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

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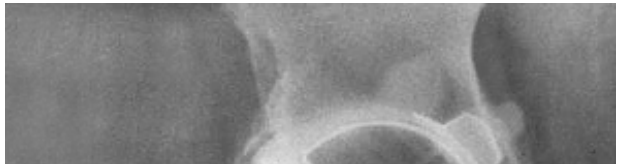
Conflicts of interest

- 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

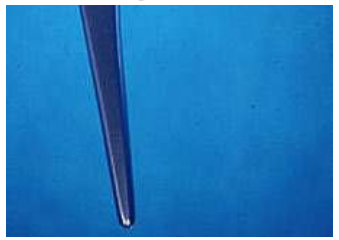
Ian D Learmonth, Claire Young, Cecil Rorabeck

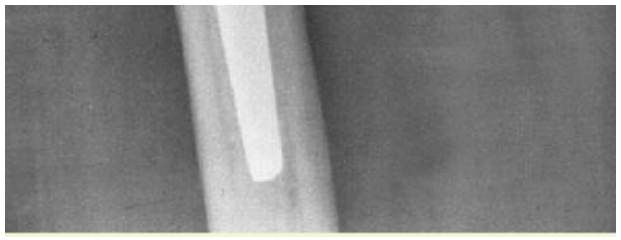
Lancet 2007; 370: 1508–19

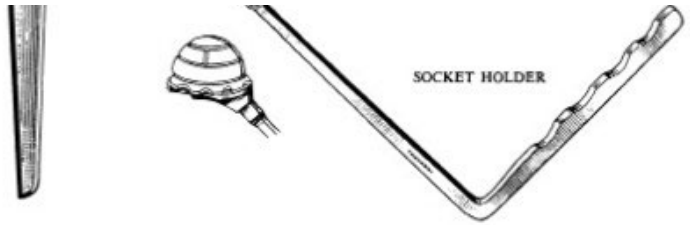
Published Online
March 29, 2007
DOI:10.1016/S0140-6736(07)60457-7

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.







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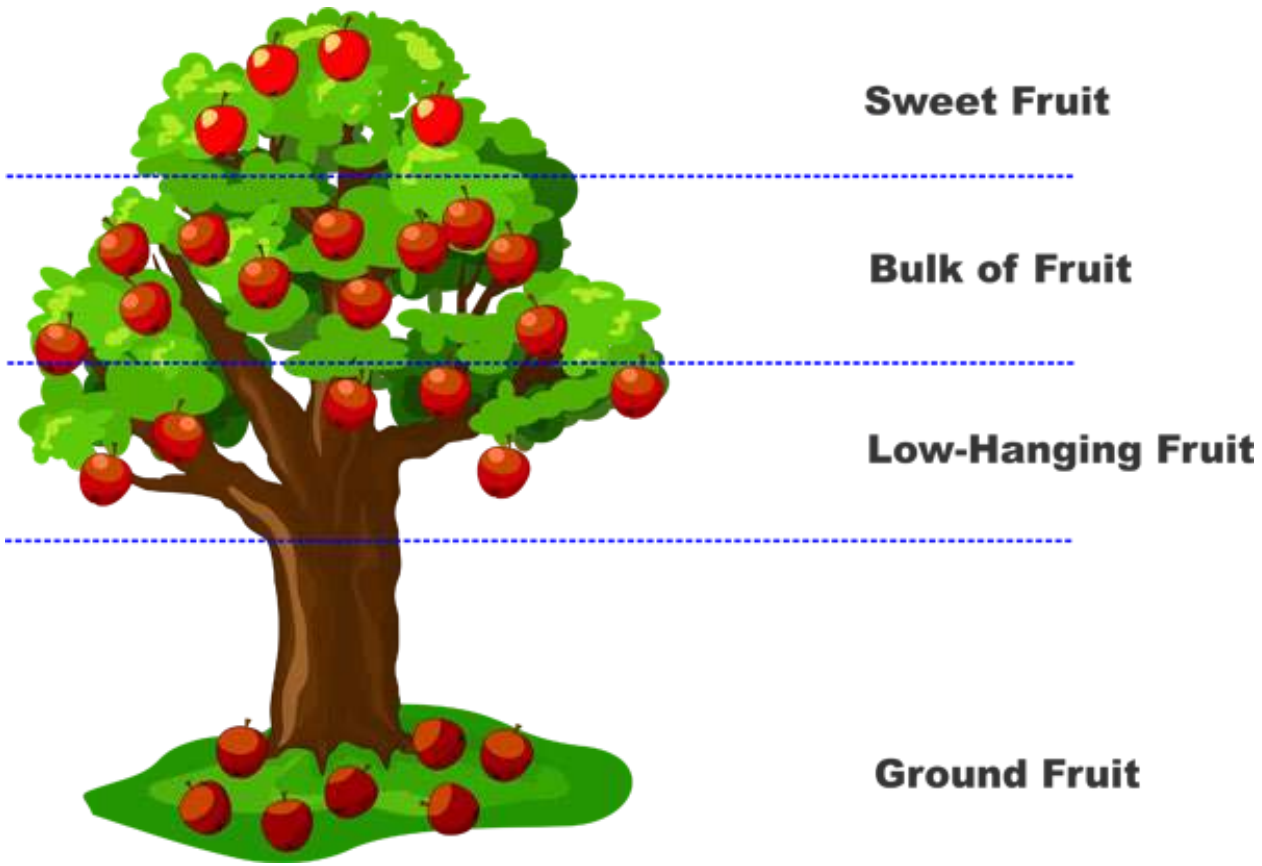
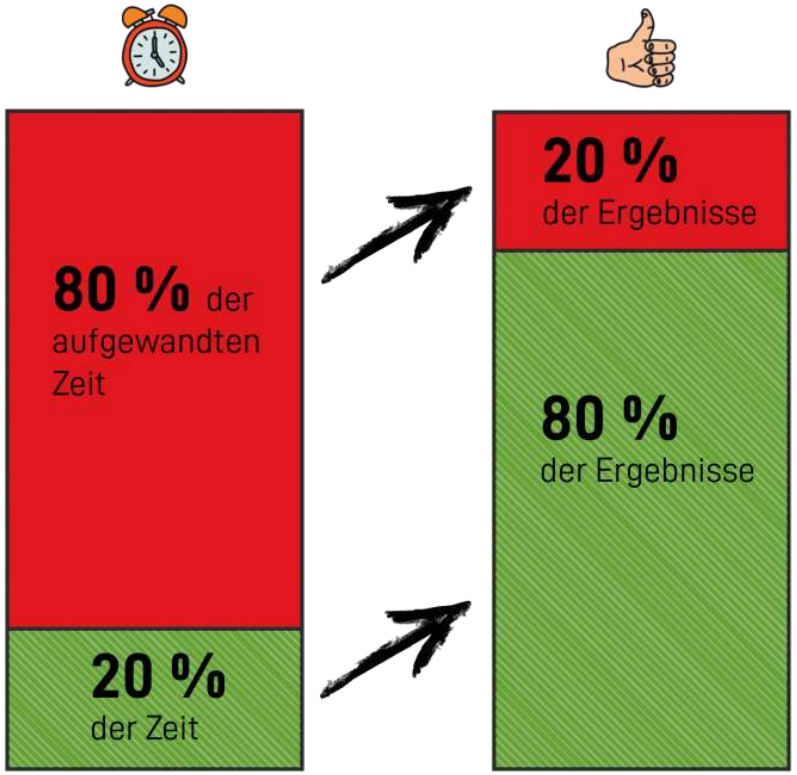
Low-Hanging Fruits & Marginal Gains?



Das Pareto-Zeitprinzip

Nebensächlich viele Situationen oder Probleme

Lebenswichtig wenige Situationen oder Probleme



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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

EU-MDR
European Medical Device Regulation

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

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Sport | Culture | Lifestyle

The Guardian

Eur

Environment Science Global development Football Tech Business Obituaries

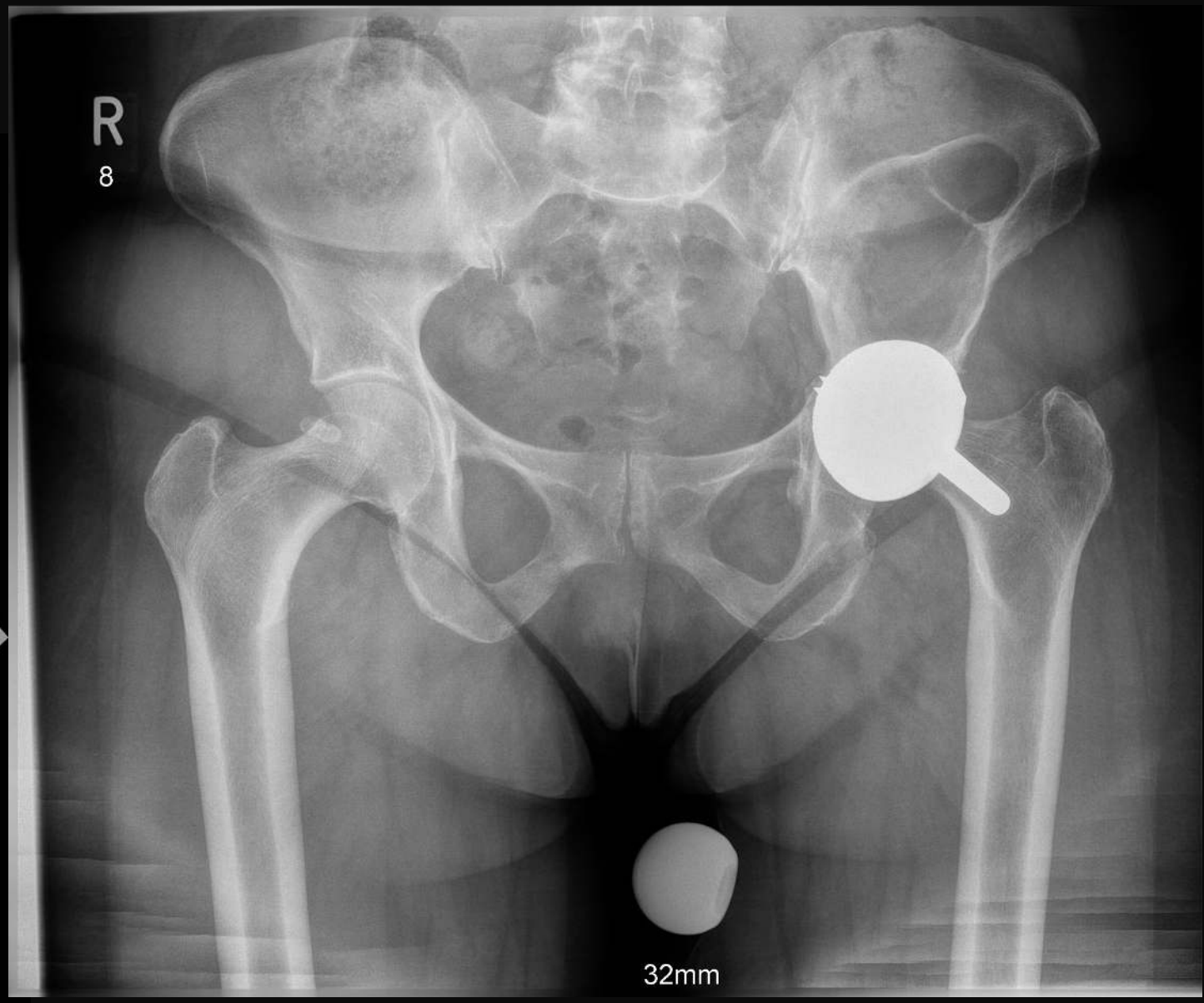
This article is more than **13 years old**

Ban metal-on-metal hip replacements, experts urge

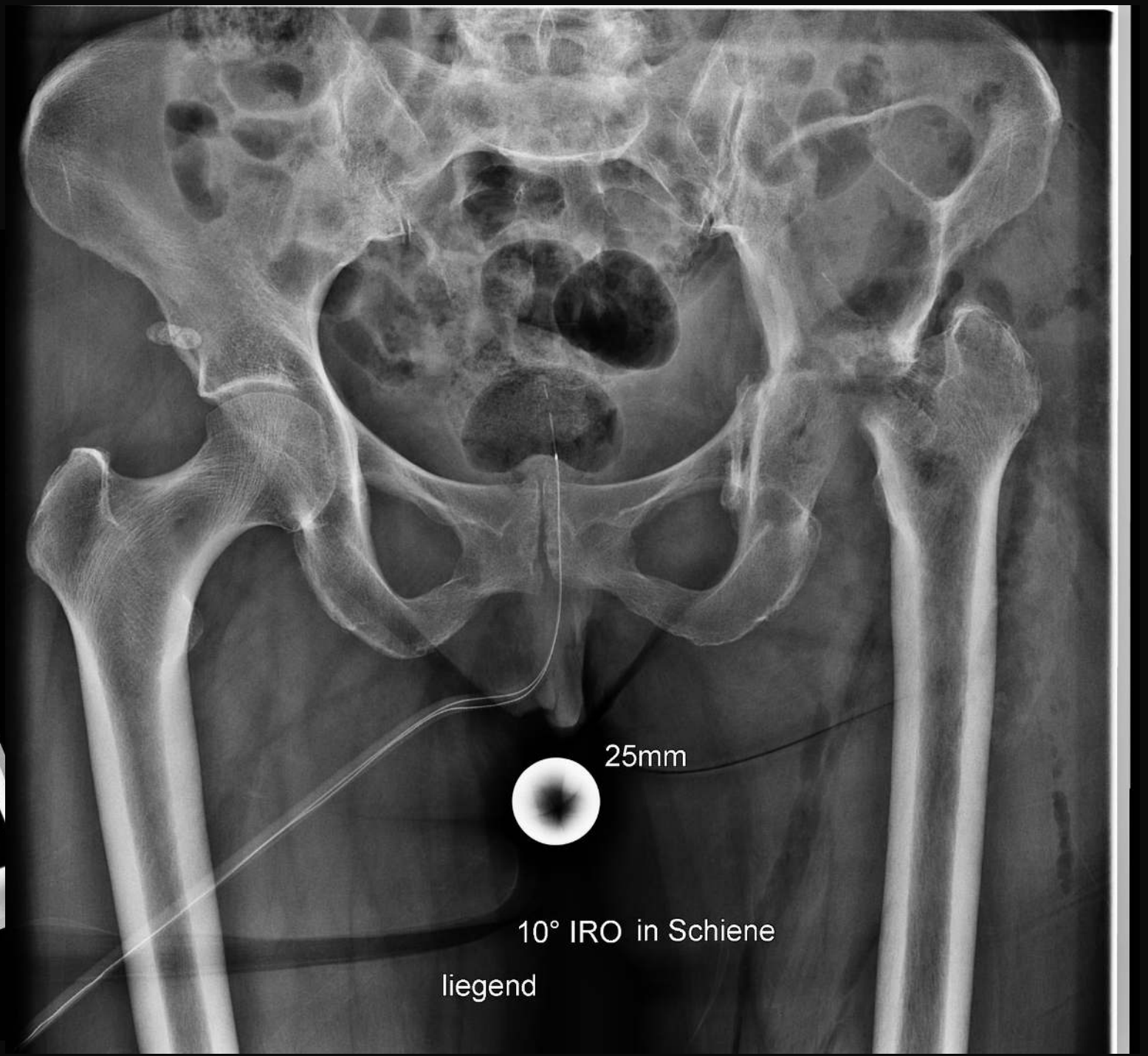
Research published in the Lancet finds 'unequivocal evidence' of high failure rates of implants, particularly among women

Advertisement

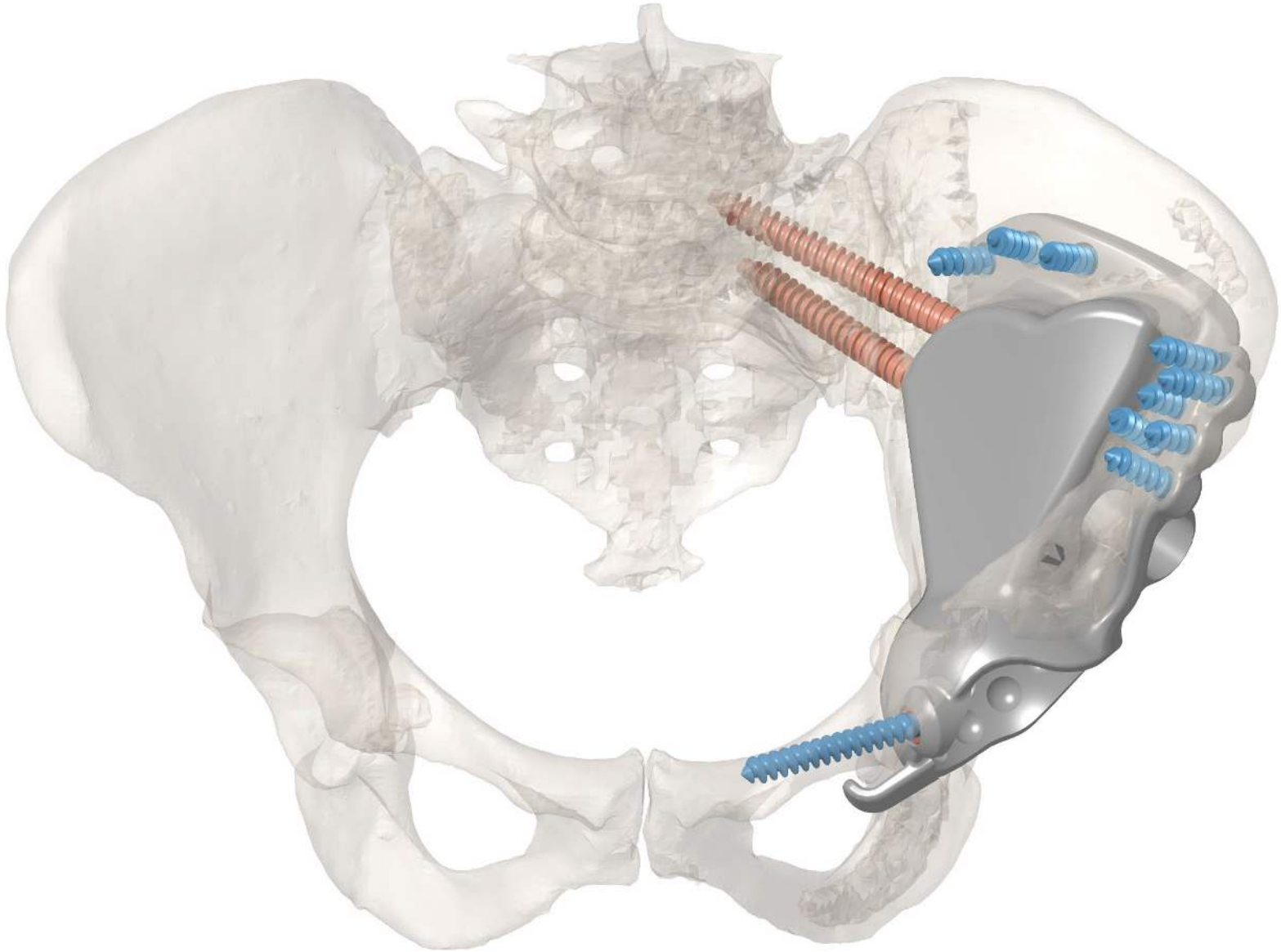
Rx. Pre-OP



Rx. Post Explant



PMI Planning



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Rx. Post-OP Outlet / Inlet

Rx. Post-OP Obturator / Ala

Yet still..

PRIMARY HIP · Volume 39, Issue 11, P2800-2806, November 2024 · *Open Access* Download Full Issue

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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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]

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And why?

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

Image Source: globalite, CC BY-SA 2.0 via Wikimedia Commons

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

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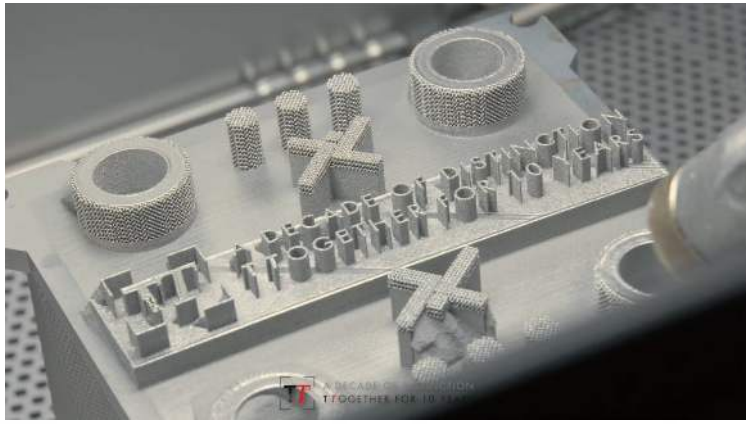
A word on 3D Printing?



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..

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MedTech development?

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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

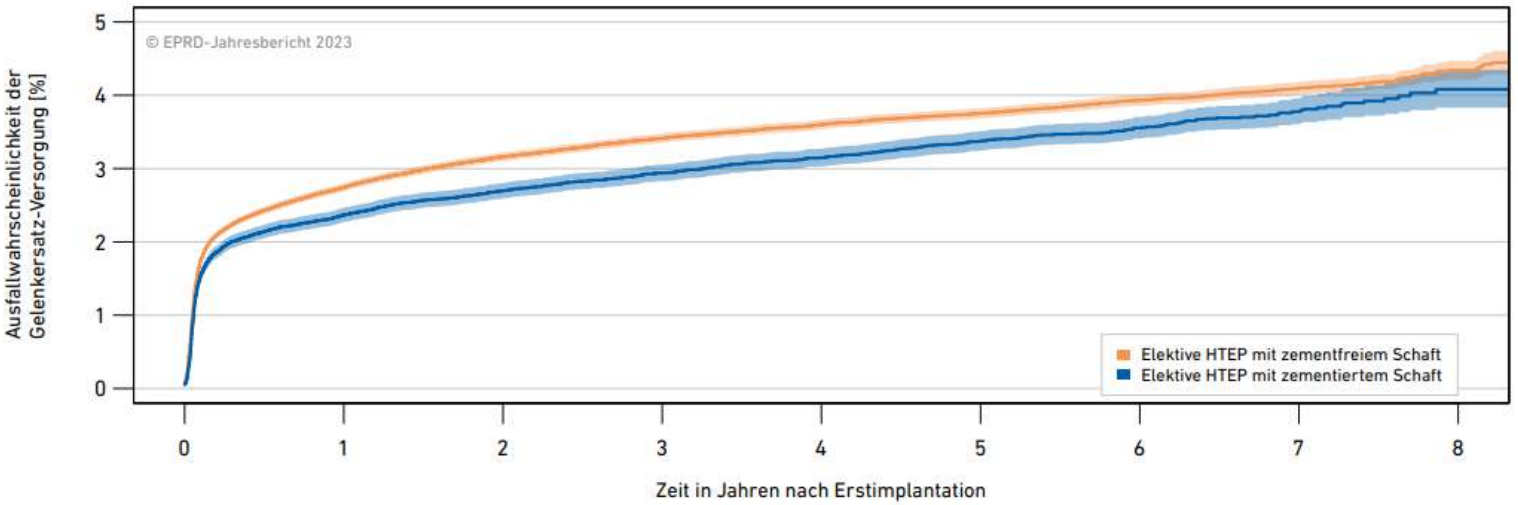
Redefining Knee Arthroplasty: Does Robotic Assistance Improve Outcomes Beyond Alignment? An Evidence-Based Umbrella Review

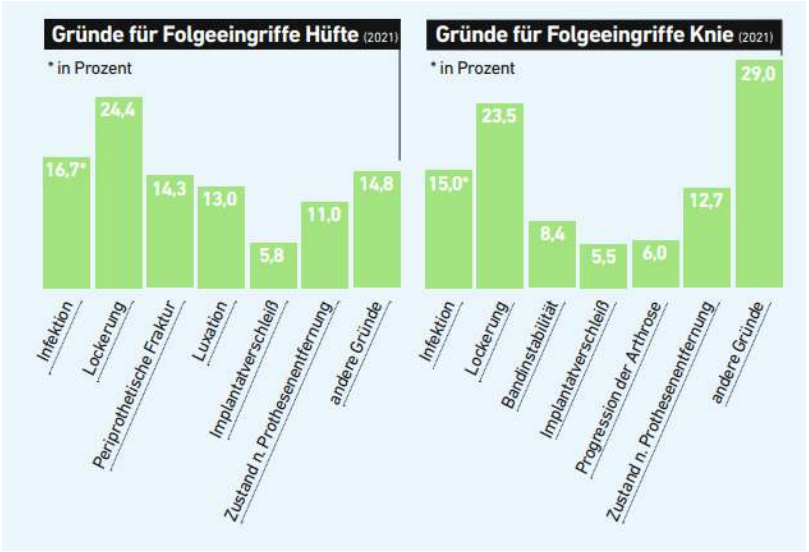
Fernando García-Sanz [1,2], María Dolores Sosa-Reina [1], Gonzalo Jaén-Crespo [1], Ángel González-de-la-Flor [1], Jorge Hugo Villafañe [1], Carlos Romero-Morales [1]

Affiliations + expand

PMID: 40283417 PMCID: PMC12028302 DOI: 10.3390/jcm14082588

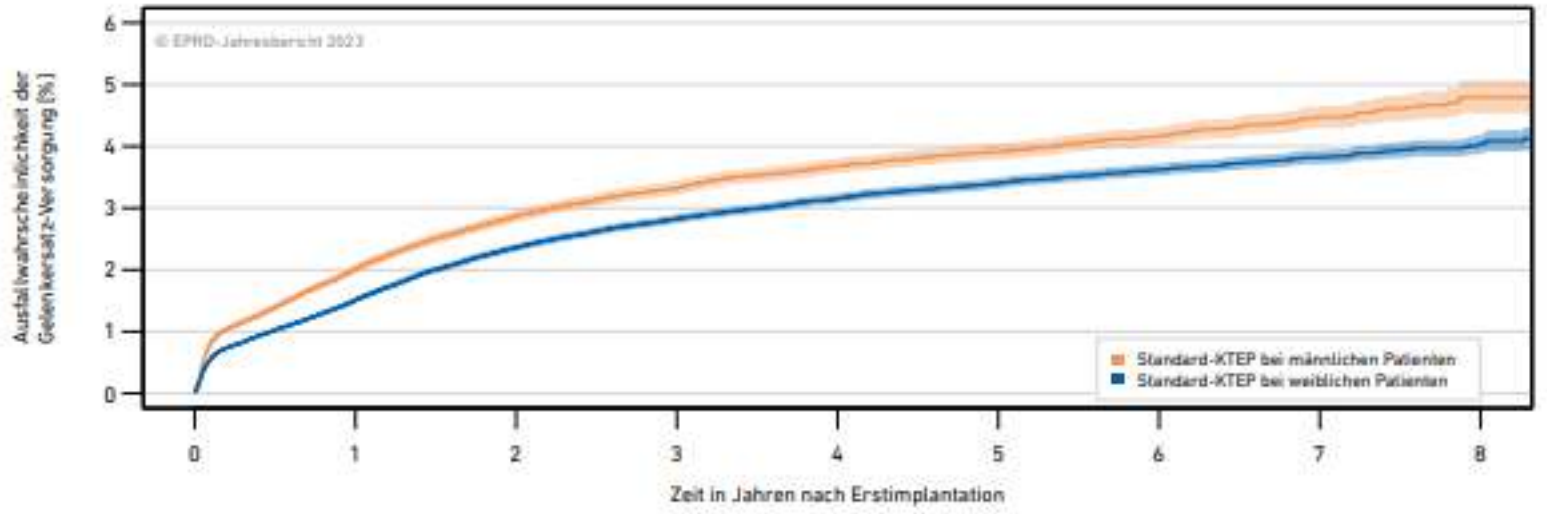
Are implant registers any help?





	Anteil [%]	Alter	m/w [%]	BMI	ASA
Alle betrachteten Versorgungen	100,0	72	40 / 60	26,8	2,3
<45-Jährige	1,7		55 / 45	27,3	1,8
45- bis 54-Jährige	6,3		52 / 48	28,4	1,9
55- bis 64-Jährige	21,1		48 / 52	28,1	2,1
65- bis 74-Jährige	30,1		40 / 60	27,5	2,2
75- bis 84-Jährige	29,9		34 / 66	26,0	2,5
85-Jährige und älter	10,9		30 / 70	24,6	2,8
Männer	40,0	69	100 / 0	27,5	2,3
Frauen	60,0	73	0 / 100	26,2	2,3
BMI bis 25	33,7	75	31 / 69		2,3
BMI >25 bis 30	36,0	72	46 / 54		2,2
BMI >30 bis 35	18,0	69	45 / 55		2,3
BMI >35 bis 40	6,4	66	41 / 59		2,4
BMI über 40	2,4	63	35 / 65		2,6
BMI unbekannt/unplausibel	3,5	72	38 / 62		2,2

© EPRD-Jahresbericht 2023



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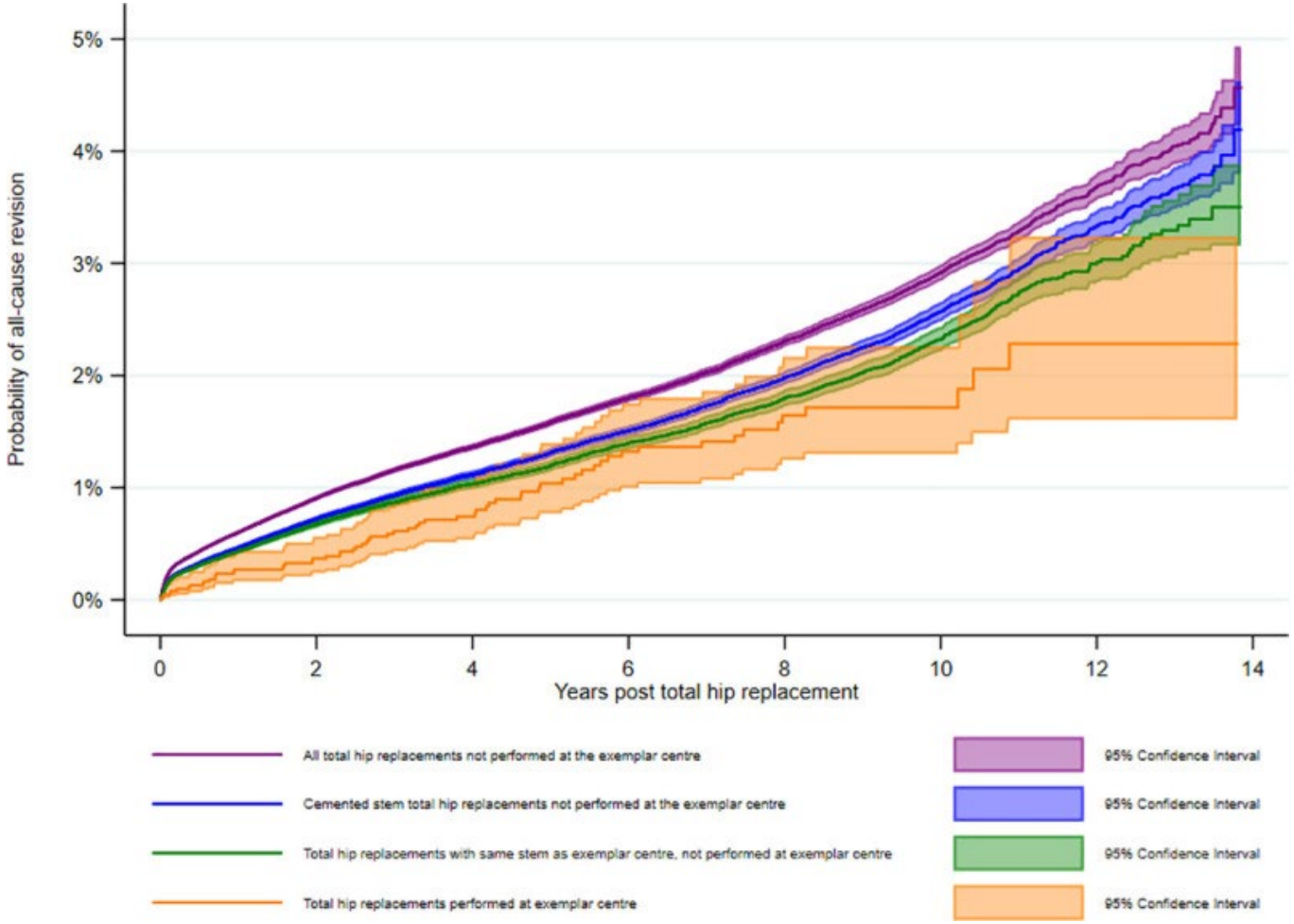
Non-believers: „But in my hands..“



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

PMCID: PMC7458308 | PMID: 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 Download Full Issue

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 Orthopedic Association National Joint Replacement Registry

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

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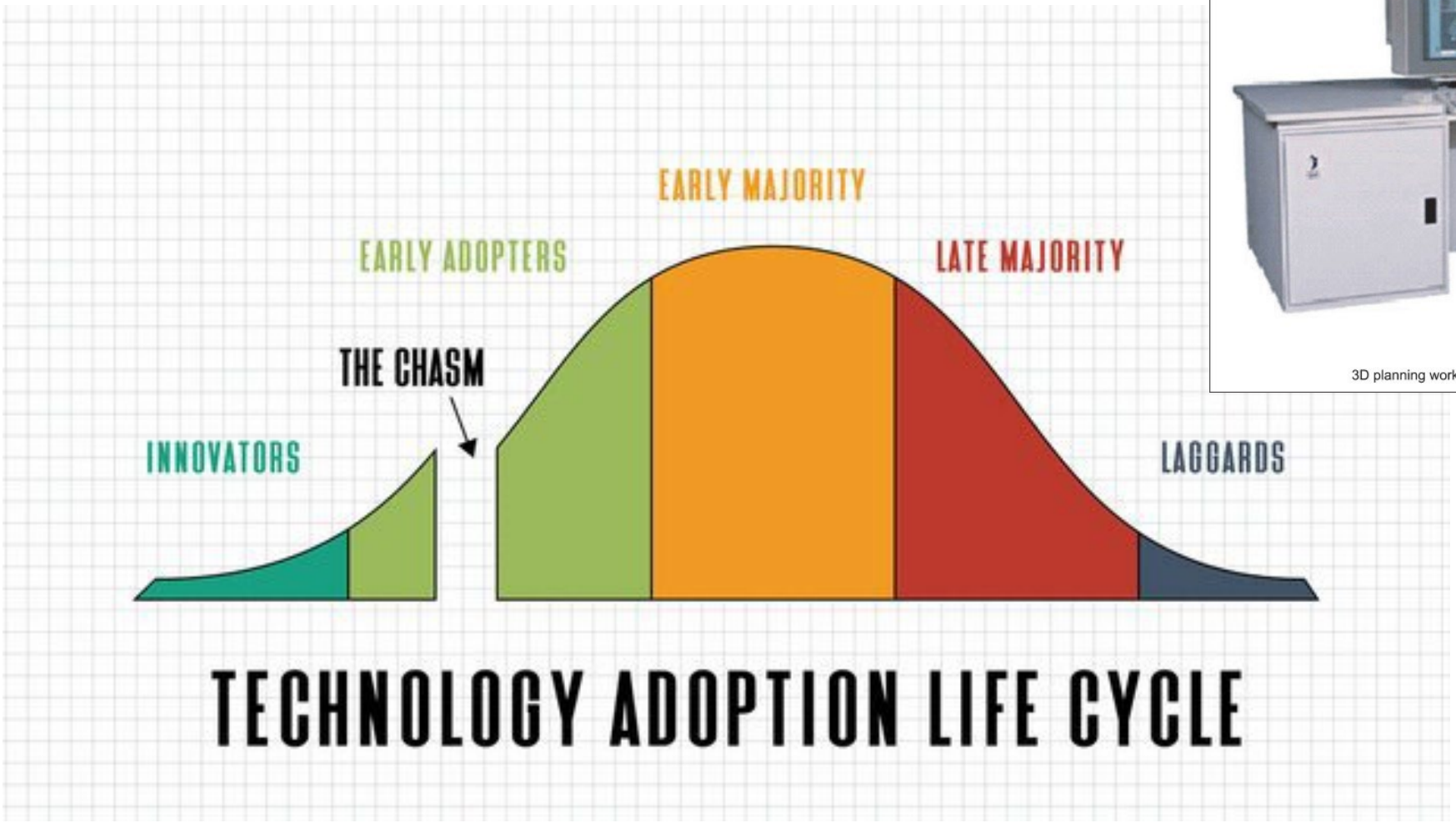
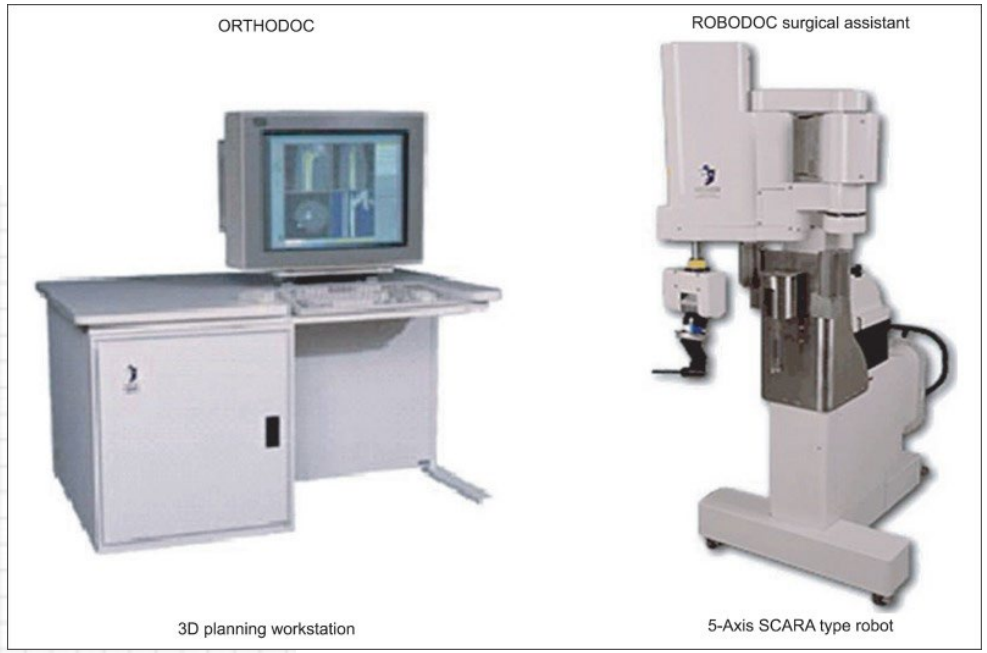
What degree of evidence do you need?





Who is driving the process? And why?

Is there an actual need?

Do I really need impovement?

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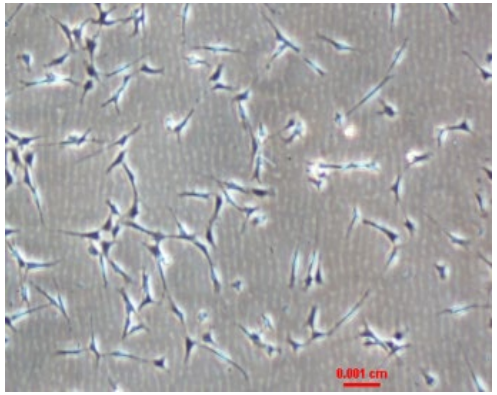
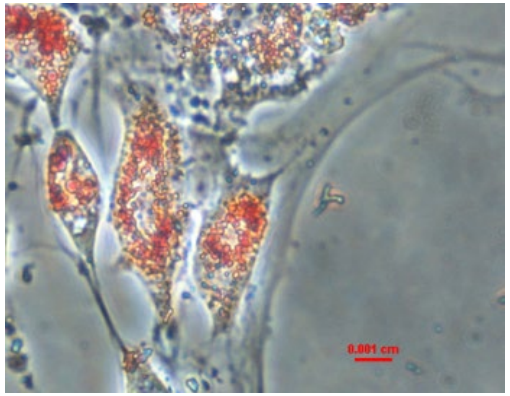
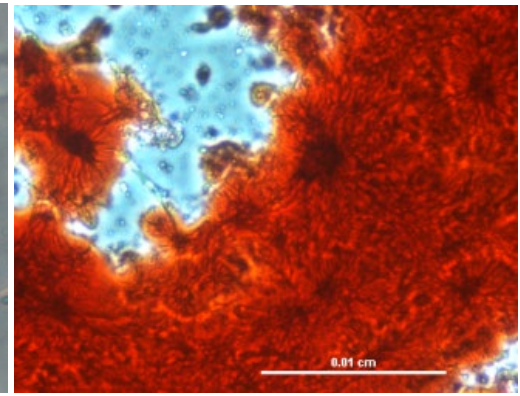
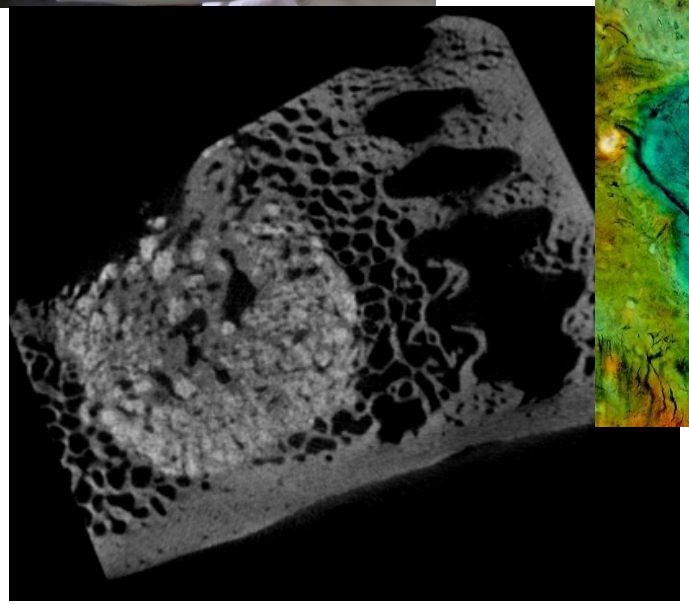
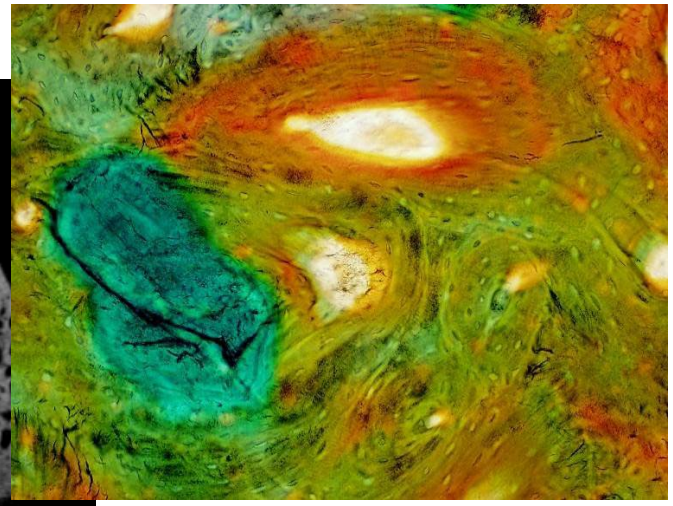
Example 2: Tissue engineering

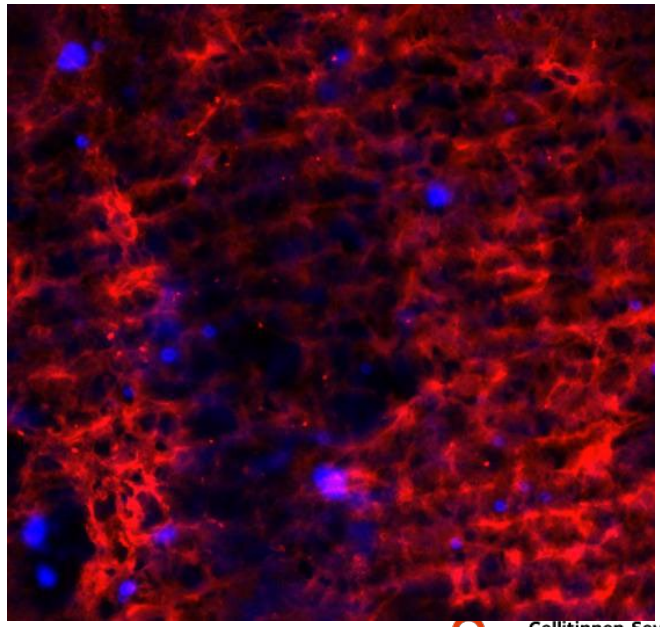












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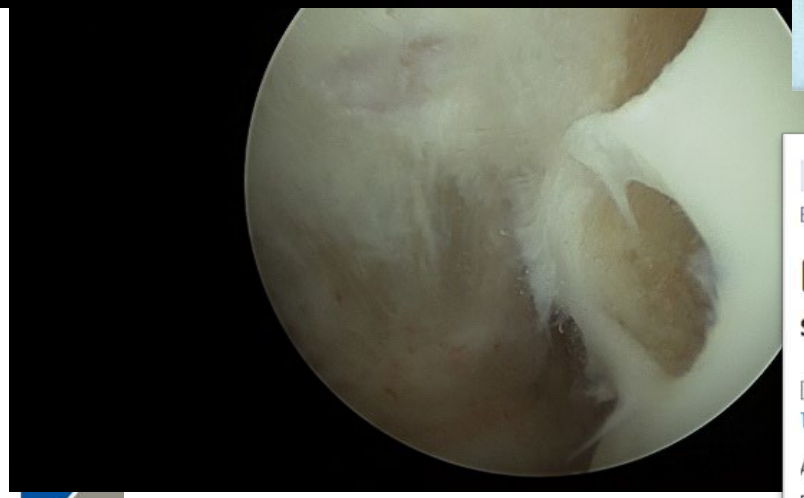
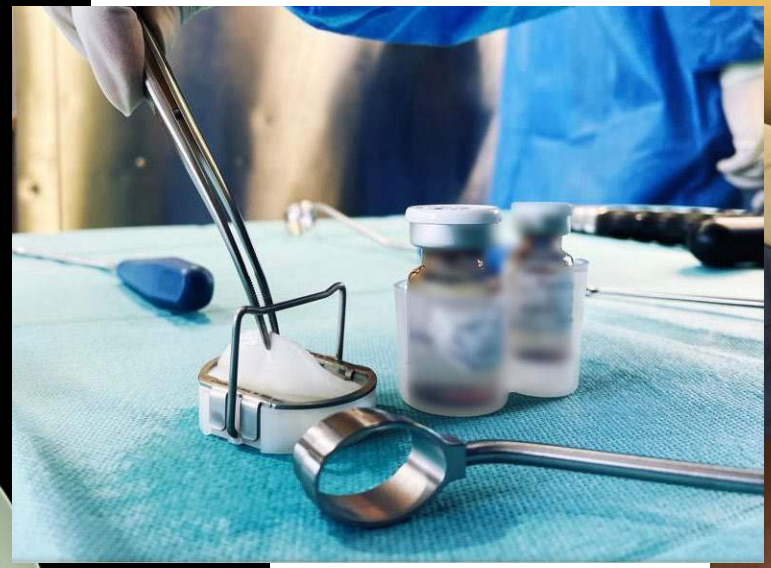
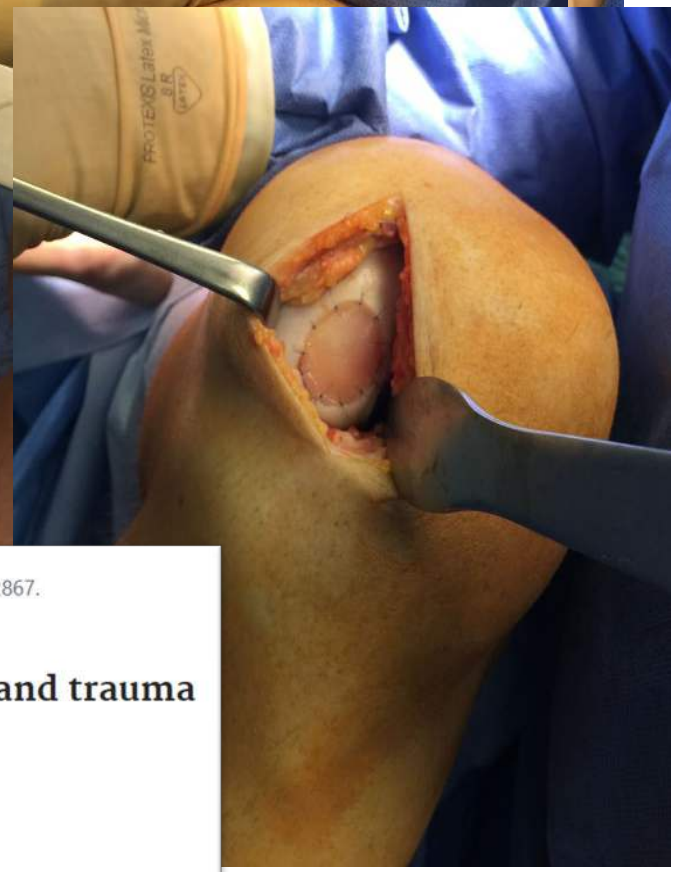
Tissue engineering







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?

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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
IIa	73,0	77,5
IIb	82,0	82,5
III	96,5	101,5

BVMed

#MDReady | Zertifikate werden nicht fristgerecht überführt

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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 identifyin
Paraguay, this research is vital due to the unique regulatory environment and the need for compliance w
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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EPISODE 266

Early Feasibility Studies in Latin America

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

00:00:00 00:42:44

1× INFORMATIONEN LINKS ABONNIEREN TEILEN

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HEU EFS

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

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**

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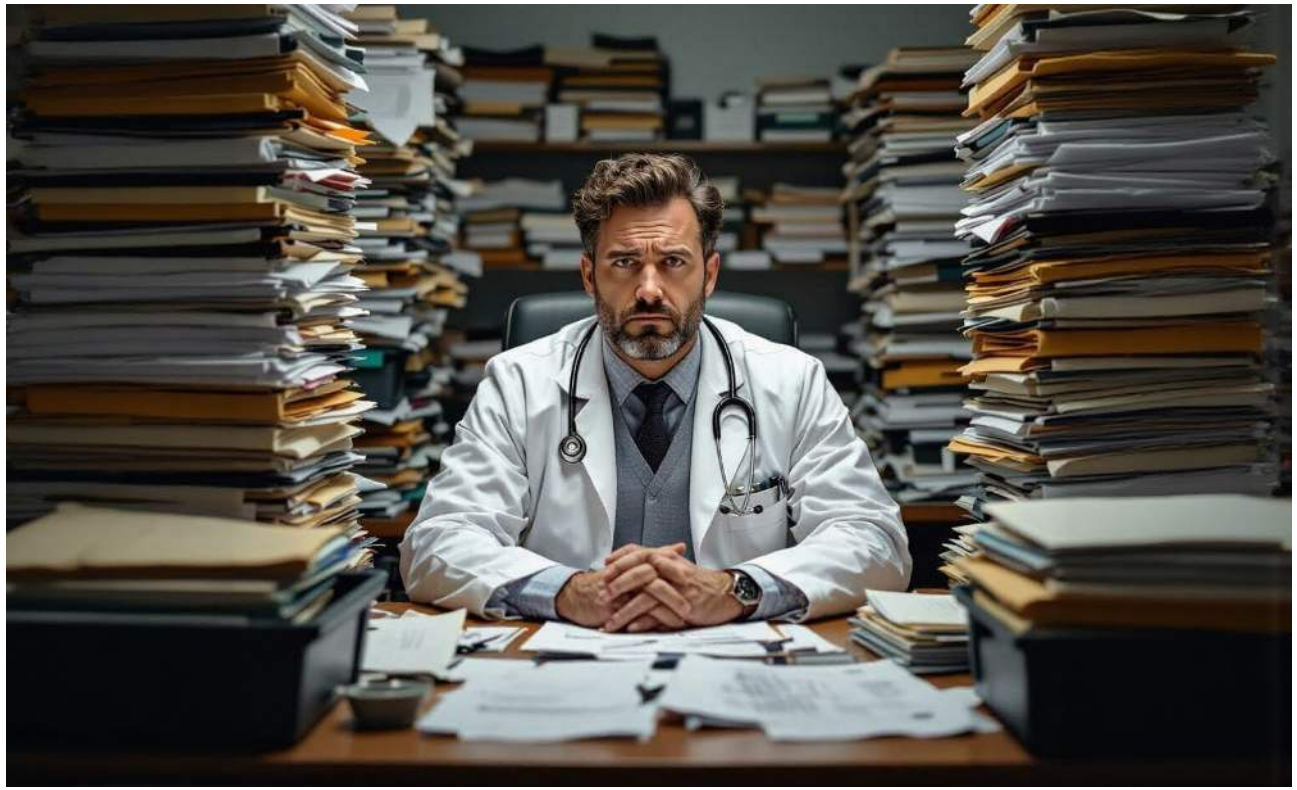
The surgeon‘s perspective

AI-generated Image



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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

Thomas Martin Randau

· Priv.-Doz. Dr. med. ·

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