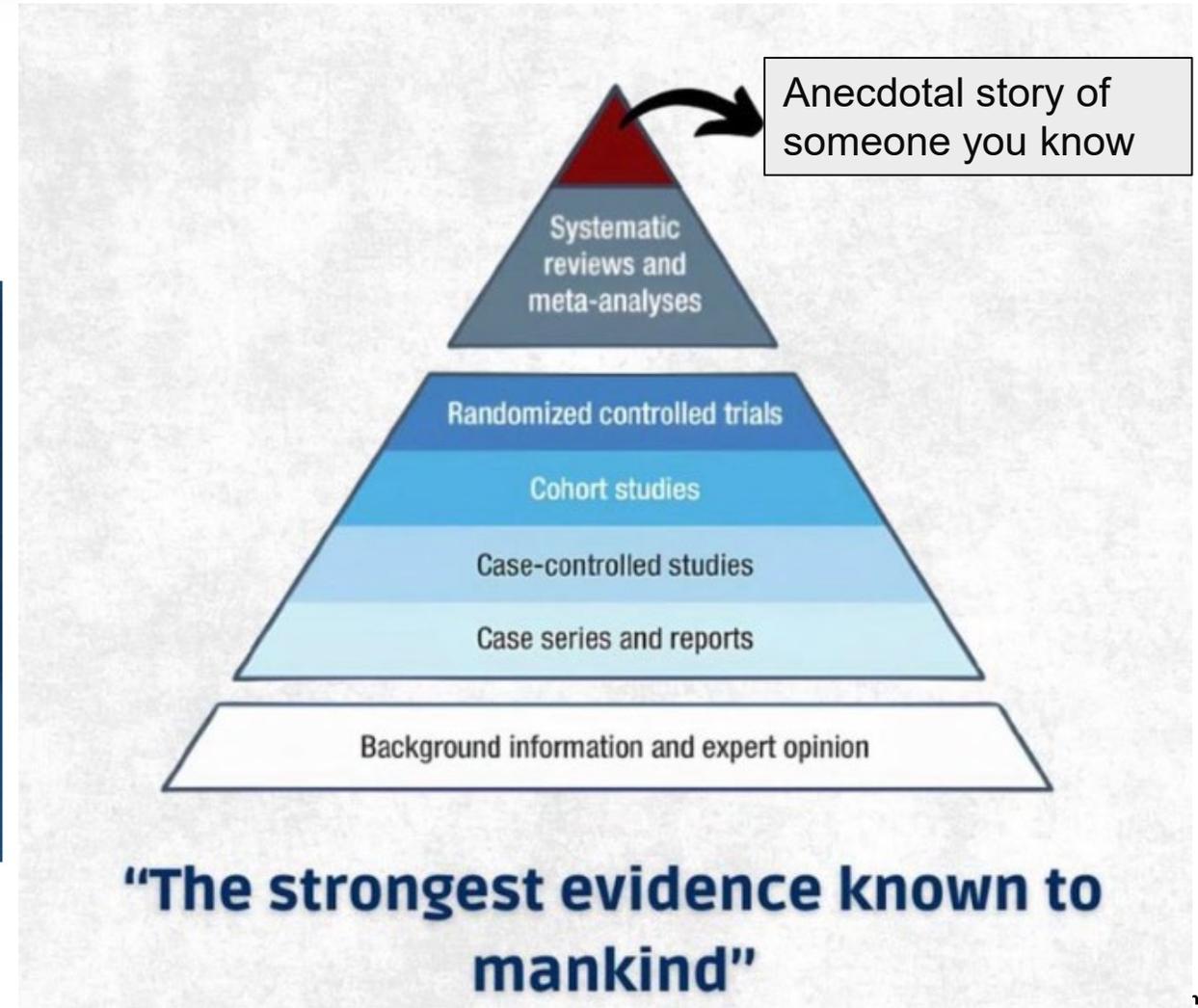
[Lola Riché^{a,b}](#), [Noémie Baccon^{a,b}](#), [Julien Girard^{a,b}](#), [Henri Migaud^{a,b}](#), [Pierre-Alban Bouché^{c,d}](#) [✉](#)

And why?

Success Of Hip Resurfacing: Insight Into Andy Murray's Comeback



Explore the game-changing success of Andy Murray's hip resurfacing surgery. Understand why it was the right choice, how it enabled a swift return to tennis, and its durability prospects.



Is the next big thing just around the corner?



Review > [Surg Technol Int. 2024 Jul 15;44:263-270. doi: 10.52198/24.STI.44.OS1798.](#)

Use of a Novel Reverse Hip Replacement System to Address Dislocation and Instability

Adolph V Lombardi Jr ^{1 2 3 4}, Joanne B Adams ¹

Affiliations + expand

PMID: 39028111 DOI: [10.52198/24.STI.44.OS1798](#)

A word on 3D Printing?



Review

Advances in 3D Printing Applications for Personalized Orthopedic Surgery: From Anatomical Modeling to Patient-Specific Implants

Marcin Prządka ¹, Weronika Pająk ² , Jakub Kleinrok ³ , Joanna Pec ² , Karolina Michno ³ , Robert Karpiński ^{4,5,*} and Jacek Baj ^{2,*} 

Innovations in three-dimensional-printed individualized bone prosthesis materials: revolutionizing orthopedic surgery: a review

Zhigang Qu, MD, PhD^a, Jiaji Yue, MD, PhD^b, Ning Song, BSc^c, Shenglong Li, MD, PhD^{d,e,f,*}

Structural differences to casted or forged implants?

Little to no discussion on cleaning, sterility, safety?

Do we really need it that much?

The surgeon's perspective

- a SAFE product
- EASY to use
- QUICKLY available
- FLEXIBLE to adopt
- to be used in many INDICATIONS
- **with excellent RESULTS for my patient**
- at an affordable PRICE

- .. and little to no paper work associated with it..

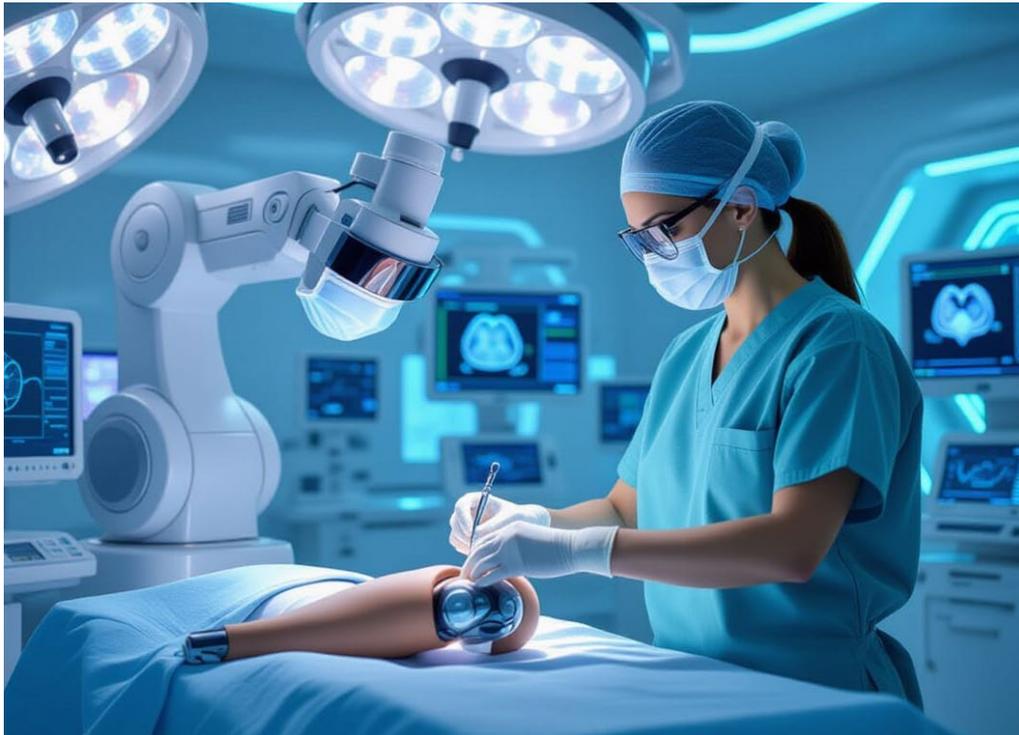


AI-generated Image

MedTech development?



Example: Robotic Surgery..



AI-generated Image

Comparative Efficacy and Precision of Robot-Assisted vs. Conventional Total Knee Arthroplasty: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Ümit Mert ¹, Moh'd Yazan Khasawneh ¹, Maher Ghandour ¹, Ahmad Al Zuabi ², Klemens Horst ², Frank Hildebrand ², Bertil Bouillon ³, Mohamad Agha Mahmoud ², Koroush Kabir ¹

Affiliations + expand

PMID: 40364281 PMCID: PMC12072899 DOI: 10.3390/jcm14093249

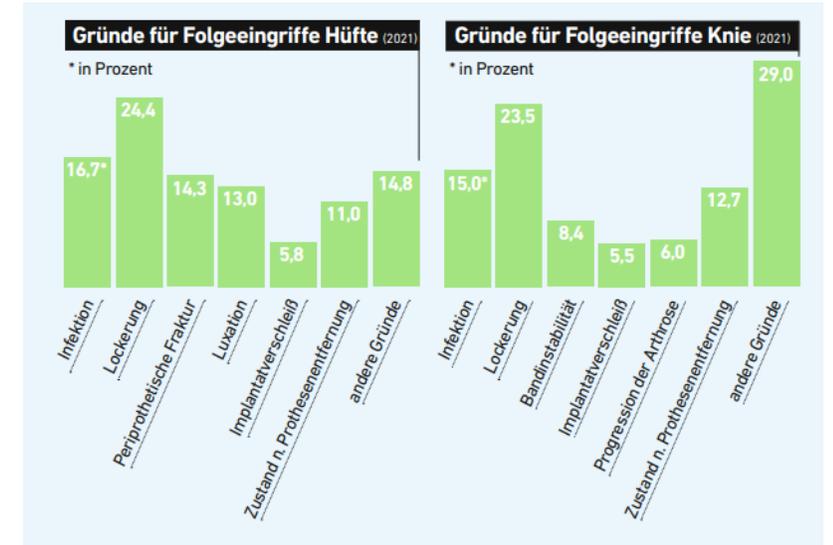
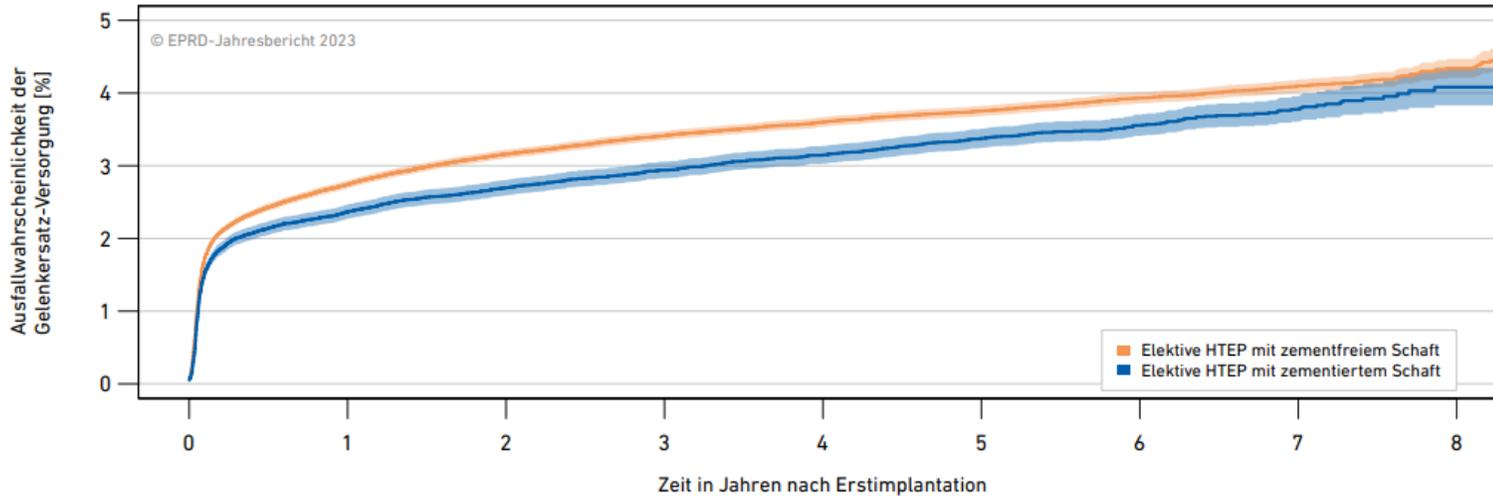
Redefining Knee Arthroplasty: Does Robotic Assistance Improve Outcomes Beyond Alignment? An Evidence-Based Umbrella Review

Fernando García-Sanz ^{1 2}, María Dolores Sosa-Reina ¹, Gonzalo Jaén-Crespo ¹, Ángel González-de-la-Flor ¹, Jorge Hugo Villafañe ¹, Carlos Romero-Morales ¹

Affiliations + expand

PMID: 40283417 PMCID: PMC12028302 DOI: 10.3390/jcm14082588

Are implant registers any help?

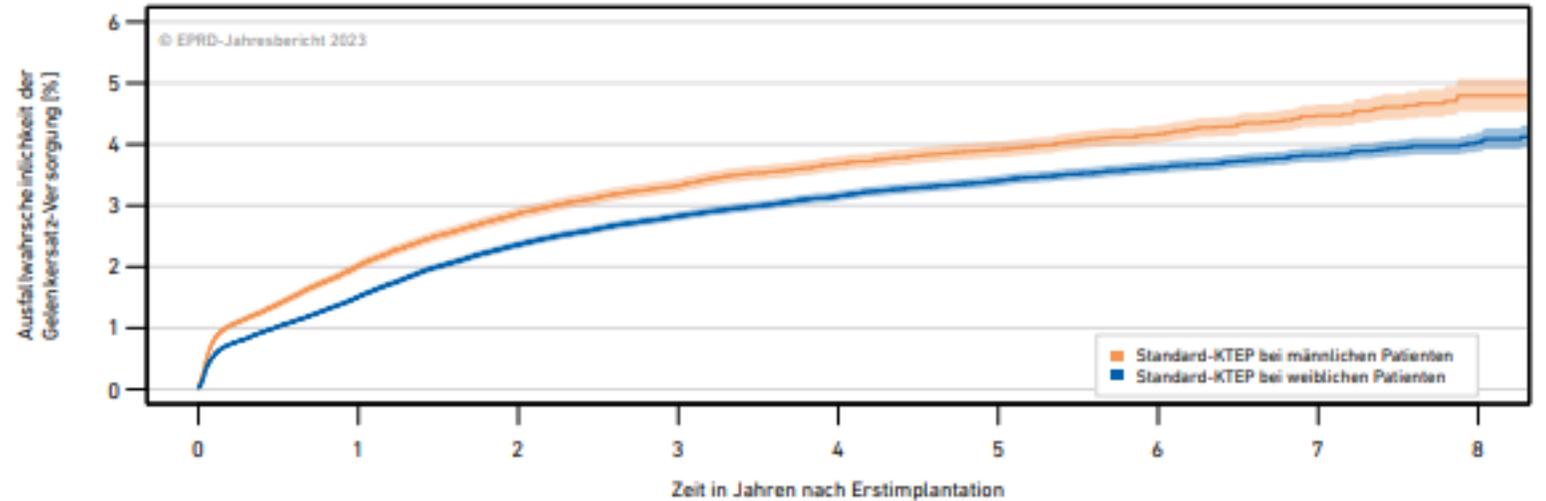


Alle betrachteten Versorgungen

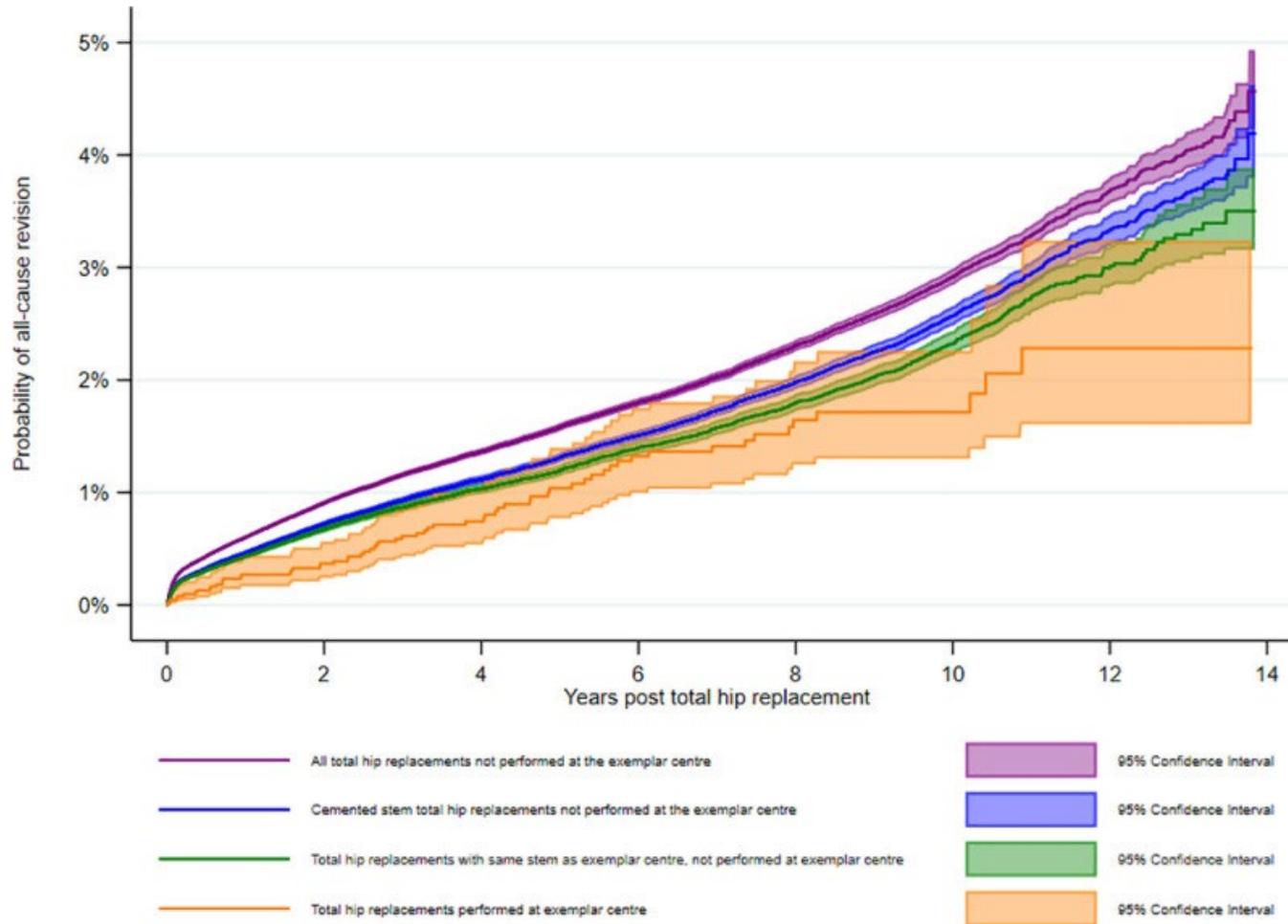
- <45-Jährige
- 45- bis 54-Jährige
- 55- bis 64-Jährige
- 65- bis 74-Jährige
- 75- bis 84-Jährige
- 85-Jährige und älter
- Männer
- Frauen
- BMI bis 25
- BMI >25 bis 30
- BMI >30 bis 35
- BMI >35 bis 40
- BMI über 40
- BMI unbekannt/unplausibel

Anteil [%]	Alter	m/w [%]	BMI	ASA
100,0	72	40 / 60	26,8	2,3
1,7		55 / 45	27,3	1,8
6,3		52 / 48	28,4	1,9
21,1		48 / 52	28,1	2,1
30,1		40 / 60	27,5	2,2
29,9		34 / 66	26,0	2,5
10,9		30 / 70	24,6	2,8
40,0	69	100 / 0	27,5	2,3
60,0	73	0 / 100	26,2	2,3
33,7	75	31 / 69		2,3
36,0	72	46 / 54		2,2
18,0	69	45 / 55		2,3
6,4	66	41 / 59		2,4
2,4	63	35 / 65		2,6
3,5	72	38 / 62		2,2

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Non-believers: „But in my hands..“



[PLoS Med. 2020 Aug; 17\(8\): e1003291. Published online 2020 Aug 31. doi: 10.1371/journal.pmed.1003291](https://doi.org/10.1371/journal.pmed.1003291)

PMCID: PMC7458308 | PMID: [32866147](https://pubmed.ncbi.nlm.nih.gov/32866147/)

Factors associated with implant survival following total hip replacement surgery: A registry study of data from the National Joint Registry of England, Wales, Northern Ireland and the Isle of Man

THE JOURNAL OF ARTHROPLASTY

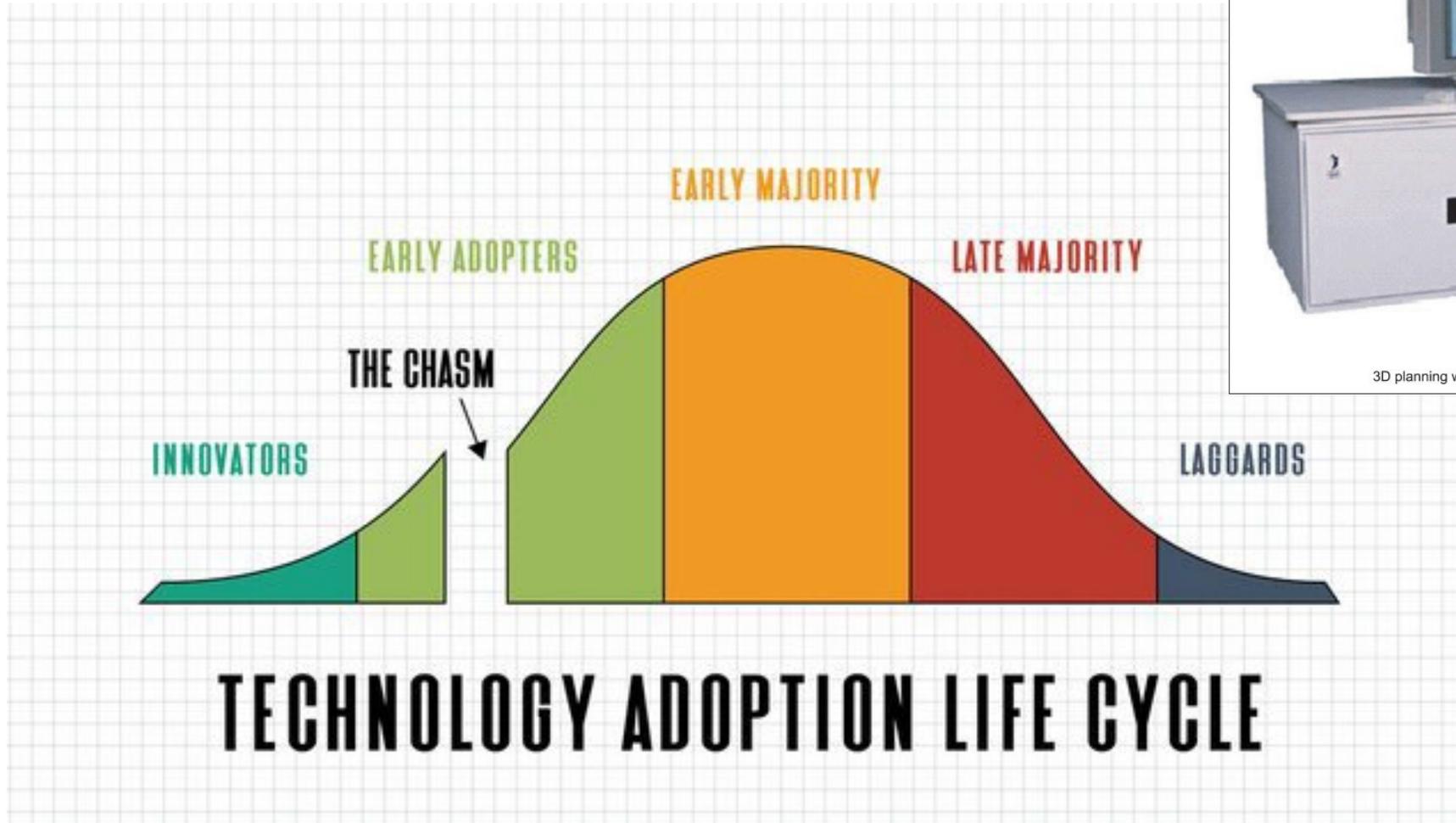
PRIMARY HIP | VOLUME 37, ISSUE 1, P110-118, JANUARY 2022

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Cemented Polished Tapered Stems Have Lower Revision Rates Than Commonly Used Cementless Implant up to 17 Years of Follow-Up: An Analysis of 201,889 Total Hip Replacements From the Australian Orthopaedic Association National Joint Replacement Registry

Sina Babazadeh, PhD • Richard N. de Steiger, PhD • Carl Holder, MBIostat • Dirk van Bavel, MBBS

What degree of evidence do you need?

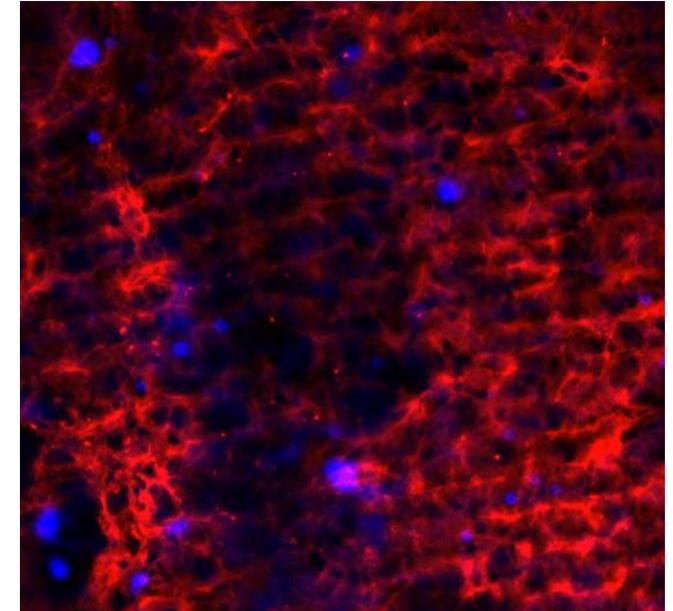
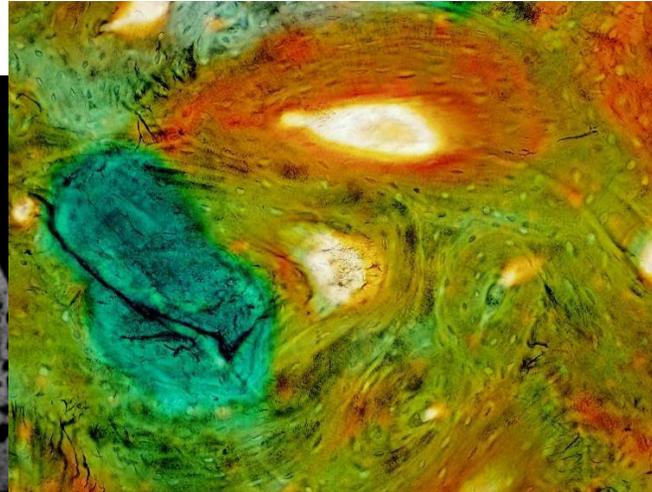
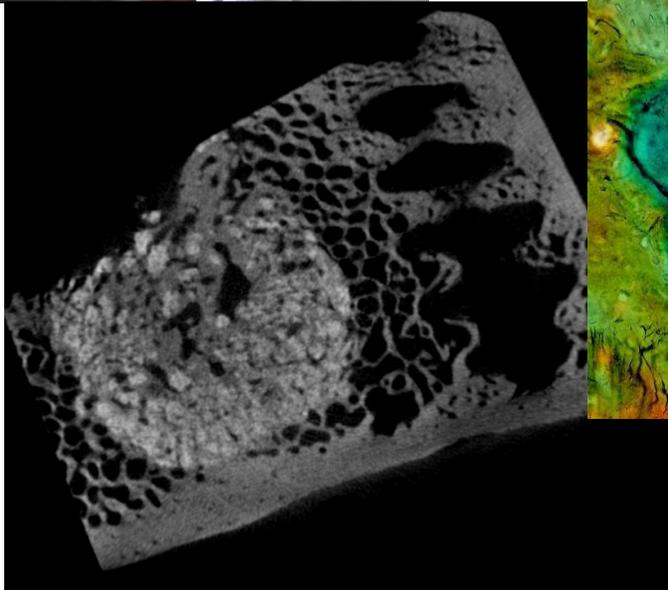
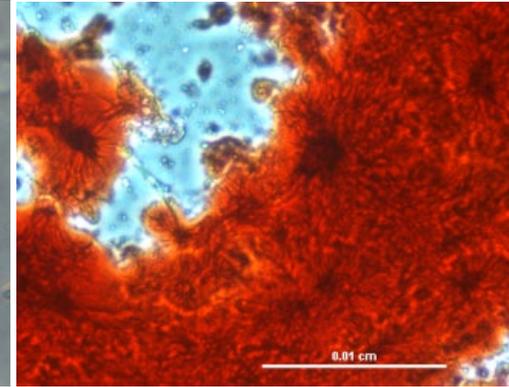
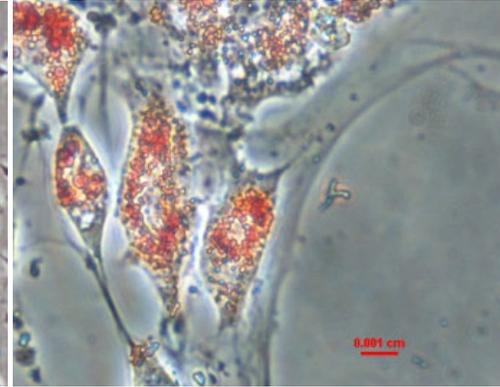
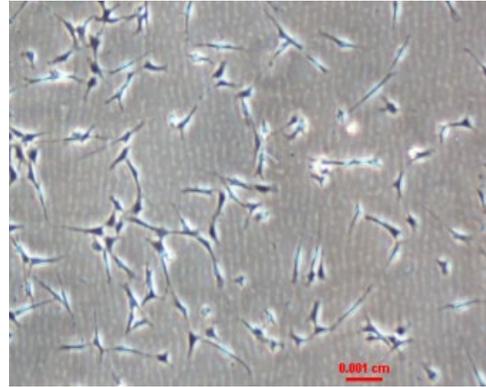


Who is driving the process? And why?

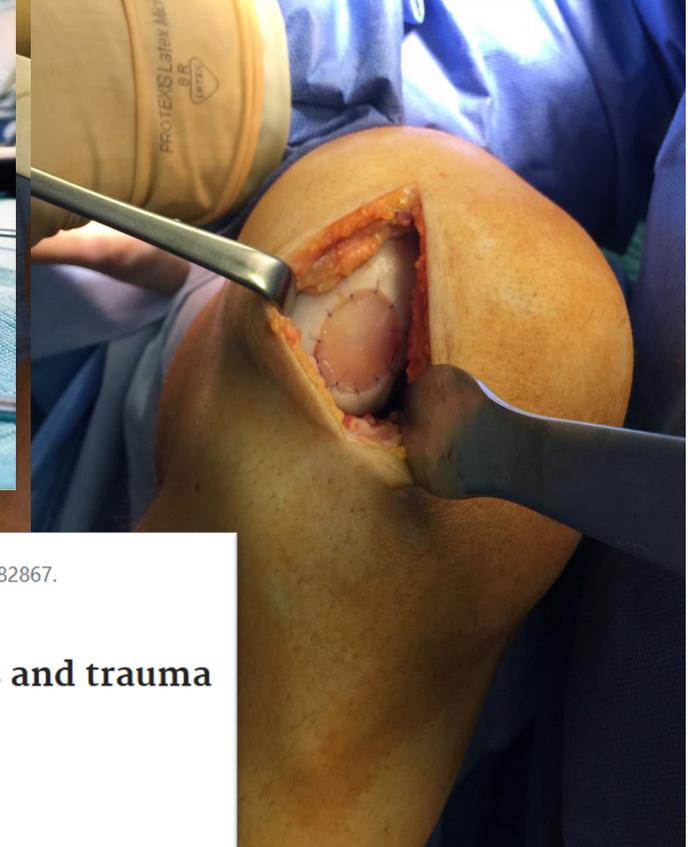
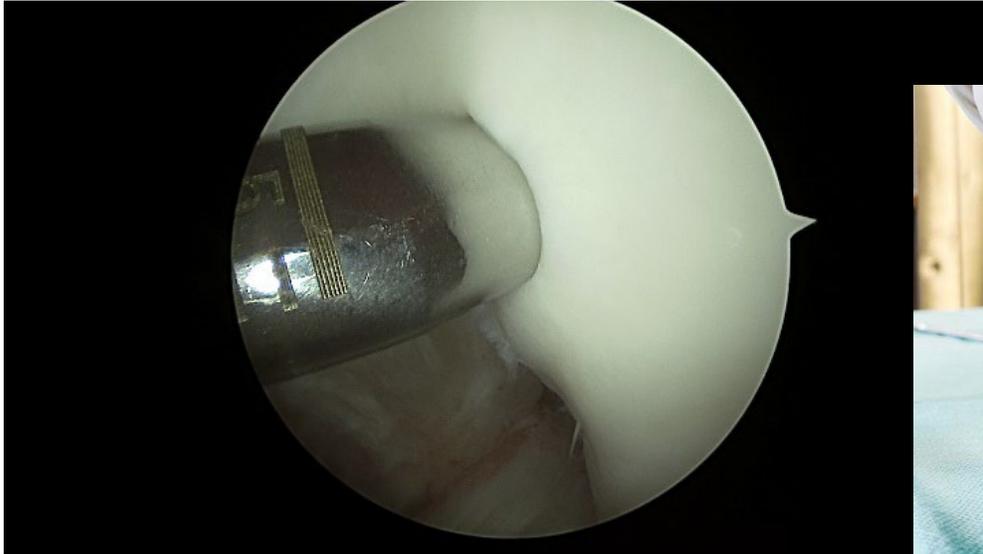
Is there an actual need?

Do I really need improvement?

Example 2: Tissue engineering



Tissue engineering



Review > [Z Orthop Unfall](#). 2014 Aug;152(4):320-7. doi: 10.1055/s-0034-1382867.
Epub 2014 Aug 21.

[Stem cell-based therapy in orthopaedics and trauma surgery - current concepts]

[Article in German]
[T M Randau](#)¹, [S Gravius](#)¹, [A Nüssler](#)²

Affiliations + expand
PMID: 25144841 DOI: [10.1055/s-0034-1382867](#)

[Free article](#)

How to obtain evidence?



All hurdles are regulatory?

Durchschnittliche Steigerung der Dauer und Kosten bei der Konformitätsbewertung von Medizinprodukten unter Einbindung einer Benannten Stelle unter der MDR im Vergleich zur MDD

Medizinprodukte-Klasse*	Durchschnittliche Steigerung der Kosten in %	Durchschnittliche Steigerung der Dauer in %
Im	72,0	84,5
Is	38,8	45,4
Ir	84,7	77,9
Ila	73,0	77,5
Ilb	82,0	82,5
III	98,5	101,5



BVMed

Cooperation partners

Stand: 3. Quartal 2022 | (n=16, MDR-Anträge/Dokumente 2021)

#MDReady | Zertifikate werden nicht fristgerecht überführt

Status



weniger als 1.000 Zertifikate ausgestellt

erst ab 01.01.2025 (lineare Extrapolation bei gleichem Tempo)



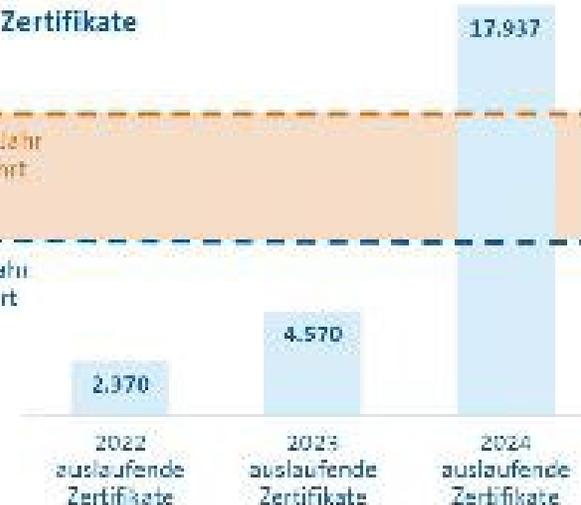
3.920 Anträge angenommen

Auslaufende Zertifikate

12.500 Anträge/Jahr müssen überführt werden

6.314 Anträge/Jahr können überführt werden

Stand September 2021



Innovation will happen outside the EU?

Understanding Early Feasibility Studies for Medical Devices in Paraguay

Initial feasibility assessments for medical products act as preliminary evaluations that assist in identifying regulatory requirements. In Paraguay, this research is vital due to the unique regulatory environment and the need for compliance with local standards. Key factors include:

- Analyzing the technical features of the device
- Comprehending patient requirements
- Evaluating medical practices

CORR[®] International – Asia-Pacific: The Opportunities and Obstacles Associated with Clinical Research in Asia

[Tae Kyun Kim](#)^{1,✉}

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PMCID: PMC5670069 PMID: [28948505](#)

GLOBAL
MEDICAL
DEVICE
PODCAST

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Early Feasibility Studies in Latin America

Episode 266 • 8th June 2022 • Global Medical Device Podcast powered by Greenlight Guru • ...



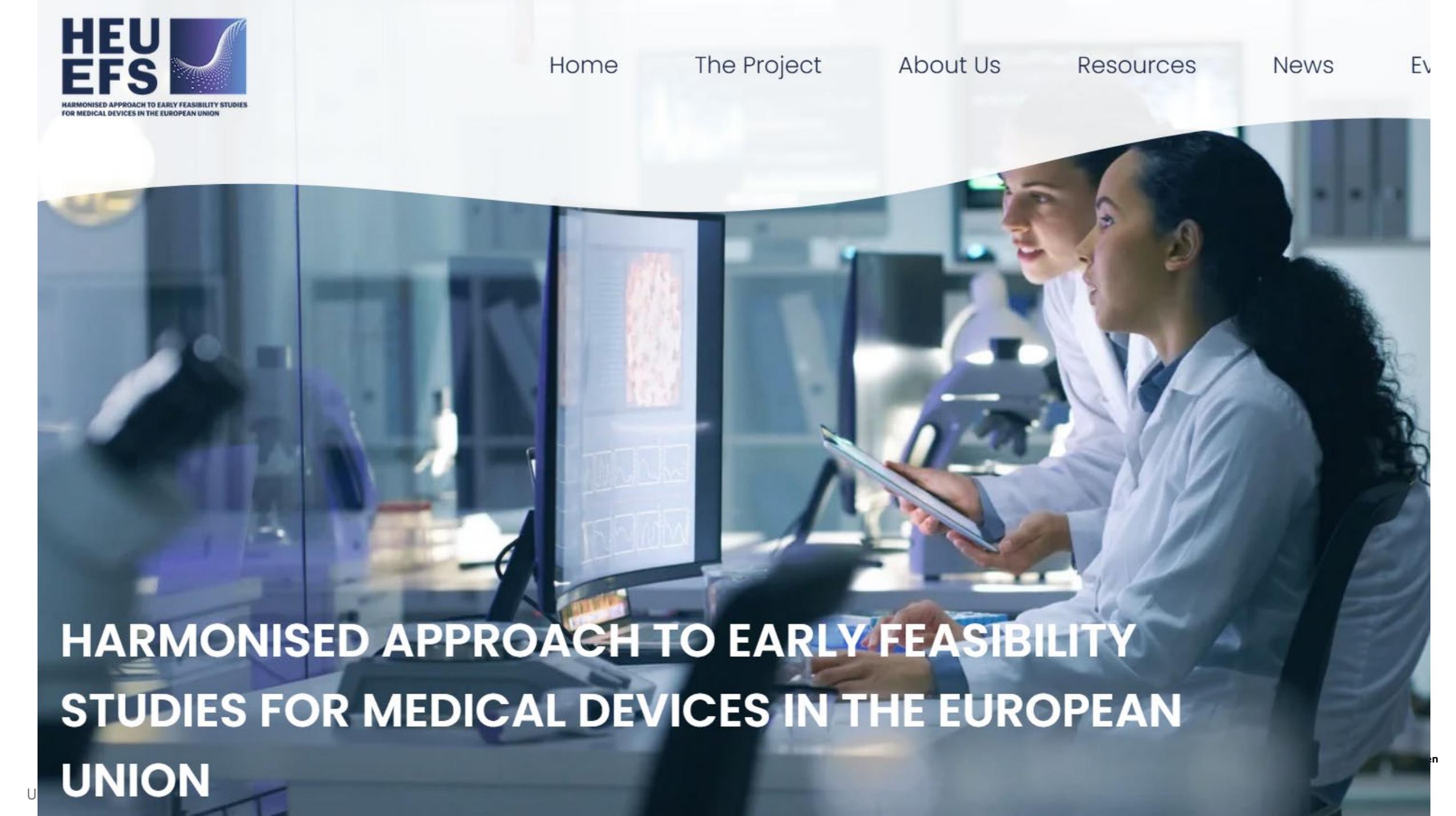
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INFORMATIONEN LINKS ABONNIEREN TEILEN



A photograph of two female scientists in white lab coats working in a laboratory. They are looking at a large computer monitor displaying a grid of data and graphs. One scientist is holding a tablet. The background shows laboratory equipment like microscopes and shelves.

HARMONISED APPROACH TO EARLY FEASIBILITY STUDIES FOR MEDICAL DEVICES IN THE EUROPEAN UNION

The surgeon's perspective

- Open to innovation BUT
- always safety-driven
- Compassionate towards patients as well as our ego!
- **We chose physical work over interlectual work when deciding for surgery**



AI-generated Image

The surgeon's perspective



AI-generated Image



AI-generated Image

How to get your surgeon to work with you..

- Industry – ask for true clinical problems
- Engineers – Involve early for practicability
- Admins – allow innovation, cooperate
- Sales – don't lie to us. Sell true value
- Regulatory – give a reliable frame work
- **Find someone else for the paperwork!!!**



AI-generated Image

Vielen Dank



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Orthopedic Surgeon - Senior Arthroplasty Specialist - Researcher - Lecturer - Quality Management and Certifications



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