

Supplemental Zimmer Total Ankle Replacement (TAR) Cutting Guide

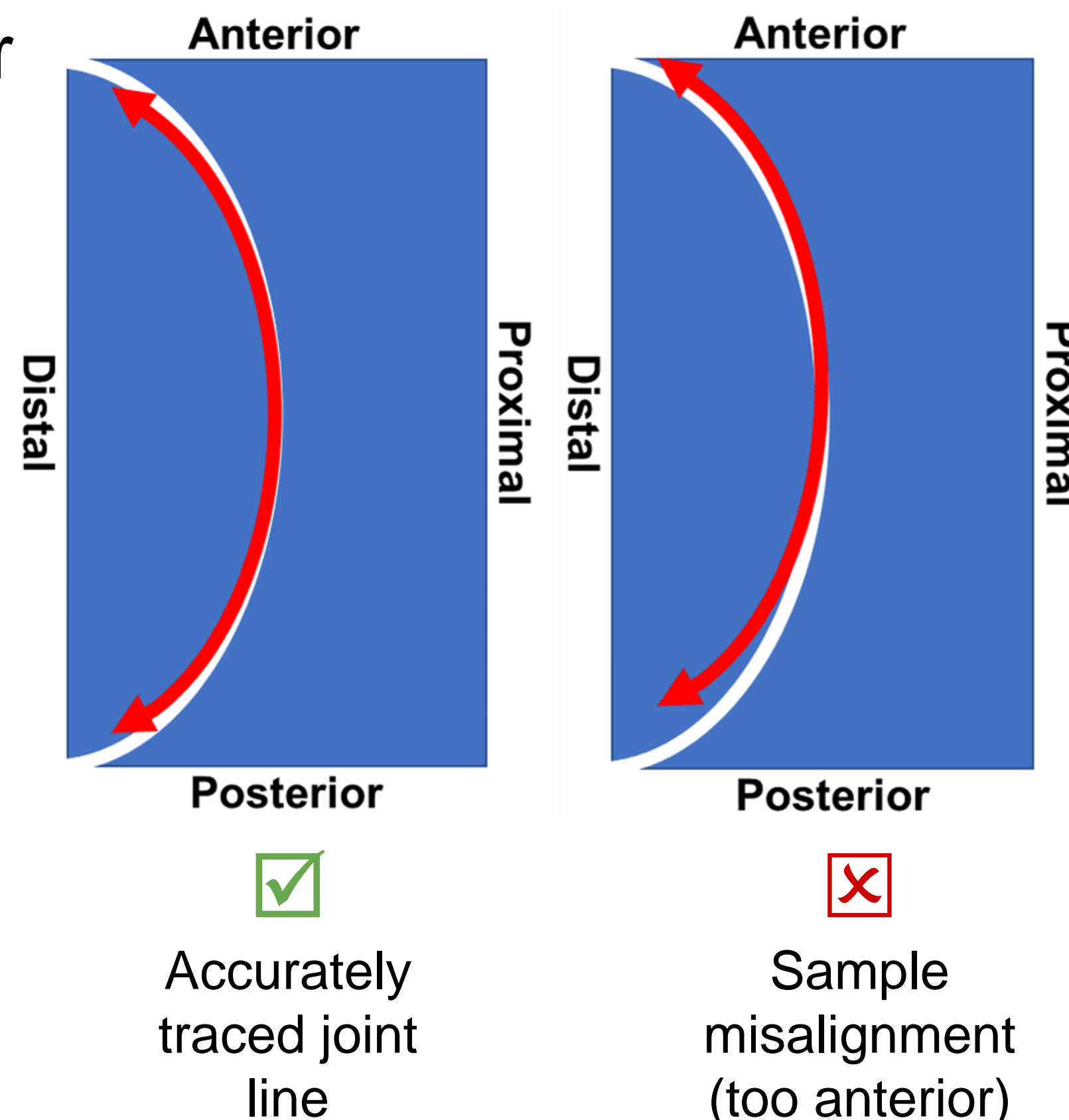
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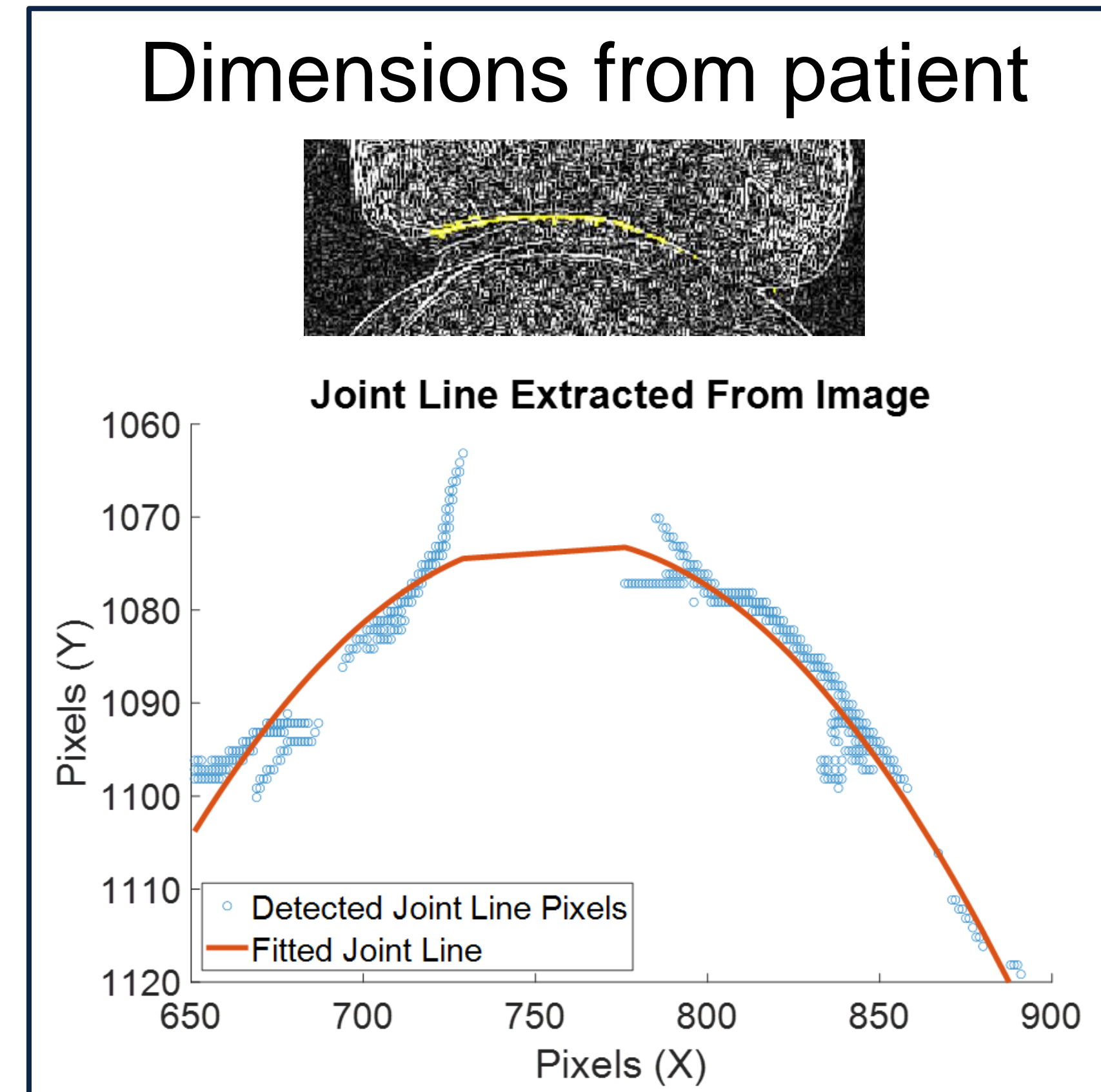
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Background and Need

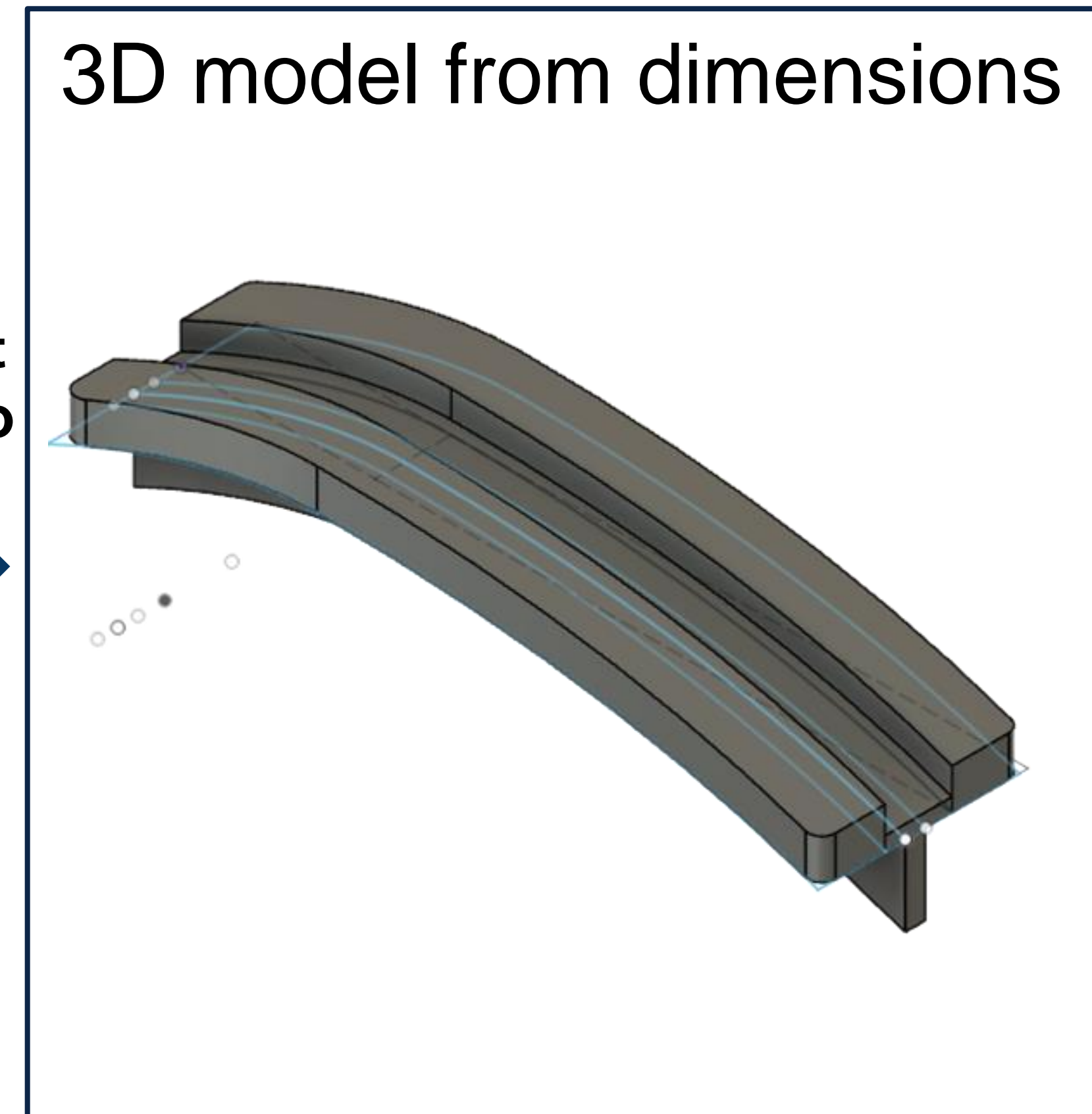
- TAR: Treatment for arthritis, in place of fusion
- Zimmer TAR:
 - Longer surgery → increased infection risk
 - Small misalignment → accelerated wear
- Revision surgery: 44% after 10 years



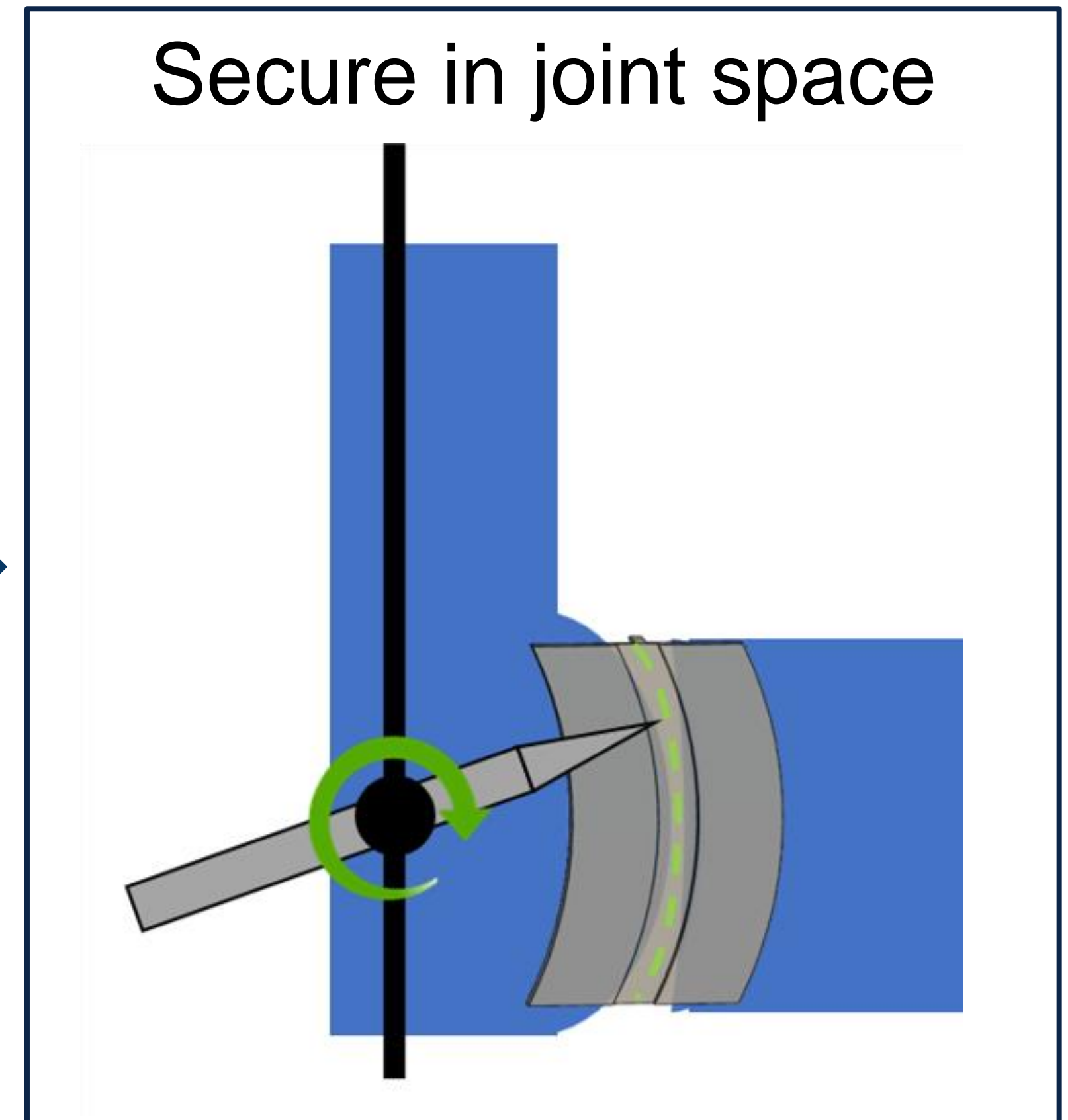
Design Overview



Convert pixels to mm



3D print



Objective

- **Patient-specific** supplemental cutting guide
- Modeled from preoperative research
- **Quickly** help surgeons usher the Cutting Guide into the **correct position**



Verification

- Standards
 - FDA Class III → **21 CFR 814 and 812**
 - Calipers and stopwatch calibration → **ISO 9001: Quality Mgmt. Systems**



Conclusion

- Supplemental cutting guides can be printed from tibiotalar joint line data extracted from ankle models



Societal Impact

- Improve alignment to decrease surgery time → decrease cost of surgery
- Decrease need for revision surgery → decrease costs up to \$6 million annually

Acknowledgments

Thank you: **Dr. Jaimie Dougherty**, Course Advisor; **Drexel BIOMED**, \$300 budget; **DrEXCEL Health**, \$500 budget

Constraints

- C.1.** Time: 7 months
- C.2.** Budget: \$800
- C.3.** Resources: CAD, 3D printers
- C.4.** Policies: Cadaveric tissue, Biocompatibility
- C.5.** Project Specific: Joint line size, compatibility with Zimmer System

Requirements

- R.1.** Accommodate talus widths 16.99 to 32.21 mm
- R.2.** Midpoint Alignment with joint line
- R.3.** Minimize product movement with hand force
- R.4.** Fits in the lateral incision site
- R.5.** Decrease procedure time (<10 min)

R	Methods	Passing Criteria
1	Find model joint line in ImageJ	Joint line can be replicated in CAD
2	Mark midpoint on model and on product	Measure the distance between midpoints
3	Attach motion sensors to guide and subject to hand force	Minimal displacement detected
4	Measure product	Measurements < incision size
5	Perform mock procedure	Procedure time < 10 min.

References: [1] E. Pianin, "Ankle replacement was once disparaged as borderline quackery, no longer," *The Washington Post*, 22-Oct-2017. [2] "Ankle Replacement Rapidly on the Rise." Florida Orthopedic Foot and Ankle Center. may 30th, 2021. [3] Labek G;Klaus H;Schlichtherle R;Williams A;Agreiter M; "Revision rates after total ankle arthroplasty in sample-based clinical studies and national registries," *Foot & ankle international*. [4] "Dr. Thomas I. Sherman, MD - US news health | find a doctor ..." [5] Trabecular Metal™ Total Ankle Surgical Technique. Zimmer Biomet. [6] Harnroongroj, T., & Chutithammanun, L. (2003). Measurements of Talus for Sizing Talar Body Prosthesis. *The Thai Journal of Surgery*, 24(3), 91-96. [7] Dr. Thomas Sherman, testimony.