



TRIVARA

AMZ PLATFORM

Alleviate anterior knee pain
Restore patella (kneecap) stability, preserve the joint, and enable a return to normal activity

Co-founders



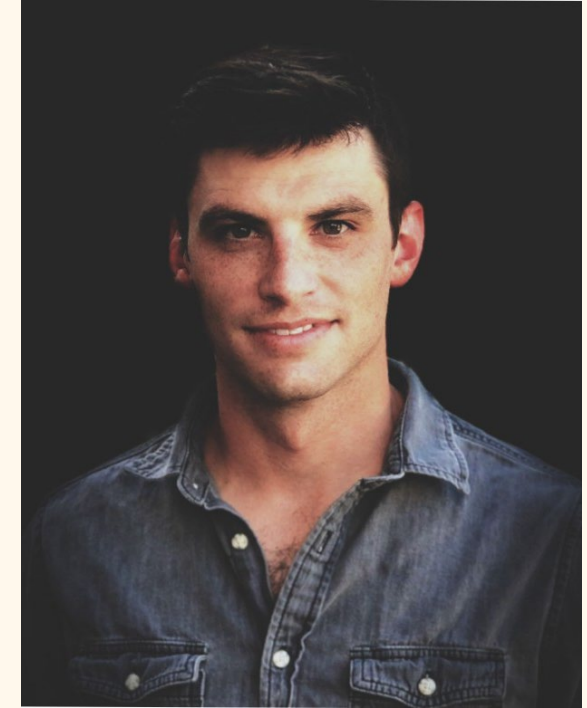
John Fulkerson, MD

- Inventor of AMZ TTO
- Performed 1,500+ TTO procedures over 45-year career
- Founder, International Patellofemoral Study Group
- Founder & President, Patellofemoral Foundation



Alyssa Glennon

- ~20 yrs industry engr medical device development
- >10 yrs patient-specific orthopedic device design, 3DP



Aiden Reuter

- ~10 yrs industry engr medical device development
- ~5 yrs industry quality engr, medical device and software

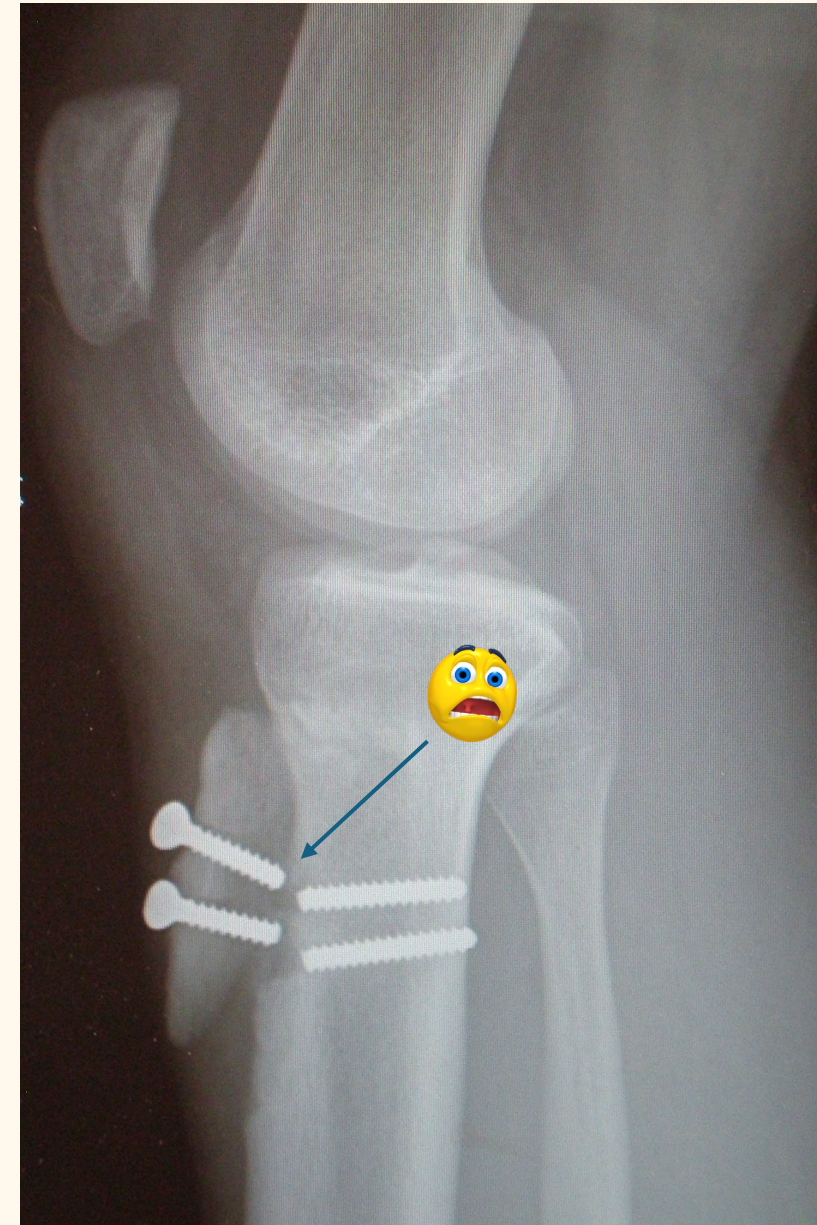
Patella Instability = Lower Quality of Life

- Young, active patients (age 15-45) develop
 - **patella instability**
 - **arthritis**
 - **consistent pain**
 - → **knee replacement**
- **Recurrent** episodes (50-70%)
- Experience **loss of work, limitations to activity**
- To realign the kneecap → surgically centralize the patellar tendon
 - **Tibial Tubercle Osteotomy (TTO)**

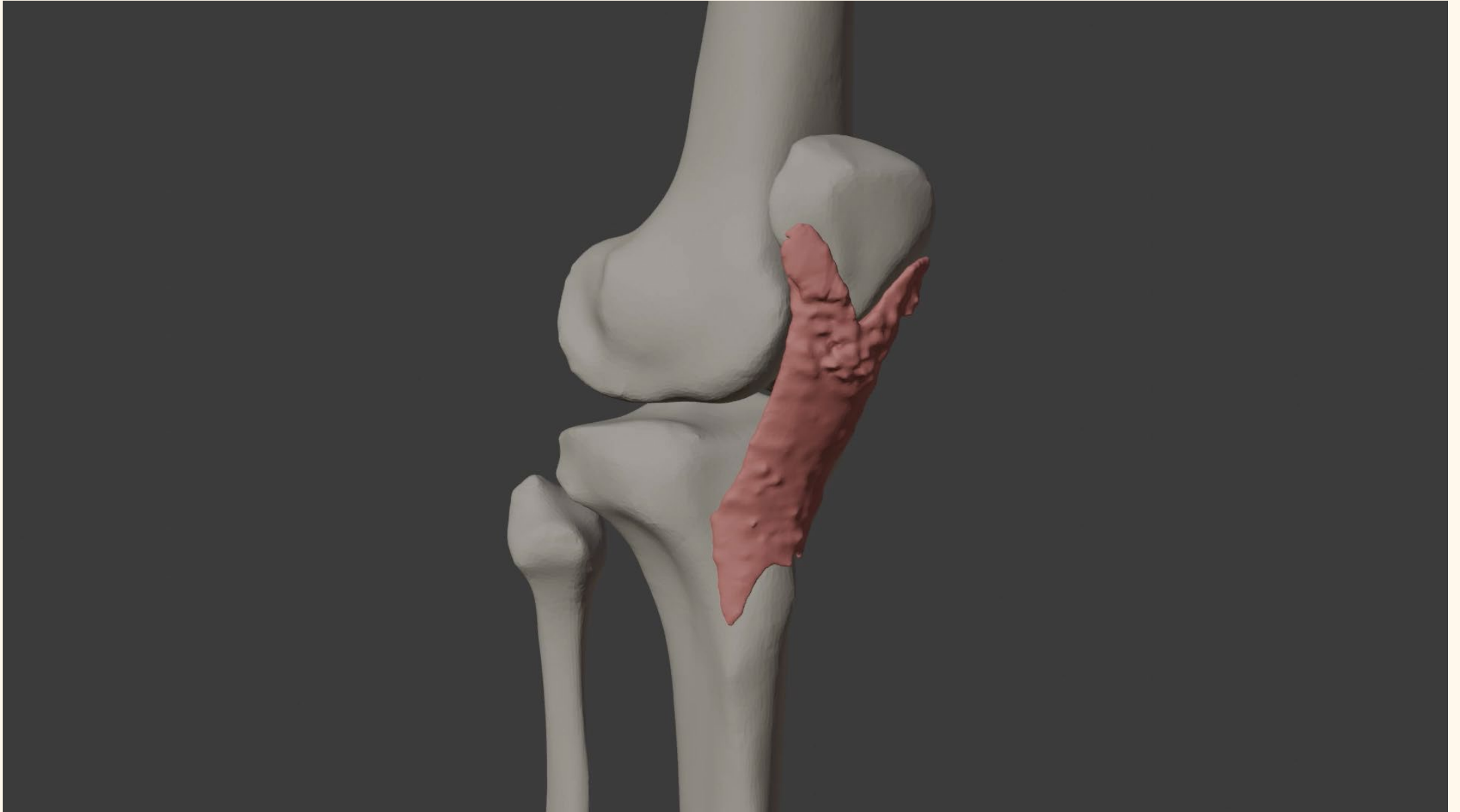


Free-handed Surgery Limits Precision

- We can mathematically define the **perfect multiplanar cut and taper angles** for each patient
- Surgeons **free-hand execute** or use an **imperfect guide**
- Existing TTO guides are:
 - **highly variable** in fit
 - **limited in precision** angulation options
 - **prone to error**
- **'Fiddle-factor'** increases surgical time = extra costs

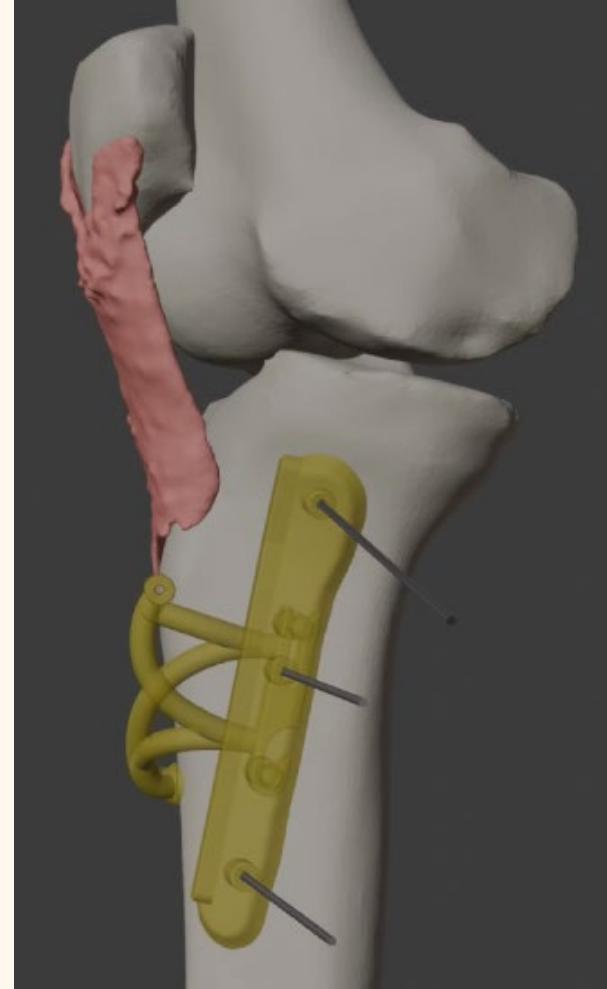


Trivara Provides Unparalleled Precision & Speed



Trivara Provides Unparalleled Precision & Speed

- ✓ No 'one size fits all'.
- ✓ Trivara creates the **ideal & customized 3D** cut plane specific to the patient.
- ✓ Optimal patella tracking and focal loading
→ **Reduced risk of procedure failure & complication.**
- ✓ **Reduced OR time** translates to:
 - ✓ Reduced anesthesia
 - ✓ Reduced fluoroscopy radiation exposure
 - ✓ Reduced cost
- ✓ **Used in 11 cases at YNHH to date**

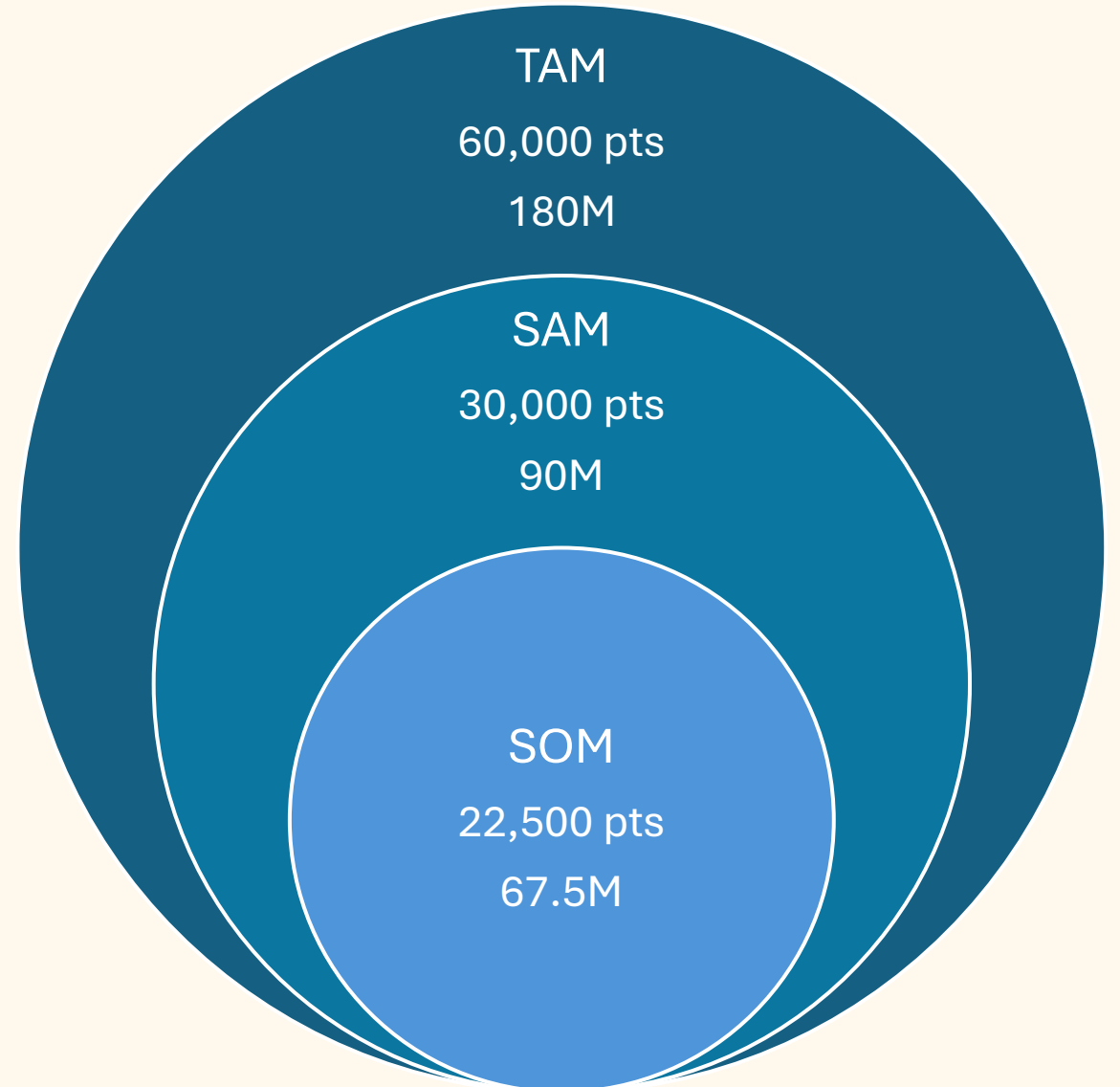


✓ Return to work ✓ Return to daily activity ✓ Return to family and hobbies

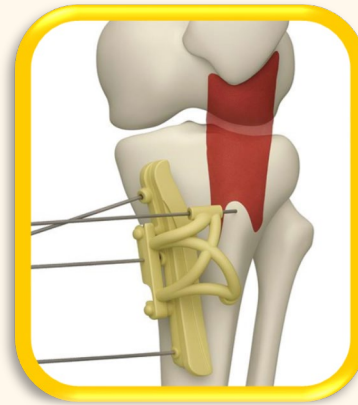
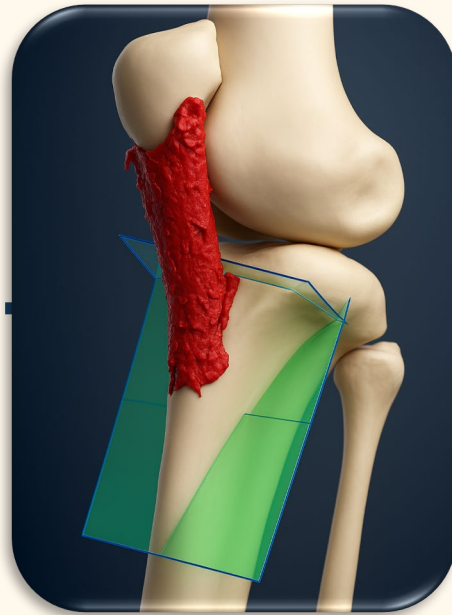
Opportunity

- TAM
 - Retrospective review of Mariner Database (150M+ patient records over 6 yrs)
 - 2600 pts/yr w/CPT code 27418 unilateral TTO, extrapolated to US population size = 6000
 - Multiply by 2 for add'l CPT codes
 - Extrapolate by factor of 5 for global markets
 - \$3000 per case
- SAM
 - 2 most common techniques – Elmslie-Trillat and Fulkerson (AMZ)
 - AMZ increasingly used, up to 50%+ of TTOs
- SOM
 - 75% market penetrance
 - PSI predicted to be an important tool in patellofemoral surgery
 - Limited competitive guides
 - Technology hype

GLOBAL MARKET

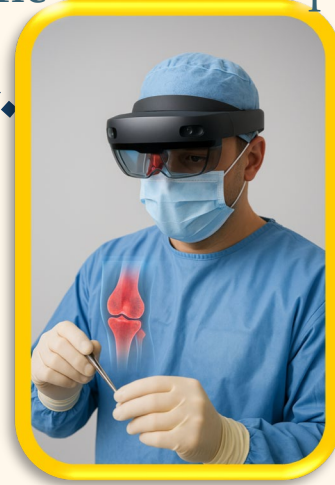


AMZ PLATFORM: App → planning → instrumentation



Trivara FANG
patient-specific

Trivara CORE
patient-matched

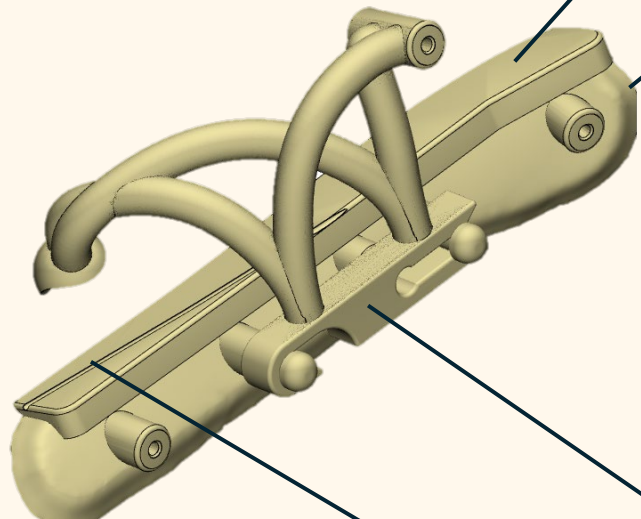


Trivara MERGE
patient-specific AR

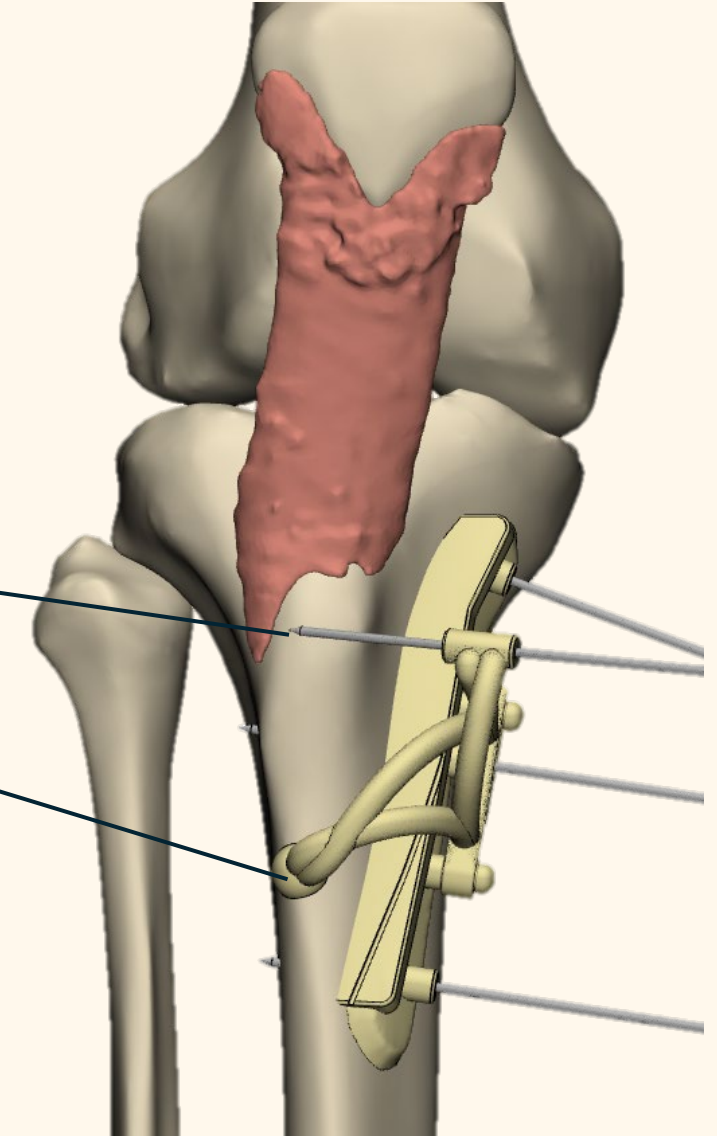
Three guidance options to translate this patient-specific plan:

- 1) 3D printed personalized guides,
- 2) fluoroscopy compatible jigs, or
- 3) AR-assisted guide placement

Trivara FANG



Angled Cutting Flange	Precisely calculated to matched the planned AMZ angle during osteotomy
Patient-Specific Registration	Direct fit to the medial surface of the patient's tibia providing reliable alignment
Anterior Node Pointer	Visible confirmation of guide placement without the need for fluoroscopy
Anterior Ridge Cue	Self-centering geometry offering stability during guide fixation
Removable Registration Aids	Tactile confirmation for confidence without adding steps
Tubercle Transfer Target	Provides visual confirmation of achieved correction prior to tubercle fixation



Business Model & Growth Strategy

Trivara FANG

- **Patient-specific guide**
- Patent pending
- **Used in multiple clinical cases at YNHH**
- **Cut OR time from ~90min to ~30min**
- Intended as a service
- Automated

Trivara CORE

- **Off-the-shelf**, similar to other surgical instruments
- Patient-matched guide
- **Patent pending**
- Web app dials in patient settings

Trivara MERGE

- **Patient specific digital plan + off-the-shelf device**
- Patent pending
- Intended as a digital service, with additional sale of off-the-shelf components
- Automated

Objective: Achieve 510(k) clearance for FANG that can be licensed along with IP for a nearly turn-key tool

Competitive Landscape

	Provides surgical guidance of gold standard AMZ TTO osteotomy	Posterior plane used in preoperative surgical planning	Correlates AMZ osteotomy with posterior plane used in surgical planning	Configurable AMZ angle resolution	Surgeon configurable TTO simulation via virtual planning portal	Patient-specific implementation of surgical plan	Tubercle translation target to match surgical plan
T3 AMZ System Arthrex®	X	X		25°			
MD3T System Kinamed®		X		Freehand			
Tracker™ AMZ Guide Mitek	X	X		Freehand			
Trivara FANG	X	X	X	1°	X	X	X
Trivara MERGE	X	X	X	1°	X	X	X
Trivara CORE	X	X	X	5°	X		

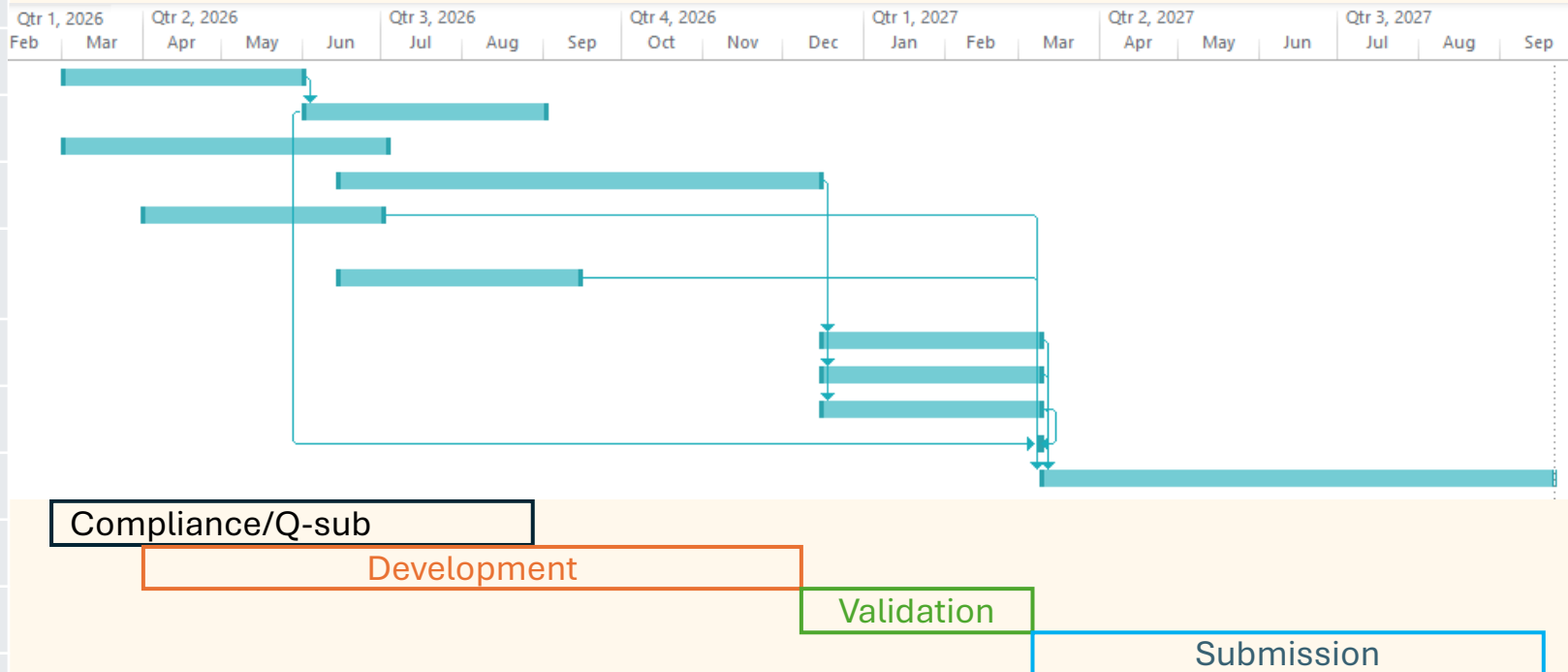
Current guides are severely limited in terms of precision and patient-specificity

Budget & Milestones

Trivara FANG 510(k) < 2 years

QMS	\$ 25,000
ISO 13485 certification	\$ 27,000
Investigate FDA Q-submission	
AR development and licenses - MERGE	\$ 50,000
Automation/scripting tools, development – web app, design	\$ 10,000
Prototyping and manufacturing	\$ 15,000
Cleaning and sterilization validation	\$ 45,000
Packaging validation	\$ 20,000
User validation labs (10 users)	\$ 9,700
Submission prep/consulting	\$ 80,000
FDA filing	\$ 18,100
TOTAL	\$ 299,800

Development plan & team are ready to execute



Short development timeline = Quick ROI for Blavatnik Award

Goal: 510(k) cleared product ready to license with favorable terms for Yale

Ongoing discussions with multiple industry partners interested in licensing this technology

References

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- ² Grimm, N.L., Lazarides, A.L. & Amendola, A. Tibial Tubercle Osteotomies: a Review of a Treatment for Recurrent Patellar Instability. *Curr Rev Musculoskelet Med* **11**, 266–271 (2018). <https://doi.org/10.1007/s12178-018-9482-3>
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- ⁷ Al Muderis, M. (June 6, 2020). *Patellar Maltracking with a strong J sign*. YouTube. <https://www.youtube.com/watch?v=xq-5j8xpUU0>
- ⁸ Bellemans, J. (April 6, 2024). *Sign in Patellar dislocation explained & how it can be treated*. YouTube. <https://www.youtube.com/watch?v=CTy4-H7h9l8>