

The Combined Effect of Tibiofemoral Conformity & Tibial Base Design on Initial Stability of Cementless TKA

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1. Introduction

- Initial fixation of cementless tibial baseplates is critical to long-term bony ingrowth
 - Key factors: bone quality, surgical technique, baseplate fixation features, and loading of the tray via the articulating surfaces

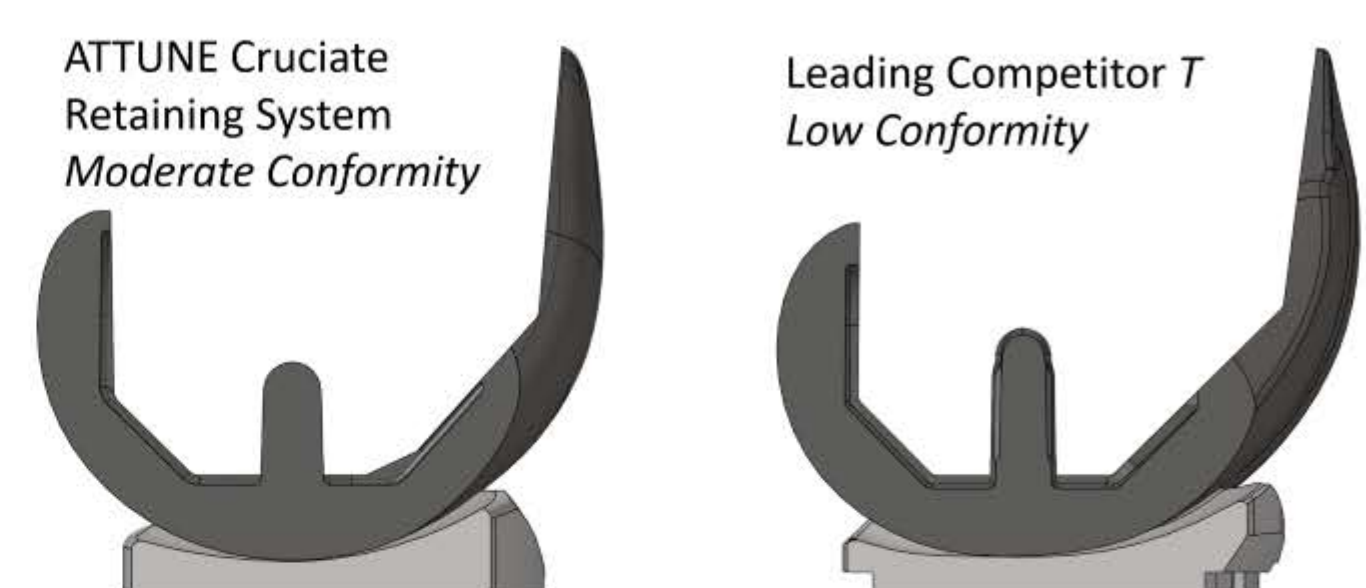


Figure 1: Examples of low and high conformity tibiofemoral articulations from commercially available knee systems

- Increased sagittal conformity between the insert and femur improves knee stability¹, but effects on tibial micromotion is unclear (Fig. 1)

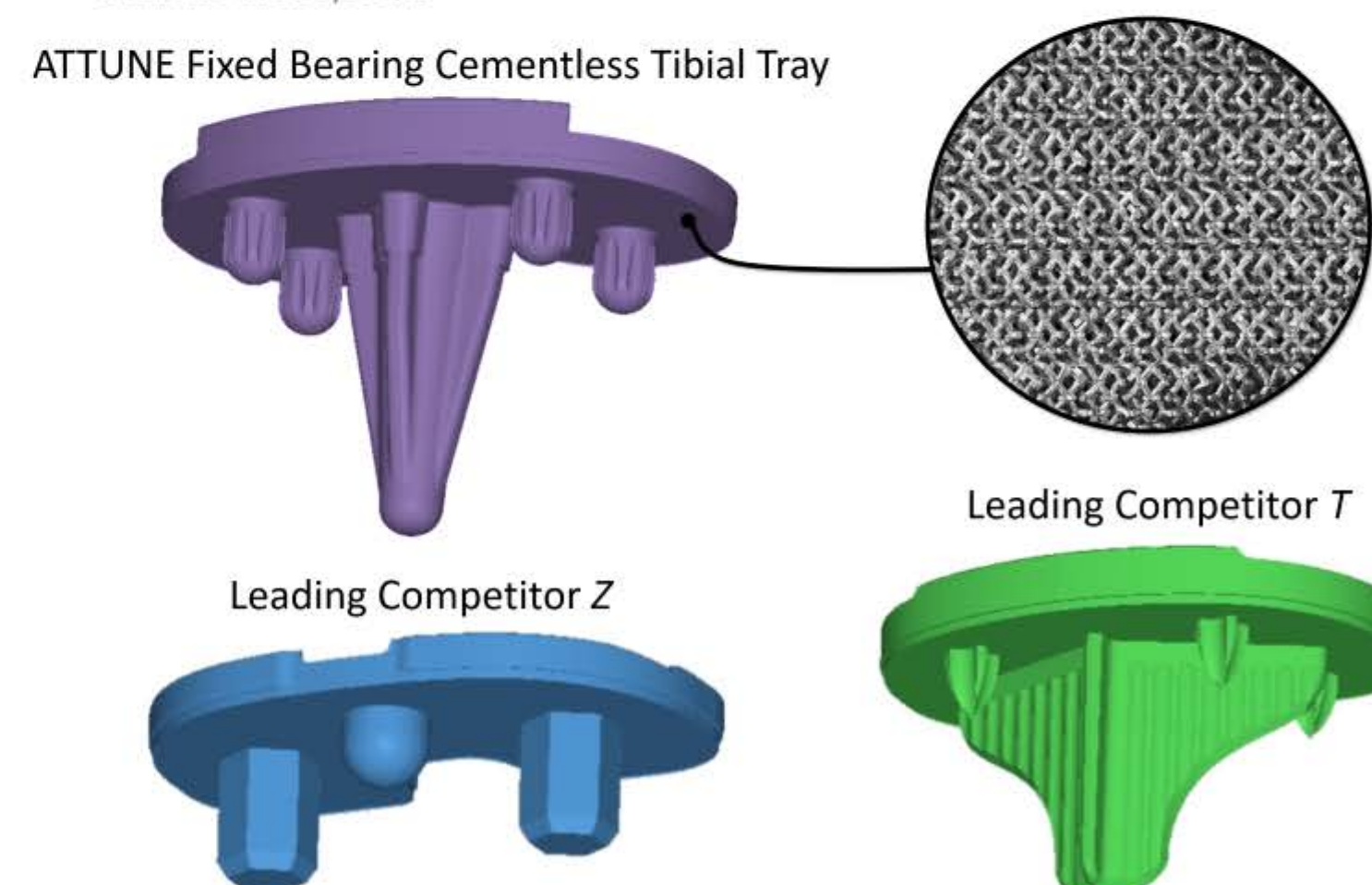


Figure 2: Tray fixation features for three different commercially available cementless tibial trays

- Goal:** characterize the affect of tibiofemoral conformity, knee kinematics, and fixation features on tibial micromotion (Fig. 2)

3. Results

- Largest tibial micromotions were observed during stair descent and gait, following a consistent pattern.
- Increased micromotion correlated with lower conformity and higher condylar translations.

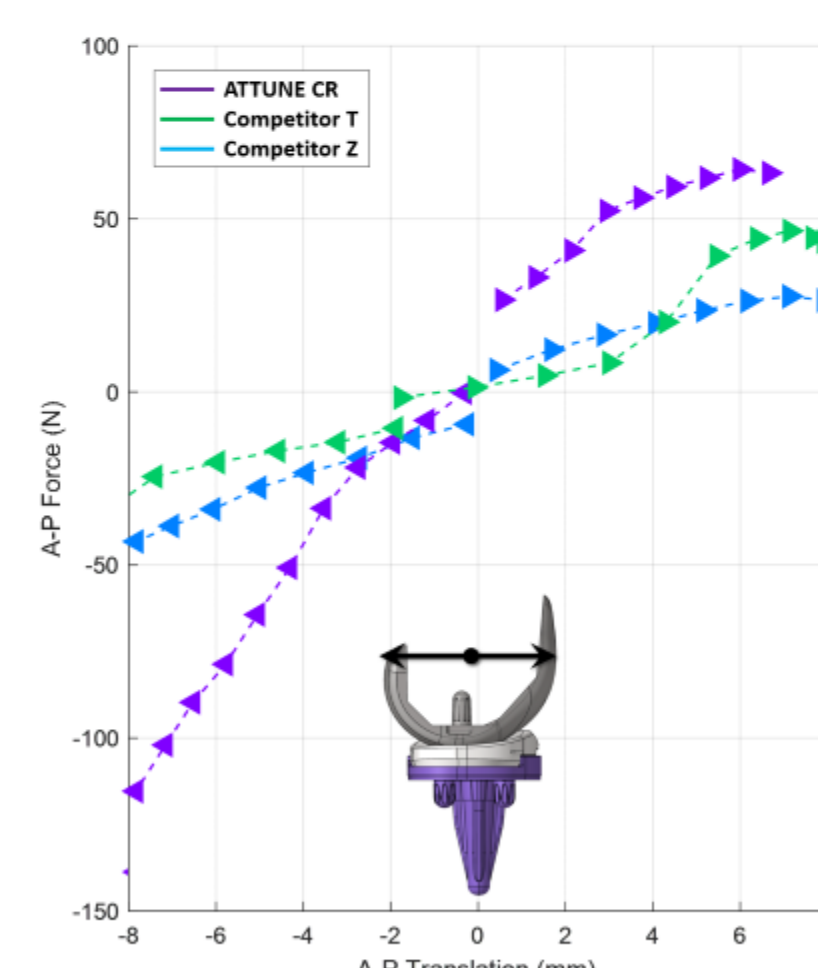


Figure 5: A-P laxity of implant articulation at full extension and 30° Flexion.

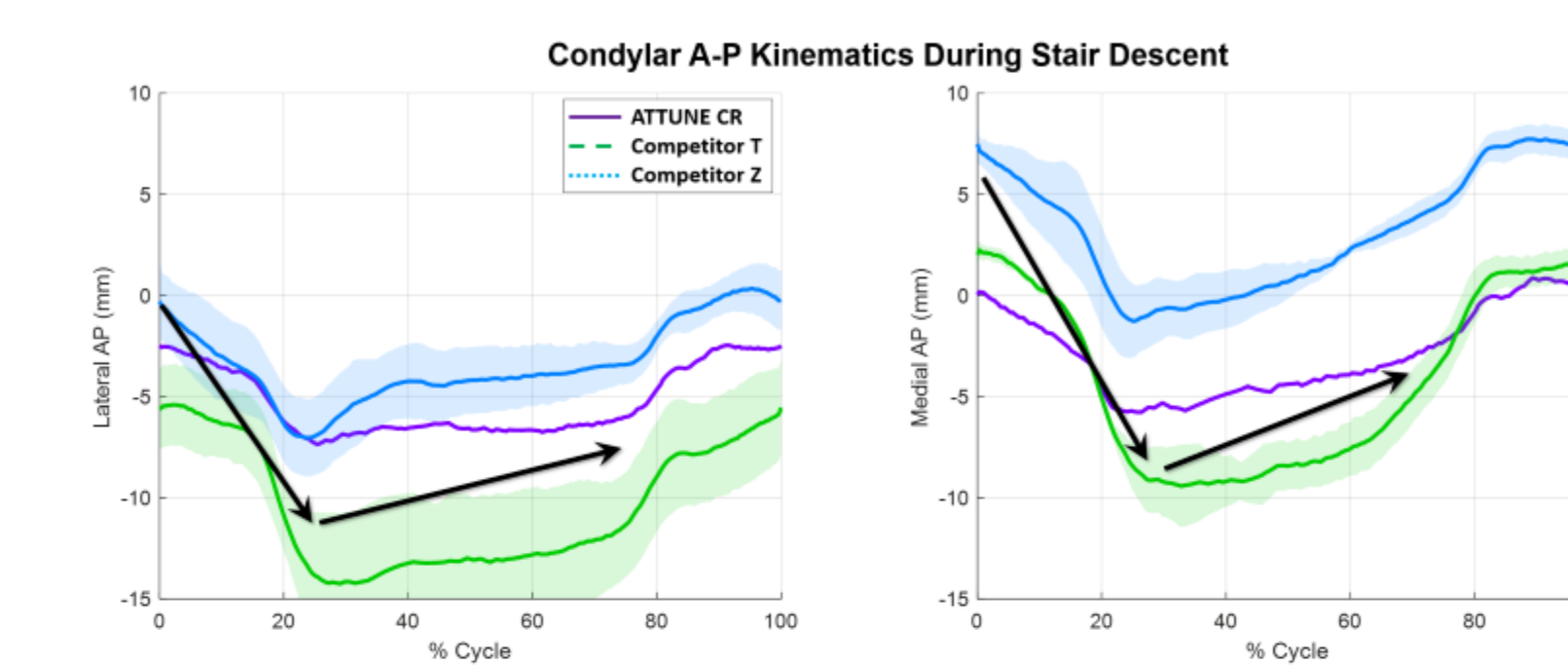
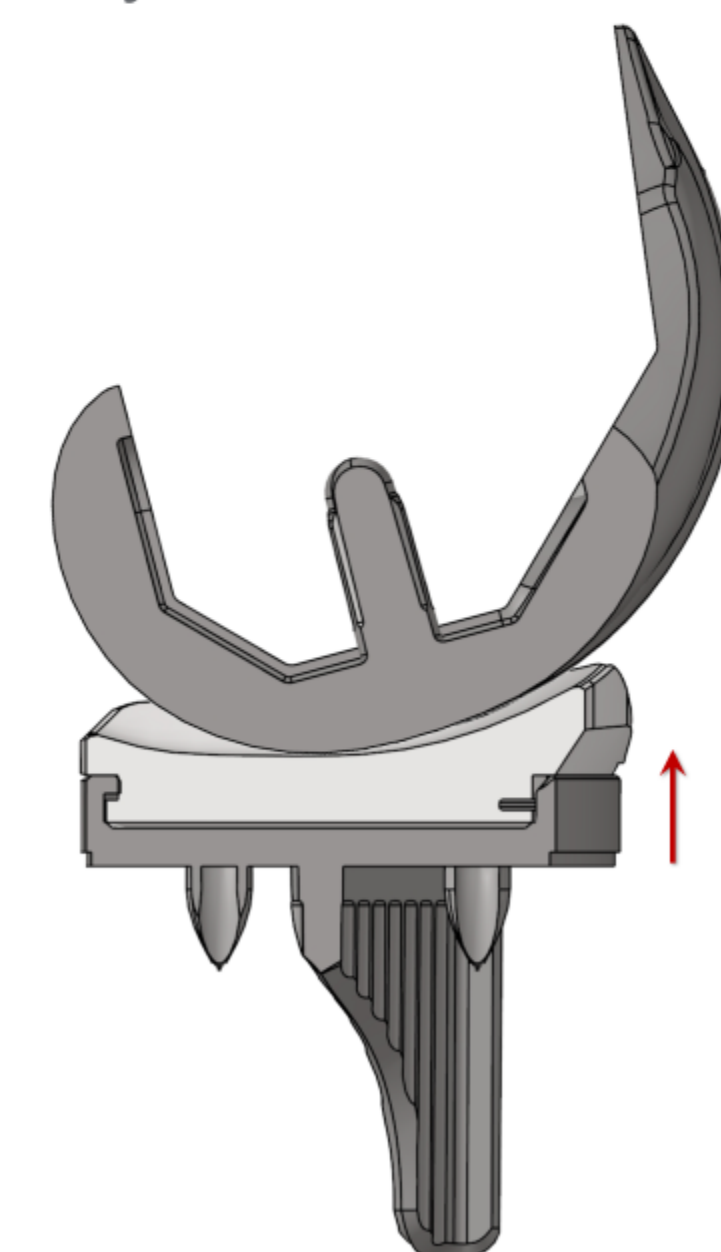


Figure 6: Femoral Condylar A-P kinematics while descending stairs

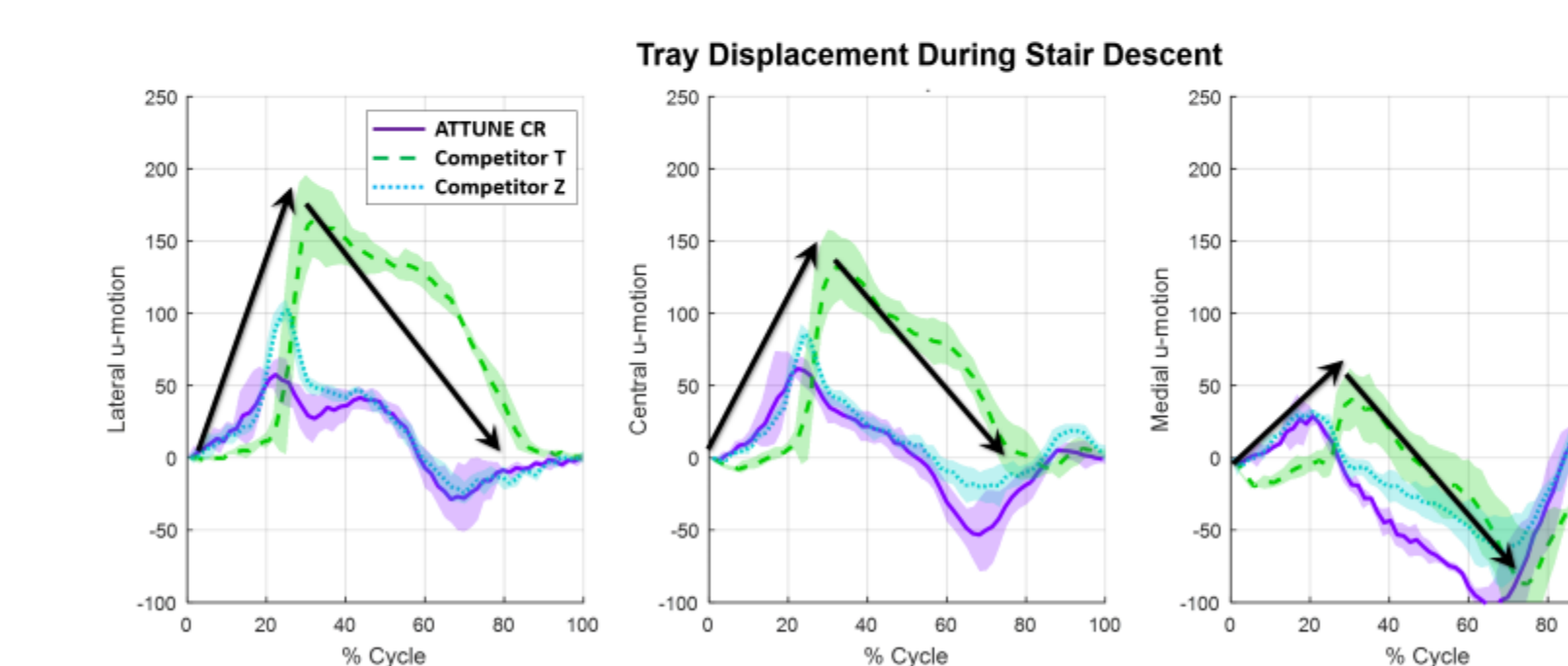
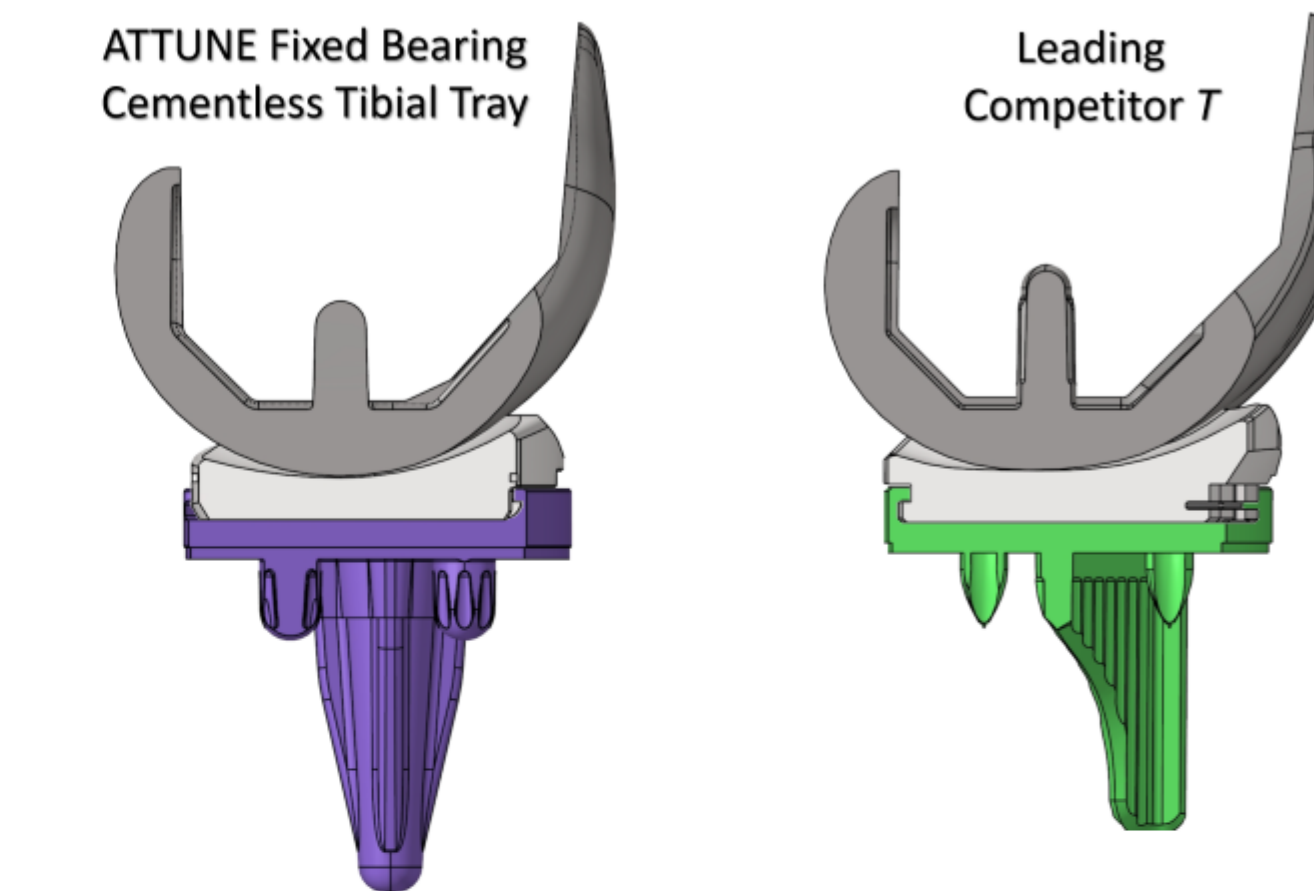


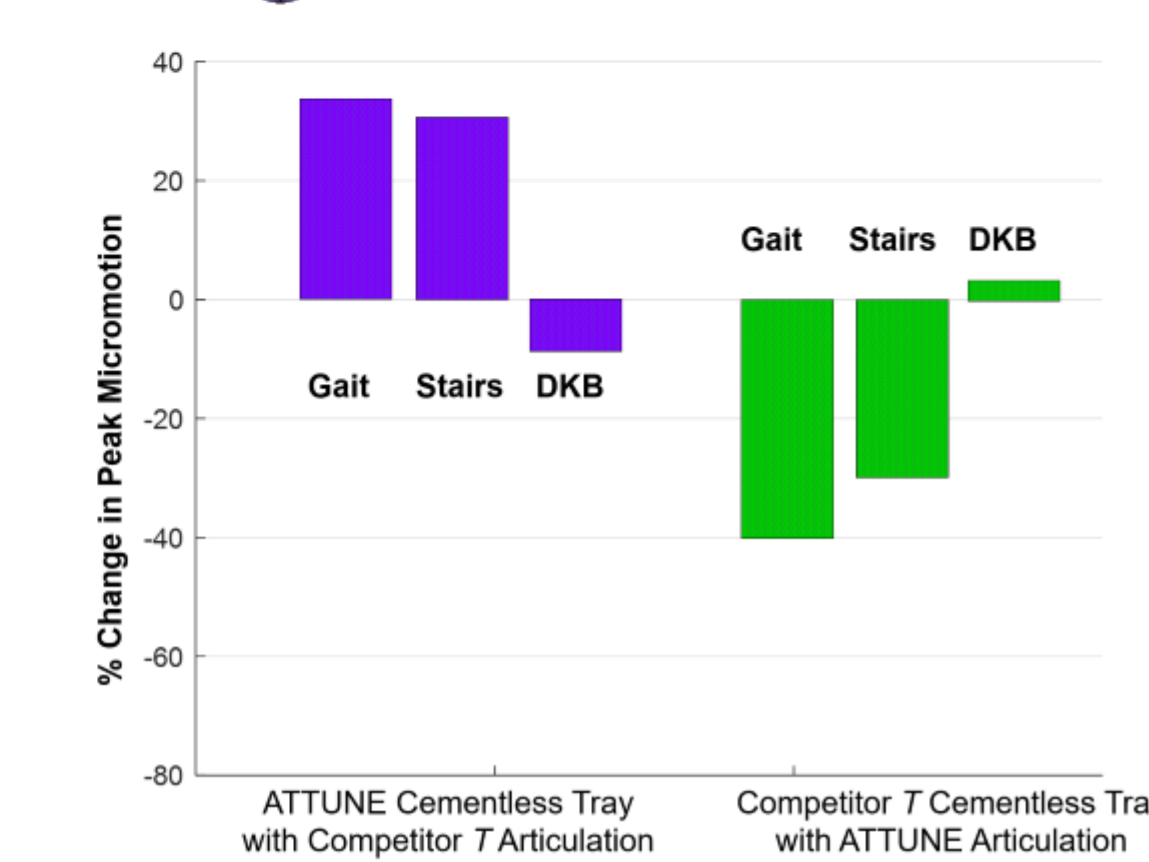
Figure 7: Tray-bone displacement measured across the anterior aspect of the tibial tray during stair descent.

4. Discussion

- Experimental evidence suggests that articulation conformity is major driver of micromotion, but what about tray design factors?



- In FE model, swapped articulating surfaces:
 - For ATTUNE® Knee, swapping with a low conformity design increased micromotion over 30% for gait and stair descent⁵
 - For Competitor T, swapping with a high conformity design reduced micromotion between 30% - 40%⁵



2. Methods

- Tibial Sawbones™ were implanted with three contemporary cementless tibial tray designs
 - Loaded via their respective femurs and inserts in an AMTI VIVO™
 - Gait, stair descent, and deep knee bend cycles²⁻⁴
 - Micromotions between the tray and bone were measured using Digital Image Correlation

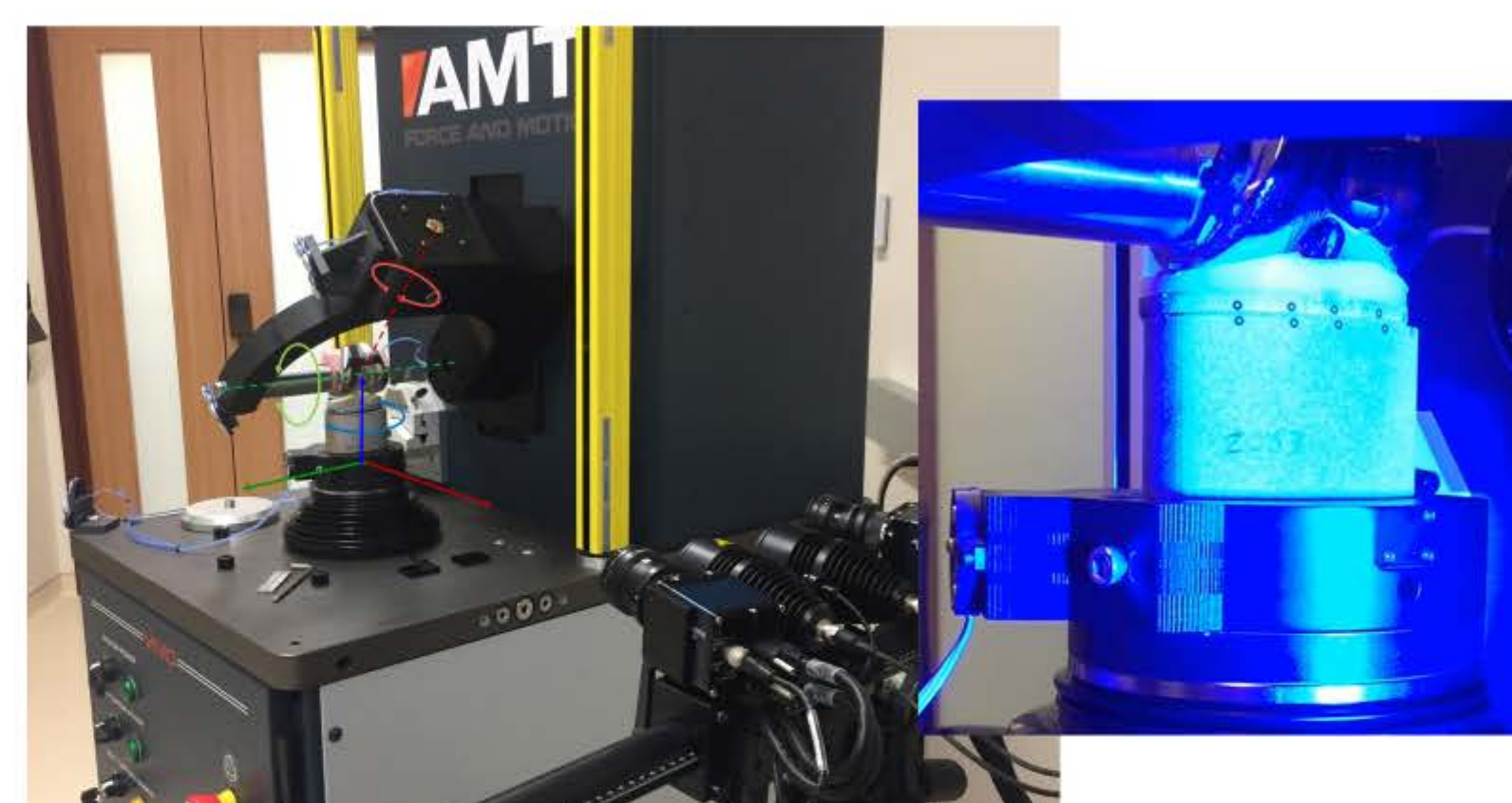


Figure 3: Experimental setup, including synthetic bone construct mounted in the VIVO with DIC

- A finite-element (FE) model of the experiment was validated using results from the testing²
 - Isolated effects of tray fixation features from articular conformity by virtually exchanging the articulating features of the highest and lowest conformity designs and predicting the resulting micromotion.

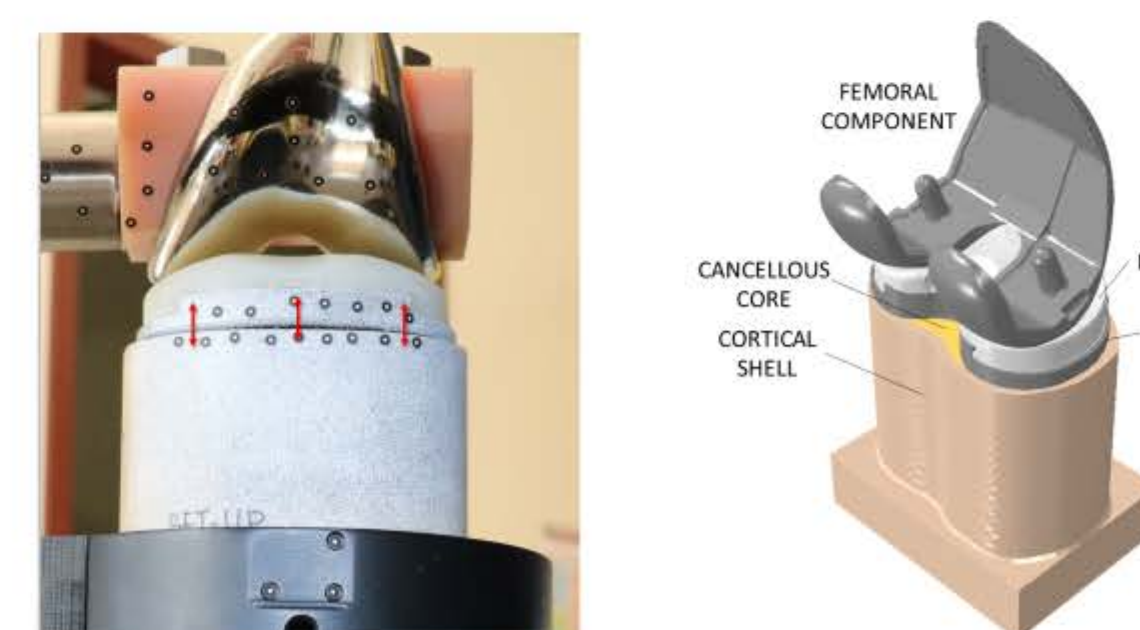


Figure 4: Synthetic foam bone construct in the VIVO (left) and the associated FE model (right)

3. Results (Cont.)

- Lowest conformity design had highest condylar translations during Gait and Stair Descent
 - Gait: 6.0mm (Attune) to 11.7mm (Competitor T)
 - Stair Descent : 6.6mm (Attune) compared to 11.7mm (Competitor T)

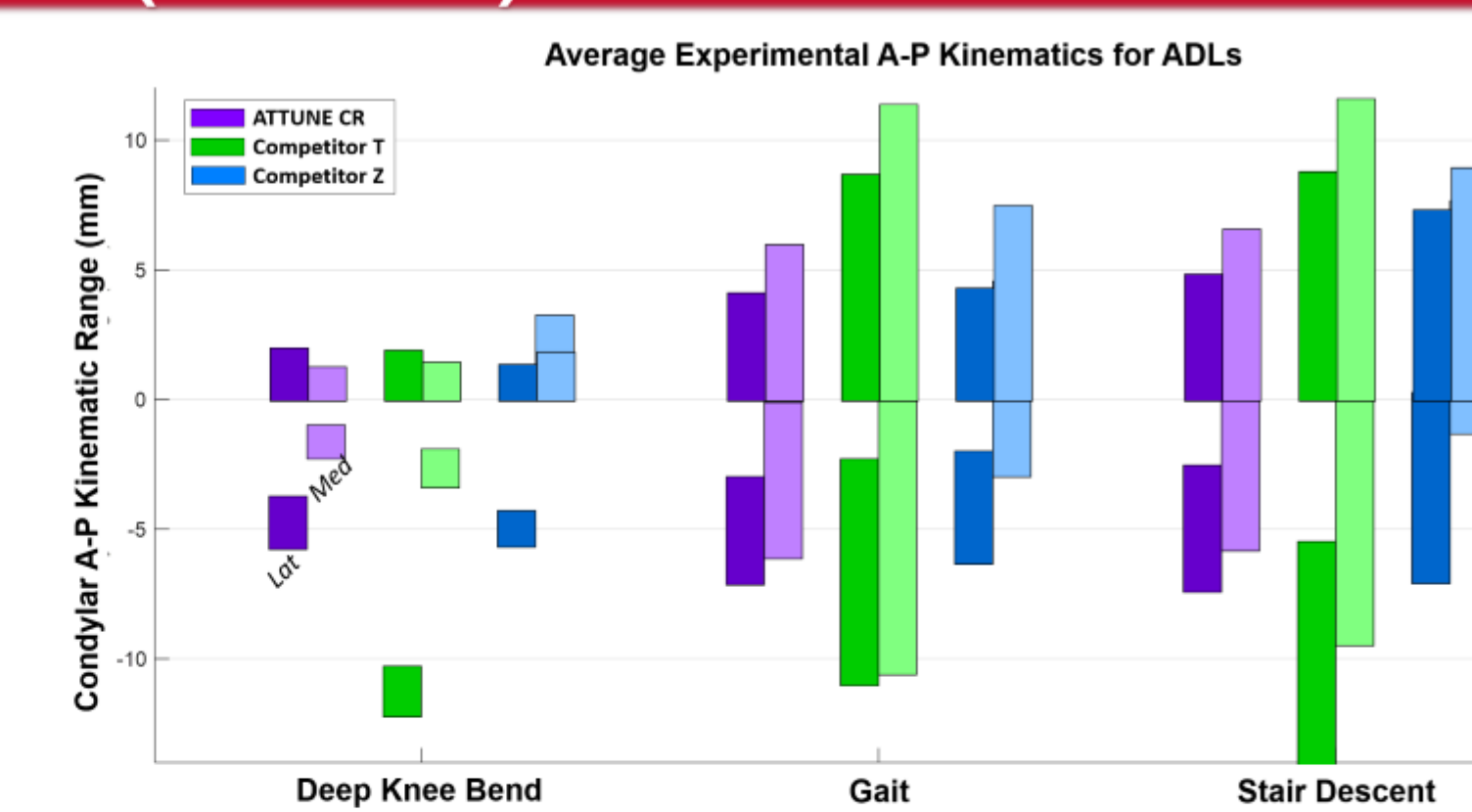


Figure 8: A-P range of condylar kinematics during activities of daily living.

- Lowest conformity design had highest micromotions during Gait and Stair Descent
 - Gait: 101.4µm (Attune) to 146.5µm (Competitor T)
 - Stair Descent : 126.7µm (Attune) compared to 160.5µm (Competitor T)

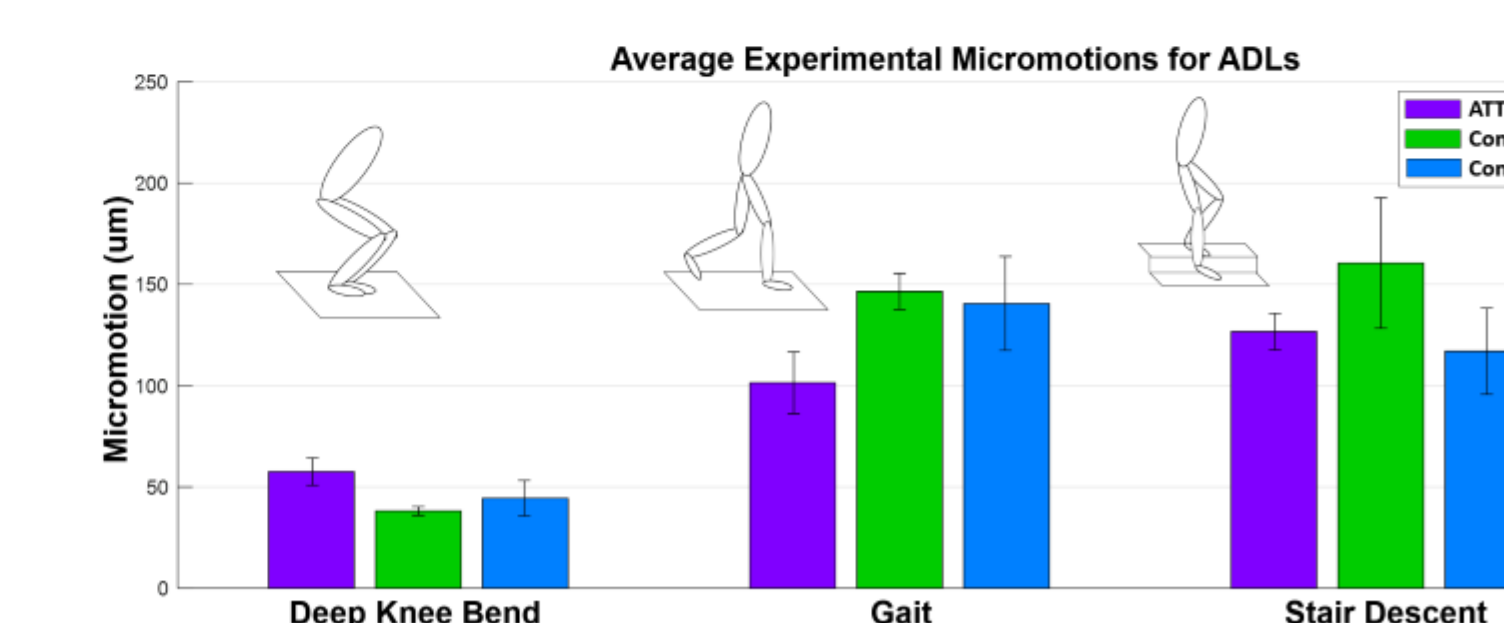


Figure 7: Average experimental micromotion (max-min) for activities of daily living

5. Conclusion

- Limitations:
 - Experimental model did not have ligamentous or muscular constraint, which may improve stability (but loading does)
 - Foam bone has different mechanical properties than real bone
 - Initial fixation is a good predictor of long-term survivorship, but clinical studies and RSA evaluation still necessary to understand clinical performance

- Conclusion: Cementless tibial tray designs with optimized fixation features and moderately increased levels of tibial-femoral conformity can reduce A-P translations during activities of daily living, thus reducing micromotion and improving initial stability of cementless tibial trays.

References:
 1)Clary CW, Fitzpatrick CR, Maletsky LP, Rullkoetter PJ. The influence of total knee arthroplasty geometry on mid-flexion stability: an experimental and finite element study. J Biomech. 2013 Apr 36;46(7):1351-7.
 2)Navachia A, Clary CW, Wilson HL, Behnam YA, Rullkoetter PJ. Validation of model-predicted tibial tray-synthetic bone relative motion in cementless total knee replacement during activities of daily living. J Biomech. 2018 Aug 22;71:115-123.
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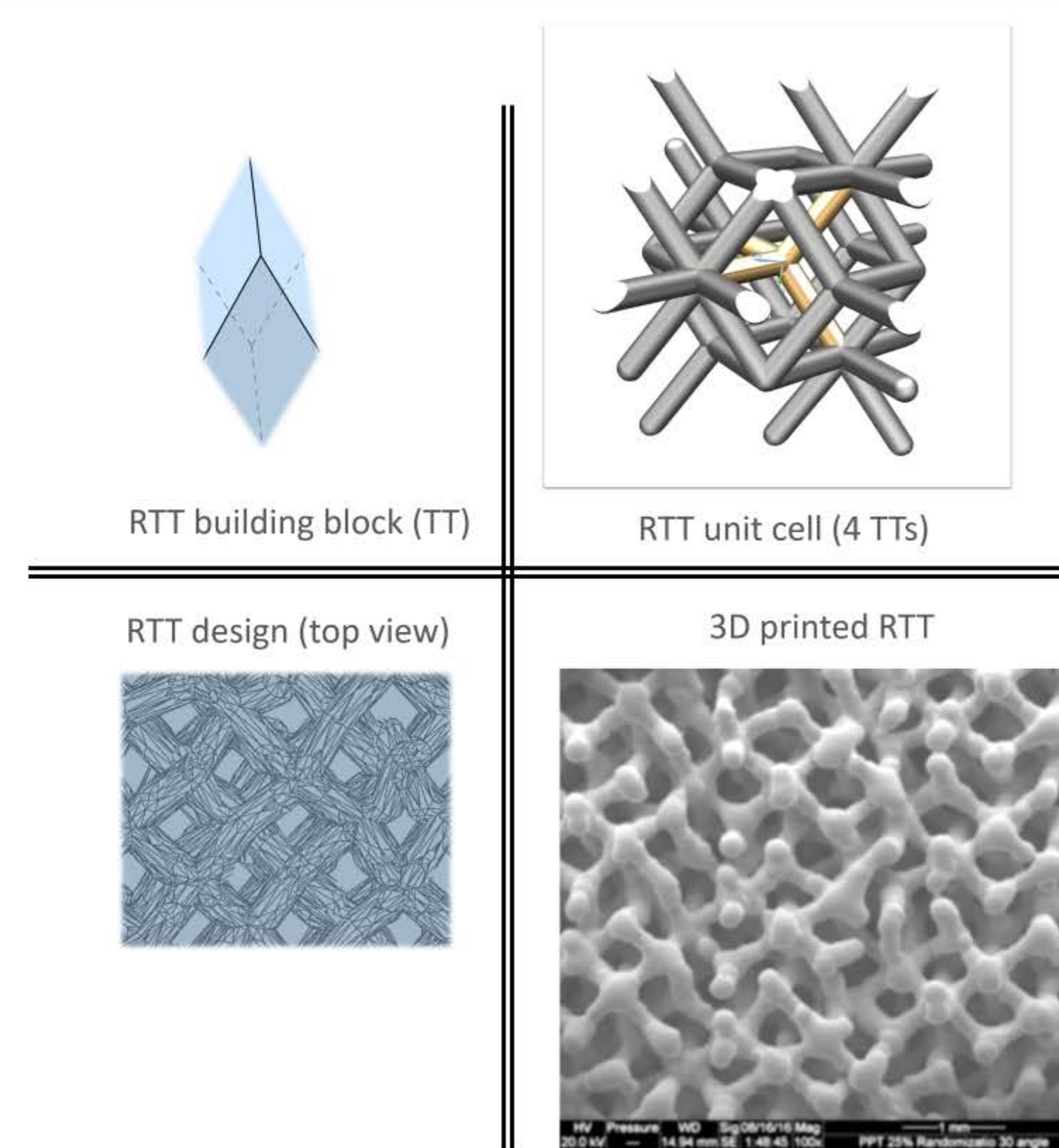
AFFIXIUM™ 3DP Technology- Designing Porous Ingrowth Structures w/ 3D Printing: A summary of work published at ORS 2020 [1]

Weidong Tong¹, Bryan Smith¹, Dwight Henninger², Robert Kane¹, Tim Muench²

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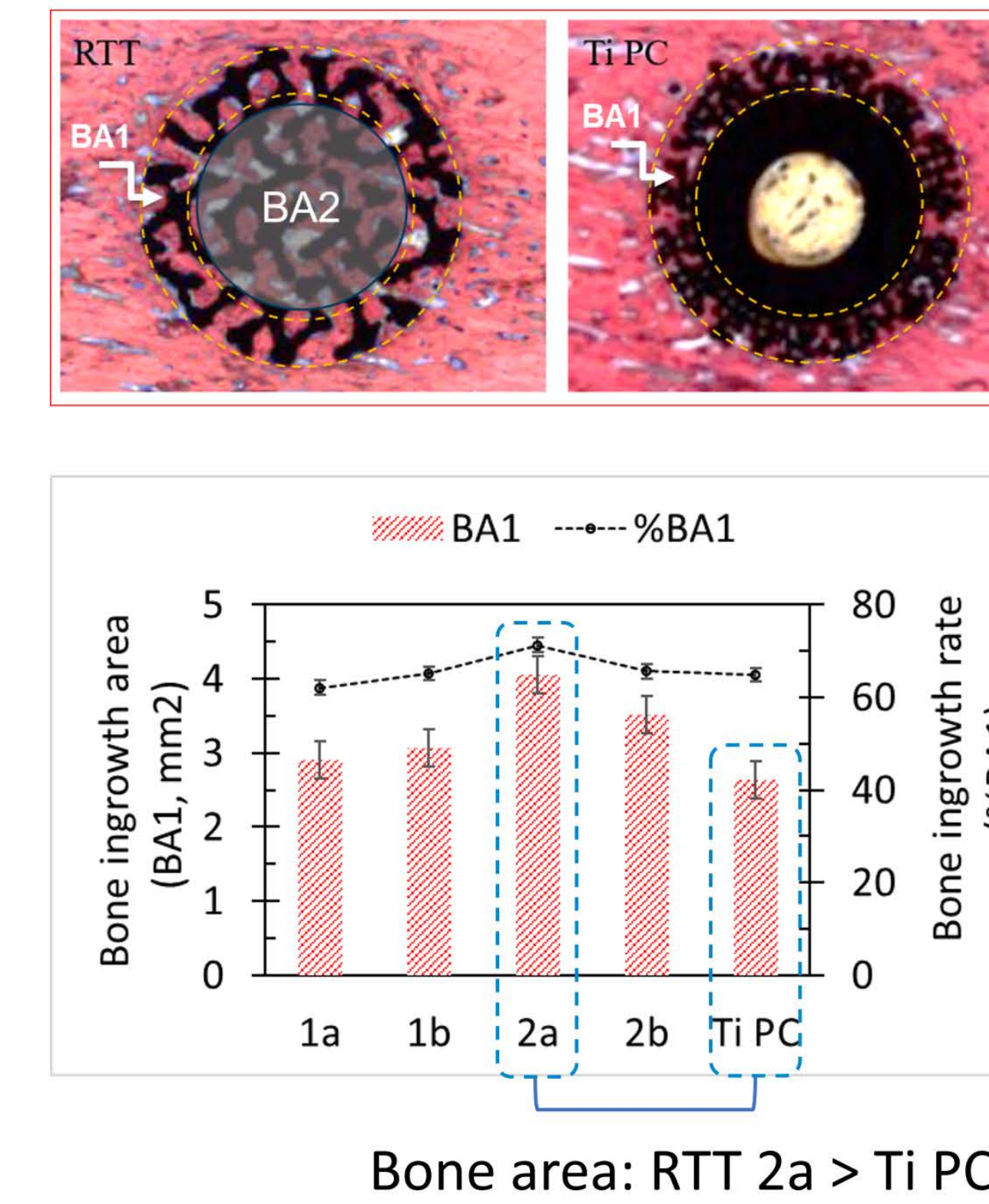
1. Introduction

- The design freedom enabled by 3D printing allows engineering of optimized bone ingrowth structure for biological fixation.
- A new Ti porous structure (RTT) was designed based on trigonal trapezohedron (TT) building blocks. The rhombus space forms highly interconnected ingrowth channel with evenly distributed pore diameter.
- In this study bone ingrowth of RTT porous structures were compared with the clinically successful Ti POROCOAT™ Porous Coating (Ti PC) in a 12-week canine transcortical bone model following Bobyn et al [2].



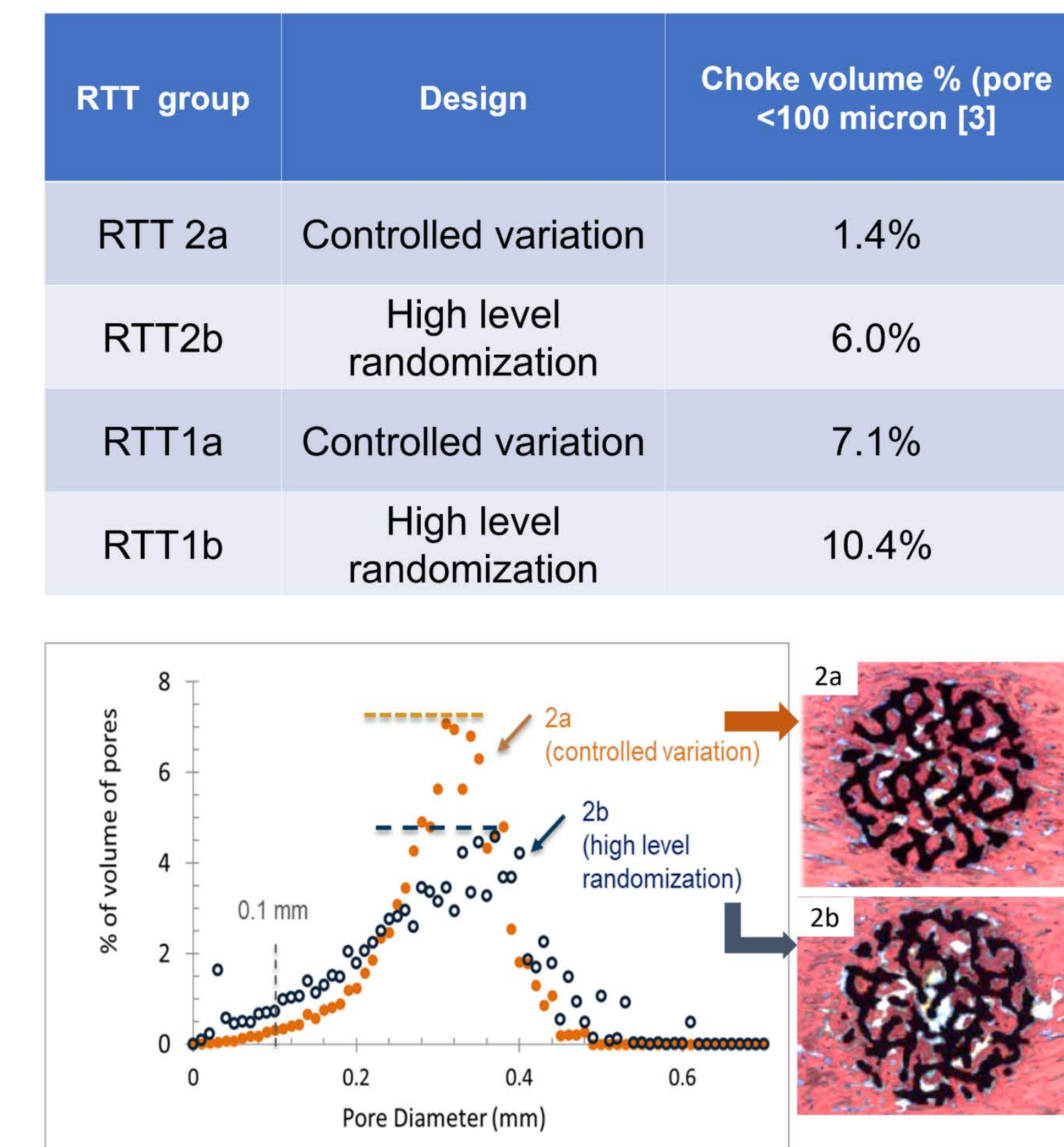
3. Results

- RTT test groups all showed good bone ingrowth and penetration to 5 mm implant diameter
- Best bone ingrowth was observed in RTT designed with high bulk porosity and controlled variation (RTT 2a)
- RTT2a has 54% more bone ingrowth compared to the Ti PC equivalent region (p<0.05)



4. Discussion

- Pore size less than 100 micron hinders vascularization and bone formation. Choke volume is the volume percentage of pore diameters less than 100 micron.
- Controlled variation has less choke volume than high level randomization (i.e. RTT2a 1.4% vs. RTT 2b 6%)
- Our data show high level randomization does NOT produce bone ingrowth advantage. On the opposite, it could yield less optimized bone ingrowth.

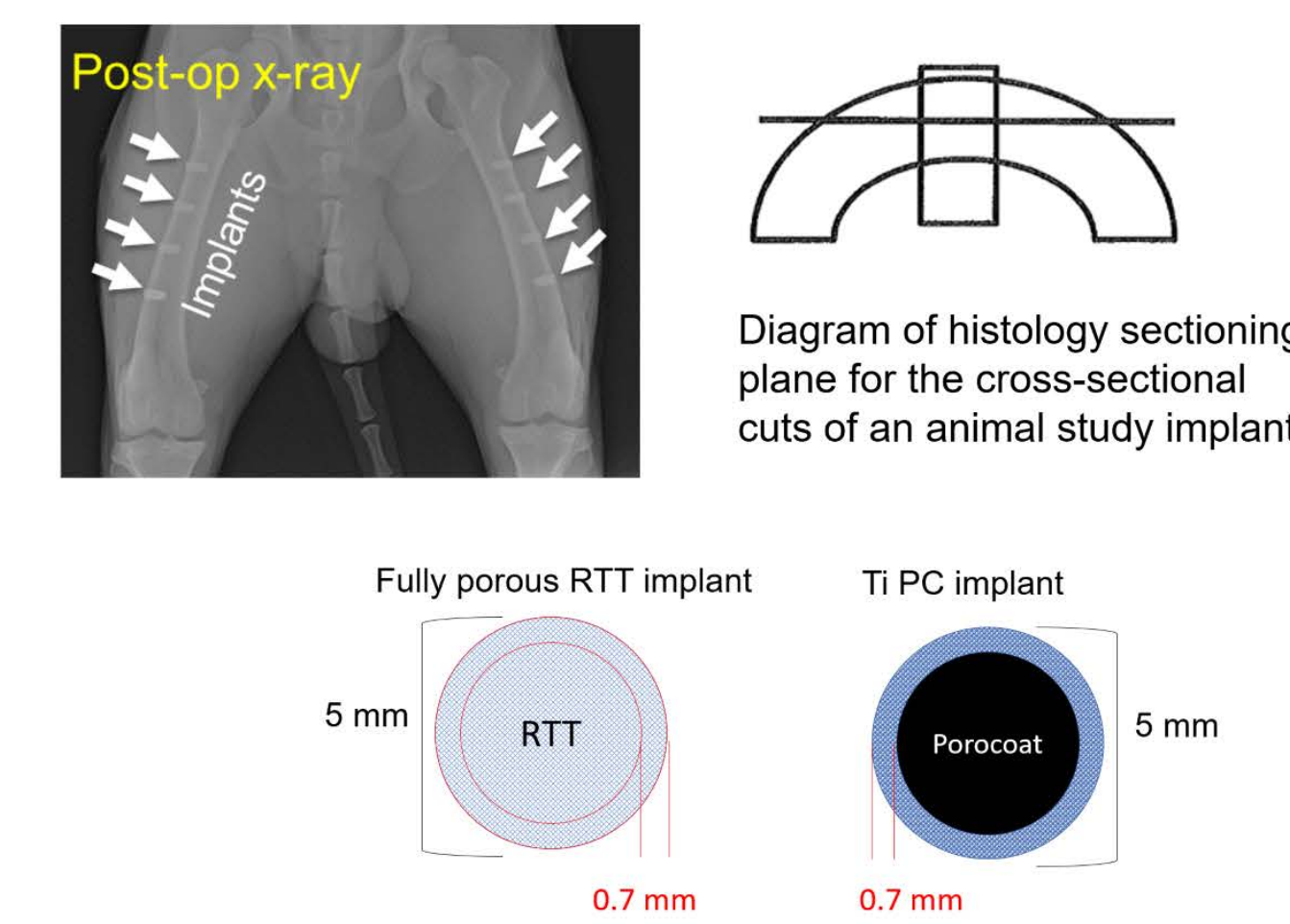


2. Methods

- RTT DOE design:
 - Four groups of fully porous implants were designed by varying bulk porosity and pore size control (controlled variation vs. high level randomization).
 - RTT implants were made by 3d printing, using a laser powder bed fusion technology.
- Animal study design:
 - 5 mixed breed hounds, 4 drill holes each femur. Implants were inserted bilaterally with a slight press-fit in the diaphyseal cortex and rotated among four implantation sites per femur

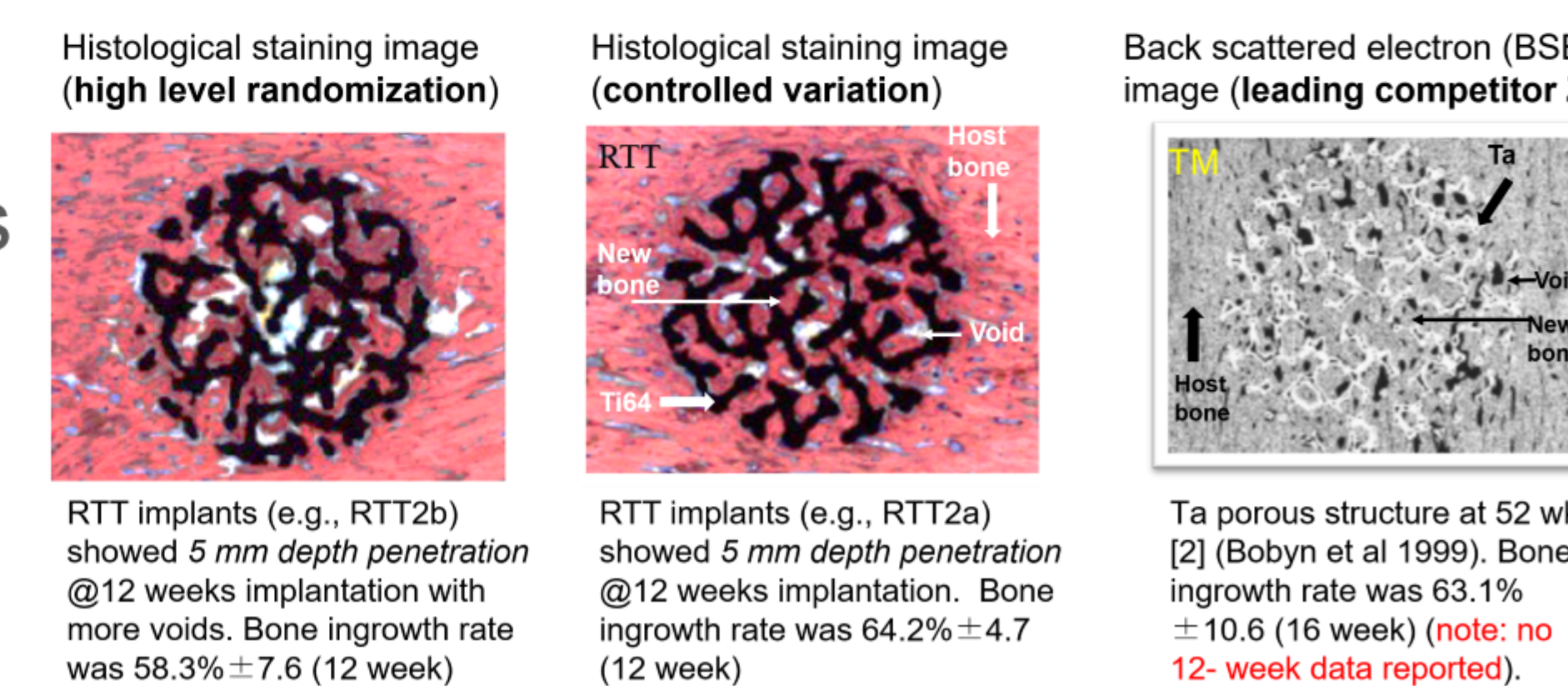
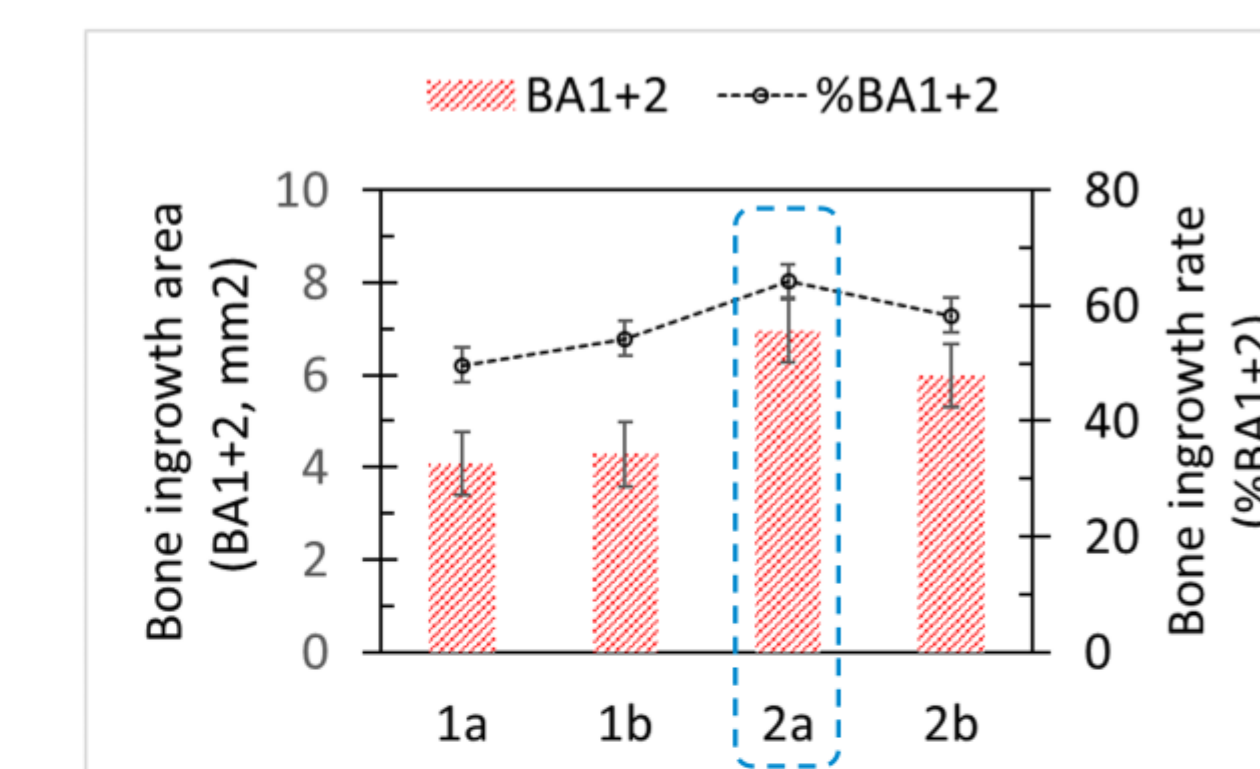
RTT DOE Design	Controlled variation	High level randomization
55%	Group 1a	Group 1b
65%	Group 2a	Group 2b

Control	Ti POROCOAT™ porous coating (Ti PC)
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3. Results (Cont.)

- RTT designed with controlled variation and high porosity (Group 2a) has highest ingrowth bone area (p<0.05) and ingrowth rate (%BA1+2). However, the latter is not statistically significant.
- Images on the right show bone ingrowth of RTT and a leading competitor Z's porous structure, evaluated following the identical animal study model and implant size [2]



5. Conclusion

- A new Ti porous structure was designed based on repeating RTT unit cell, and made using laser powder bed fusion, 3D printing technology.
- While both could replicate trabeculae of cancellous bone, RTT designed with controlled variation had less choke volume and more bone ingrowth than high level randomization.
- RTT with controlled variation and 65% bulk porosities shows excellent osteoconduction and has 54% more bone ingrowth than the clinically proven Ti POROCOAT™ Porous Coating in this 12-week canine transcortical bone study.

References:

- [1] Tong W, Smith B, Henninger D, Kane R, Muench T. Bone Ingrowth of RTT porous structure. 2020 ORS Annual Meeting (Feb 8-11, Phoenix, AZ). Paper No 337.
- [2] Bobyn J, Stackpool G, Hacking S, Tanzer M, Krygier. Characterization of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. JBJS [Br] 1999;81-B:907-14
- [3] DePuy Synthes, Pore size measurements of additively manufactured coupons used for animal study. Aug 26, 2019. #WR 150193

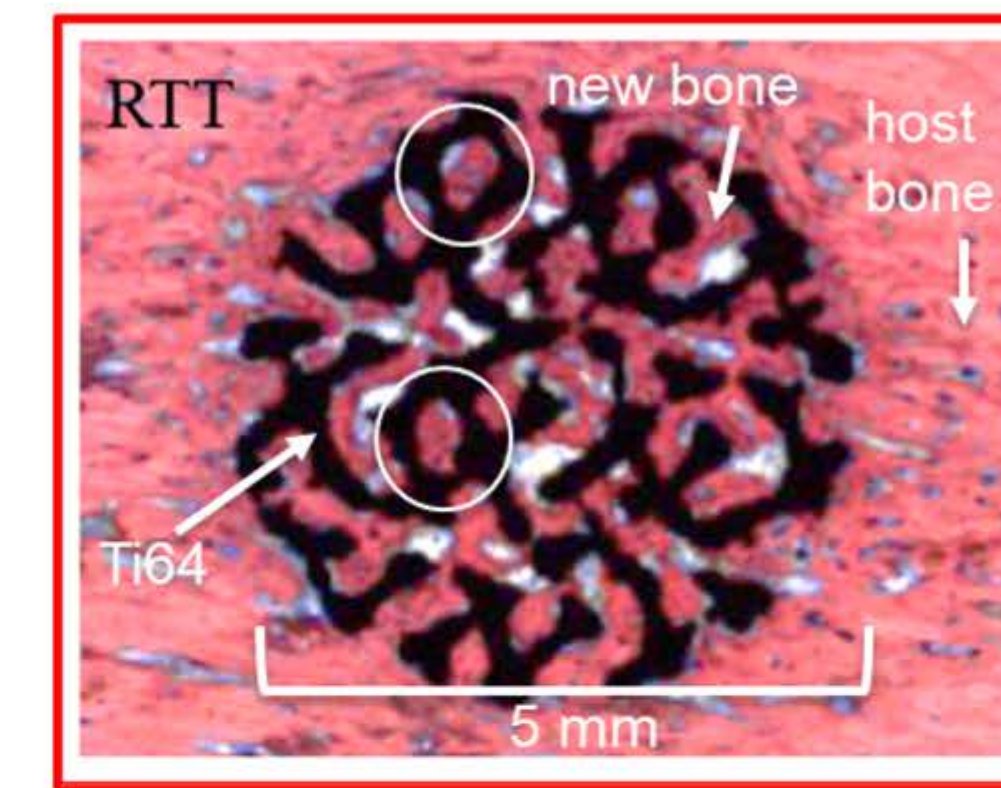
AFFIXIUM™ 3DP Technology- The Science of Bone Ingrowth with Engineered Porosity: A summary of work published at ORS 2021 [1]

Weidong Tong¹, Brett English¹, Cortney Henderson², Robert Kane¹, Bryan Smith¹

¹ Front End R&D, DePuy Synthes Joint Reconstruction, Warsaw, IN; ² Preclinical Research, DePuy Synthes, Cincinnati, OH

1. Introduction

•We have previously reported an engineered Ti porous structure (RTT) designed by controlled variation and made by 3D printing. It showed osteoconduction to a diameter of 5 mm @12 weeks in a canine **transcortical bone animal model** [2]. In this study, we investigated how engineered RTT porosity affected bone ingrowth using an ovine **cancellous bone animal model**.



RTT was created to replicate trabecular bone. The connecting struts form rhombus shape, a 2-dimensional projection of the Trigonal Trapezohedron (TT) building blocks. (Circles: example of RTT rhombic bone ingrowth channels in 2D)

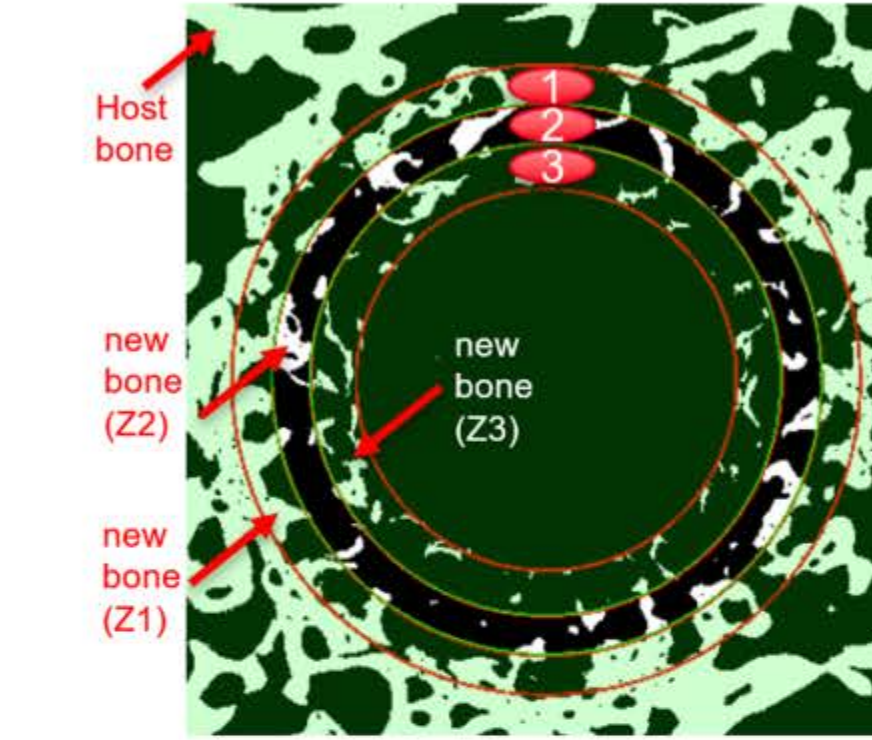
3. Results

•Histogram shows extensive bone ingrowth occurred at RTT surface in Z1 (0-380 microns). There is a gradient of increasing new bone formation from Z3 to Z1.

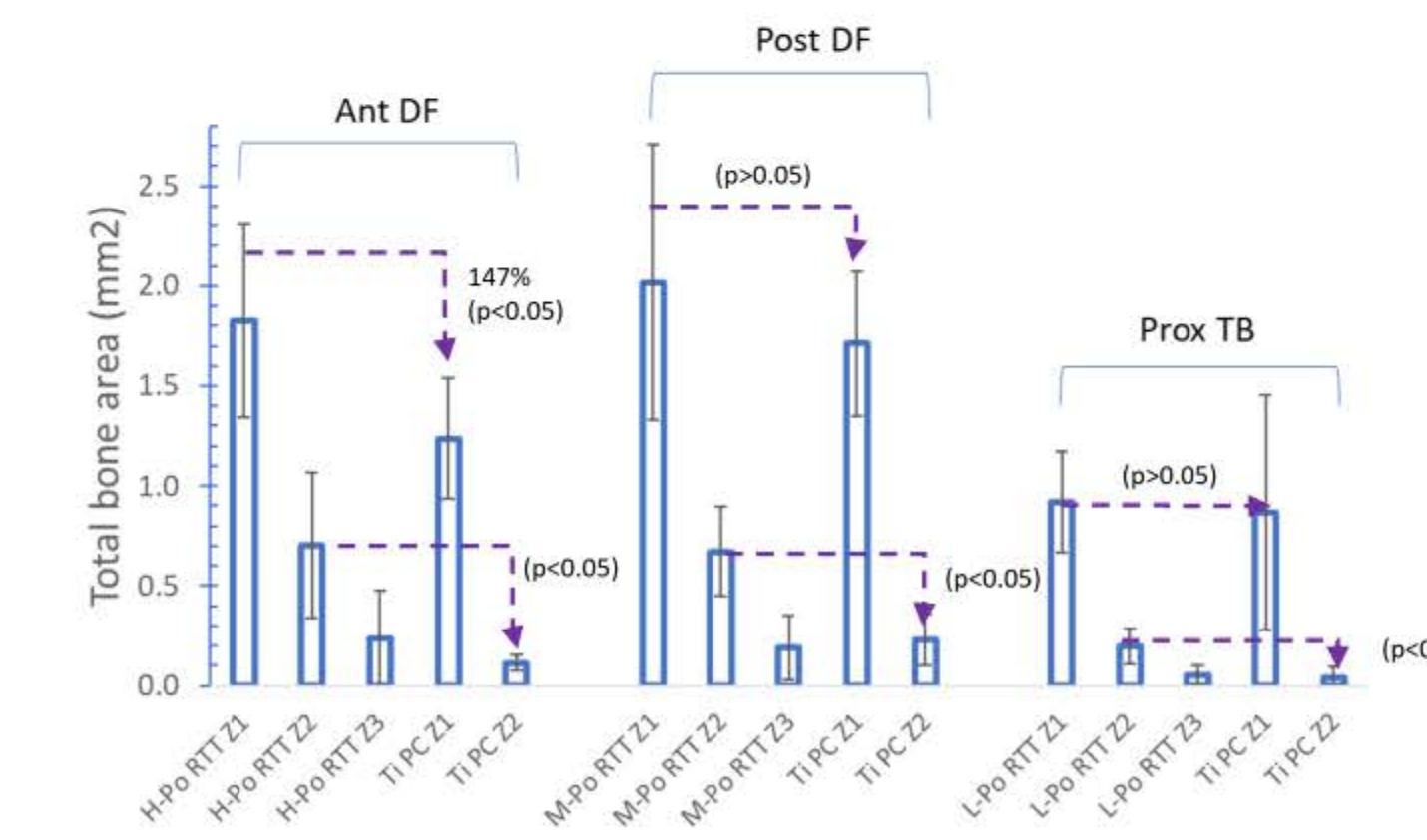
•Compared to Ti PC, H-Po RTT shows 47% more bone area in zone 1 ($p < 0.05$).

•M-Po and L-Po RTT also have higher bone area (10-20%) than Ti PC in zone 1 but results are not statistically significant.

•All RTT groups have more bone ingrowth than Ti PC in Z2 ($p < 0.05$).



Example of a Ti masked histological image. Extensive bone ingrowth occurred at bone/implant interface with increasing gradient from Z3 to Z1



4. Discussion

•RTT designed with controlled variation showed equivalent or more bone ingrowth than clinically proven Ti PC. There is a correlation of bone ingrowth and bulk porosity.

•Extensive bone formation occurred at Z1, with increasing gradient from Z3 to Z1. The highest Z1 bone ingrowth correlated to the highest surface porosity, which came concomitantly with low choke volume. Choke pores hinder vascularization and bone formation.

•Characterization of a leading competitor Z's porous structure shows a choke volume of 0.9% [3]. This is due to presence of 'small' pores (portals) connecting the dodecahedron (large pores) originated from the vitreous carbon skeleton [4].

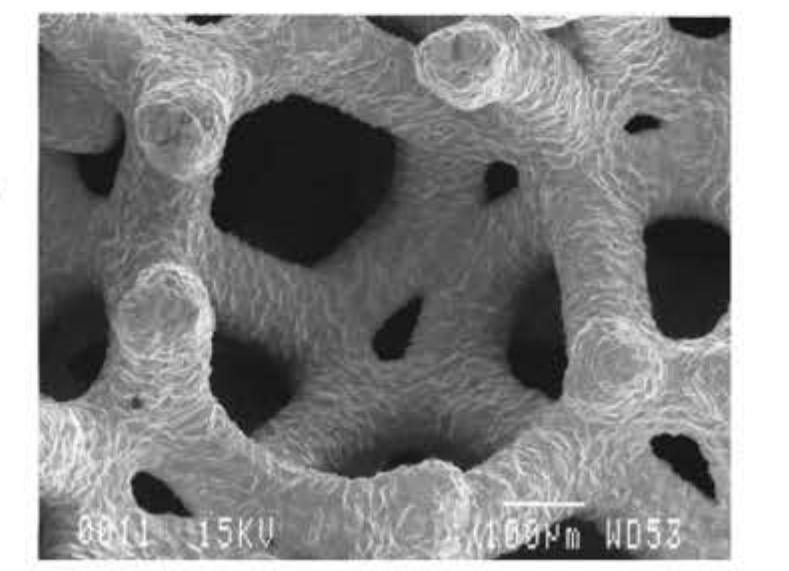


Fig. 1b 'Small' pores (portals) of leading competitor's Ta porous structure [4].

2. Methods

•Animal study implants:

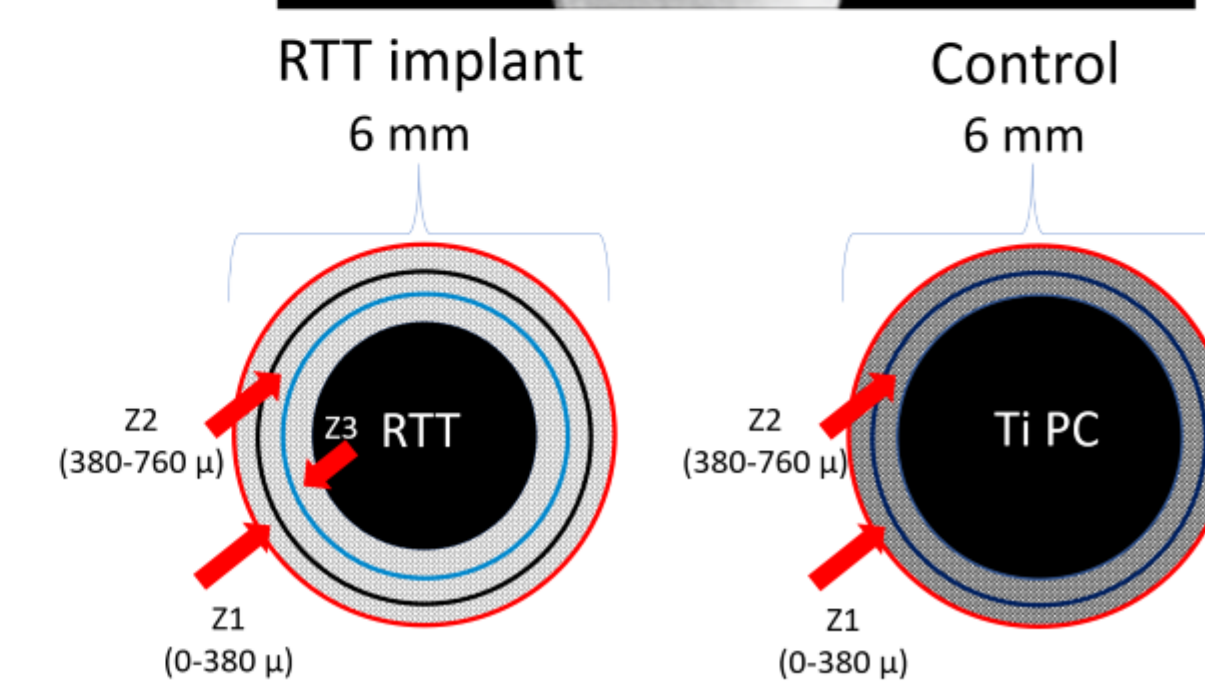
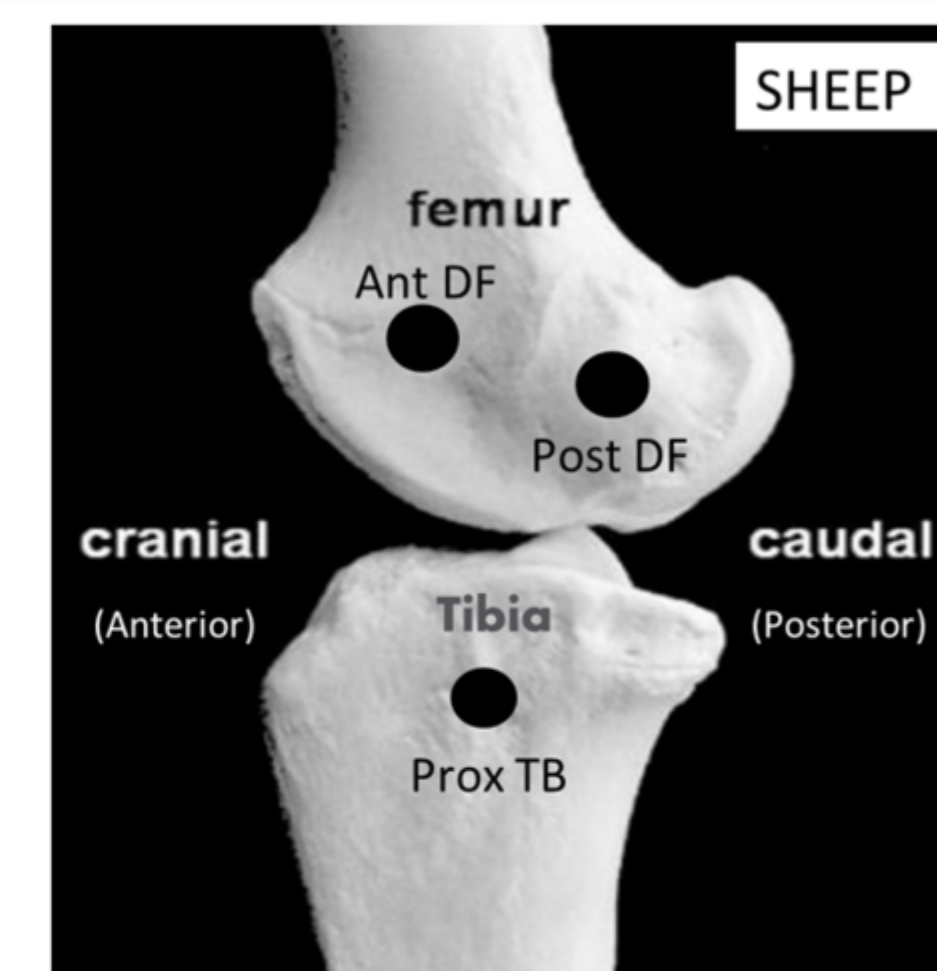
–Ti6Al4V RTT porous coating implants targeting high, medium and low porosity (H-Po, M-Po and L-Po) were made by **laser powder bed fusion**, 3D printing technology.

–All RTT coatings were designed using **Controlled Variation**, which **minimizes choke volume** (volume percentage of pore diameter less than 100 microns)

–**Ti POROCOAT™** Porous Coating (Ti PC) controls were made through a beads sintering process.

•Animal study design:

–The animal study involved six skeletally mature sheep and three bilateral implantation locations per animal. Implants were harvested after **8-weeks** of implantation and ingrowth of bone were characterized in Z1, Z2 and Z3 (Z3 not for Ti PC).

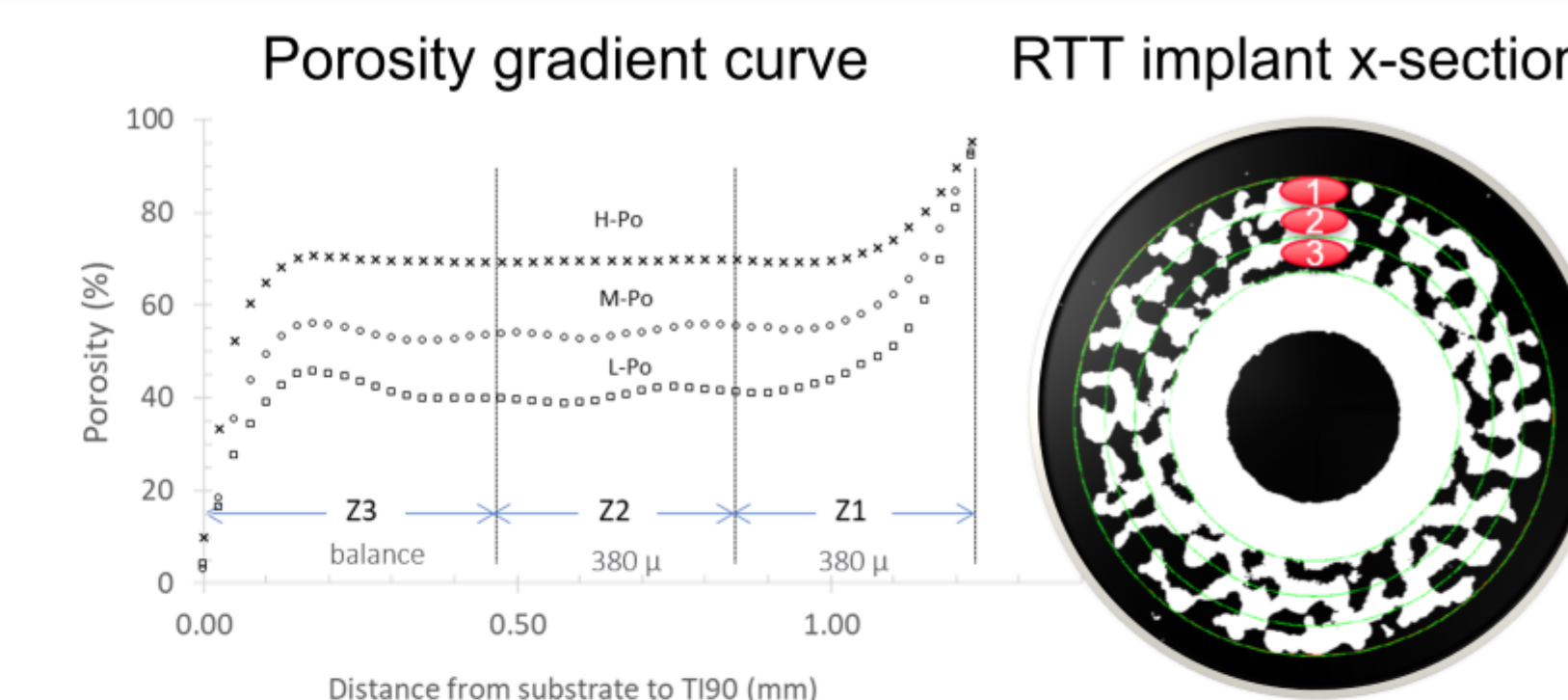


3 Results (Cont.)

•RTT porosity gradient curves show distinctively high surface porosity (Z1), reproducible 'bulk' porosity (Z2 and part of Z3) and lower porosity at coating/solid interface (Z3) for enhanced coating interfacial strength.

•The surface porosity and pore size increase with bulk porosities while the choke volume decreases (Table).

•We can achieve low choke volume (0.1%) by engineering porosity and RTT design.



ROI	Surface region (Zone 1)		
	Porosity (%)	Pore (micron)	Choke Vol. (%)*
RTT	73.7 (1.5)	541 (10)	0.1 (0.0)
H-Po	62.5 (0.3)	403 (4)	0.6 (0.1)
M-Po	52 (1.3)	320 (9)	2.1 (0.5)

*Choke volume %: volume percentage of pores, diameter < 100 micron.

5. Conclusion

•This sheep cancellous bone animal study demonstrates that surface porosity in conjunction with pore morphometry of a coating can substantially affect bone ingrowth.

•RTT porous structure designed with controlled variation has large pore size (>300 microns) and low choke volume at surfaces (Z1).

•Extensive bone ingrowth occurred at surface (Z1), with increasing gradient from Z3 to Z1

•High bulk porosity and controlled variation design produced statistically significant more bone ingrowth (47%) than a clinically proven Ti POROCOAT™ Porous Coating when tested in this 8-week ovine cancellous bone model.

References:

- [1] Tong W, English B, Henderson C, Kane R, Smith B. RTT Cancellous Bone Ingrowth and Pore Morphometrics. 2021 ORS Annual Meeting (Feb 12-16, virtual conference). Poster No. 0410.
- [2] Tong W, Smith B, Henninger D, Kane R, Muench T. Bone ingrowth of RTT porous structure. 2020 ORS Annual Meeting (Feb 8-11, Phoenix, AZ). Paper No 337.
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- [4] Bobyn J, Stackpool G, Hacking S, Tanzer M, Krygier. Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. JBJS [Br] 1999;81-B:907-14

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Designing ATTUNE® FB Tibial Base for Durability - Ti Alloy

Selection and HIP Heat Treatment

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¹ Front End R&D, DePuy Synthes Joint Reconstruction, Warsaw, IN; ² 3D Printing Innovation & Customer Solutions, J&J, Miami, FL

1. Introduction

Commercially pure titanium (cpTi) and Ti-6Al-4V ELI (Ti64) are the most used alloys in the medical device industries. Nevertheless, the superior mechanical properties of Ti64, make it by far the preferred alloy for the most demanding applications. The uncertainty of fatigue performance of 3D printed titanium restricts their further applications [1,2,3]. Although, superficial defects can be removed or suppressed mechanically, internal defects (e.g., microporosity) cannot be fully eliminated by 3D printing [4]. Hence, hot isostatic pressing (HIP) post process is used to improve the microstructure, eliminate internal defects and enhance the fatigue performance of 3D printed materials.

In this study, we investigated the capability of HIPing for closing/healing internal pores [5] and evaluated the tensile and fatigue performance of 3D printed Ti64 (HIP condition) and cpTi (stressed relieved), materials used in making ATTUNE® Porous Fixed Knee Tibial Base with AFFIXIUM™ 3DP Technology, and a Leading Competitor S' knee tibial trays, respectively.

2. Methods

• Capability of HIP for closing critical size defects

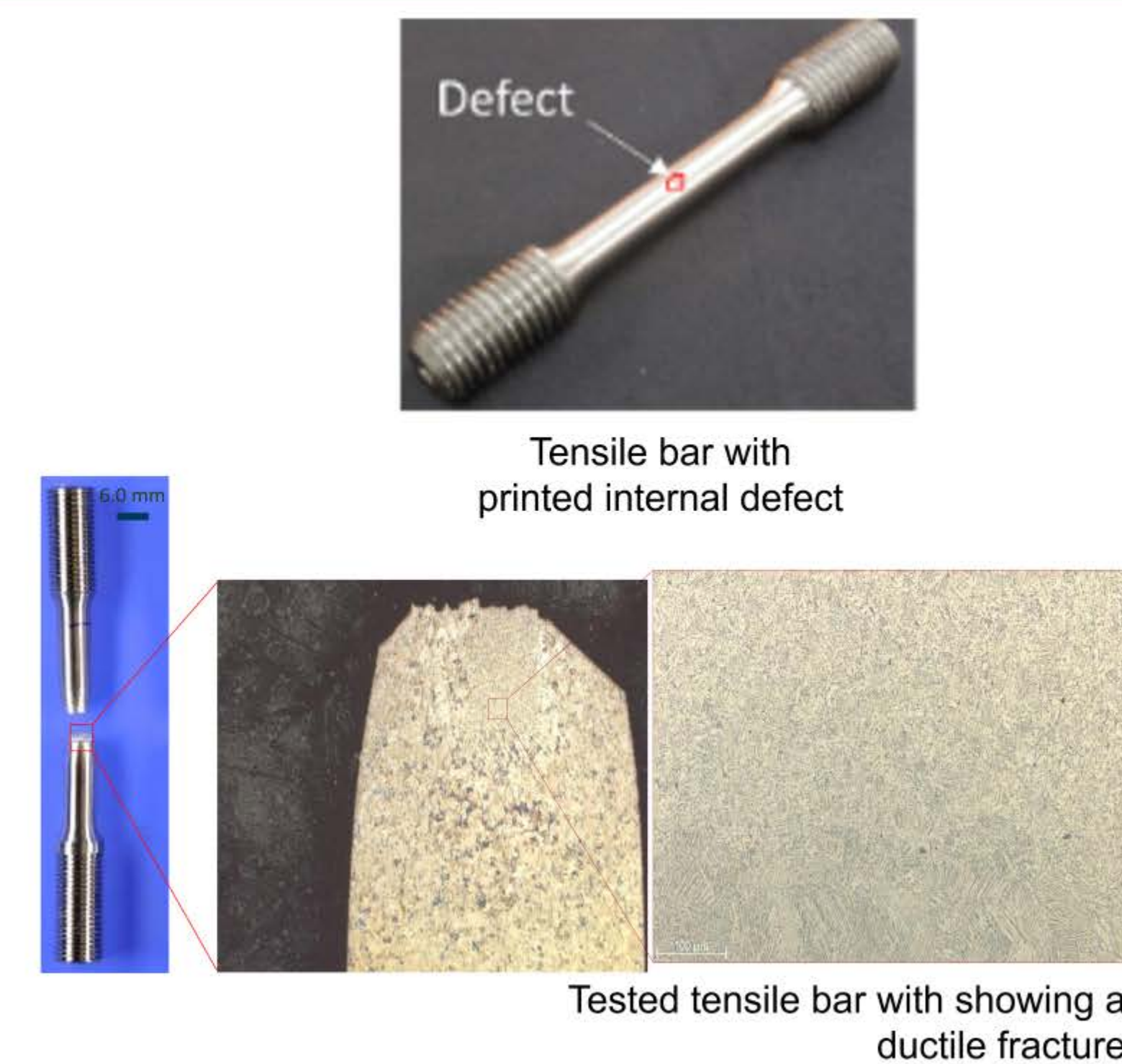
– An internal defect (Ø 2.5 mm x 2.5 mm), 100 times larger than the expected in 3D printed material was purposely printed inside tensile bars. These bars were later HIPed, tested and analyzed metallurgically to assess the defect closure and effects on tensile properties.

• Tensile and Fatigue Properties

– Tensile testing was carried out per ASTM E8 [6] and fatigue testing was performed as per ISO 1143 [7].

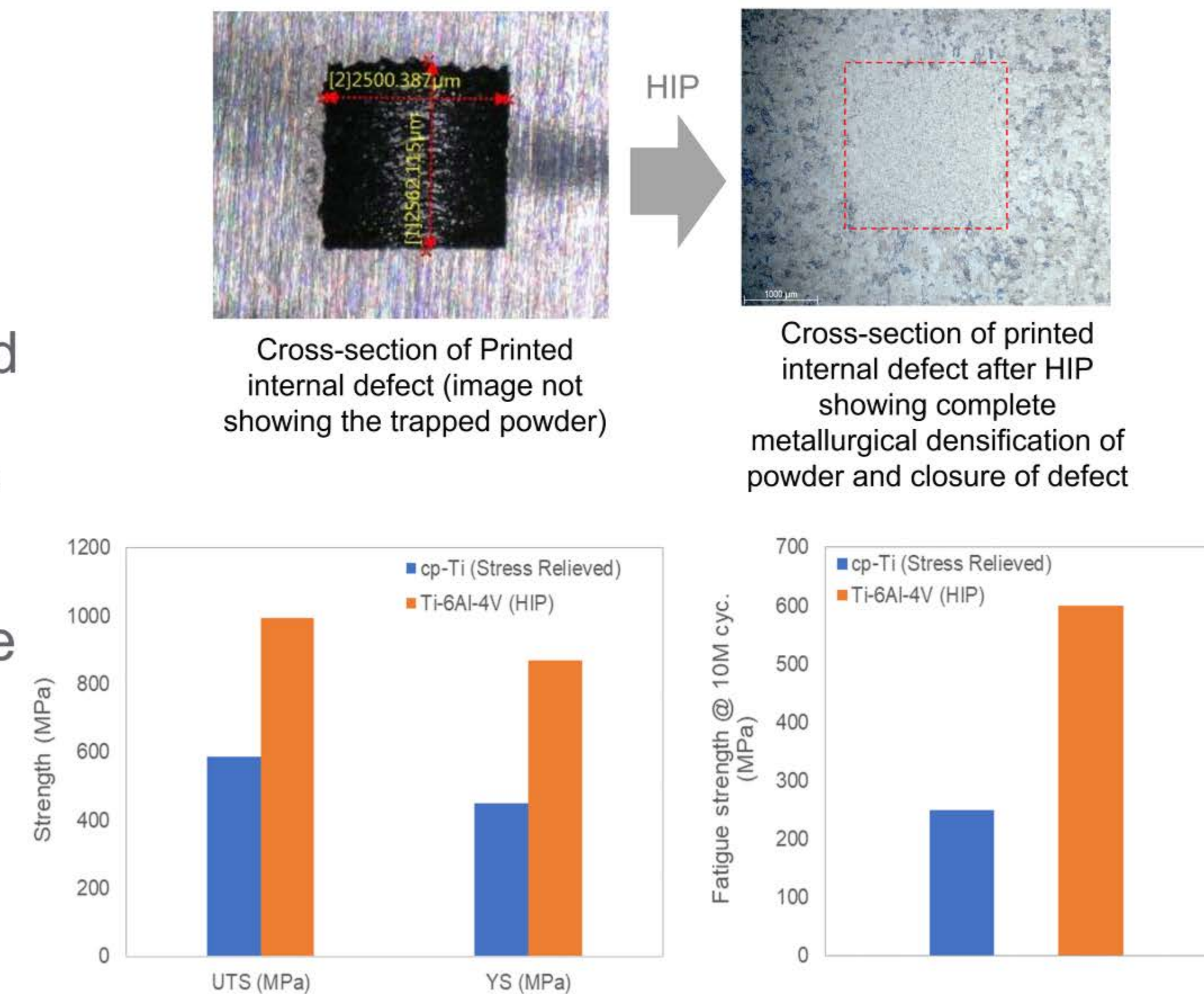
• Metallurgical Analysis

– A leading competitor S' tibial tray with 3D printed cone and ATTUNE AFFIXIUM FB Tibial Base made by laser powder bed fusion (LPBF) 3D printing technology were examined for internal defects.



3. Results

- Our validated HIP cycle managed to close the artificially generated defect (Ø 2.5 mm x 2.5mm).
- Utilization of HIP was found to improve the fatigue performance and ductility of 3D printed material.
- Superior tensile and fatigue performance of Ti64 + HIP compared to cpTi under stress relief [8].

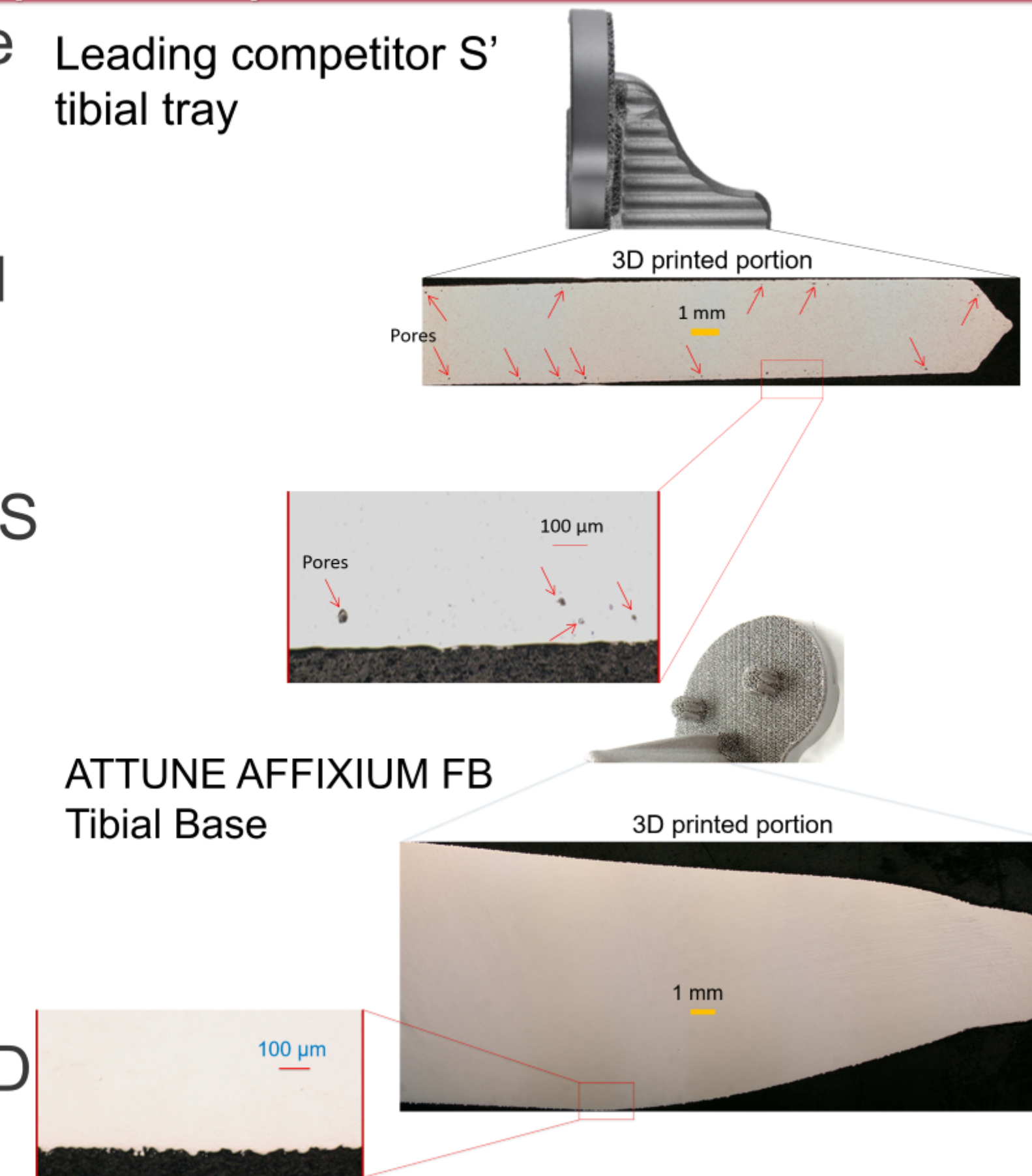


4. Discussion

- ATTUNE AFFIXIUM 3DP Technology FB Tibial Tray uses Ti64+HIP while the leading competitor S uses cpTi without HIP.
- We demonstrated that Ti64 after HIP is stronger than cpTi under stress relief in static and fatigue properties.
- 3D printed material typically shows numerous internal pores/defects in the range of 20-100um. It has been reported that internal pores/defect in 3D printed material reduce fatigue performance greatly [10]. We demonstrated that HIPing can close defects as large as Ø 2.5 mm x 2.5 mm. Providing a magnitude of safety margin to close critical size defects.
- The leading competitor S' tibial tray's keel depicted numerous internal pores in relation to their heat treatment process (non-HIP). On the contrary, all internal defects in the 3D printed material were closed in ATTUNE AFFIXIUM 3DP Technology FB Tibial Tray due to our validated HIPing process.

3. Results (Cont.)

- Metallurgical examination revealed that the bases of these trays were made from wrought Ti64 (non-3D printed).
- The keel or cone (cruciform) and biological fixation coatings of these trays were 3D printed.
- For 3D printed portion, leading competitor S used cpTi while AFFIXIUM FB Tibial Base used Ti64.
- Bright field optical microscopy examination revealed that there were numerous internal pores adjacent to the surface in competitor S' 3D printed keel.
- No internal pores/defects were found on 3D printed cone AFFIXIUM Tibial Base [9].



5. Conclusion

- Compared to 3D printed cpTi (stress relief), 3D printed Ti64 (HIP) has both stronger static mechanical and fatigue properties.
- Numerous internal pores existed in the 3D printed materials (e.g., keels) of the leading competitor S' tibial tray due largely to its post treatment process, whereas no internal pores existed in 3D printed materials (e.g., cones) of ATTUNE AFFIXIUM FB Tibial Base because HIP is required as the post treatment process.
- 3D printed Ti64 materials with HIP post process produced higher quality of materials when compared to 3D printed cpTi without HIP.

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Computational Design of Fixation Peg Placement Envelopes for a Cementless Tibia Tray System

David Wolfson, Mark Heldreth: DePuy Synthes

A review of work previously presented by University College Dublin, Dublin, Ireland

1. Introduction

- Pegs, may be added to cementless tibial baseplates in total knee arthroplasty (TKA) to enhance initial stability².
- The size and location of such features should not result in impingement with the cortical wall.
- A computational, population-based study was developed¹ and used in the development of the ATTUNE® Cementless Tibial Base³.



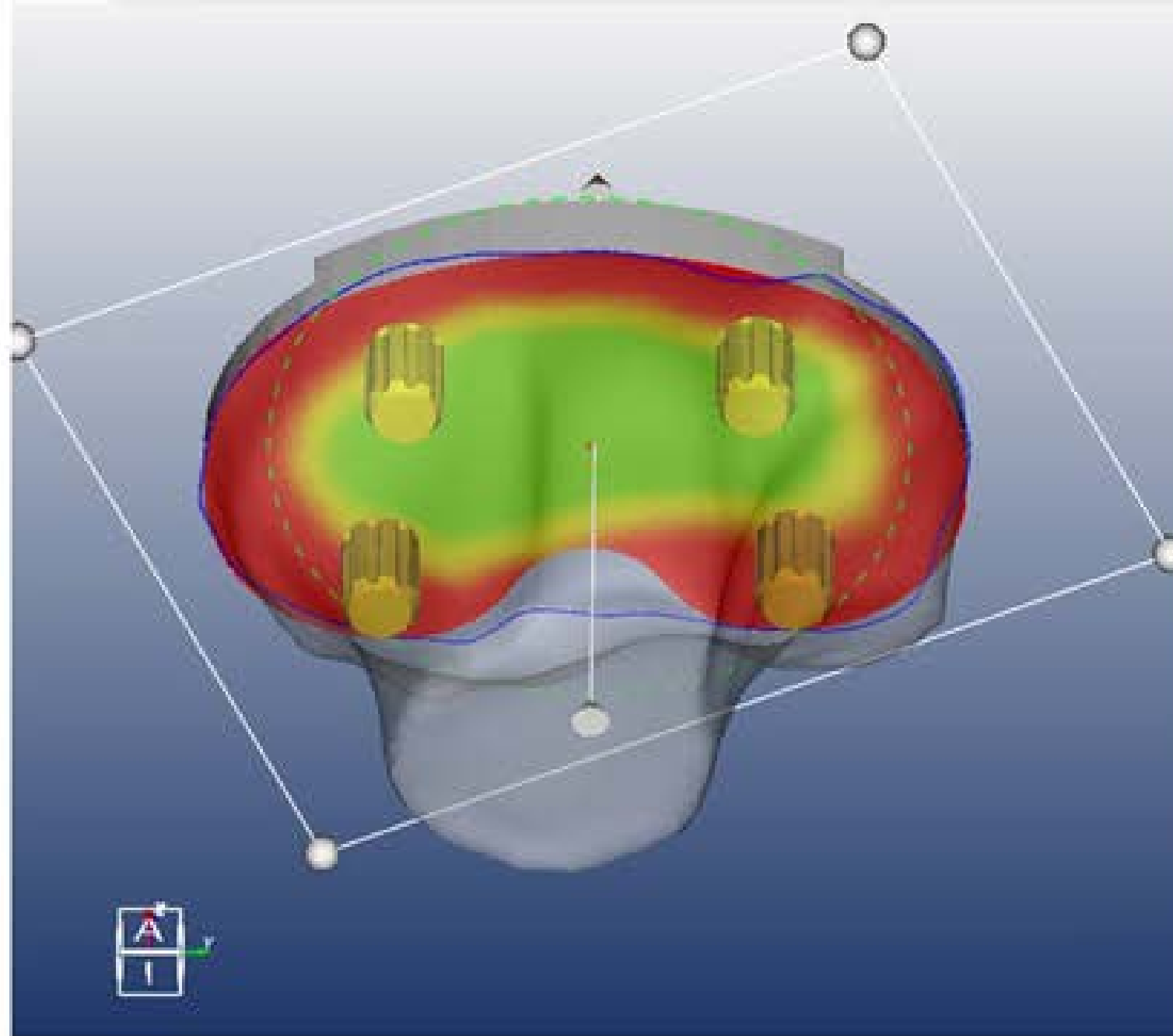
ATTUNE CR RP Cementless Knee

3. Methods

The following procedure was used for simulated implantation:

- Random patient anatomy generated
- Random local rotation applied
- Alignment algorithm used to size and position implants

The **shortest distance** from each peg to cortical bone was measured and probability of this being less than the bone thickness computed.



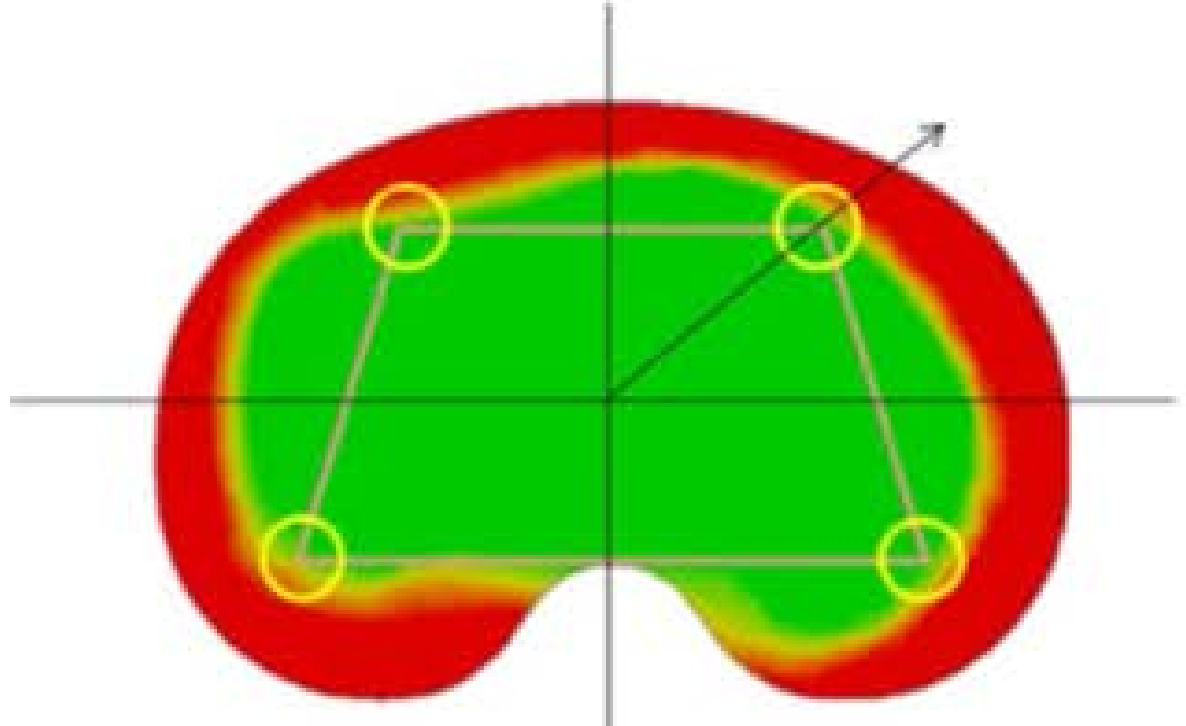
Automatically implanted proximal tibia model. The shortest distance between the fixation pegs and the proximal tibia model is visualized on the inferior tray surface (red - 0, green - max).

4. Application

Peg placement envelopes were used to guide the size and position of the 4 peripheral pegs of the ATTUNE Cementless RP Tibial Base.

- Computational design verification studies used the TRUMATCH® Personalized Solutions CT dataset (N=14,250) to compare peg location to the MBT DUOFIX™ Tibial Base³.
- The average distance from the peg to the cortical edge was showed a trend to being larger for the ATTUNE Cementless RP Tibial Base than for MBT DUOFIX Tibial Base.

These results suggest a reduced likelihood for cortical impingement with the ATTUNE Cementless RP Tibial Baseplate compared to the MBT DUOFIX Baseplate.



Optimizing the location for the 4-Pegs on the ATTUNE Cementless RP Tibial Baseplate. (Adapted from¹)



2. Materials

- A study (Curtis *et al.*)² used a computer-based simulation of cortical bone impingement in a virtually implanted **population** of sample patients.
- A statistical shape model (SSM) of tibial anatomical variability was constructed from a training set (>100 proximal tibial models) segmented from CT scans of the knee.
- Cylindrical peg geometries were added to ten variable sized tibia trays, based on the MBT tibial baseplate (DePuy Synthes, Warsaw, IN).

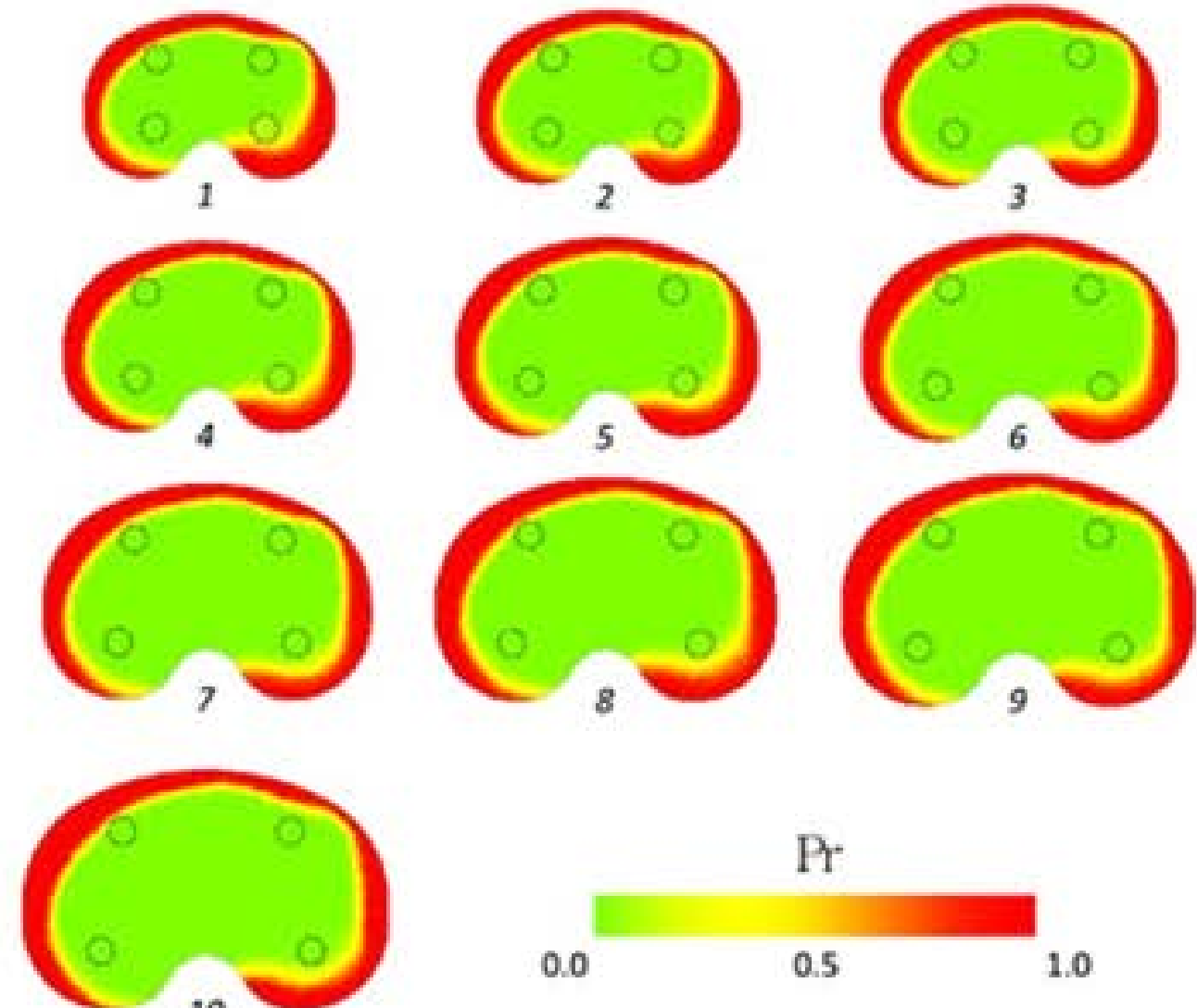


ATTUNE RP Cementless Tibial Baseplate with radial pegs

3. Results

- The simulation was validated by verify the accuracy of the probabilistic envelopes using 100 patient models excluded from the SSM and hypothetical peg geometries.
- There was no statistically significant difference between the cortical bone impingement rates predicted by the simulation and the test population ($p \leq 5\%$).

Peg placement envelopes with low probability of impingement were generated



Hypothetical ten size tibial tray system illustrating probabilistic peg placement envelopes and peg positions in areas where the probability of cortical bone - peg impingement (Pr) is low (i.e. < 5%).

5. Conclusion

- A computational simulation was developed to virtually implant a tibial baseplate in a random population¹
- Positional envelopes with low probability of peg impingement were identified and used to guide the design of the **ATTUNE RP Cementless Tibia**
- Design verification studies showed the likelihood of cortical peg impingement was less than for the MBT DUOFIX Tibial Base³



ATTUNE PS RP Cementless Knee

REFERENCES
 [1] Curtis *et al.* Computational Design of Fixation Peg Placement Envelopes for a Cementless Tibia Tray System. Poster No 1087, Annual Meeting of ORS, San Antonio, TX, 26-29 Jan 2013
 [2] Taylor M *et al.*, Influence of loading and activity on the primary stability of cementless tibial trays. *J Orthop Res.* 2012;30(9):1362-1368. doi:10.1002/jor.22056
 [3] DePuy Synthes, Cementless Peg Location Verification. 19 Aug 2015. ADAPTIV #DVA-107010-DVER

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