stryker

Restoration®

Anatomic Shell

Restoration Anatomic Shell Design Rationale

The Restoration Anatomic Shell is an evolution in revision acetabular shell design focused on offering a potential simple solution for a number of the clinical challenges faced by surgeons when revising the acetabulum such as hip instability, mechanical loosening and soft tissue irritation.

Anatomic placement of the acetabular component is one of the surgeon's goals at the time of revision THA. However, acetabular loosening with subsequent implant migration, progressive superior bone destruction, or severe pelvic osteolysis may prevent the surgeon from obtaining the adequate host bone – implant contact needed for a successful reconstruction while maintaining a normal hip center.[1]

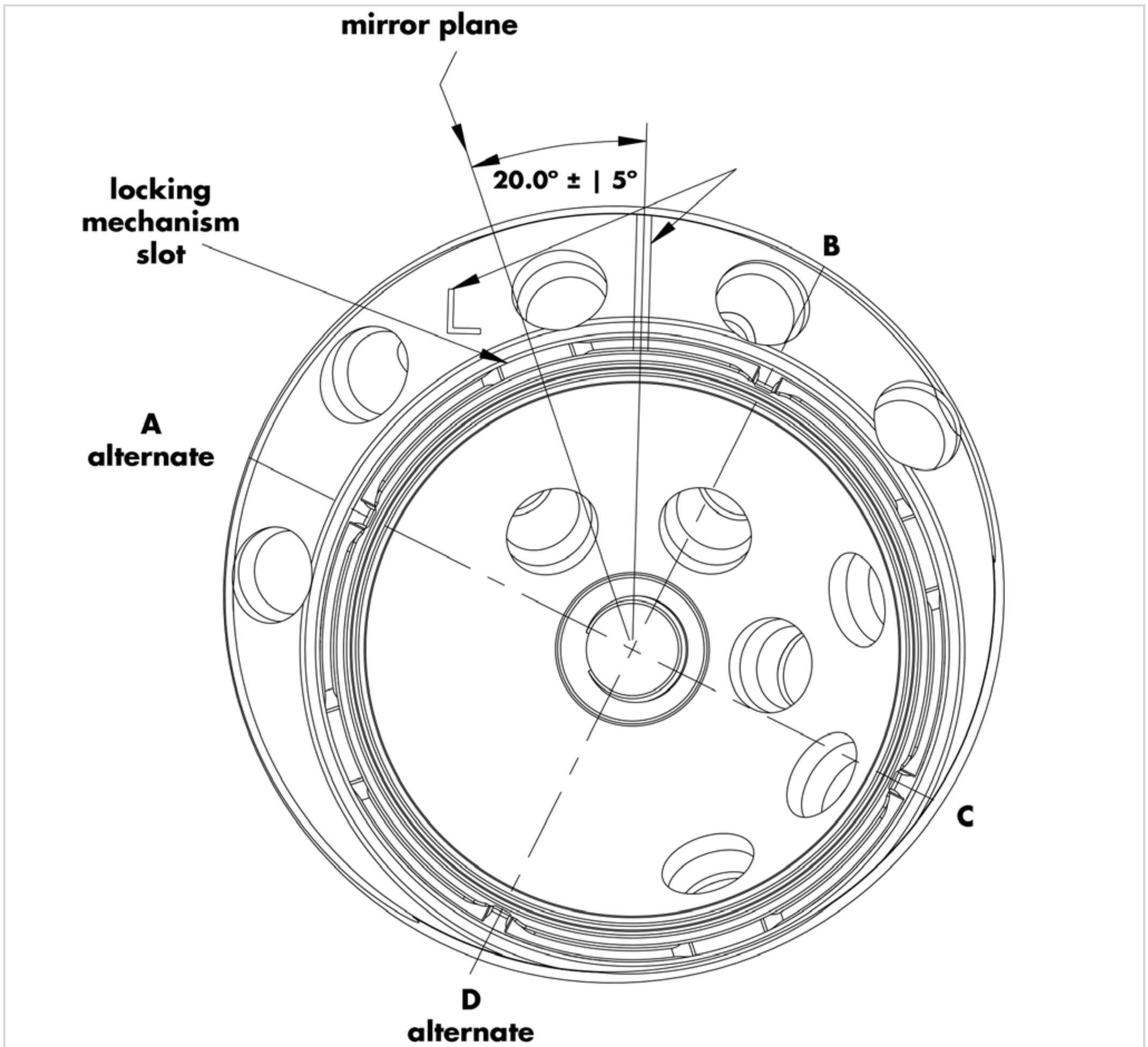
The Restoration Anatomic Shell may offer a solution for these cases.

Shell design

The use of an oversized or “jumbo” acetabular shell is an effective treatment option for failed acetabular components and its clinical success has been documented.[2]

However jumbo shells may also be associated with hip center elevation, limited screw fixation options, and anterior soft tissue impingement.[3]

The Restoration Anatomic Shell was designed with an offset center of rotation, peripheral screw hole options and a beveled anterior and superior rim as an alternative to a conventional jumbo shell.



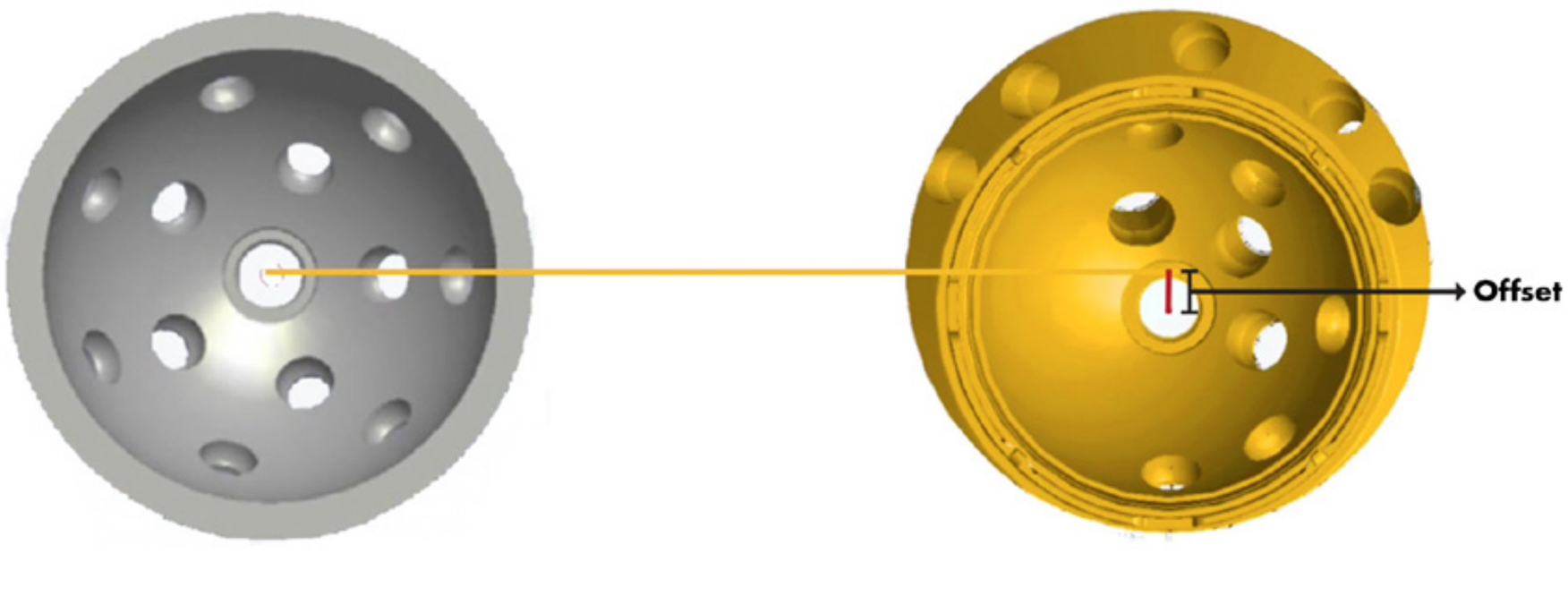
Offset center of rotation

Hip center elevation may occur with the use of a jumbo shell owing to reaming superiorly and/or because of the increased diameter of the jumbo shell compared with the native acetabulum.[4]

Surgeon concerns with an elevated hip center include decreased strength of the abductor muscles, which may alter hip biomechanics as well as increased hip loads leading to the potential for component loosening.[5] Additionally, although the causes of hip instability after revision arthroplasty are multifactorial, hip center elevation resulting in soft tissue laxity could be a contributing factor.[6]

Joint biomechanics

- Offset center of rotation



The Restoration Anatomic Shell design includes an offset center of rotation that is designed to maintain the center of rotation closer to the anatomic hip center[2] and may reduce hip center elevation.

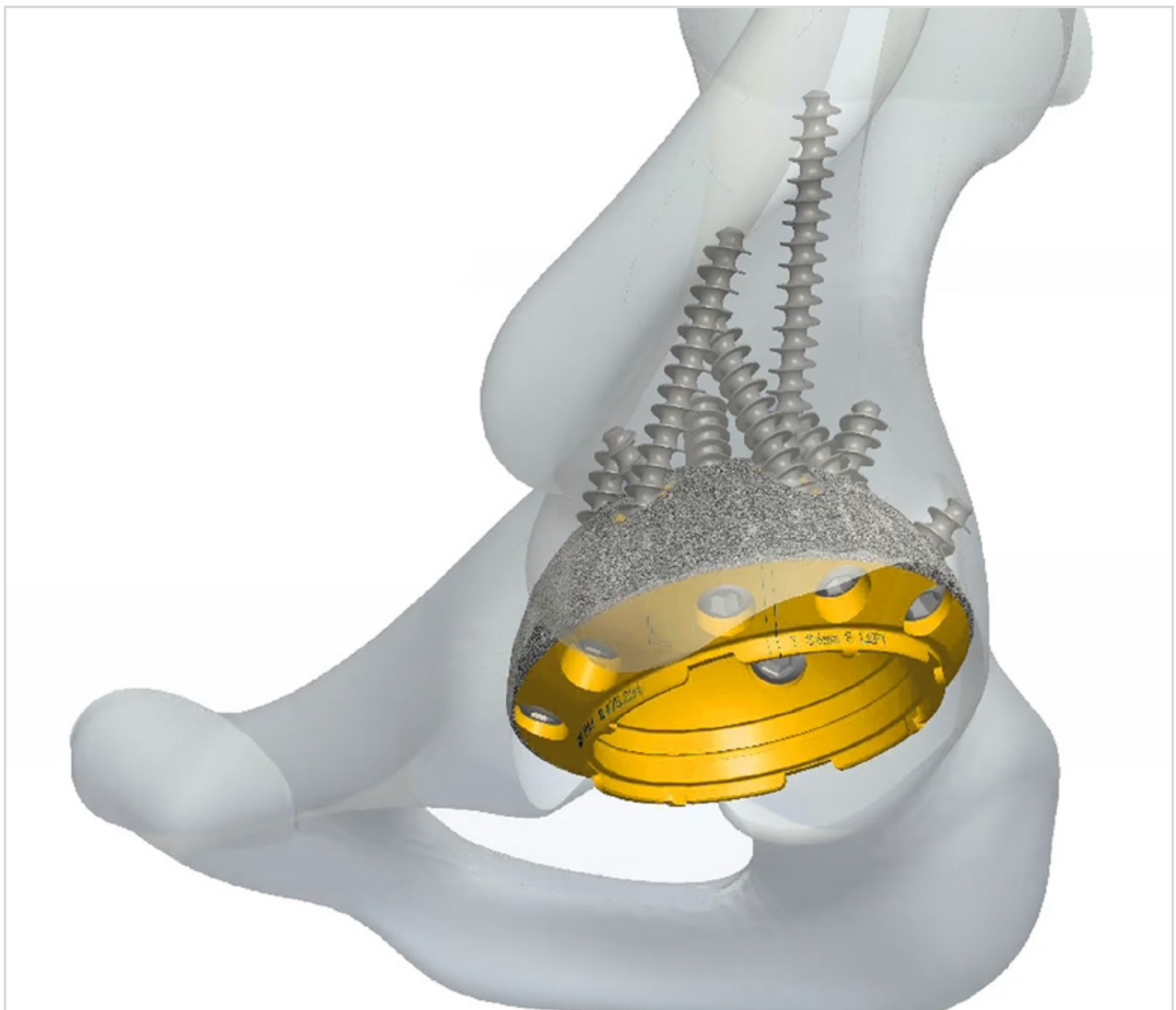
Peripheral rim screws

Although revision acetabular shells are seated directly against host bone, initial fixation of the component frequently relies on the use of screws. Screw fixation, however, may be limited by poor pelvic bone stock, unsafe areas of screw fixation anteriorly, and implant screw hole locations, which may restrict the trajectories of multiple screws into the posterior column of pelvic bone.[3]

In addition to conventional dome screws, a thicker superior rim of the Restoration Anatomic Shell is designed to permit the use of multiple peripheral screws directed into the posterior column of the pelvis.[3]

Bone fixation

- Perioheral screw holes
  - SOMA designed trajectory
- Tritanium surface
  - Allows for initial and long-term fixation



SOMA designed

Unlike typical revision shell designs with peripheral rim screw holes perpendicular to the shell's rim, the placement and trajectories of the screw holes of the Restoration Anatomic Shell were optimized by using Stryker's Orthopaedics Modeling and Analytics (SOMA) system the heart of which is a large database of high resolution CT scans* of bones.[7] Restoration Anatomic Shells are left and right side specific to take advantage of the screw trajectories into the best bone of the illium.

*Optimized fit based on sample size of 265 scans of skeletally mature pelvic CT scans

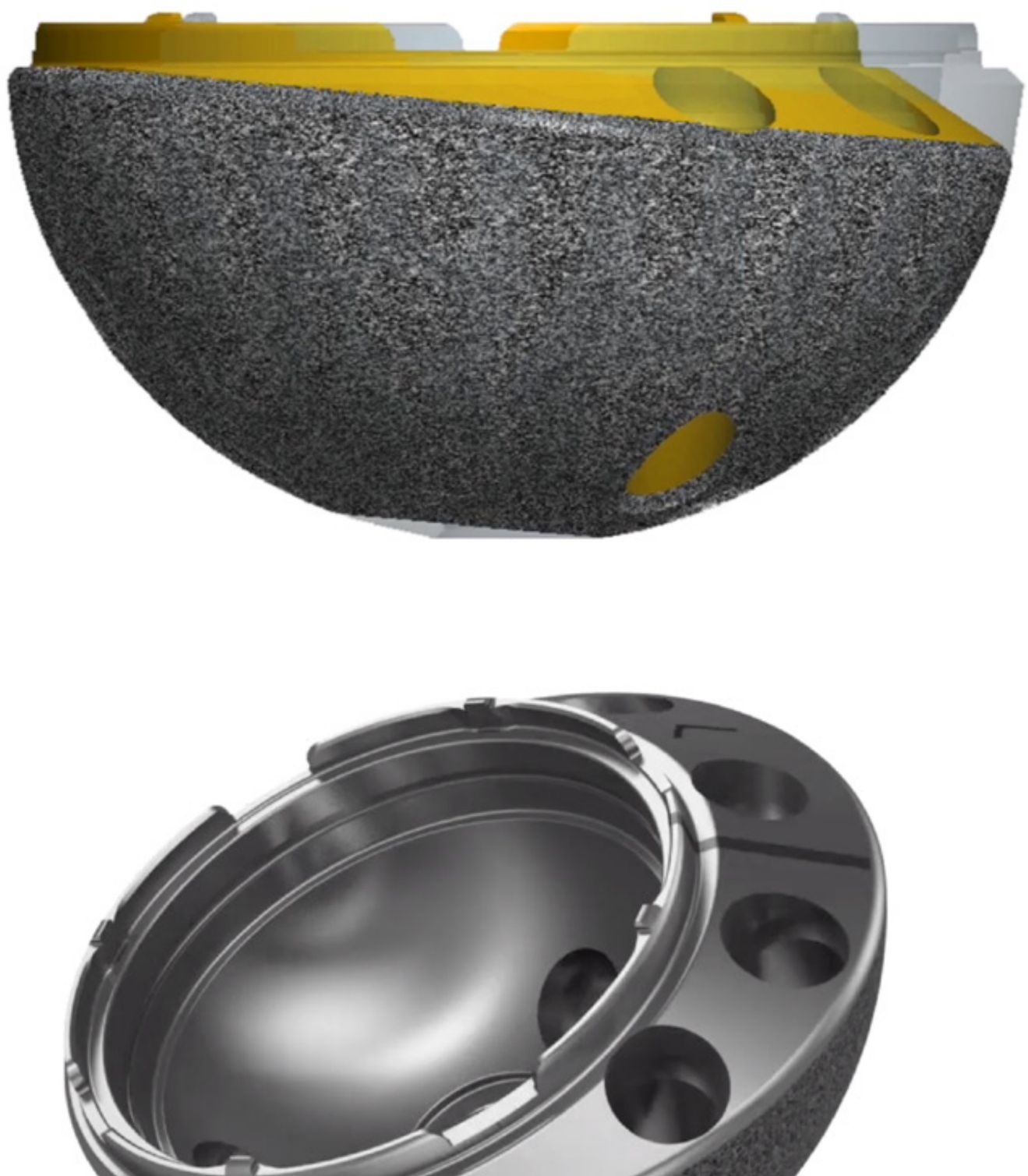
Anterior/superior beveled rim

The use of a jumbo shell may result in a shell diameter larger than the native acetabulum diameter. This may result in protrusion of the anterior edge of the shell beyond the anterior wall and removal of anterior column bone, potentially leading to iliopsoas impingement. Iliopsoas tendonitis can cause groin pain after total hip arthroplasty due to soft tissue impingement against the anterior edge of the cup.[8]

The anterior and superior bevel is designed to allow for a relief to potentially avoid soft tissue impingement particularly in the region of the iliopsoas tendon.[3]

Soft tissue relief

- Superior / Anterior bevled rim
- Potentially avoid soft tissue impingement[3]



PLAY VIDEO

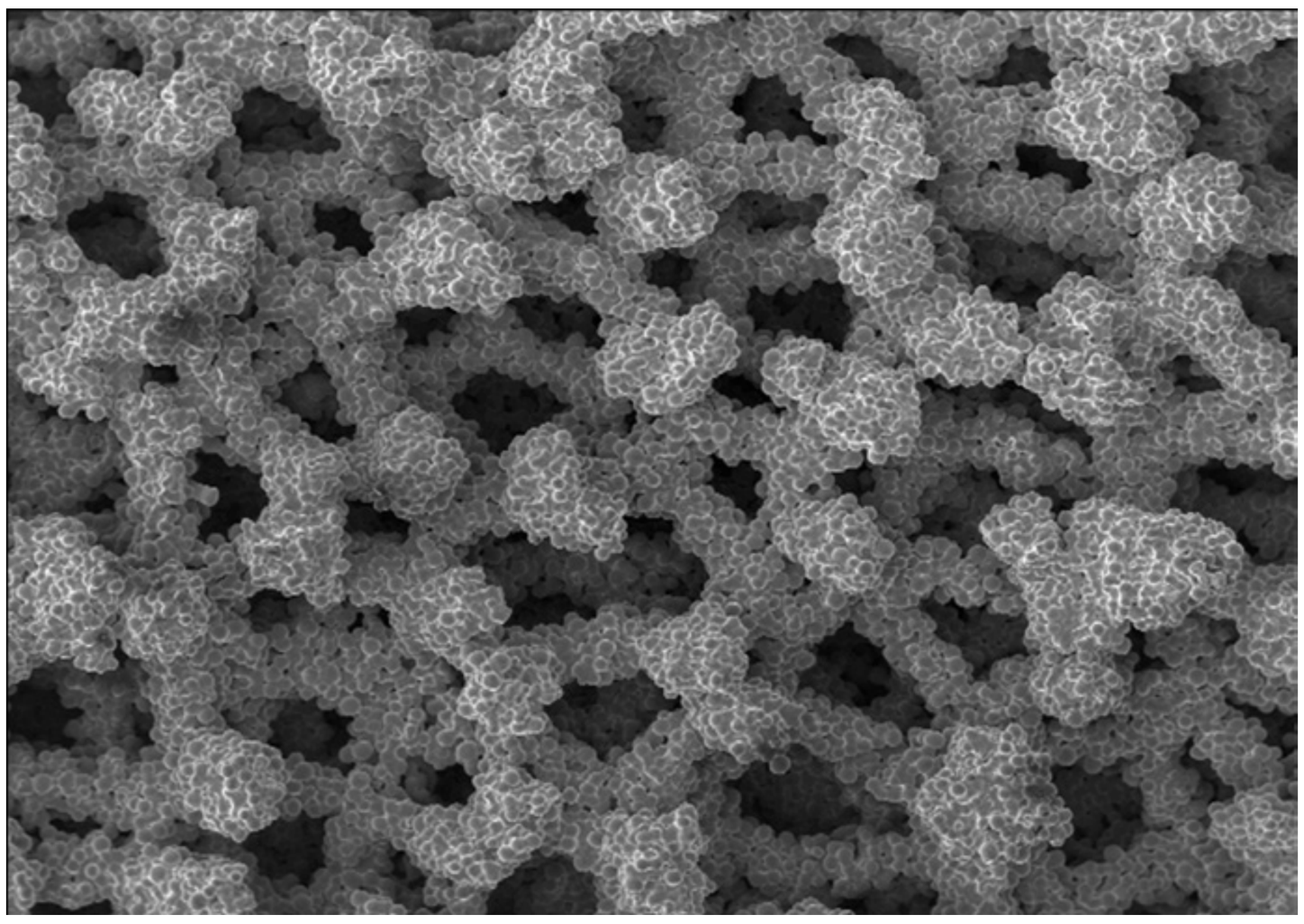
Advanced bearing options

The Restoration Anatomic Shell features a patented[11] locking mechanism that is designed to reduce backside wear[12] and increase jump distance for increased stability with Stryker's MDM.[13,14]

The shell is compatible with X3 polyethylene liners and MDM X3 to allow surgeons to address the wide breadth of reconstruction challenges they may face in hip surgeries.

Tritanium material

The surface of the Restoration Anatomic Shells consists of highly porous and roughened Tritanium created from a 3-Dimensional matrix of commercially pure Titanium (CPTi) designed to allow for initial stability and resist micromotion.[9,10]



Instrumentation

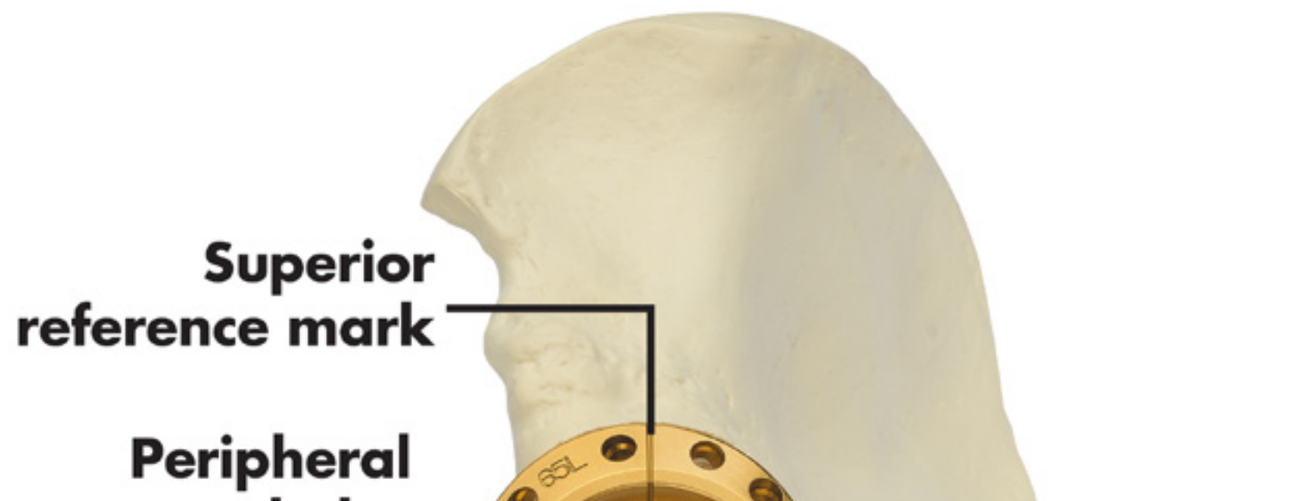
Window trials

Restoration Anatomic window trials are left and right side specific due to the orientation of the peripheral screw holes, the ischial screw holes and superior / anterior rim bevel.

Window Trials are 1mm smaller than the implant outer diameter so as not to impair press-fit stability of the implant.

The trials are color coded (gold – left trial / black – right trial) and marked with an "L" for left and "R" for right for easy identification.

To help assess screw hole location, the Window Trials include the position of the implant peripheral screw holes and incorporate two inferior scribe lines indicating the center of the ischial screw hole positions. Additionally, the trials incorporate a scribe line on the superior bevel surface for reference.



Drill guides

The Restoration Anatomic Shell instrumentation includes two drill guides, a 3.3mm and 4.0mm. The drill guides have a shorter barrel to help prepare for the dome screws and a longer barrel, which engages the peripheral screw holes.

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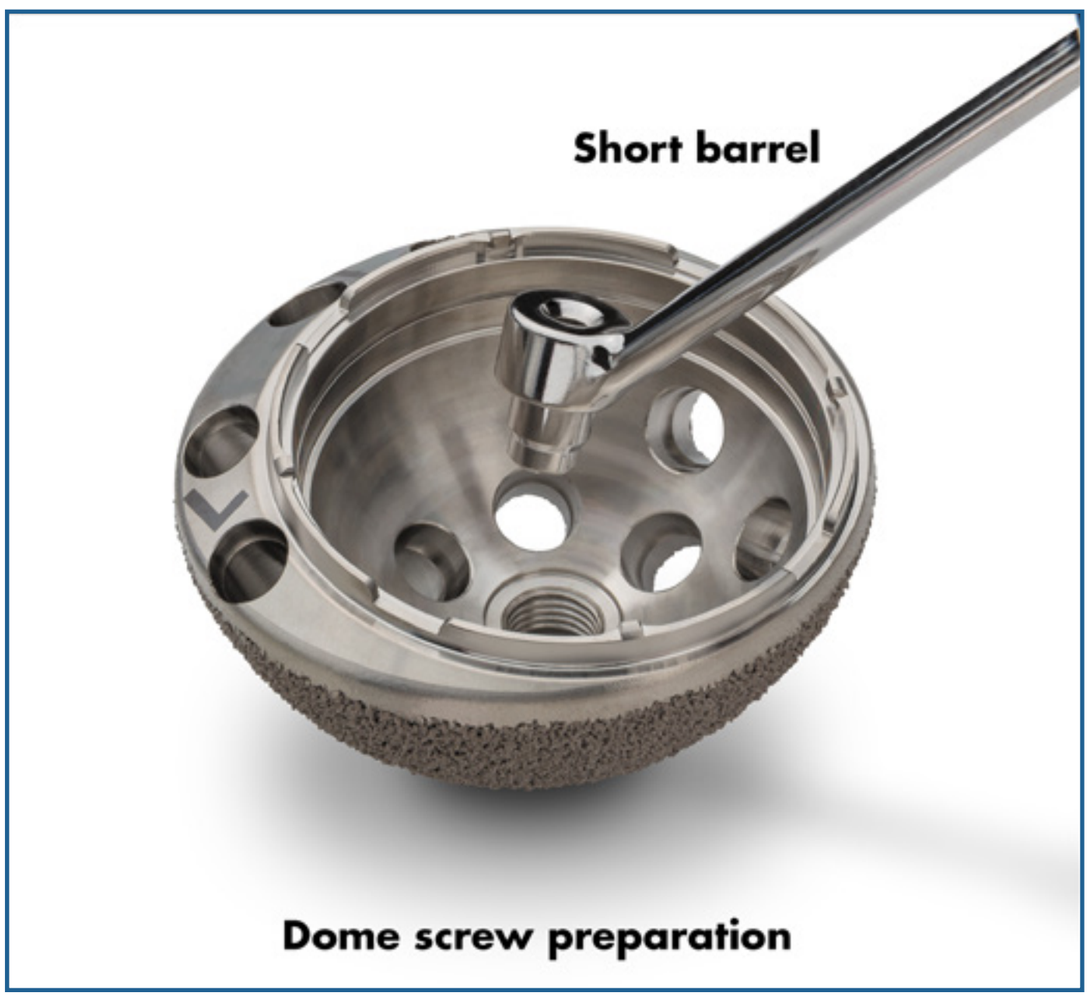
Peripheral screw preparation



Dome screw preparation

Computer simulation study

- Journal of Arthroplasty - January 2016[3]
- A 3-D computer simulation was used to assess head center position and safe screw trajectories
- Results indicate that a modified hemispherical implant geometry may reduce head center elevation while permitting favorable screw fixation trajectories into the pelvis in comparison to a conventional jumbo cup

VIEW STUDY

Instruments & implants

Catalog numbers

Catalog #	size (mm)	side
504-02-54C-L	54	left
504-02-56D-L	56	left
504-02-58D-L	58	left
504-02-60D-L	60	left
504-02-62E-L	62	left
504-02-64E-L	64	left
504-02-66F-L	66	left
504-02-68F-L	68	left
504-02-70G-L	70	left
504-02-72G-L	72	left
504-02-74H-L	74	left
504-02-76H-L	76	left
504-02-78H-L	78	left
504-02-80H-L	80	left
504-02-54C-R	54	right
504-02-56D-R	56	right
504-02-58D-R	58	right
504-02-60D-R	60	right
504-02-62E-R	62	right
504-02-64E-R	64	right
504-02-66F-R	66	right
504-02-68F-R	68	right
504-02-70G-R	70	right
504-02-72G-R	72	right
504-02-74H-R	74	right
504-02-76H-R	76	right
504-02-78H-R	78	right
504-02-80H-R	80	right

Dimension & compatibility

Compatible inserts & liners

MDM Liner and insert compatibility with Restoration Anatomic Shells

Restoration Anatomic Shell (mm)	54	56, 58, 60	62, 64	66, 68	70, 72	74, 76, 78, 80
Liner alpha code	**C**	**D**	**E**	**F**	**G**	**H**
MDM CoCr Liner	36C	38D	42E	46F	48G	52H
Poly Insert OD (mm)	36	38	42	46	48	52
Poly Insert ID (mm)	22.2	22.2	28	28	28	28
Nominal Poly Thickness (mm)	6.7	7.7	6.8	8.8	9.8	11.8

Femoral Head, X3 liner and shell compatibility chart

Shell size, liner alpha code, and liner thickness (mm) for standard liners

Restoration Anatomic Shell (mm)		54	56, 58, 60	62, 64	66, 68	70, 72	74, 76, 78, 80
Liner alpha code		**C**	**D**	**E**	**F**	**G**	**H**
Anatomic Femoral Heads	44mm	–	–	–	3.8	5.4	7.1
	40mm	–	–	3.8	5.8	7.4	9.1
	36mm	–	3.9	5.9	7.9	9.4	11.2
Femoral Heads	32mm	4.9	5.9	7.9	9.9	11.4	13.2
	28mm	6.9	7.9	9.9	11.9	13.4	15.2
	26mm	7.9	8.9	10.9	12.9	14.4	16.2
	22mm	9.8	10.8	12.8	14.8	16.3	18.1

Trident Polyethylene Insert compatibility

Restoration Anatomic Shell (mm)	54	56, 58, 60	62, 64	66, 68	70, 72	74, 76, 78, 80
Liner alpha code	**C**	**D**	**E**	**F**	**G**	**H**
Trident 0°, 10° Inserts (mm)	22, 26	22, 26, 28, 32, 36*	22, 26, 28, 32, 36, 40*	22, 26, 28, 32, 36, 40*, 44*	22, 26, 28, 32, 36, 40*, 44*	22, 26, 28, 32, 36, 40*, 44*
Trident Eccentric 0°, 10° Inserts (mm)	28	28, 32	28, 32, 36	28, 32, 36	28, 32, 36	28, 32, 36
Trident 0° Constrained Inserts (mm)	–	22	22	28	28	32
Trident Elevated Rim Inserts (mm)	–	–	22	22	28	28

Restoration Anatomic Shell screw holes

Restoration Anatomic Shell (mm)
54, 56, 58

Total # of screw holes (peripheral)
8 (2)

Restoration Anatomic Shell (mm)
60, 62, 64, 66, 68, 70, 72

Total # of screw holes (peripheral)
11 (5)

Restoration Anatomic Shell (mm)
74, 76, 78, 80

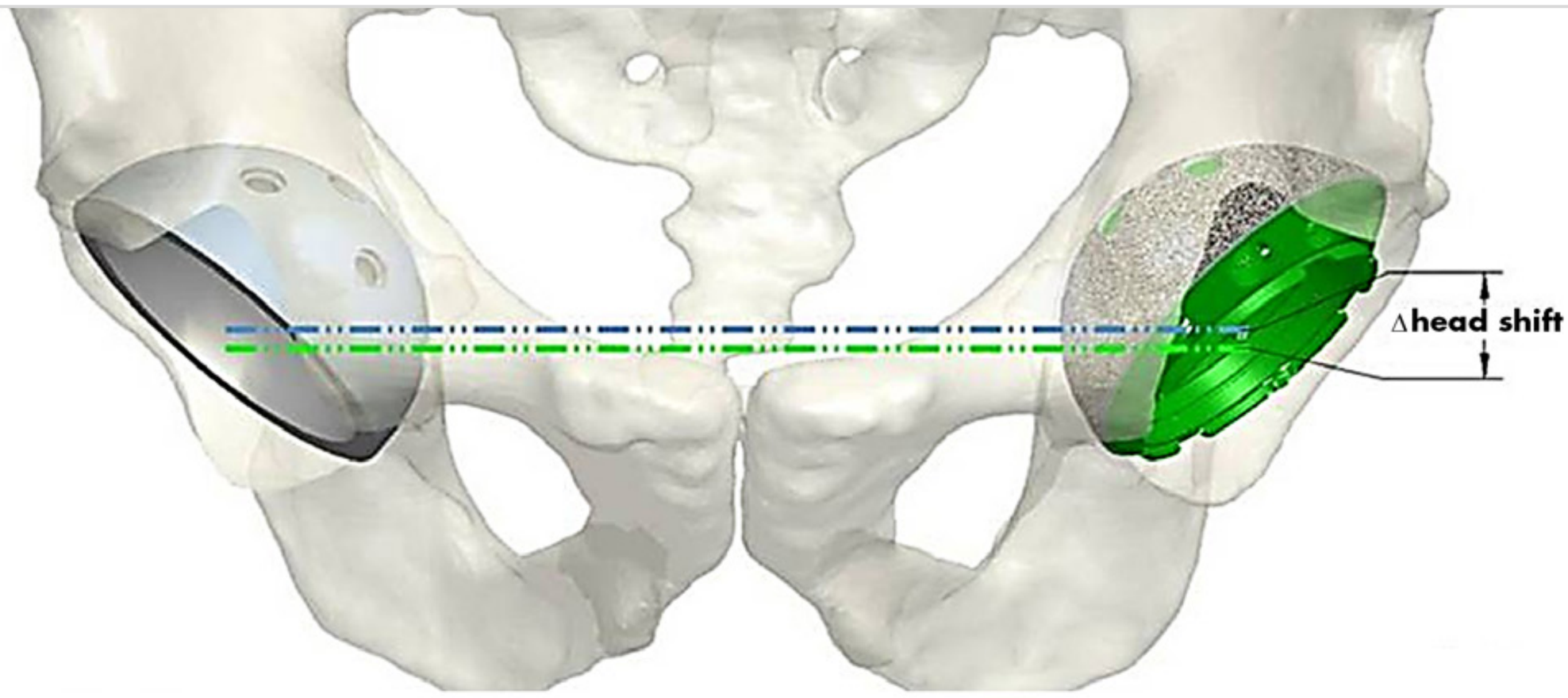
Total # of screw holes (peripheral)
12 (5)

Anterior – A **Superior – S**

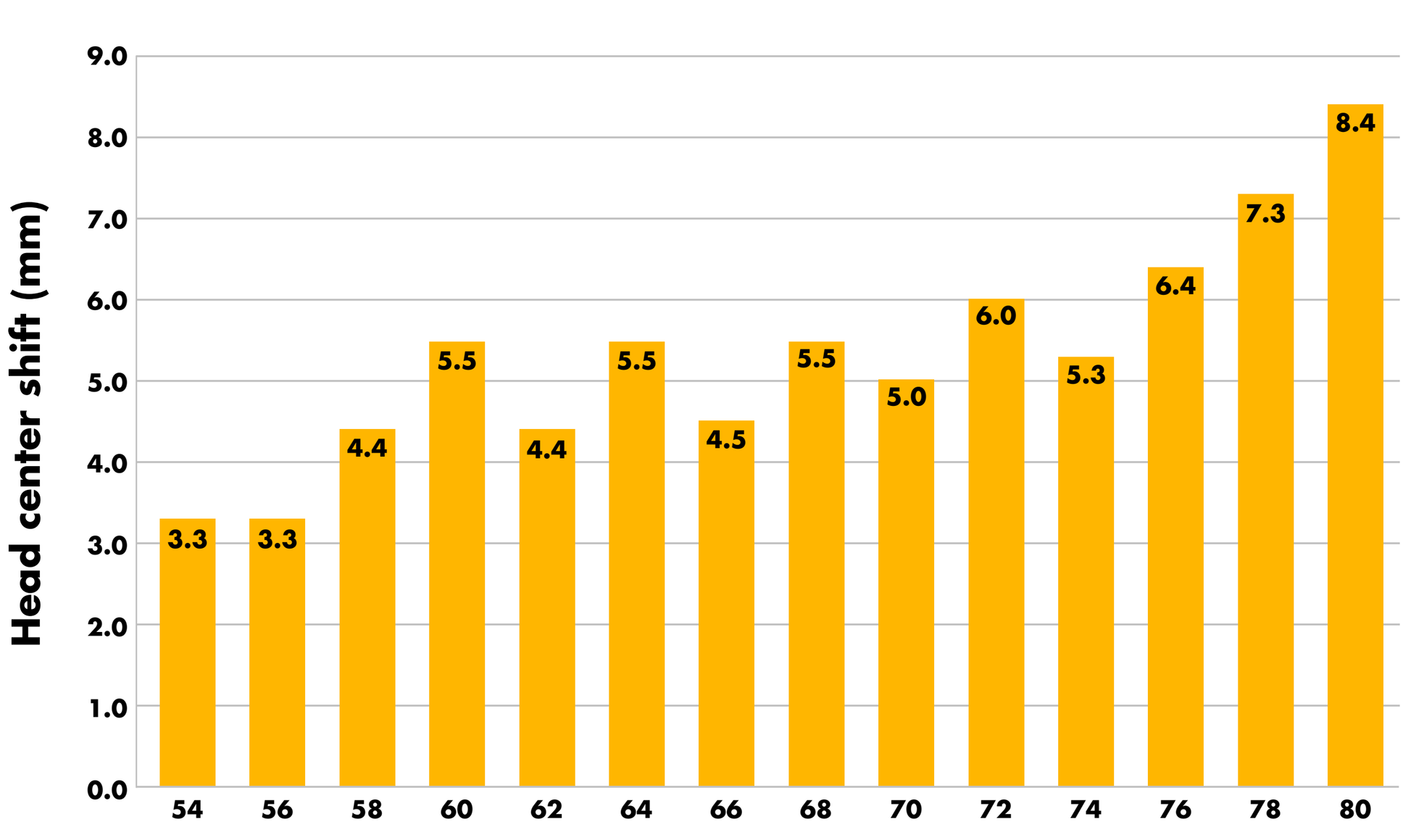
Posterior – P **Inferior – I**

All components depicted are left shells.

Head center shift



Restoration Anatomic Shell head center shift



Q1. What screws are compatible with the RAS?

A. Both 6.5mm GAP Torx screws (2080-00XX) and Osteolock Hex screws (5260-5-0XX) are compatible with the RAS shell.

VIEW SURGICAL PROTOCOL

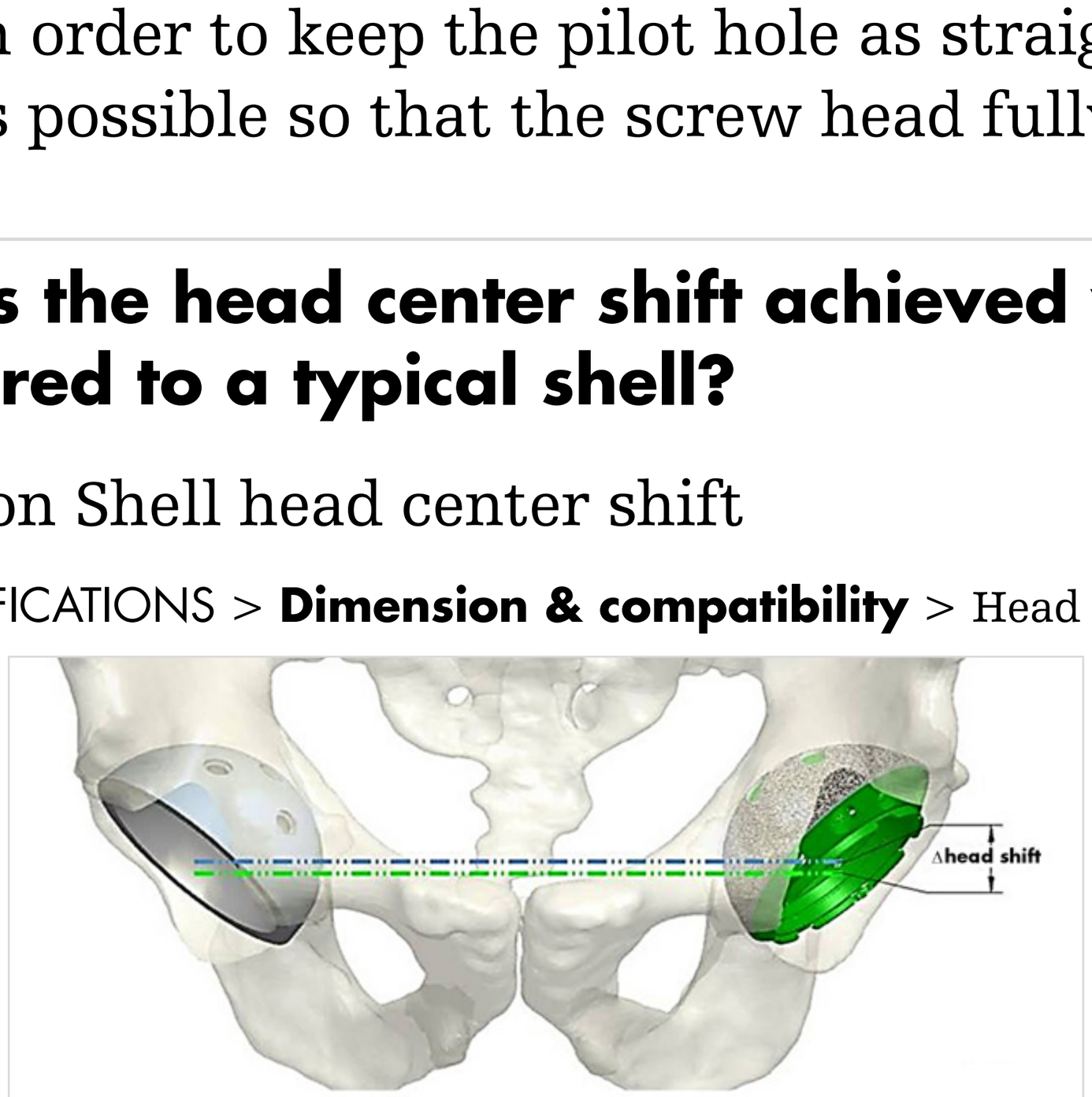
Q2. Can I use any Drill Guide with the RAS?

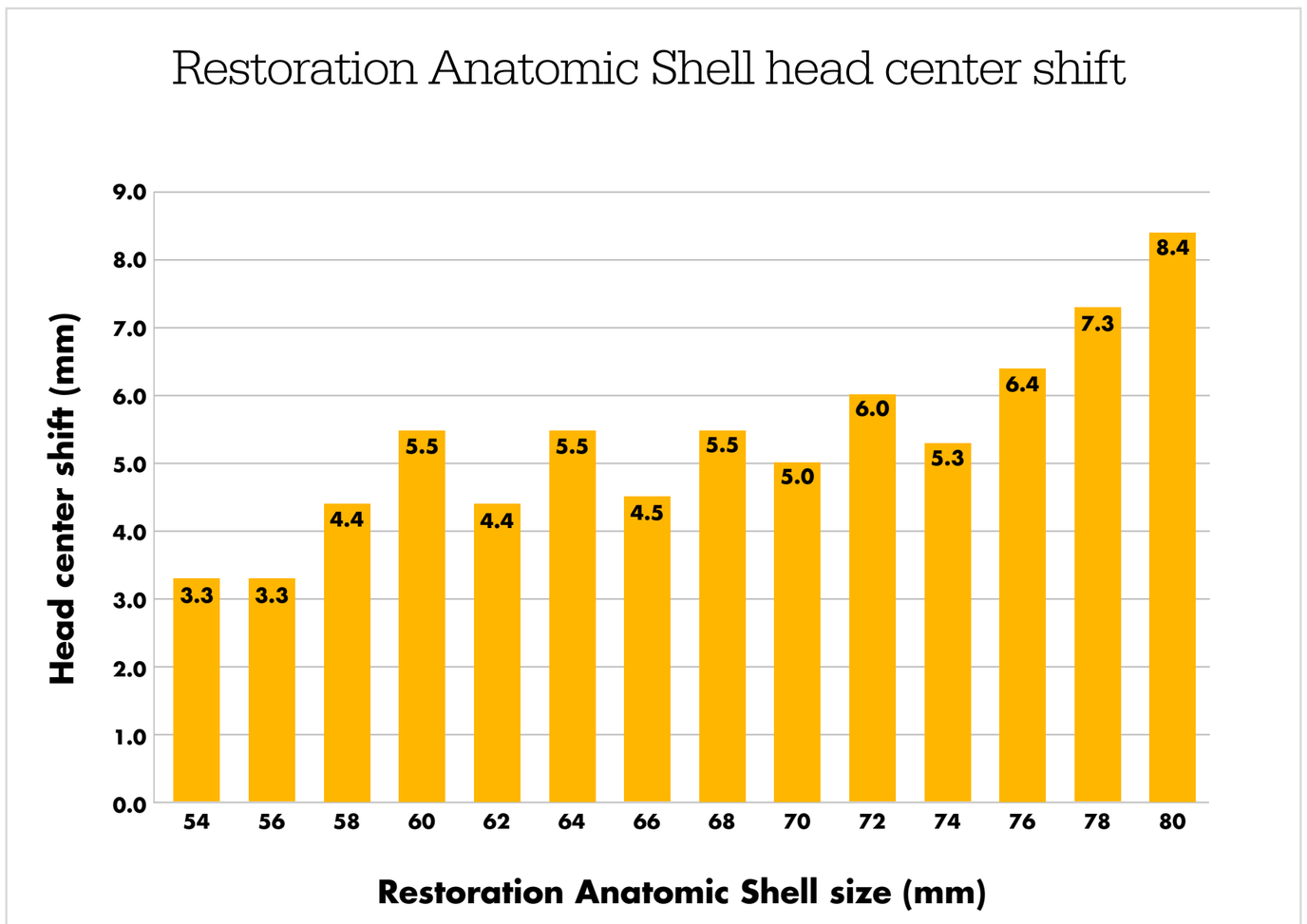
A. Only the 3.3mm or 4.0mm Drill Guides supplied with the RAS instrumentation should be used. The Drill guides have a shorter barrel to help prepare for the dome screws and a longer barrel which engages into the peripheral screw holes. It is important to use the Drill Guides when preparing for the screws in order to keep the pilot hole as straight and concentric as possible so that the screw head fully seats.

Q3. What is the head center shift achieved with the RAS compared to a typical shell?

A. Restoration Shell head center shift

TECHNICAL SPECIFICATIONS > **Dimension & compatibility** > Head center shift





Q4. How many screw holes does the RAS offer?

A. The image provided on each product label will also provide you with a visual as to number of screw holes and approximate location for each shell size.

TECHNICAL SPECIFICATIONS > **Dimension & compatibility** > Screw holes

Q5. Why are there left and right shells?

A. The position and trajectory of the screw holes were optimized utilizing the SOMA database and result in left and right specific shells.

DESIGN > **Peripheral rim screws** > SOMA designed

Q6. Why are there no holes in the anterior quadrant of the shell?

A. The design of the shell does not include any screw hole options in the anterior quadrant to minimize risk to intrapelvic structures and maintain as much Tritanium coating surface for intial stability.

DESIGN > **Peripheral rim screws**

Q7. Does the RAS utilize the primary or revision Tritanium coating?

A. The RAS is manufactured with the Revision Tritanium coating, a highly porous and roughened CPTi coating.

TECHNOLOGY > **Tritanium material**

Q8. What liners are compatible with the RAS shell?

A. The RAS shell design incorporated the Trident Locking Mechanism found on Stryker's Trident and Tritanium shells. The same X3, MDM and constrained liners are compatible with the RAS. The RAS is not cleared for use with ceramic liners.

TECHNICAL SPECIFICATIONS > **Dimension & compatibility** > Compatible inserts & liners

Q9. What drill bit to use for preparing the peripheral holes?

A. Utilizing the approriate 3.3mm or 4.0mm Drill Guide, a long drill bit should be used to compensate for the increased thickness of the shell in the peripheral region.

Q10. What are the liner alpha codes for each RAS shell?

A. These alpha codes are smaller than typical Trident or Tritanium shells of the same size due to the head center shift.

TECHNICAL SPECIFICATIONS > **Dimension & compatibility** > Compatible inserts & liners

Q11. Which patients may be the best candidates for the RAS shell?

A. The RAS is indicated for cementless use only and is intended for primary and revision procedures. The RAS is available in sizes 54mm through 80mm and is a simple alternative to jumbo shells. Jumbo shells have been defined in the literature as 62mm or larger in females and 66mm or larger in males.

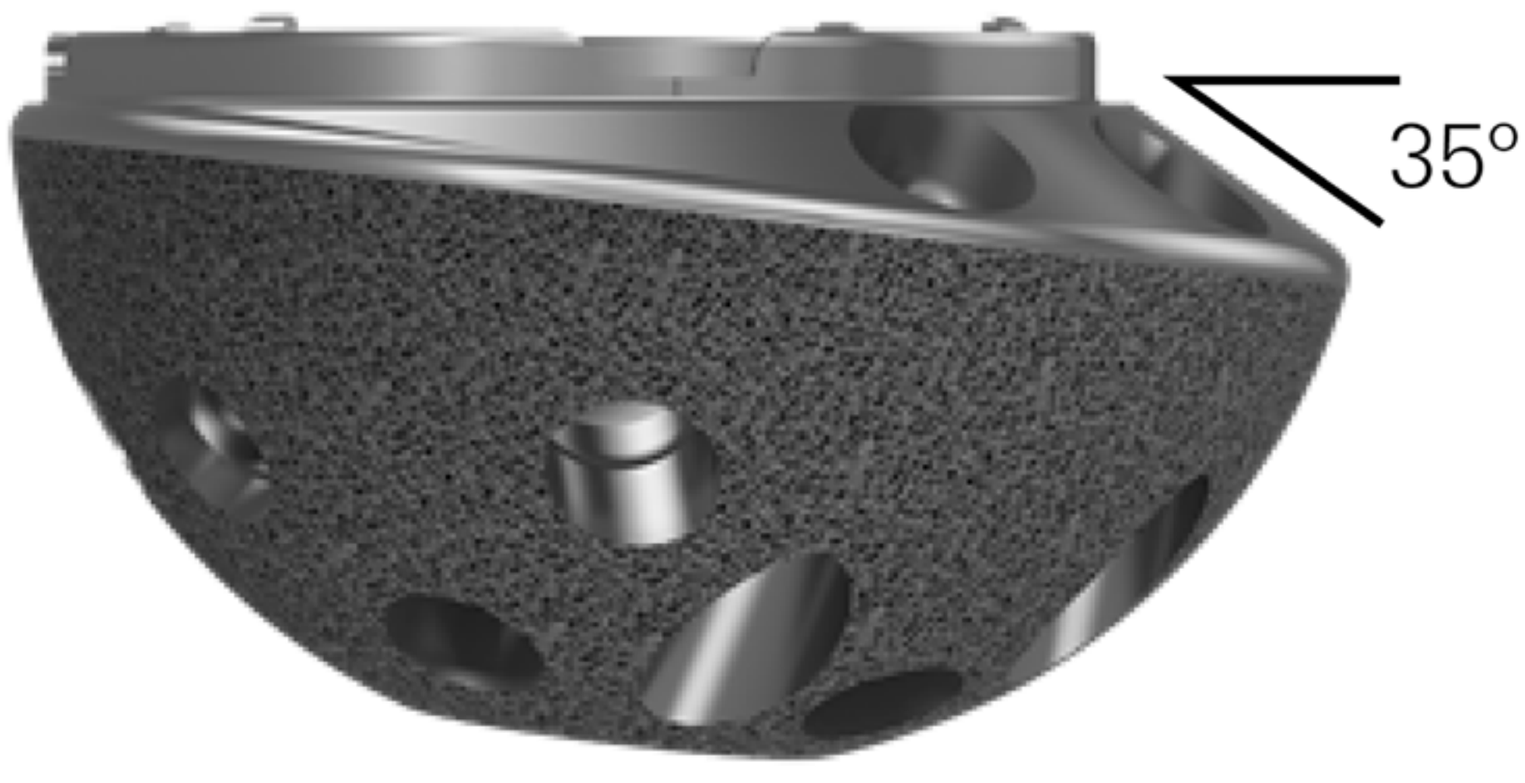
Q12. What instruments are needed to prepare for the RAS?

A. The RAS has its own set of left and right Window Trials and Drill Guides to prepare for the screw holes. The procedure is based purely on implanting a hemispherical shell with conventional instruments and technique.

Q13. What is the angle of the bevel of the rim?

A. The bevel of the rim is swept back 35°.

DESIGN > **Anterior/superior beveled rim**



Q14. What is the significance of the black scribe line on the shells?

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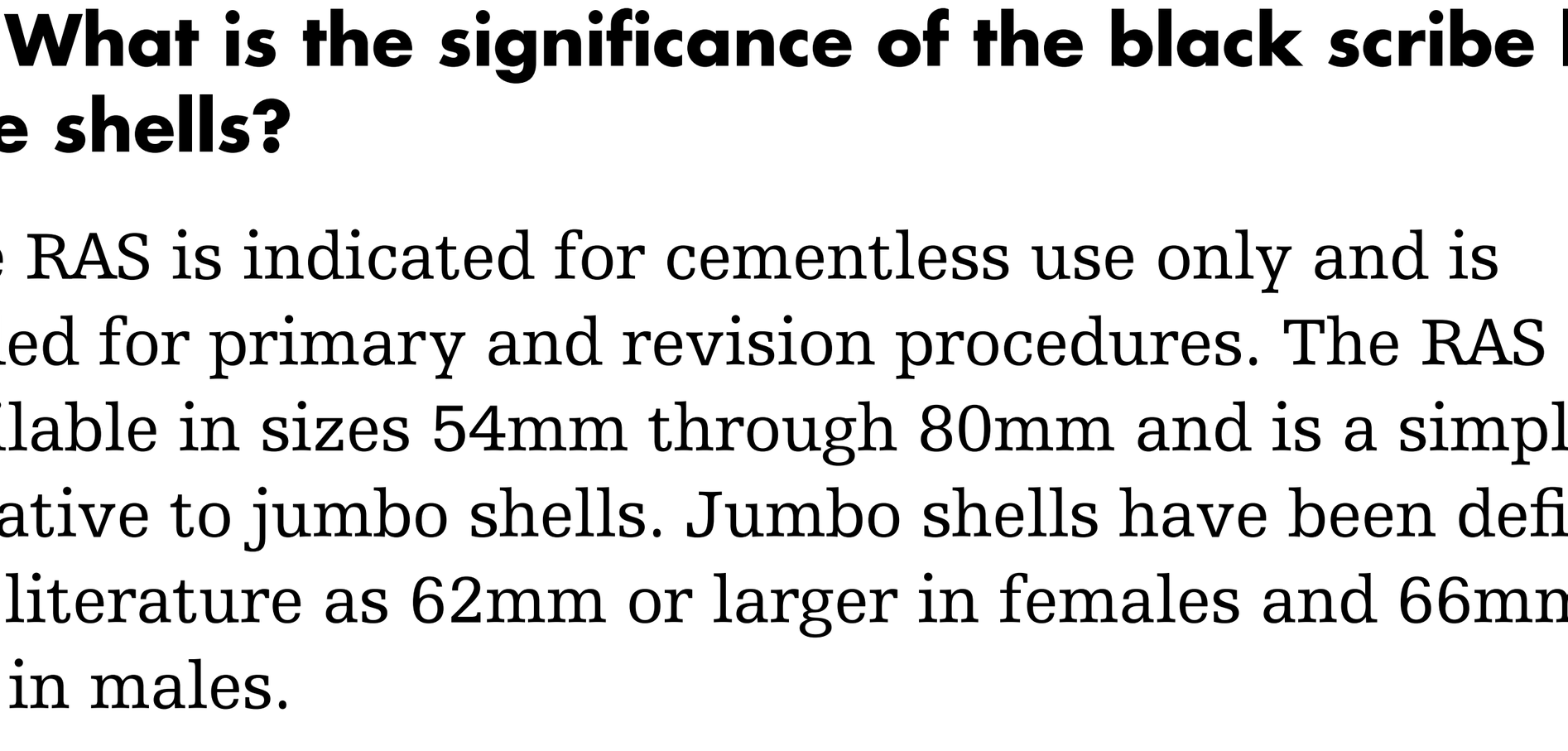

Superior reference mark size 58mm through 80mm shells

Superior reference mark size 54mm and 56mm shells

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REFERENCES AND DISCLAIMER

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