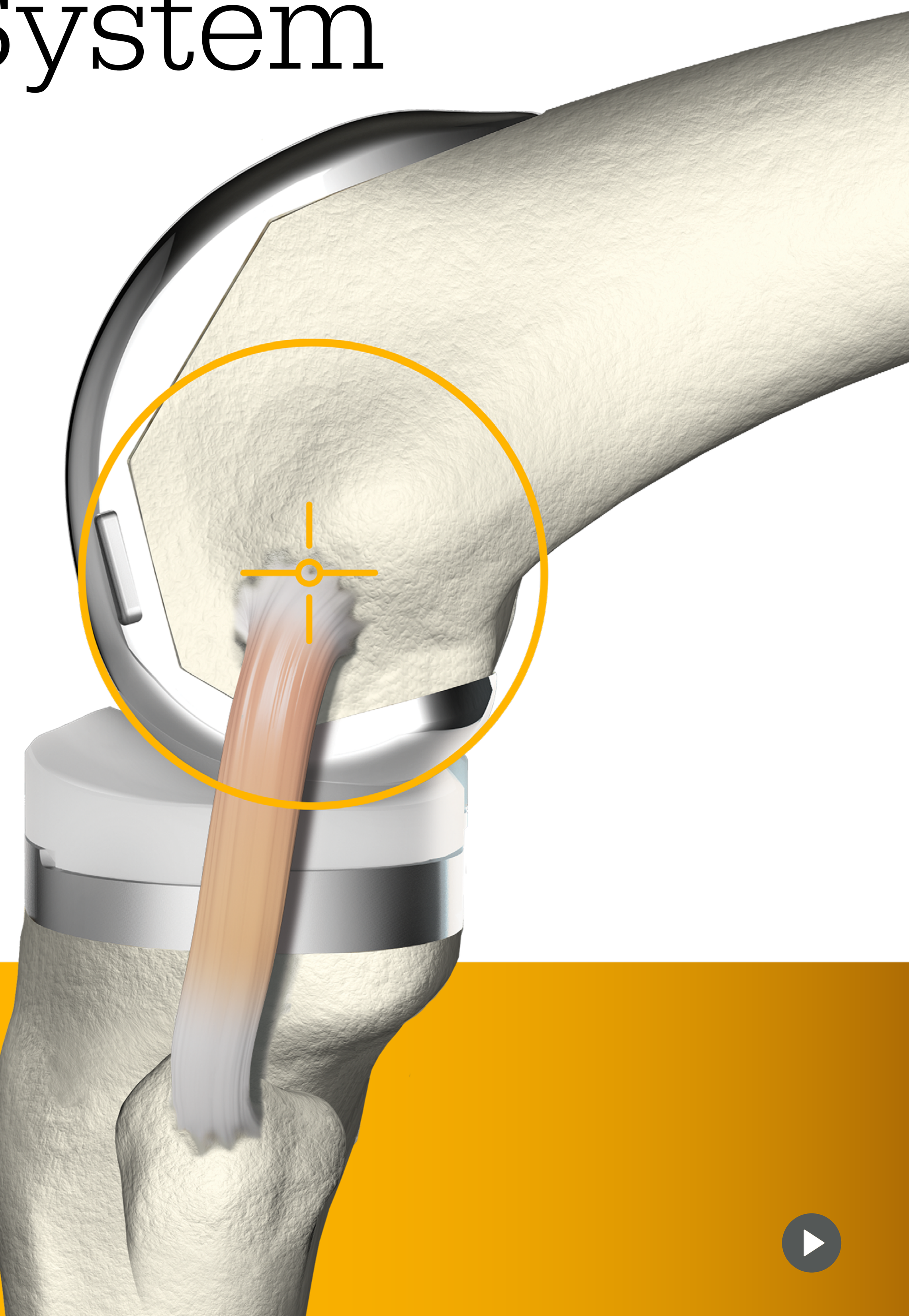
stryker

Triathlon®

Total Knee System



Triathlon® Total Knee System design rationale

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Designed to work with the body

Triathlon and the single radius are designed to work with the patient's body. With over 15 years and over 3 million implantations worldwide, Triathlon has a long clinical history.[1,80] Triathlon was designed to incorporate some of the most studied features of Stryker's prior designs that have been shown to address many of the main reasons for revision TKA such as instability, patellofemoral tracking complications and loosening/osteolysis.[80]

The Triathlon Total Knee System offers surgeons a variety of options depending on disease, deformity and patient demand including cruciate-retaining, condylar-stabilizing, posterior-stabilizing and difficult primary options. Studies have consistently shown that Triathlon and the single radius provide:

Stability

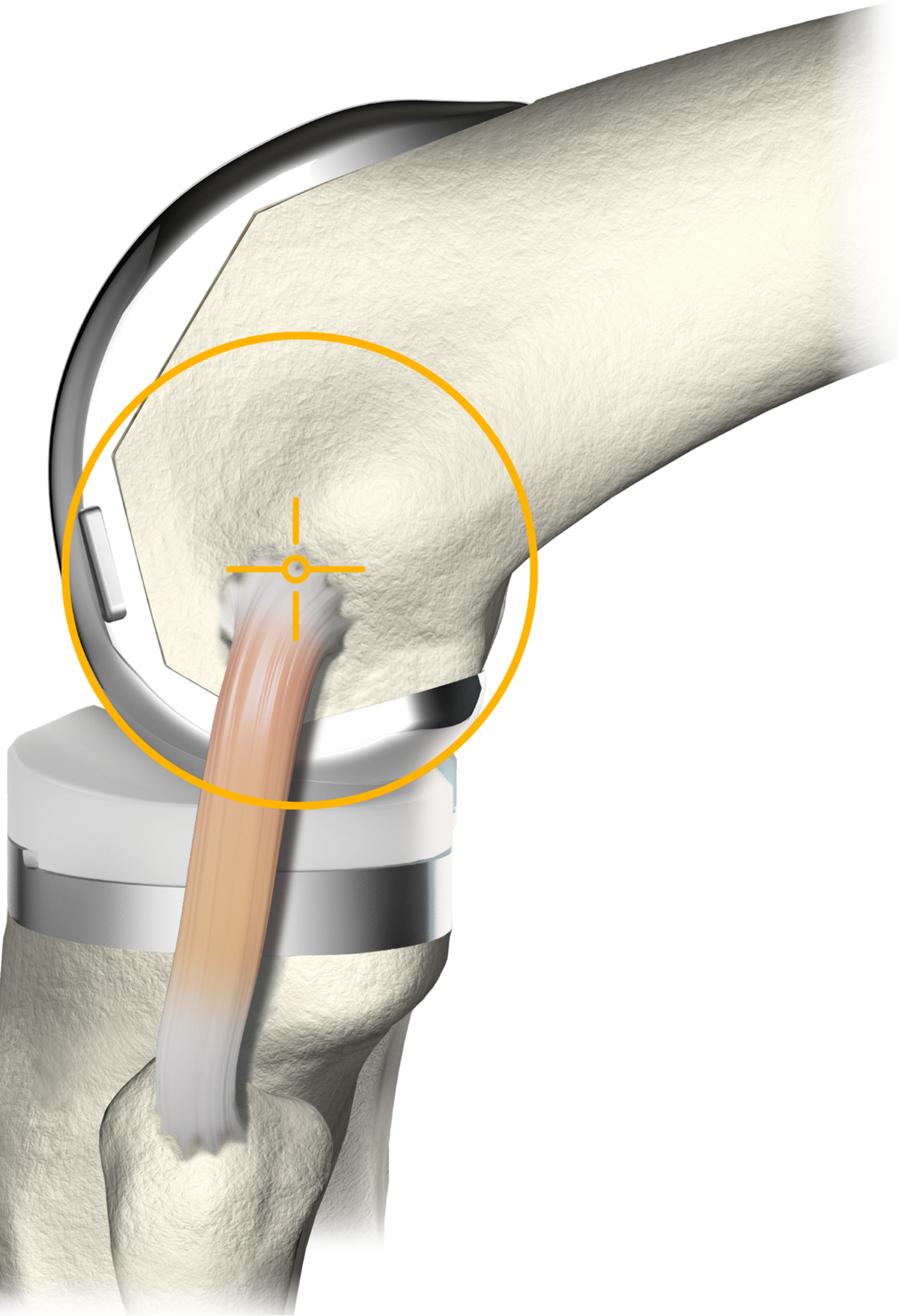
Triathlon's single radius design allows for mid-flexion stability.[26,45,82] A single vs. multi-radius functional outcome study concluded that Triathlon's advantages in stability, walking, stair climbing and knee straightening stem from the single radius design, particularly its longer moment arm and enhanced ligament stability based on maintained isometry throughout knee range of motion.[26] A fluoroscopic study on Triathlon patients showed the femoral component was kinematically stable in mid-flexion ranges.[45] Additionally, gait reviews comparing patients with a single or multi-radius knee implant showed that patients with a single radius knee implant experienced gait patterns that more closely mimicked that of the non-diseased control group.[82]

Satisfaction

Triathlon continues to demonstrate excellent long-term results with high patient satisfaction rates. One study reported 98.9% satisfaction at three-year follow-up among patients who received Triathlon implants.[136] In a separate study, 90.5% satisfaction was reported at eight-year follow-up among patients who received Triathlon implants.[137]

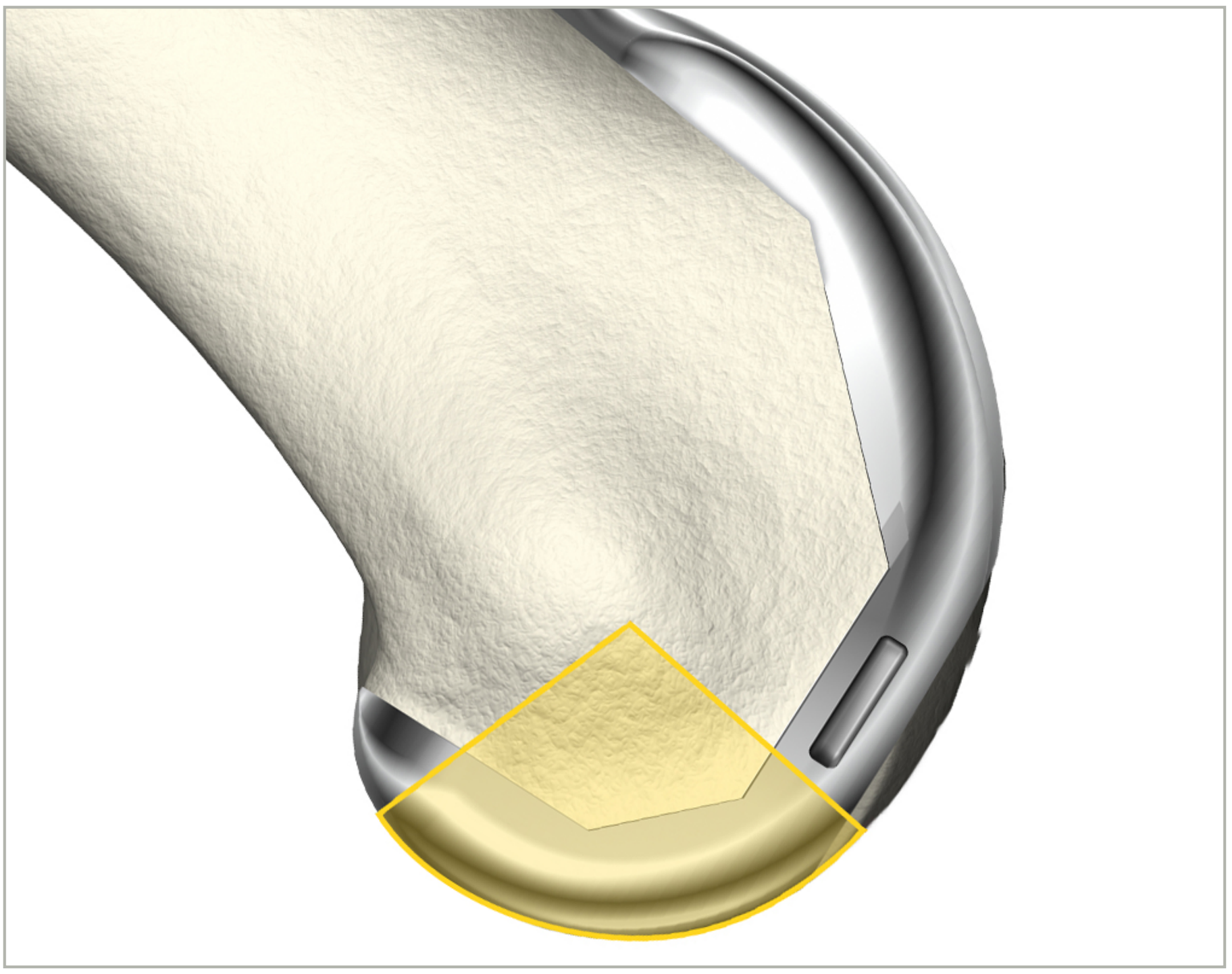
Survivorship

Multiple studies and joint registries[5,80,89,111] from around the world consistently show a high rate of survivorship with Triathlon with more than 10 years of follow-up.

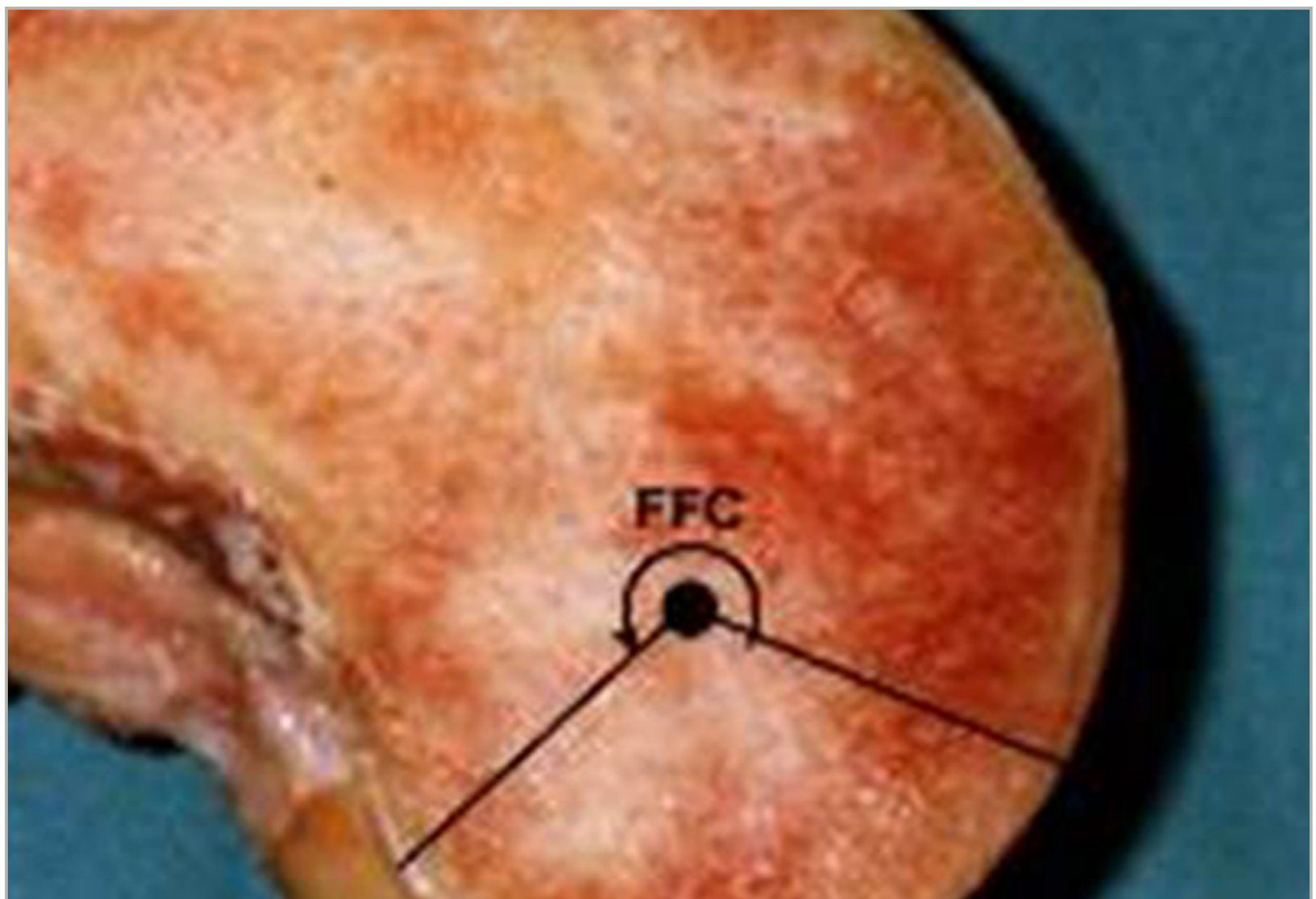


Single radius

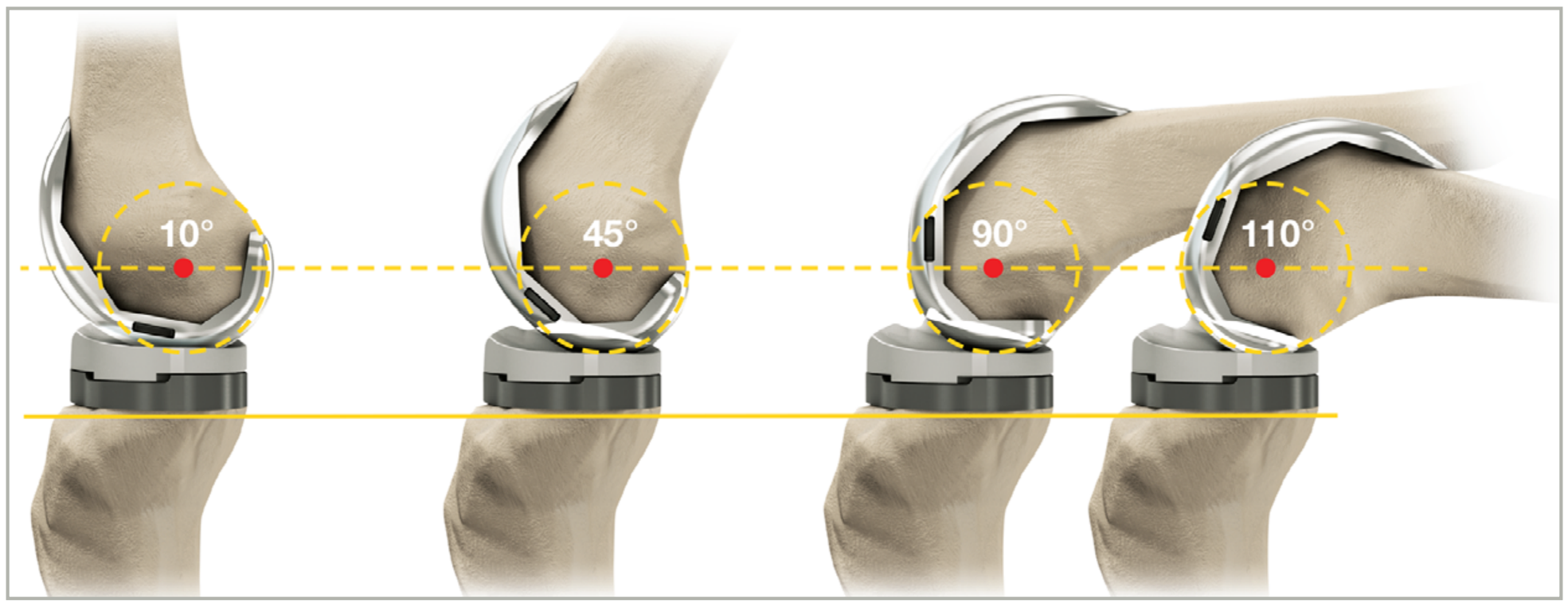
The Triathlon single radius is designed to address stability during active flexion, where most motion occurs.[2,26,82,107]



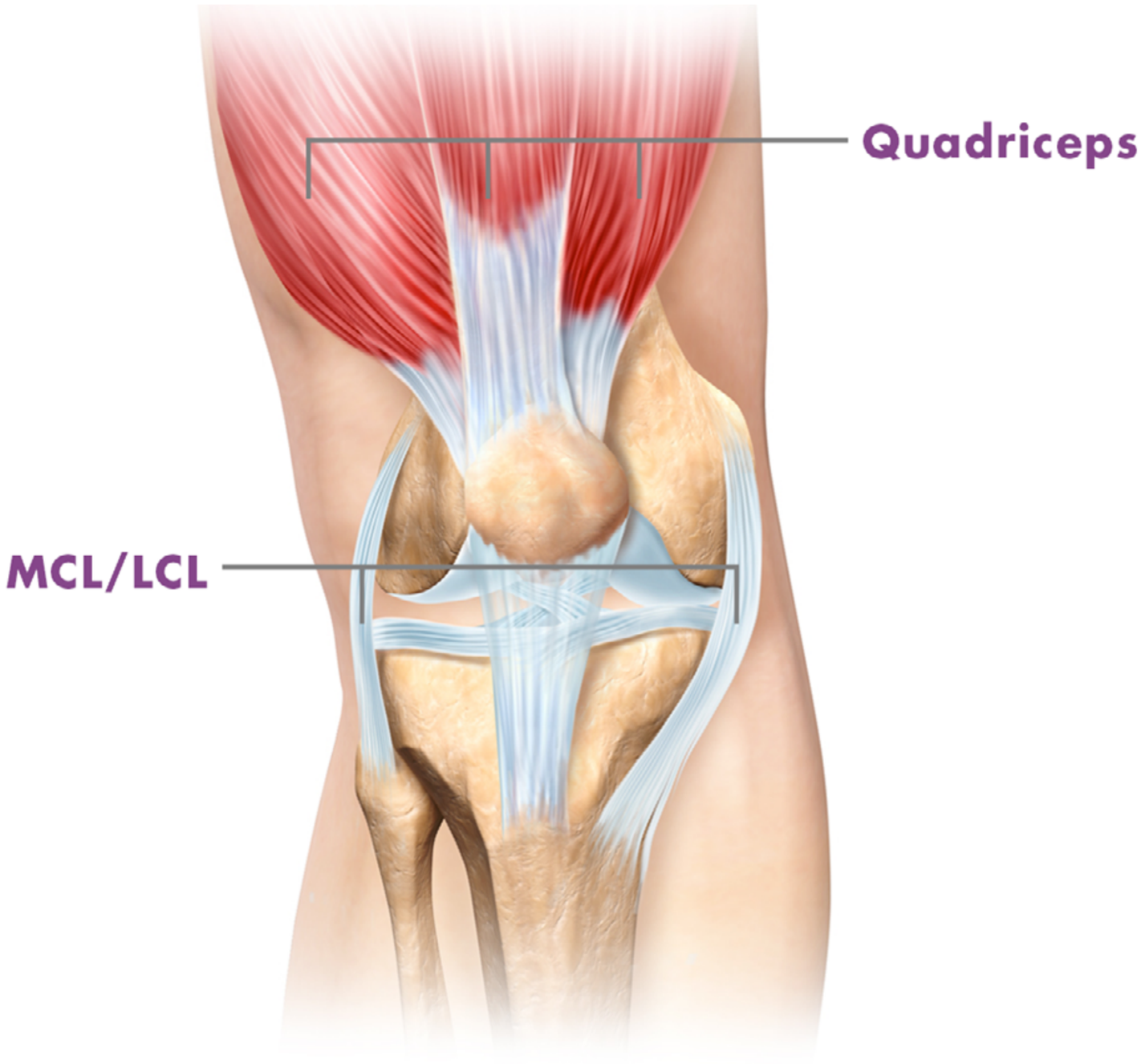
The single radius philosophy is based on observations from cadaver studies as well as our SOMA database.[21,22, 53]



The single radius is designed to restore the knee's single center of rotation during active flexion.[21,22] This allows for constant ligament tension and stability in flexion.[2,26,82,107]

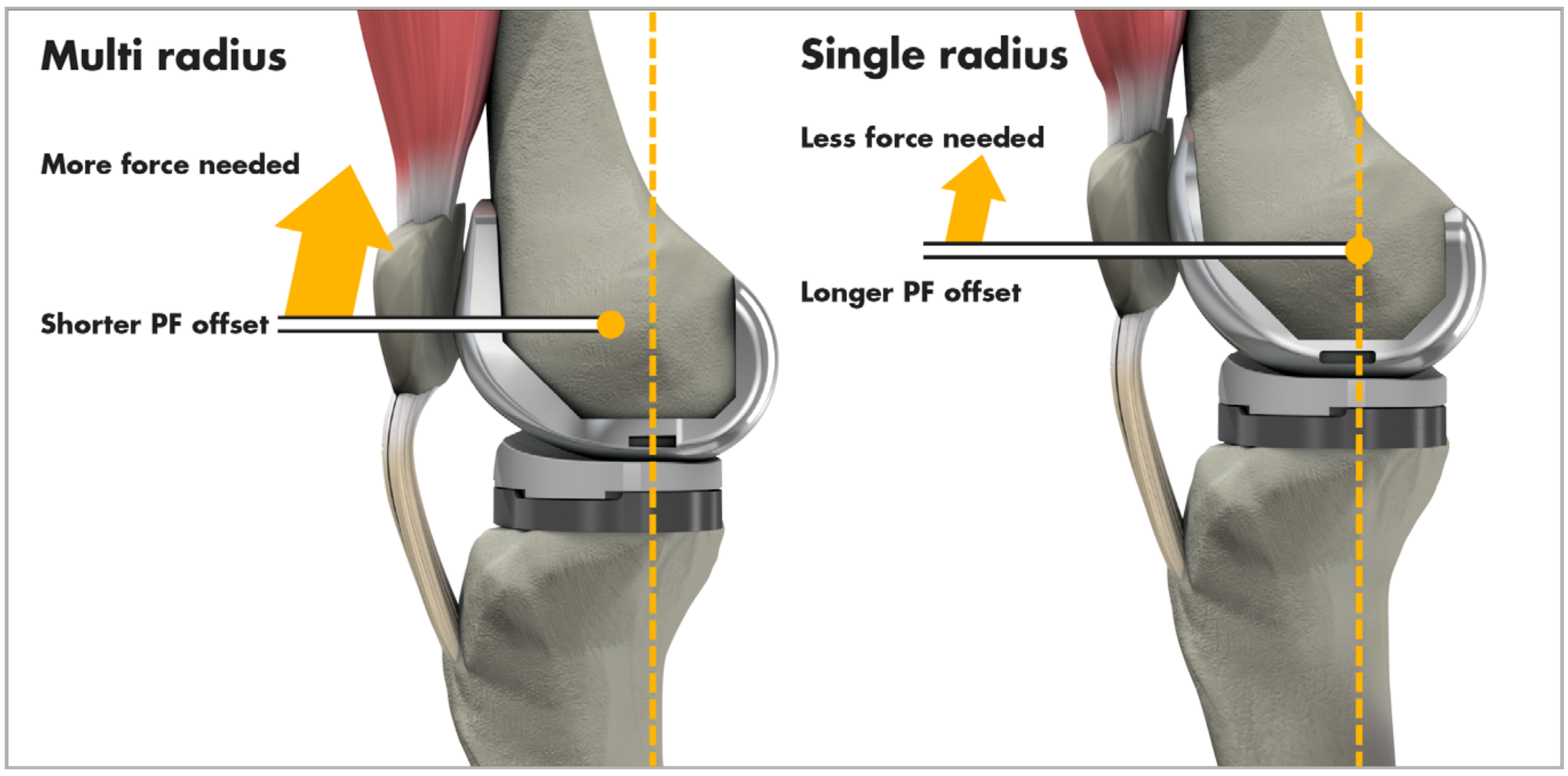


There are a number of structures and soft tissues present pre-TKA that are removed during TKA. Triathlon is designed to work with the soft tissues that remain. The key is the single radius.



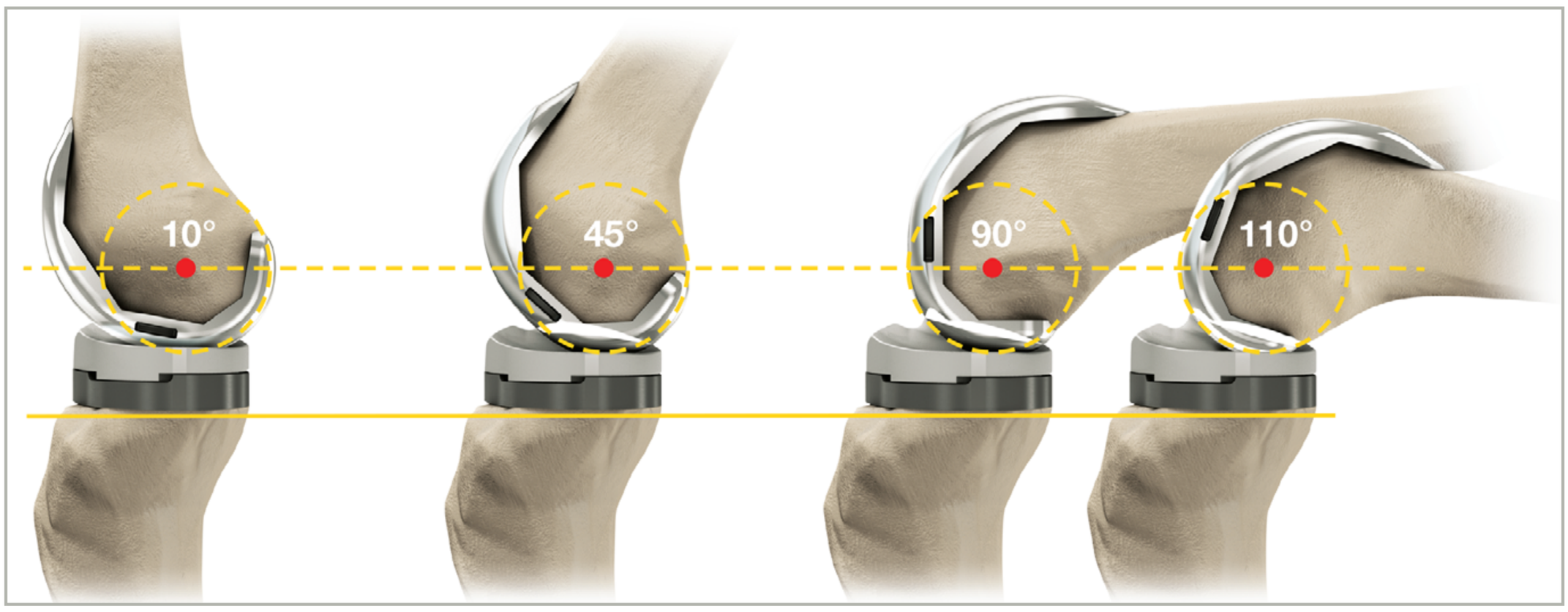
Quadriceps

The quadriceps help stabilize the knee during gait. The single radius allows for constant ligament balance[1-3] and less force required by the quadriceps.[4]



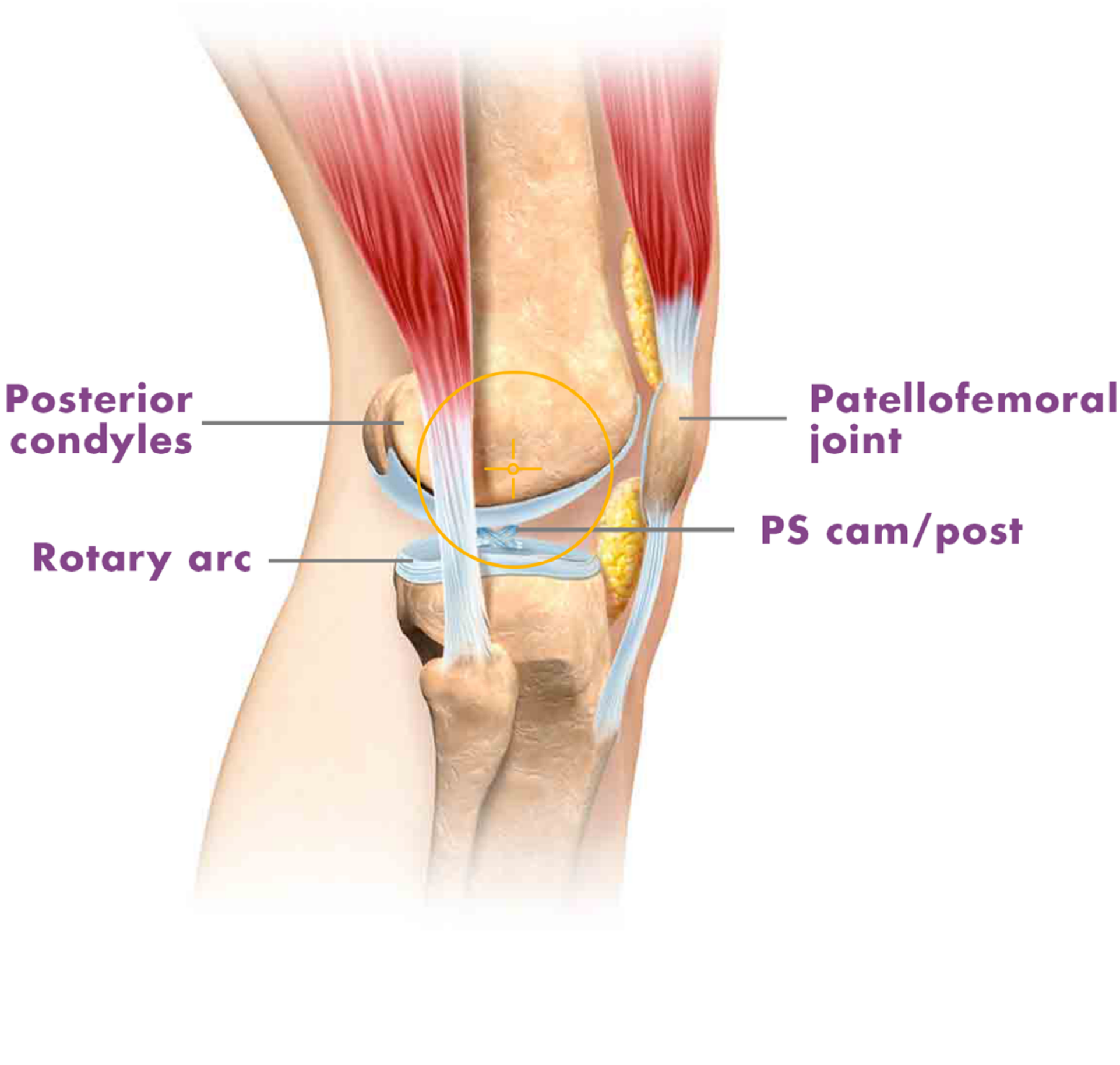
MCL/LCL

The single radius allows for constant ligament balance.[1-3]



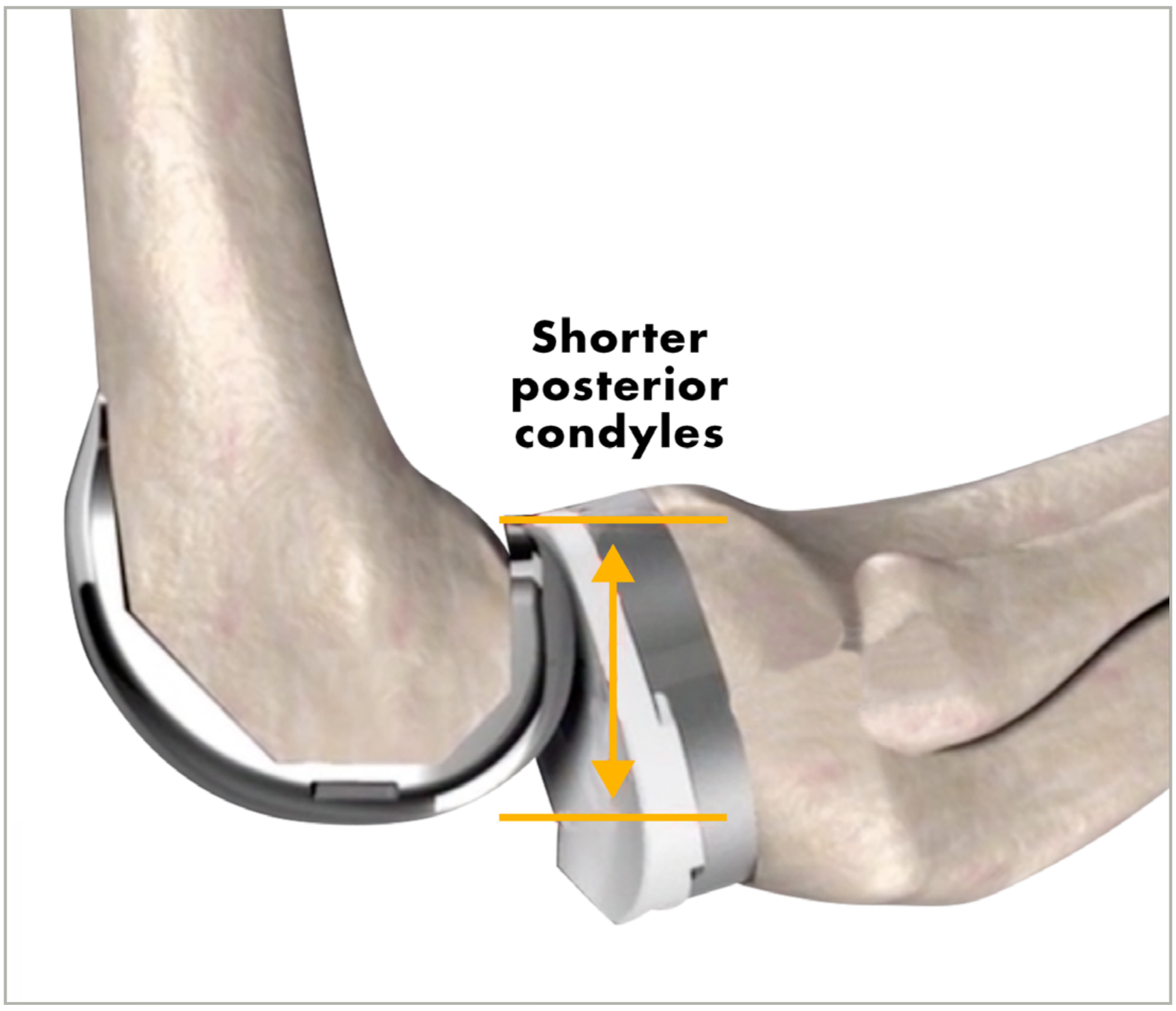
Key features

While the single radius works with the ligaments and muscles that remain,[1-4] the other key features of Triathlon are designed to work with the body to accommodate motion, not force it.



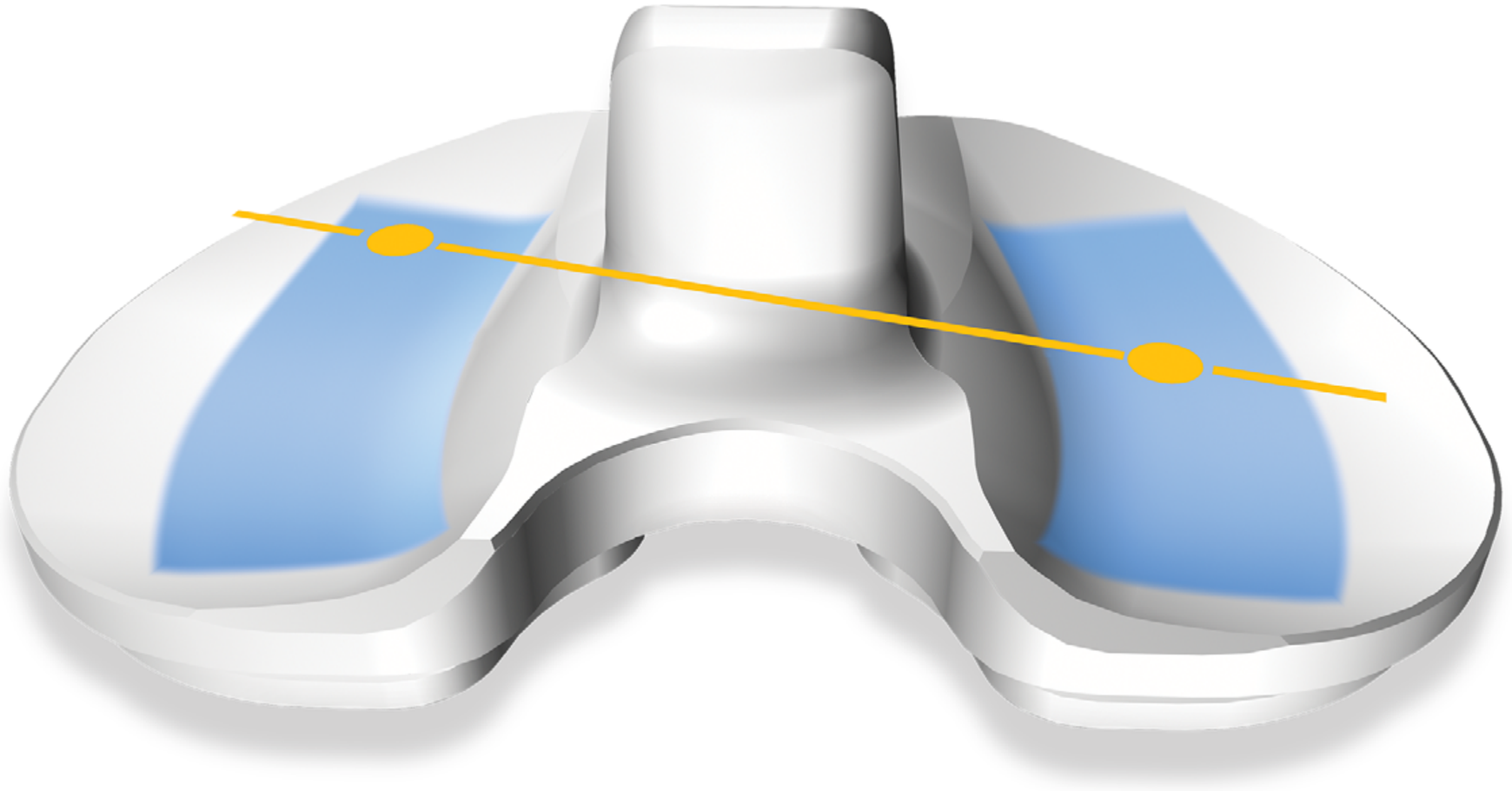
Posterior condyles

Triathlon's shortened, flared posterior condyles are designed to facilitate the relaxation of the soft tissues to enable deep flexion without excessive slope.[6]



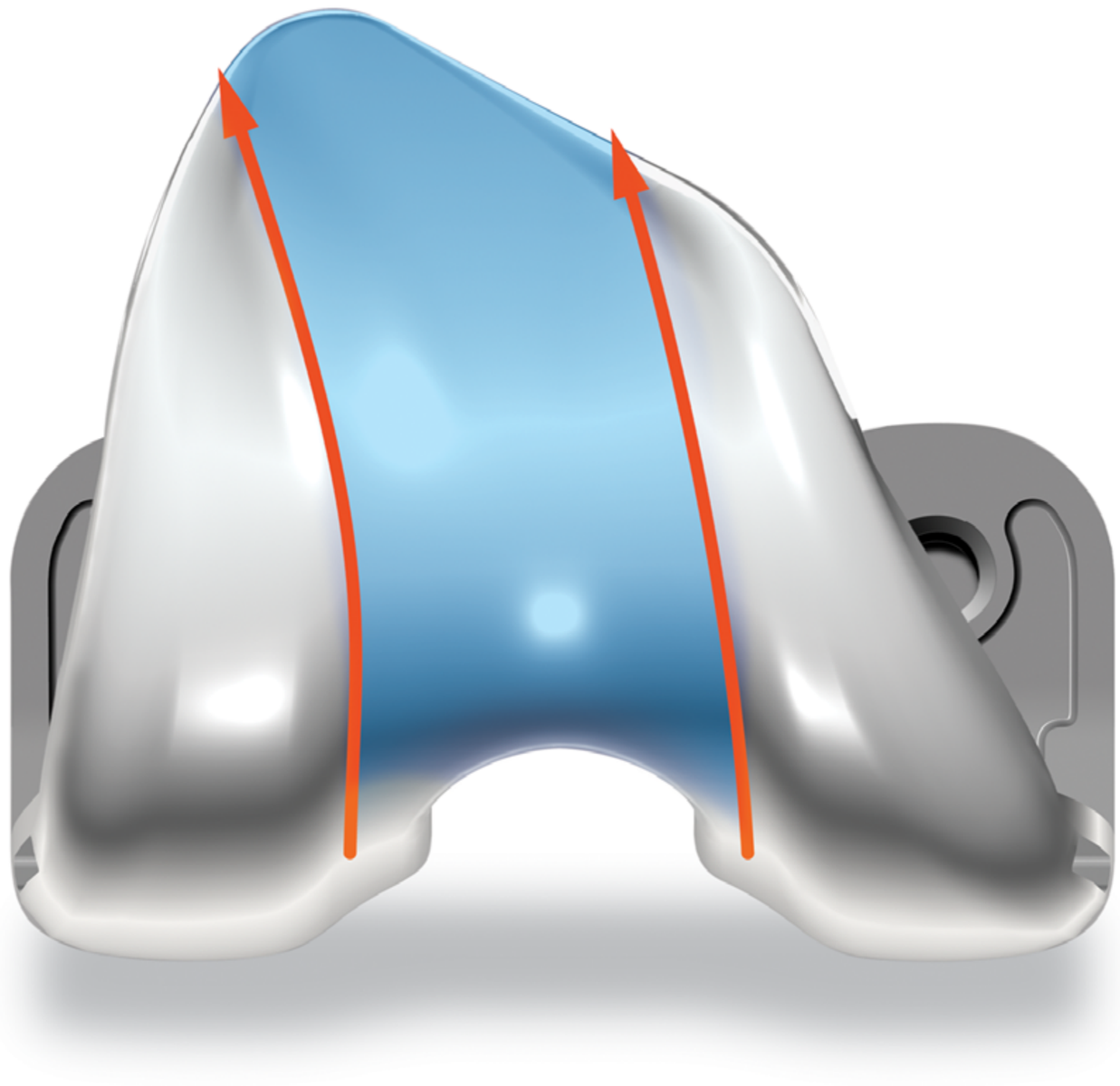
Rotary arc

The Triathlon rotary arc design allows for +/- 20º of internal/external rotation and reduces contact stresses.[6] This may lessen the potential for wear and loosening.[44]



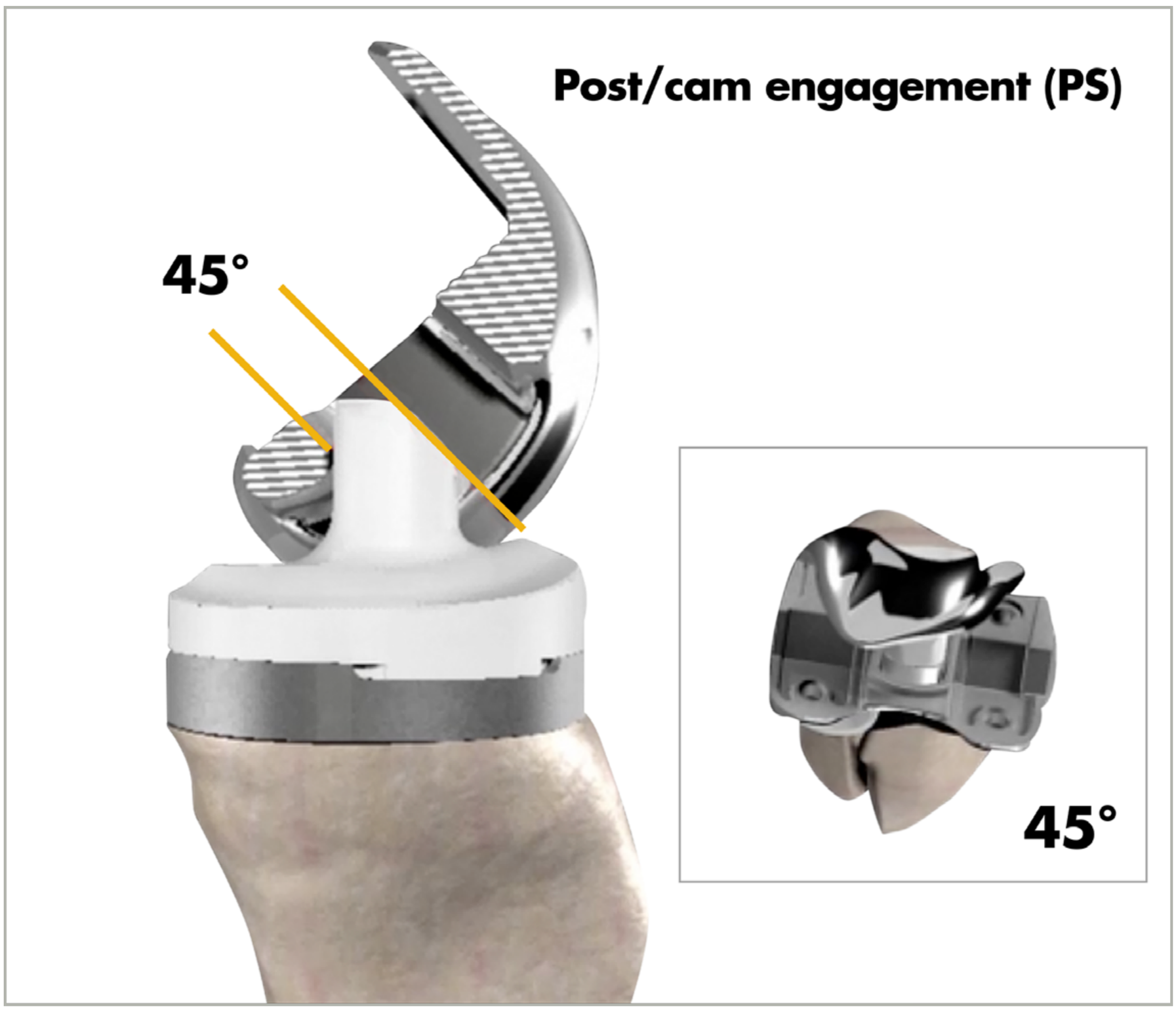
Patellofemoral joint

Triathlon's deepened trochlear groove is designed to help relax the extensor mechanism, enable deeper flexion and reduce contact stresses exerted across the patella.[8] Triathlon incorporates the same patellofemoral design as Duracon, which demonstrated <1% patellofemoral complication rates in multiple studies.[41,42]



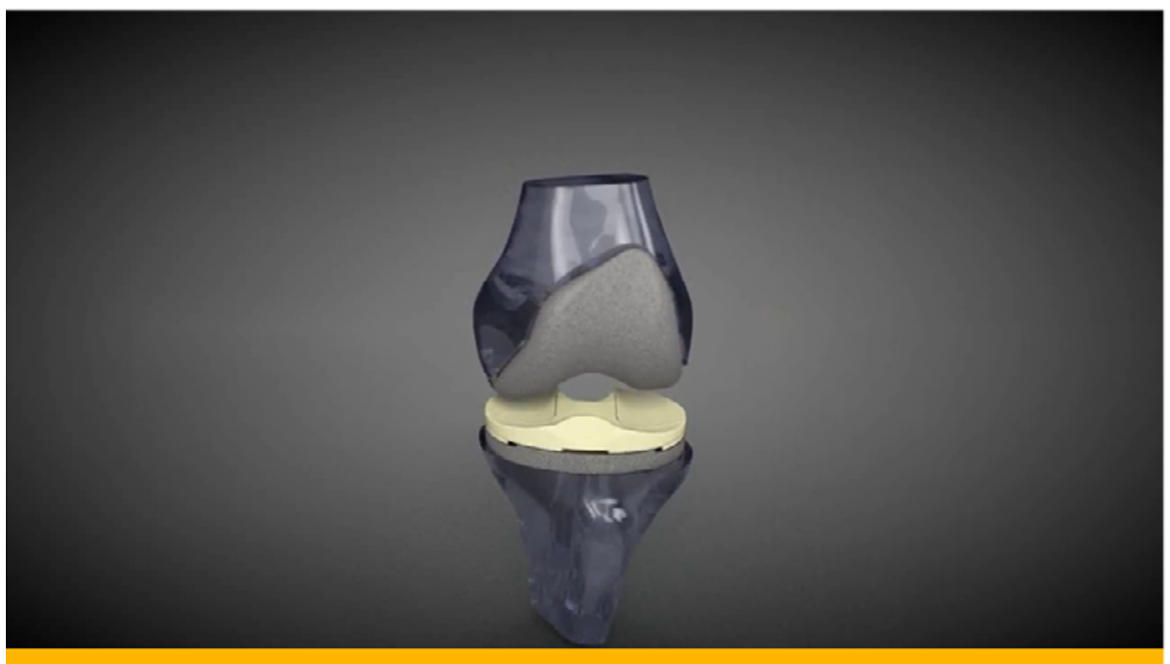
PS cam/post

Pre-TKA, the PCL engages at approximately 45°. Triathlon's cam and post are designed to engage at approximately 45° as well.[49] Competitive designs engage later in flexion[60,98,104] and rely on the post to drive rollback. Triathlon PS is designed to provide stability throughout gait and allow for deep flexion.[82,107]

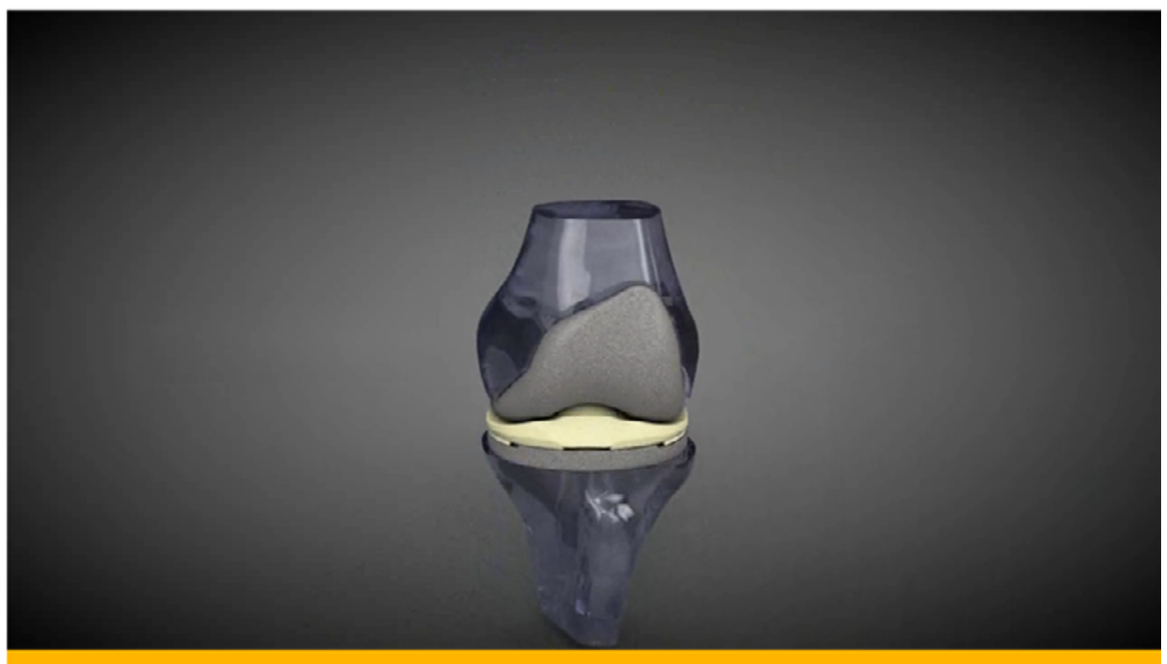


Options

The Triathlon Total Knee System offers surgeons a variety of options depending on disease, deformity and demand.



Triathlon® CR



Triathlon® CS

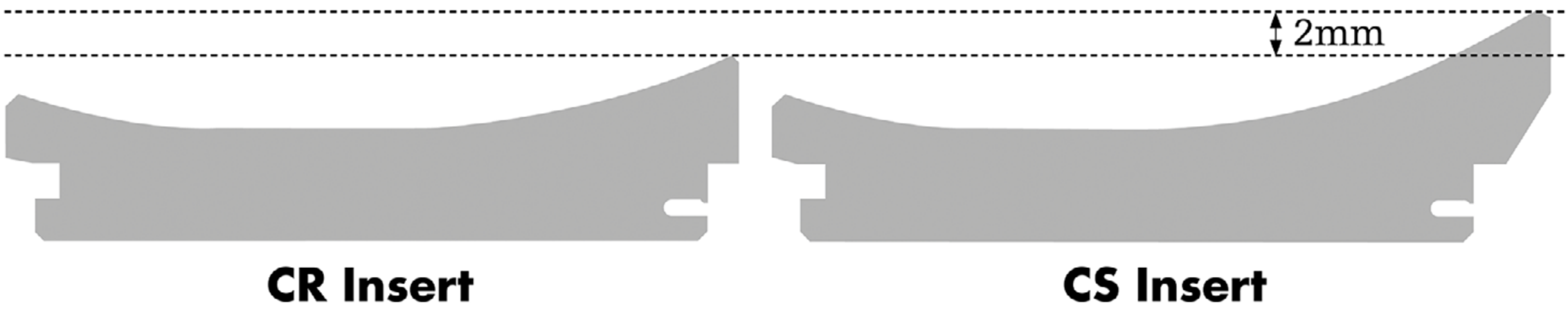
Triathlon® PS

Triathlon® PS Femur with TS insert

Option	Varus/valgus constraint	Internal/ external rotation constraint	Maximum flexion
CR	None	+/- 20º	150º
CS	None	+/- 20º	150º
PS	None	+/- 20º	150º
TS	+/- 2º	+/- 7º	135º

Triathlon CS insert

The Triathlon CS insert offers, on average, 2mm more height on the anterior lip than the CR insert. A prospective randomized investigation of patients who received either a Triathlon CS or PS insert was conducted.[87] The PCL was sacrificed in all patients. There were no significant differences between groups for the Knee Society Scores, the Lower Extremity Activity Scale, range of motion or alignment (preoperative versus five-year postoperative). This supports that Triathlon CS can be a suitable option for patients with a PCL deficiency.

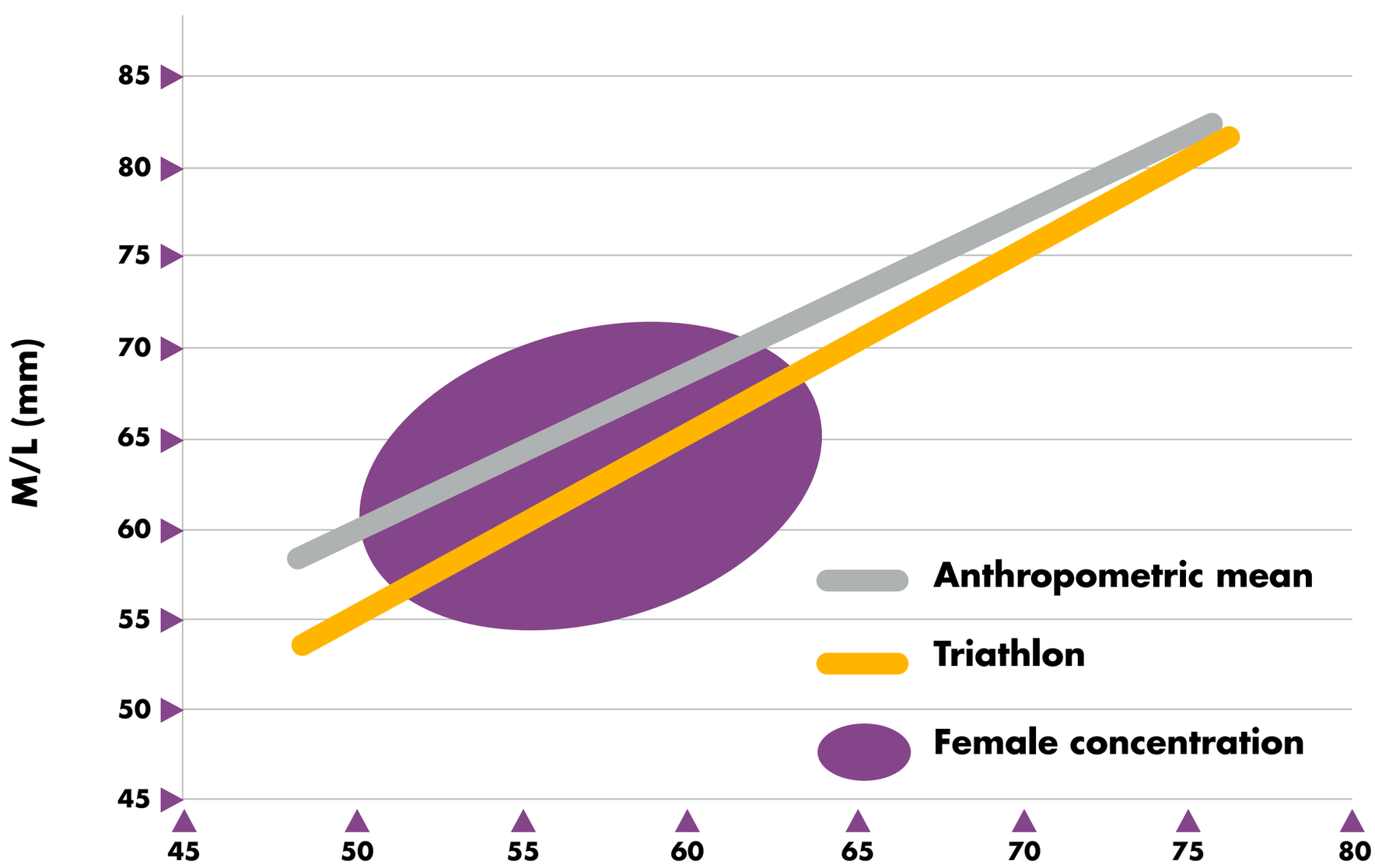


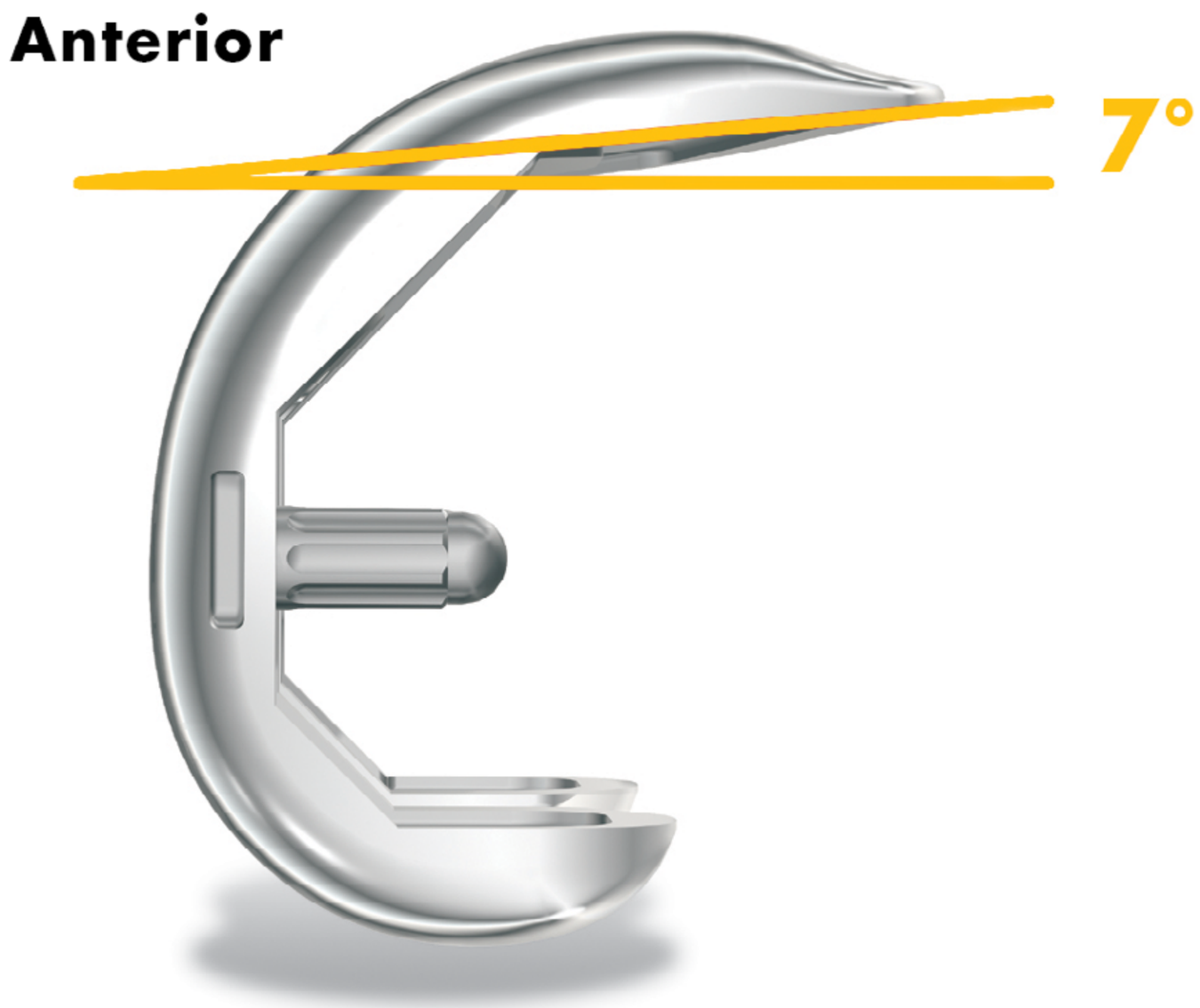
Fit – femur features

Triathlon's broad range of size offerings is based on an anthropometric measurement study[10] for improved interplay between implant geometry and anatomic structure for women and men.

The Triathlon femoral component is designed to address smaller anatomies, often found in female patients, heavily concentrated in the region shown,[10] while still accommodating larger male patients. The unique 7° anterior flange design of Triathlon is designed to provide the flexibility to downsize the femoral component while avoiding the occurrence of notching.

Anthropometrically based design[10] (femoral component)

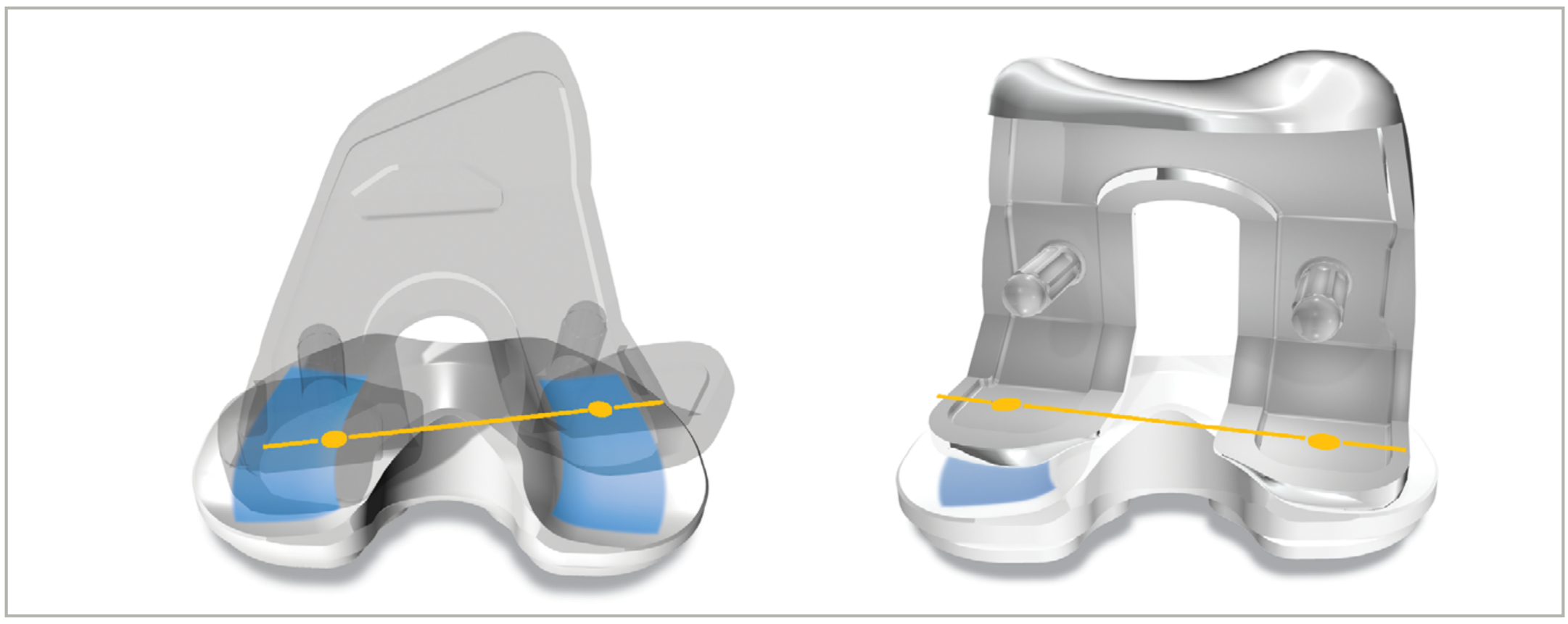


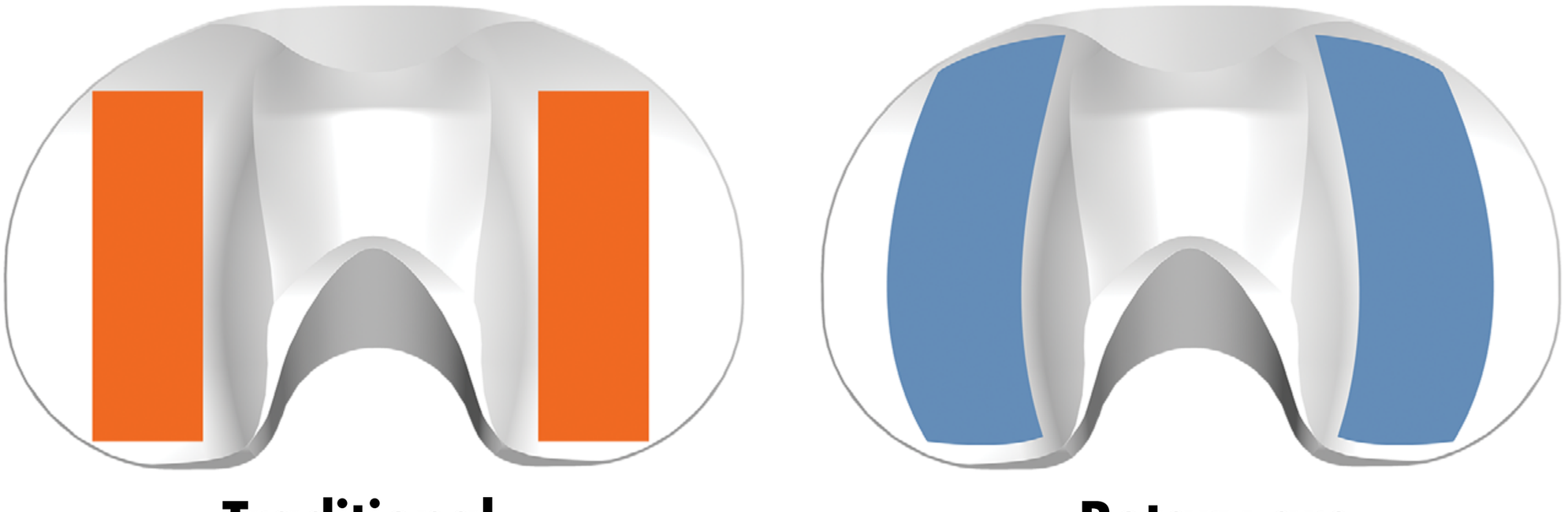


Fit – tibia coverage

Symmetric baseplates have been shown to produce positive clinical results[1,3,5,9,17,26,32] and adequate surface coverage in relation to tibial aspect ratio.[13] In fact, a study by Incavo et al. demonstrated symmetric baseplates provided greater coverage in anterior quadrants when compared to asymmetric designs.[13] Another study showed an asymmetric tray had higher rates of posterolateral and posteromedial overhang compared to symmetric designs, including Triathlon.[69]

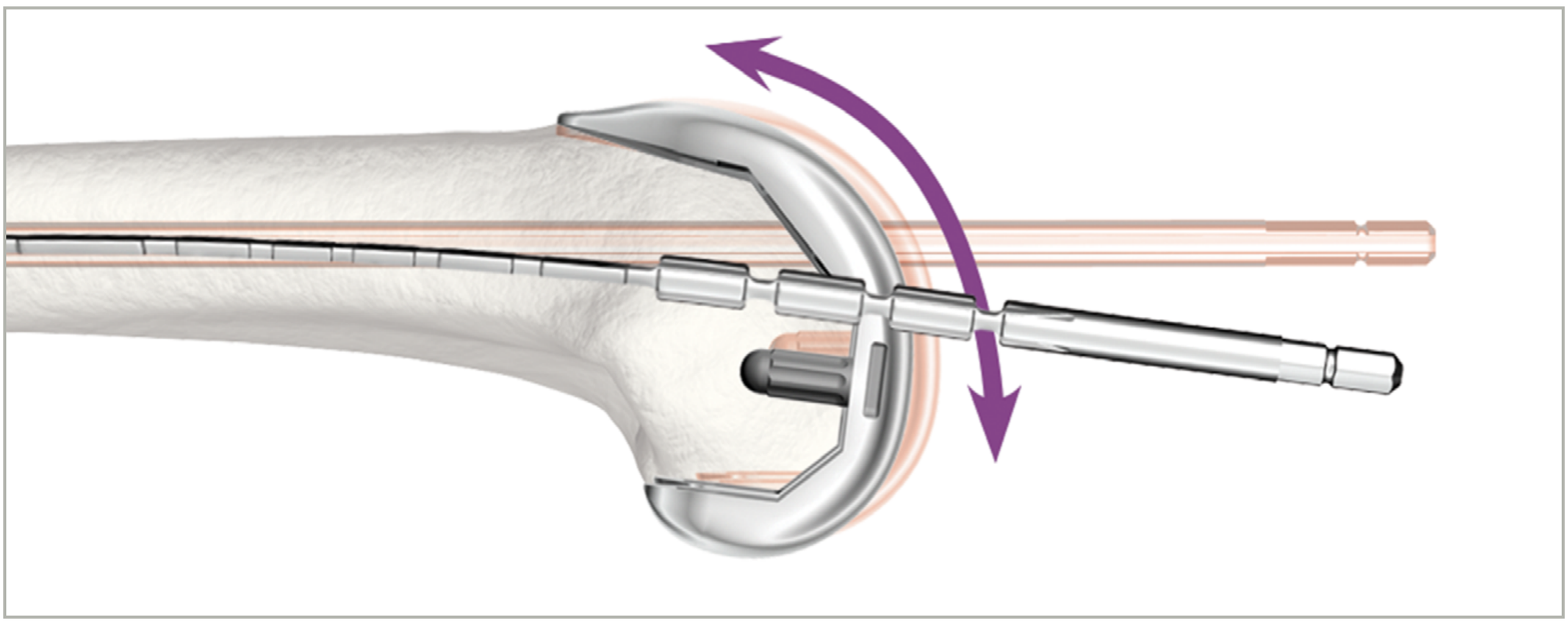
A clinical study of 281 patients who received a Triathlon implant demonstrated no incidences of tibial component subsidence.[80]





Orientation and fit with FlexRod

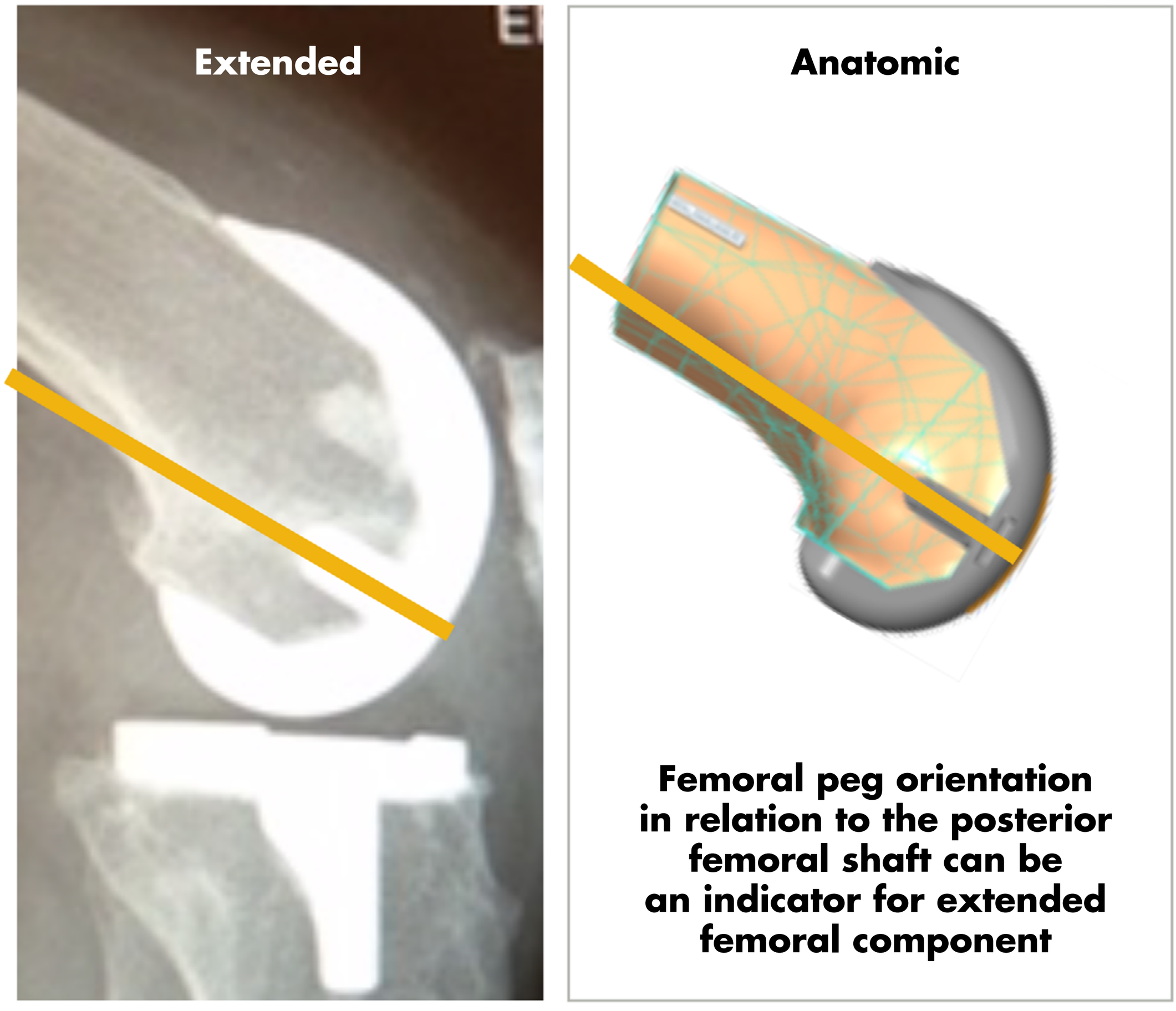
The FlexRod is designed to flex to accommodate the anterior bow of the patient's femur.[12]



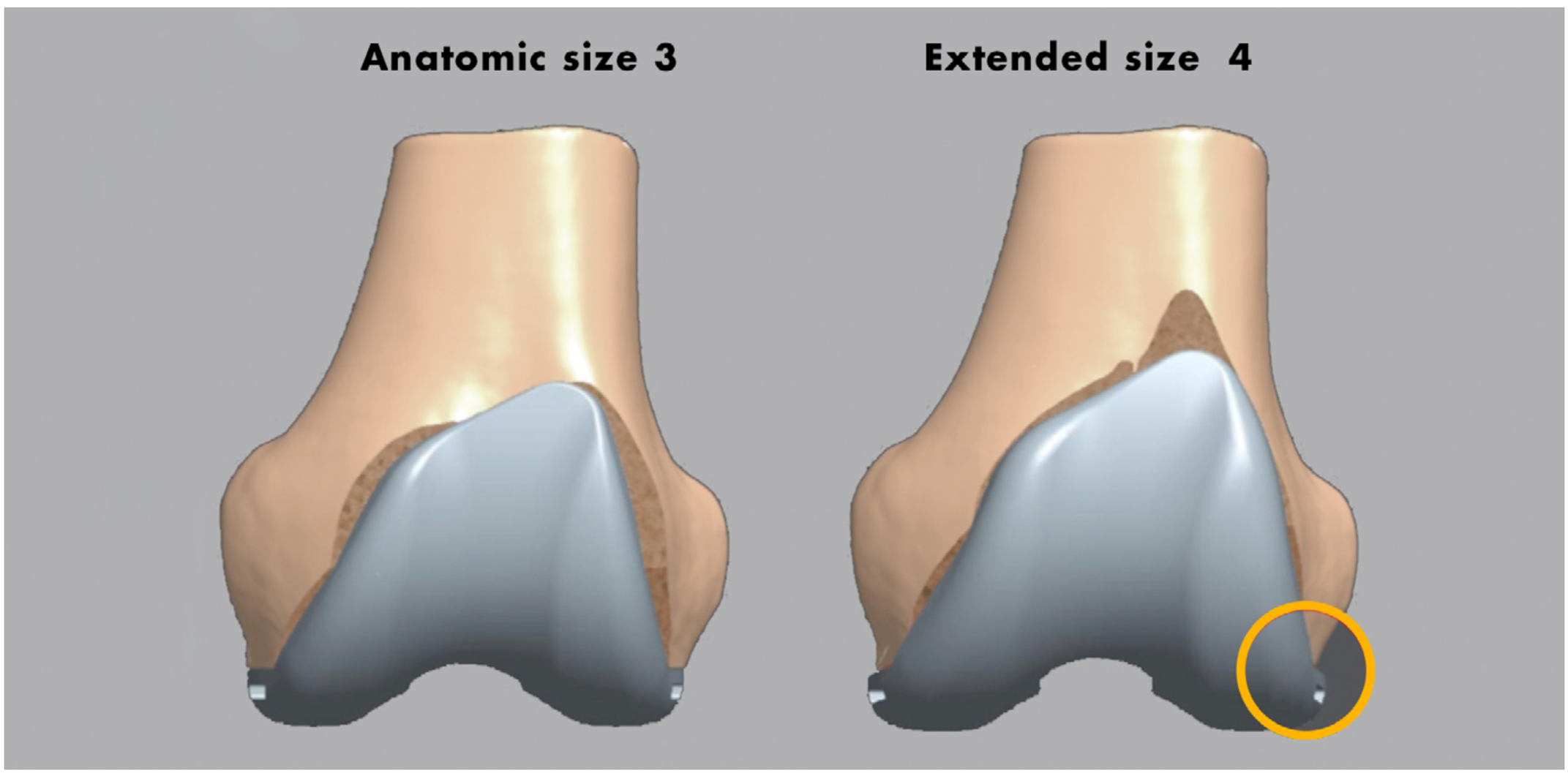
Traditionally, a rigid intramedullary (IM) rod is used for distal femoral preparation.

Anterior bow of the femur varies widely.[31]

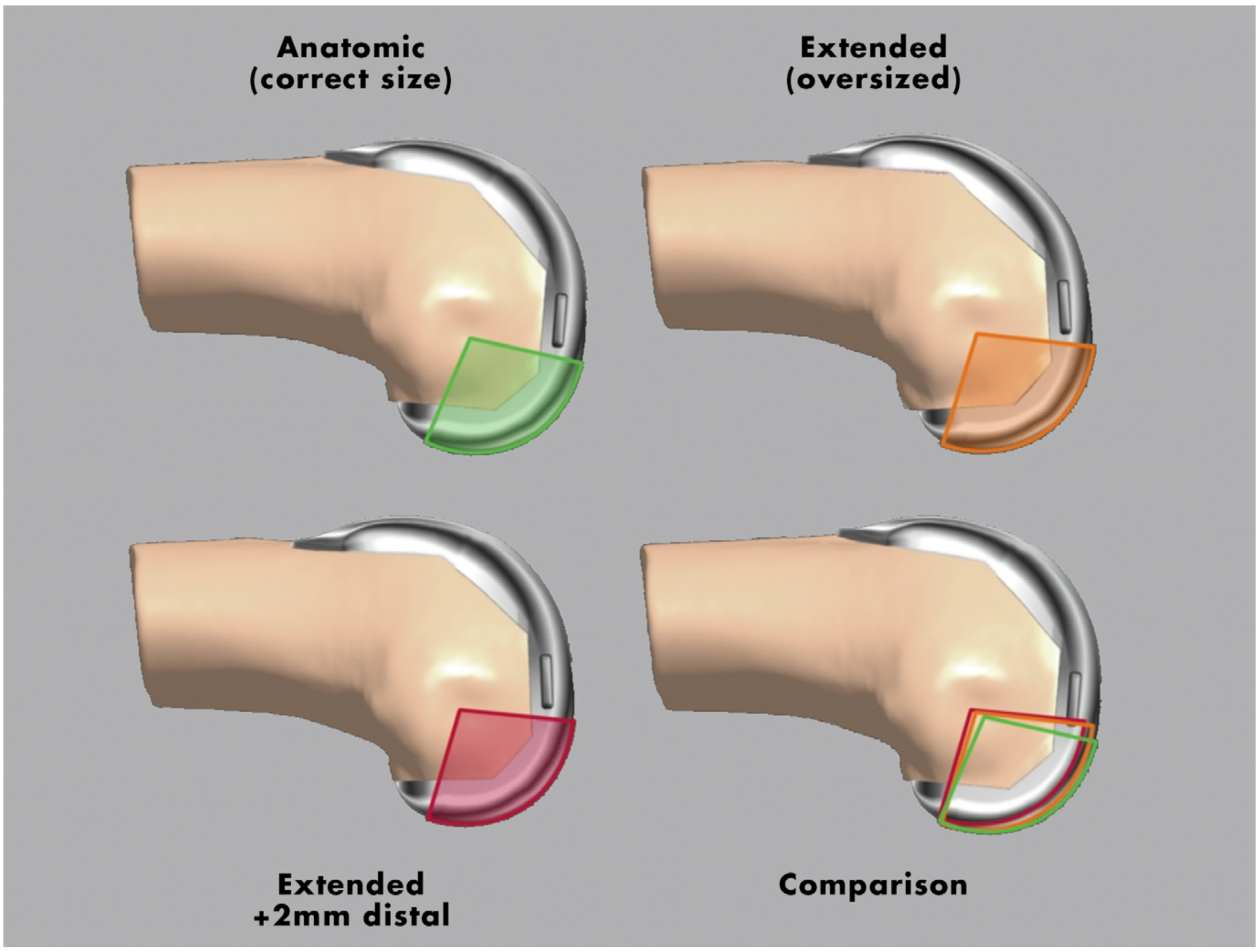
A rigid IM rod that does not take the bow of the patient's femur into account can potentially lead to an oversized component positioned in extension.[12]

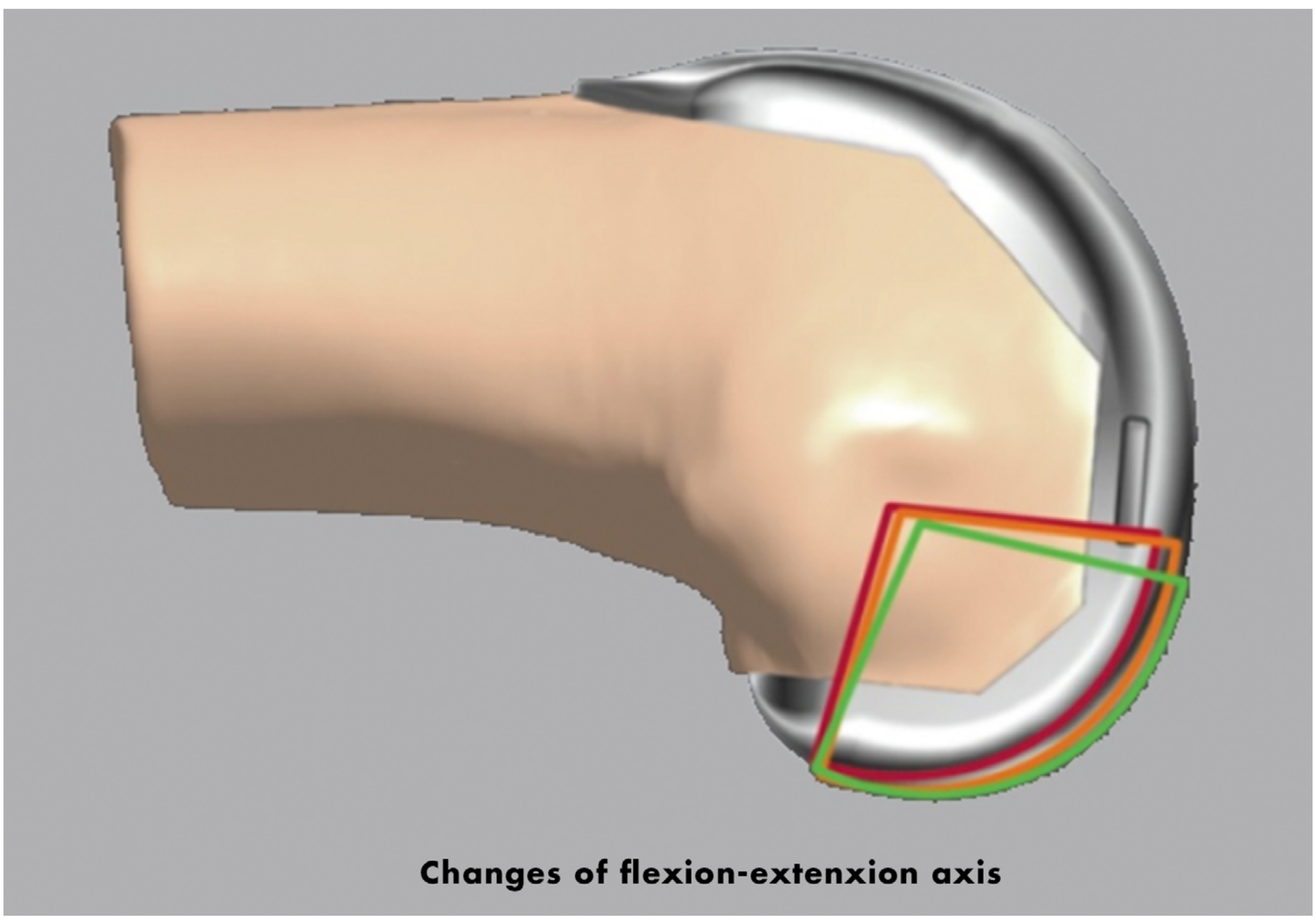


This situation may lead to medial-lateral overhang, soft tissue impingement and pain.[12]

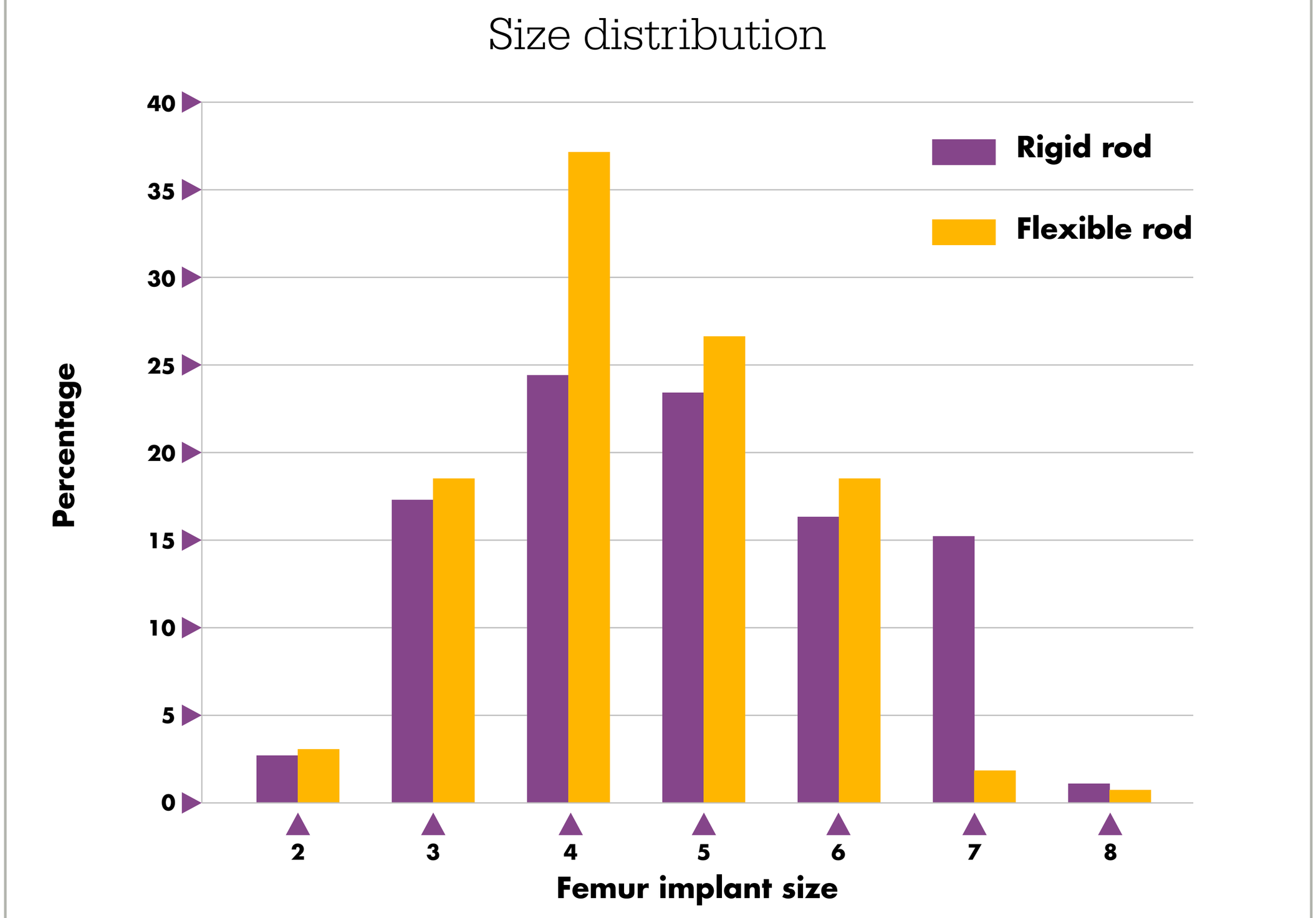


Additionally, the FlexRod can help to position the single radius of the femoral component in alignment with the single radius of the patient's knee. Proper placement of the single radius may aid in balancing the knee.





Studies show patients who received TKAs with the FlexRod had better improvements in range of motion and Knee Society Scores and decreased risk of oversizing compared to patients who received TKAs with the rigid IM rod.[12]



ROM and KSS Pain/Motion

ROM[31]						
	pre-op	6 weeks	3 months	1 year	2 years	% change at 2 years
Rigid	101.1	103.1	113.6	119.0	123.6	**22.2%**
Flexible	99.7	107.0	118.2	124.3	127.9	**28.3%**
% diff	-1.5%	3.8%	4.1%	4.4%	3.4%	**6.1%**

KSS Pain/Motion[31]						
	pre-op	6 weeks	3 months	1 year	2 years	% change at 2 years
Rigid	37.25	73.9	80.31	88.52	90.5	**143.0%**
Flexible	35.74	76.9	82.75	90.1	92.73	**159.5%**
% diff	-4.1%	4.1%	3.0%	1.8%	2.5%	**16.5%**

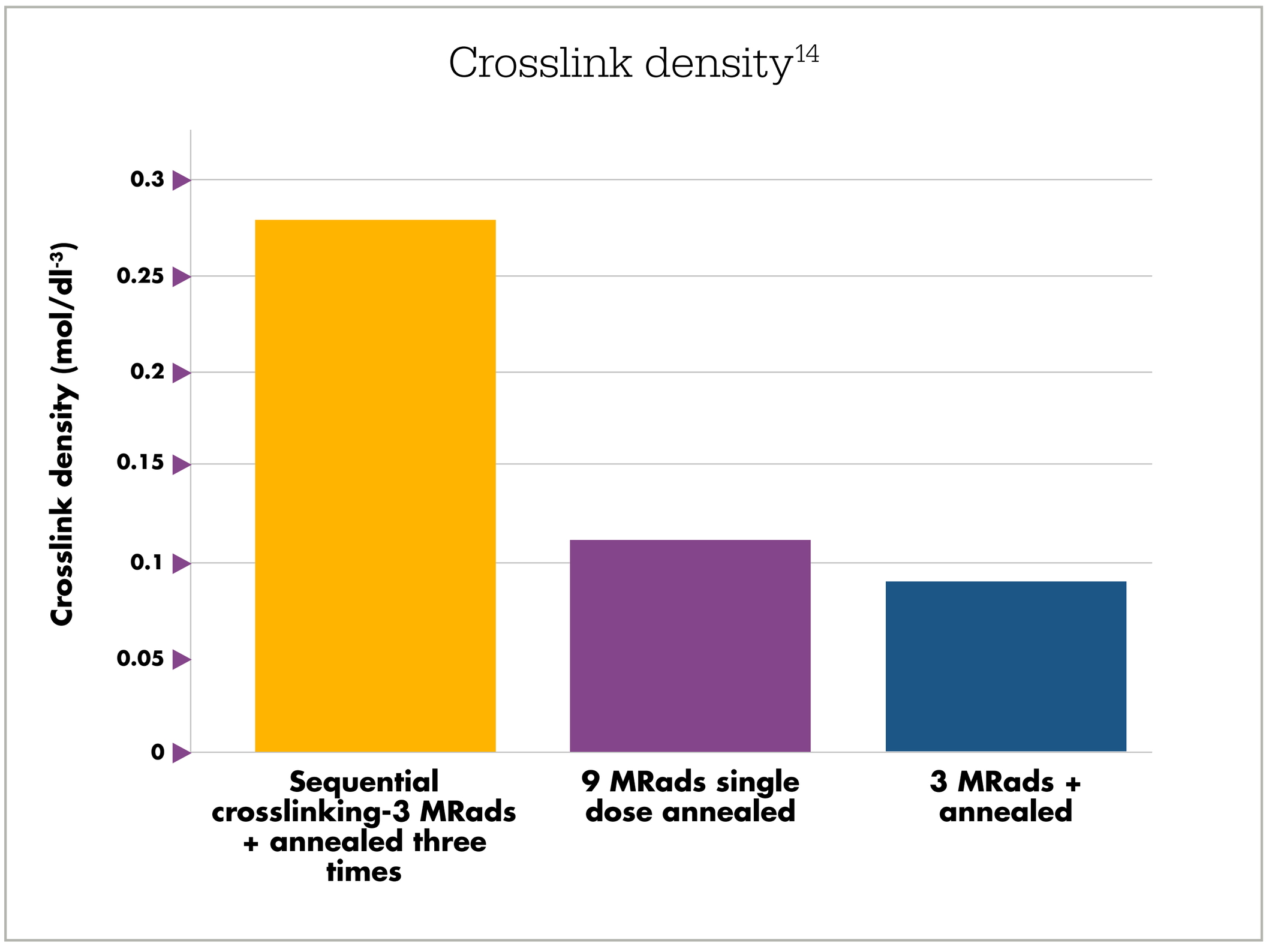
X3 polyethylene

Research has identified that the main objective for polyethylene innovation in orthopaedics is to reduce wear through crosslinking without sacrificing strength or oxidation.[19,33] X3's patented[50] sequential irradiation and annealing (heating below melting point) process (seen in the video below) has been shown to achieve this objective without the use of additives.[19,33]

Prior to 2018, any X3 data published included product manufactured using compression molding consolidation and gas plasma sterilization. In 2018, Stryker added ram extrusion consolidation and EtO sterilization capabilities to the X3 manufacturing process.

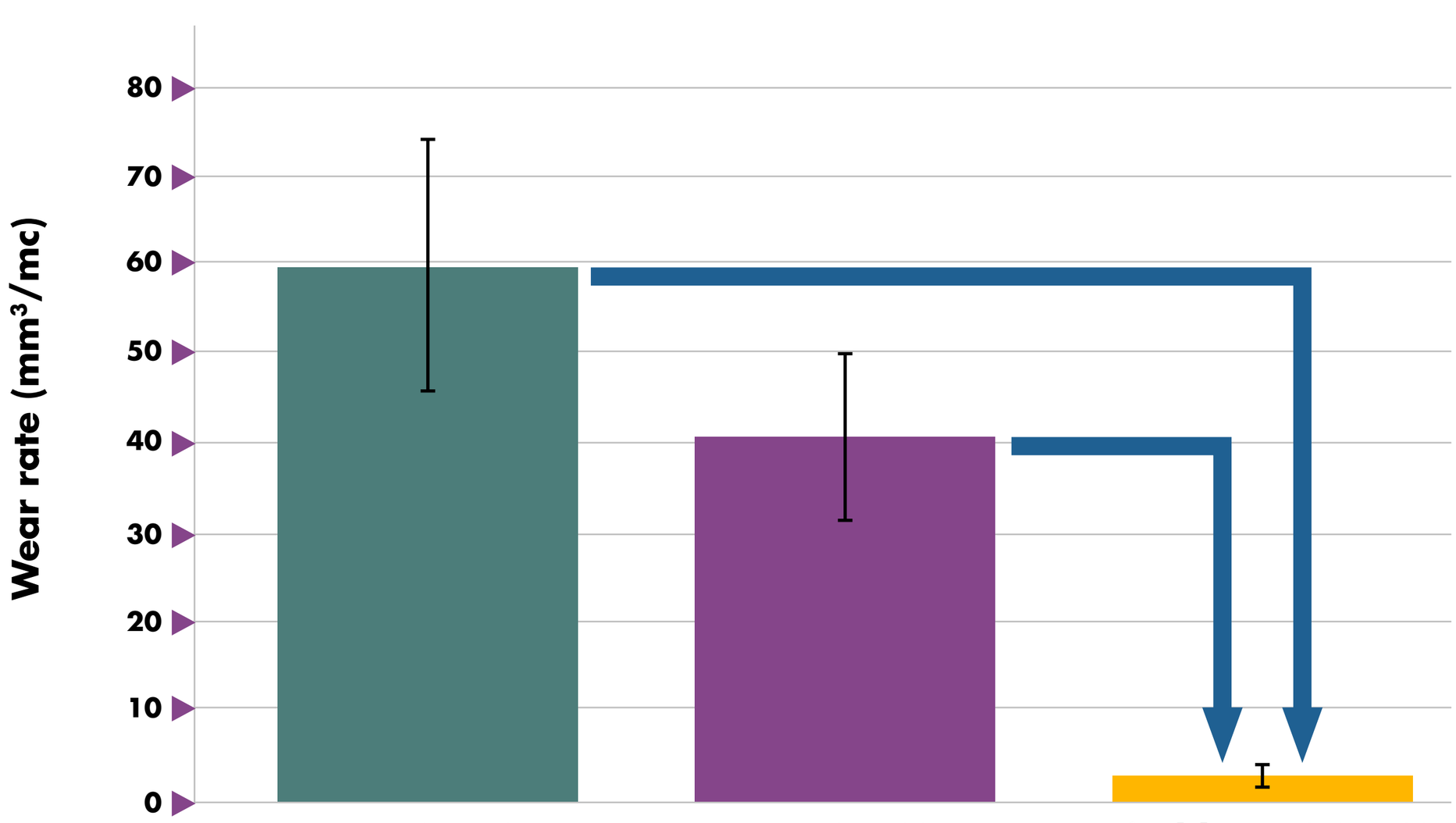
Wear resistance

Sequential irradiation provides greater crosslinking density versus a single dose as demonstrated in the chart below. The X3 process is a proprietary three-step process of irradiation with 3 MRads (total 9 MRads) of gamma radiation and annealing.[14]



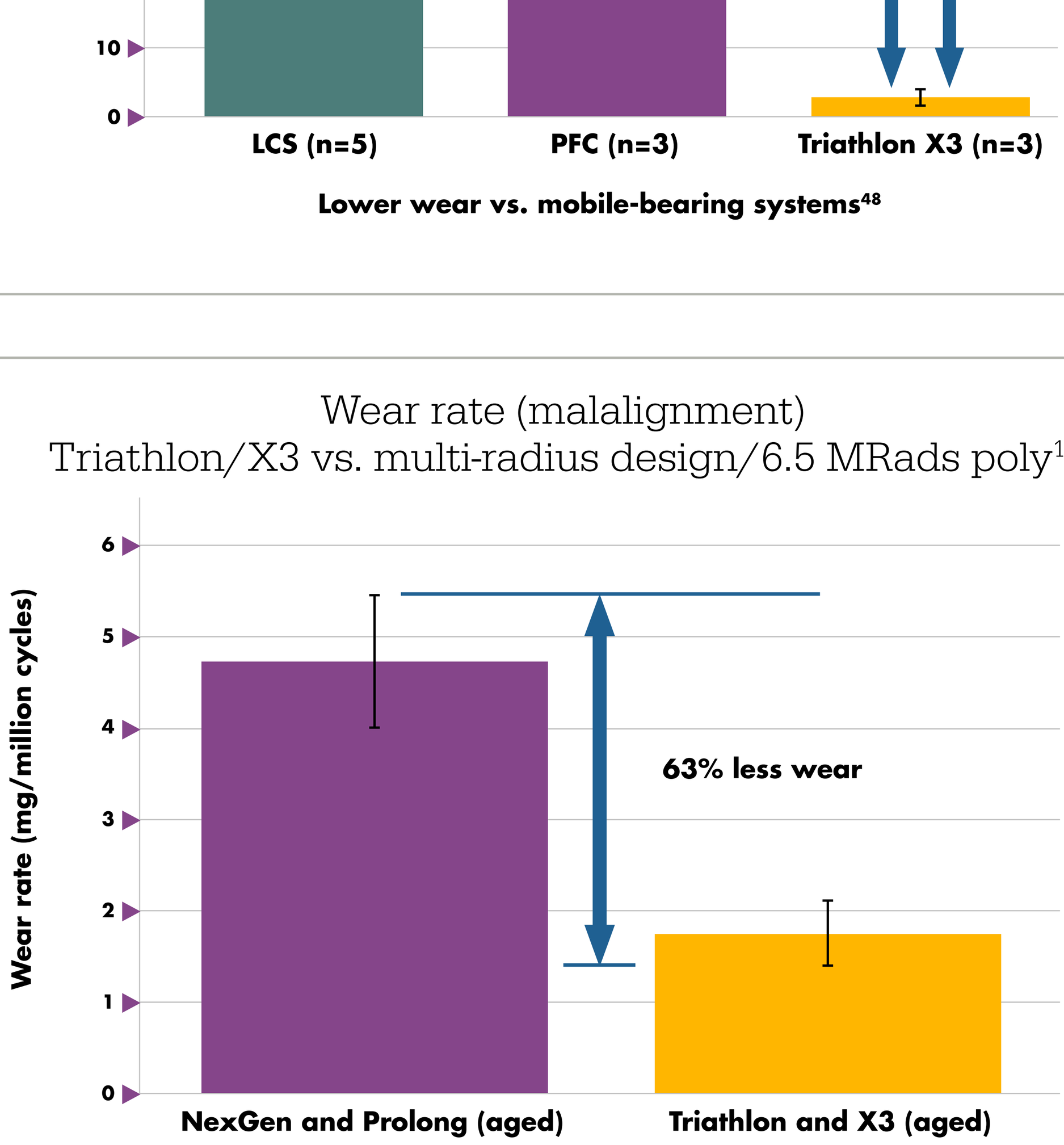
Wear rate

Triathlon/X3 vs. mobile-bearing devices[48]



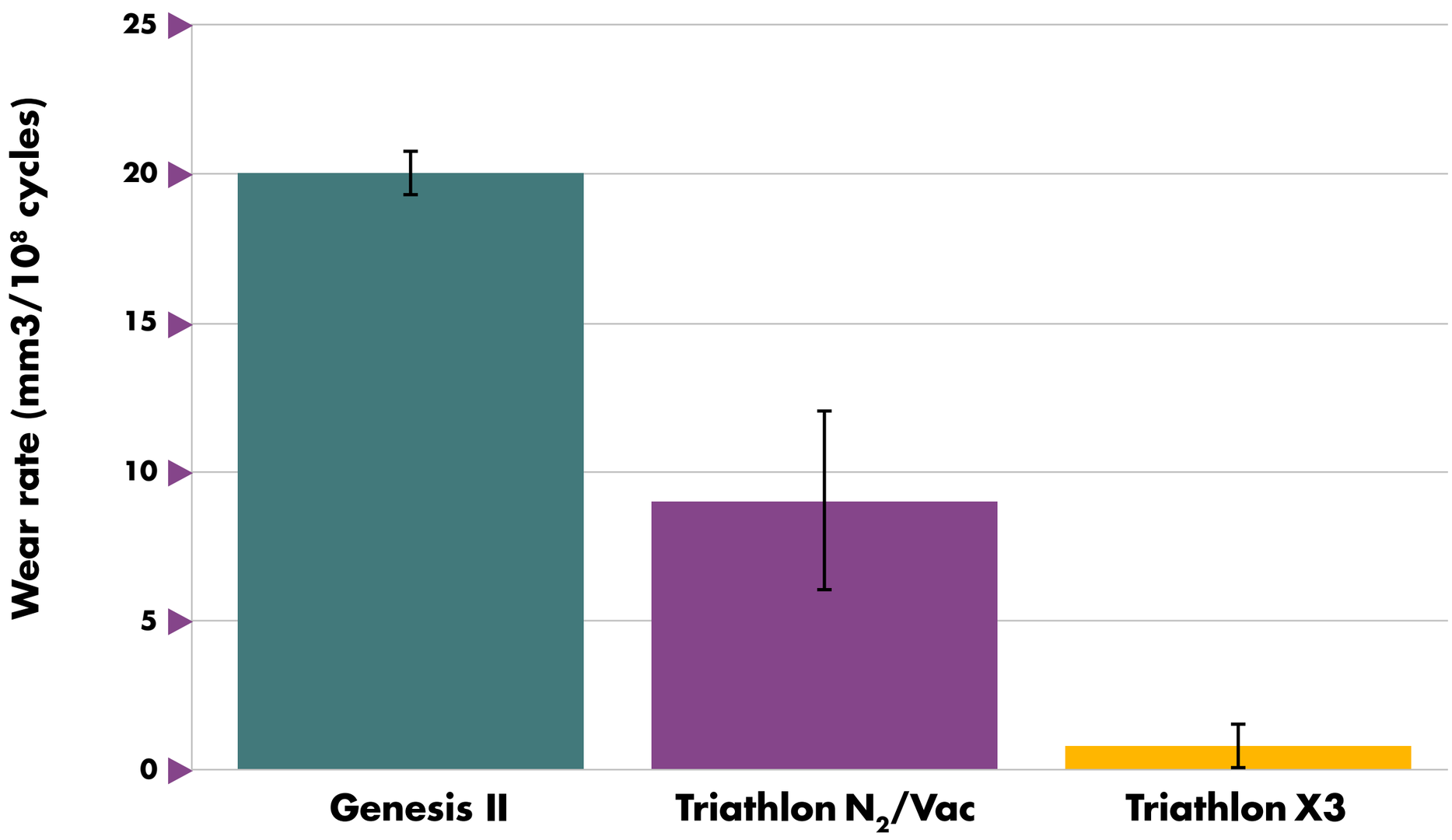
Lower wear vs. mobile-bearing systems[48]

Wear rate (malalignment)
Triathlon/X3 vs. multi-radius design/6.5 MRads poly[19]

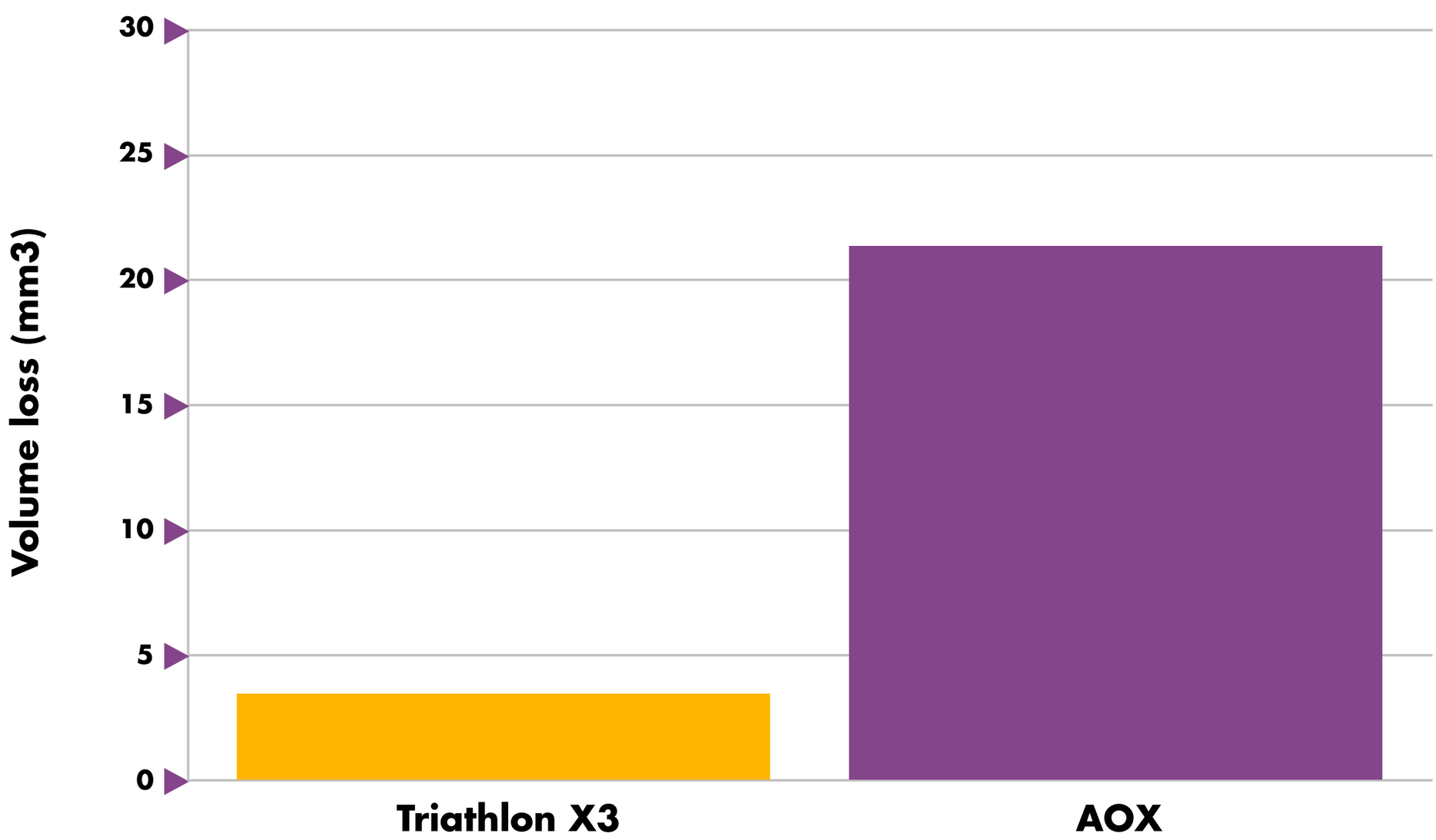


Lower wear vs. 6.5 MRads remelted insert[19]

Wear rates (aggressive stair climb) Triathlon vs. oxidized metal-bearing surface[88]



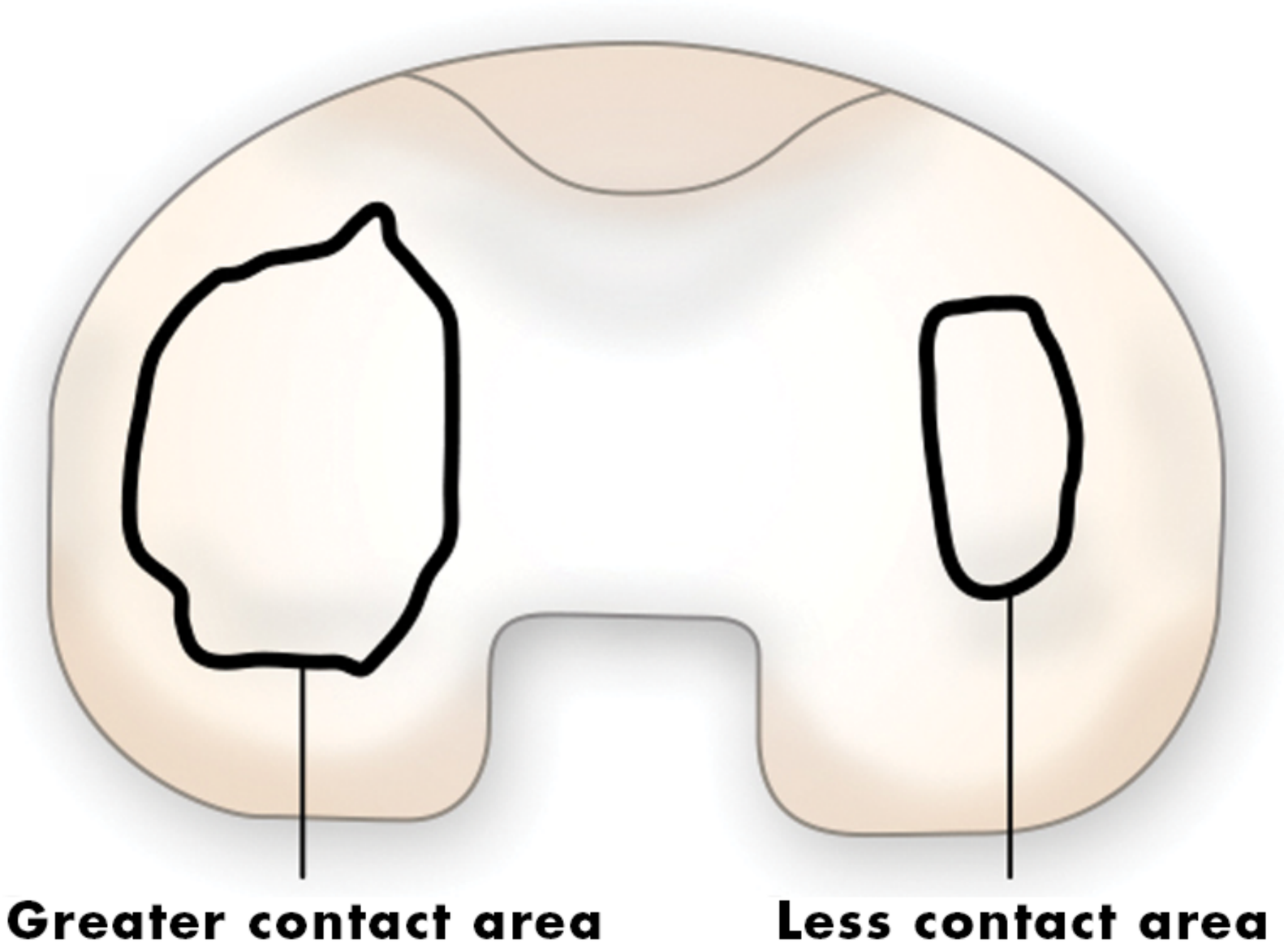
Volume loss (X3 vs. additive polyethylene)[121]



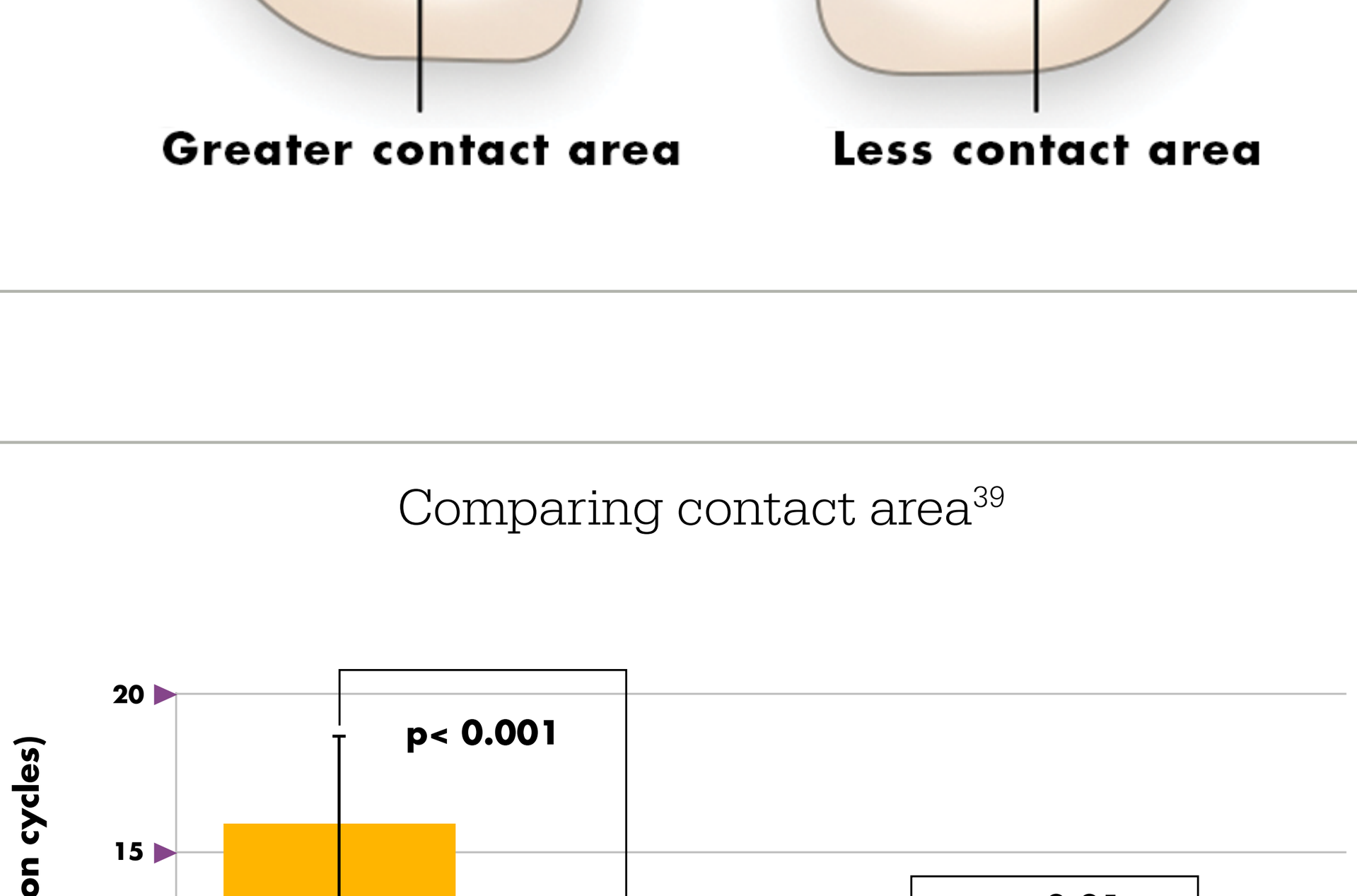
83% less wear with X3

Comparing contact area

Designs with smaller contact areas, like Triathlon,[40] have been shown to wear less than designs with larger contact areas.[39]

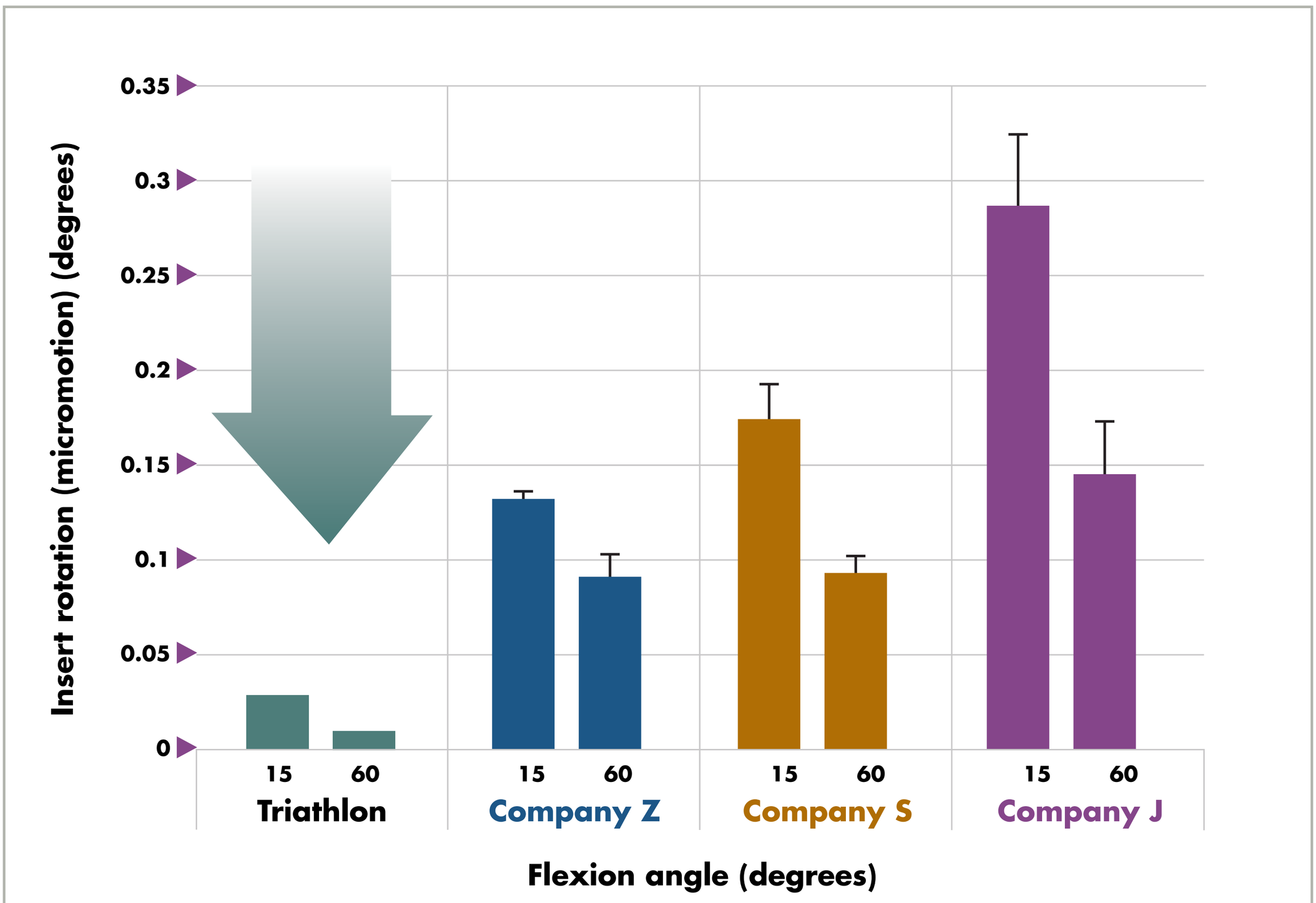


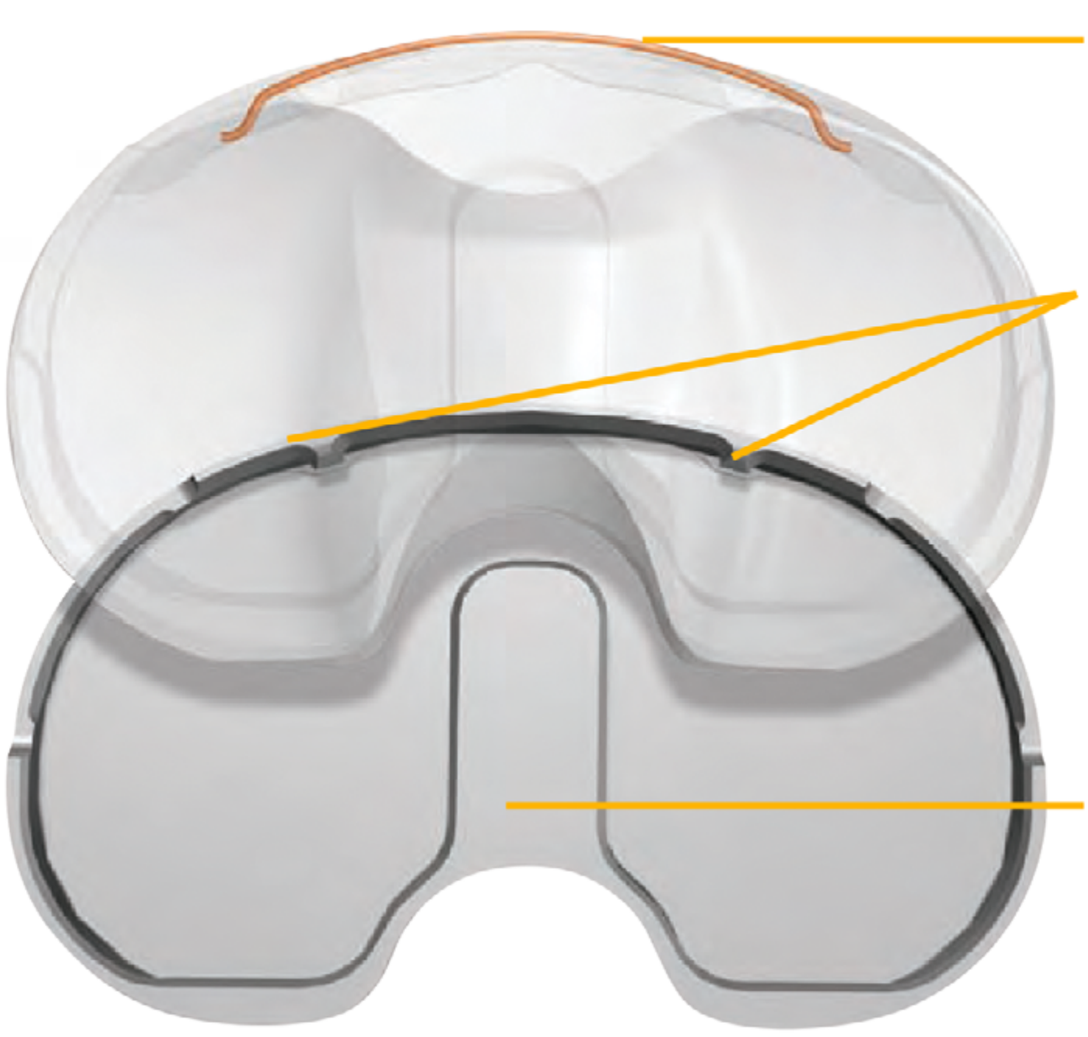
Comparing contact area[39]



Micromotion and backside wear

Micromotion is a factor that contributes to backside wear.[85] Triathlon's full periphery locking rim, locking wire and anti-rotation island have demonstrated less micromotion than other designs.[84]

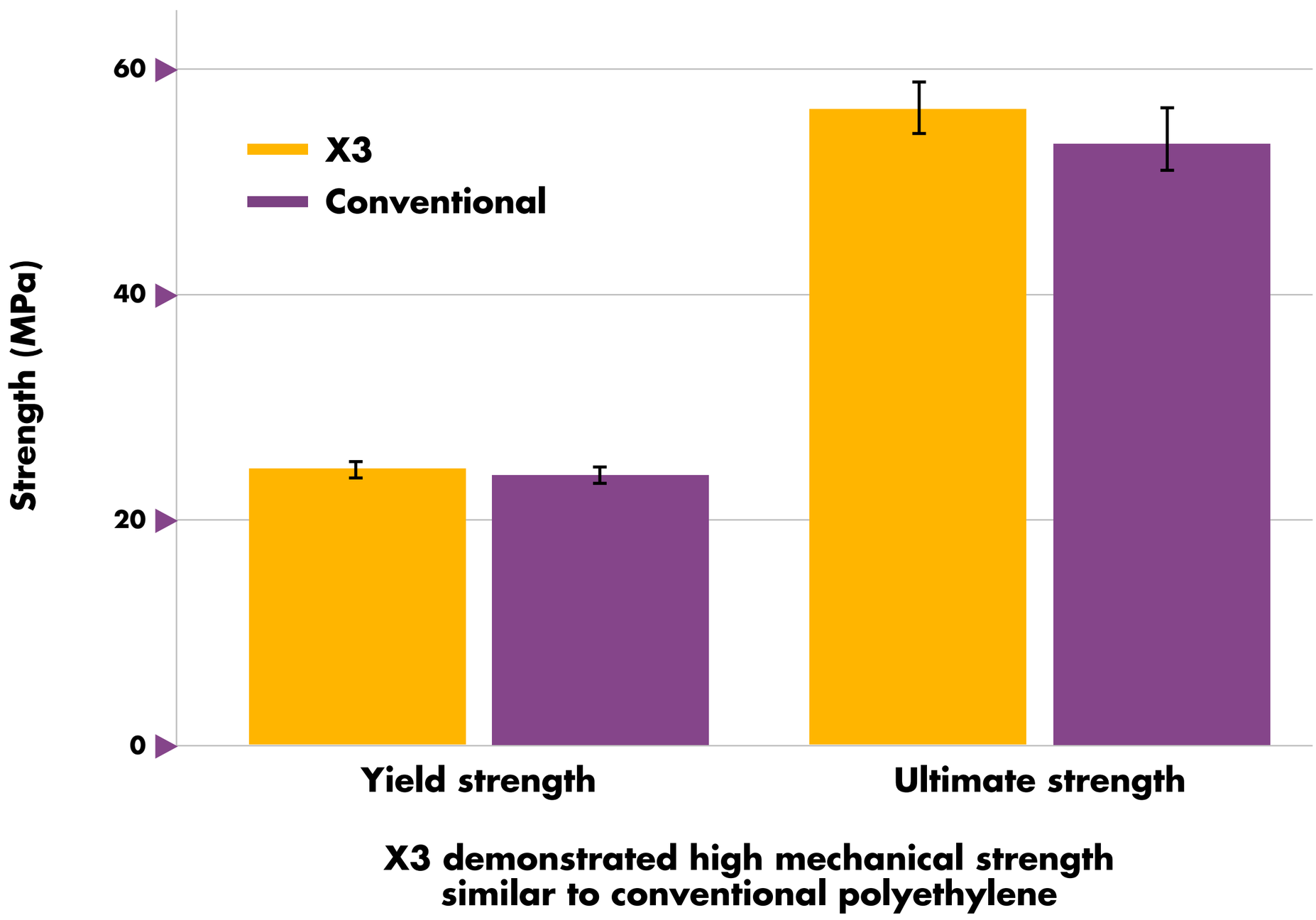




Mechanical strength

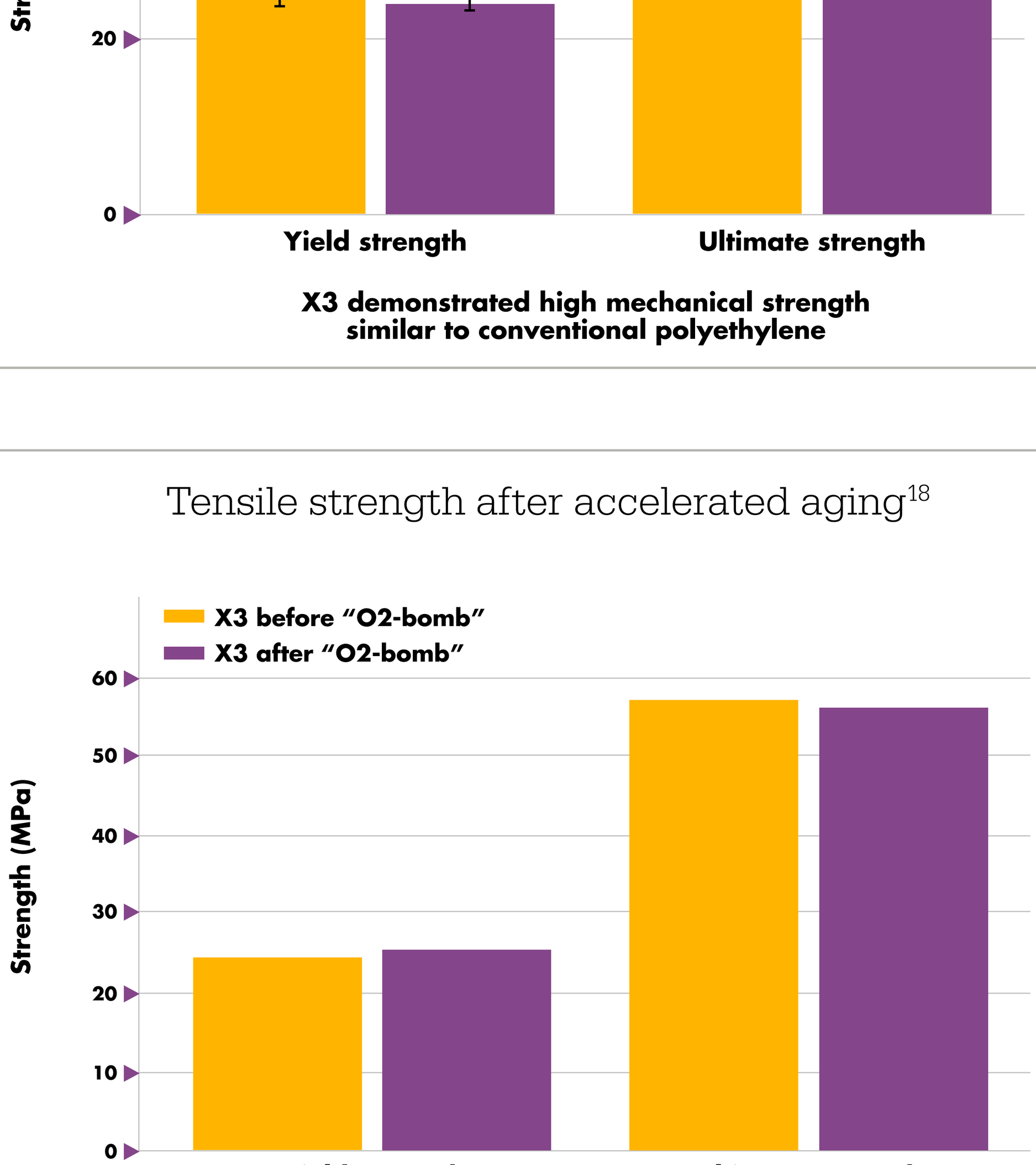
X3 is annealed, allowing it to maintain its mechanical strength.[33]

Tensile strength[33]



X3 demonstrated high mechanical strength similar to conventional polyethylene

Tensile strength after accelerated aging[18]



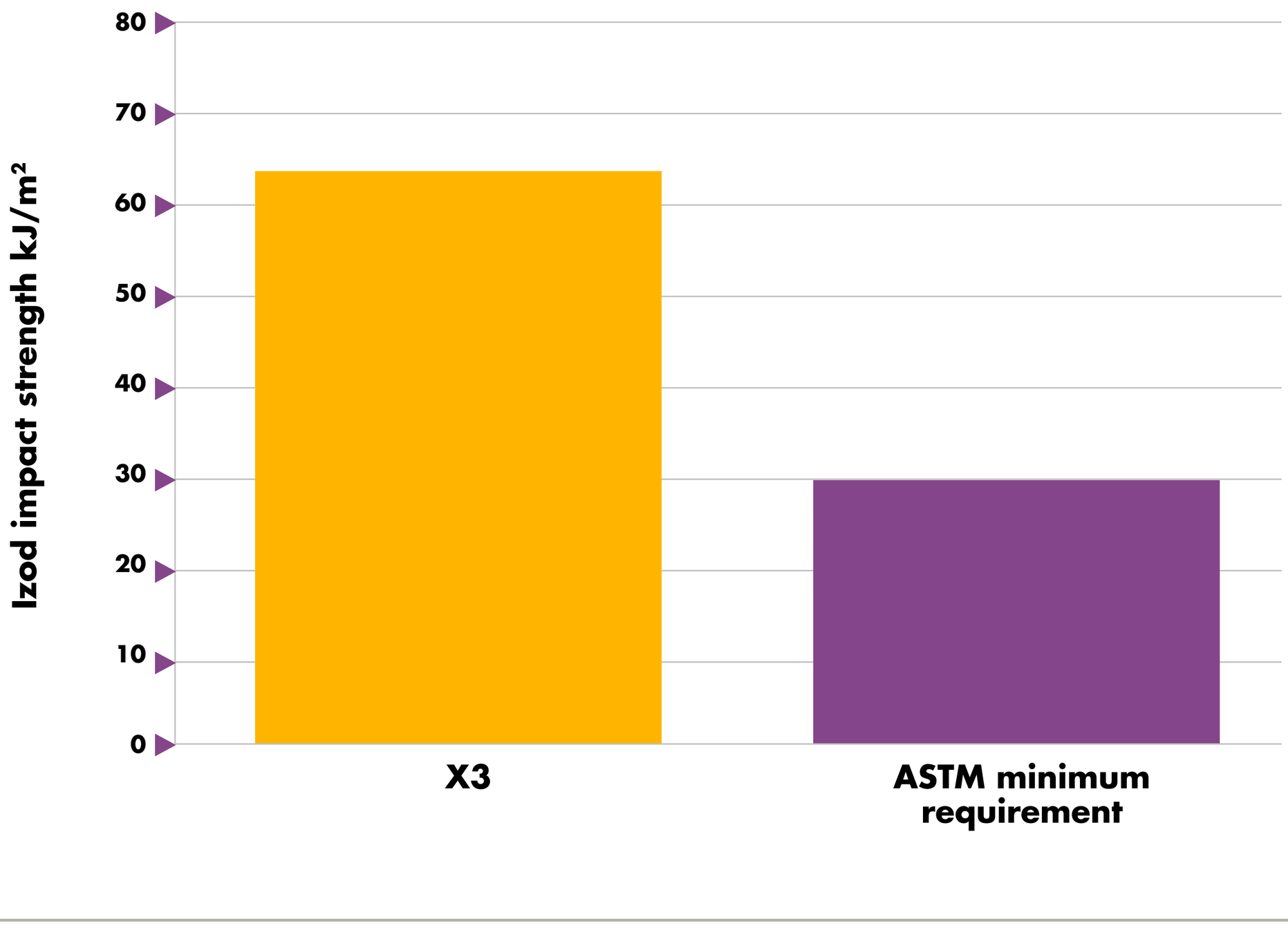
X3 maintained mechanical strength even after accelerated aging[18]

Impact strength

An accelerated aging simulation showed that wear and mechanical integrity of X3 PS inserts was unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum requirement for TKA.[18]

Meneghini et al. demonstrated no mechanical failure or osteolysis in patients who received a Triathlon PS device with X3.[86] Minimum follow-up was 5 years.

Fracture toughness[18]



Reported fracture of antioxidant insert

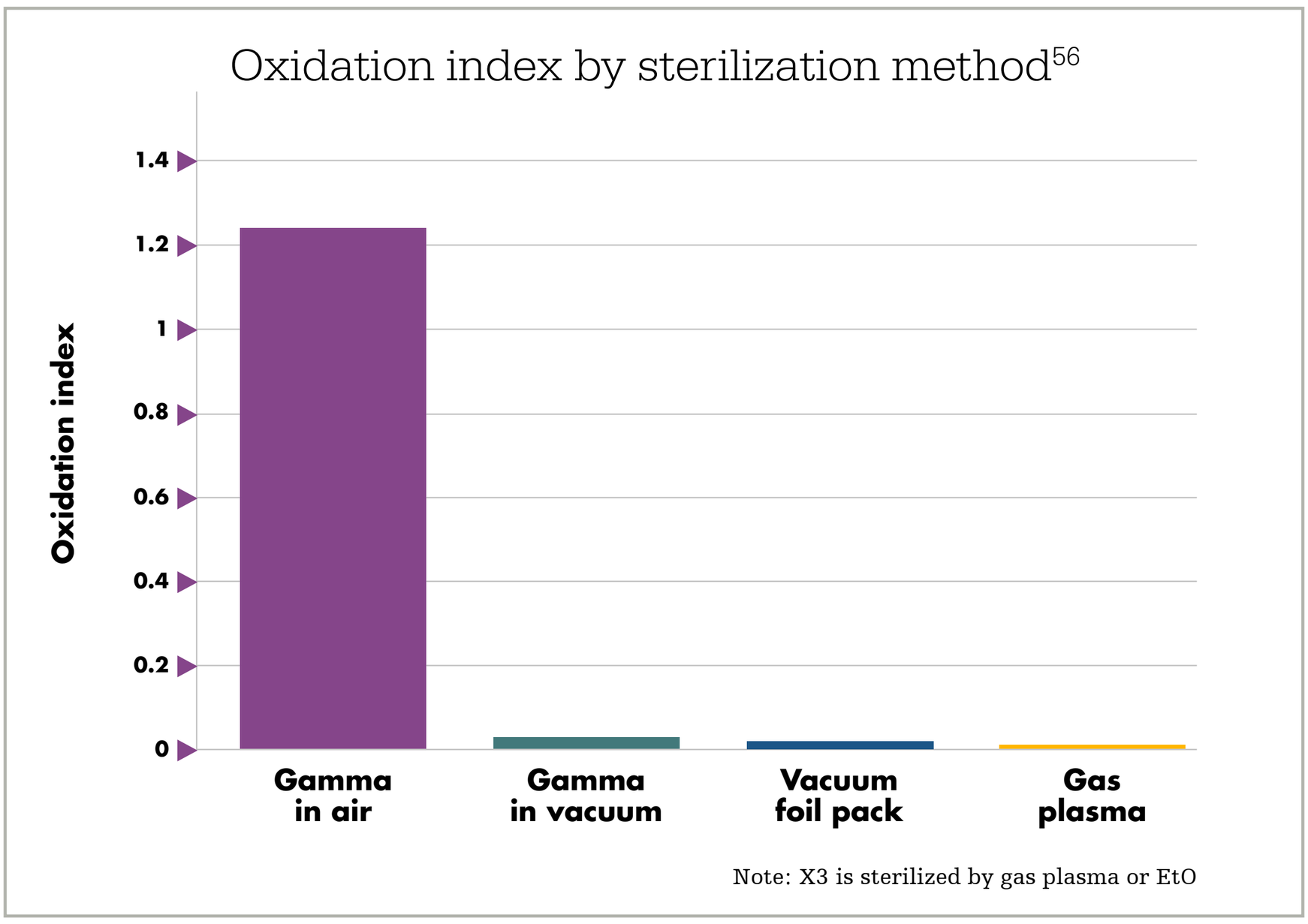
A 2013 case study was published on a fractured tibial insert with an additive antioxidant polyethylene. Analysis of the retrieved insert suggested that fracture was probably a combination of clinical and component factors. Component factors included:[81]

- 5.1mm minimum poly thickness
- Gross macromotion related to the locking mechanism, which has no peripheral capture
- Diminished material properties

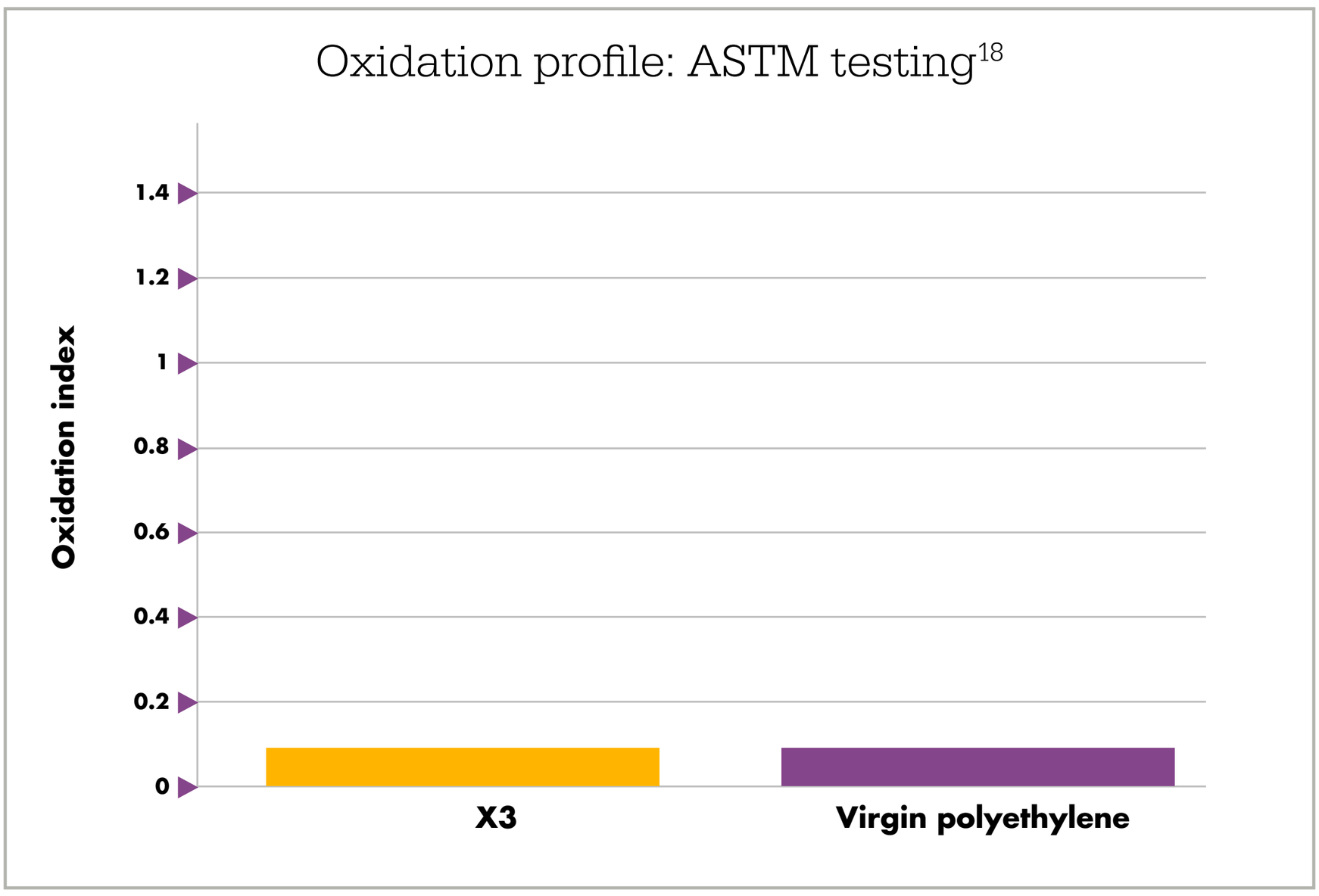
As with any new technology, additive polyethylene should be followed closely to understand any potential impact it may have.

Oxidation resistance

Multiple laboratory tests have confirmed that X3 virtually eliminates free radicals.[19,33] X3 oxidation resistance is similar to that of virgin polyethylene.[33] Real-time shelf-life [five years] testing also demonstrated no change in free radical content over time.[82]



X3 is sterilized in either gas plasma or EtO. As depicted in the above graph, one study showed that polyethylene inserts sterilized in gas plasma yielded the lowest oxidation index in comparison to other current sterilization methods.[56] In a separate study of twenty retrieved knees that were implanted for 0.5-10 years, EtO-sterilized polyethylene inserts showed a low average oxidation index of 0.08 and stable oxidative properties.[135]



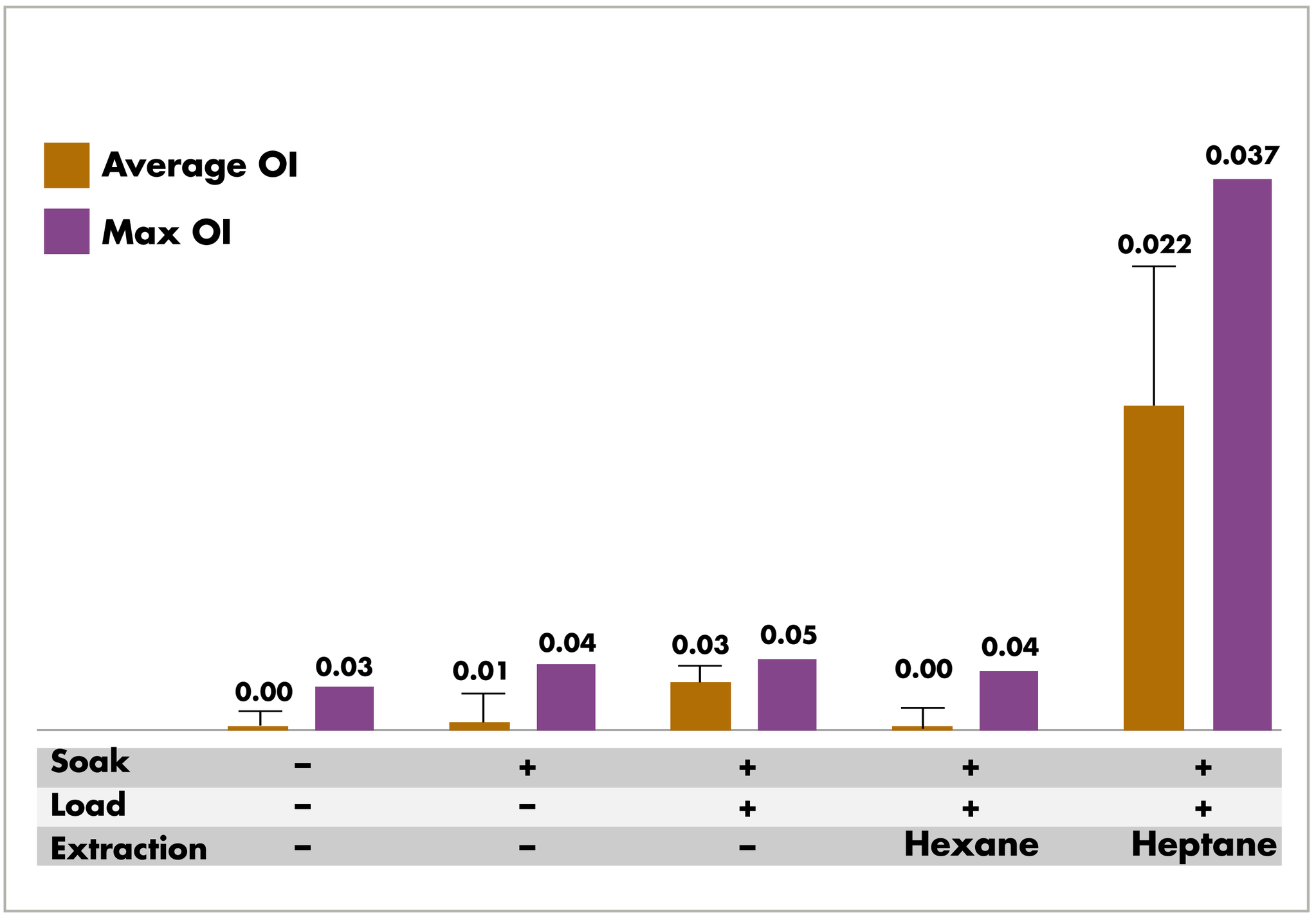
Kurtz et al. studied the largest cohort of X3 retrievals commissioned for any published study to date, showing that X3 exhibits a similar profile for oxidation in vivo to conventional polyethylene. None of the inserts examined in the study were subject to mechanical failures related to oxidative damage.[134]

Discoloration

Investigations into polyethylene retrieval testing have helped to clarify the potential causation of discoloration, oxidation index and white bands. Discoloration seen on retrieved polyethylene may be attributed to residual absorbed body fluids. The image below depicts the results of a test demonstrating reduction in discoloration of a retrieved X3 insert over the course of three weeks in an environment of regular ambient light.[65]

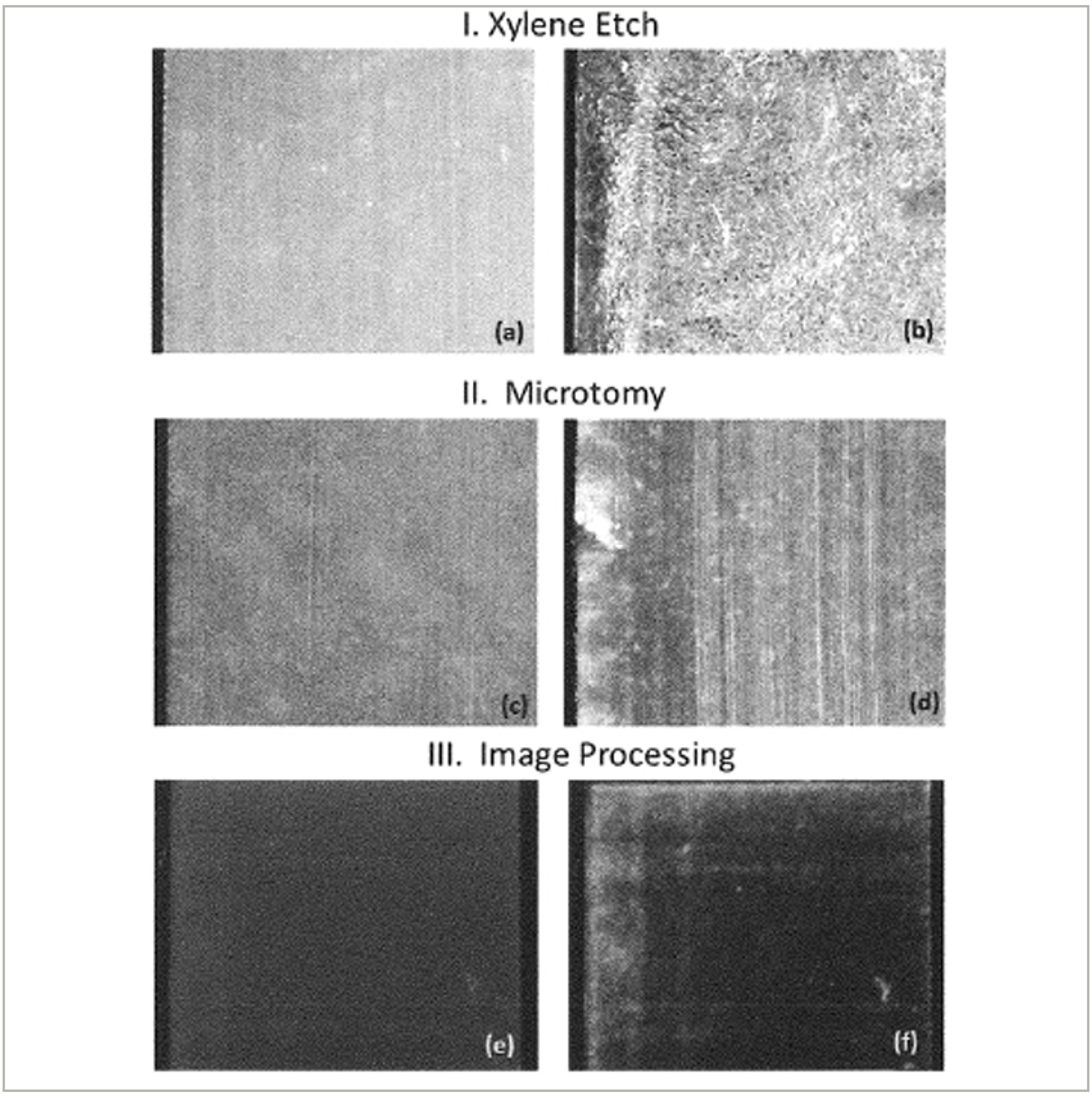
Oxidation index

Some researchers have published on the presence of oxidation on polyethylene retrievals.[57,58] The test methods used by these retrieval centers have been called into question.[47] Data supports that the test methods used by institutions like Dartmouth[58] and Massachusetts General Hospital[57] can even induce oxidation when using extraction solutions such as heptane.[47]



White bands

Evidence also supports that the way retrieval specimens are cross sectioned and processed can create the appearance of white bands.[126] The images below show how variables within different steps of the retrieval process can cause the appearance of white bands.



What issues are antioxidants trying to solve?

In an effort to reduce the residual free radicals that could lead to oxidation, many traditional polyethylenes were remelted. Remelting has been shown to improve oxidation resistance, however remelting has also been shown to decrease strength.[34]

Today, some polyethylenes are manufactured with antioxidant additives.[35,36] In doing so, these polyethylenes avoid the remelting process that reduces mechanical strength.[34] Antioxidant additives are used in an attempt to address concerns over the reduced mechanical strength of remelted polyethylenes.[46] There is no clinical evidence to support that new antioxidant additive polyethylene provides superior oxidation resistance.

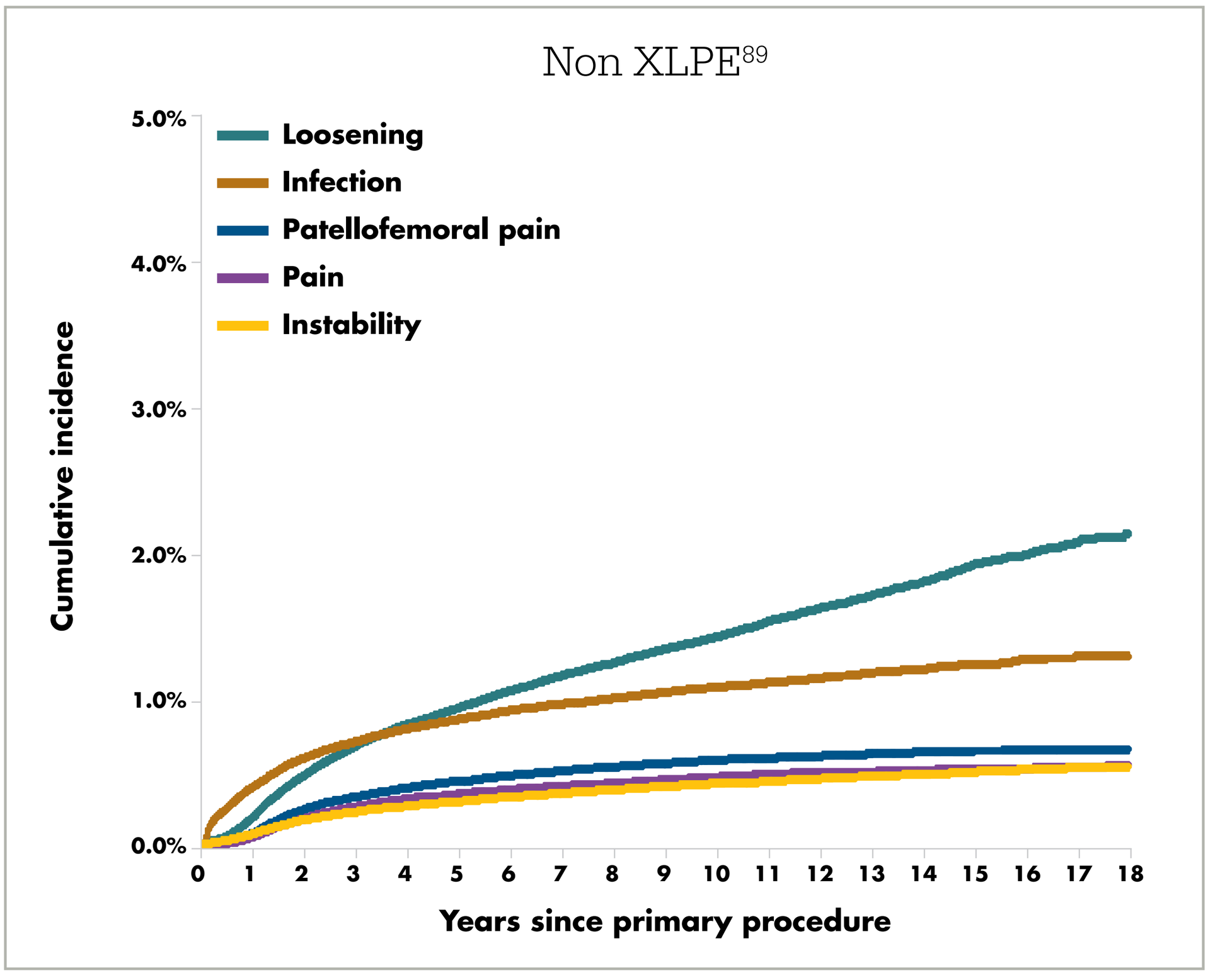
Here are results of competitors' prior attempts to incorporate additives in polyethylene:

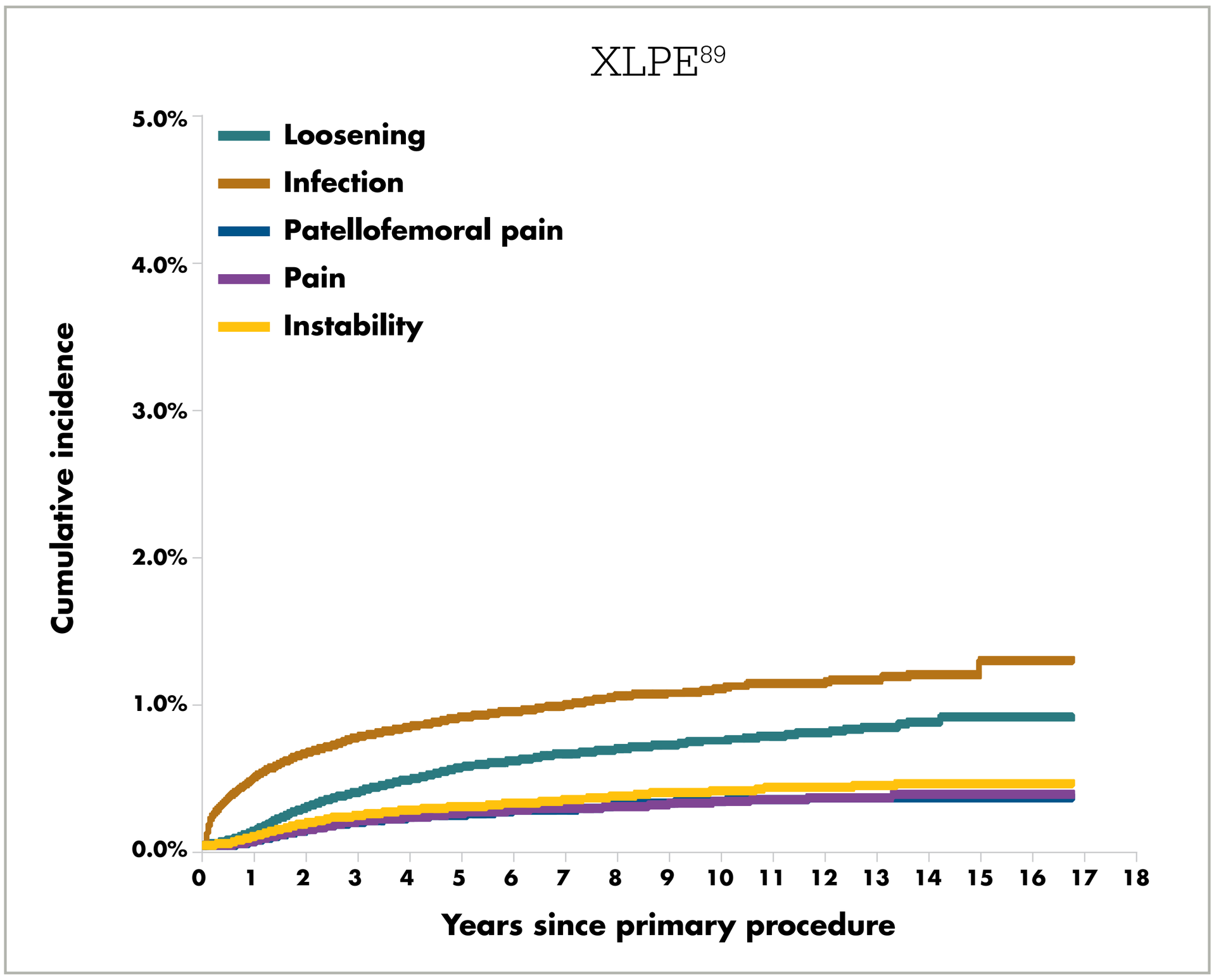
- Carbon fiber[38] – A carbon fiber additive was intended to improve wear and mechanical strength characteristics. It was later discovered that the additive was associated with polyethylene damage including fibers pulled from the surface, broken fibers and polyethylene removed from the surface fibers.
- Calcium stearate[51] – One study showed that a calcium stearate additive in polyethylene induced bone resorption and promoted inflammation.
- Vitamin E[37] – In a lab test, vitamin E was confirmed to leach from inside of vitamin E-blended polyethylene.

Revision rates based on polyethylene type

The Australian Joint Registry data (shown below) shows there is potential long-term benefit in preventing loosening using HXLPE compared to non-HXLPE.[89] The registry also reports there is an increase in survivorship at 10 years with Triathlon PS and X3 compared to non-HXLPE, with a sample size of thousands of patients.[89]

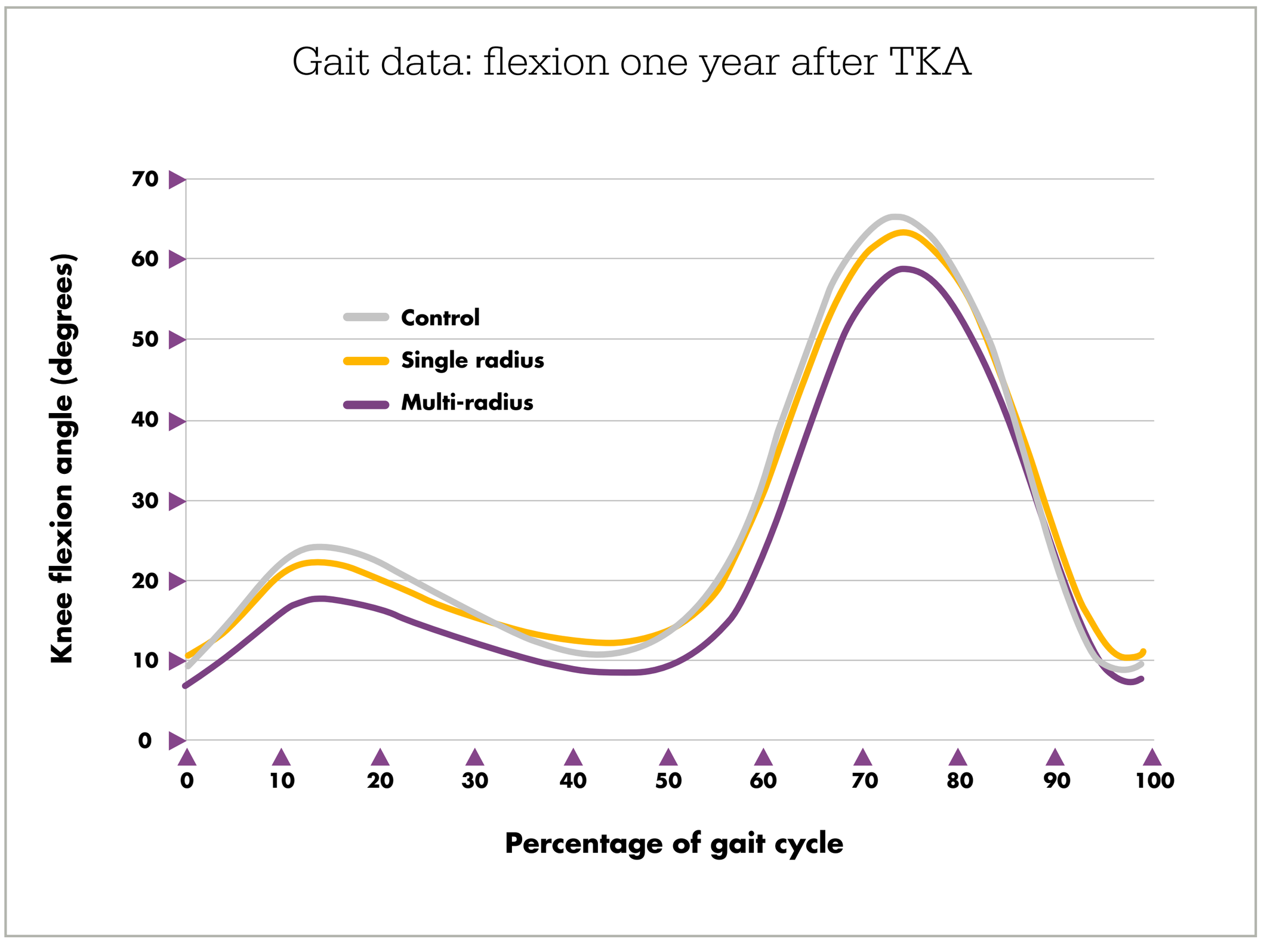
Furthermore, it has been demonstrated that X3 may be especially beneficial for younger and heavier patient populations. One study comparing X3 to conventional polyethylene showed that X3 had a significantly better survival rate among patients who were younger than 60 years old and/or had a BMI greater than 35.[138]




XLPE[89]
5.0%
4.0%
3.0%
2.0%
1.0%
0.0%
Cumulative incidence
Loosening
Infection
Patellofemoral pain
Pain
Instability
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
Years since primary procedure

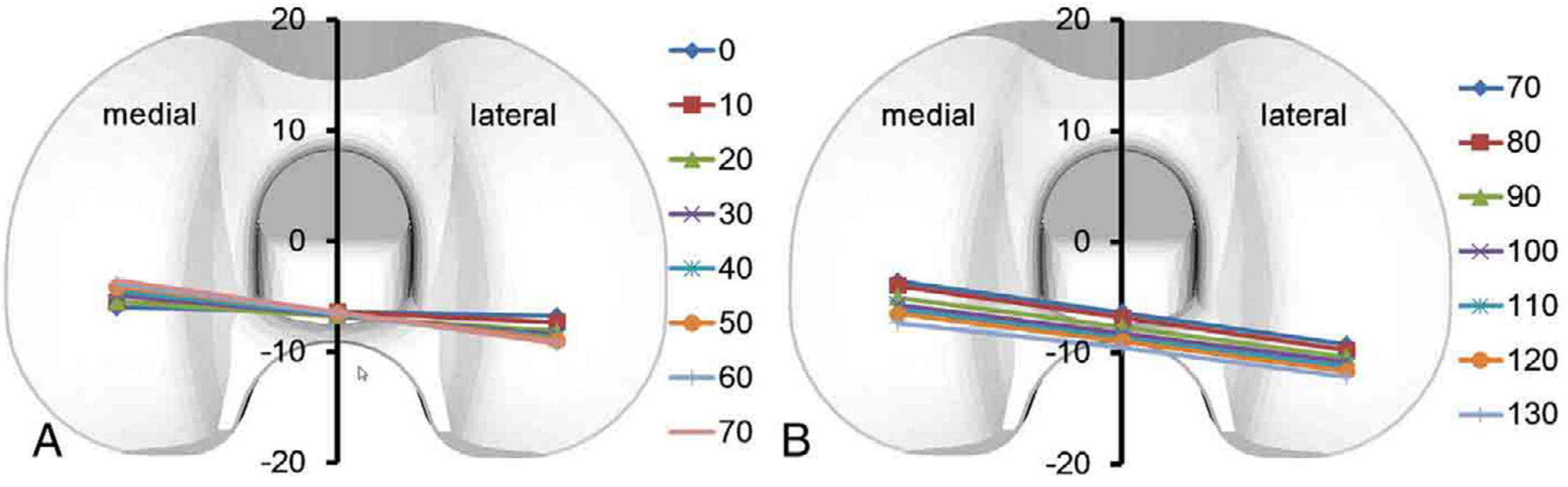
Gait

A 2015 gait investigation comparing patients with a single or multi-radius knee showed that patients with a single radius knee experienced gait patterns that more closely mimicked that of the non-diseased control group while the multi-radius knee group differed in important knee kinetic and kinematic properties.[82]



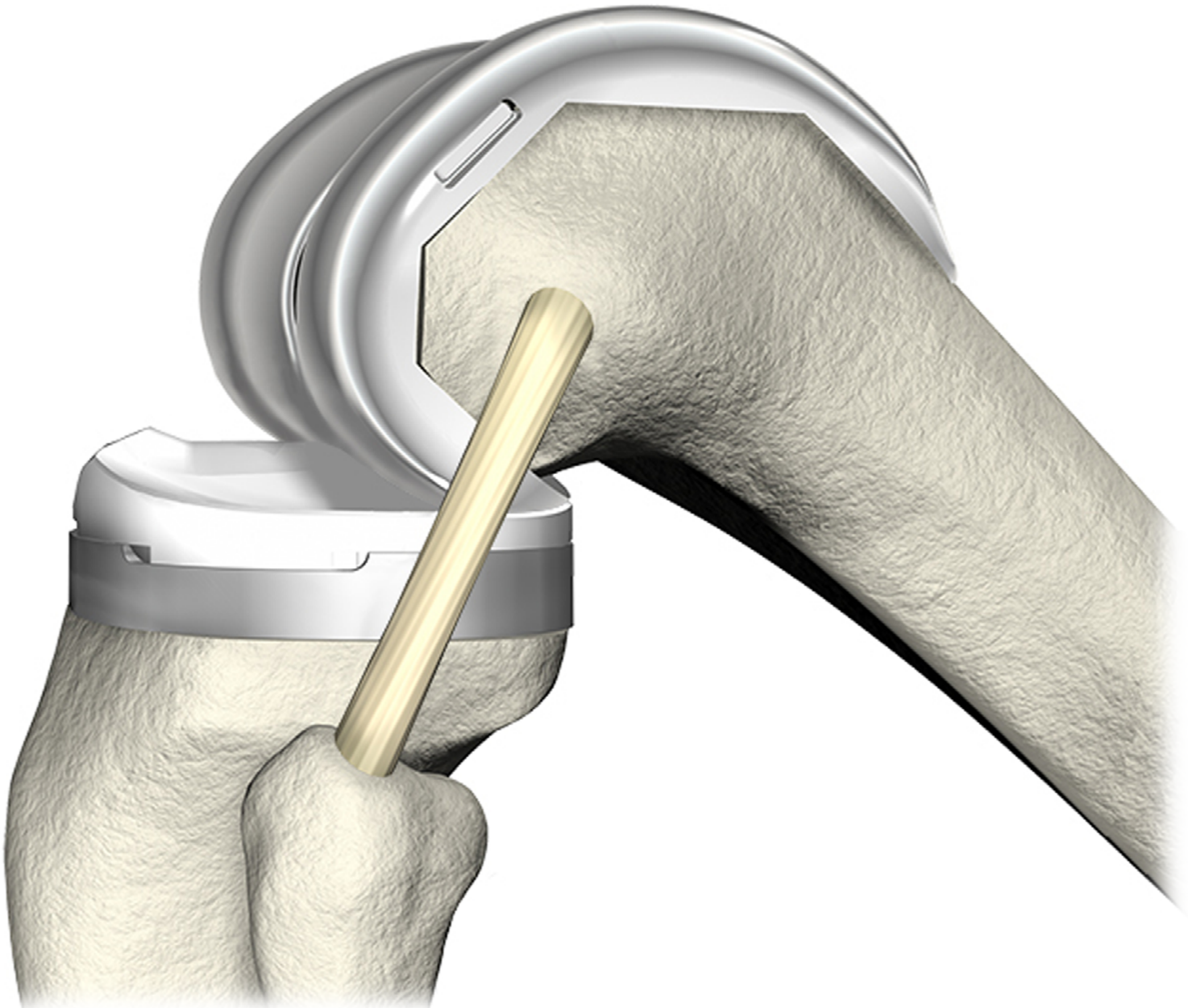
Pivot

Fluoroscopic data showed that Triathlon allows for medial pivot without features that drive a medial pivot.[107]



Deep flexion

Triathlon is designed to accommodate up to 150º of deep flexion.[28] This is achieved through the interaction of the shortened, flared posterior condyles and rotary arc. The flared posterior condyles[7] and the rotary arc[6] are designed to accommodate up to 20º of internal/external rotation. The shortened posterior condyles are designed to facilitate the relaxation of the soft tissues.[6] The recommended tibial slope for Triathlon is no more than 3º.[68] A 2014 publication showed that in TKA revised for flexion instability, the average pre-revision slope was approximately 7º.[129]

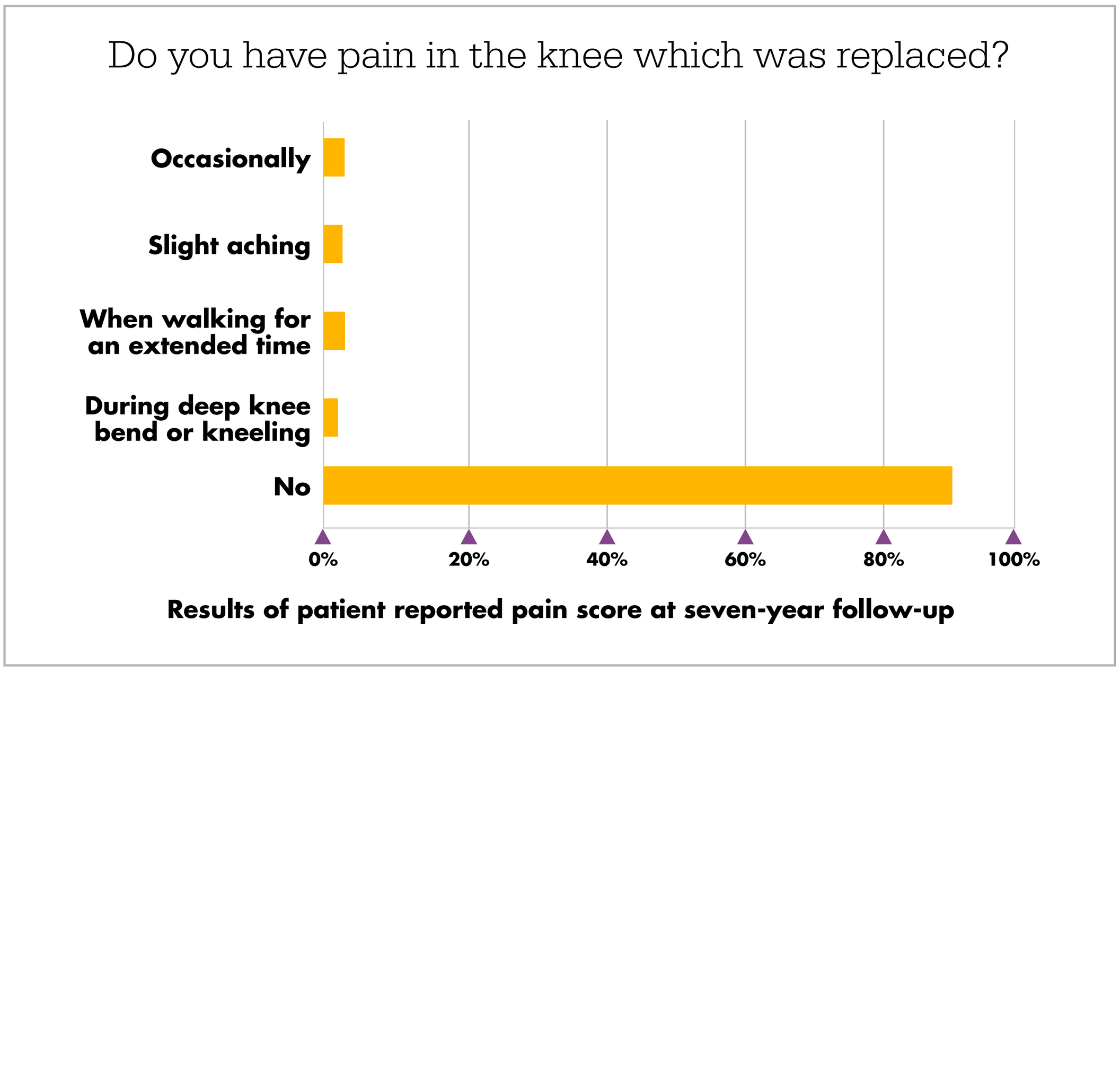


Hyperextension/extension

Triathlon is designed to allow for +/- 10º of rotation in hyperextension and extension.[44] In these early degrees of motion, Triathlon has demonstrated less post impingement and torque forces than other designs.[44]

Pain scores

An investigation of Triathlon patients showed a high level of satisfaction, as evidenced by their patient-reported pain scores. This level was maintained at seven years.[132]



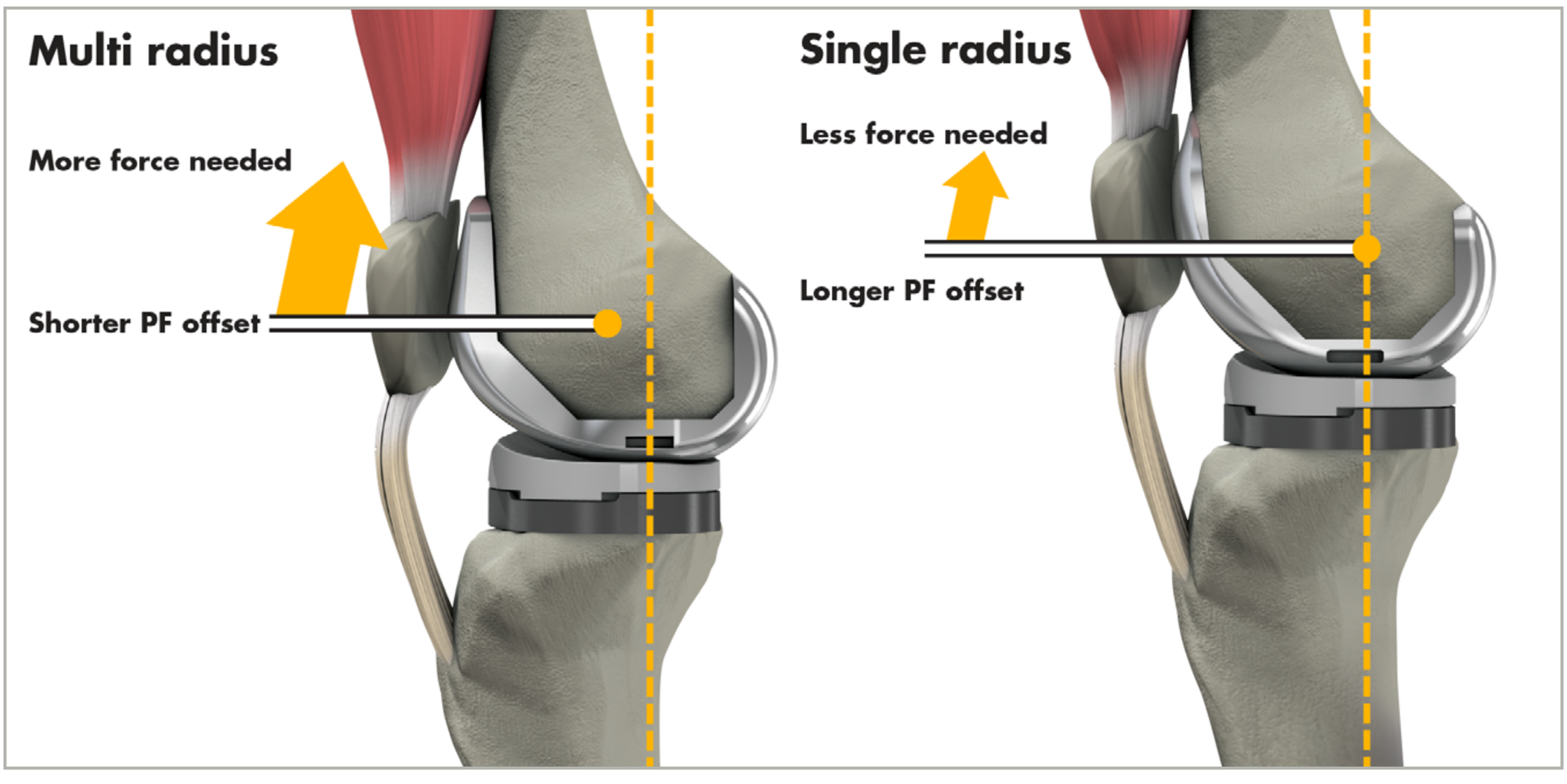
Results of patient reported pain score at seven-year follow-up

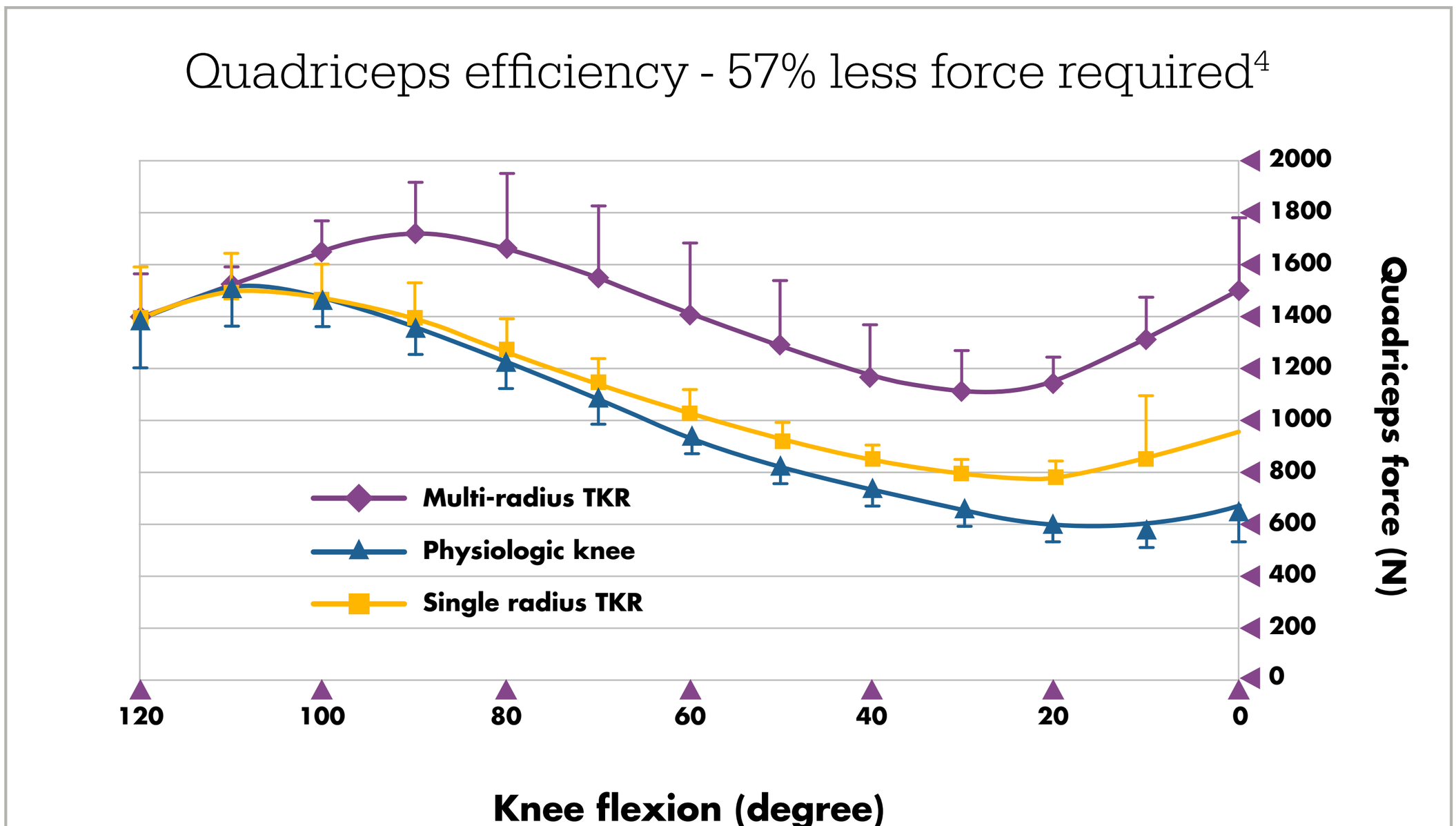
Recovery

Triathlon's single radius design allows for greater quadriceps efficiency in extension.[4] Given the quadriceps' role in mobility, any undue strain may have an impact on recovery time. The single radius design may also allow for enhanced function by a reduction in the muscle work required to achieve the same level of activity.[128]

Studies on Stryker's single radius knee systems have shown:

- Fewer physiotherapy sessions[1]
- Less use of assistive devices[1,26]
- Greater muscle function in mid-flexion[128]
- Less need for muscle compensation in sit-to-stand activity[3]





Studies and registries

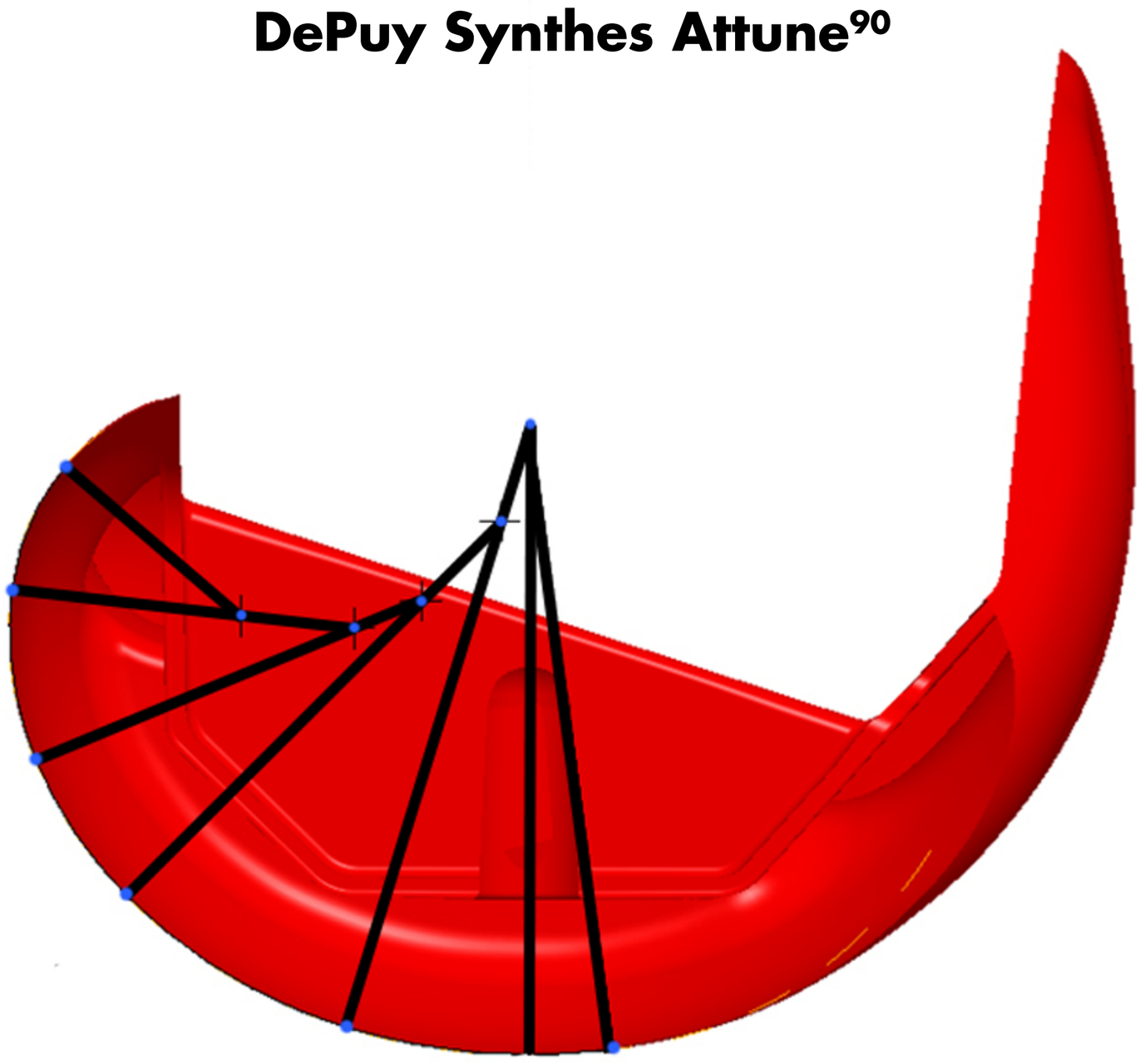
Multiple studies[80,111] and joint registries[5,89] from around the world consistently show a high rate of survivorship with Triathlon.

Source	Survivorship
2019 Australian Orthopaedic Association National Joint Replacement Registry[89]	96.3% (CR), 94.7% (PS) at 10 years (including infection)
2019 National Joint registry (U.K./Wales)[5]	96.4% at 13 years (including infection)
Mistry et al.[80] 2016	99.0% at 10 years (including failure for all cause)
Scott et al.[111] 2019	97.9% at 10 years

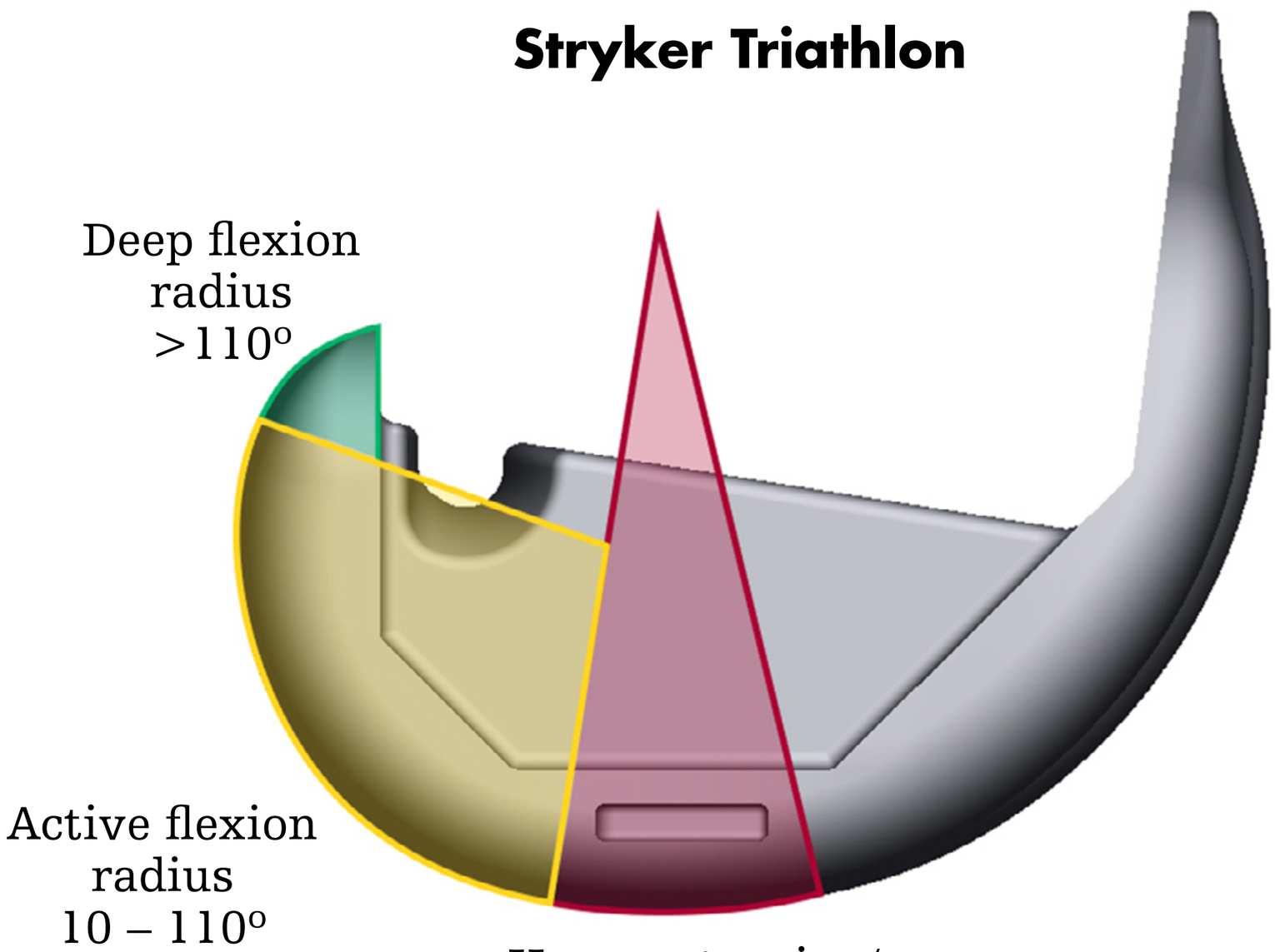
Femoral geometry

The single radius is designed to restore the knee's single center of rotation during active flexion.[21,22] This allows for constant ligament tension and stability in flexion.[2,26,82,107]

DePuy Synthes Attune[90]



Stryker Triathlon



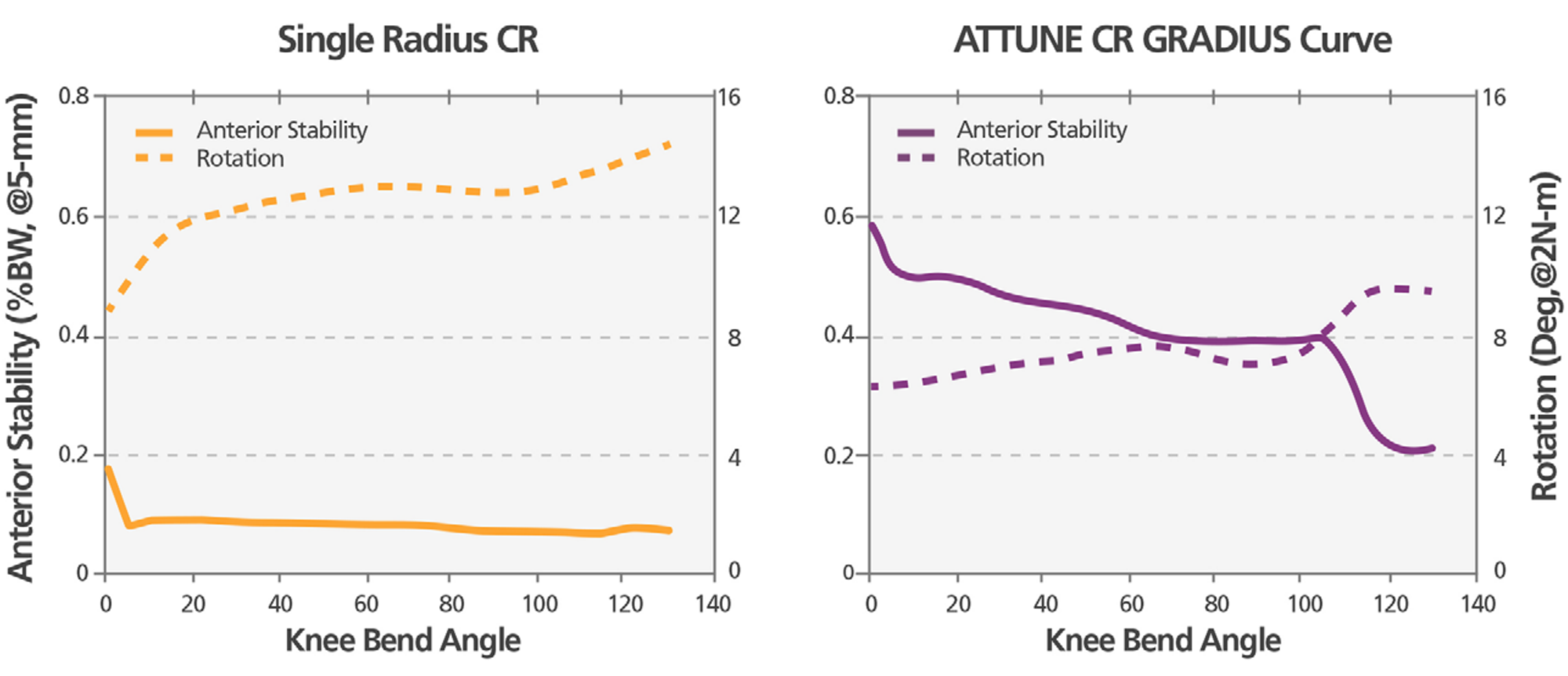
Potential contradictions in DePuy materials

Many of the past references that DePuy had used to draw comparisons to Triathlon were simulations and lab tests. Clinical studies on Triathlon and the single radius have been published for years and offer a more clinical perspective of Triathlon patient outcomes.

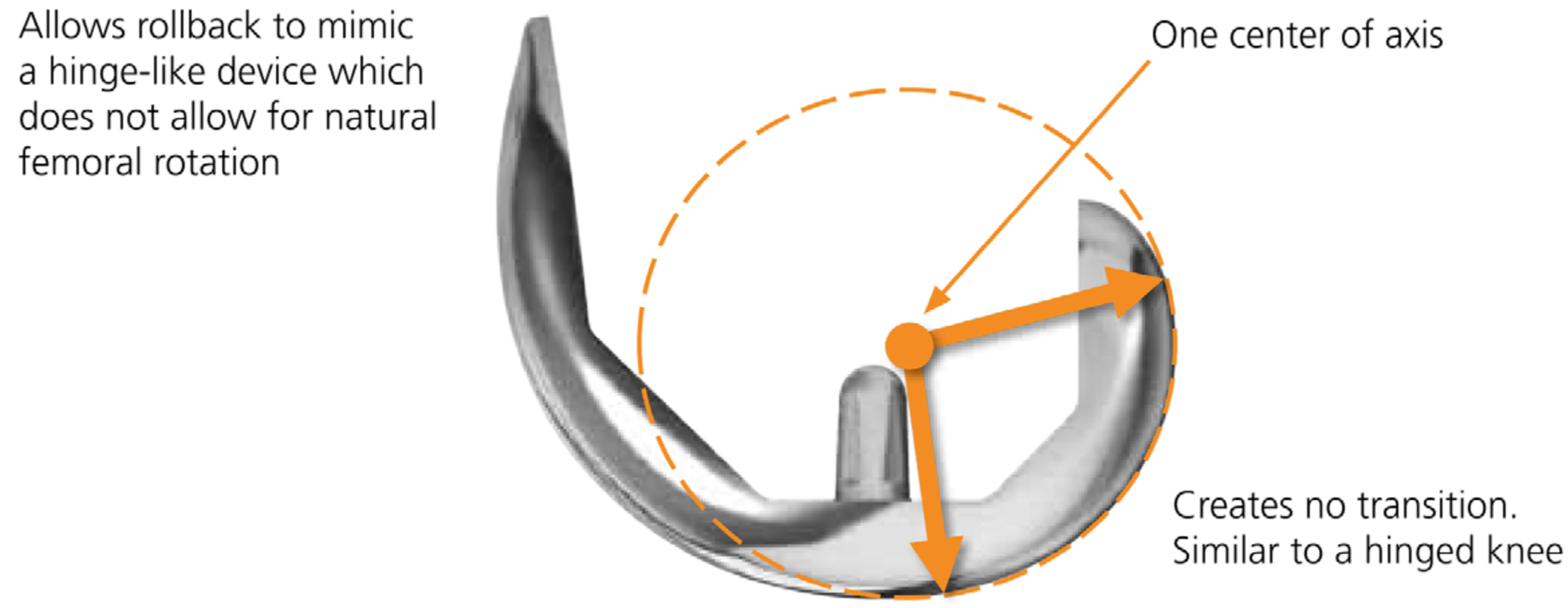
A closer look at past marketing materials that Depuy previously used reveals some contradictions that should raise some questions about their data.

Stability – which one is "correct"?

Claim 1: This chart from a past Attune brochure suggested that Triathlon allows for more rotation than Attune.[96]



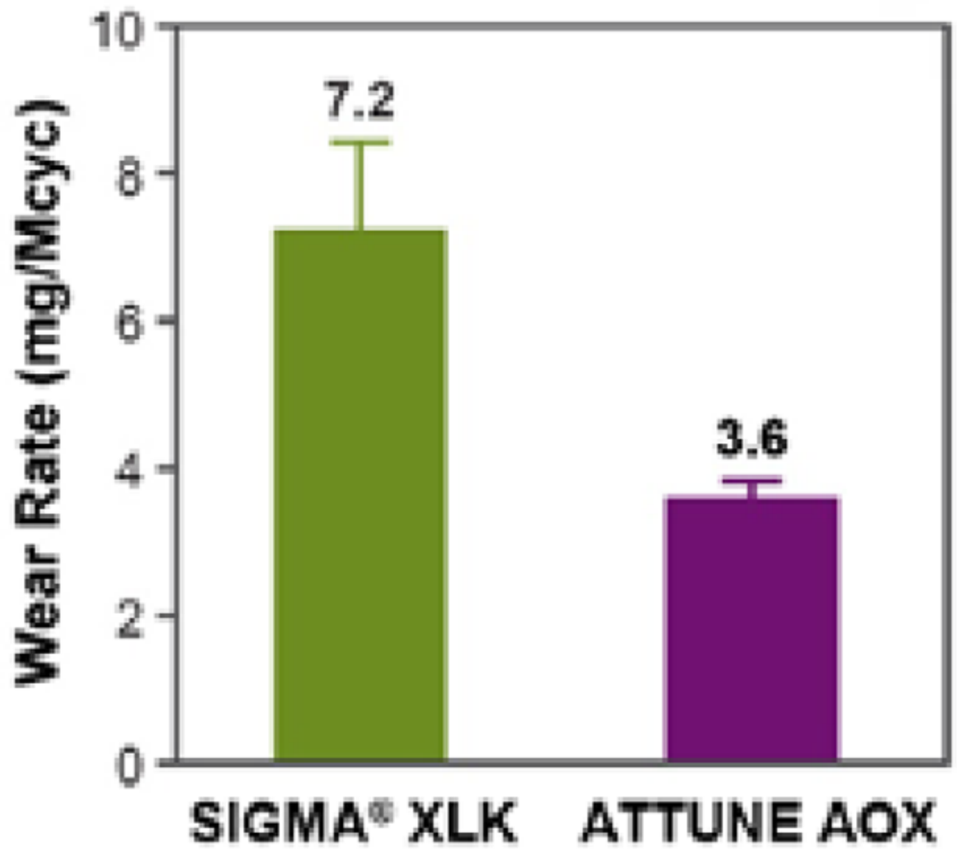
Claim 2: This chart from that same past Attune brochure suggested that Triathlon does not allow for femoral rotation and acts more like a "hinge."[96]



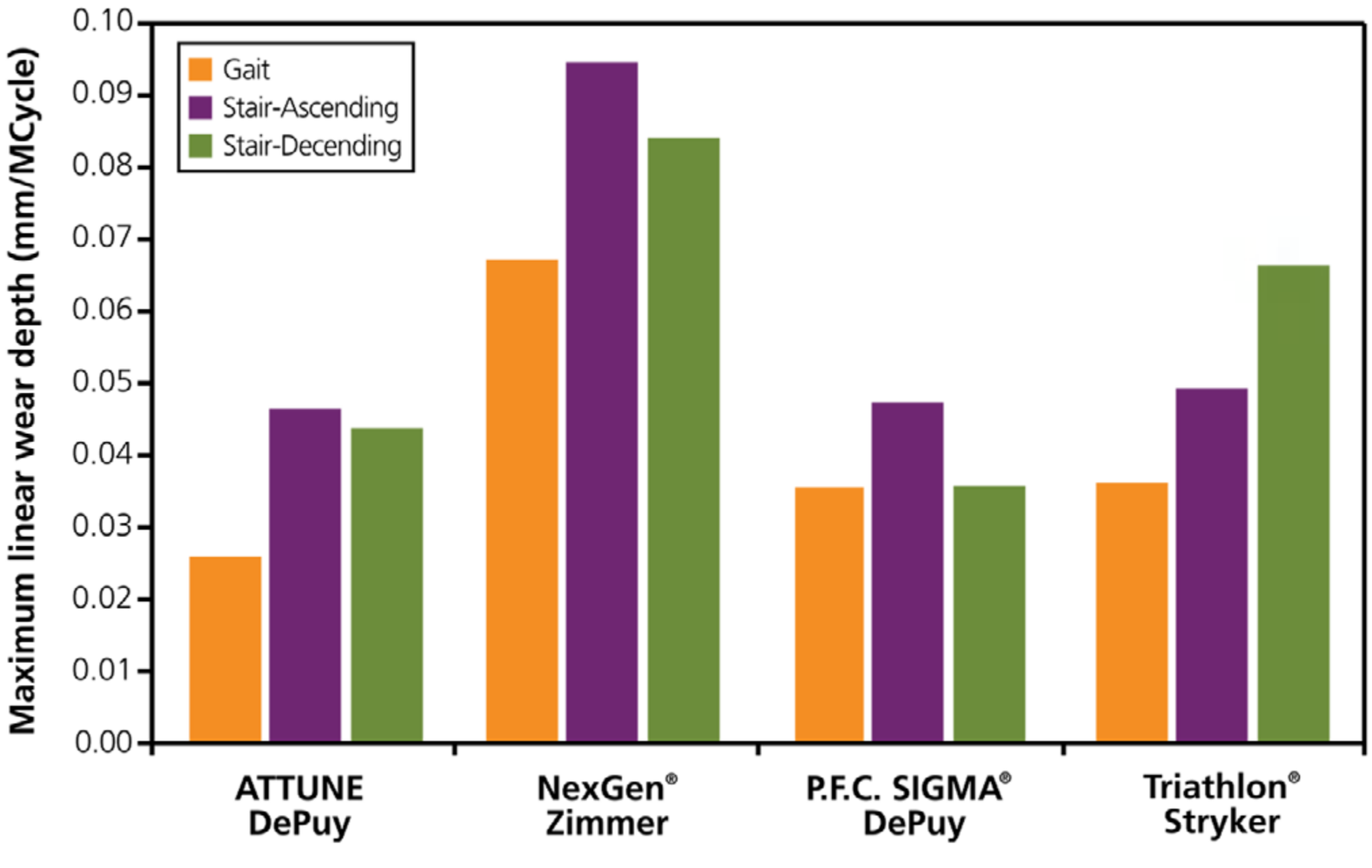
The below content from a past Attune brochure demonstrates inconsistencies in the results of a computer simulator that was used in an attempt to make comparisons to Triathlon.

Wear – which one is "correct"?

Claim 1: This caption suggested that Attune provides a 50% lower wear rate than Sigma.[96]



Claim 2: This chart from the same past Attune brochure suggested that Attune has higher wear than Sigma in certain activities.[96]

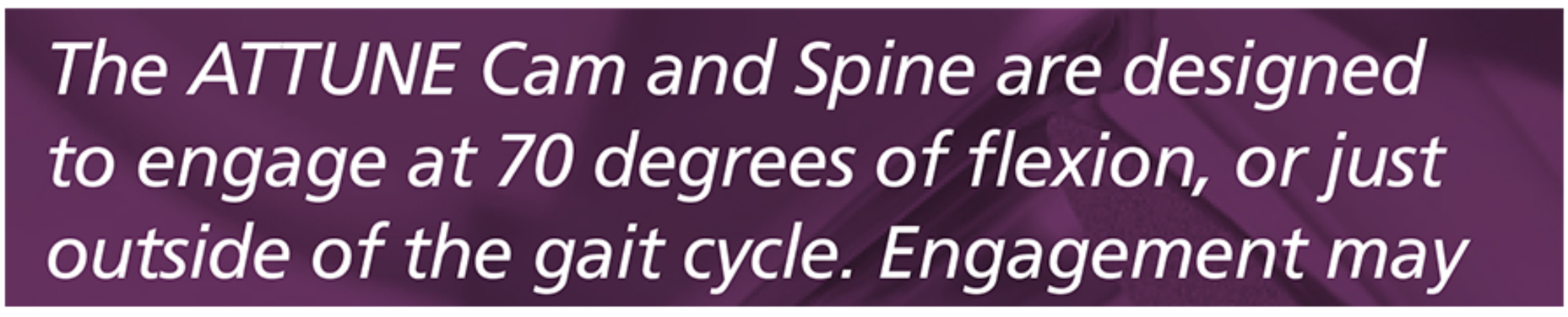


Cam/post – which is "correct"?

Claim 1: This chart from a past Attune brochure suggested that Attune PS cam and spine engage at 87º of flexion.[60]

	DePuy Synthes ATTUNE PS	Zimmer NexGen LPS-Flex	Stryker Triathlon PS
Flexion at engagment (º)	87	90	53
Distance (mm)	4.8	15.1	5.2
Contact velocity (mm/º)	0.10	0.22	0.08

Claim 2: A separate past Attune brochure stated that Attune PS cam and spine engage at 70º of flexion.[97]



Stability

- In a quantitative assessment comparing gait between sixteen patients who received a single radius and sixteen patients who received a multi-radius total knee, Triathlon single radius patients experienced gait patterns that mimicked those of healthy individuals.[82]
- Triathlon's cam/post is designed to engage at approximately 45°, where natural PCL loading occurs.[9] Attune cam-post engagement occurs after the gait cycle between 70° and 87°.[60,97] Note the difference in location of the femoral component between Triathlon and Attune when the cam and post engage.[130] In a lab test, the Attune component did not engage the post and slid anteriorly.[130]

DePuy Synthes Attune[90]

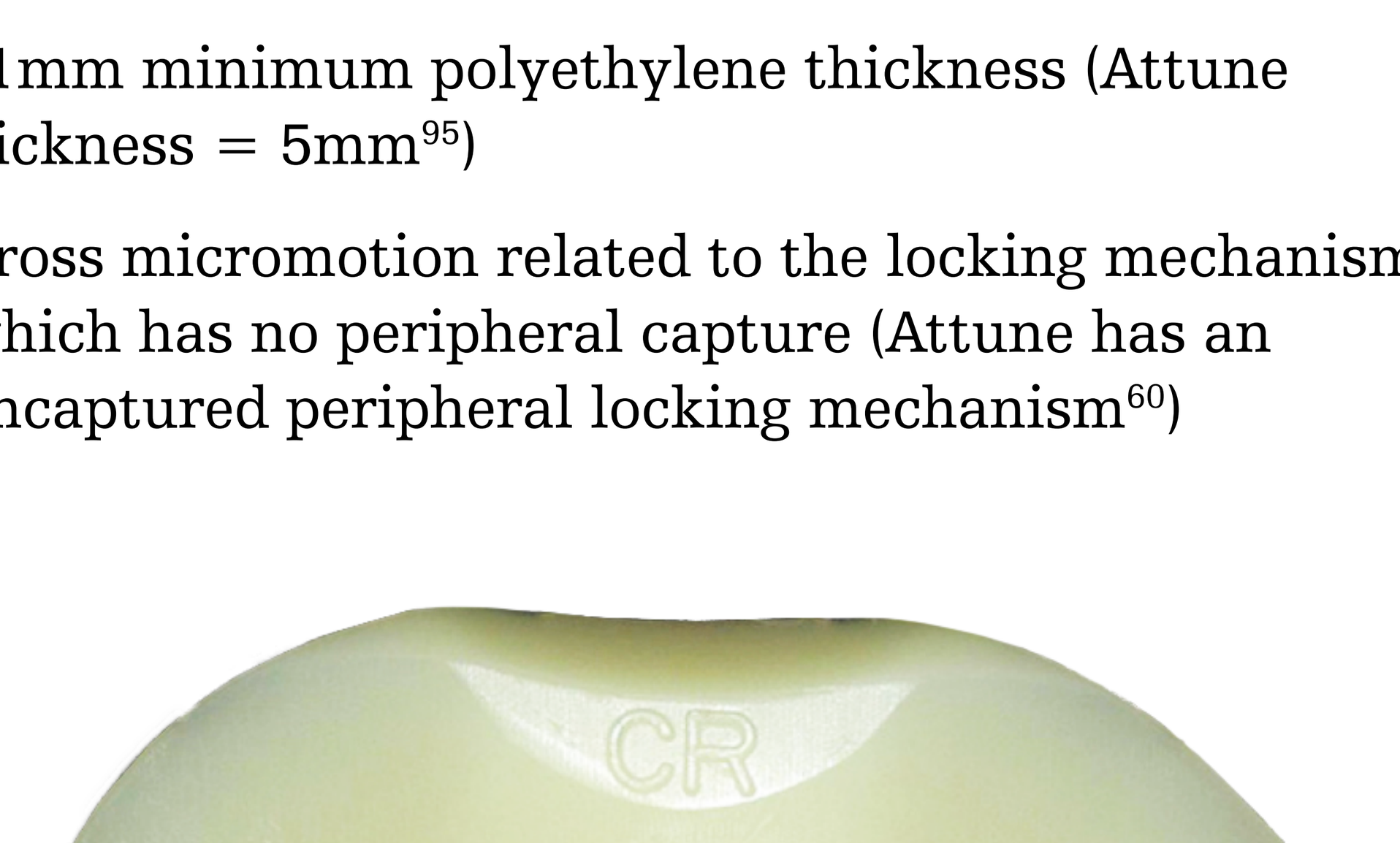
Stryker Triathlon

Deep flexion

- A clinical study showed that Triathlon is designed to accommodate up to 150º of flexion.[28] Triathlon's shorter, flared posterior condyles are designed to facilitate the relaxation of the soft tissues to enable deep flexion while maintaining contact area for stability in flexion.[6,7]
- Triathlon achieves deep flexion with minimal tibial slope. Attune recommends up to 7º of tibial slope for the CR design.[62] A recent publication showed that in TKA revised for flexion instability, the average pre-revision slope was approximately 7º.[129]

Polyethylene

- A published study showed that wear and mechanical integrity of X3 PS inserts were unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum ASTM F648 requirement.[18]
- Lab testing showed an 83% wear reduction with X3 compared to AOX.[121]A recent case study was published on a fractured additive antioxidant polyethylene. Analysis of the retrieved insert suggested that fracture was probably a combination of clinical and component factors. [81]
- The polyethylene design in this study has some similarities to Attune/AOX.
  - 5.1mm minimum polyethylene thickness (Attune thickness = 5mm[95])
  - Gross micromotion related to the locking mechanism,[81] which has no peripheral capture (Attune has an uncaptured peripheral locking mechanism[60])



Size charts

DePuy Attune CR – A/P and M/L dimensions[112]			
Size	**Overall A/P**	**Anterior cortex A/P**	**Overall M/L**
1	47.7	43.7	54.1
2	50.8	46.7	57.2
3N	53.6	49.5	56.8
3	53.9	49.7	60.3
4N	56.6	52.5	59.9
4	57.1	52.7	63.4
5N	59.7	55.6	63.0
5	60.1	55.7	66.5
6N	62.8	58.6	66.1
6	63.4	58.8	69.6
7	66.5	61.8	72.7
8	69.6	64.9	75.8
9	72.9	68.0	78.9
10	76.1	71.1	82.0

DePuy Attune CR – Condyle dimensions[112]			
Size	**Posterior thickness**	**Distal thickness**	**Condyle length**
1	8.0	9.0	30.8
2	8.0	9.0	32.2
3N	8.0	9.0	33.8
3	8.0	9.0	33.8
4N	8.0	9.0	35.3
4	8.0	9.0	35.3
5N	8.0	9.0	37.0
5	8.0	9.0	37.0
6N	8.0	9.0	38.7
6	8.0	9.0	38.7
7	8.0	9.0	40.6
8	8.0	9.0	42.5
9	8.0	9.0	44.5
10	8.0	9.0	46.6

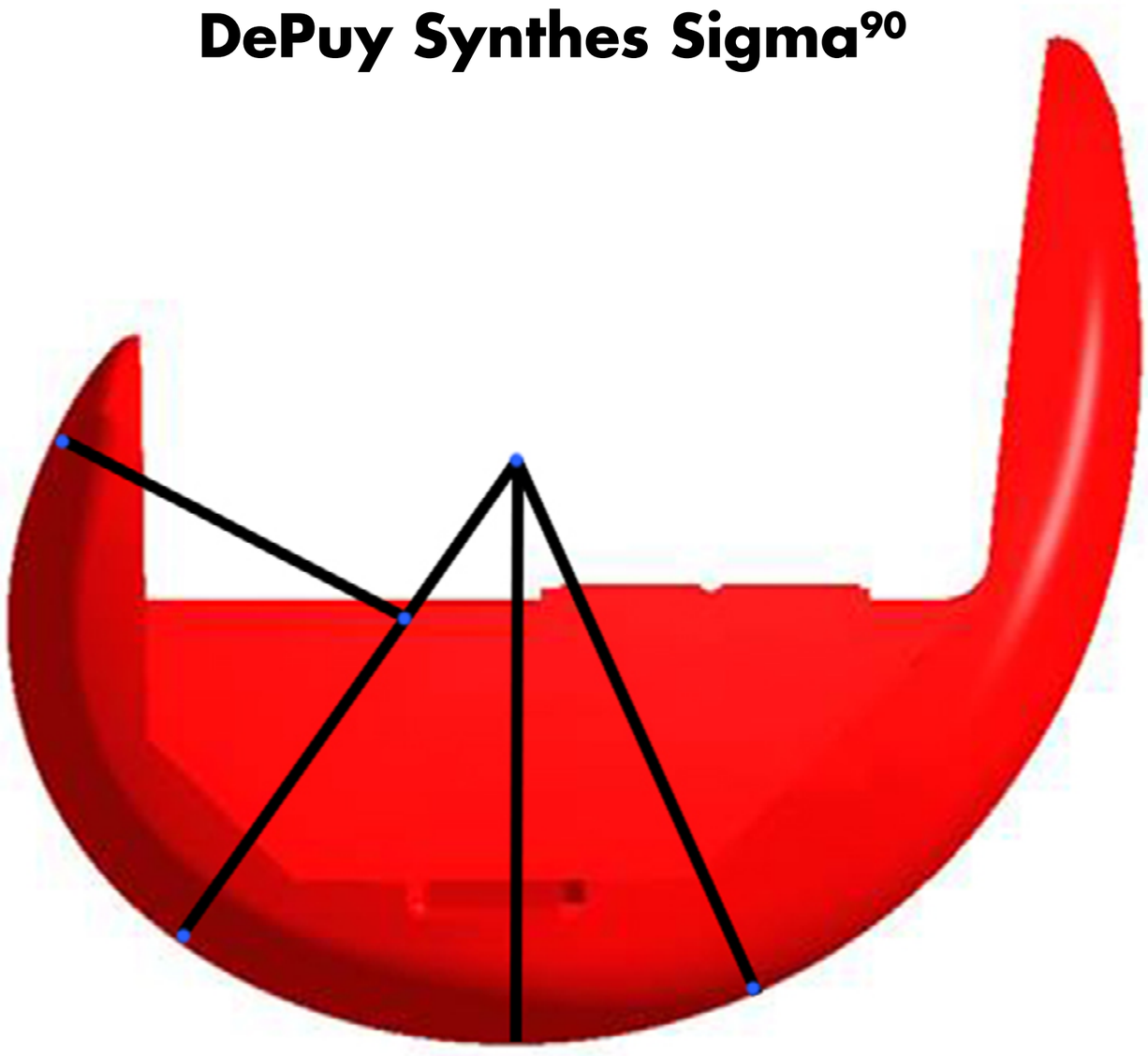
DePuy Attune PS – A/P and M/L dimensions[112]			
Size	**Overall A/P**	**Anterior cortex A/P**	**Overall M/L**
1	48.6	44.7	54.1
2	51.7	47.6	57.2
3N	54.5	50.5	56.8
3	54.8	50.6	60.3
4N	57.6	53.5	59.9
4	58.0	53.7	63.4
5N	61.0	56.5	63.0
5	61.0	56.6	66.5
6N	63.7	59.5	66.1
6	64.2	59.8	69.6
7	67.5	62.8	72.7
8	70.8	65.9	75.8
9	74.0	69.0	78.9
10	77.3	72.1	82.0

DePuy Attune PS – Condyle dimensions[112]			
Size	**Posterior thickness**	**Distal thickness**	**Condyle length**
1	9.0	9.0	29.4
2	9.0	9.0	30.9
3N	9.0	9.0	32.3
3	9.0	9.0	32.4
4N	9.0	9.0	33.8
4	9.0	9.0	33.9
5N	9.0	9.0	35.5
5	9.0	9.0	35.5
6N	9.0	9.0	37.1
6	9.0	9.0	37.2
7	9.0	9.0	38.9
8	9.0	9.0	40.7
9	9.0	9.0	42.7
10	9.0	9.0	44.7

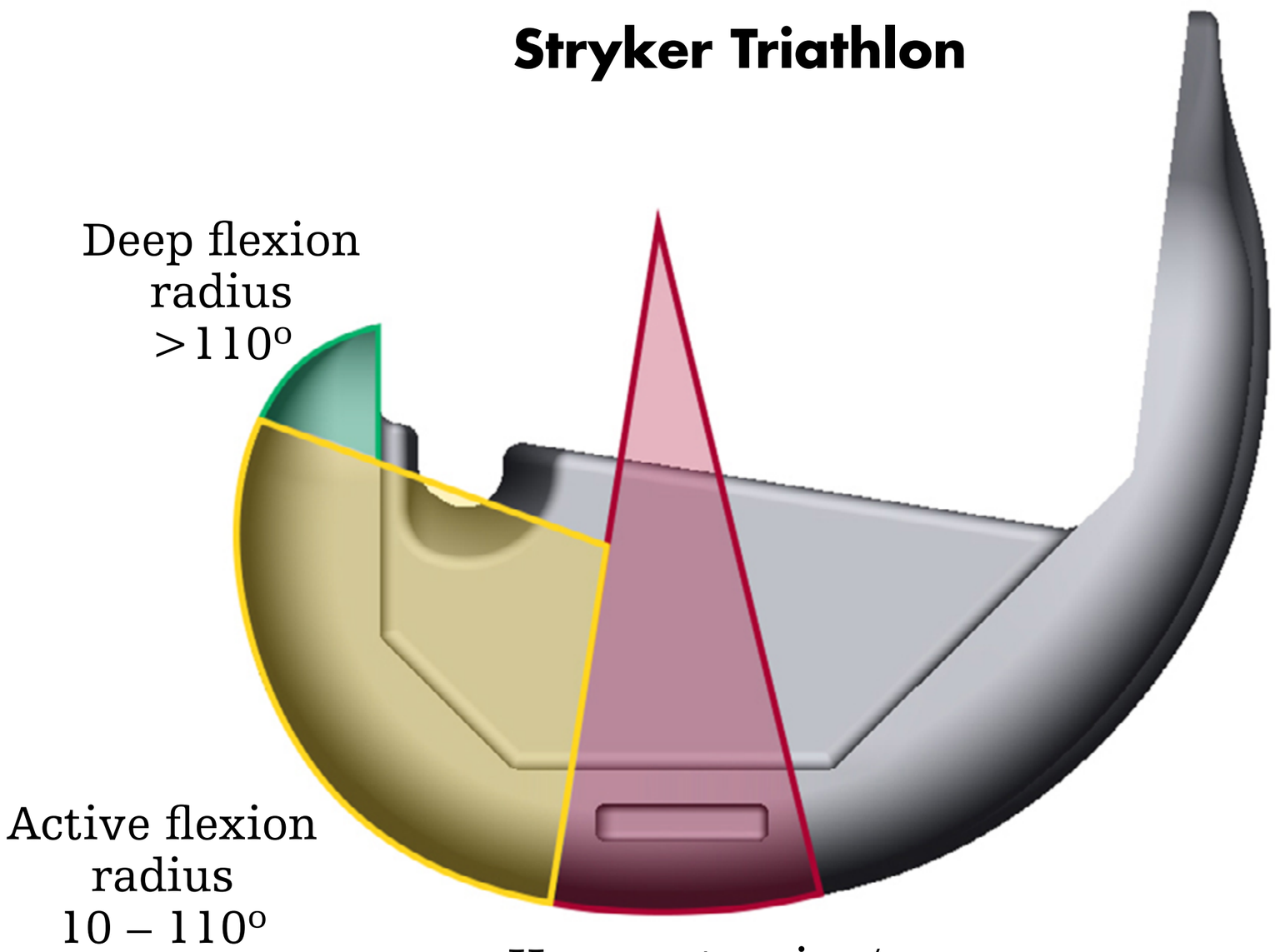
Femoral geometry

The single radius is designed to restore the knee's single center of rotation during active flexion.[21,22] This allows for constant ligament tension and stability in flexion.[2,26,82,107]

DePuy Synthes Sigma[90]



Stryker Triathlon



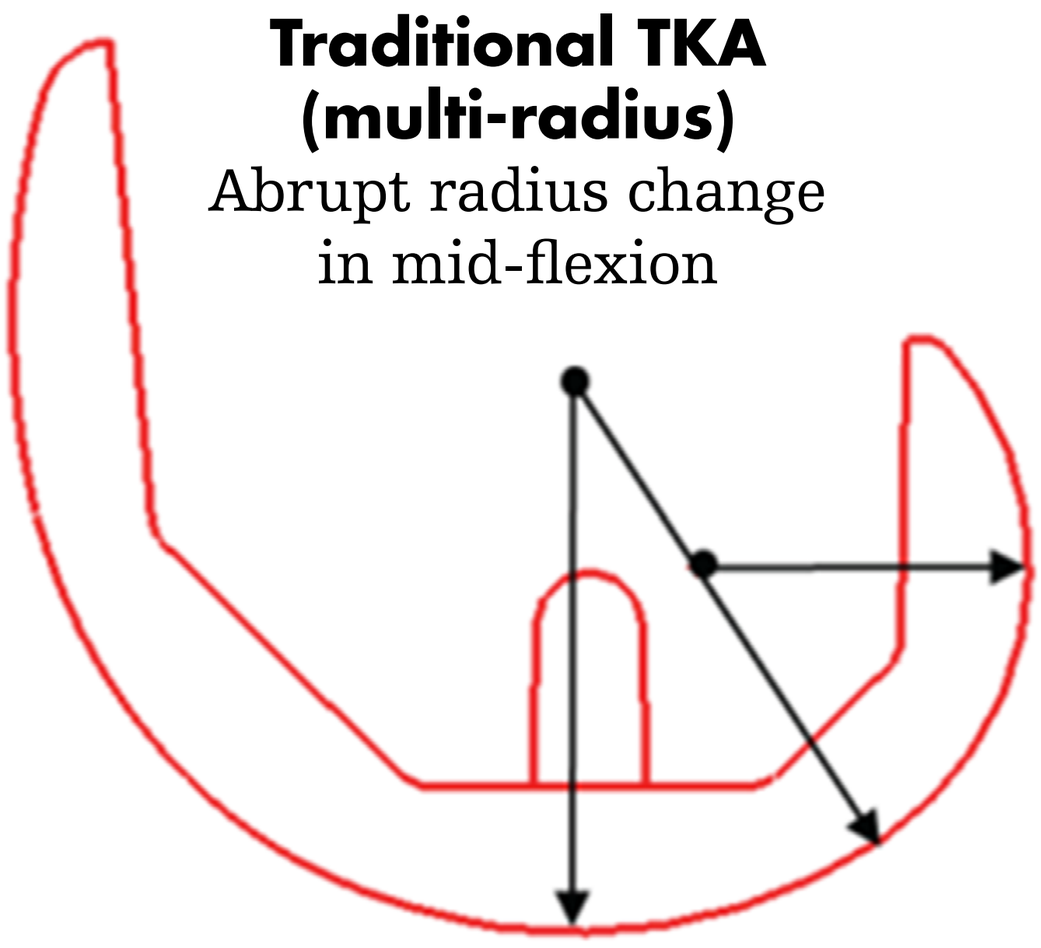
Rotating platform TKA

Triathlon is designed to accommodate up to 20º of internal and external rotation.[6,7] Triathlon and X3 have also demonstrated 97% reduced wear versus mobile bearing designs.[48] The full periphery locking rim, locking wire and anti-rotation island have demonstrated less micromotion than other fixed-bearing designs.[84]

Furthermore, a clinical study of twenty prostheses (nine mobile-bearing and eleven fixed-bearing) conducted in Europe showed no kinematic advantages of a Triathlon mobile-bearing versus Triathlon fixed-bearing implant.[103]

Stability

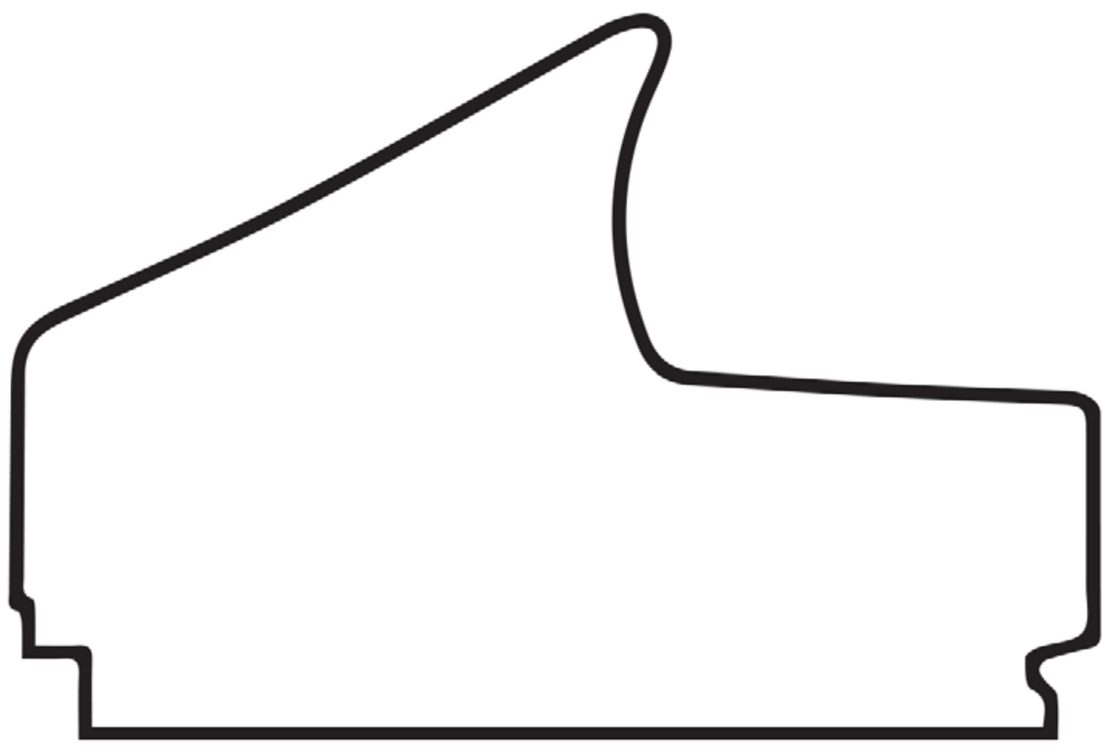
- In a quantitative assessment comparing gait between sixteen patients who received a single radius and sixteen patients who received a multi-radius total knee, Triathlon single radius patients experienced gait patterns that mimicked those of healthy individuals.[82]
- Triathlon's cam/post is designed to engage at approximately 45°, where natural PCL loading occurs.[93] Sigma cam/post engagement occurs after the gait cycle at 70°.[98]
- Research published by DePuy suggests that mid-flexion instability with multi-radius designs may occur due to the change in radius that occurs in mid-flexion.[93]



- Two studies have shown a relatively high incidence of patellar clunk with Sigma PS designs.[99,100]
- Triathlon provides less rotational constraint than Sigma.[44]

Deep flexion

- Triathlon's shorter, flared posterior condyles are designed to facilitate the relaxation of the soft tissues to enable deep flexion while maintaining contact area for stability in flexion.[6,7] Sigma posterior condyles are longer than Triathlon which may create more tension in the posterior capsule.[6,90]
- A closer look at Sigma's post design (below) shows how the post is used to lever the femur back as the cam travels up the post.[101]



Polyethylene

- A published study showed that wear and mechanical integrity of X3 PS inserts were unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum ASTM F648 requirement.[18]
- XLK, the polyethylene utilized with DePuy's Sigma system, is a remelted polyethylene. DePuy has claimed that with remelted polyethylene, "The consequence of the loss in crystallinity is a modest loss in mechanical strength and fatigue resistance."[102]

Size charts

DePuy Sigma CR – A/P and M/L dimensions[112]			
Size	**Overall A/P**	**Anterior cortex A/P**	**Overall M/L**
1.5	52.7	47.3	56.9
2	55.7	50.4	60.0
2.5	58.8	53.2	63.0
3	61.7	55.8	66.0
4N	65.6	60.0	66.0
4	65.0	60.0	71.0
5	69.8	64.0	73.0
6	75.4	69.7	76.5

DePuy Sigma CR – Condyle dimensions[112]			
Size	**Posterior thickness**	**Distal thickness**	**Condyle length**
1.5	7.7	9.0	32.3
2	7.6	9.0	33.6
2.5	7.7	9.0	35.0
3	7.7	9.0	36.3
4N	7.7	9.0	38.1
4	7.7	9.0	37.3
5	7.6	9.0	40.0
6	8.5	10.0	42.0

DePuy Sigma PS – A/P and M/L dimensions[112]			
Size	**Overall A/P**	**Anterior cortex A/P**	**Overall M/L**
1.5	52.7	47.3	56.9
2	55.7	50.4	60.0
2.5	58.8	53.2	63.0
3	61.7	55.8	66.0
4N	65.6	60.0	66.0
4	65.0	60.0	71.0
5	69.8	64.0	73.0
6	75.4	69.7	76.5

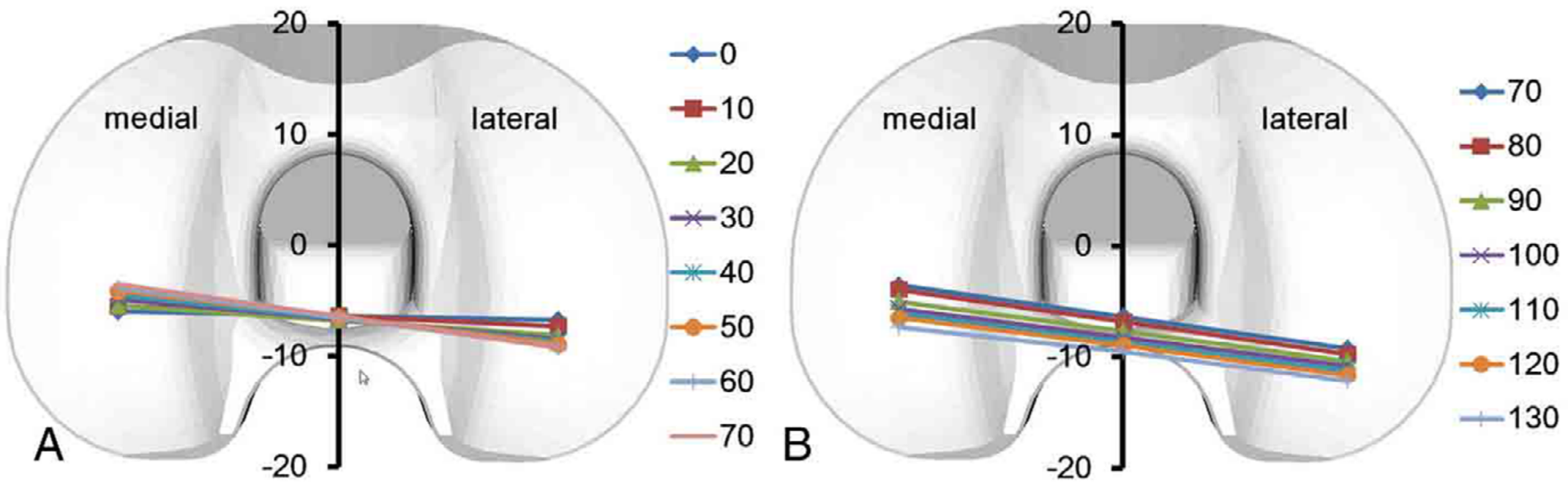
DePuy Sigma PS – Condyle dimensions[112]			
Size	**Posterior thickness**	**Distal thickness**	**Condyle length**
1.5	7.7	9.0	32.9
2	7.6	9.0	34.3
2.5	7.7	9.0	35.4
3	7.7	9.0	38.2
4N	7.6	9.0	40.2
4	7.6	9.0	40.2
5	7.6	9.0	41.8
6	8.5	10.0	43.0

DePuy Sigma CR 150 – A/P and M/L dimensions[112]			
Size	**Overall A/P**	**Anterior cortex A/P**	**Overall M/L**
1.5	52.7	47.3	56.9
2	55.7	50.4	60.0
2.5	58.8	53.2	63.0
3	61.7	55.8	66.0
4N	65.6	60.0	66.0
4	65.0	60.0	71.0
5	69.8	64.0	73.0
6	75.4	69.7	76.5

DePuy Sigma CR 150 – Condyle dimensions[112]			
Size	**Posterior thickness**	**Distal thickness**	**Condyle length**
1.5	9.7	9.0	32.2
2	9.6	9.0	34.2
2.5	9.7	9.0	34.8
3	9.7	9.0	37.4
4N	9.6	9.0	39.8
4	9.6	9.0	39.8
5	9.6	9.0	41.2
6	10.5	10.0	42.4

Stability

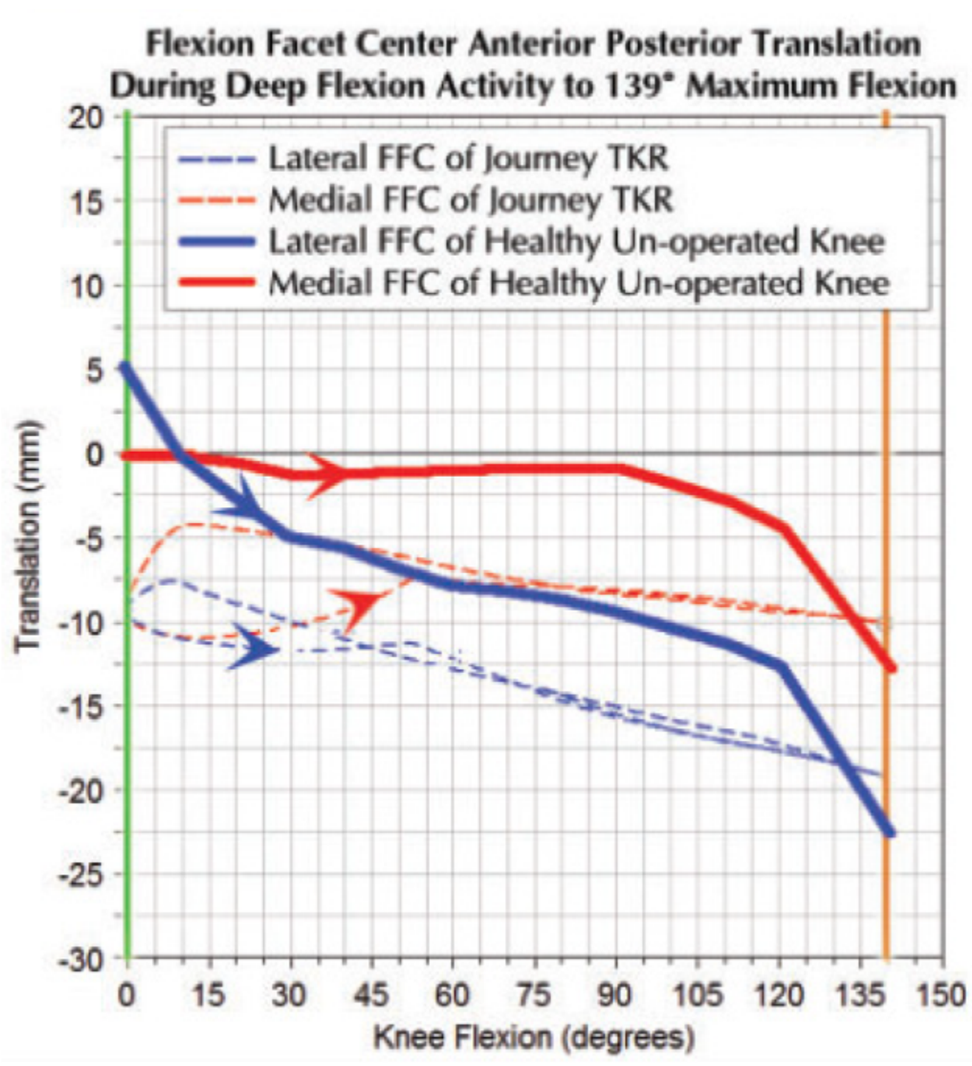
- In a quantitative assessment comparing gait between sixteen patients who received a single radius and sixteen patients who received a multi-radius total knee, Triathlon single radius patients experienced gait patterns that mimicked those of healthy individuals.[82]
- Fluoroscopic data of Triathlon patients showed that medial pivot is possible without features that force a medial pivot.[107]

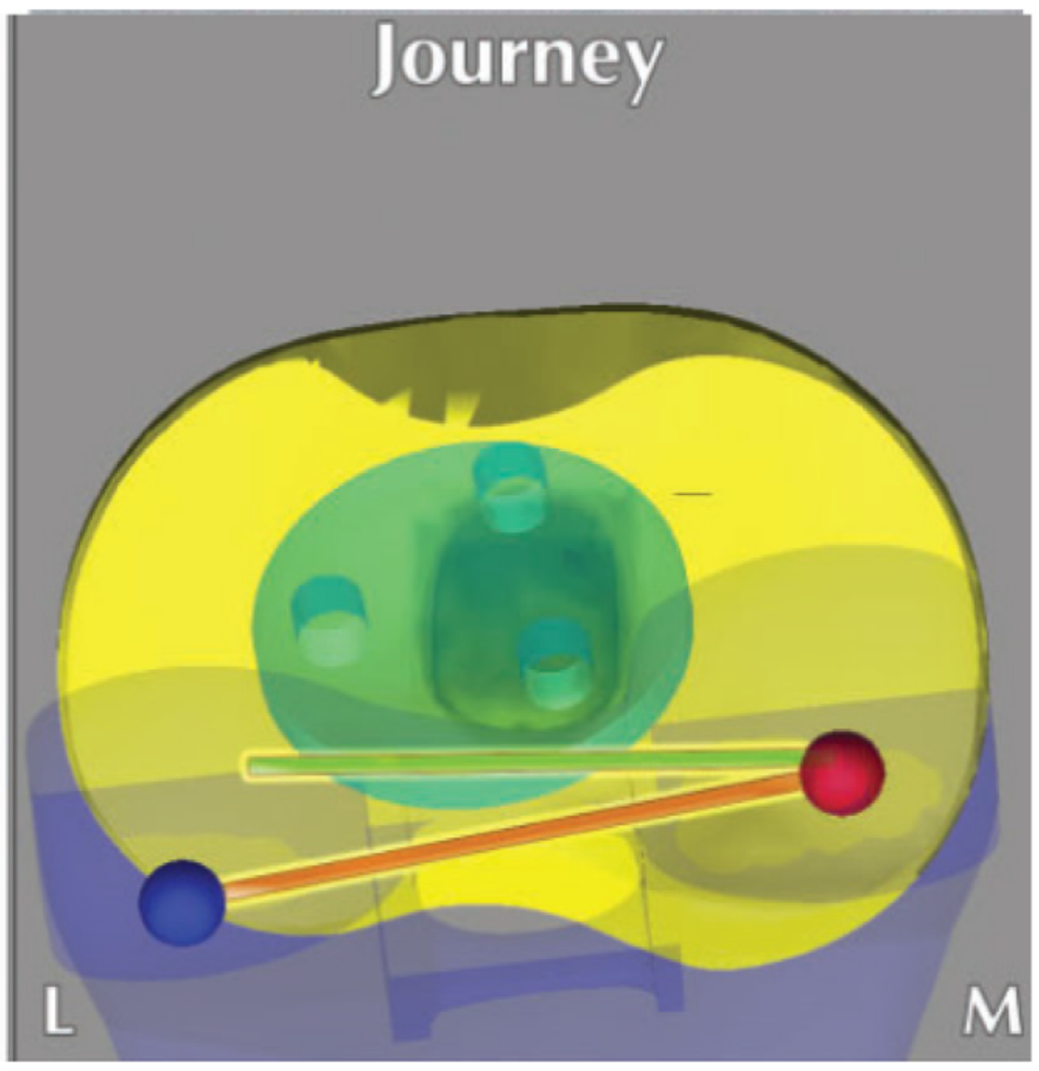


Deep flexion

A clinical study showed that Triathlon is designed to accommodate up to 150º of flexion.[28] Triathlon's shorter, flared posterior condyles are designed to facilitate the relaxation of the soft tissues to enable deep flexion while maintaining contact area for stability in flexion.[6,7]

LifeMod, the simulator used to design Journey 2, showed approximately 15º less flexion with Journey 2 compared to original Journey.[92,109]





Polyethylene

A study showed that wear and mechanical integrity of X3 PS inserts were unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum ASTM F648 requirement.[18]

Size charts

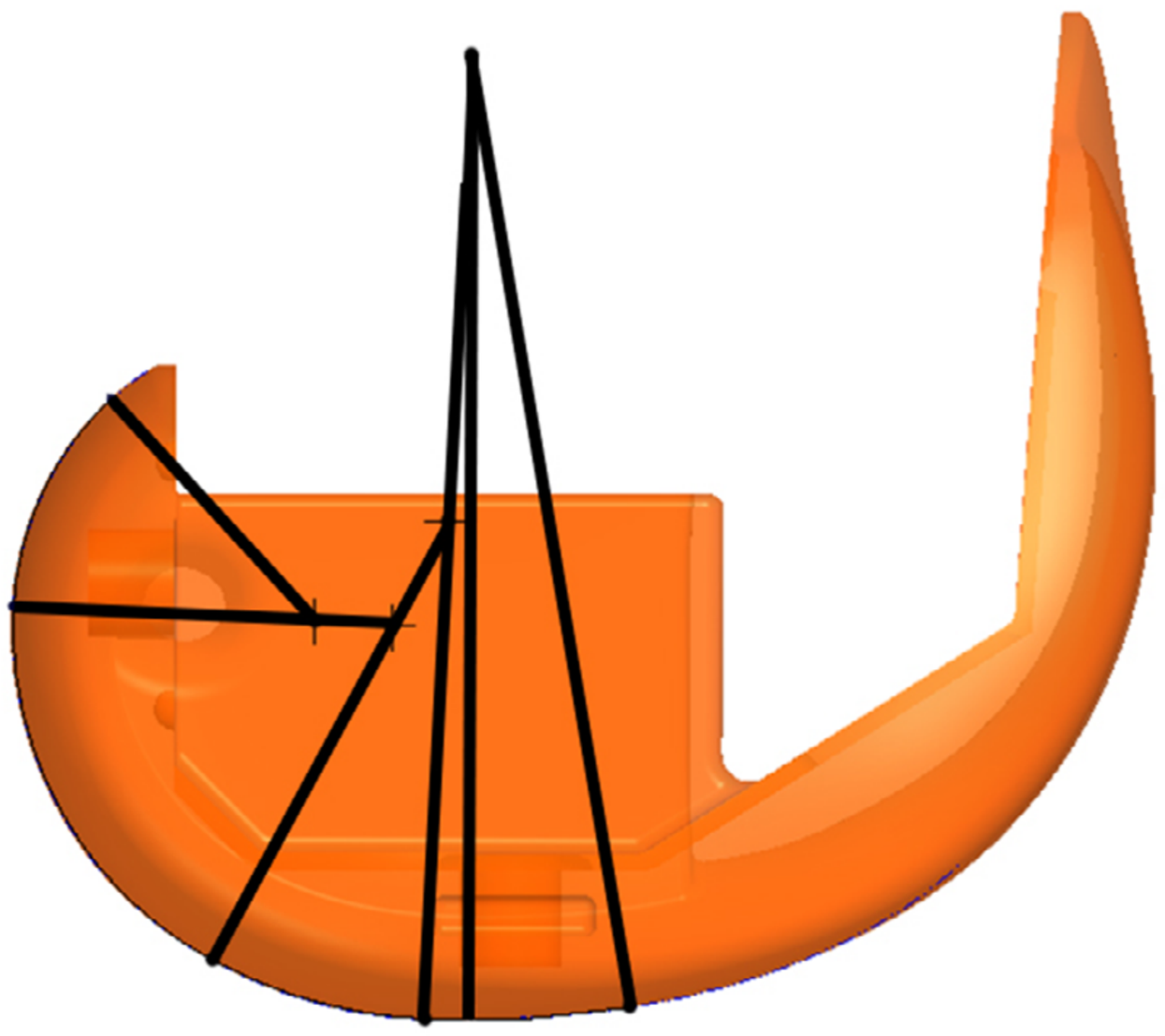
Smith & Nephew Journey 2 BCS – femoral component[114]			
Size	**M/L (mm)**	**A/P**	**Box width**
1	59	51.7	16.5
2	60	53.7	16.5
3	61.5	56.7	16.5
4	64.5	59.7	16.5
5	67.5	62.7	16.5
6	70.5	65.7	16.5
7	73.5	68.8	16.5
8	76	71.8	16.5
9	80	75.8	16.5
10	82	79.8	16.5

Smith & Nephew Journey 2 BCS – tibial component[114]		
Size	**M/L (mm)**	**A/P**
1	60	42
2	64	45
3	68	48
4	71	50
5	74	52
6	77	54
7	81	56
8	85	59

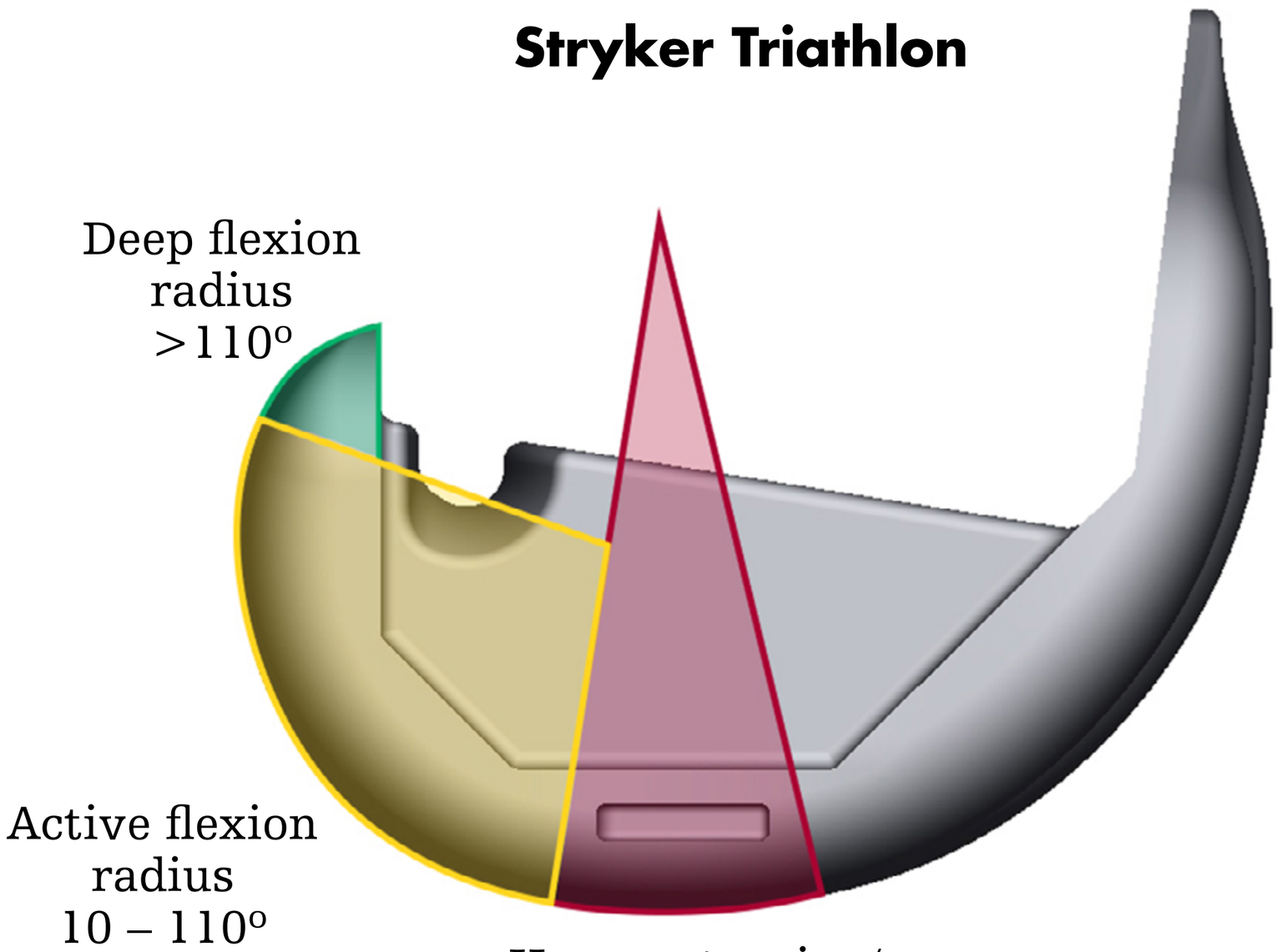
Femoral geometry

The single radius is designed to restore the knee's single center of rotation during active flexion.[21,22] This allows for constant ligament tension and stability in flexion.[2,26,82,107]

Smith & Nephew Gen II/Legion[90]



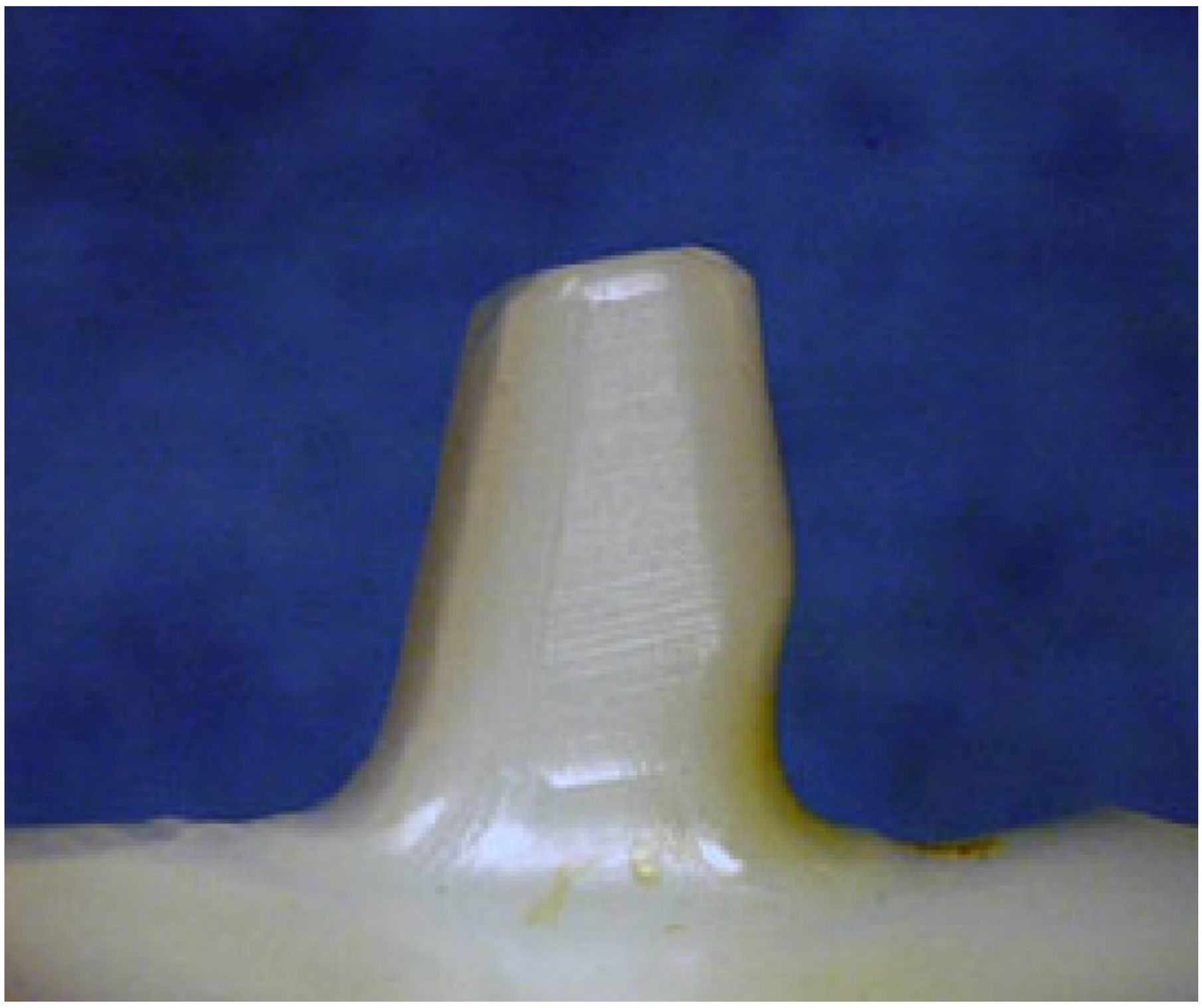
Stryker Triathlon



Stability

- In a quantitative assessment comparing gait between sixteen patients who received a single radius and sixteen patients who received a multi-radius total knee, Triathlon single radius patients experienced gait patterns that mimicked those of healthy individuals.[82]
- Triathlon's cam/post is designed to engage at approximately 45º, where natural PCL loading occurs.[93] Gen II/Legion cam-post engagement occurs at 60-70º.[104] A lab study showed that compared to Triathlon, Gen II demonstrated higher stress on the post when it engaged with the cam.[108]

A retrieval study showed that the Gen II post demonstrated significant posterior wear damage.[105]



Deep flexion

A clinical study showed that Triathlon is designed to accommodate up to 150º of flexion.[28] Triathlon's shorter, flared posterior condyles are designed to facilitate the relaxation of the soft tissues to enable deep flexion while maintaining contact area for stability in flexion.[6,7] Gen II/Legion posterior condyles are longer than Triathlon's, which may create more tension in the posterior capsule.[6,90]

Triathlon can achieve deep flexion with minimal slope. Gen II/Legion recommends 7º slope.[113] One publication showed that in TKA revised for flexion instability, the average pre-revision slope was approximately 7º.[129]

Polyethylene

A published study showed that wear and mechanical integrity of X3 PS inserts were unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum ASTM F648 requirement.[18]

Size charts

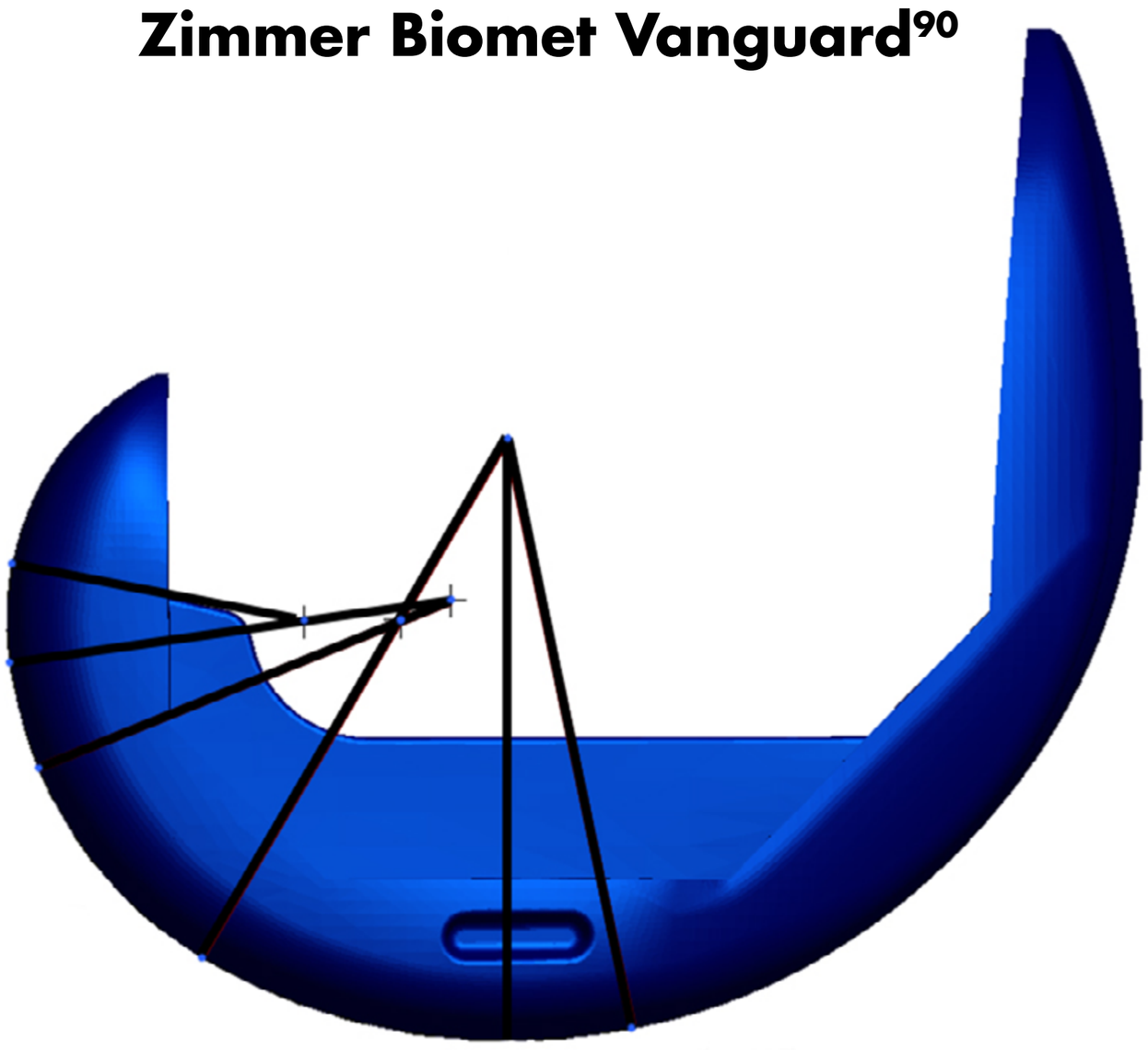
Smith & Nephew Genesis II – femoral component[113]		
Size	**M/L (mm)**	**A/P**
1	55	47
2	58	50.5
3	62	54.5
4	66	58.5
5	70	62
6	73	65.5
7	77	69.5
8	80	75

Smith & Nephew Genesis II – tibial component[113]		
Size	**M/L (mm)**	**A/P**
1	60	42
2	64	45
3	68	48
4	71	50
5	74	52
6	77	54
7	81	56
8	85	59

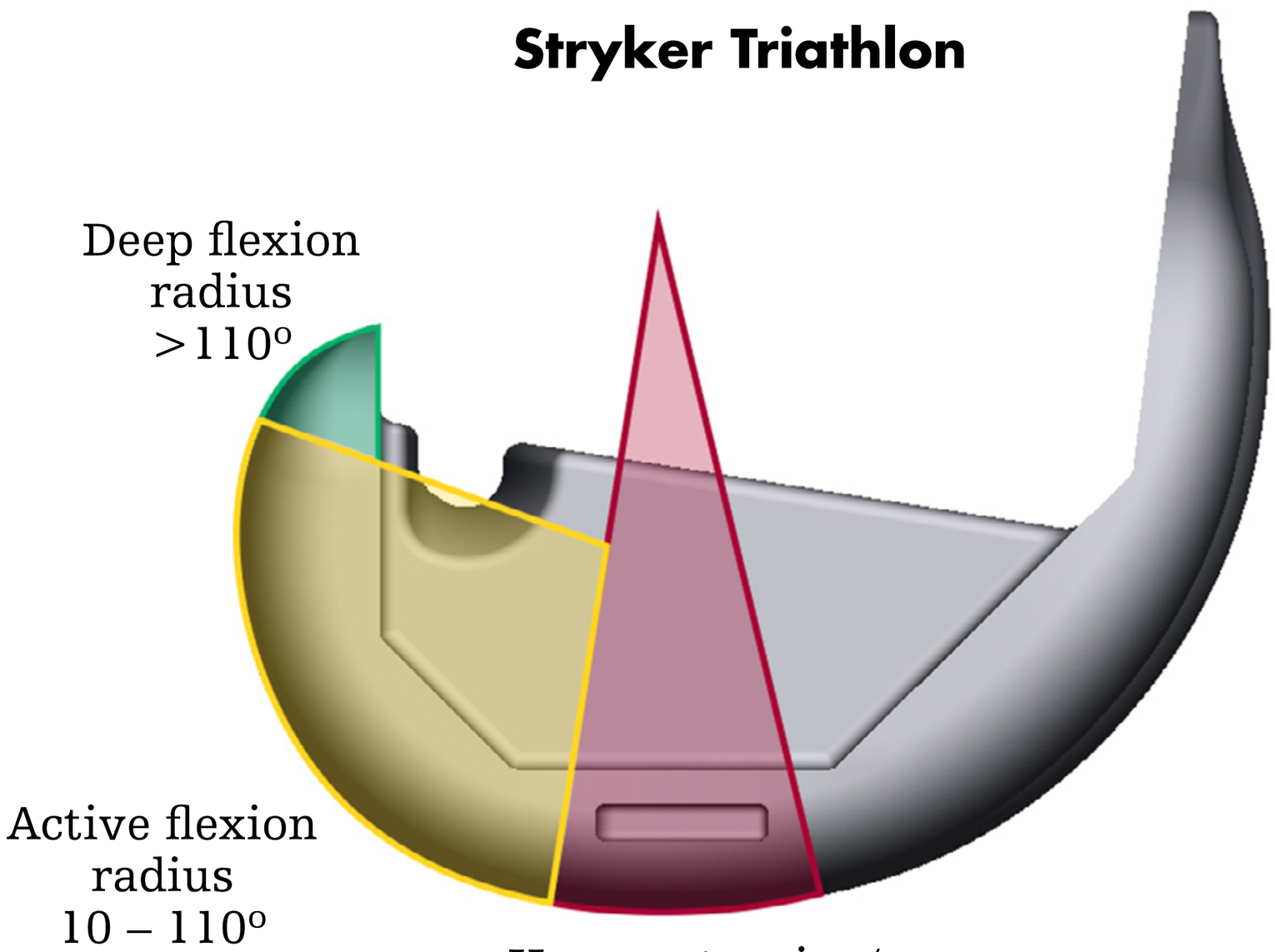
Femoral geometry

The single radius is designed to restore the knee's single center of rotation during active flexion.[21,22] This allows for constant ligament tension and stability in flexion.[2,26,82,107]

Zimmer Biomet Vanguard[90]

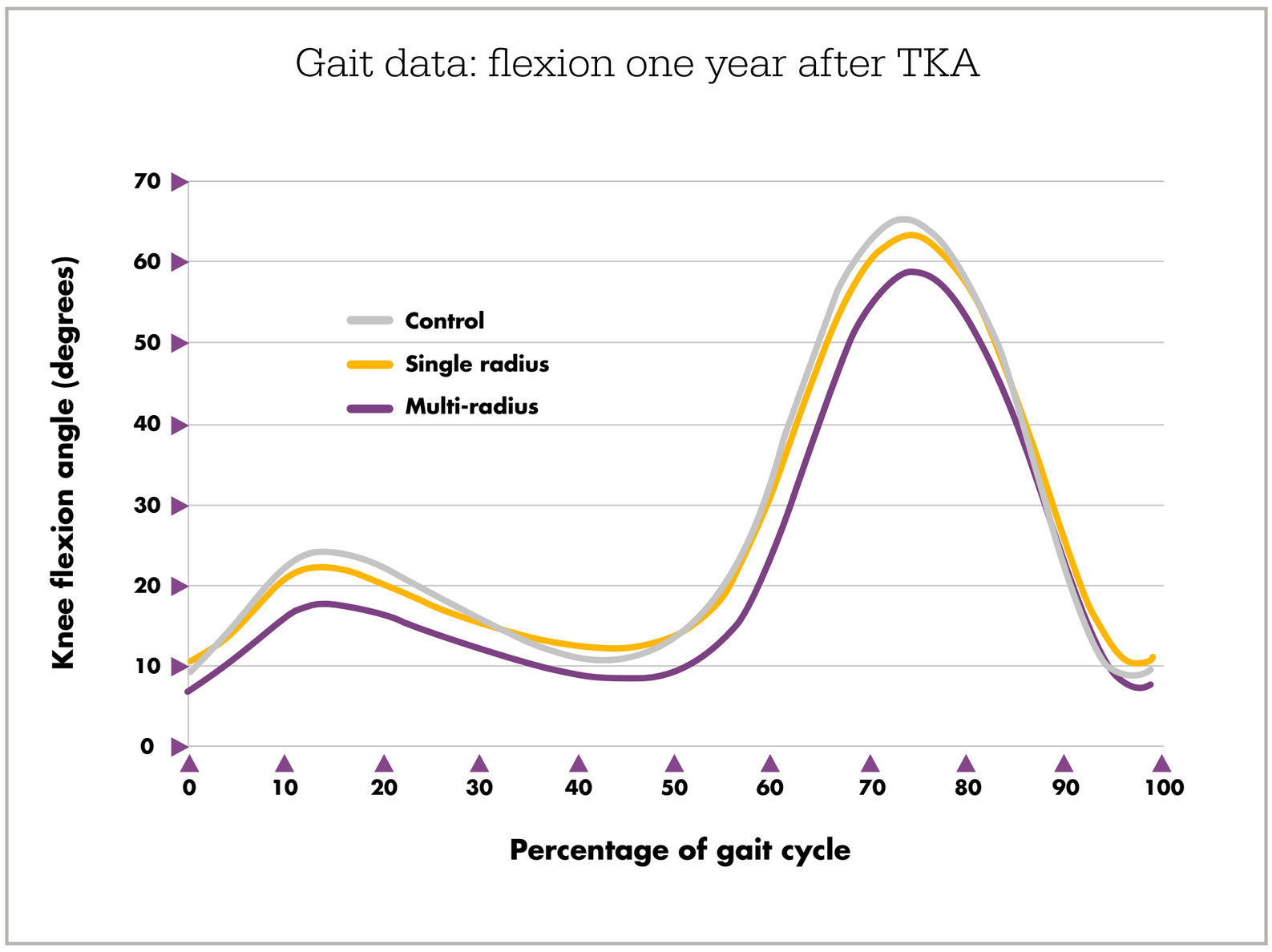


Stryker Triathlon



Stability

In a quantitative assessment comparing gait between sixteen patients who received a single radius and sixteen patients who received a multi-radius total knee, Triathlon single radius patients experienced more natural gait than patients with a Vanguard multi-radius design.[82]



- In the Vanguard multi-radius design, there are abrupt changes in the femoral geometry during active flexion when gait occurs.[82,90] A lab study showed that compared to Triathlon, Vanguard demonstrated higher stress on the post when it engaged with the cam.[108] Cam-post engagement was found to occur after 70º of flexion, later than Triathlon.[108]
- Triathlon PS femurs articulate with constrained (TS) inserts which is an intraoperative option for increased stability in a primary TKA. Vanguard PS femurs articulate with their PS+ inserts but offer less internal/external rotation.[91]

PS femur/insert options	Triathlon	Vanguard[91]
Standard PS	+/- 20º I/E rotation	+/- 15º I/E rotation
Constrained	+/- 7º I/E rotation	+/- 2º I/E rotation

Deep flexion

A clinical study showed that Triathlon is designed to accommodate up to 150º of flexion.[28] Triathlon's shorter, flared posterior condyles are designed to facilitate the relaxation of the soft tissues to enable deep flexion while maintaining contact area for stability in flexion.[6,7] Vanguard posterior condyles are longer than Triathlon's, which may create more tension in the posterior capsule.[6,90]

Polyethylene

- A published study showed that wear and mechanical integrity of X3 PS inserts were unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum ASTM F648 requirement.[18]
- A recent case study was published on a fractured Biomet E1 insert with a Vitamin E additive.[81] Fracture was probably a combination of clinical and component factors. Component factors included:
  – 5.1mm minimum polyethylene thickness
  – Gross micromotion related to the locking mechanism, which has no peripheral capture
  – Diminished material properties

Size charts

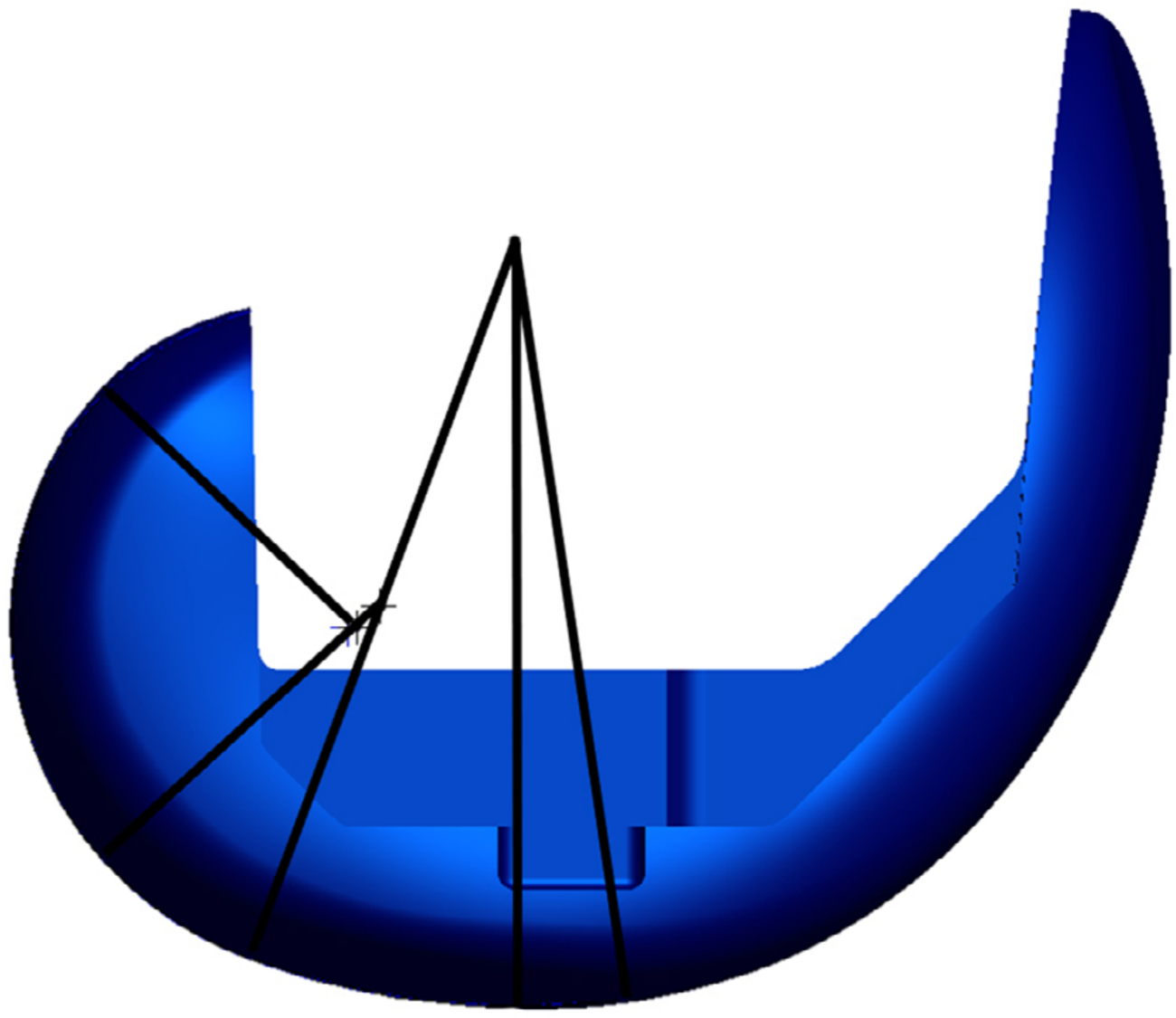
Biomet Vanguard – femoral component[124,125]		
Size	**M/L (mm)**	**A/P**
55	59	55
57.5	61	57
60	64	59
62.5	66	61
65	68	63
67.5	71	66
70	73	68
72.5	75	72
75	78	74
80	83	77

Biomet Vanguard – tibial component[124,125]		
Size	**M/L (mm)**	**A/P**
59	59	38
63	63	41
67	67	43
71	71	46
75	75	48
79	79	51
83	83	53
87	87	56
91	91	58

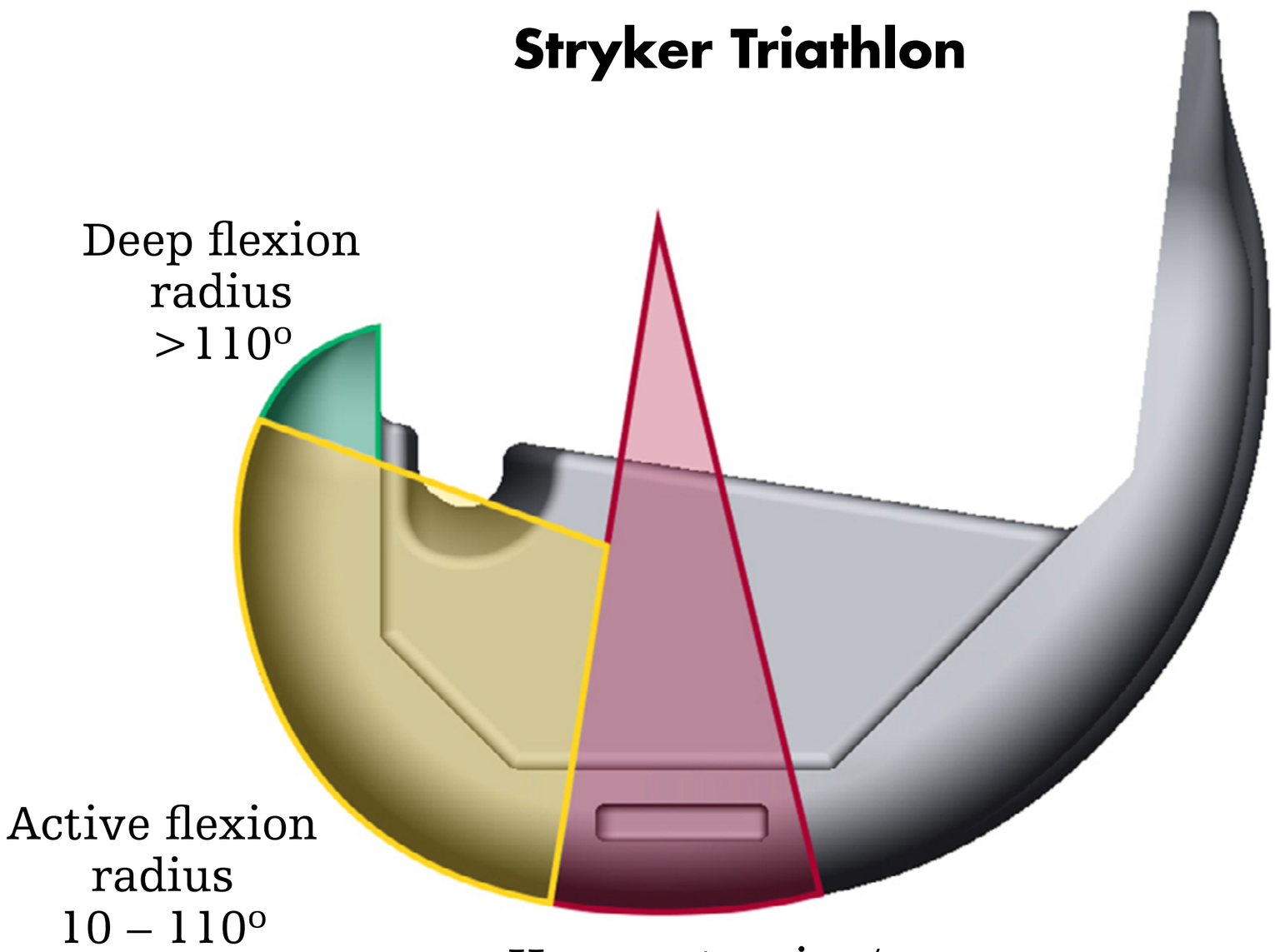
Femoral geometry

The single radius is designed to restore the knee's single center of rotation during active flexion.[21,22] This allows for constant ligament tension and stability in flexion.[2,26,82,107]

Zimmer Biomet NexGen LPS-Flex[90]



Stryker Triathlon



The value of Zimmer "premium" technologies

Triathlon is a modern knee backed by clinical data.[1,3,9,17,26] Other orthopaedics companies have historically positioned products as premium technology, yet the clinical and/or lab data has not always shown an advantage compared to Triathlon. While some data has shown a potential advantage, the data below has shown either no difference or even decreased performance.[73-75]

"Premium" technology: Gender solutions

Promoted benefit: "This allows surgeons to address the female population with unprecedented accuracy."[70]

Published results: No statistical difference in range of motion, pain, or satisfaction between the gender-specific and non gender-specific designs.[75]

"Premium" technology: "Flex" knee

Promoted benefit: Designed to accommodate resumption of high-flexion daily activities.[71]

Published results: The Zimmer high-flex design demonstrated higher femoral loosening than conventional designs.[73-74]

Single vs. multi-radius designs in mid-flexion

Zimmer Biomet NexGen is a multi-radius knee. Competitors such as Zimmer may cite a Stryker-funded study, "The Kinematics and Stability of Single-Radius Versus Multi-Radius Femoral Components Related to Mid-Range Instability after TKA", which purportedly showed no difference between single and multi-radius designs in mid-flexion.

Response

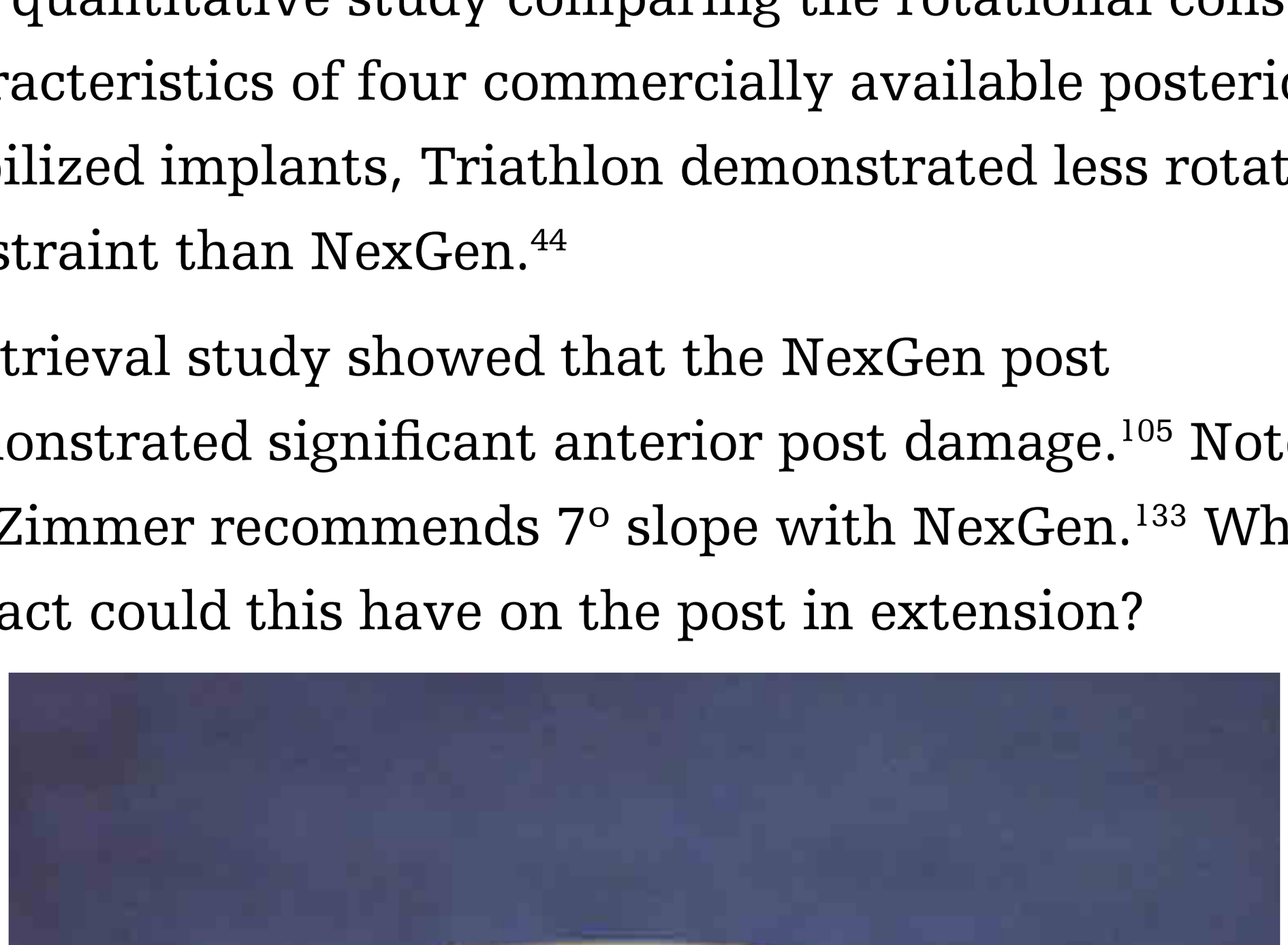
Stryker funded a cadaver lab study to further examine the potential benefits of a single radius (Triathlon) compared to a multi-radius (Kinemax) TKA design. After the experiment was conducted, the authors acknowledged that a limitation of the study was that the loads applied were not typical of loads seen in mid-flexion activities like descending stairs. These clinically relevant loads could not be applied due to the frailty of the specimens. [127]

Furthermore, a clinical study involving actual Triathlon and Kinemax patients did show a difference in muscle function during a mid-flexion activity.[128]

Cadaver studies have limitations and should be compared to actual clinical results when possible. Numerous studies, both funded and non-funded by Stryker, have validated the potential benefits offered by Triathlon and the single radius design.[1,3,26,82,111]

Stability

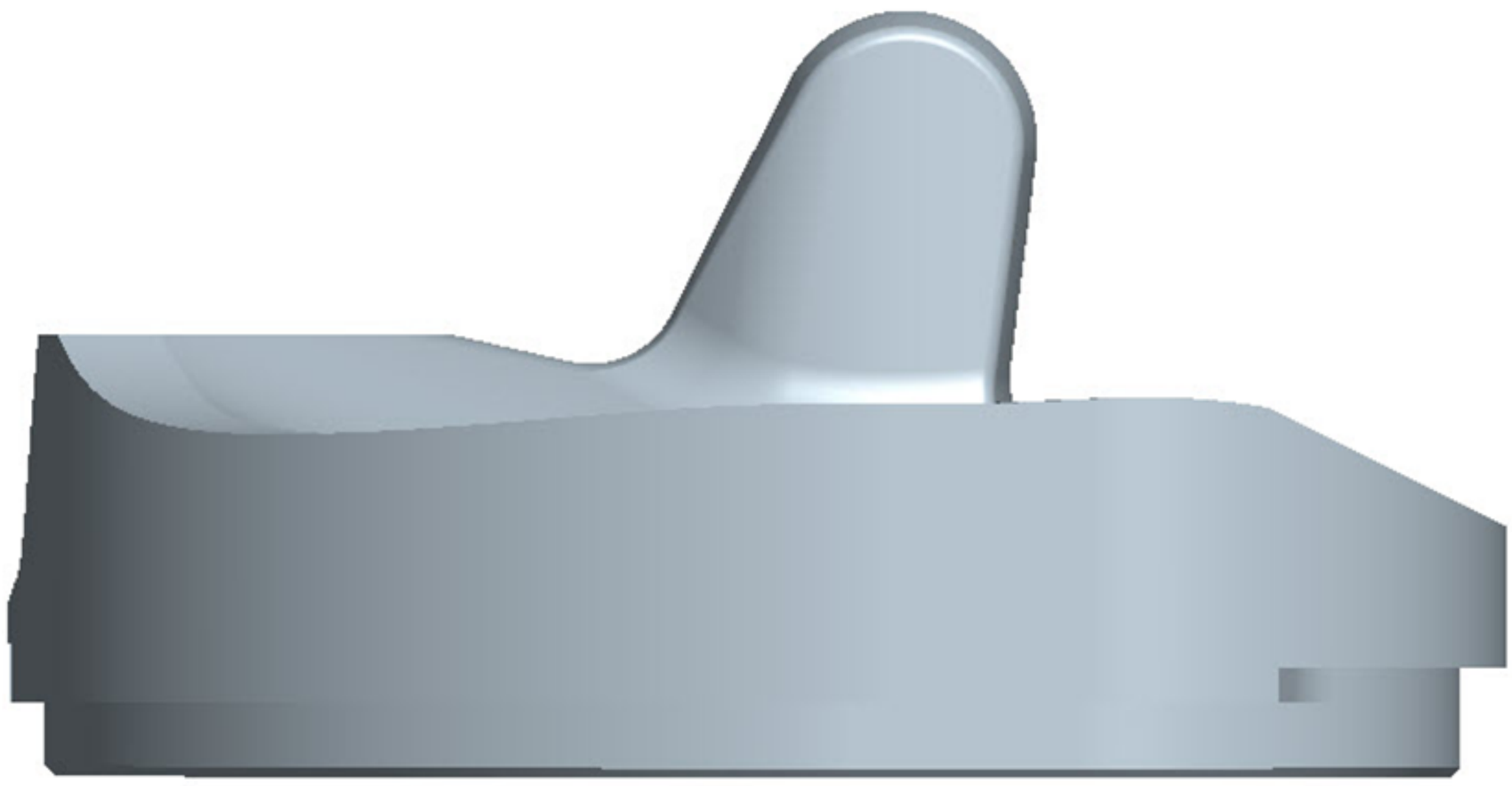
- In a quantitative assessment comparing gait between sixteen patients who received a single radius and sixteen patients who received a multi-radius total knee, Triathlon single radius patients experienced gait patterns that mimicked those of healthy individuals.[82]
- Fluoroscopic data of Triathlon patients showed that medial pivot is possible without features that force a medial pivot.[107]
- Triathlon's cam/post is designed to engage at approximately 45º, where natural PCL loading occurs.[9] NexGen cam/post engagement occurs after the gait cycle at 90º.[60]
- In a quantitative study comparing the rotational constraint characteristics of four commercially available posterior-stabilized implants, Triathlon demonstrated less rotational constraint than NexGen.[44]
- A retrieval study showed that the NexGen post demonstrated significant anterior post damage.[105] Note that the Zimmer recommends 7º slope with NexGen.[133] What impact could this have on the post in extension?



Deep flexion

Triathlon can achieve deep flexion without excessive tibial slope. NexGen calls for 7º of slope.[133] A publication showed that in TKA revised for flexion instability, the average pre-revision slope was approximately 7º.[129]

A closer look at NexGen's post design shows how the post is used to lever the femur back as the cam travels up the post.



Polyethylene

- A published study showed that wear and mechanical integrity of X3 PS inserts were unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum ASTM F648 requirement.[18]
- Prolong, the polyethylene used with the NexGen system, is a remelted polyethylene. Zimmer has claimed that the remelting process reduces strength.[110]

Size charts

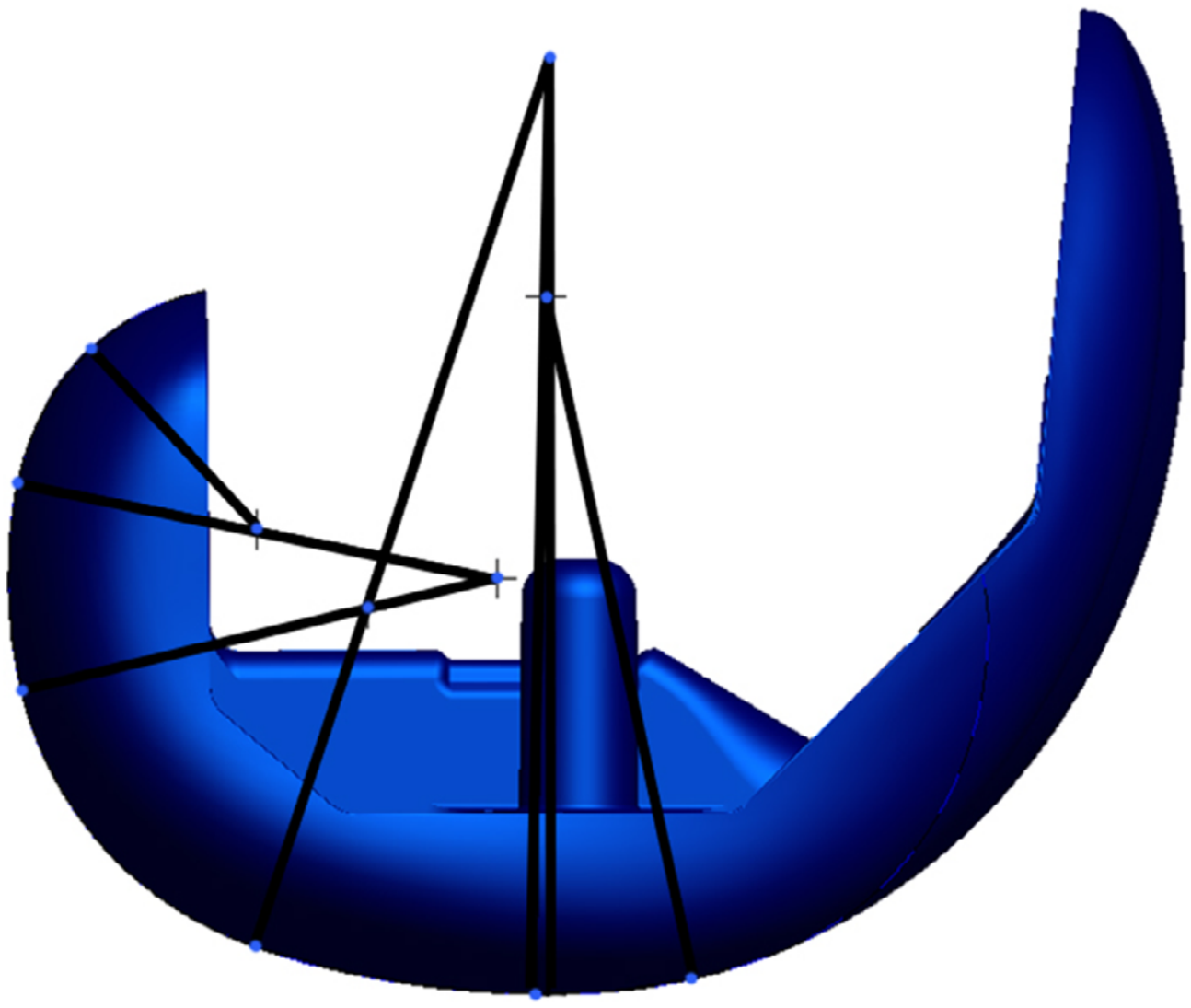
Zimmer NexGen – CR Flex femoral component[116]			
Size	**M/L (mm)**	**A/P (standard)**	**A/P (minus size)**
B	58	48.5	N/A
C	60	53.5	51.5
D	64	57.5	55.5
E	68	61.5	59.5
F	72	65.5	63.5
G	76.5	70.5	68.5

Zimmer NexGen – LPS Flex femoral component[117]		
Size	**M/L (mm)**	**A/P**
A	54	46.5
B	58	50.3
C	60	54.5
D	64	58.6
E	68	62.5
F	72	66.5
G	76.5	71.6

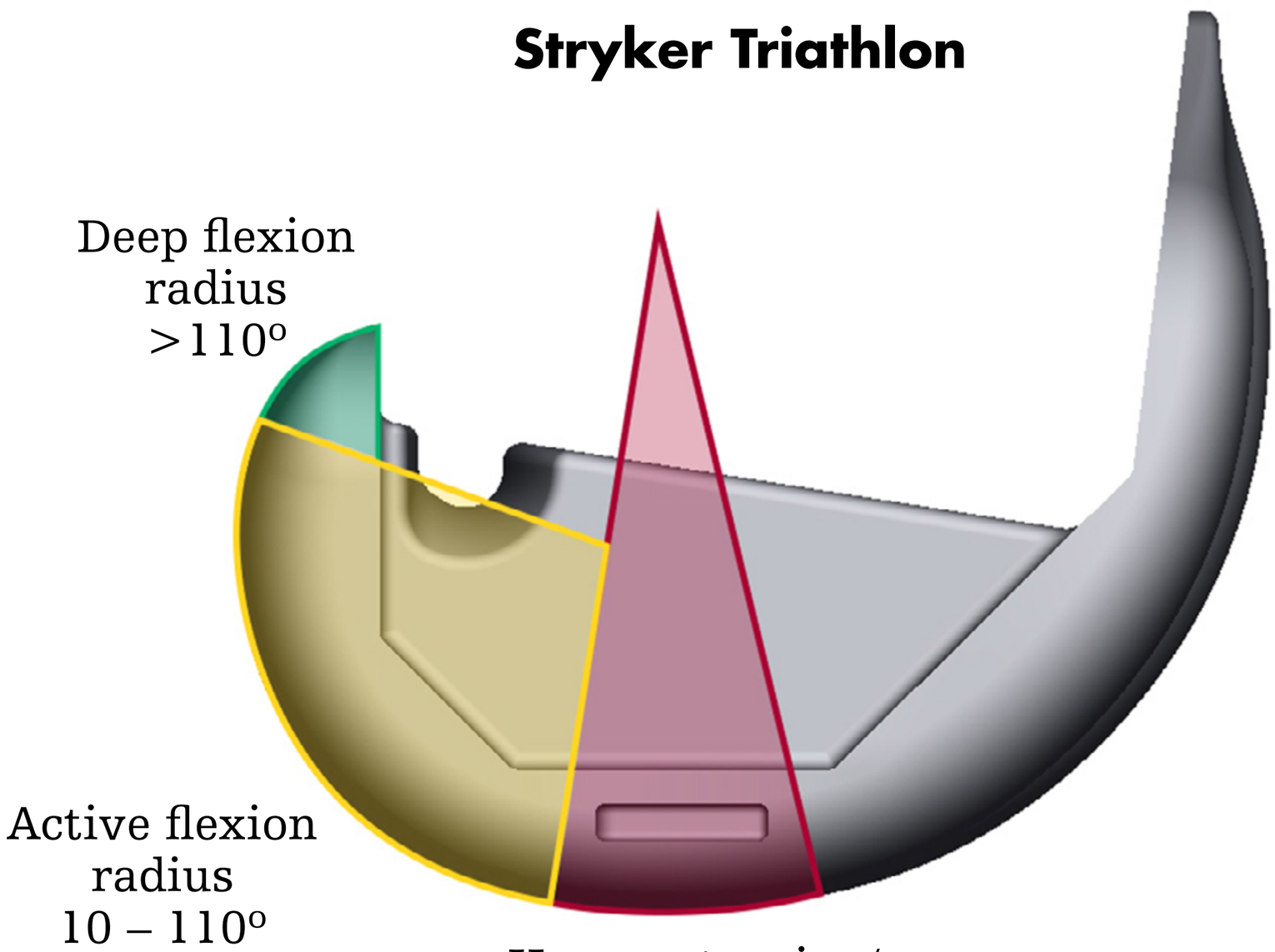
Femoral geometry

The single radius is designed to restore the knee's single center of rotation during active flexion.[21,22] This allows for constant ligament tension and stability in flexion.[2,26,82,107]

Zimmer Biomet Persona[90]

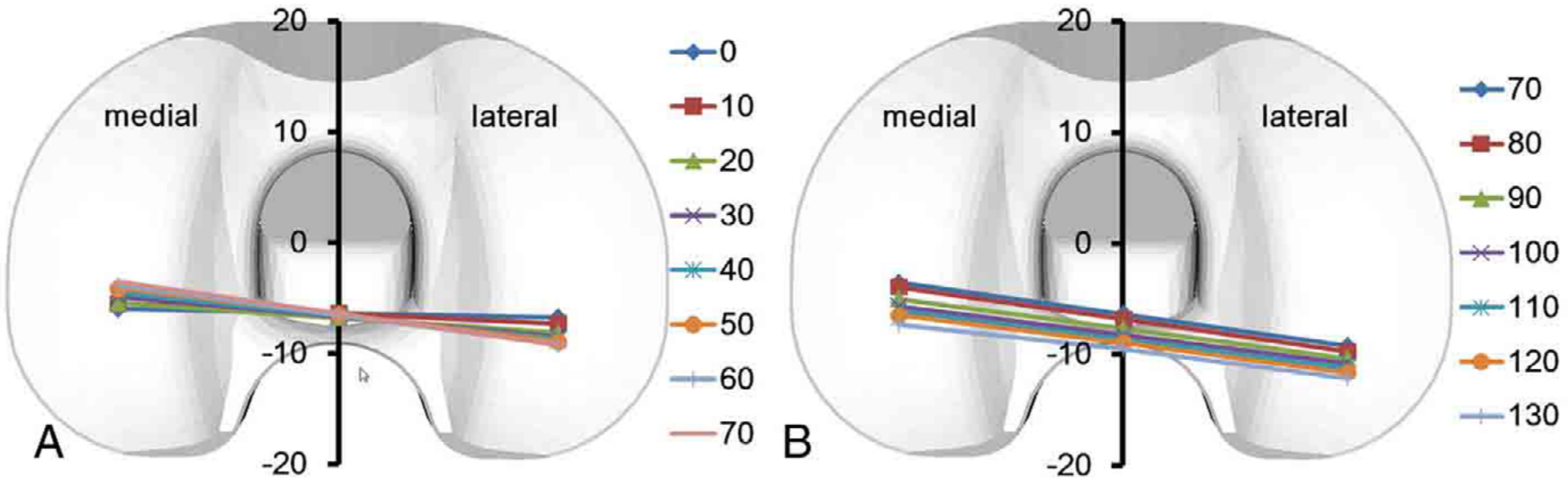


Stryker Triathlon



Stability

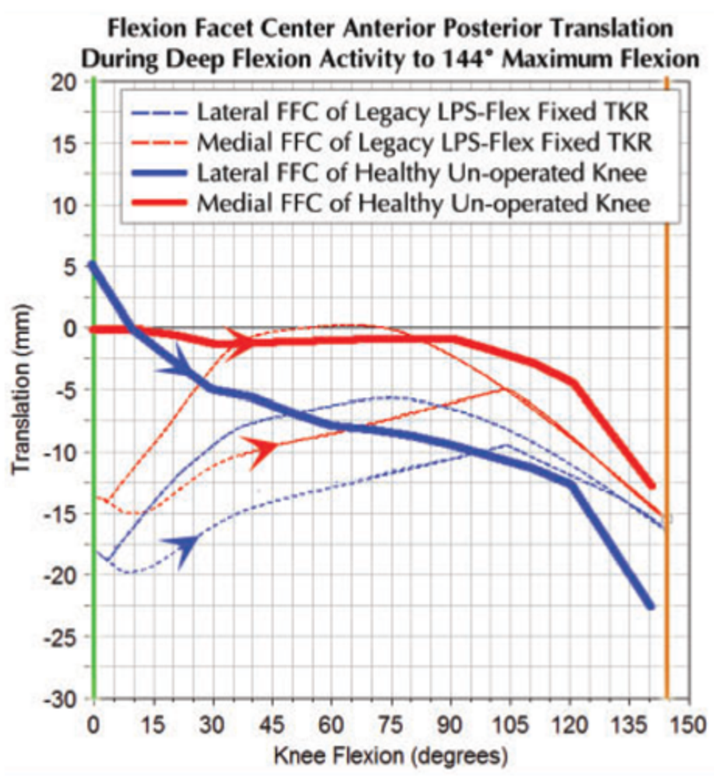
- In a quantitative assessment comparing gait between sixteen patients who received a single radius and sixteen patients who received a multi-radius total knee, Triathlon single radius patients experienced gait patterns that mimicked those of healthy individuals.[82]
- Fluoroscopic data of Triathlon patients showed that medial pivot is possible without features that force a medial pivot.[107]

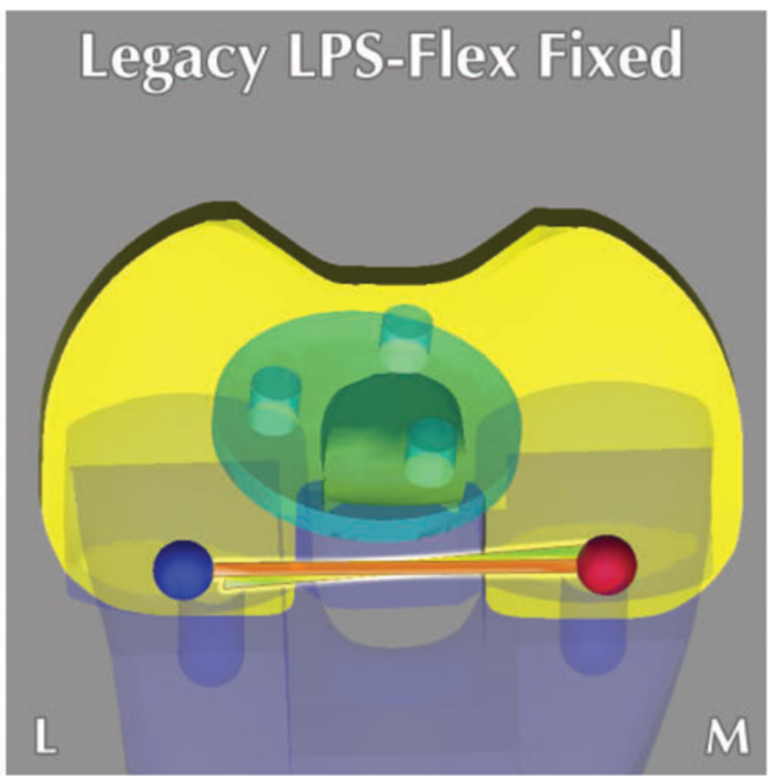


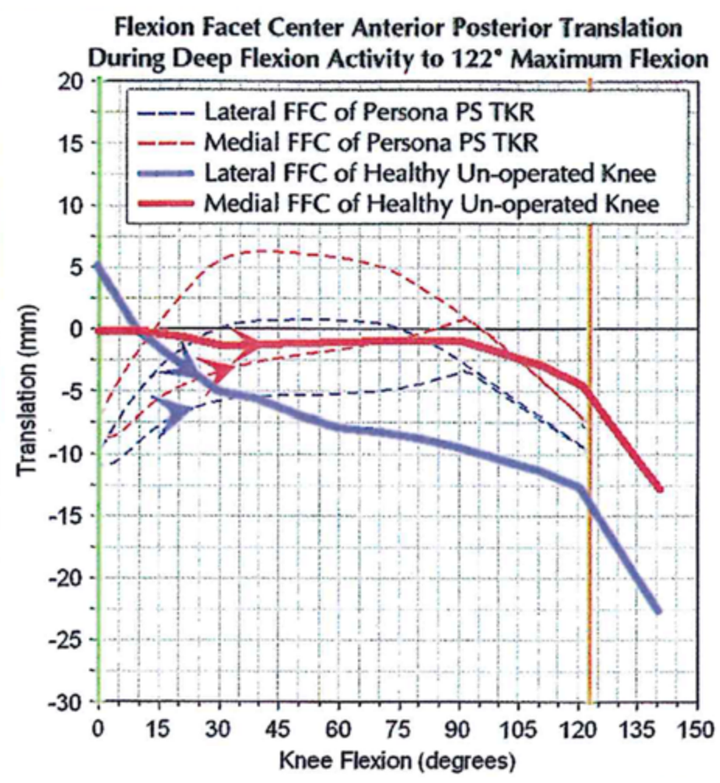
Deep flexion

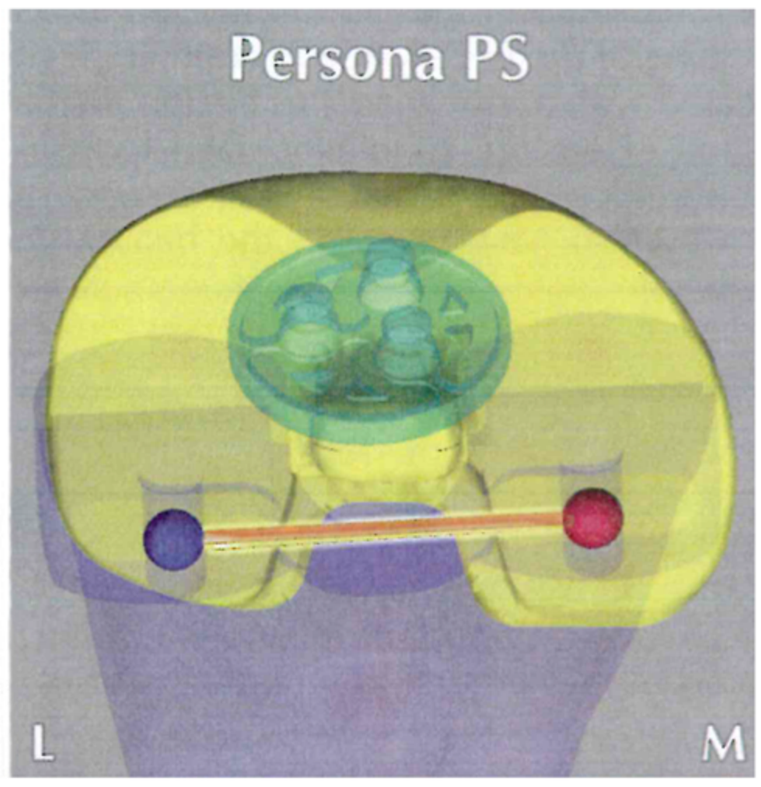
Triathlon can achieve deep flexion without excessive tibial slope. The surgical technique for Persona calls for 7º of slope.[131] One publication showed that in TKA revised for flexion instability, the average pre-revision slope was approximately 7º.[129]

Zimmer uses LifeMod data to promote flexion with their implants.[119] One LifeMod publication showed 22º less flexion with Persona compared to NexGen-LPS Flex.[109]

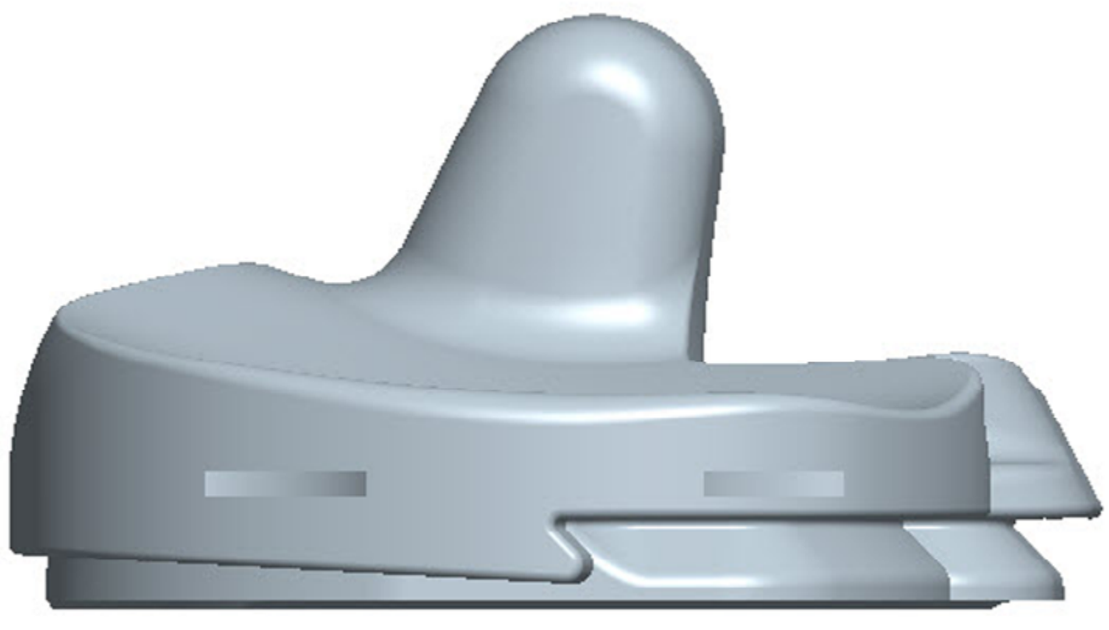








A closer look at Persona's post design shows how the post is used to lever the femur back as the cam travels up the post. Persona uses implant-driven motion to achieve deep flexion.



Polyethylene

- A published study showed that wear and mechanical integrity of X3 PS inserts were unaffected by accelerated aging, even after a rigorous stair-climbing test.[16] Furthermore, the fracture toughness of X3 is double the minimum ASTM F648 requirement.[18]
- Zimmer Persona is available with Vitamin E polyethylene.[63] One case study reported early fracture of this Vitamin E polyethylene tibial insert following primary TKA.[81]

Size charts

Zimmer Persona CR – A/P and M/L dimensions[115]					
Size	**Functional A/P (mm)**	**M/L Narrow (mm)**	**M/L Std. (mm)**	**Overall A/P Narrow**	**Overall A/P Standard**
1	41	55.5	N/A	48	N/A
2	43	57	N/A	50	N/A
3	45	58.5	62.5	52	53
4	47	60	64.25	54	55
5	49	61.5	66	56	57
6	51	63	67.75	58	59
7	53	64.5	69.5	60	61
8	55	66	71.25	62	63
9	57	67.5	73	64	65
10	59	69	74.75	66	67
11	61	70.5	76.5	70	71
12	65	N/A	77.5	N/A	78

Zimmer Persona PS – A/P and M/L dimensions[115]					
Size	**Functional A/P (mm)**	**M/L Narrow (mm)**	**M/L Std. (mm)**	**Overall A/P Narrow**	**Overall A/P Standard**
1	42	55.5	N/A	48	N/A
2	44	57	N/A	50	N/A
3	46	58.5	62.5	52	53
4	48	60	64.25	54	55
5	50	61.5	66	56	57
6	52	63	67.75	58	59
7	54	64.5	69.5	60	61
8	56	66	71.25	62	63
9	58	67.5	73	64	65
10	60	69	74.75	66	67
11	62	70.5	76.5	70	71
12	66	N/A	77.5	N/A	78

Zimmer Persona PS – box dimensions[115]	
Box Width	**Box Height**
14.1	8
14.1	8
17	8
17	8
17	8
18.1	8
18.1	8
18.1	8
18.1	8
21.5	12
21.5	12
21.5	12

Zimmer Persona Stemmed Tibial – A/P and M/L dimensions[115]				
Size	**Functional A/P (mm)**	**M/L Narrow (mm)**	**M/L Std. (mm)**	**Overall A/P Narrow**
A	40.20	35.10	57.70	1
B	42.50	37.23	60.80	1
C	44.90	39.48	63.80	1
D	47.20	41.75	67.00	1.5
E	50.20	44.55	71.00	2
F	53.30	47.40	75.10	2.5
G	56.50	50.21	79.00	3
H	59.80	53.32	82.97	3.5
J	63.53	56.66	88.06	4

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