Insights and challenges of AI adoption in Healthcare and MedTech

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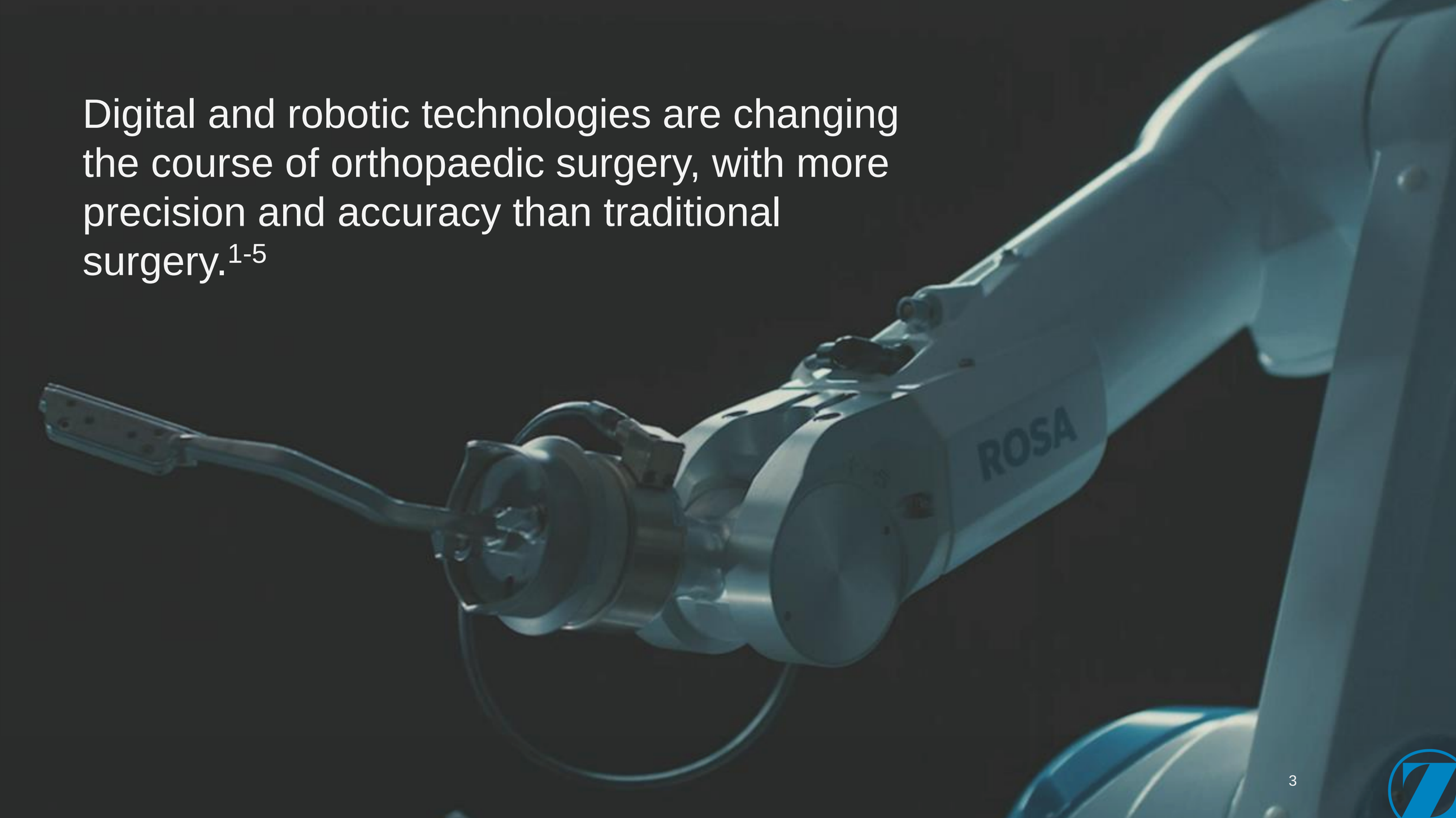
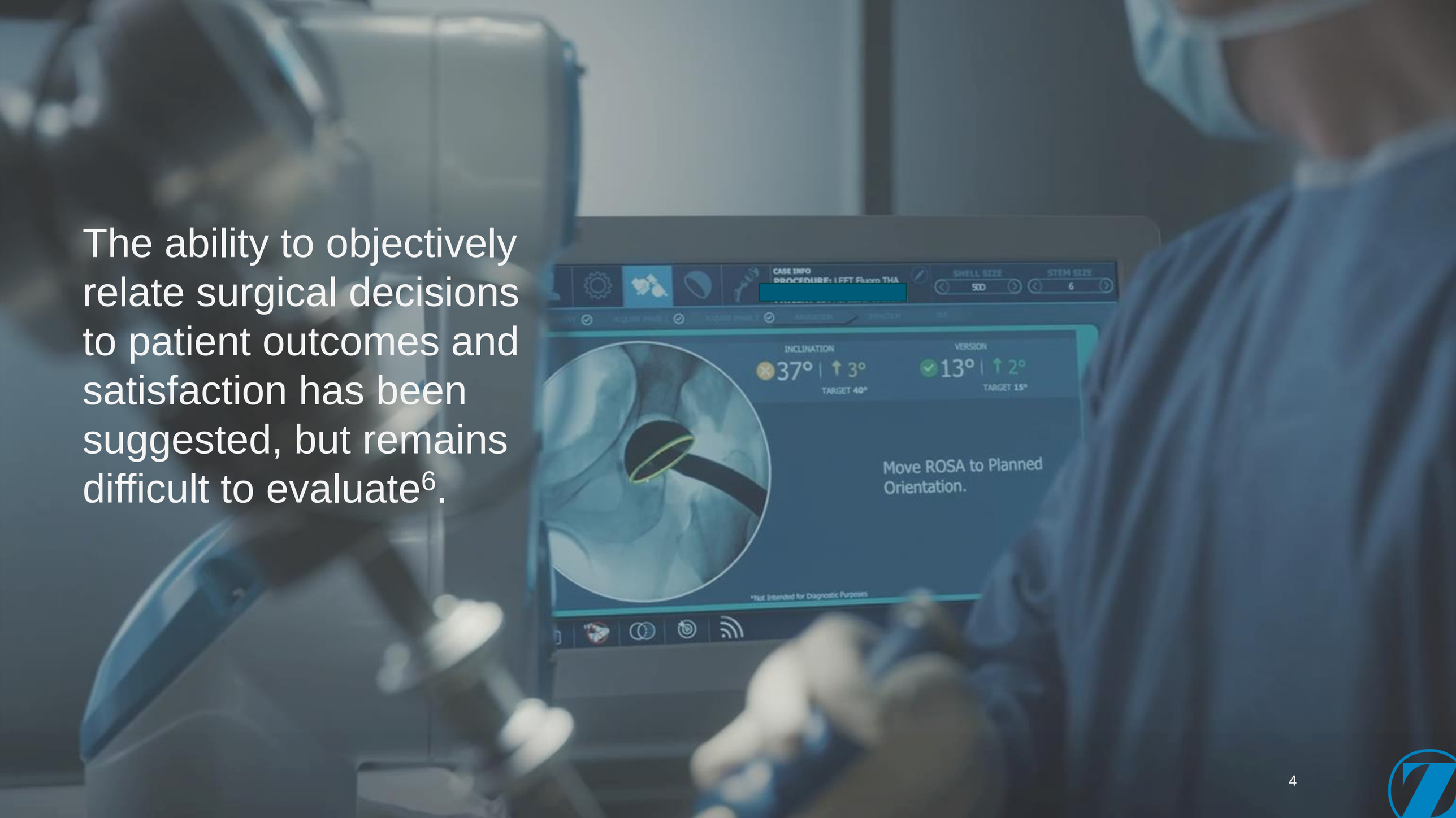
Zimmer Biomet – our products

“Our mission is to alleviate pain and improve the quality of life for people around the world.”

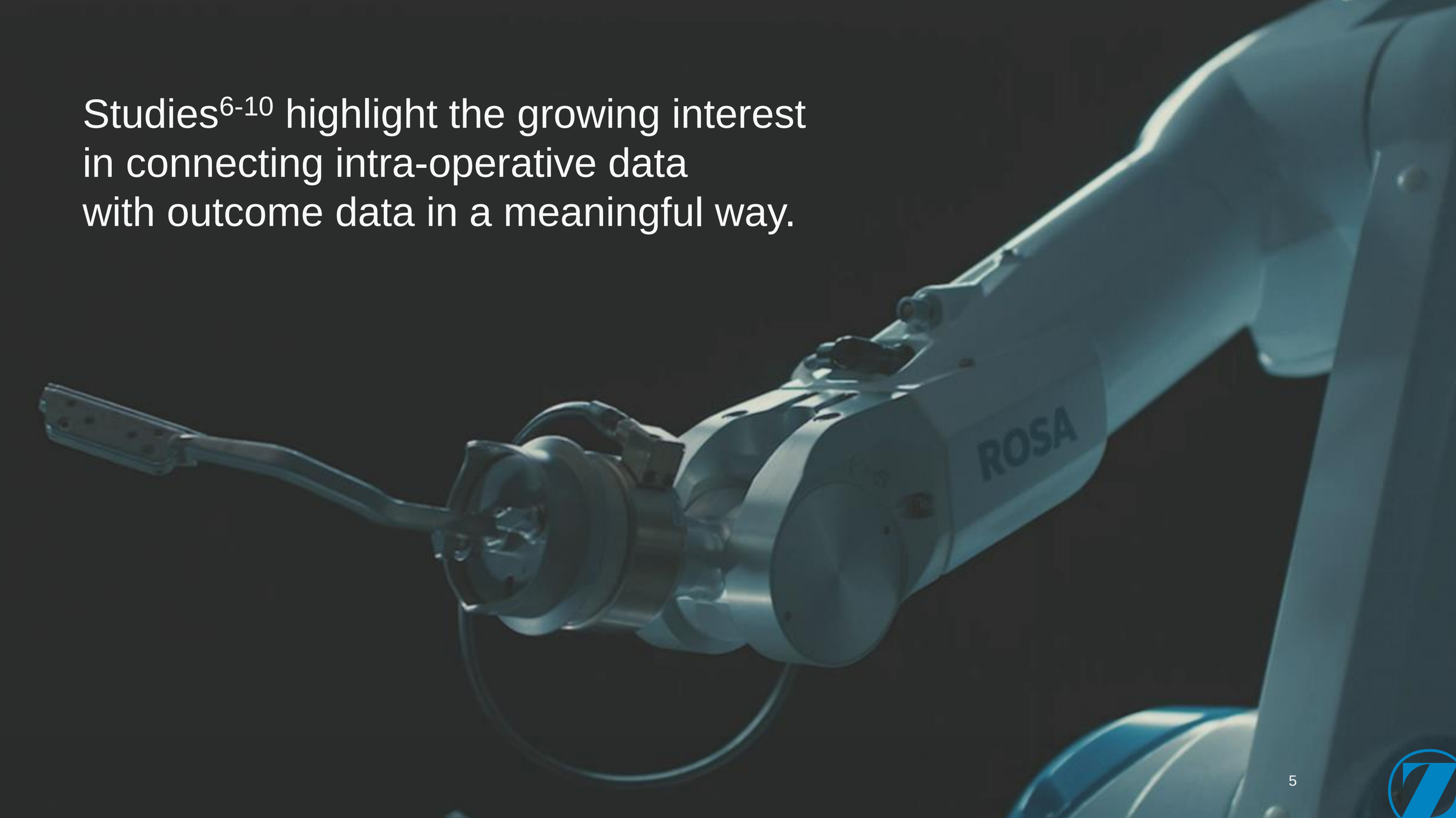
Digital and robotic technologies are changing the course of orthopaedic surgery, with more precision and accuracy than traditional surgery.[1-5]



The ability to objectively relate surgical decisions to patient outcomes and satisfaction has been suggested, but remains difficult to evaluate[6].

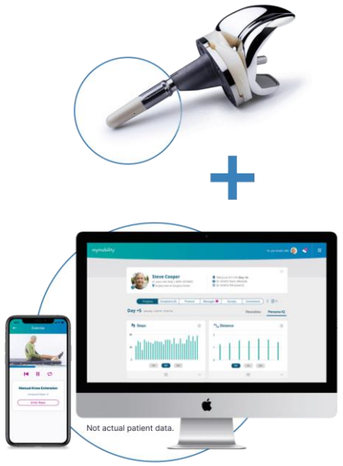


Studies[6-10] highlight the growing interest in connecting intra-operative data with outcome data in a meaningful way.



Our Digital Footprint of Orthopaedics

PRE-OPERATIVE CARE → **INTRA-OPERATIVE** → **POST-OPERATIVE CARE** → **PATIENT OUTCOME**



Patient satisfaction
Pain and function scores
Patient mobility

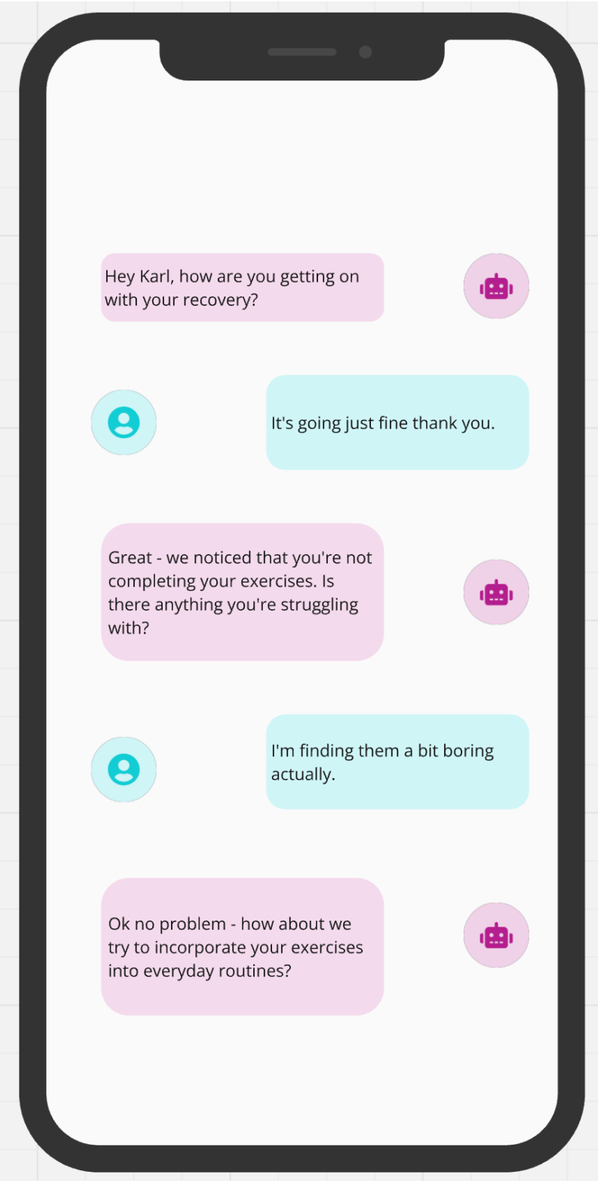
Challenges and opportunities

Validation and safety of AI products

- For non-regulated products:
  - Build, test, validate (including red-teaming);
  - Launch, seek feedback;
  - Iterate.

- For medical applications:
  - Full risk analysis, including documentation of where risks are mitigated.
  - Full documentation of requirements, then evidence of testing against requirements.

Mock-up for illustration purposes only.

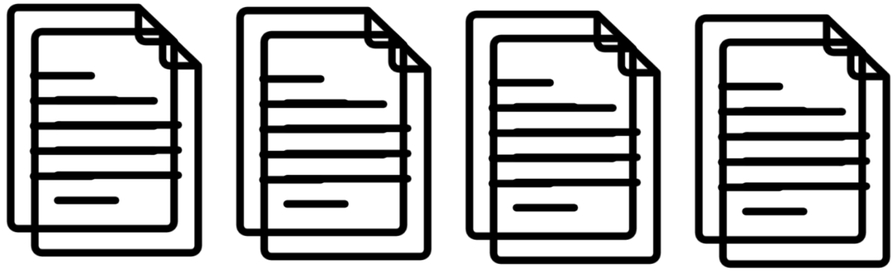


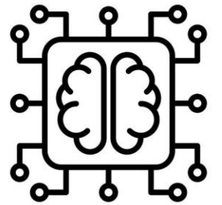
The documentation footprint of regulated industries

Our adherence to various regulations and guidelines generate
extensive documentation:

- ISO standards;
- Regulations (FDA, European Medical Device Regulation);
- Government legislation (EU AI Act)

Large-language model technologies can be used in the creation of these documents, as well as to mine these documents to make internal processes more efficient.





"Where have we used a similar component in previous products?"

"Have we had this feedback from regulators before, and how did we deal with it?"

Challenges and opportunities

Validation and safety of AI products

What is the role that your AI system is playing?

- “Practicing medicine”?
- Implementing existing protocols on behalf of doctor?

Regulatory and risk implications of this decision.

What if clinician has specified this as treatment, and there are no other issues?

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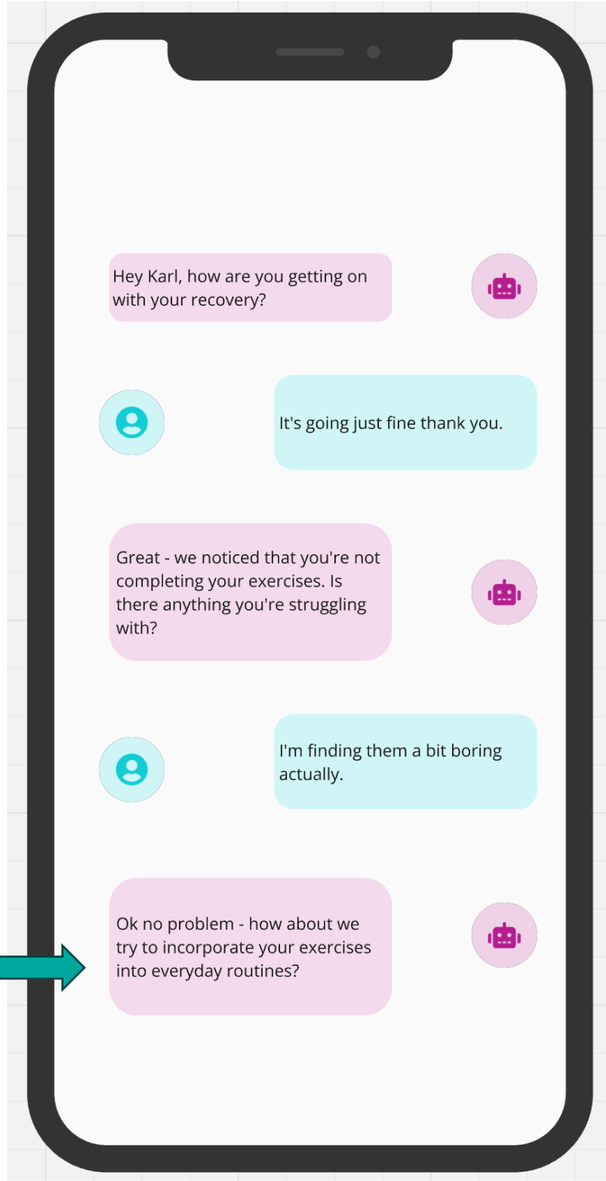


Challenges and opportunities

Data stewardship and ownership

- How can we monitor AI products with the fundamental premise that clinician/patient conversation is confidential?

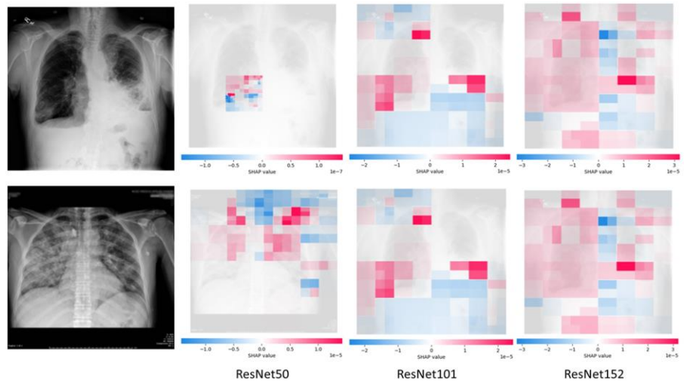
- How do we balance the needs of multiple stakeholders: patient, care team/surgeon, provider, payor, device manufacturer
  - Who owns the data?
  - What is consented use?

Challenges and opportunities
User experience

User experience of AI-based products is critically important

- What do clinicians need to see in order to inform their decision?
- Do they have time to consume that information? Where and when in care pathway is this info delivered?
- What do patients want from AI systems?

Regulations placing increasing importance on validating the User Experience.



Stephen Lee, *Jamia Open*, Volume 7, Issue 2, July 2024, ooae035, https://doi.org/10.1093/jamiaopen/ooae035

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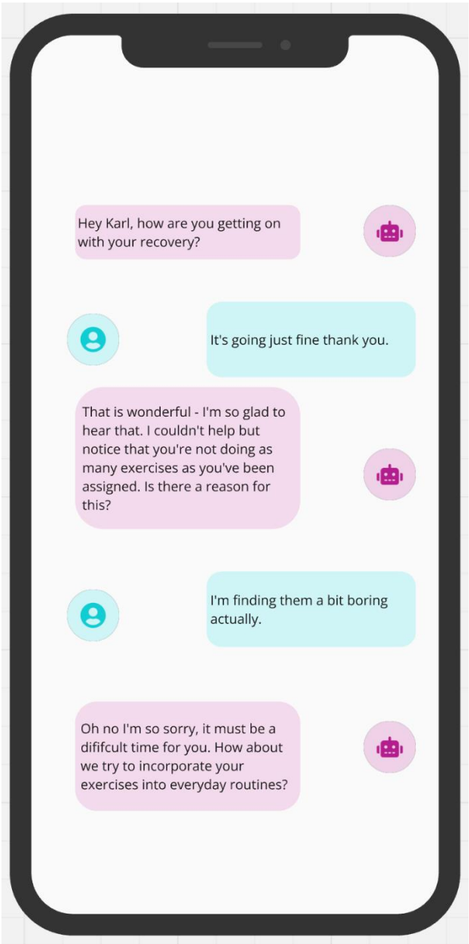

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Regulations placing increasing importance on validating the User Experience.

7. **Focus Is Placed on the Performance of the Human-AI Team:** Where the model has a "human in the loop," human factors considerations and the human interpretability of the model outputs are addressed with emphasis on the performance of the Human-AI team, rather than just the performance of the model in isolation.

https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

Challenges and opportunities
Getting internal partners on board

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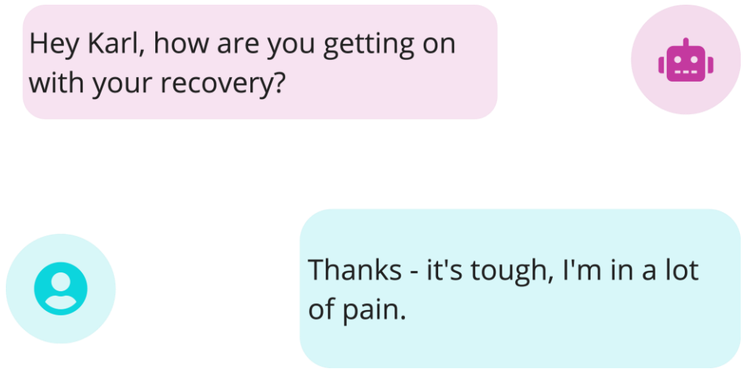
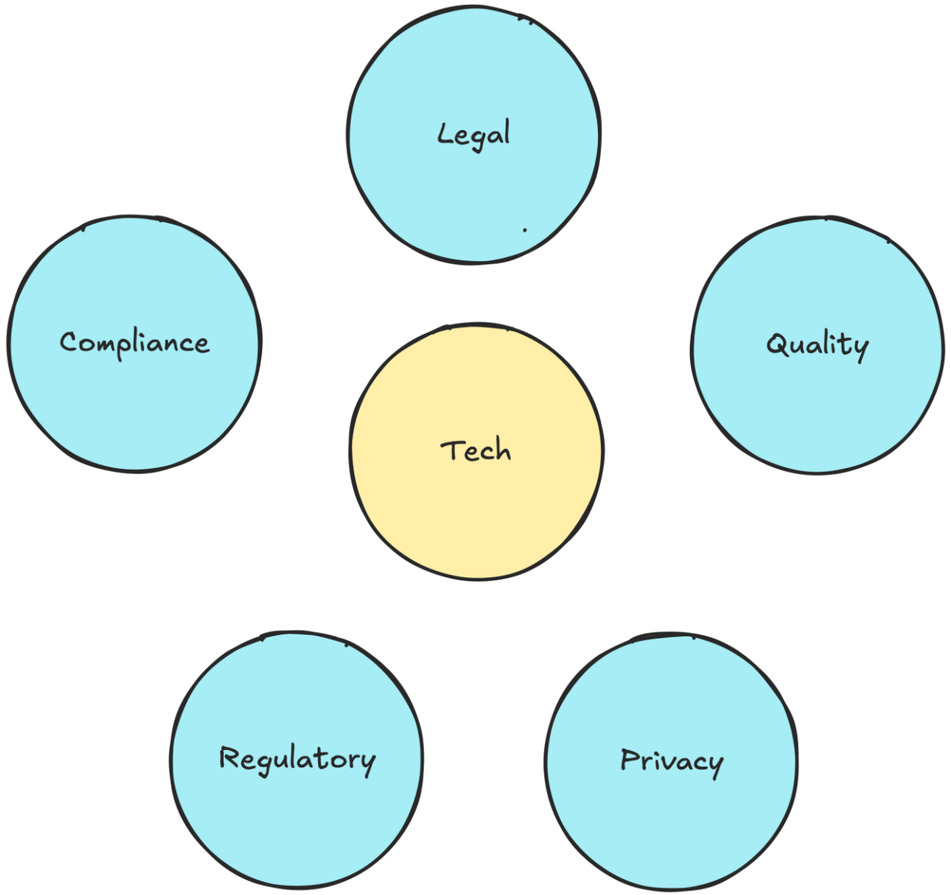


- Is it to do with the implant?
- Do we need to treat it as a potential complaint?

Challenges and opportunities
Getting internal partners on board

- Using AI in products makes some internal stakeholders' lives more difficult
  - Increase monitoring
  - Documentation
  - Risk
- As an AI function, demonstrate to these groups how AI can improve their work and improve their effectiveness



Key takeaways

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- Orthopaedics is ripe for data-driven innovation using AI.
- Deployment of AI into healthcare requires many additional considerations around risk and privacy.
- AI is likely to make the above more complex *whilst also making it* more efficient.
- Transparency and careful consideration of user experience is critical to both patients, clinicians and multi-disciplinary stakeholders.

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Laboratory and animal testing are not necessarily indicative of clinical results

Disclosure: 7. funded by Zimmer Biomet

Q & A

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