

Mako Total Knee 2.0

SmartRobotics™

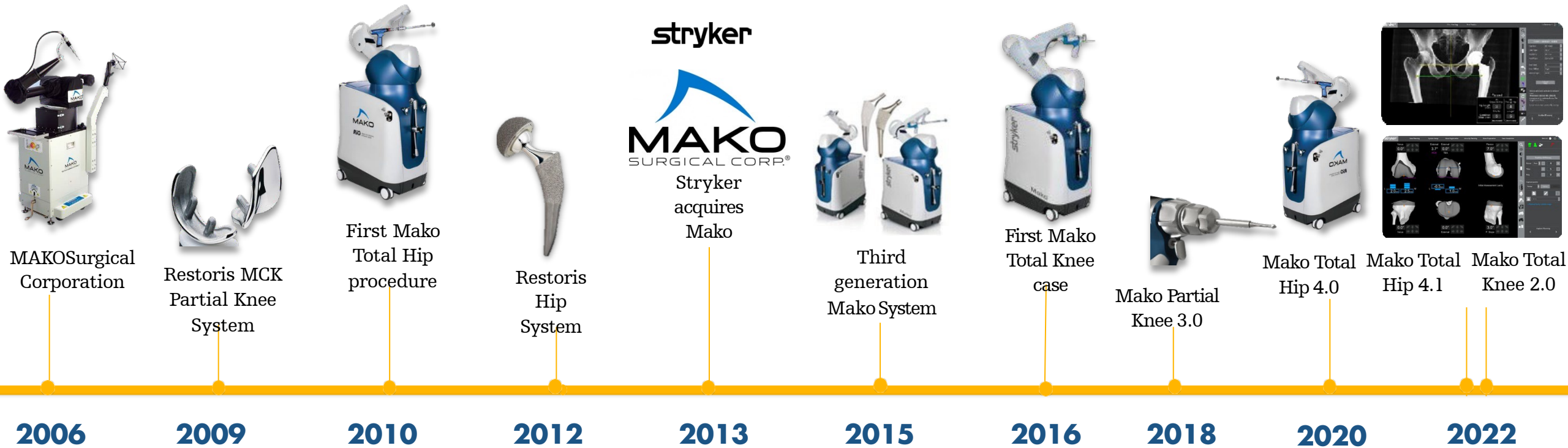
Overview deck

Mako Total Knee 2.0



Evolution of Mako SmartRobotics™

stryker



Leading a robotics market

6
years

Mako Total Knee
surgery experience

500k+
Mako Total Knee
procedures

have been performed*

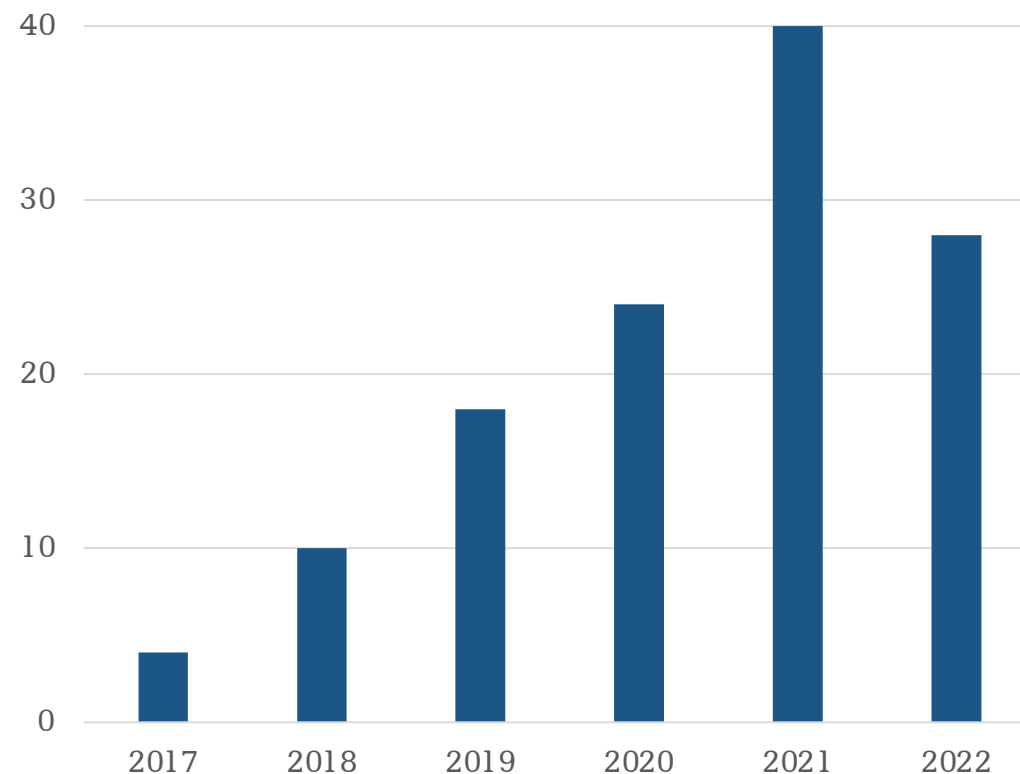
58%
Robotic knee

cementless mix*

54%
Triathlon knees

implanted robotically*

120+ Mako Total Knee peer-reviewed published manuscripts



*Stryker's 2022 sales data

Varus
0.0°

External
3.7°
PCA

External
0.0°
TEA

Flexion
7.0°

The outcomes you expect.

The experience you deserve.

2.0mm
7.0mm

0.0°
Varus

0.0°
External

3.0°
P. Slope

Triathlon CR Primary

Femur	Post.	-	4	+
Tibia		-	5	+
Poly		-	9	+

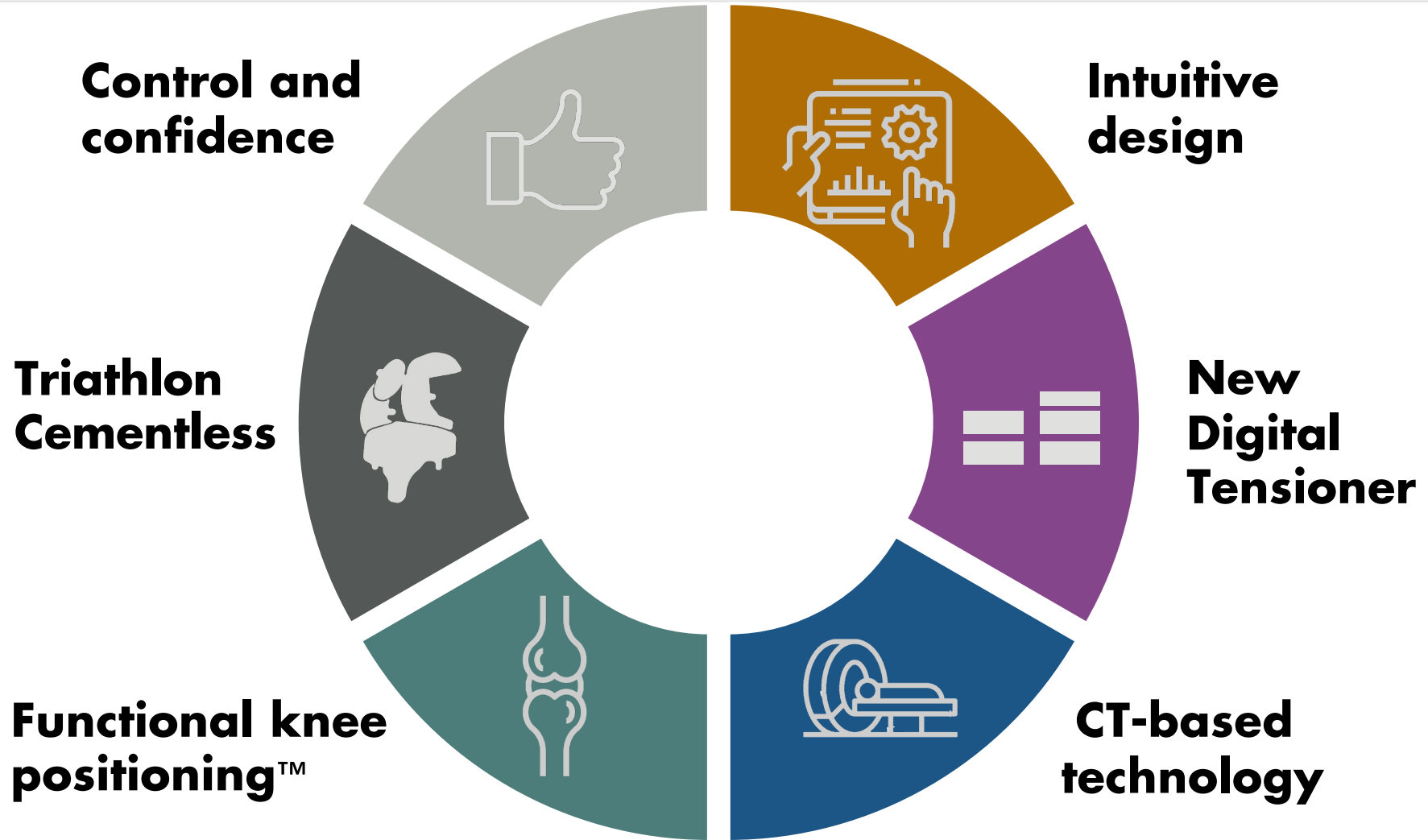
Capture points

Femur

4f 5t

Implant Planning

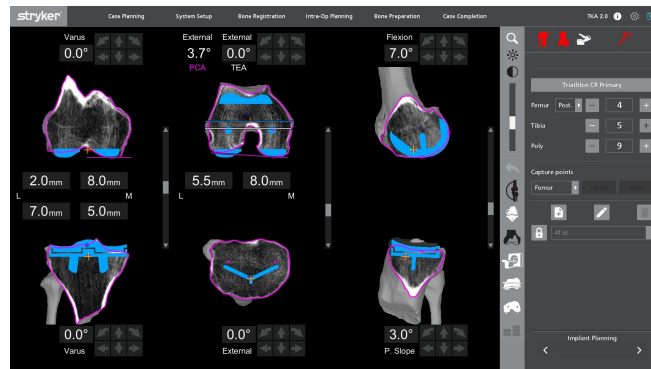
Mako Total Knee 2.0



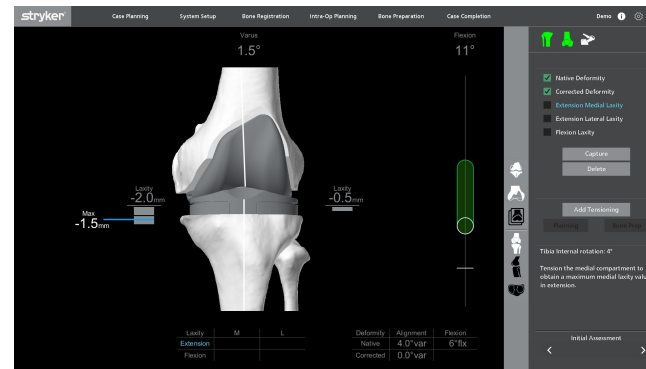
Three core features

Mako Total Knee 2.0

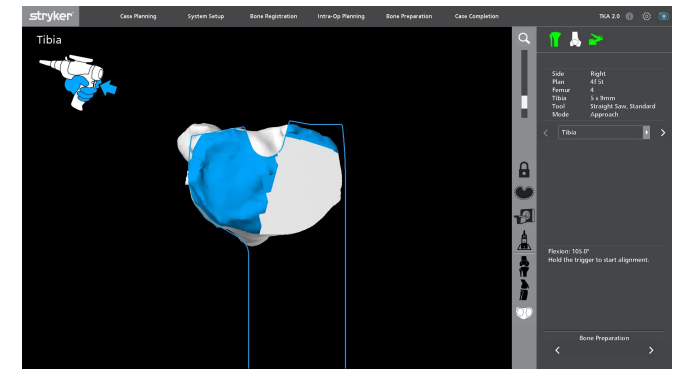
3D CT-based planning



Dynamic joint balancing

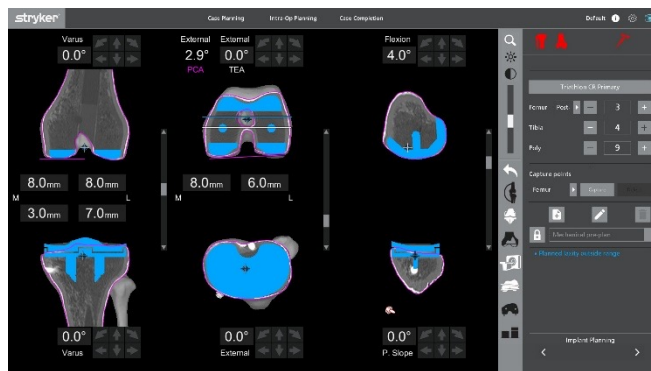


AccuStop™ haptic technology

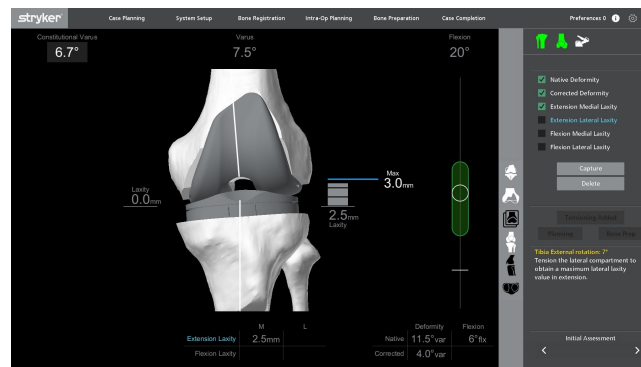


Mako Total Knee 2.0

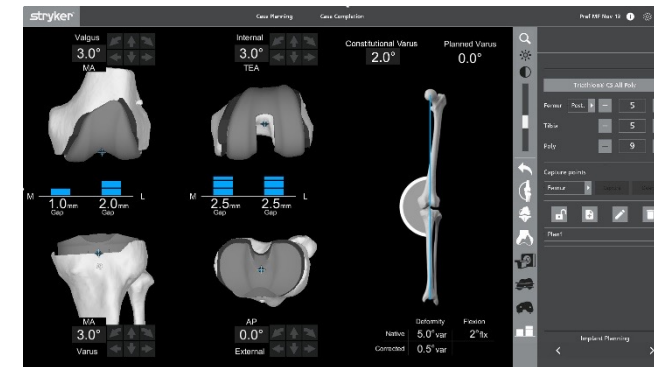
Functional Knee Positioning™



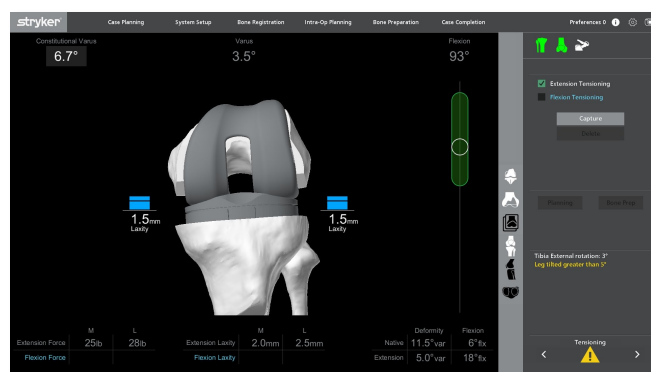
3D CT-based preoperative plan



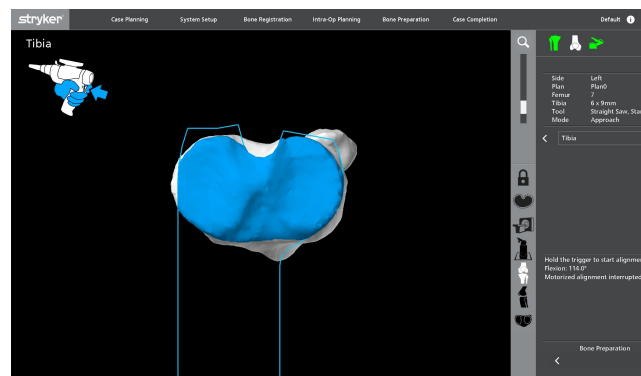
Intraoperative assessment



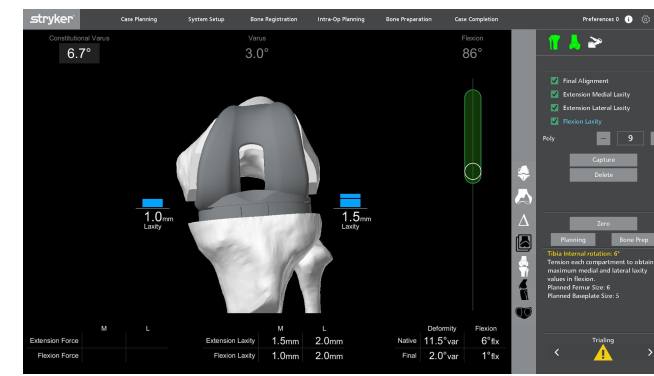
Intraoperative planning



Tensioning
(Midresection only)

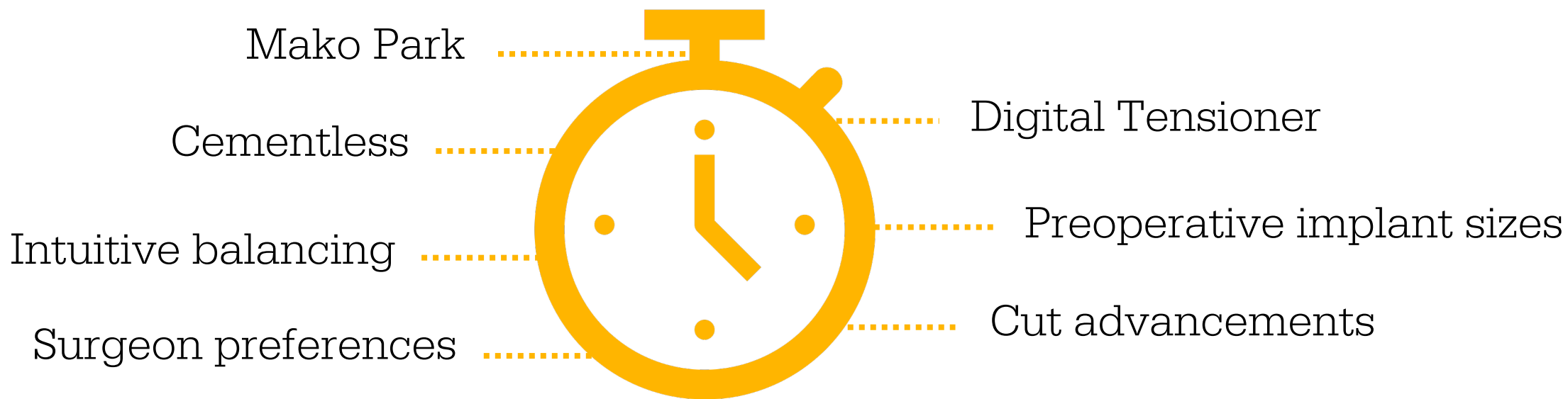


AccuStop™ haptic technology



Trialing

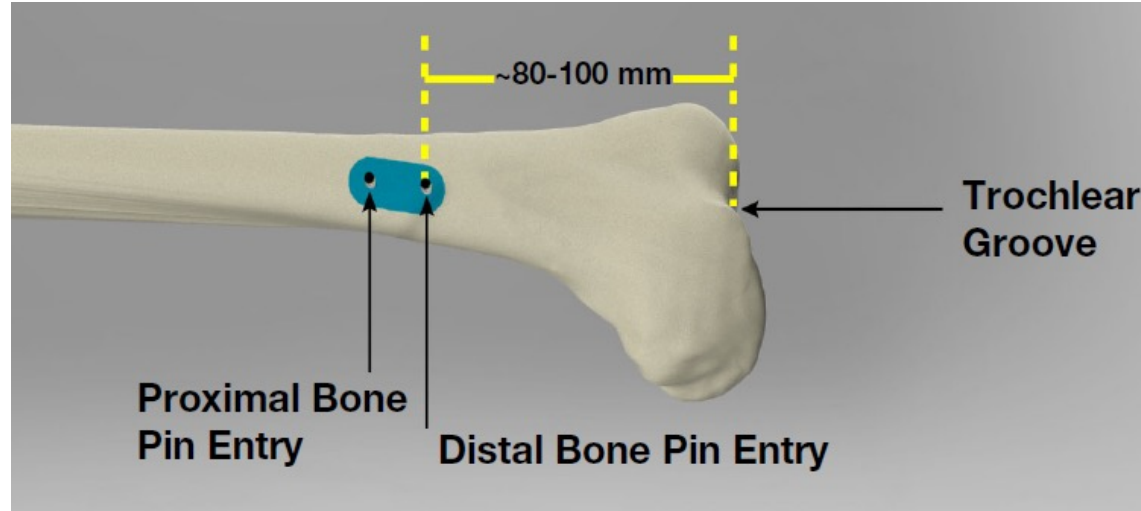
Prioritizing surgical efficiencies



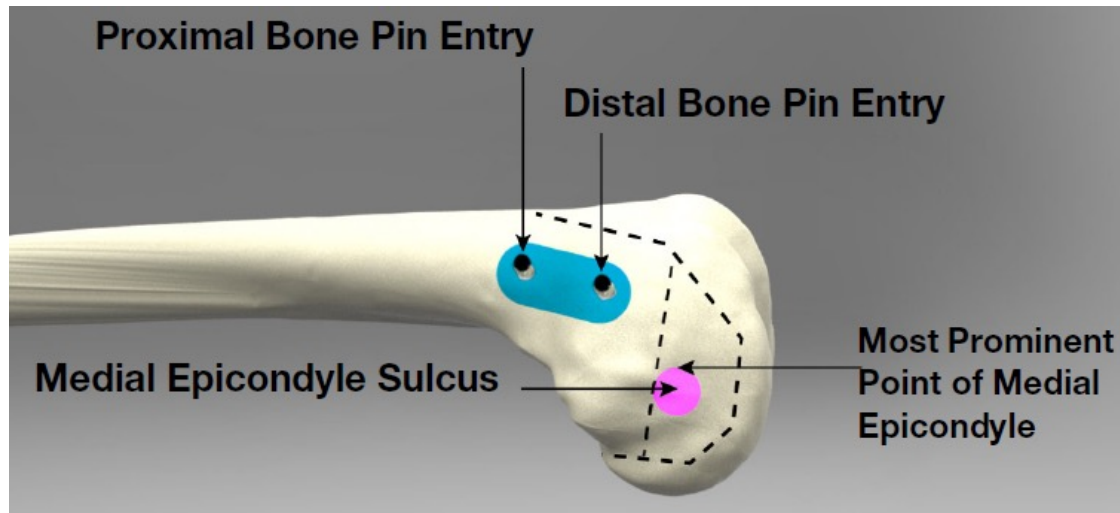
Setup

Femur pin and array placement

Extra-incision

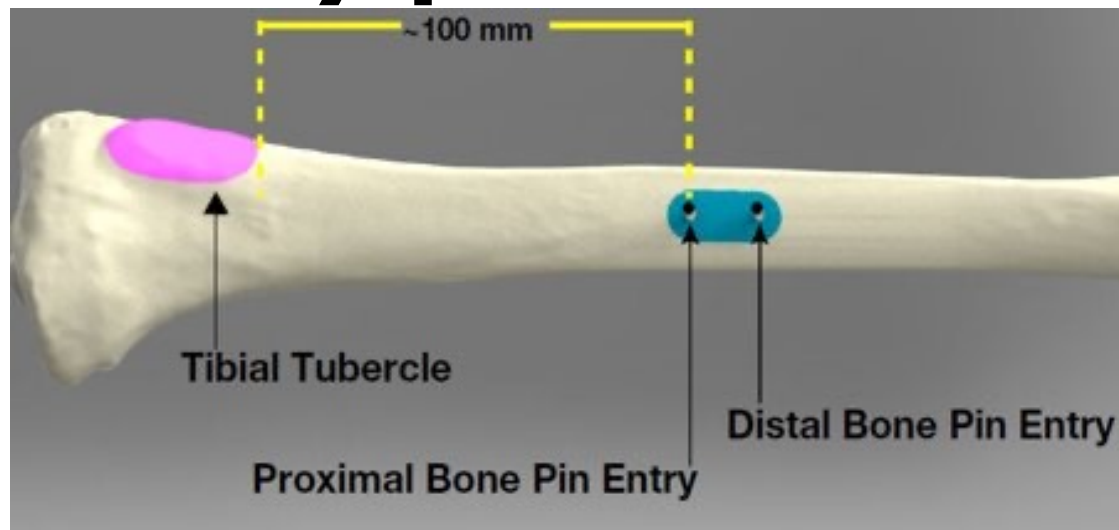


Intra-incision

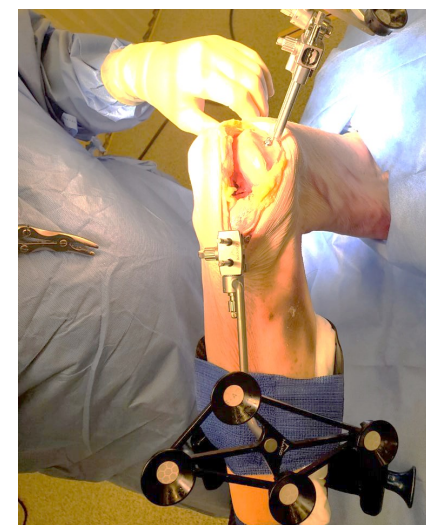
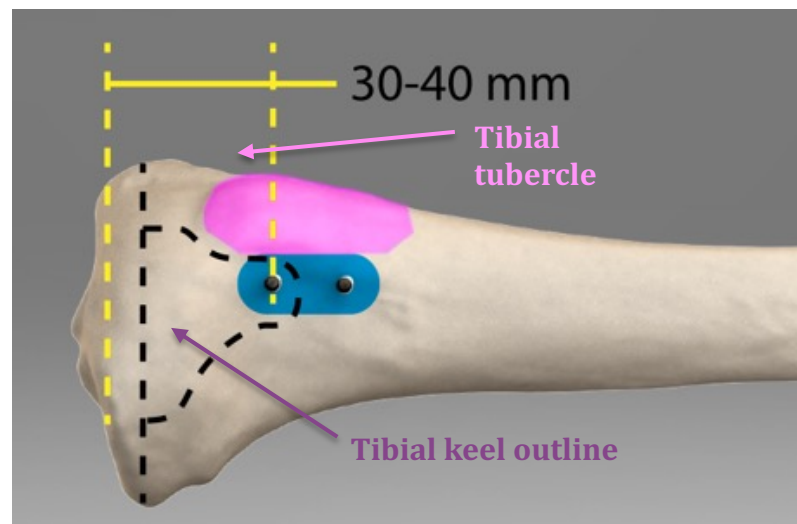


Tibia pin and array placement

Extra-incision



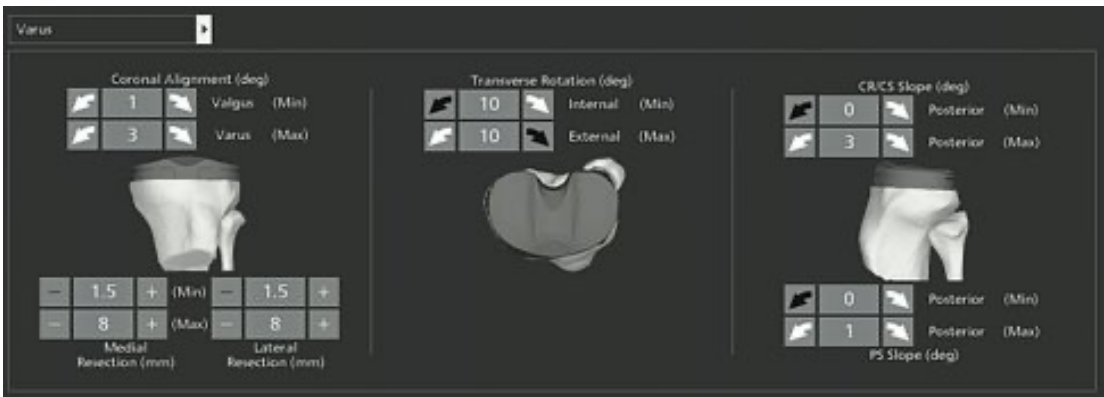
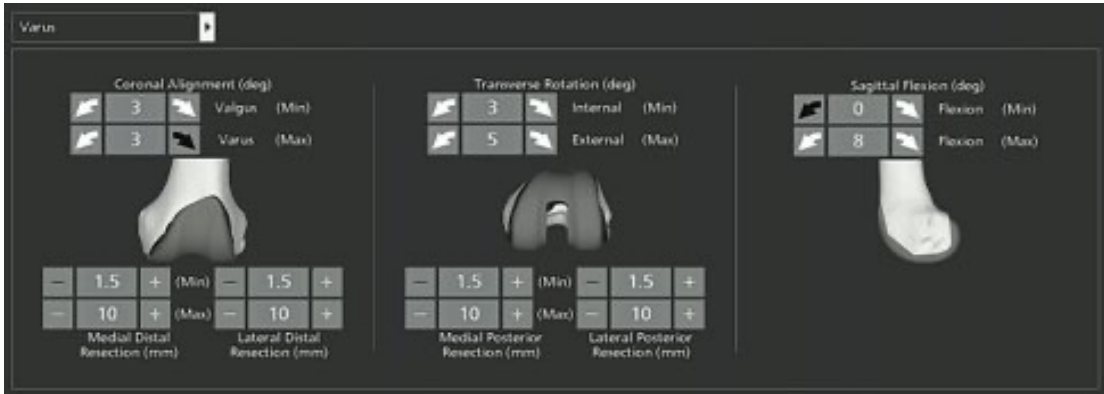
Intra-incision



Planning preferences

- The surgeon can set their own personalized implant parameters in the surgeon preferences to customize the workflow. Resection depths and rotational limits are two examples.
- If a value goes outside these bounds, a notification appears on the planning screen as a blue box around that value.

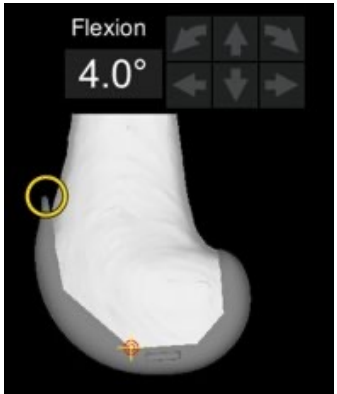
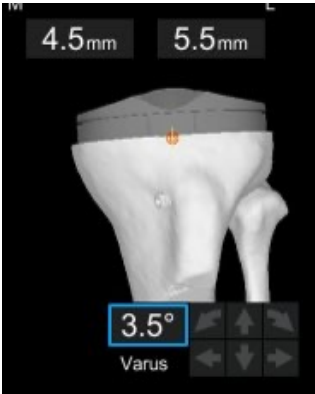
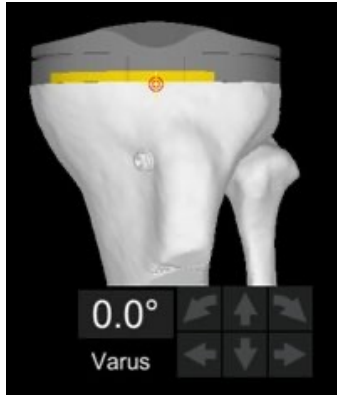
Resection and rotation limits



Notifications



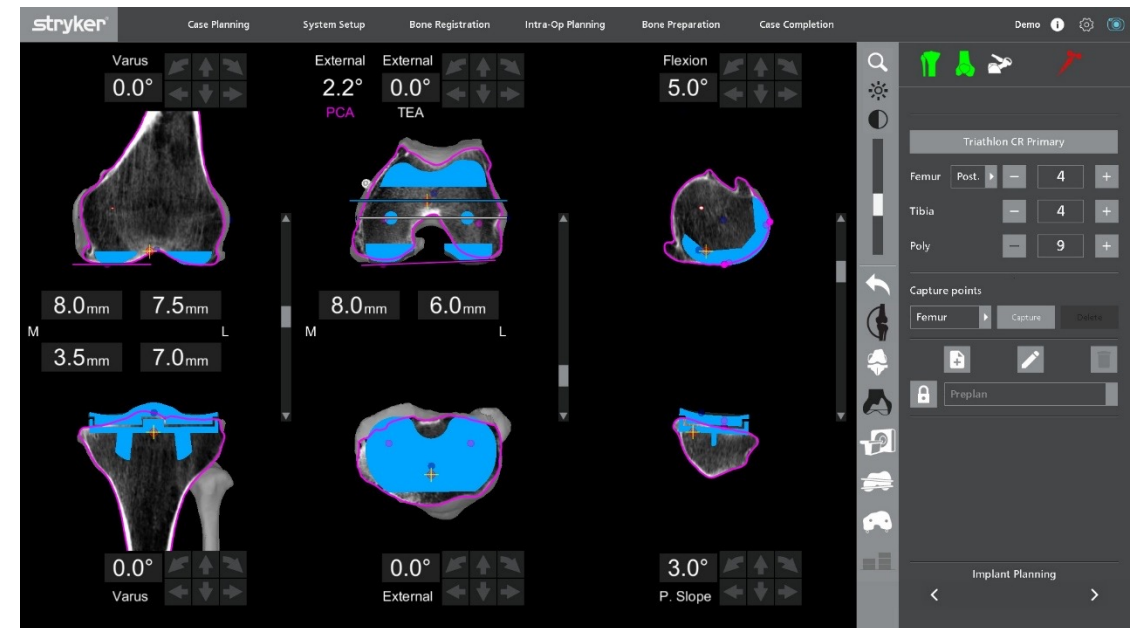
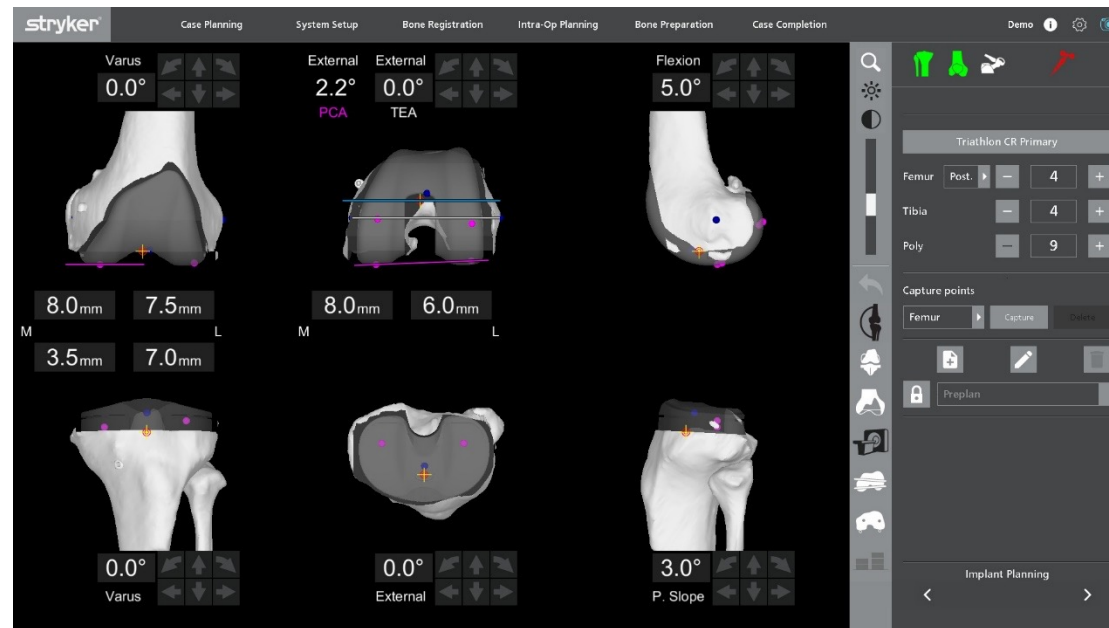
Warnings



CT-based planning

3D CT-based planning

- Mako's 3D CT-based planning allows you to **see more** of your patient's **unique anatomy** and **virtually plan Triathlon** in the **coronal, transverse and sagittal** planes for each patient.¹
- **Functional knee positioning™** is achieved by use of the **3D CT-based** preoperative plan based on the patient's bony anatomy and acknowledging **proxies** for **knee function**.



Functional planning guidelines

- The functional planning guidelines enable the surgeon to prioritize the attributes of the knee that have the most impact on function, before and after assessing the soft tissue laxities.
- Follow the counterclockwise sequence on the implant planning screen to complete the functional planning guidelines assessment.

The screenshot displays the Stryker implant planning software interface with the following parameters and measurements:

- Varus:** 0.0°
- External:** 2.2° (PCA)
- External:** 0.0° (TEA)
- Flexion:** 5.0°
- Medial (M) Dimensions:** 8.0mm (top), 3.5mm (bottom)
- Lateral (L) Dimensions:** 7.5mm (top), 7.0mm (bottom)
- Tibial Varus:** 0.0°
- External:** 0.0°
- P. Slope:** 3.0°

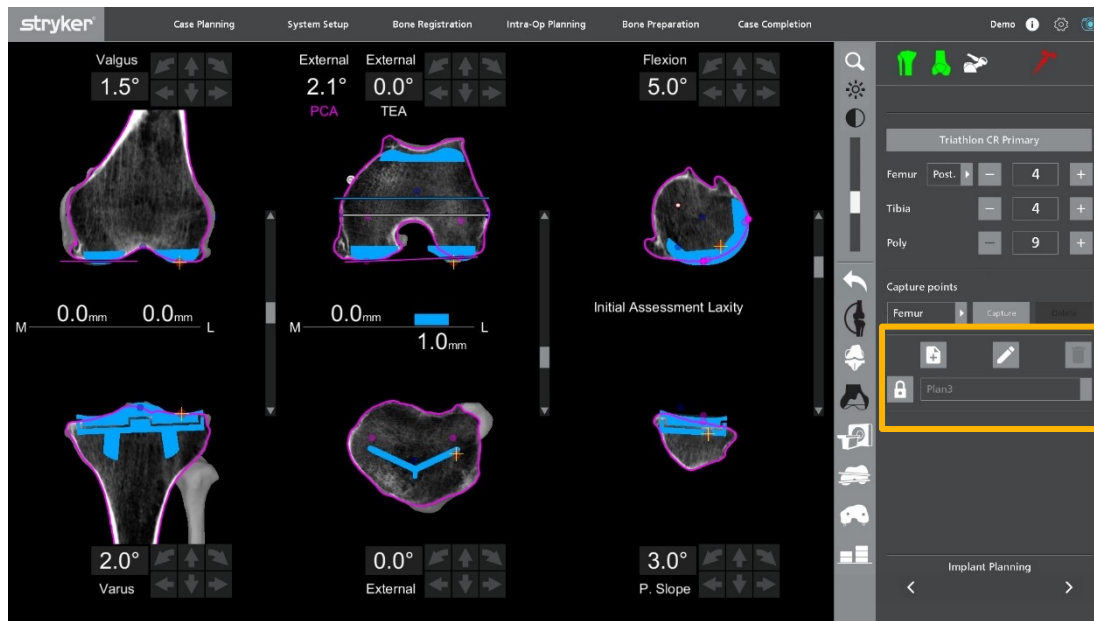
The six functional planning guidelines are indicated by dashed lines:

1. Medial concentricity
2. Trochlea congruity
3. Lateral column
4. Tibial varus
5. Tibia sizing
6. Tibial slope

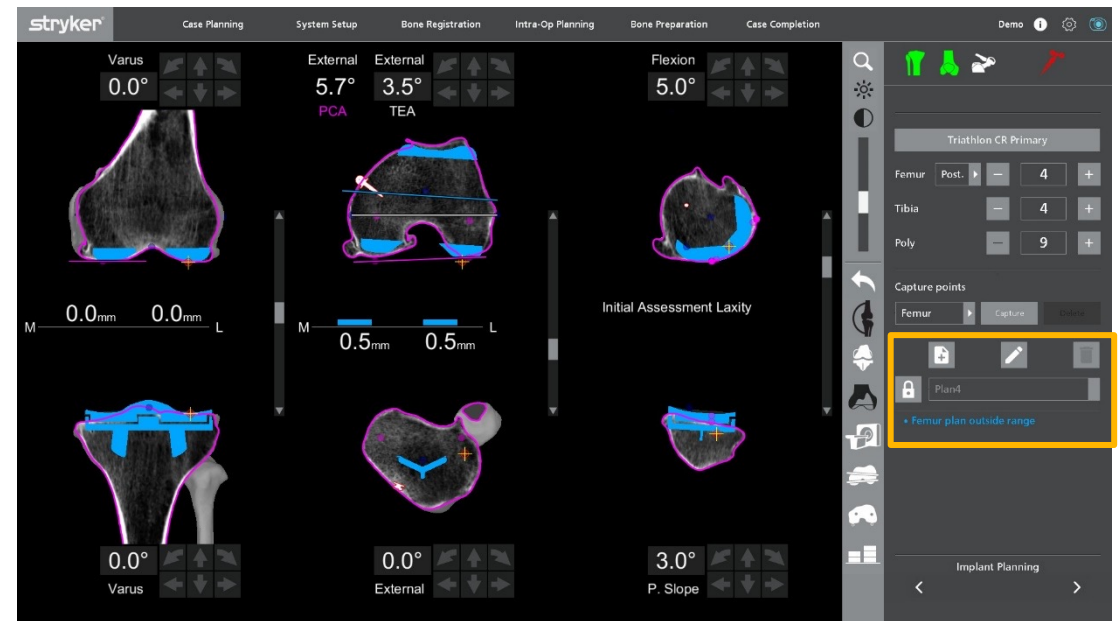
Multiple saved plans

- The surgeon can save multiple plans within a patient's session file and has the ability to balance each individually before choosing the final plan.
- Allows surgeons to evaluate different decision-making hierarchies efficiently and simply.

Plan 1



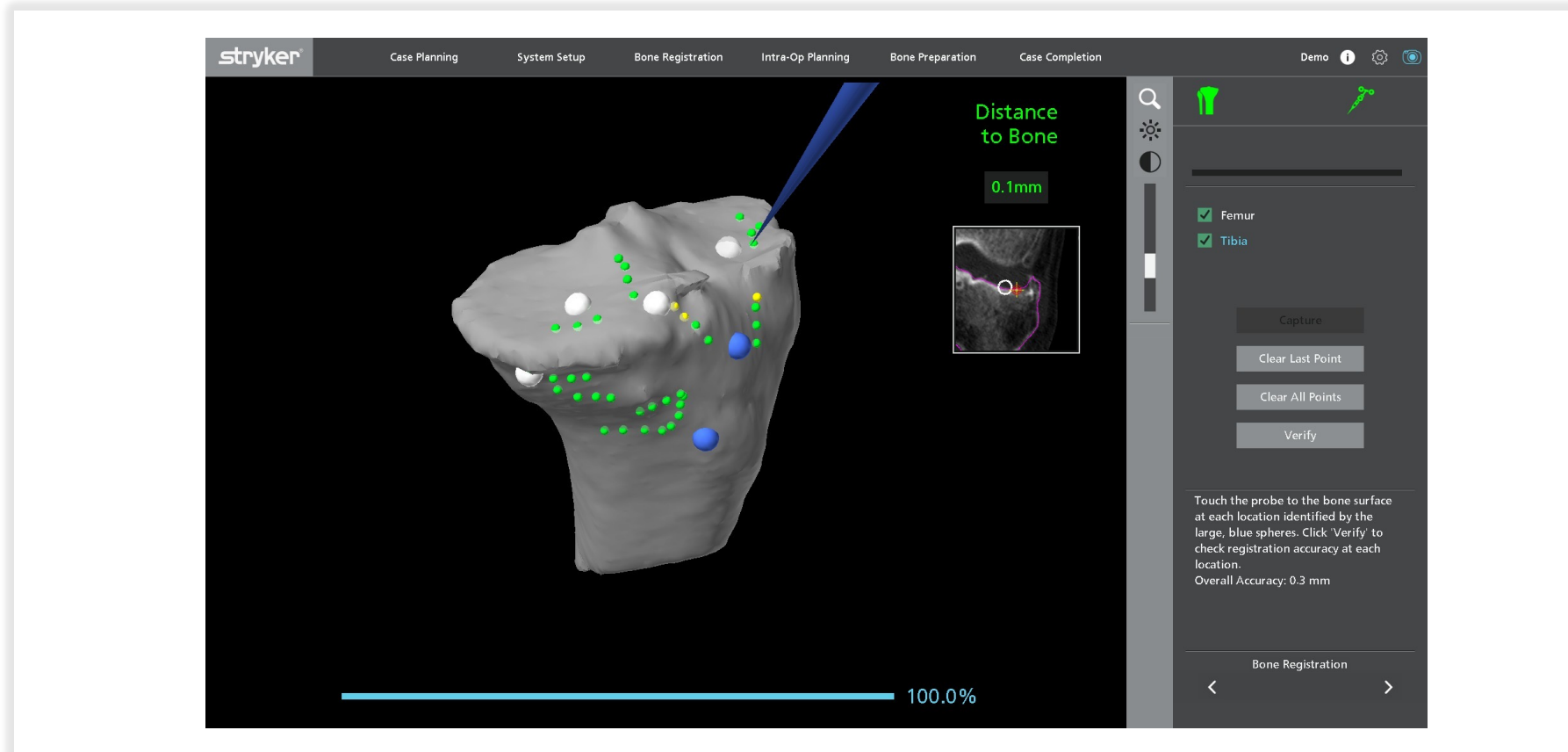
Plan 2



Bone registration

Bone registration

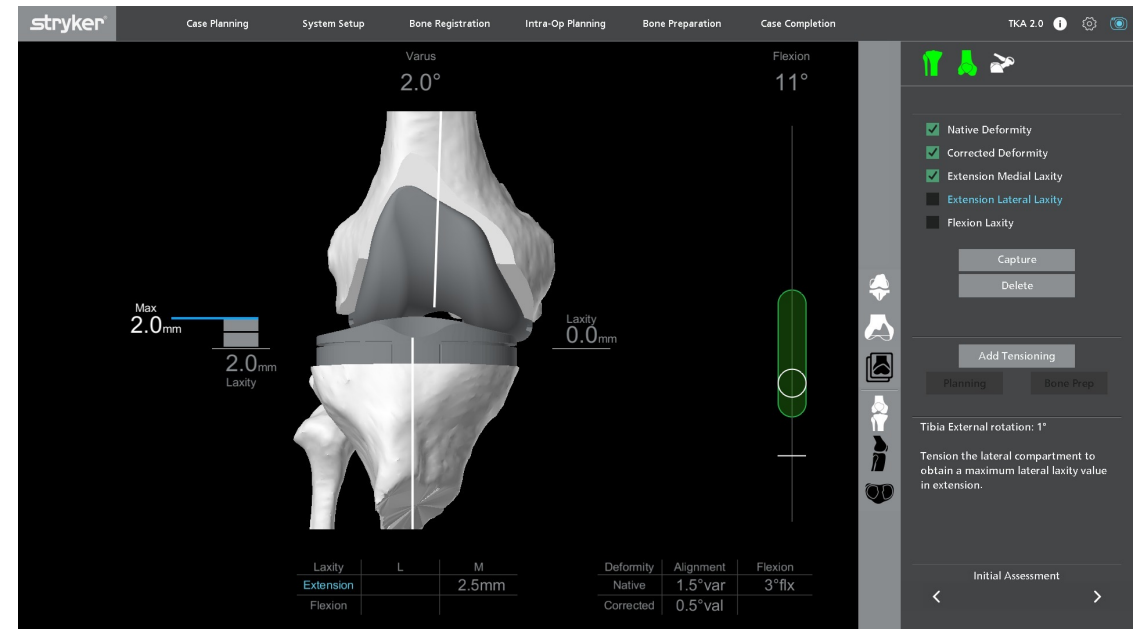
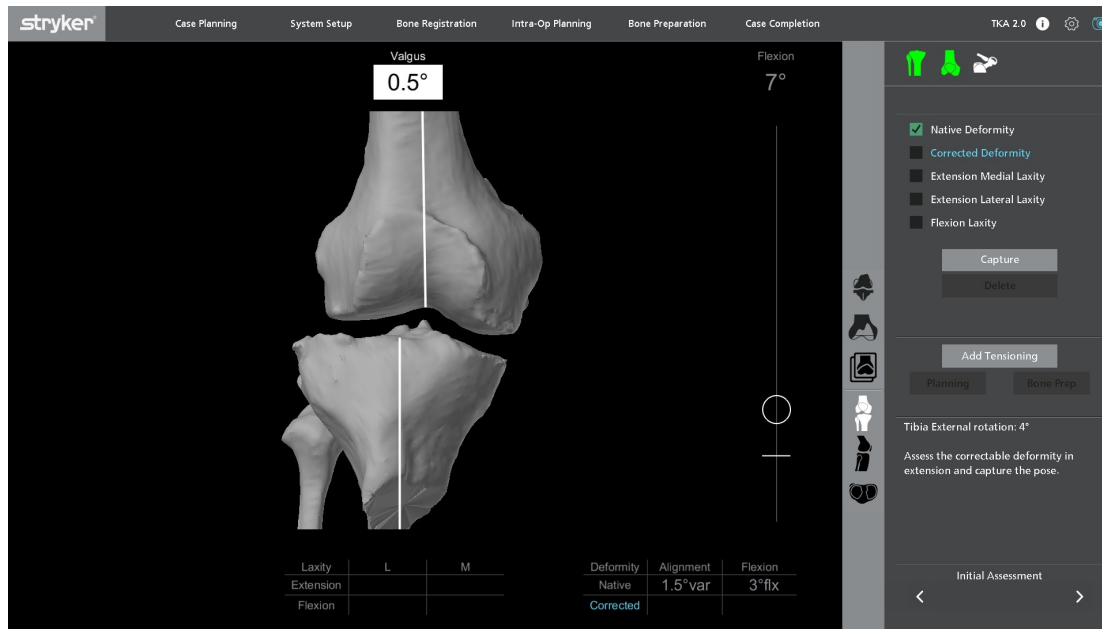
- Surgeon completes bone registration on the femur and tibia by collecting points on the surface of the patient's bones. This step confirms that the CT-based model is aligned to the patient's anatomy within 0.5mm.



Deformity and laxity assessment

Initial Assessment

- The surgeon can capture the **native deformity and the corrected deformity** to assess the limb, and then capture the **extension and flexion laxity data**.
- The medial and lateral compartments in extension and flexion can be assessed together or separately; this is customizable in surgeon preferences.

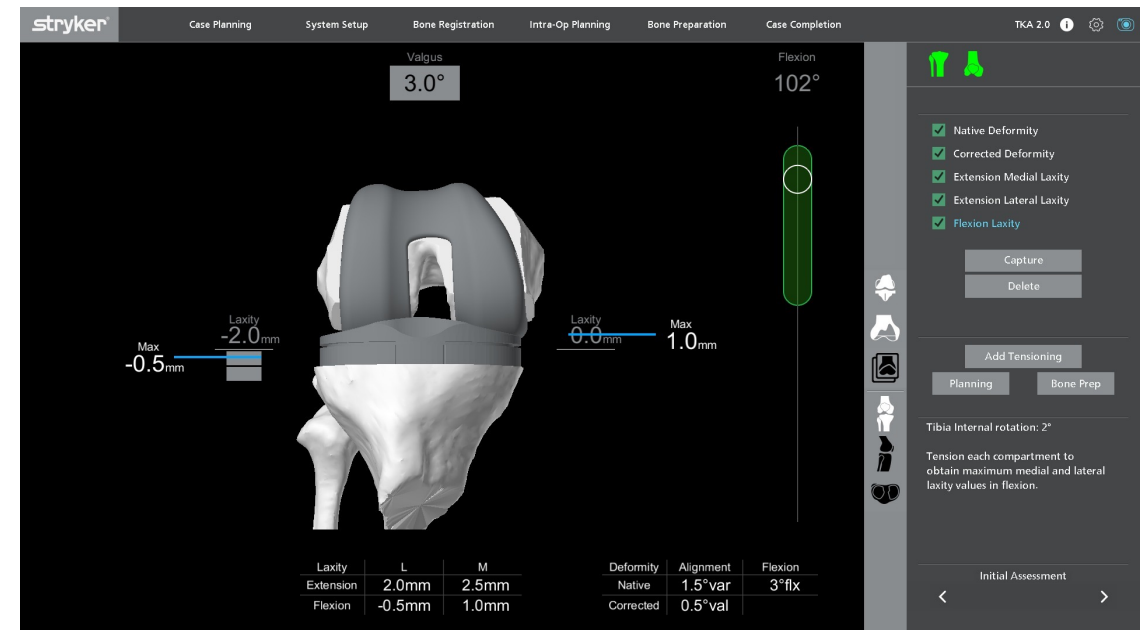
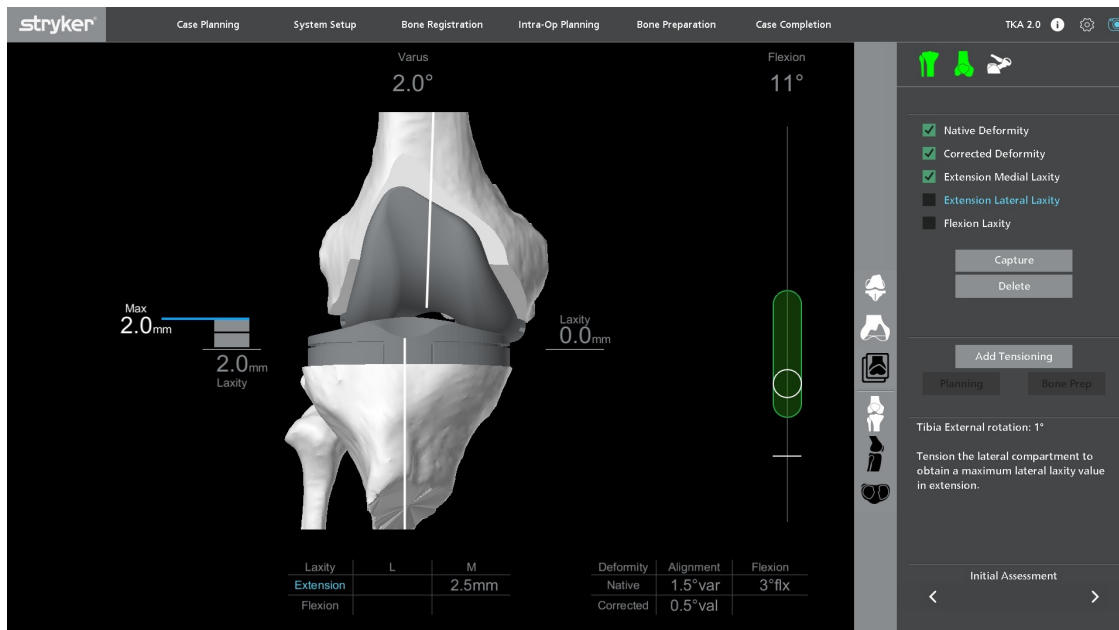


Mako Total Knee 2.0 features a new **Digital Tensioner** to assess ligament laxity

- No additional instrumentation or hardware.
- Medial and lateral compartment laxity in both flexion and extension can be captured independently and measured every 0.5mm.
- Audible and visual guidance during ligament assessment.
- The maximum amount of laxity that is achieved for each compartment will be automatically stored.

Why the Digital Tensioner?

- Ligament tension can be **subjective**.²
- The digital tensioner has been shown to have excellent intra-user **repeatability**³ (ICC ≥ 0.96) and inter-user **reproducibility**³ (ICC ≥ 0.90)³ minimizing subjectivity and potentially leading to a more predictable surgery.



Digital Tensioner – how it works...

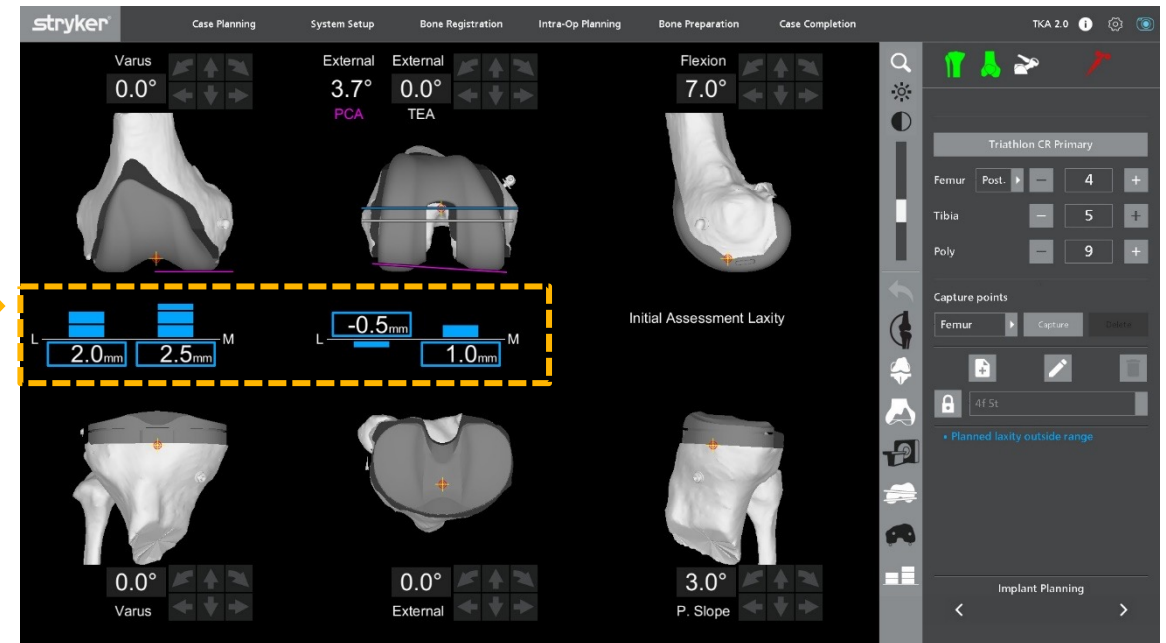
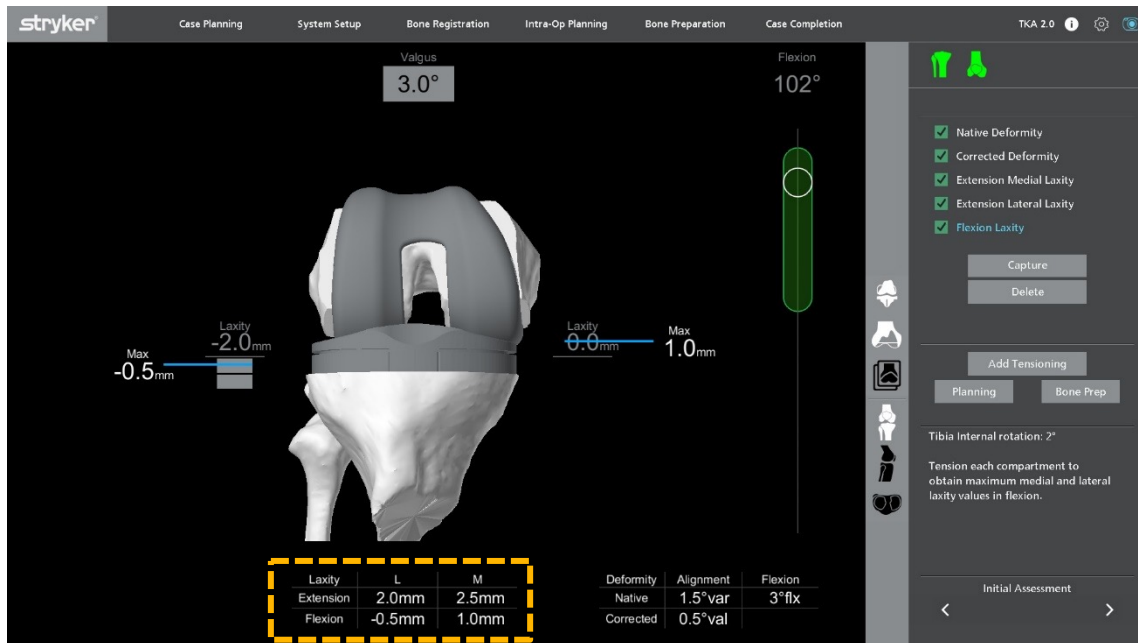
- 1 As the surgeon applies tension to the ligaments and opens each compartment, an audible and visual cue will be provided every 0.5 millimeters.
- 2 As the surgeon opens a compartment, they may reference the audible cues. Once the surgeon finds the end stop of the ligament, by referencing the plateau of the stress/strain curve, the audible and visual feedback will start to slow and eventually stop. That signifies to capture this point.
- 3 The system will temporarily store the maximum laxity value assessed, after which the value can be captured into the laxity table by the Mako Product Specialist. Once captured, the surgeon can move onto the next compartment.



Intraoperative implant adjustments

Intraoperative planning

- The laxity information is transferred to the implant planning page to allow the surgeon to balance the knee.
- The balancing page provides all the necessary information on one page, including the ability to balance the knee in CT view.
- The surgeon can balance the knee in conjunction with the functional planning guidelines to help achieve functional knee positioning™.



Intraoperative planning – targets

When balancing, consider the following target ranges:*

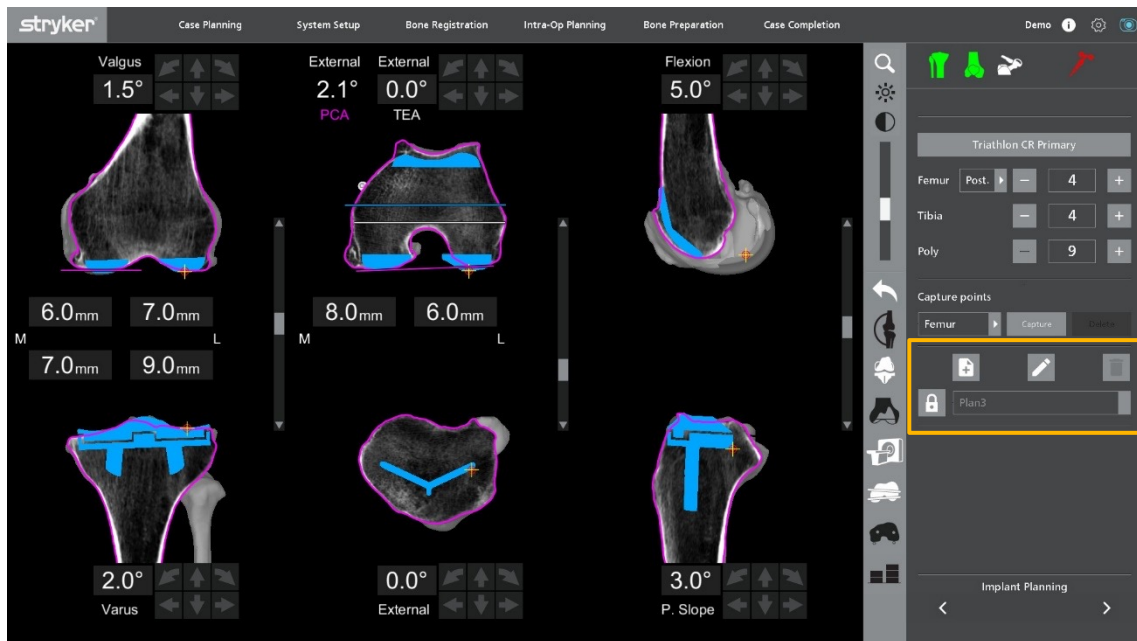
- Extension medial: 0-0.5mm
- Extension lateral: 0-0.5mm
- Flexion medial: 0-0.5mm
- Flexion lateral: 0-1mm

*This is a recommendation. The deformity, flexion contracture and hyper extension of each individual knee should be considered.



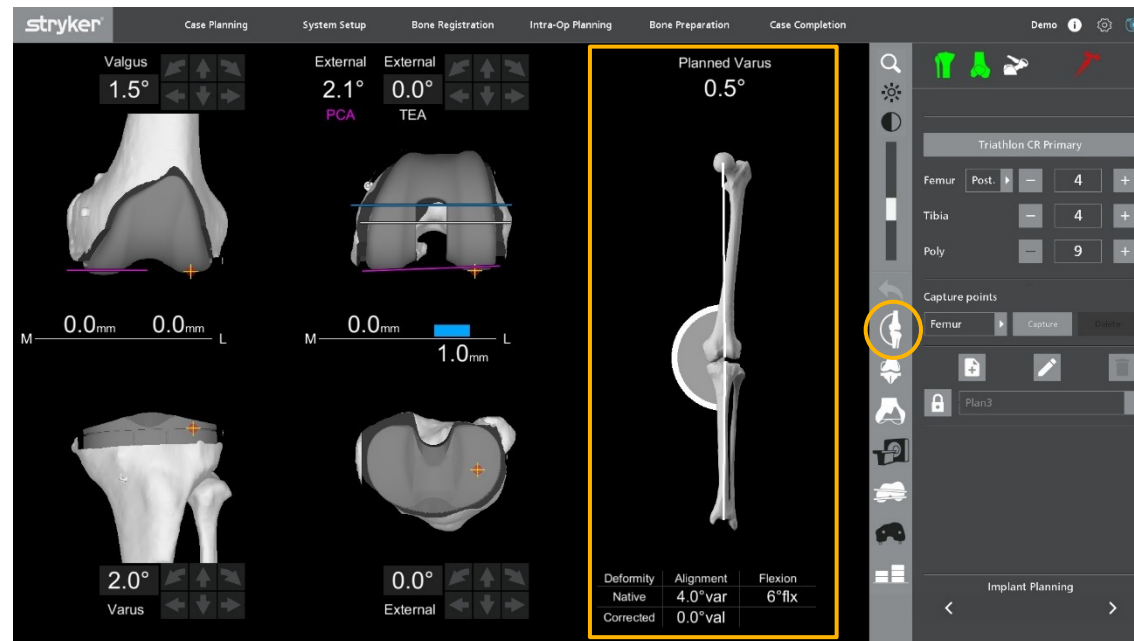
Intraoperative planning features

Multiple plans



- Utilizing the multiple plan feature, the surgeon can balance the plan in different ways.

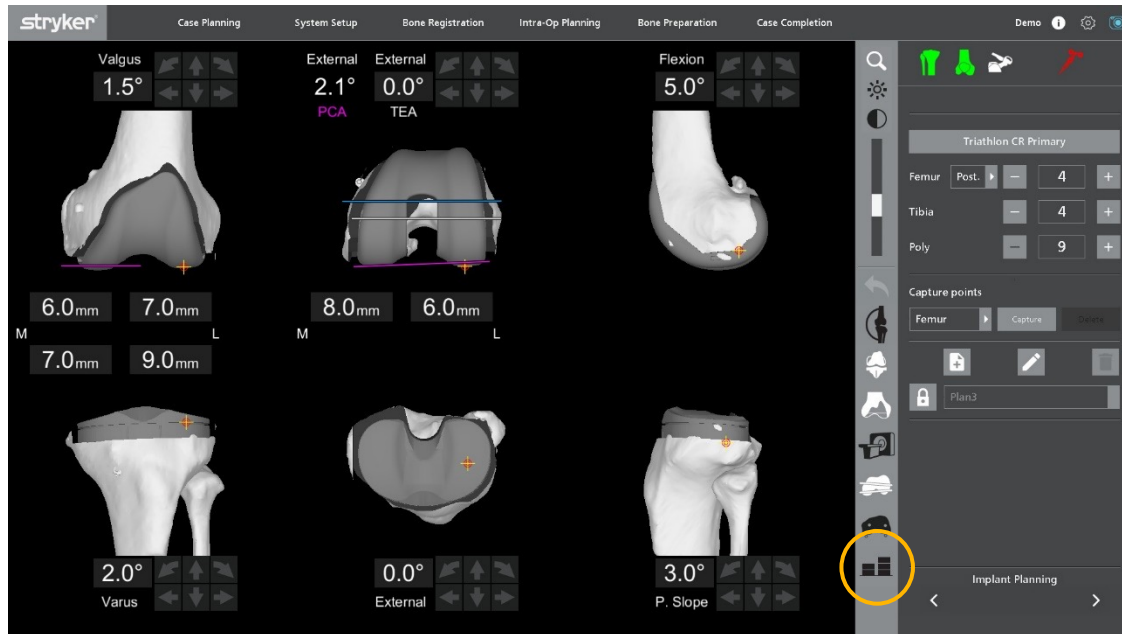
Full limb view



- The surgeon can reference the overall limb alignment, native and corrected deformity values in full limb view.

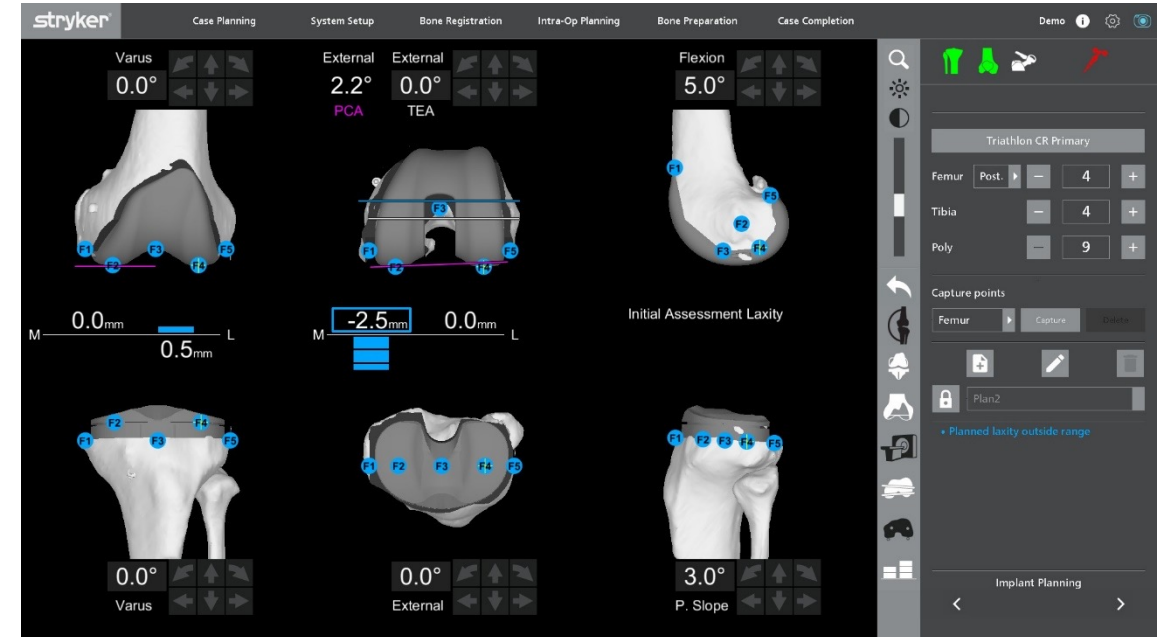
Intraoperative planning features

Resection values



- Toggle between laxity values and display the resection values by clicking the button on the right.

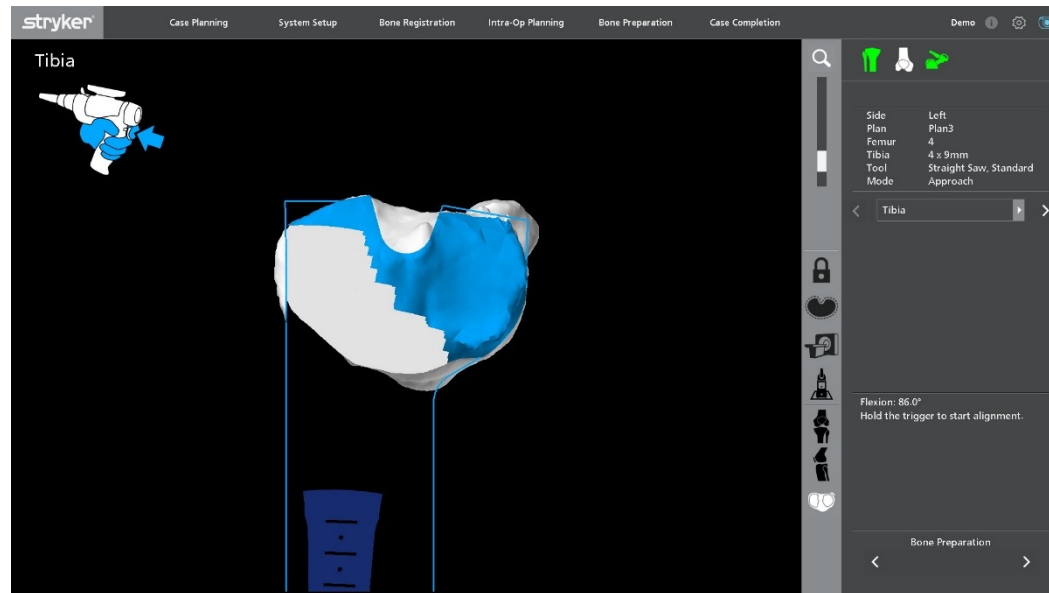
Anchor points



- Preset anchor points are provided to help maximize and streamline implant adjustments.

AccuStop™
haptics

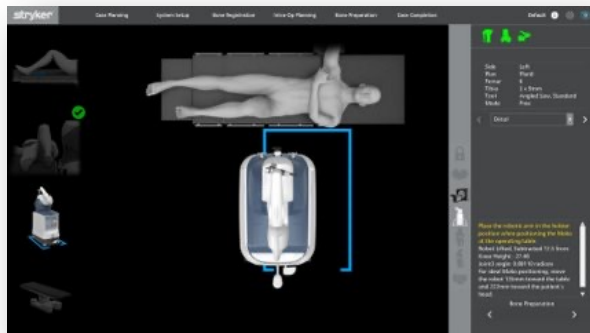
AccuStop™ haptic technology



- Constrains the saw within a virtual boundary that is established by the surgeon's patient-specific plan
- Is no longer limited by cutting blocks and manual techniques
- Allows the surgeon to accurately execute the final plan⁴ while protecting soft tissues⁵ when compared to manual cutting blocks

Mako Total Knee 2.0 – bone prep features

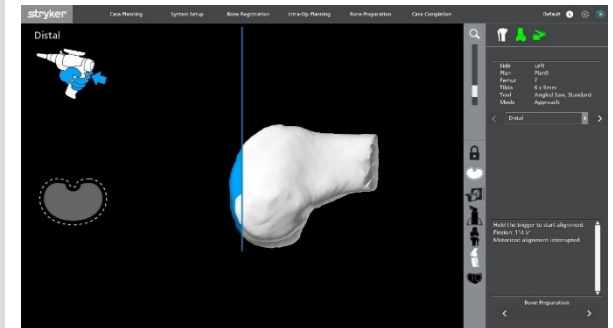
Mako Park



Advancing cuts

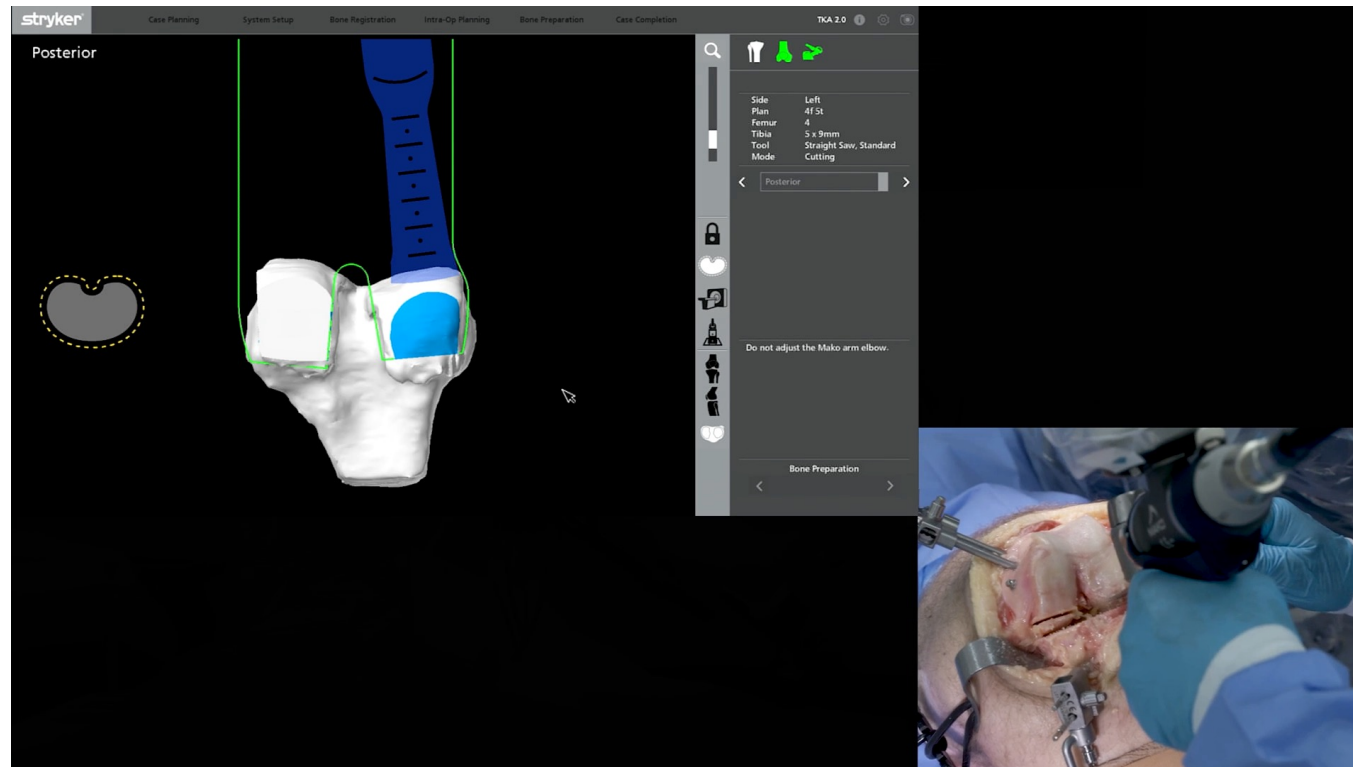


Extended boundaries



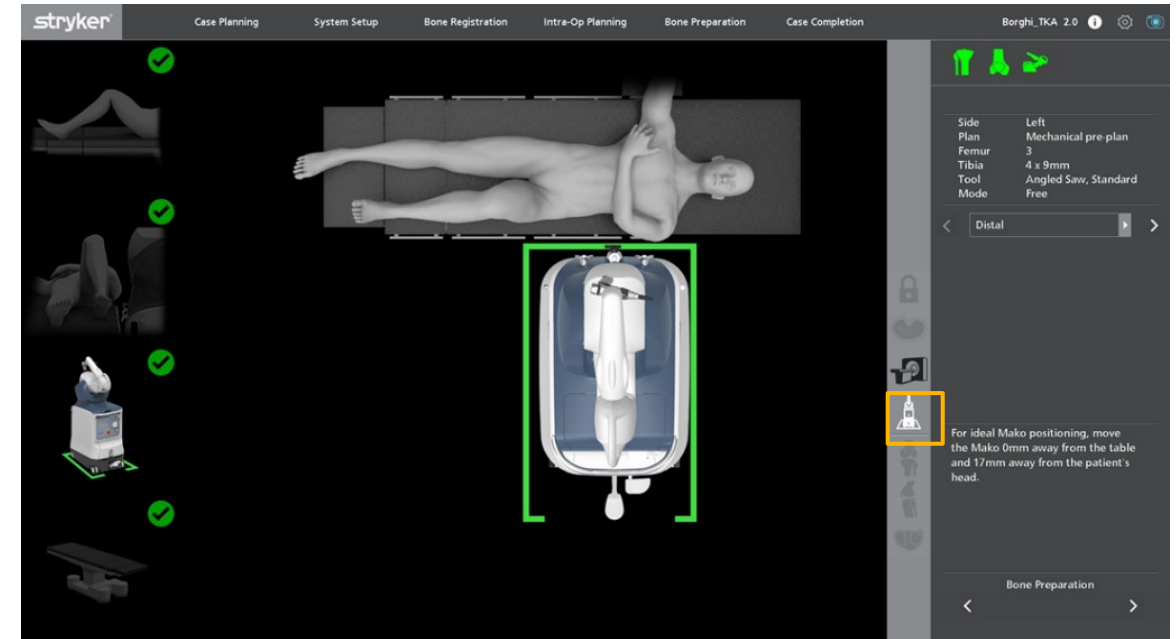
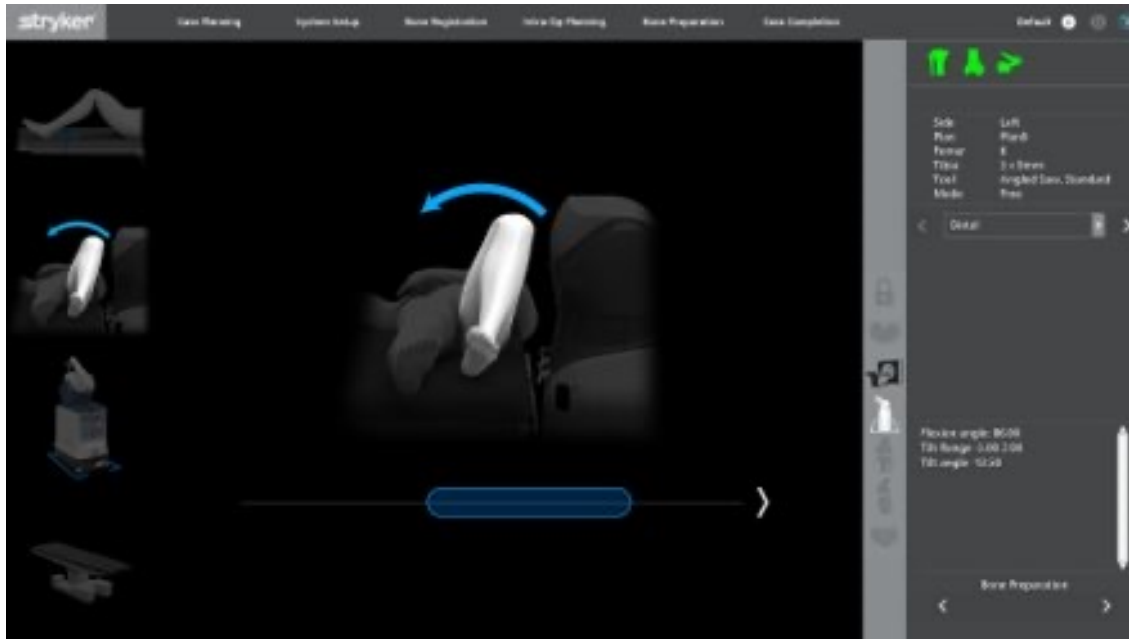
AccuStop™ haptic technology

- The surgeon can **advance through their cut sequence** by double clicking the MICS trigger or pressing the foot pedal.
- Default **extended boundaries can be pre-set** in preferences and the **narrow saw blade** can be used for all cuts.



Mako Park

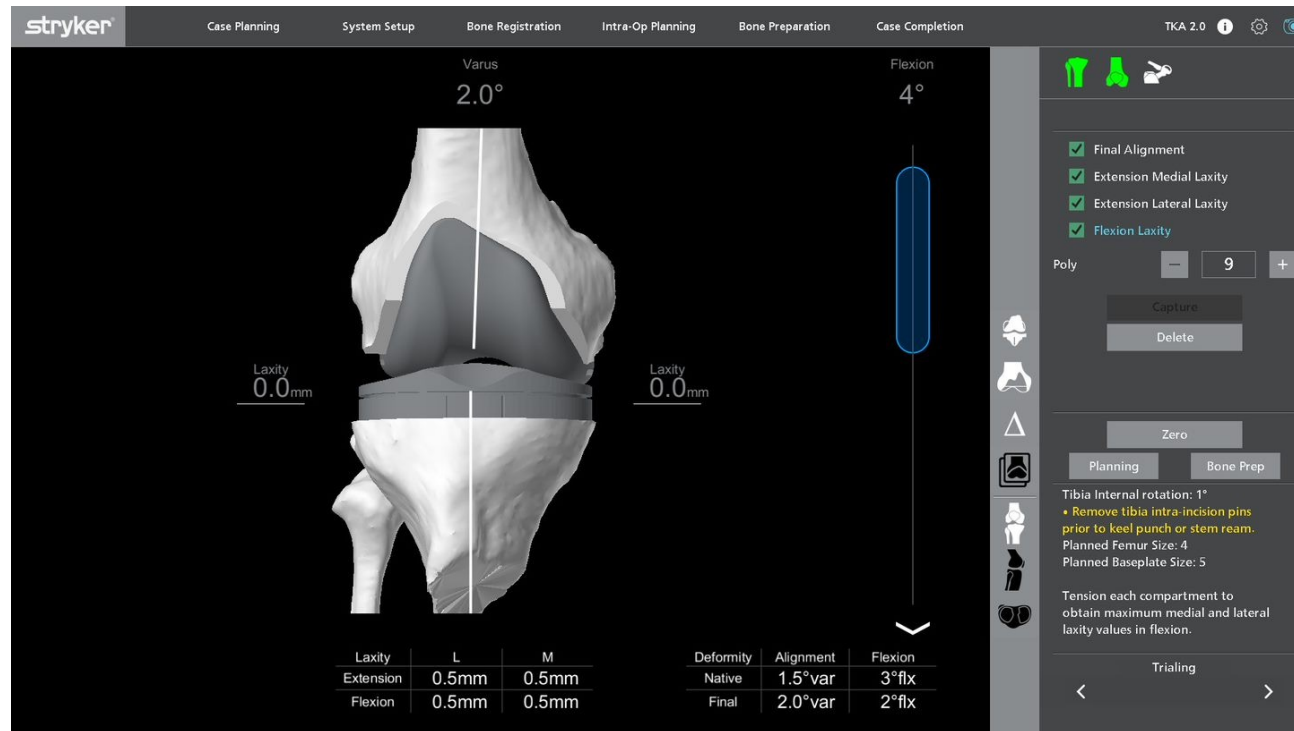
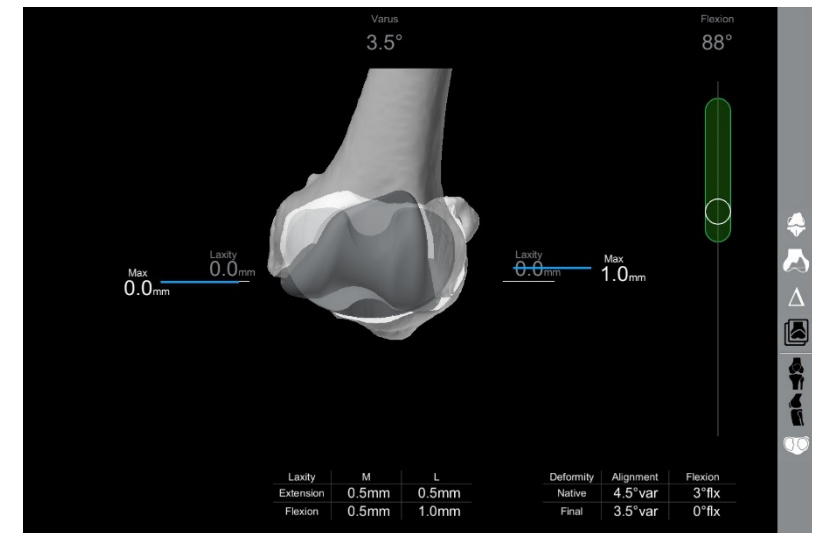
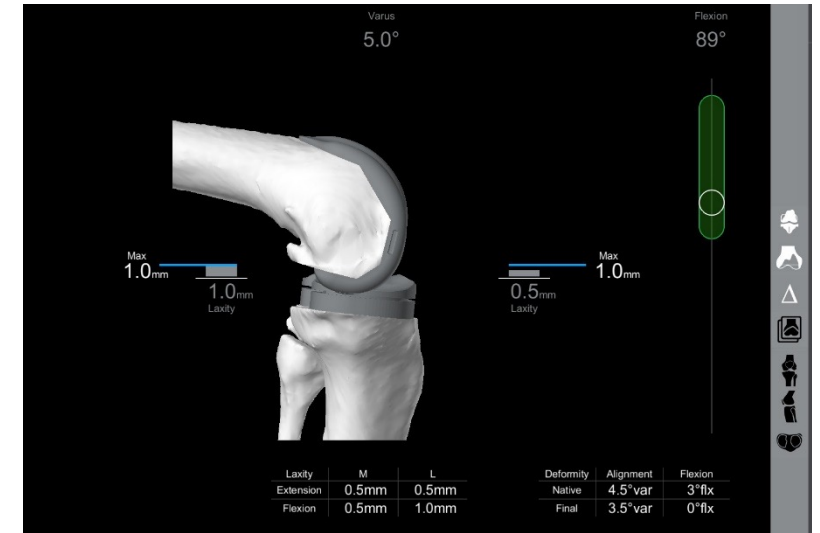
- Mako Park ensures that the Mako System is positioned into the most optimal spot for cutting. This will allow the surgeon to access each cut with ease and complete bone prep efficiently.



Trialing

Trialing

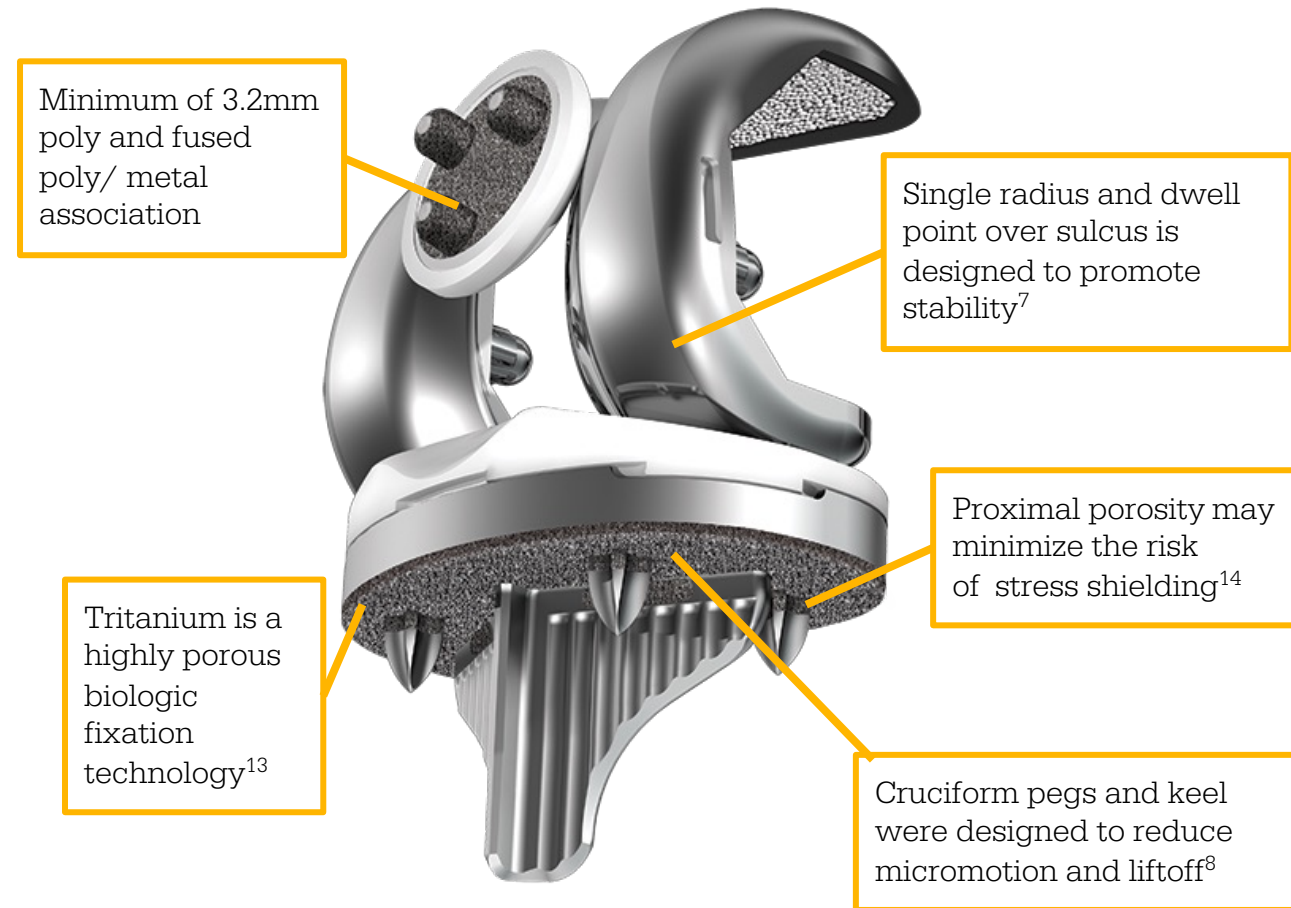
- The new trialing page allows the surgeon to capture the patient's final alignment as well as the final extension and flexion laxities, utilizing the digital tensioner.
- The surgeon can utilize the sagittal and transverse preset views to ensure the medial and lateral translations and shuck test.



Triathlon Cementless Knees

Improved efficiency and outcomes⁸⁻¹¹

- **Over 1 million Triathlon Cementless knees** have been implanted since cleared in 2013 and **make up over half of the Mako Total Knees implanted** in the U.S⁶
- The American Joint Registry has shown:
 - **Triathlon Tritanium baseplates achieved 98.9% survivorship** at 5 years across 37,105 cases⁹
 - **Triathlon Tritanium metal-backed patellas achieved 99.0% survivorship at 4 years** across 28,257 cases¹⁰
- Several studies have shown using Triathlon Cementless can **save up to 22 minutes of OR time** by eliminating the need to mix and apply bone cement^{11,12}



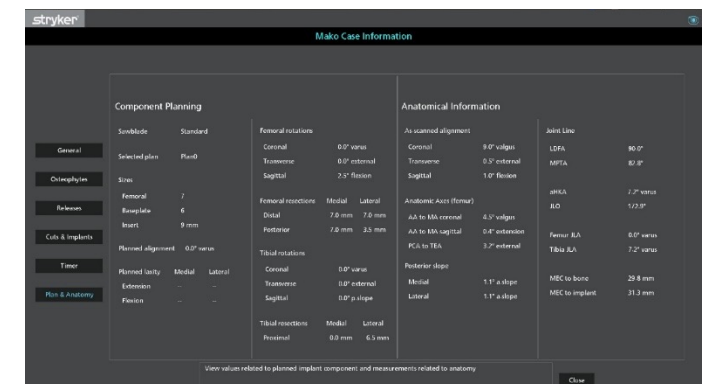
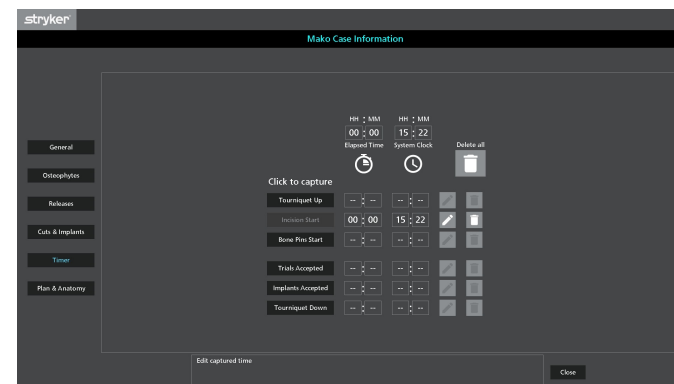
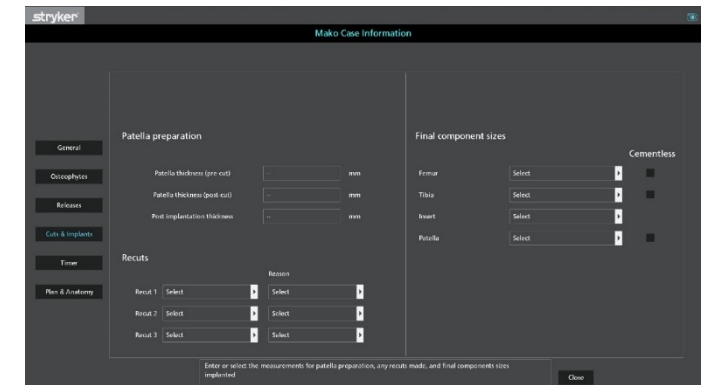
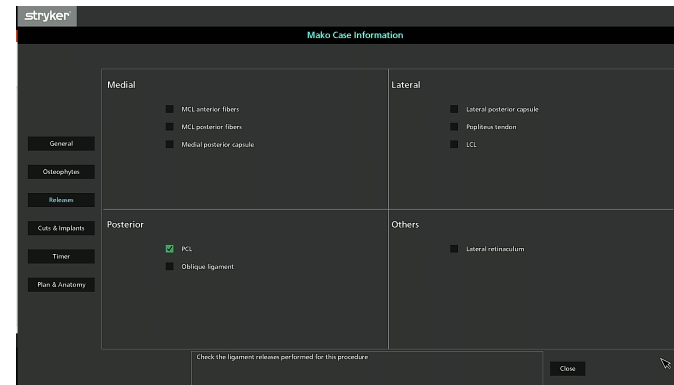
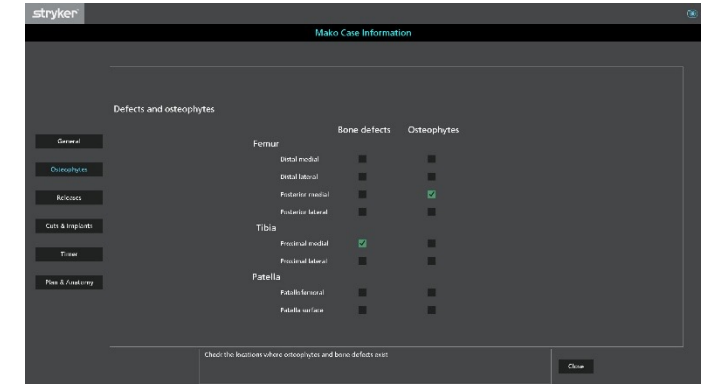
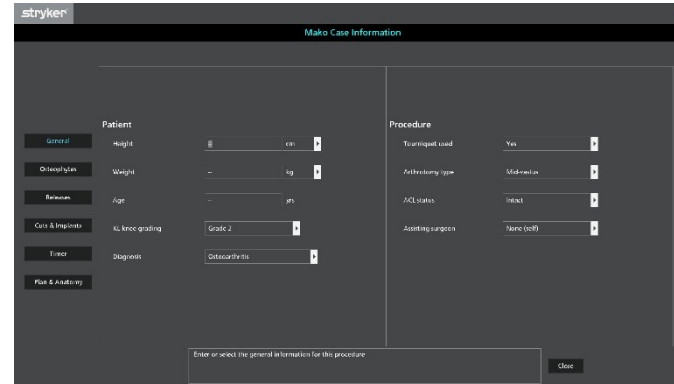
Mako Case Information

Mako Case Information

Plan and Anatomy

There are six tabs:

1. General
2. Osteophytes
3. Releases
4. Cuts and implants
5. Timer
6. Plan and Anatomy



Mako Case Information

Plan and Anatomy

Allows the surgeon to view case-related info pertaining to the selected implant plan and the patient's anatomical dimensions.

The screenshot displays the 'Mako Case Information' window with a sidebar on the left containing menu items: General, Osteophytes, Releases, Cuts & Implants, Timer, and Plan & Anatomy (which is highlighted). The main content area is divided into two primary sections: Component Planning and Anatomical Information.

Component Planning			Anatomical Information		
Sawblade	Standard		Femoral rotations		
Selected plan	Plan0		Coronal	0.0° varus	
Sizes	Femoral	7	Transverse	0.0° external	
	Baseplate	6	Sagittal	2.5° flexion	
	Insert	9 mm	Femoral resections		
Planned alignment	0.0° varus		Distal	Medial	Lateral
Planned laxity	Medial	Lateral	Posterior	7.0 mm	3.5 mm
	Extension	--	Tibial rotations		
	Flexion	--	Coronal	0.0° varus	
			Transverse	0.0° external	
			Sagittal	0.0° p.slope	
			Tibial resections		
			Proximal	Medial	Lateral
				0.0 mm	6.5 mm
			As-scanned alignment		
			Coronal	9.0° valgus	
			Transverse	0.5° external	
			Sagittal	1.0° flexion	
			Anatomic Axes (femur)		
			AA to MA coronal	4.5° valgus	
			AA to MA sagittal	0.4° extension	
			PCA to TEA	3.2° external	
			Posterior slope		
			Medial	1.1° a.slope	
			Lateral	1.1° a.slope	
			Joint Line		
			LDFA	90.0°	
			MPTA	82.8°	
			aHKA	7.2° varus	
			JLO	1/2.9°	
			Femur JLA	0.0° varus	
			Tibia JLA	7.2° varus	
			MEC to bone	29.8 mm	
			MEC to implant	31.3 mm	

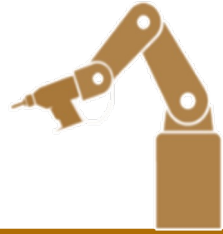
View values related to planned implant component and measurements related to anatomy

Close

Clinical evidence

Mako Total Knee 2.0

The outcomes you expect...



Greater precision to plan

Studies have shown 3D CT planning and haptic boundaries allow surgeons to deliver a more accurate and precise procedure to plan,¹ with less soft tissue damage compared to manual.^{5,15}



Less pain, fewer meds

Patients experienced less pain,¹⁶ and required less pain relief¹⁷ compared to manual total knee replacement.



Improved early recovery

Patients hit postoperative goals earlier and were discharged home sooner.¹⁶ Physical function scores continued to be favorable three-years post-surgery.¹⁸



Improved mid-term survivorship

In the Australian Registry, Four-year survivorship of the Triathlon CR implanted with Mako had a relative improvement of 19% over manual TKA.¹⁹

Mako Total Knee 2.0

...the experience you deserve.



Confidence and control

In a cadaveric study, 95% of users surveyed reported overall increased confidence intra-operatively compared to manual total knee.²⁰



Intuitive design

In a cadaveric study, 84% of users surveyed reported intuitive use of the system.²⁰



New Digital Tensioner

A cadaveric study has shown excellent repeatability and reproducibility when using the Digital Tensioner.³



Accurate 3D CT registration

A cadaveric study has shown that registration landmarks are more accurately identified using a 3D CT scan compared to intra-op digitization.²¹

Mako Total Knee 2.0

Confidence and control

- After a cadaveric lab, three established, high-volume surgeons were asked to compare their experience of the new Mako Total Knee 2.0 software to manual total knee arthroplasty.²⁰
- The surgeons reported new Mako Total Knee 2.0 software provided overall increased confidence, as well as improved confidence when performing initial assessment and implant adjustment compared to MTKA.²⁰

Confidence

95% report overall increased intra-operative confidence²⁰



Control

100% more confident in intra-operative implant adjustment²⁰



Mako Total Knee 2.0

Intuitive design

- After a cadaveric lab, established, high-volume surgeons were asked to compare their experience of the new Mako Total Knee 2.0 software to manual total knee arthroplasty.²⁰
- Surgeons found overall use of RATKA was intuitive and were satisfied with overall use of the application.²⁰

Intuitive Design

84% report
intuitive use of the
system²



Overall satisfaction

90% report overall
satisfaction with the
new software²


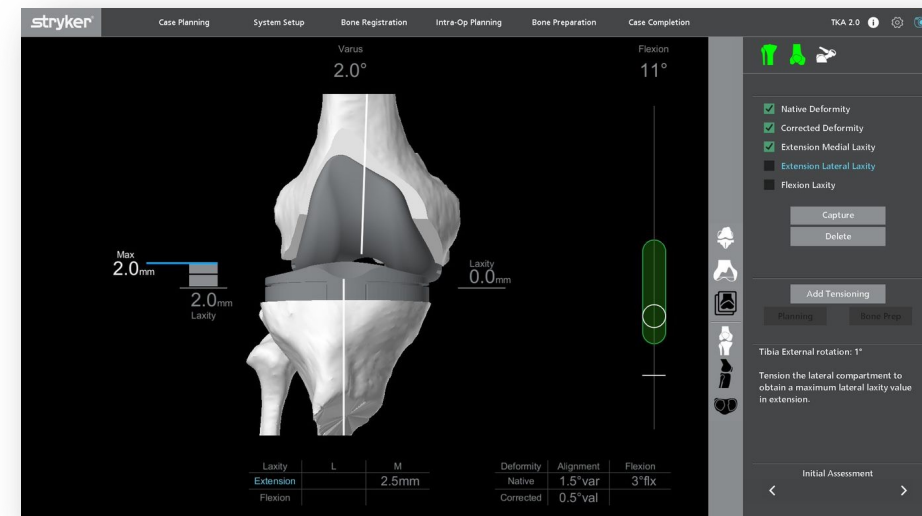


Mako Total Knee 2.0

Digital Tensioner - repeatability

- A cadaveric study has shown that when using the digital tensiometer average variation **between use by the same surgeon** was 0.31mm.³
- Intraclass correlation coefficient (ICC) analysis showed excellent repeatability (ICC \geq 0.96)³
- Repeatability was within 1mm 96% of the time and within 1.5mm every time.³

Repeatability
 Mean: 0.31mm
 100% < 1.5mm³

Mako Total Knee 2.0


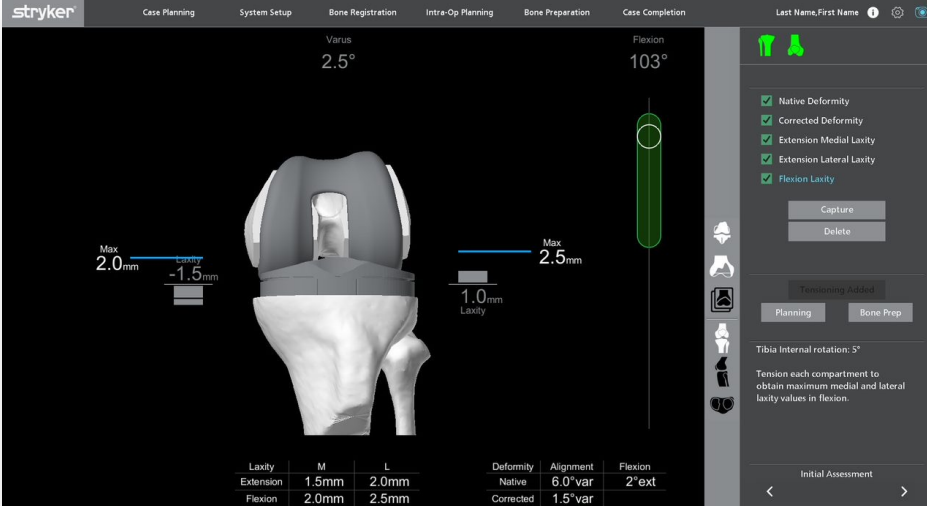
Digital Tensioner - reproducibility

- A cadaveric study has shown that when using the digital tensiometer average variation **between use by different surgeons** was 0.6mm.³
- Intraclass correlation coefficient (ICC) analysis showed excellent reproducibility (ICC \geq 0.90).³
- Reproducibility was within 1mm 99% of the time and within 1.5mm every time.³

Reproducibility

Mean: 0.6mm

100% < 1.5mm³

	M	L	Deformity	Alignment	Flexion
Extension	1.5mm	2.0mm	Native	6.0°var	2°ext
Flexion	2.0mm	2.5mm	Corrected	1.5°var	

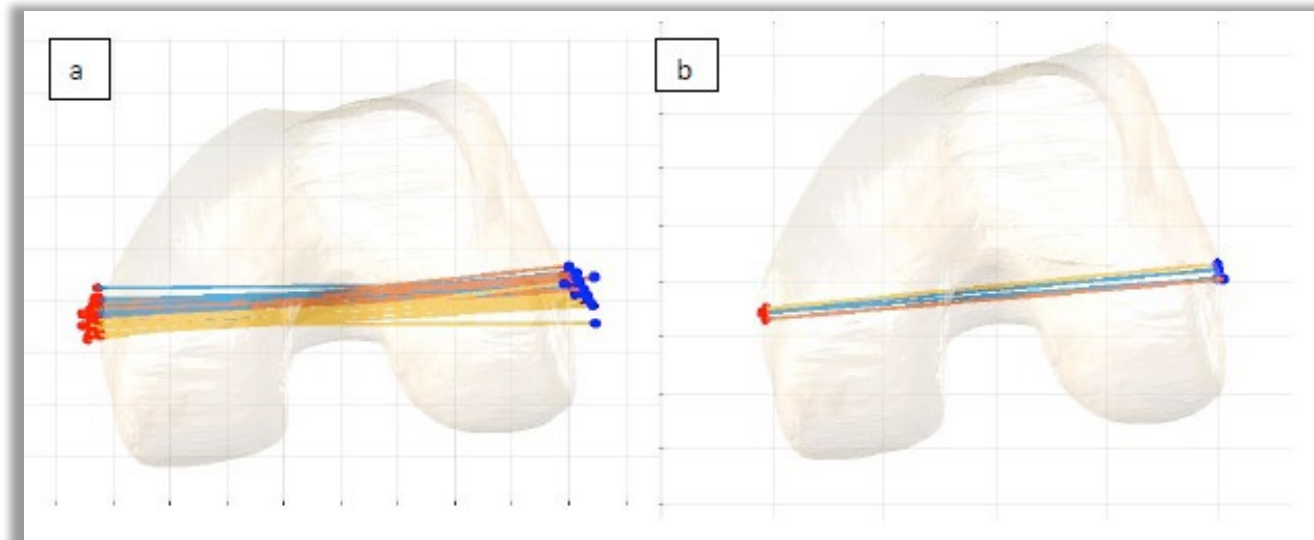
Mako Total Knee 2.0

Accurate 3D CT registration

- A cadaveric study has shown that manually selecting rotational landmarks intraoperatively resulted in increased error compared to digitally selecting preoperatively using a 3D CT scan.²¹
- Greater reliability of landmark identification was observed in the anterior/posterior direction when using the CT scan, indicating that using CT based images may better identify the axis often used to set femoral component rotation, as compared to intraoperative manual identification.²¹

Accuracy

28% relative
reduction in error
in the rotational
plane²¹



TEA angle variation for (a) intraoperative landmark digitisation and (b) pre-operative 3D CT landmark digitisation.

Thank you

References

1. Bhimani SJ, Bhimani RB, Feher A, Smith LS, D'John ML, Malkani AL. Accuracy of preoperative implant sizing using 3D preplanning software for robotic-assisted total knee arthroplasty. Presented at: American Association of Hip and Knee Surgeons (AAHKS) Annual Meeting; November 2-5, 2017; Dallas, TX
2. Kwak DS, Kong CG, Han SH, Kim DH, In Y. Development of a pneumatic tensioning device for gap measurement during total knee arthroplasty. *Clin Orthop Surg.* 2012;4(3):188-192. doi:10.4055/cios.2012.4.3.188
3. Scholl L, Caba M, Hampp E, Ali A, Crutcher J, Mont M, Mahoney O: Robotic-assisted total knee arthroplasty technology helps provide a repeatable and reproducible method of assessing soft tissue balance. Poster 1683. Orthopaedic Research Society 2023 Annual Meeting; February 10-14; Dallas Texas.
4. Deckey DG, Rosenow CS, Verhey JT, et al. Robotic-assisted total knee arthroplasty improves accuracy and precision compared to conventional techniques. *Bone Joint J.* 2021;103-B(6 Supple A):74-80. doi:10.1302/0301-620X.103B6.BJJ-2020-2003.R1
5. Kayani B., Konan S., Pietrzek J., Haddad F. S. Iatrogenic Bone and Soft Tissue Trauma in Robotic-Arm Assisted Total Knee Arthroplasty Compared With Conventional Jig-Based Total Knee Arthroplasty: A Prospective Cohort Study and Validation of a New Classification System *The Journal of Arthroplasty* 2018.03.042
6. Stryker Sales data on file
7. Bhimji et al. Rotational constraint of posterior-stabilized total knee prostheses. *J Knee Surg.* 2008;21(4):315-319. doi:10.1055/s-0030-1247838
8. Bhimji et al. Micromotion of cementless tibial baseplates: keels with adjuvant pegs offer more stability than pegs alone. *J Arthroplasty.* 2014;29(7):1503-1506. doi:10.1016/j.arth.2014.02.016
9. Nam D, Bhowmik-Stoker M, Mahoney OM, Dunbar MJ, Barrack RL. Mid-Term Performance of the First Mass-Produced Three-Dimensional Printed Cementless Tibia in the United States as Reported in the American Joint Replacement Registry. *J Arthroplasty.* 2023;38(1):85-89. doi:10.1016/j.arth.2022.07.020
10. Bhowmik-Stoker, M., Nevelos, J., Barrack, R., Mont, M, Mahoney, M., Dunbar, M and Nam, D. Mid-term Performance of 28,257 Metal-Backed Patellae from the American Joint Replacement Registry (AJRR). [Poster presentation]. 2021 AAHKS Annual Meeting, 11-14 November 2021, Dallas, TX.

References

11. Nam D, Lawrie CM, Salih R, Nahhas CR, Barrack RL, Nunley RM. Cemented Versus Cementless Total Knee Arthroplasty of the Same Modern Design: A Prospective, Randomized Trial. *J Bone Joint Surg Am.* 2019 Jul 3;101(13):1185-1192. doi: 10.2106/JBJS.18.01162. PMID: 31274720; PMCID: PMC6641115.
12. Cohen RG, Sherman NC, James SL. Early Clinical Outcomes of a New Cementless Total Knee Arthroplasty Design. *Orthopedics.* 2018;41(6):e765-e771. doi:10.3928/01477447-20180828-05
13. Stryker technical report: Report number RD-12-044. Tritanium patella static tensile bond strength of poly/metal interface. 2013.
14. Stryker technical report: Report number RD-13-107. Effect of geometry on peg fixation strength. 2013.
15. Fontalis A, Kayani B, Asokan A, et al. Inflammatory Response in Robotic-Arm-Assisted Versus Conventional Jig-Based TKA and the Correlation with Early Functional Outcomes: Results of a Prospective Randomized Controlled Trial. *J Bone Joint Surg Am.* 2022;104(21):1905-1914. doi:10.2106/JBJS.22.00167
16. Kayani B, Konan S, Tahmassebi J, Pietrzak JRT, Haddad FS. Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty: a prospective cohort study. *Bone Joint J.* 2018;100-B(7):930-937. doi:10.1302/0301-620X.100B7.BJJ-2017-1449.R1
17. Bhimani SJ, Bhimani R, Smith A, Eccles C, Smith L, Malkani A. Robotic-assisted total knee arthroplasty demonstrates decreased postoperative pain and opioid usage compared to conventional total knee arthroplasty. *Bone Jt Open.* 2020;1(2):8-12. Published 2020 Oct 27. doi:10.1302/2633-1462.12.BJO-2019-0004.R1
18. Marchand RC, Scholl L, Taylor KB, et al. Clinical Outcomes after Computed Tomography-Based Total Knee Arthroplasty: A Minimum 3-Year Analysis [published online ahead of print, 2023 Jan 19]. *J Knee Surg.* 2023; 10.1055/s-0042-1759790. doi:10.1055/s-0042-1759790
19. Australian Orthopaedic Association. AOANJR. Hip, Knee & Shoulder Arthroplasty Annual Report 2022. [<https://aoanjrr.sahmri.com/annual-reports-2022>]
20. Valentino A, Scholl L, Caba M, Hampp E, Mont M, Mahoney O: Assessing Surgeon Confidence and Efficiencies when Utilizing Robotic Assisted Total Knee Arthroplasty. Poster 1680. Orthopaedic Research Society 2023 Annual Meeting; February 10-14; Dallas Texas.
21. Chen A, Caba M, Ali A, Crutcher J, Mont M, Mahoney M: What is the best way to identify the transepicondylar axis for femoral component rotation? Poster 0855. Orthopaedic Research Society 2023 Annual Meeting; February 10-14; Dallas Texas.

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