RESULTS OF IN-VIVO TESTING OF A NOVEL MACRO-SCALE OSSEOINTEGRATION SURFACE MORPHOLOGY

4th INTERNATIONAL PEEK SYMPOSIUM
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AUTHORS

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DISCLOSURES RELEVANT TO TOPIC

PICHA GJ: PRESIDENT AND CEO: APPLIED MEDICAL RESEARCH

PRICE J: EMPLOYEE: APPLIED MEDICAL TECHNOLOGY

CAUSEY G: CONSULTANT: APPLIED MEDICAL TECHNOLOGY

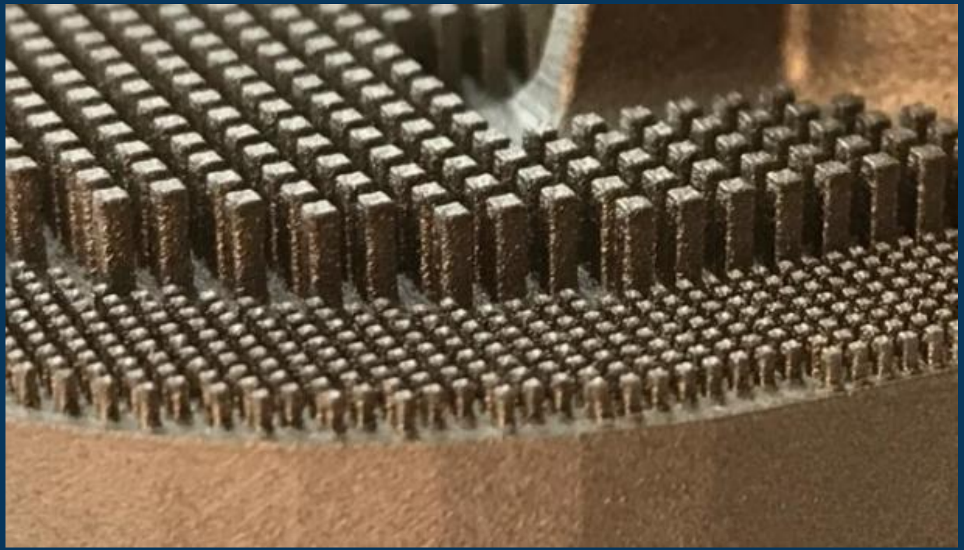
WALSH WR, PELLETIER M, WANG T: NONE

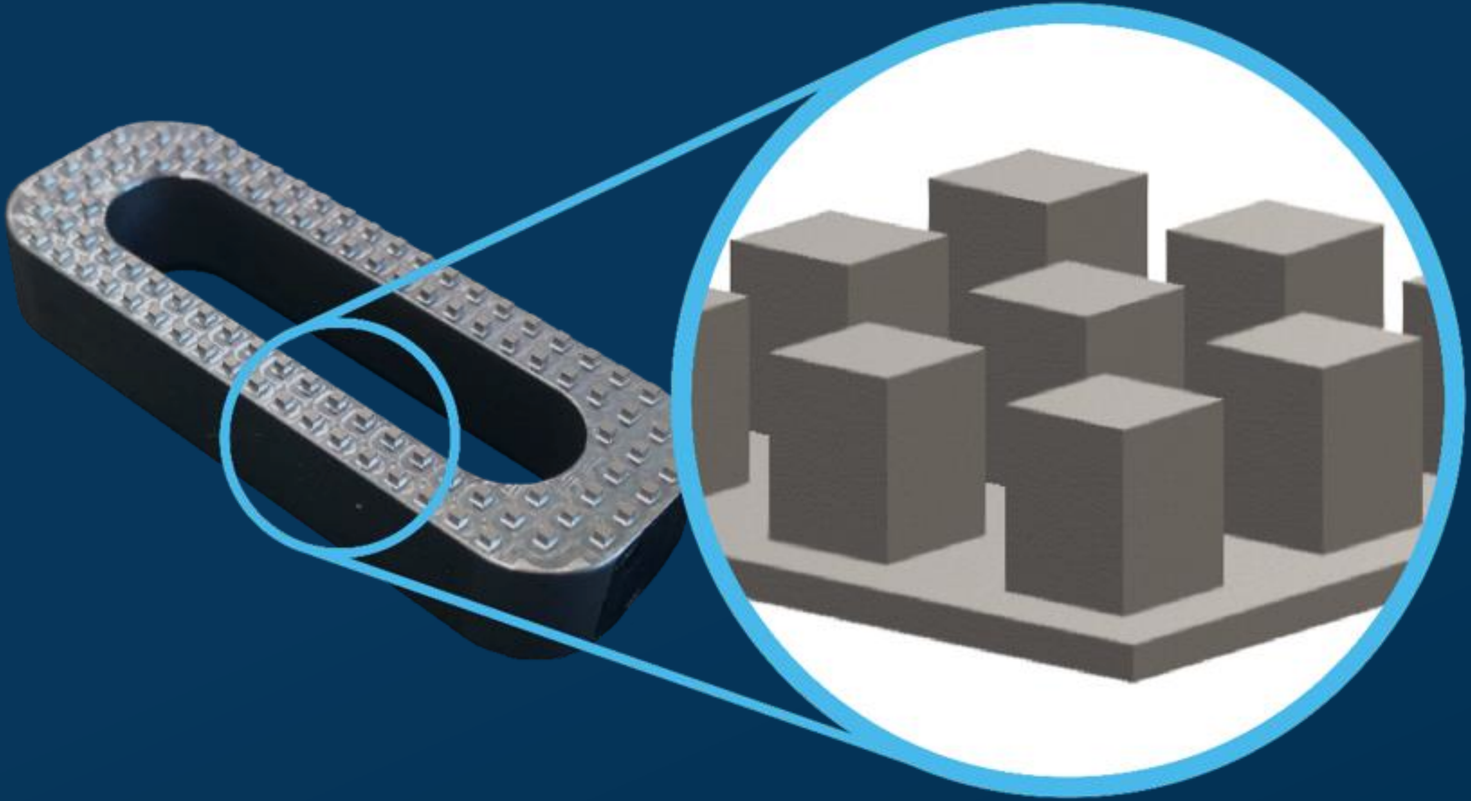
WHAT IS THE SURFACE MORPHOLOGY?

- PLATFORM TECHNOLOGY FOR ORTHOPEDIC SURFACES
- OPEN ARRAY OF MACRO-SCALE PILLARS ENABLING CONTINUOUS BONY IN-GROWTH
- COMPLIMENTARY TO MICRO/NANO TECHNOLOGY

Auxano™

Continuous Bone Fixation Interface



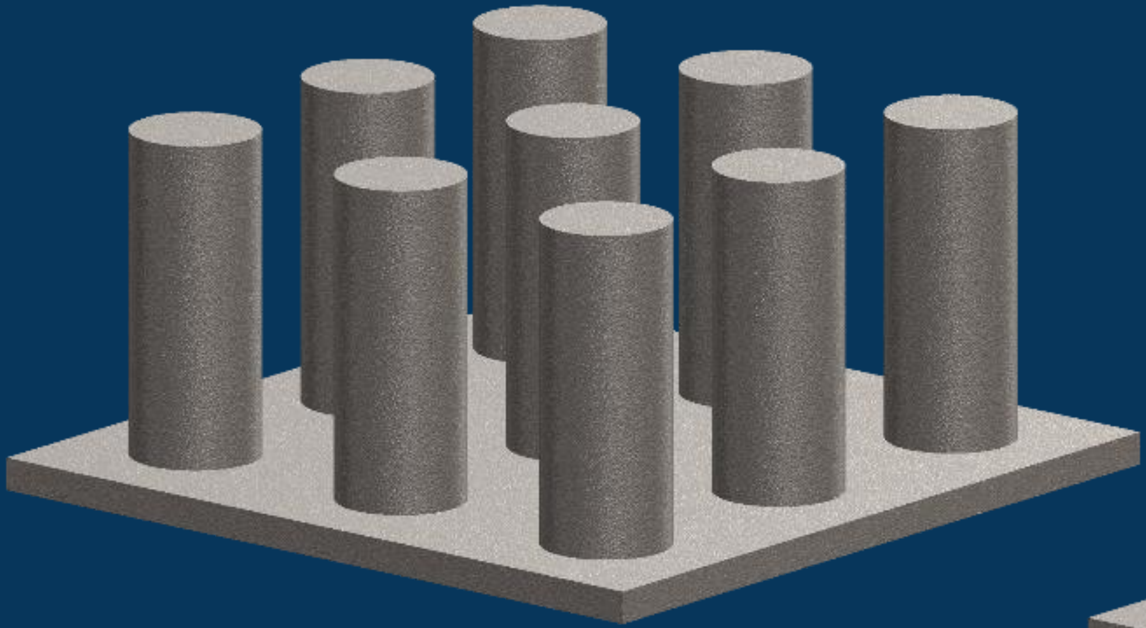


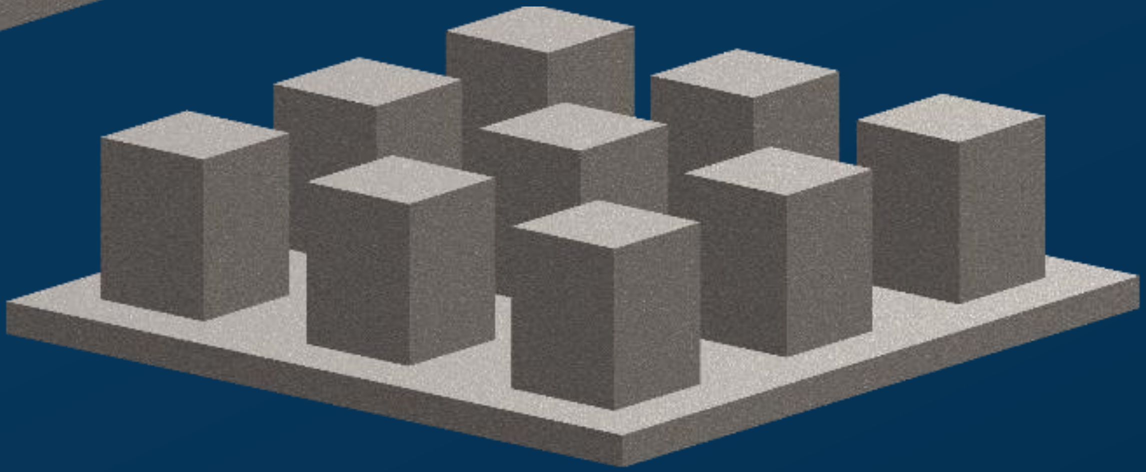
WHAT IS THE SURFACE MORPHOLOGY?

FULLY ENGINEERED INTERFACE TAILORED TO UNDERLYING BONY ANATOMY AND BIOMECHANICAL REQUIREMENTS

PILLAR GEOMETRY

- HEIGHT
- PROFILE
- SHAPE





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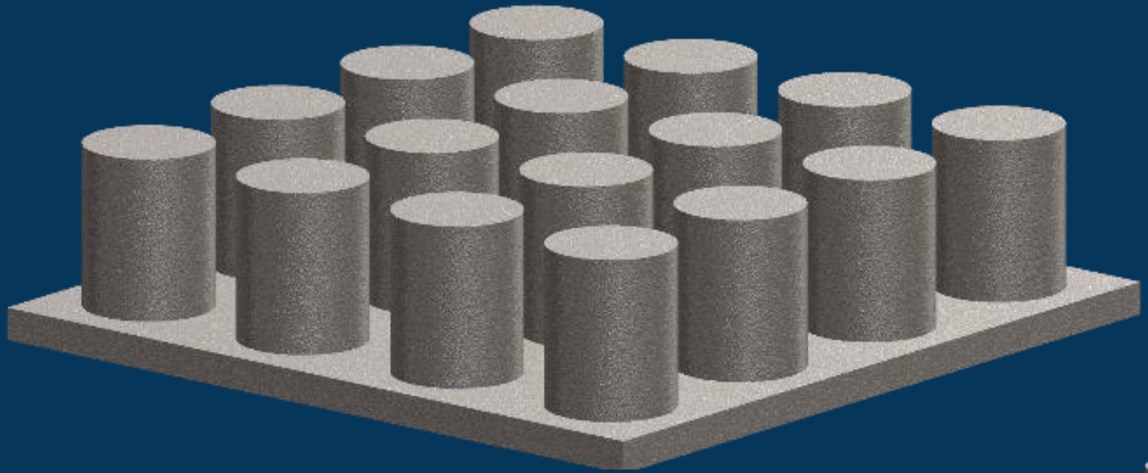
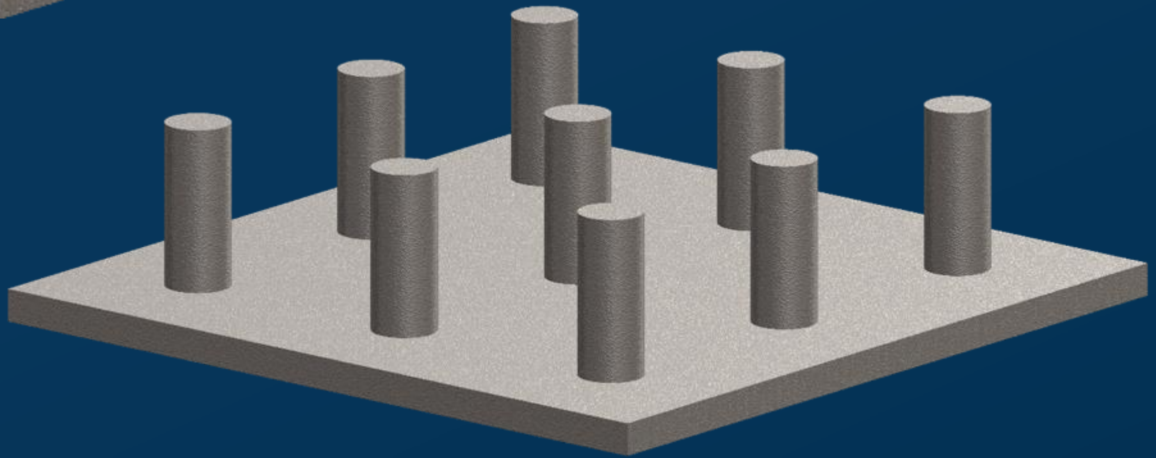
SURFACE MORPHOLOGY
- SPACING
- DENSITY





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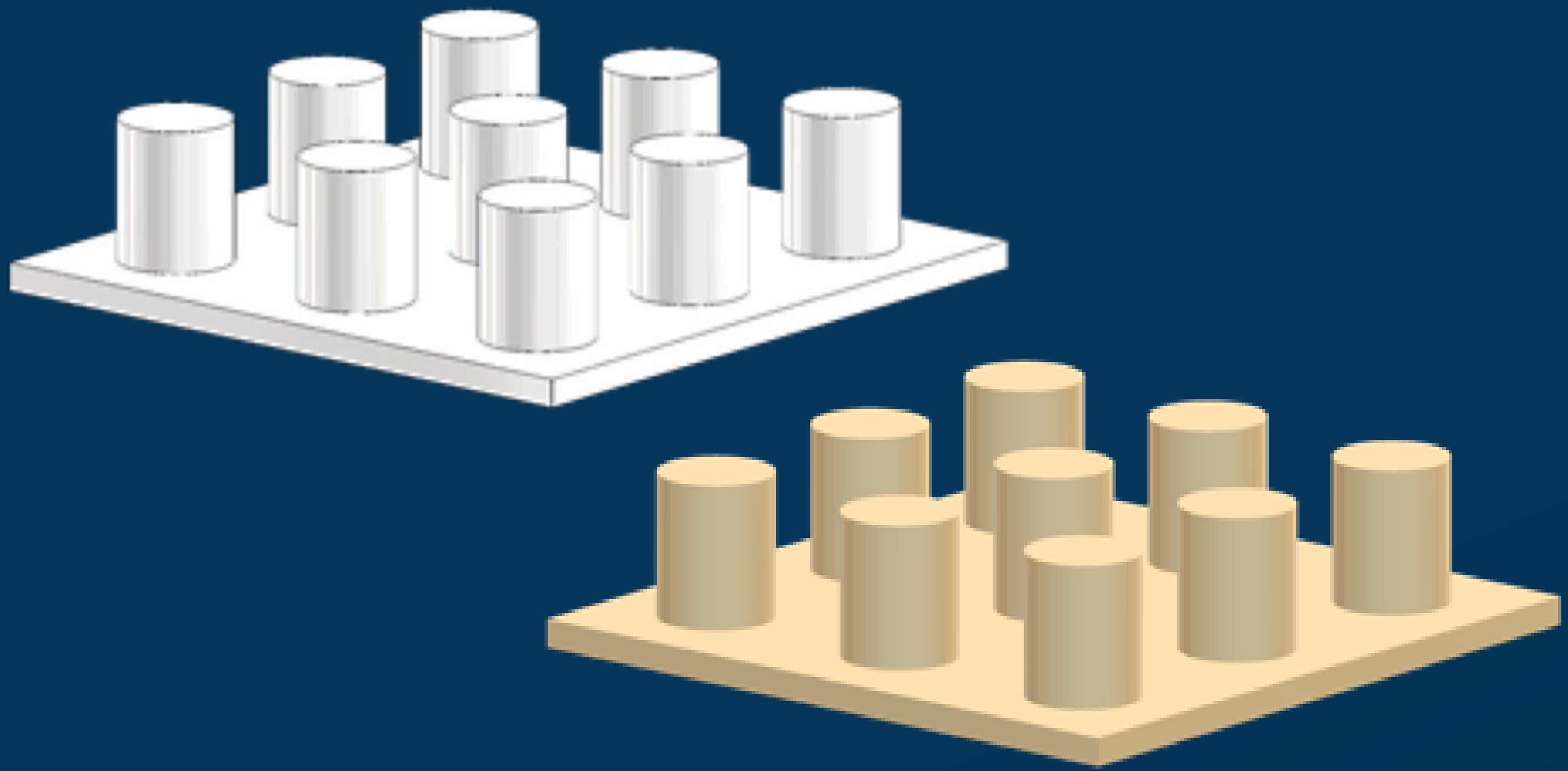
- PILLAR GEOMETRY
  - HEIGHT
  - PROFILE
  - SHAPE
- SURFACE MORPHOLOGY
  - SPACING
  - DENSITY
- IMPLANT MATERIAL
  - METALS
  - POLYMERS
  - ALLOGRAFT BONE



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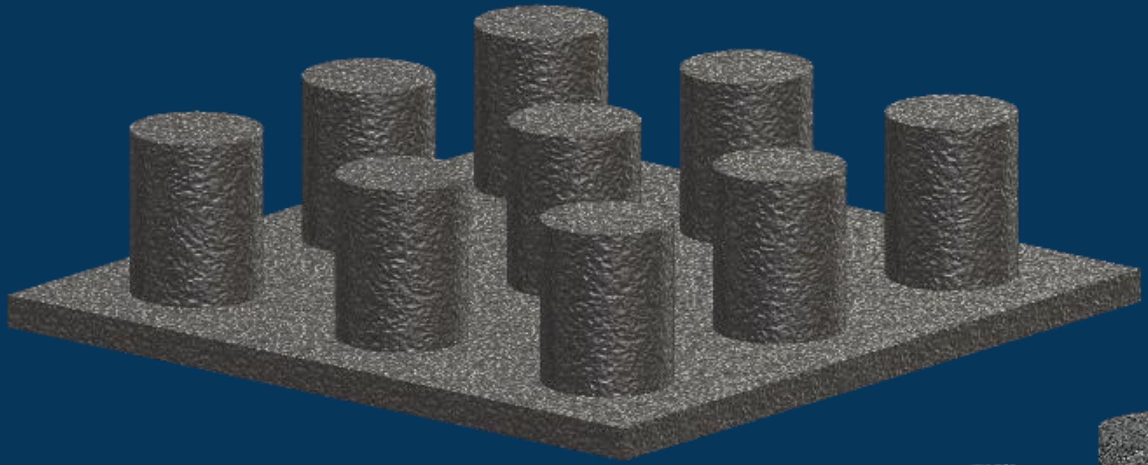
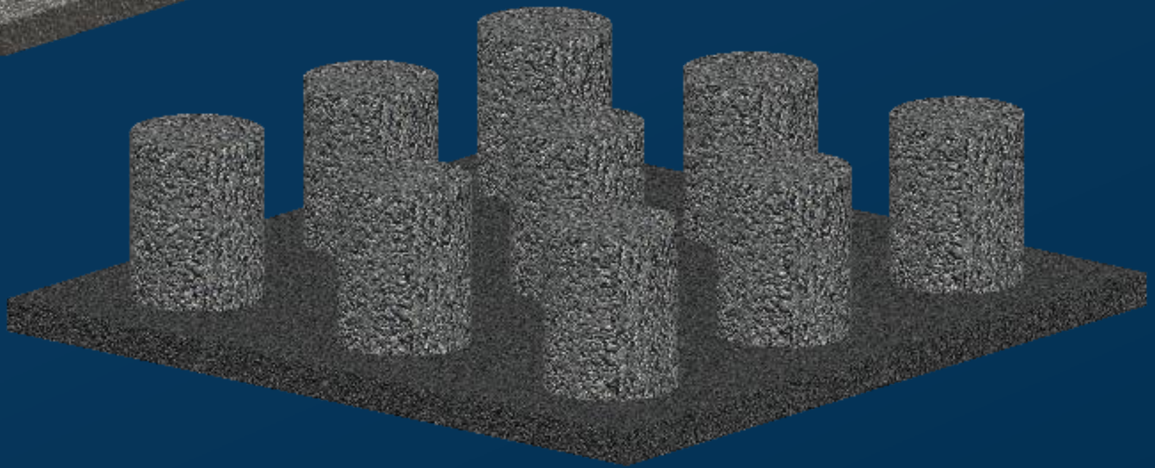
- SURFACE FINISH
  - COATED
  - GRIT BLAST
  - ACID ETCH
  - POROUS





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SURFACE MORPHOLOGY
- SPACING
- DENSITY

IMPLANT MATERIAL
- METALS
- POLYMERS
- ALLOGRAFT BONE

SURFACE FINISH
- COATED
- GRIT BLAST
- ACID ETCH
- POROUS

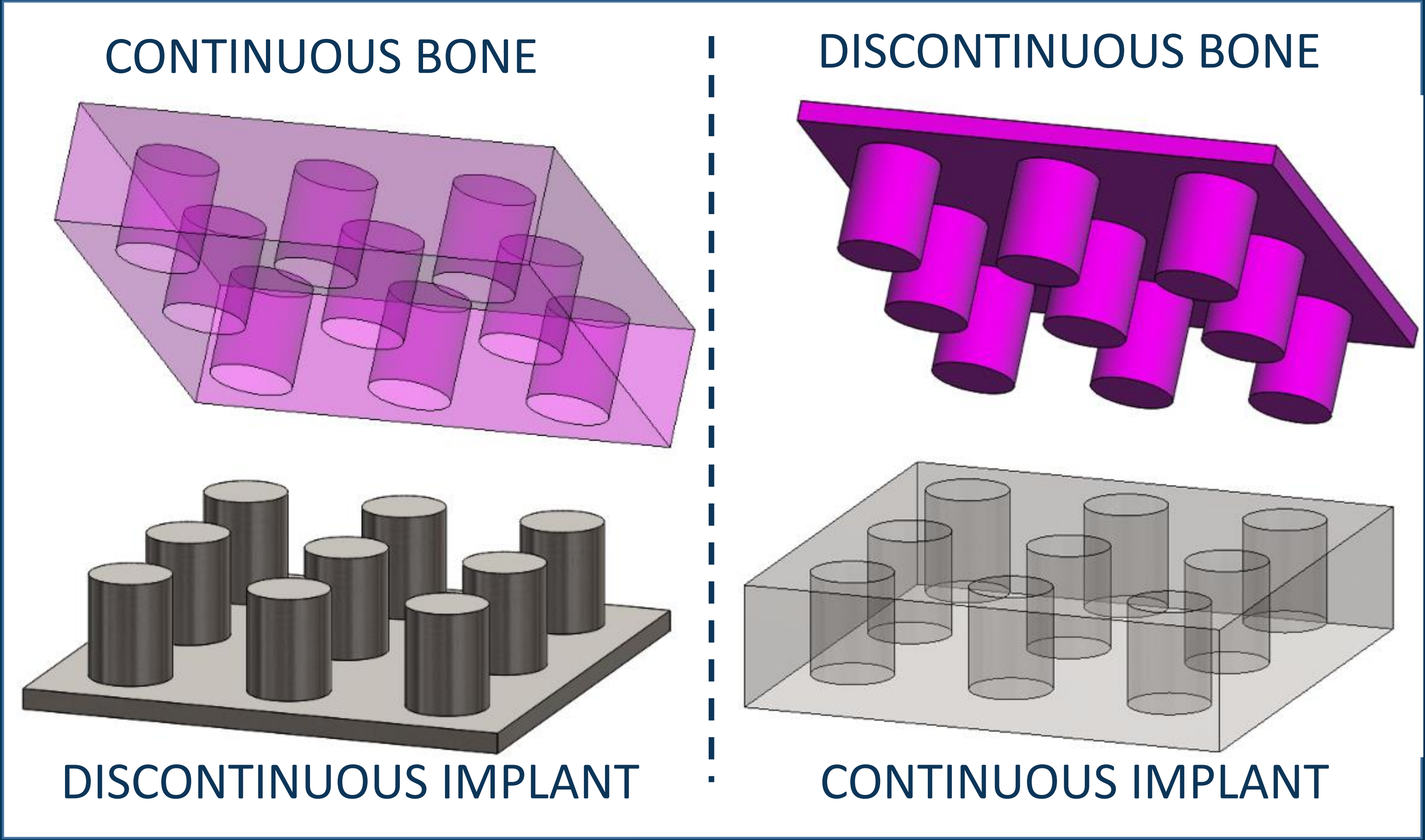
MANUFACTURING
- ADDATIVE
- SUBTRACTIVE
- MOLDING

BIOLOGIC: CONTINUOUS BONY PHASE

CONTINUOUS BONE & DISCONTINUOUS IMPLANT

CONTINUOUS PHASE ENABLES

- ROBUST INTERDIGITATED BONE IN-GROWTH
- LARGE VOID VOLUME
- HIGHLY AND FULLY INTERCONNECTED GROWTH SPACE
- EASILY ACCESSIBLE GROWTH SPACE



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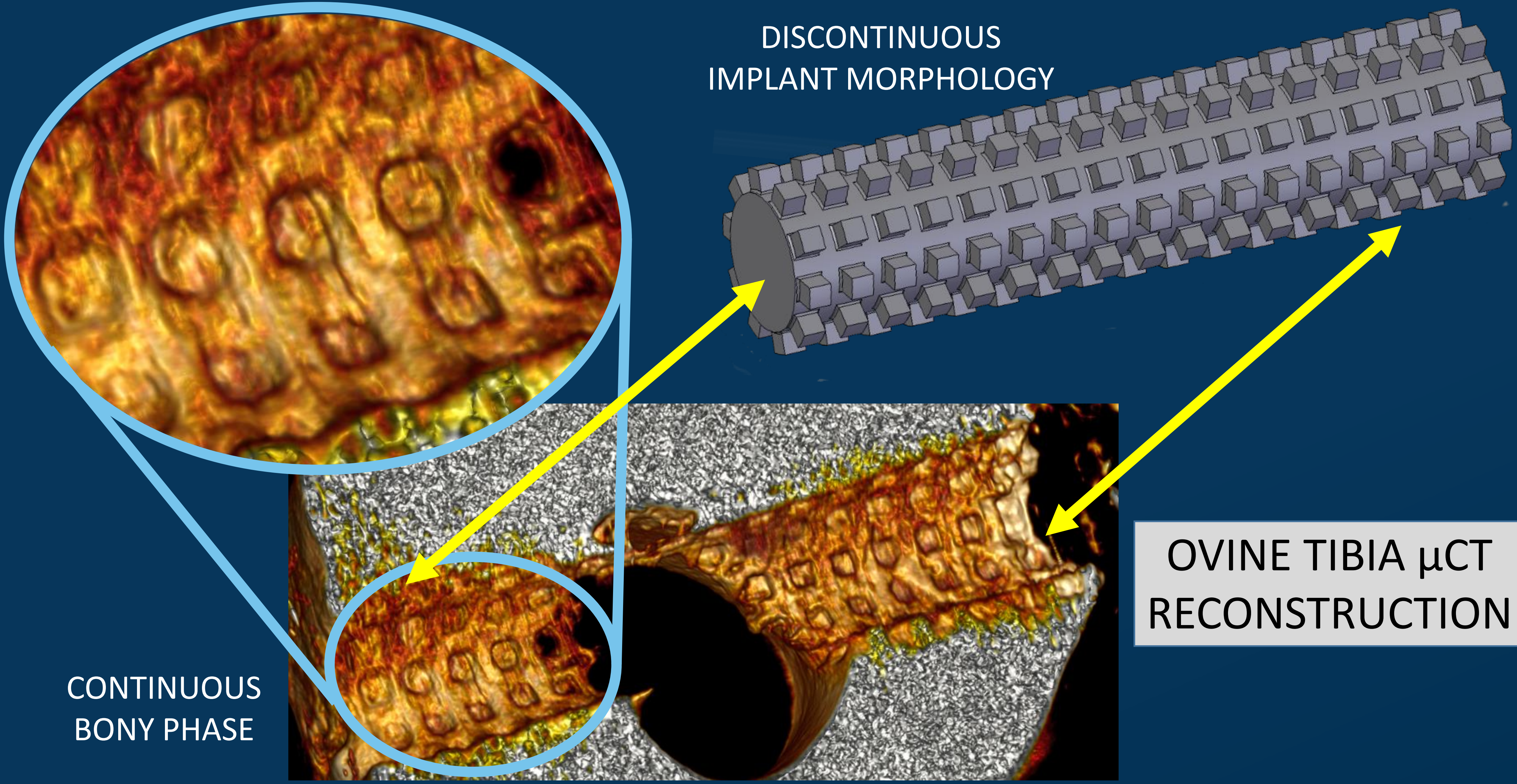


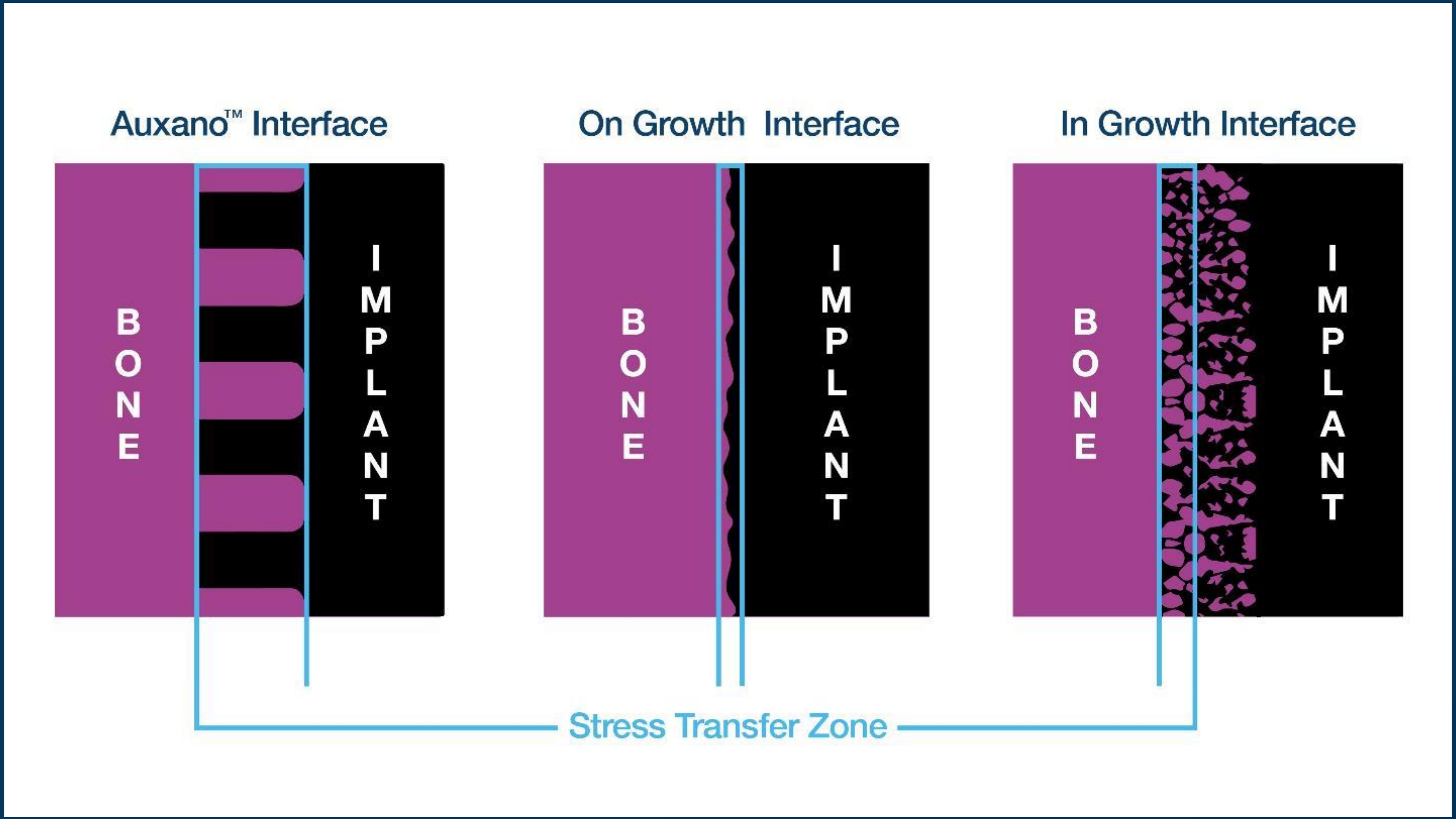
OVINE TIBIA μCT RECONSTRUCTION

BIOMECHANICAL: STRESS TRANSFER

STRUCTURAL MORPHOLOGY TO EFFECTIVELY TRANSFER STRESS

GRADUAL STRESS TRANSFER THROUGH TRANSITION ZONE

DISTRIBUTION OF MATERIAL



IN-VIVO PHASE I: PROOF OF CONCEPT, PILLAR SPACING
2009 CANINE STUDY, PEEK IMPLANTS

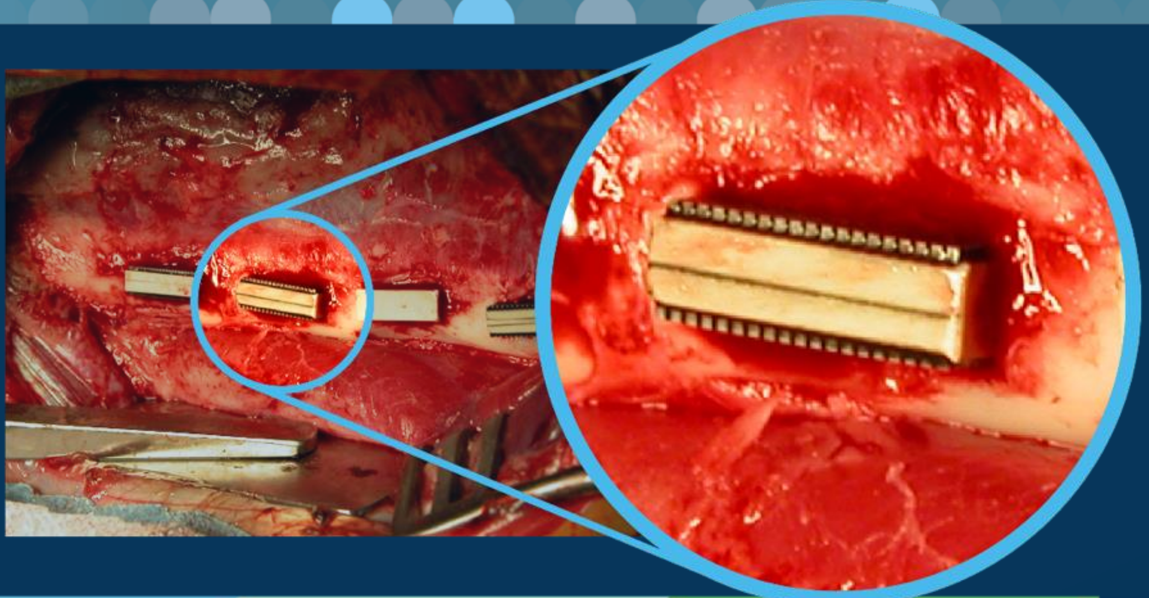
<u>DETAILS</u>: 6 CANINES, 6WK

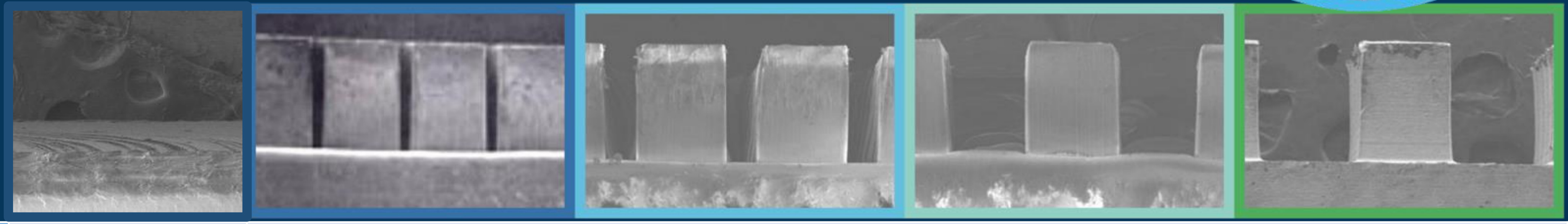
<u>IMPLANTS</u>: 12x8x4mm PLATES, PEEK

<u>END POINTS</u>: HISTOLOGY, PUSHOUT

<u>MAIN FINDINGS</u>: OVER 50% VOID VOLUME:

- SOLID BONY IN-GROWTH
- INCREASED PUSHOUT RESISTANCE



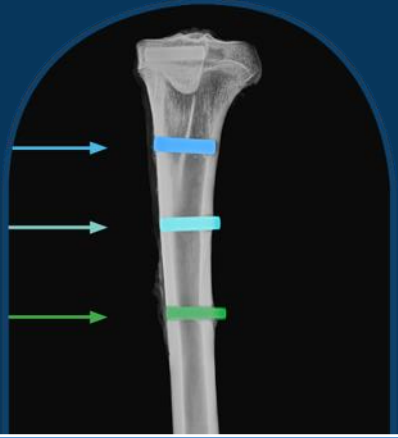


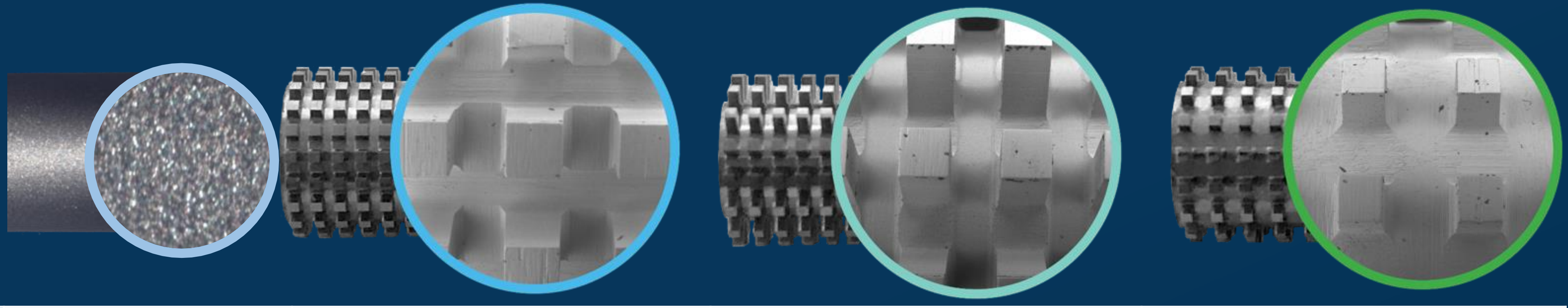
PILLAR GEOMETRY	N/A	400x400µm x 500µm TALL			
PILLAR SPACING	N/A	100µm	200µm	400µm	400µm
MATERIAL	PEEK				TITANIUM
VOID VOLUME %	0%	36%	56%	75%	75%

IN-VIVO PHASE II: GEOMETRY ASSESSMENT

2015 OVINE STUDY – W.R. WALSH PH.D. – UNSW

DETAILS: 8 SHEEP, 4 EACH AT 4&12 WK
IMPLANTS: 6mm DOWELS, LINE TO LINE FIT
END POINTS: HISTOLOGY, PUSHOUT
MAIN FINDINGS:
- FULLY IN-GROWN BONE
- INCREASED PUSHOUT RESISTANCE



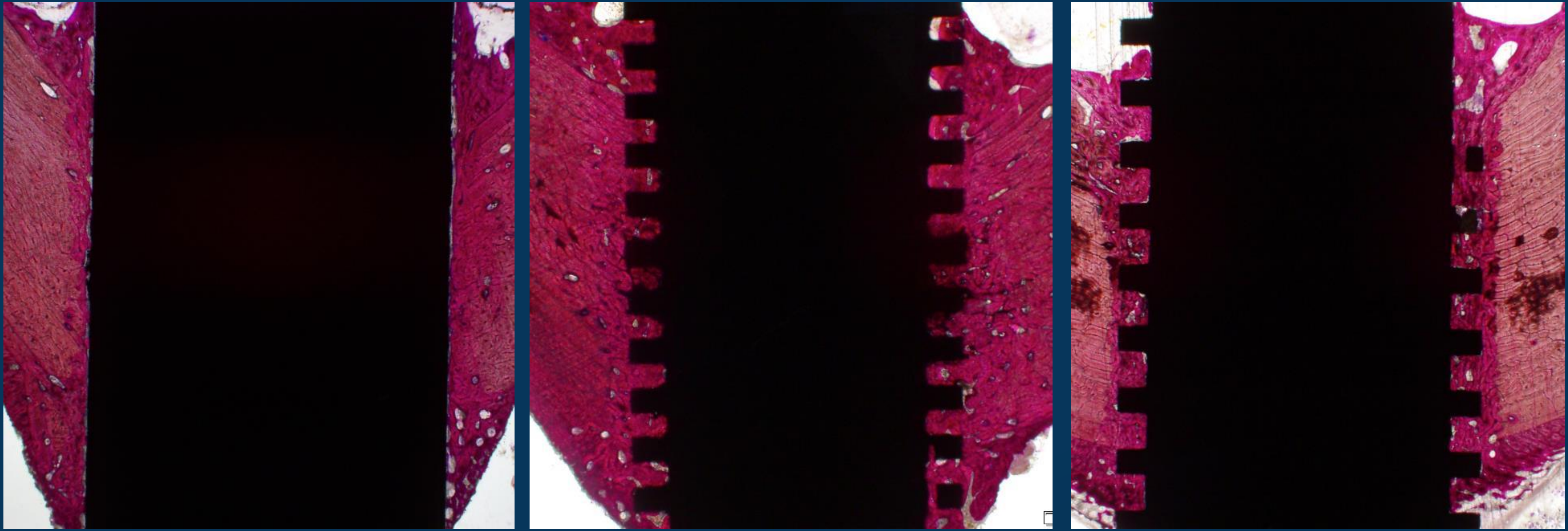


PILLAR HEIGHT	N/A	500µm	1000µm	500µm
PILLAR SPACING	N/A	400µm	400µm	600µm
VOID VOLUME %	0%	77%	80%	85%

IN-VIVO PHASE II: GEOMETRY ASSESSMENT

2015 OVINE STUDY – W.R. WALSH PH.D. – UNSW

12 WEEK HISTOLOGY



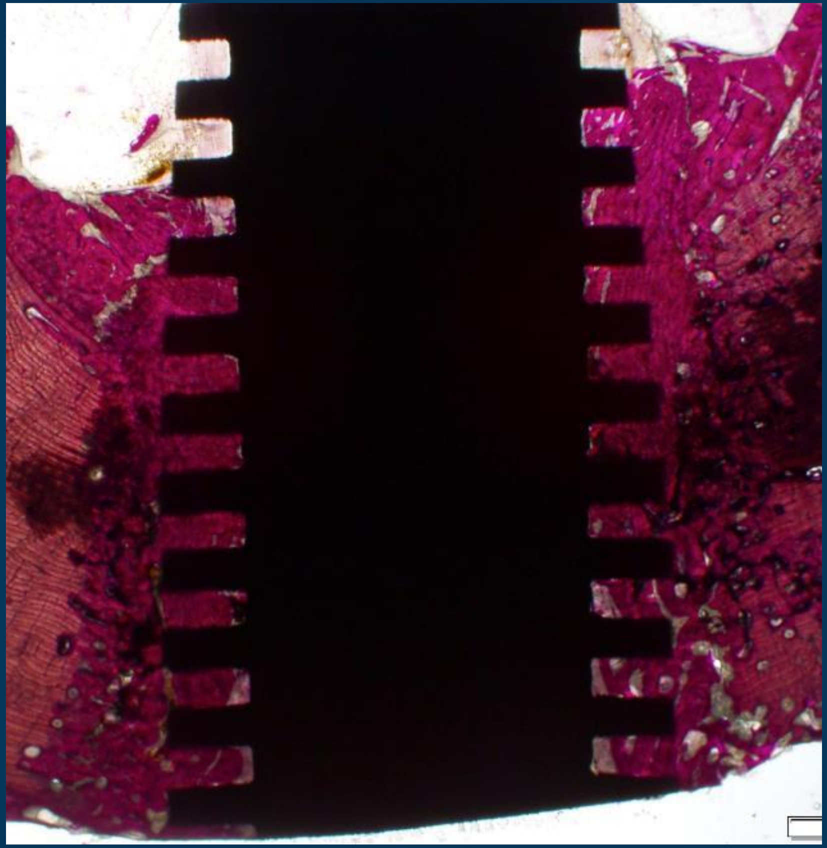
TITANIUM GRIT BLAST

TITANIUM 400µm SPACING

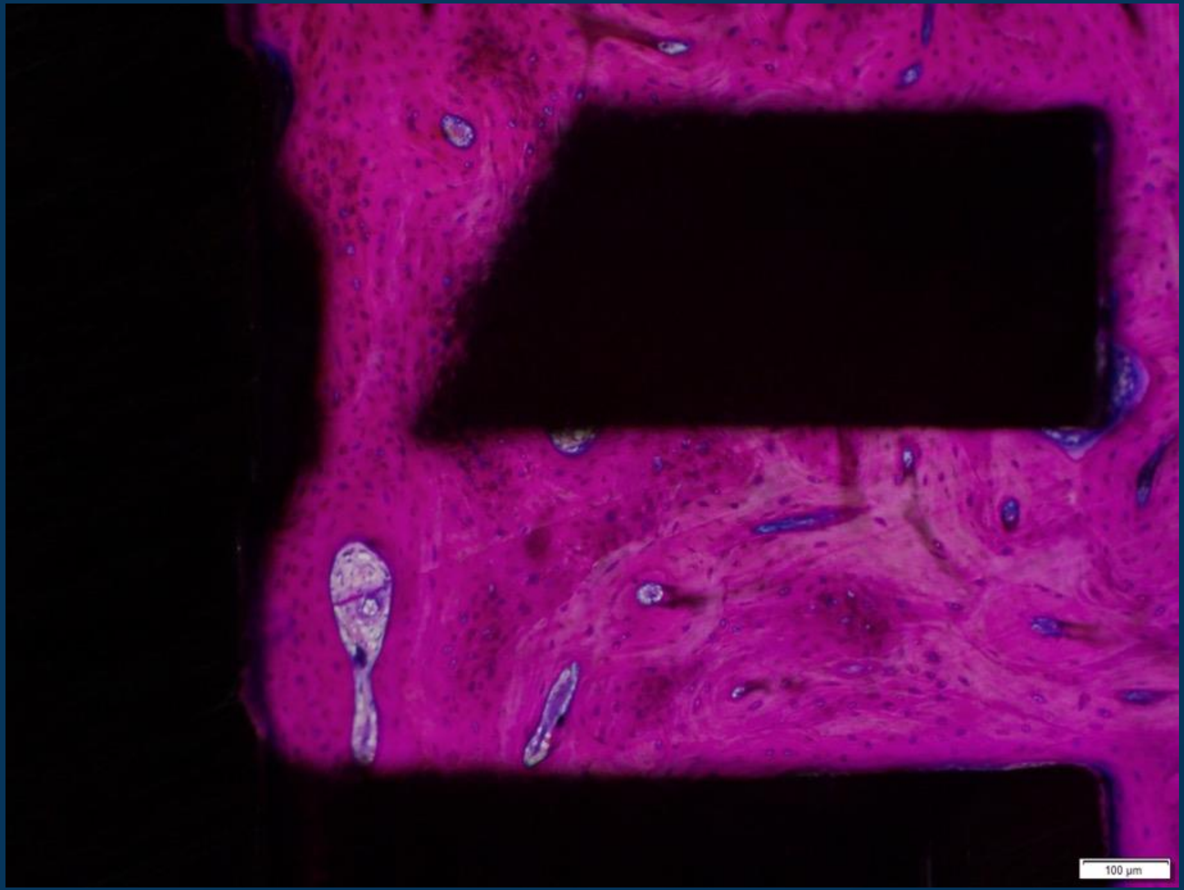
TITANIUM 600µm SPACING

IN-VIVO PHASE II: GEOMETRY ASSESSMENT
2015 OVINE STUDY – W.R. WALSH PH.D. – UNSW

12 WEEK HISTOLOGY



TITANIUM TALL
400µm SPACING



TITANIUM TALL 400µm
SINGLE PILLAR VIEW

IN-VIVO PHASE III: MATERIAL COMPOSITION

2018 OVINE STUDY – W.R. WALSH PH.D. - UNSW

<u>DETAILS</u>: 12 SHEEP, 6 EACH AT 6&12 WK

<u>IMPLANTS</u>: 6mm DOWELS, LINE TO LINE FIT

<u>END POINTS</u>: HISTOLOGY, µCT, PUSHOUT

<u>MAIN FINDINGS</u>:

- ROBUST BONY IN-GROWTH INTO ALL MATERIALS
- IN-GROWTH AGNOSTIC TO IMPLANT MATERIALS

<table>
<tr><th>MATERIAL</th><th>SQUARE PILLAR WIDTH</th><th>PILLAR HEIGHT</th><th>PILLAR SPACING</th><th>VOID VOLUME %</th></tr>
<tr><td>TALL PEEK*</td><td>400µm</td><td>1000µm</td><td>400µm</td><td>80%</td></tr>
<tr><td>PEEK*</td><td rowspan="6">750µm</td><td rowspan="6">750µm</td><td rowspan="6">665µm</td><td rowspan="6">77%</td></tr>
<tr><td>PEEK HA[ξ]</td></tr>
<tr><td>PEEK* TI COATED[ϕ]</td></tr>
<tr><td>TITANIUM</td></tr>
<tr><td>UHMWPE</td></tr>
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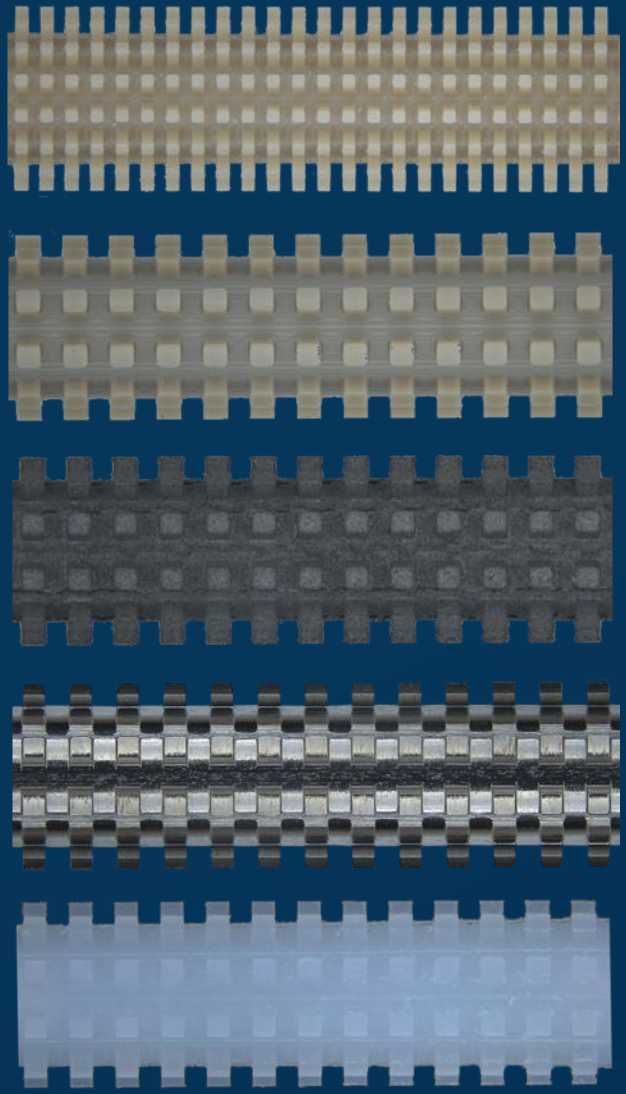
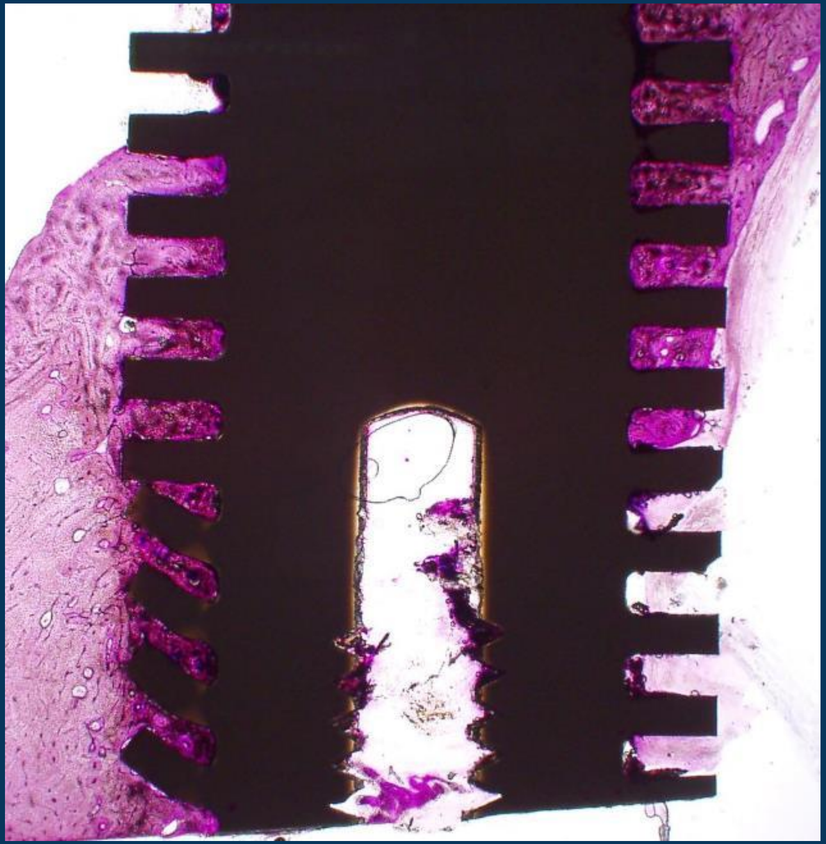


*Evonik [ξ]Invibio [ϕ]Orchid Orthopedics

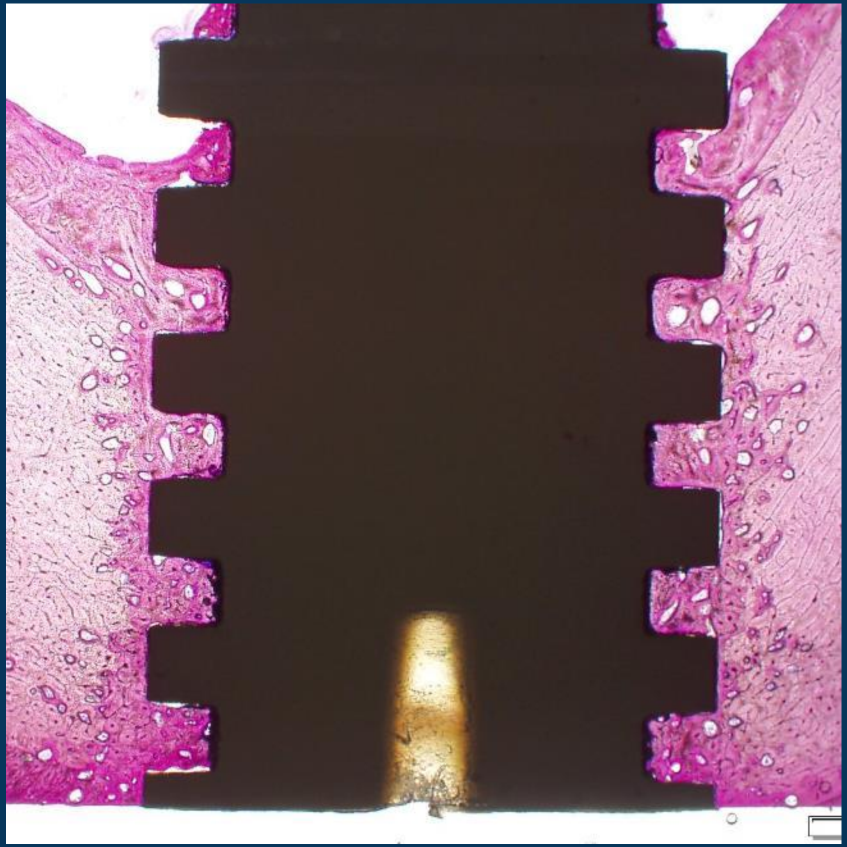
IN-VIVO PHASE III: MATERIAL COMPOSITION

2018 OVINE STUDY – W.R. WALSH PH.D. - UNSW

12 WEEK HISTOLOGY PILLARED IMPLANT



TALL PEEK, 400µm

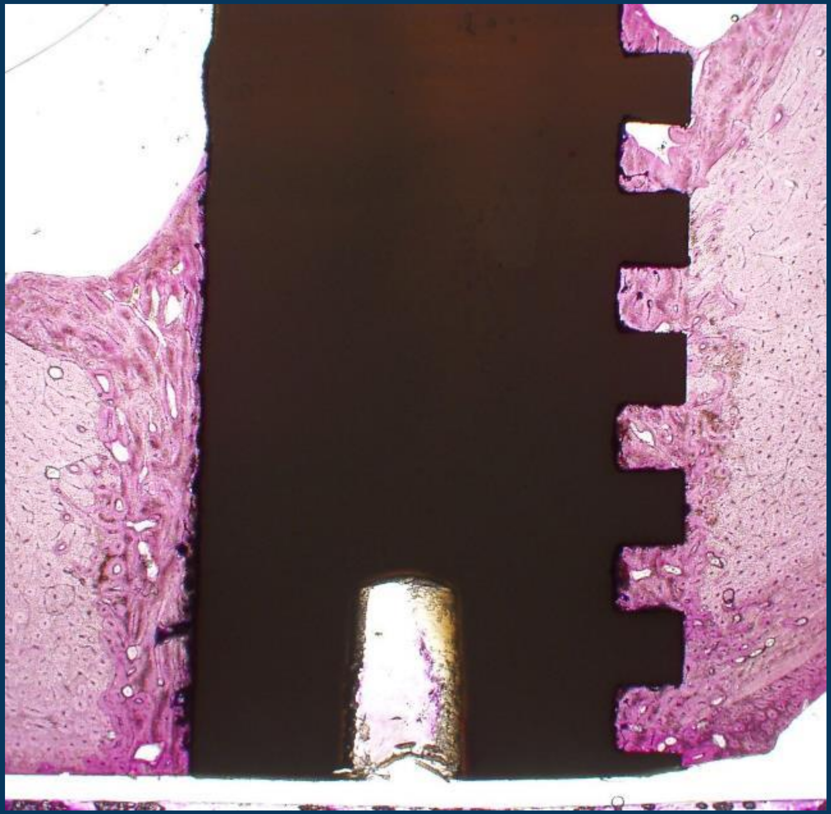


PEEK

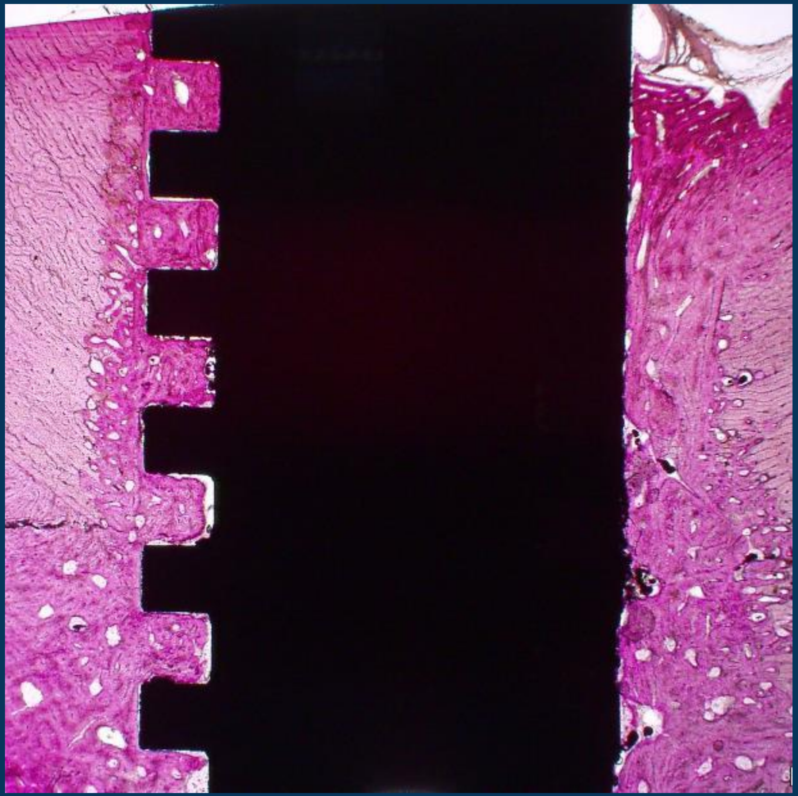
PEEK HA

IN-VIVO PHASE III: MATERIAL COMPOSITION
2018 OVINE STUDY – W.R. WALSH PH.D. - UNSW

12 WEEK HISTOLOGY PILLARED IMPLANT



TI COATED PEEK



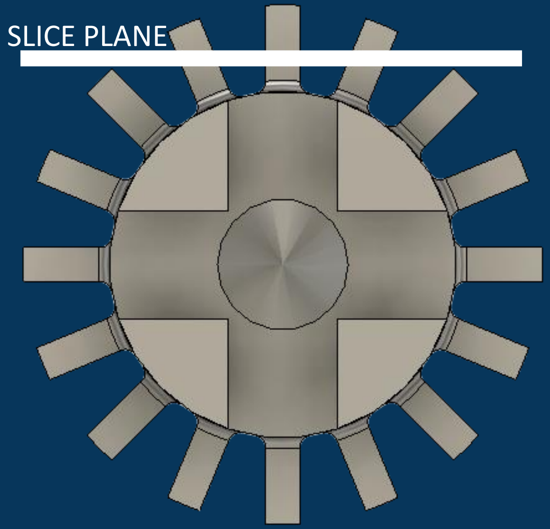
TITANIUM

UHMWPE

IN-VIVO PHASE III: MATERIAL COMPOSITION

2018 OVINE STUDY – W.R. WALSH PH.D. - UNSW

12 WEEK HISTOLOGY: OFF-AXIS SLICE PLANE THROUGH PILLARES



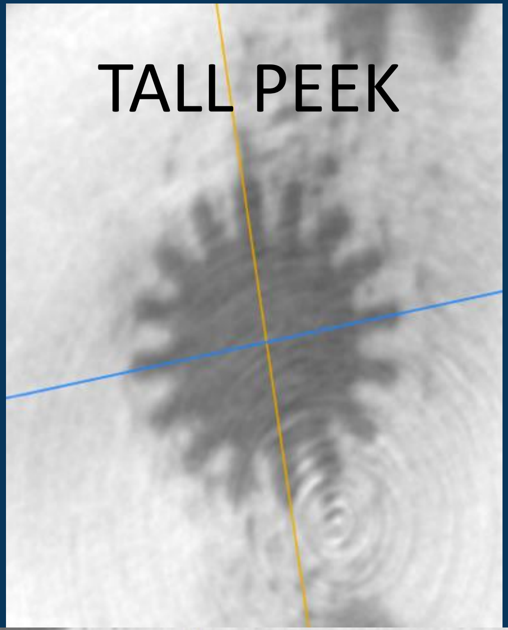
TI COATED PEEK

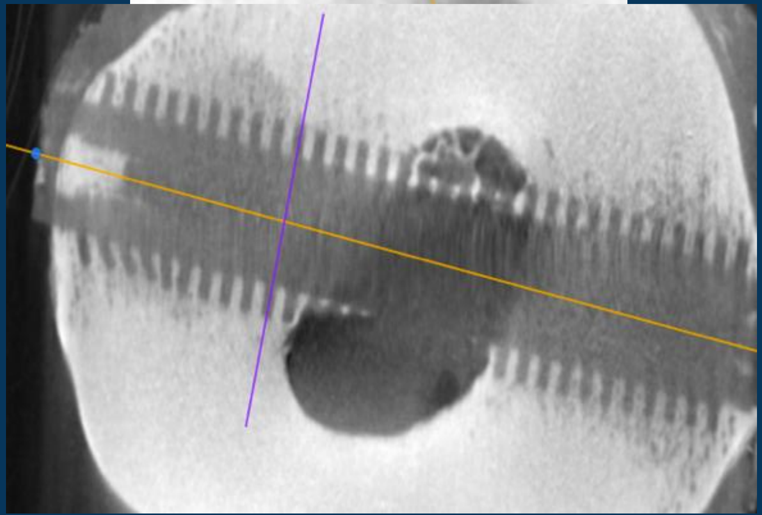
TALL PEEK, 400μm SPACING

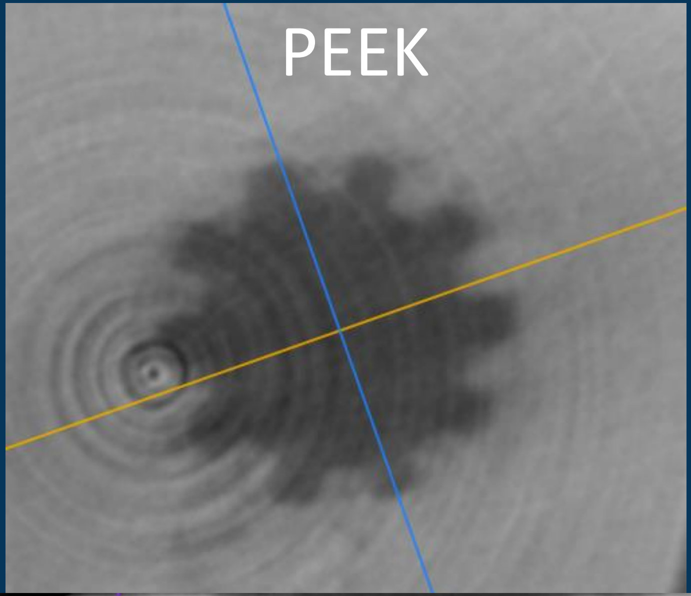
IN-VIVO PHASE III: MATERIAL COMPOSITION

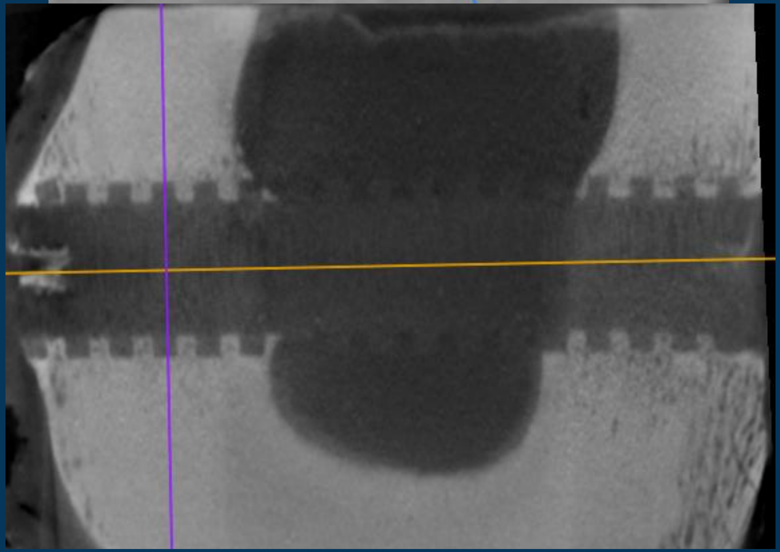
2018 OVINE STUDY – W.R. WALSH PH.D. - UNSW

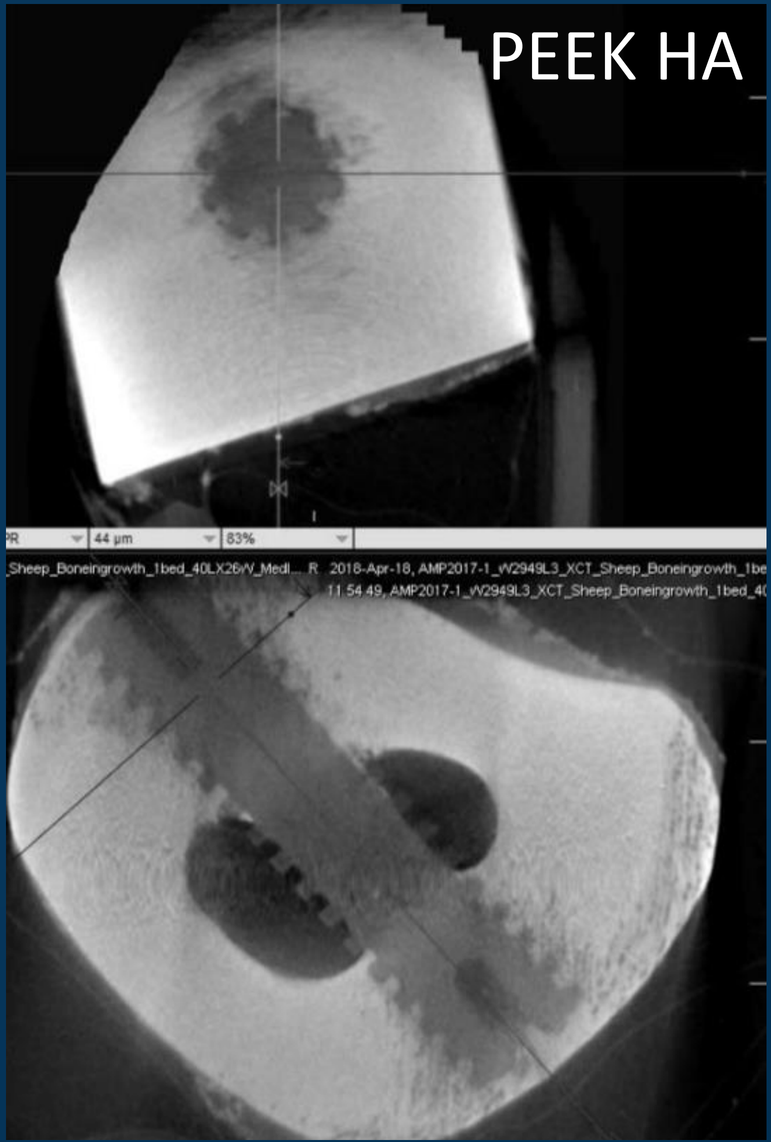
12 WEEK µCT PILLARED IMPLANT







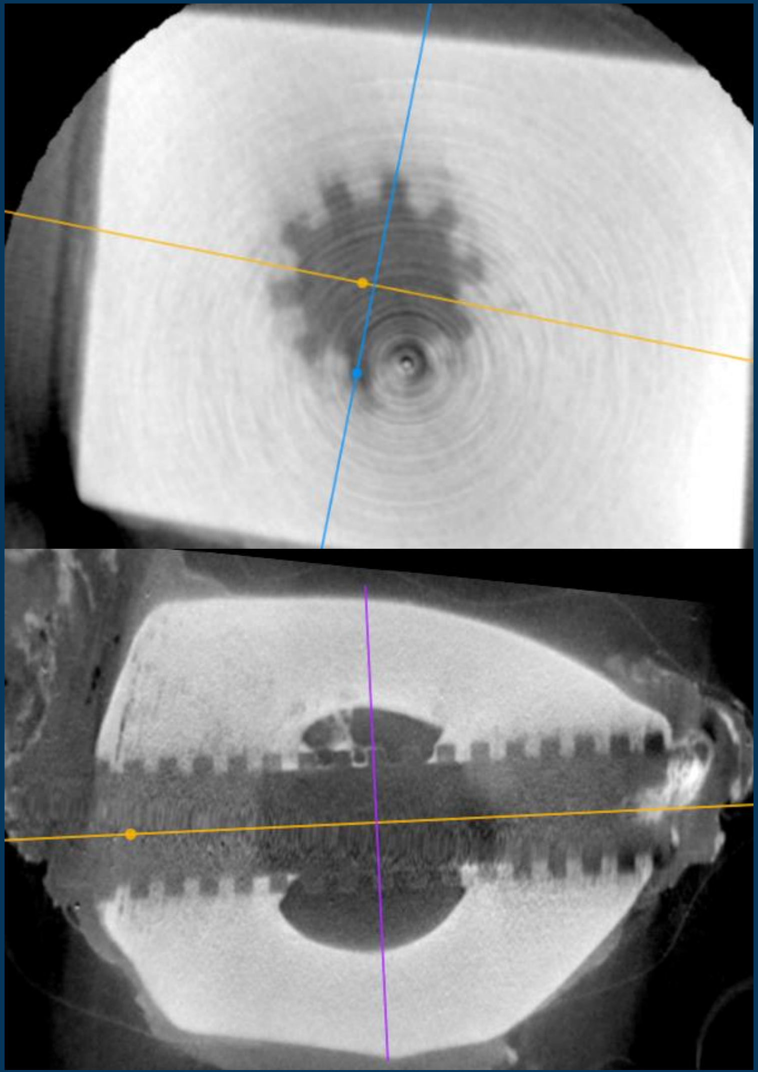




IN-VIVO PHASE III: MATERIAL COMPOSITION

2018 OVINE STUDY – W.R. WALSH PH.D. - UNSW

12 WEEK µCT PILLARED IMPLANT



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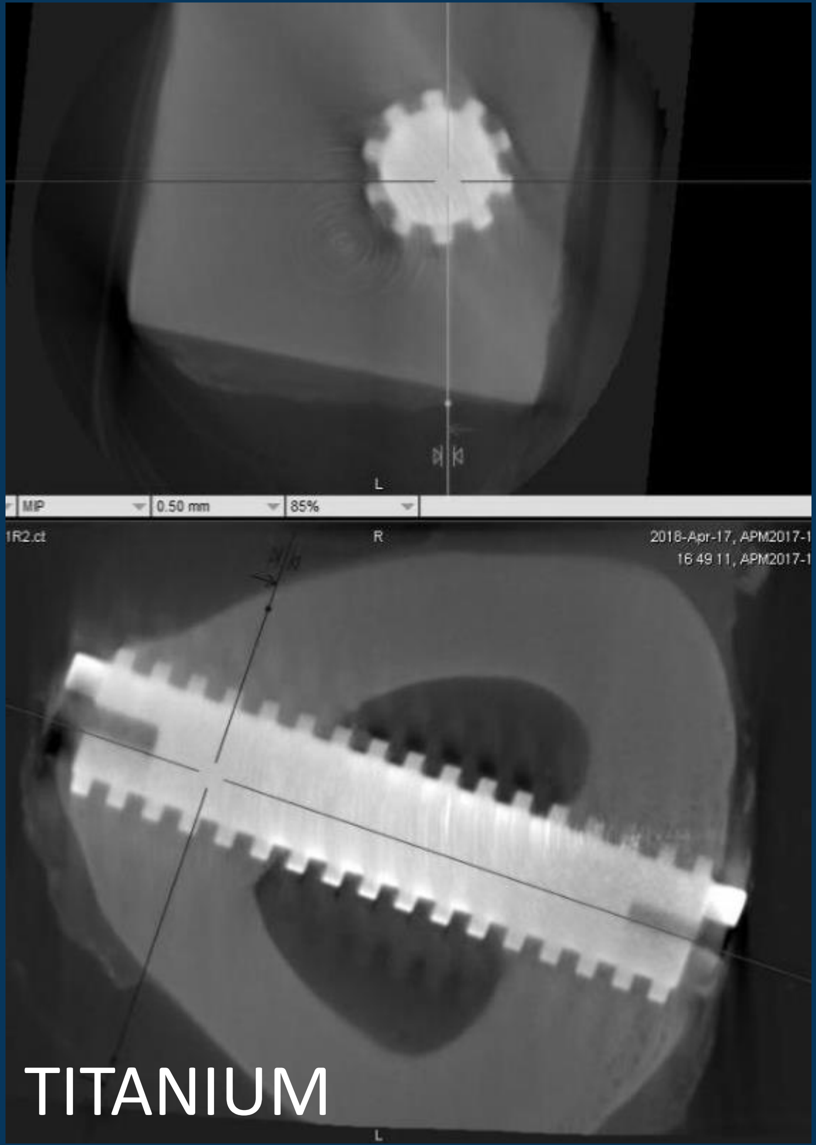
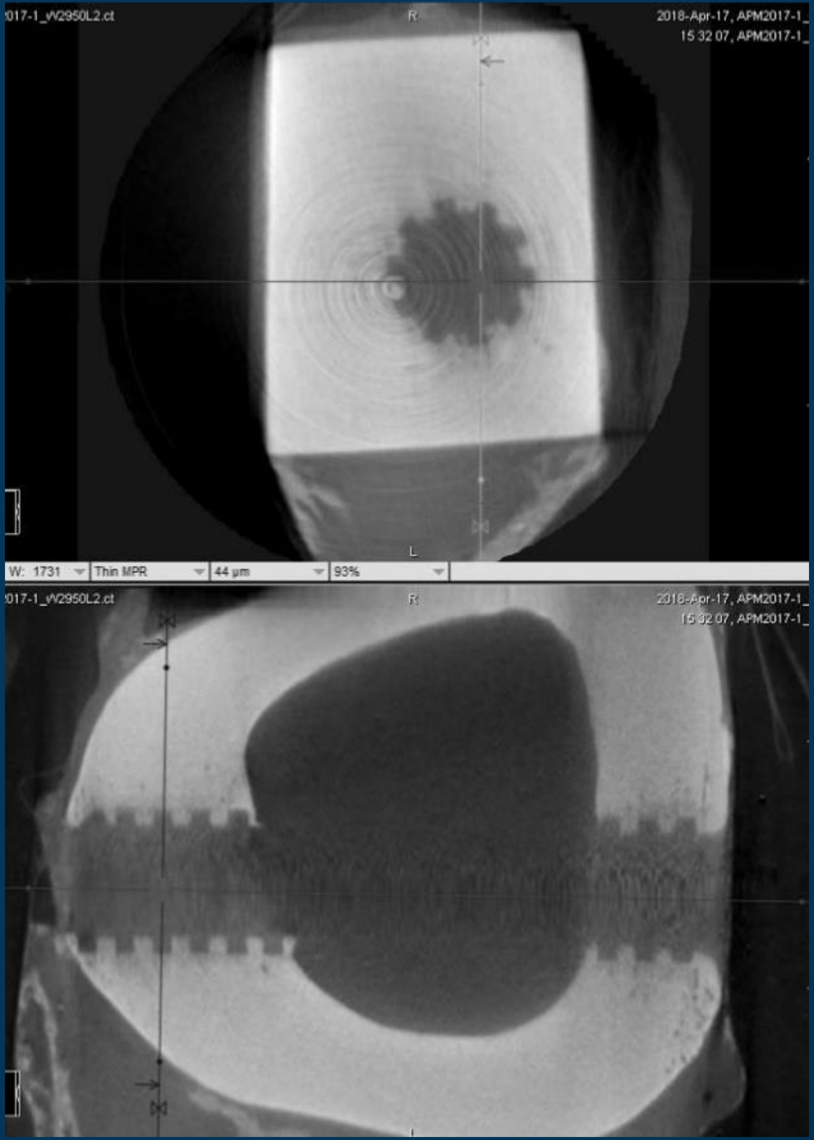


TITANIUM

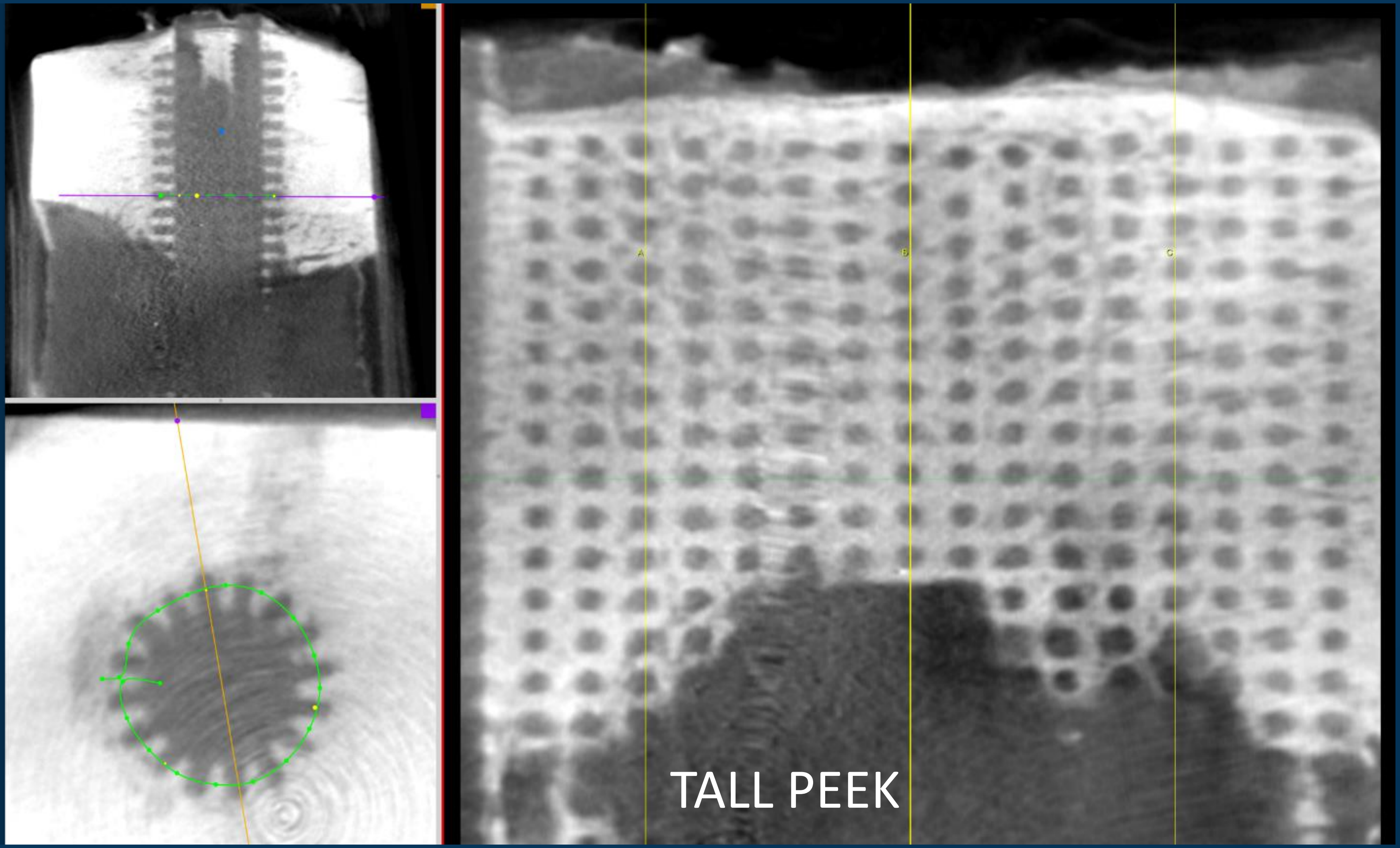


UHMWPE

IN-VIVO PHASE III: MATERIAL COMPOSITION

2018 OVINE STUDY – W.R. WALSH PH.D. - UNSW

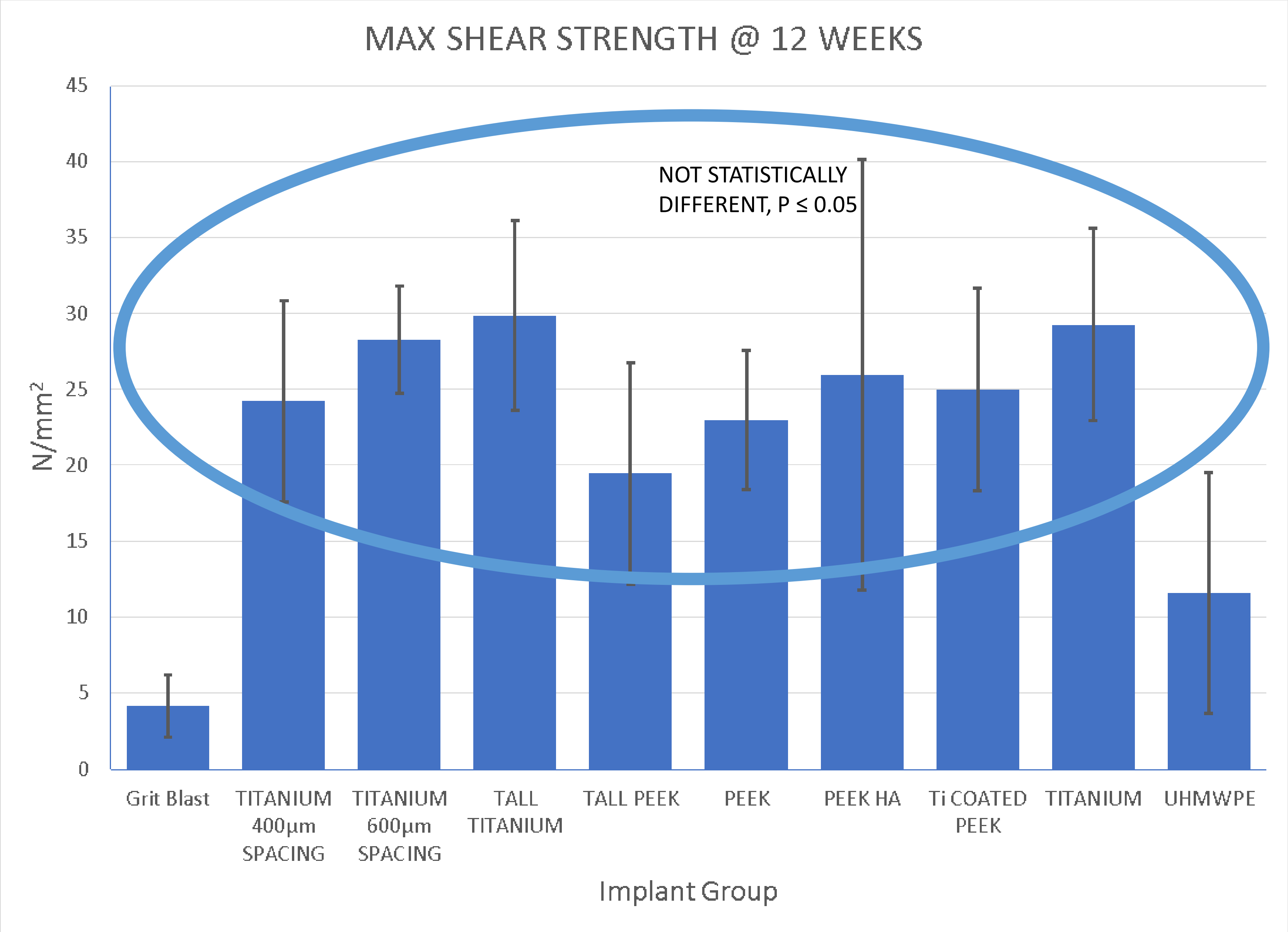
12 WEEK µCT: “UNWRAPPED” SLICE PLANE, TALL PEEK, 400µm SPACING



PUSHOUT TESTING: INTERFACE STRENGTH / STIFFNESS

NO DIFFERENCE IN PUSHOUT BETWEEN PEEK AND TITANIUM PILLARS

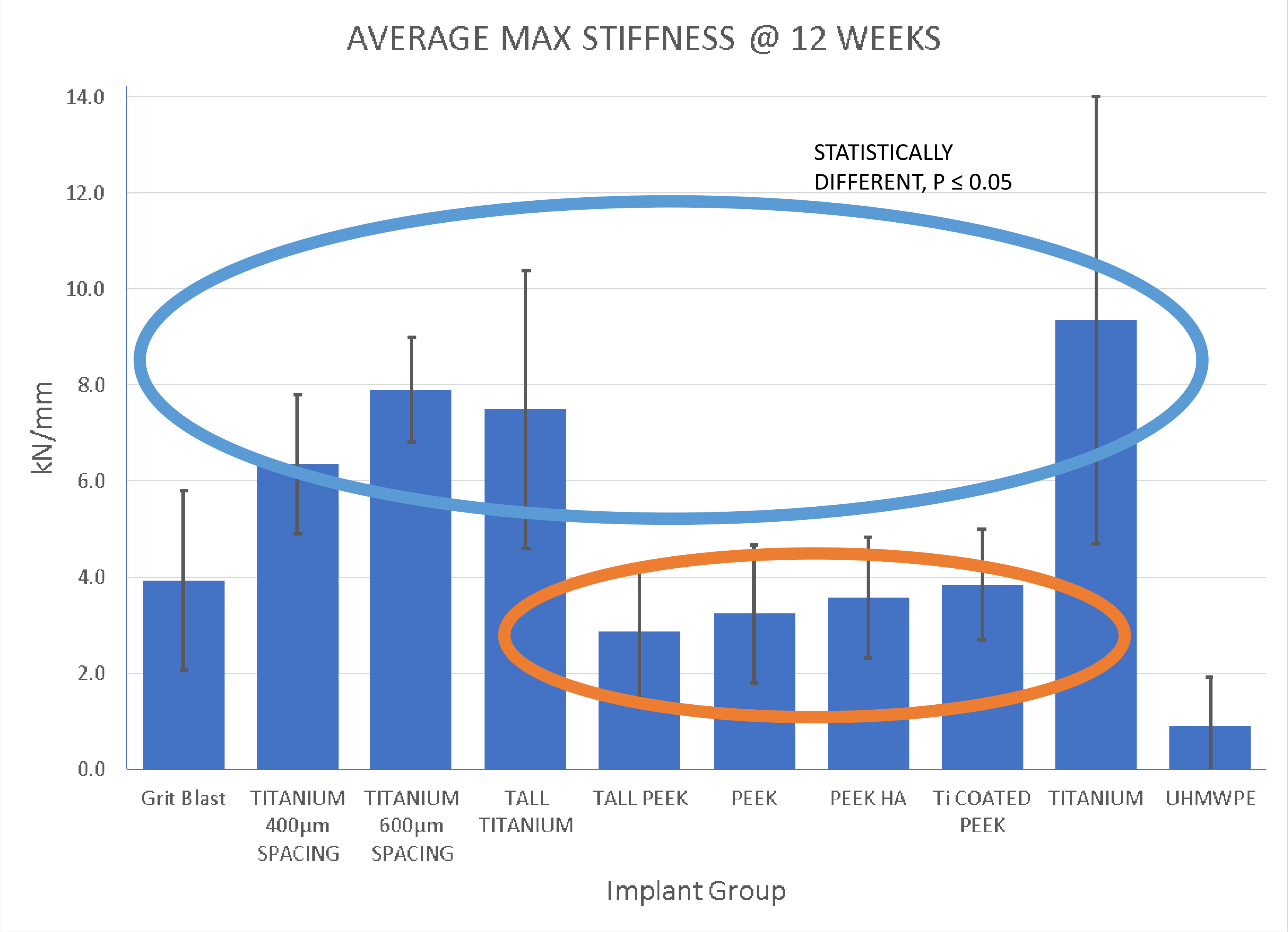
SMALL SAMPLE SIZE AND LARGE STANDARD DEVIATION



PUSHOUT TESTING: INTERFACE STRENGTH / STIFFNESS

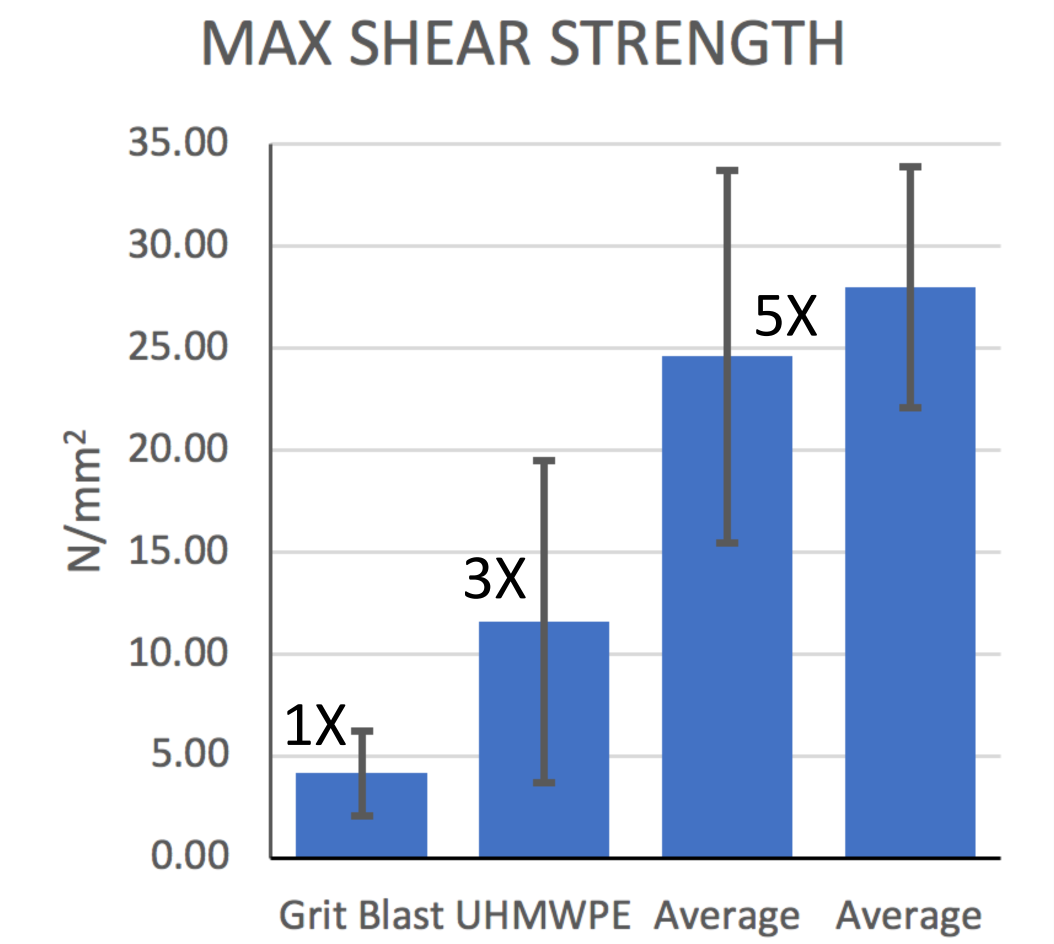
TITANIUM PILLAR INTERFACE IS STIFFER THAN PEEK PILLAR INTERFACE

SMALL SAMPLE SIZE AND LARGE STANDARD DEVIATION

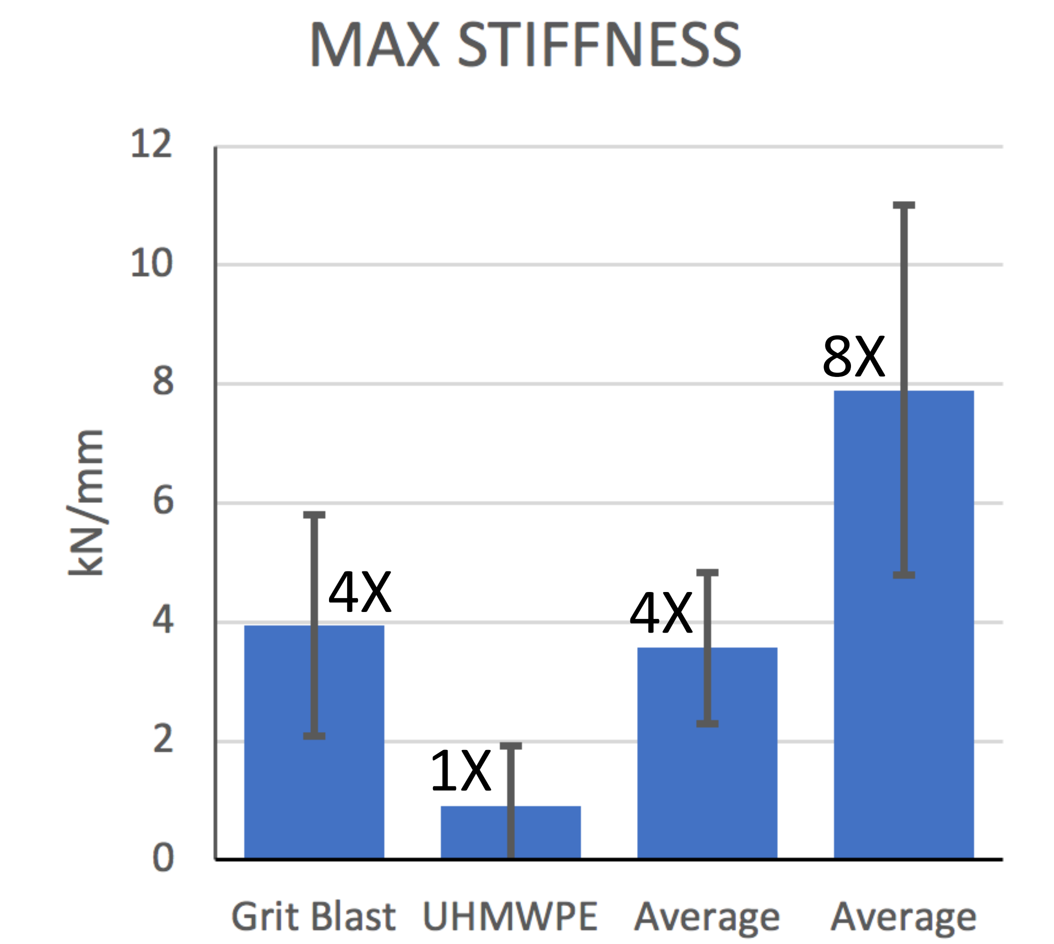


PUSHOUT TESTING: INTERFACE STRENGTH VS STIFFNESS

METAL ON-GROWTH SURFACE VS POLYMERS WITH PILLARED SURFACE GEOMETRY



* PEEK, PEEK HA, Ti COATED PEEK
** ALL TITANIUM IMPLANTS



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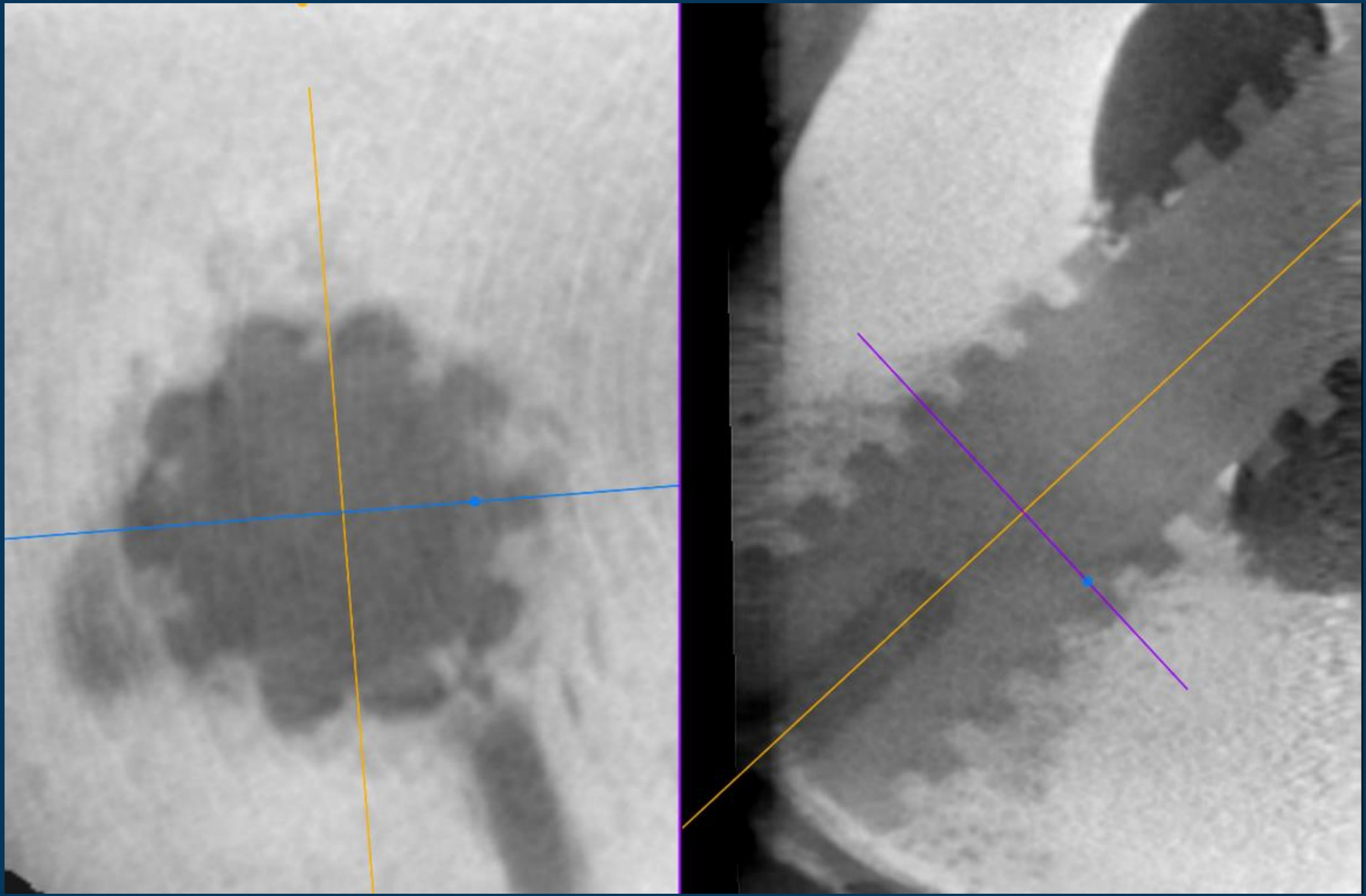
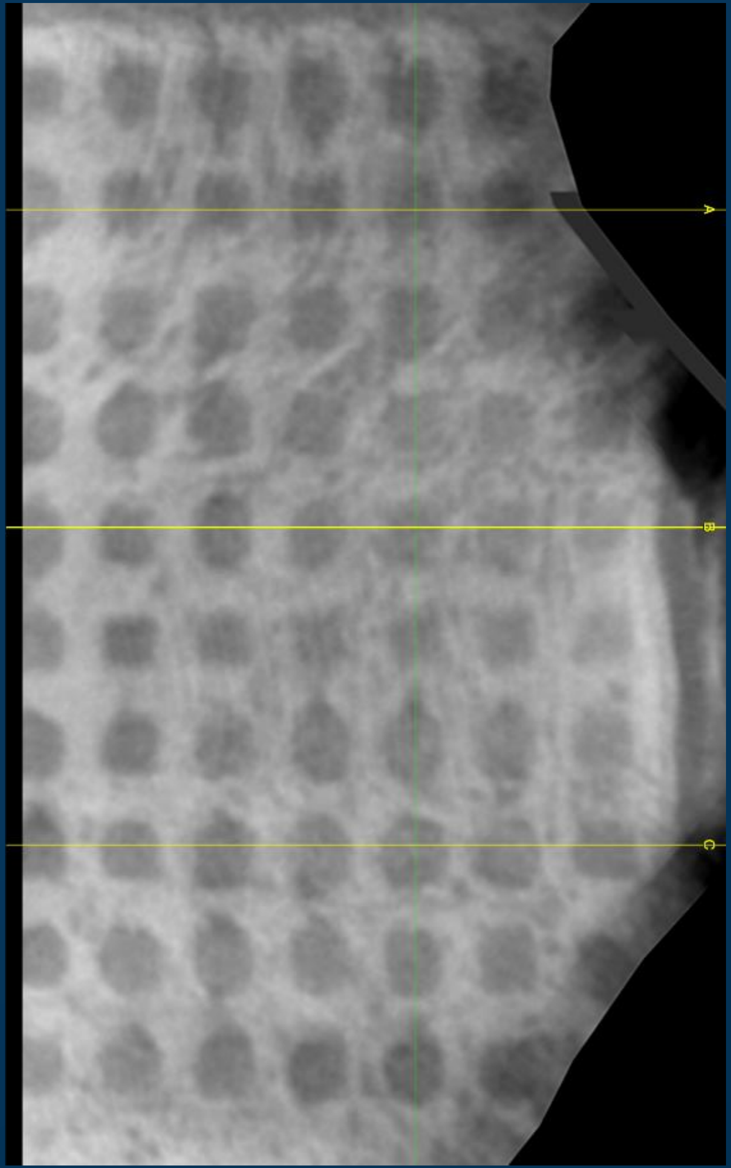
PUSHOUT TESTING: INTERFACE STRENGTH VS BULK MATERIAL PROPERTIES

PEEK HA
µCT DEMONSTRATED SOLID BONY IN-GROWTH AT 12 WEEKS

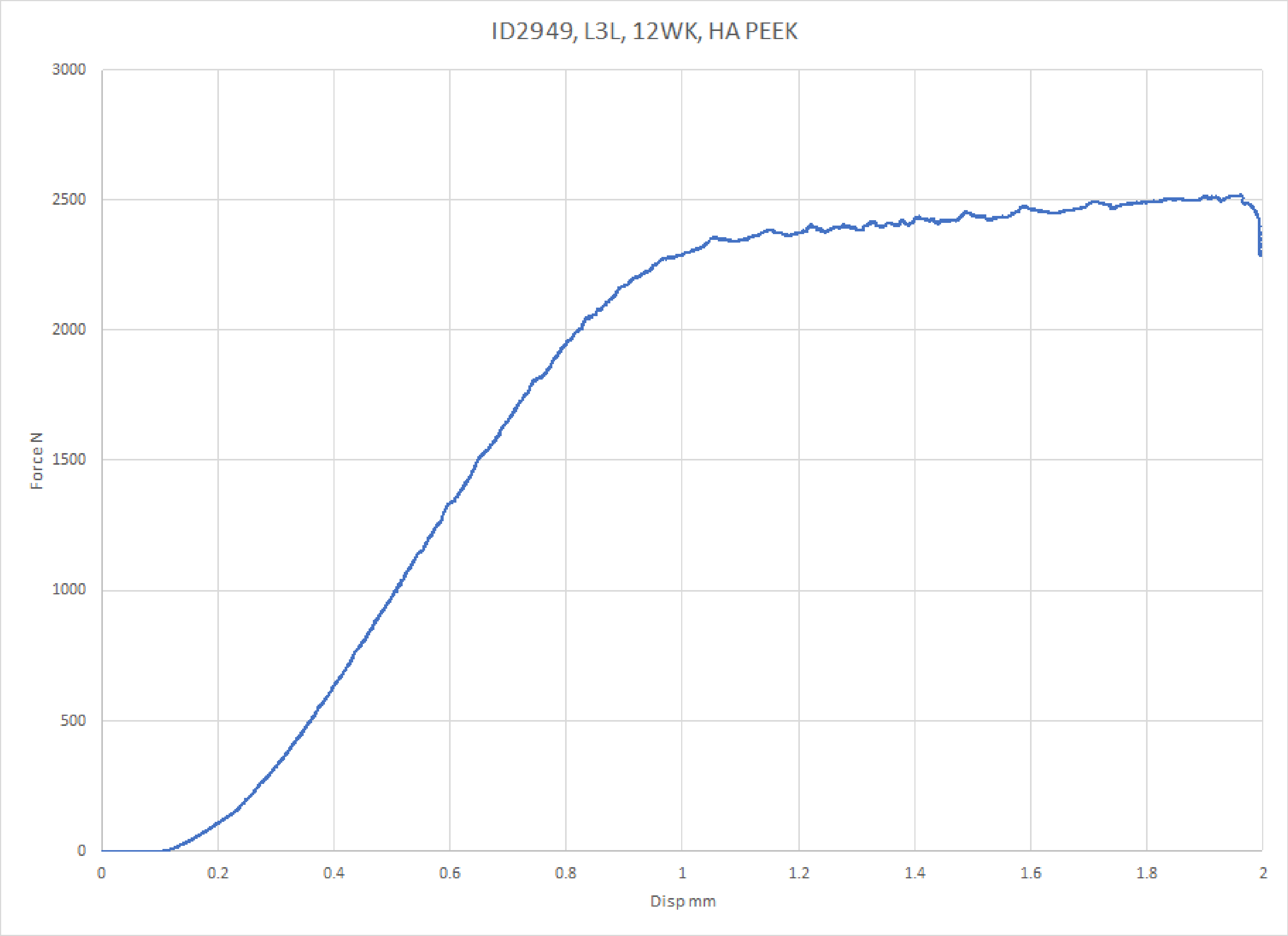




PUSHOUT TESTING: INTERFACE STRENGTH VS BULK MATERIAL PROPERTIES

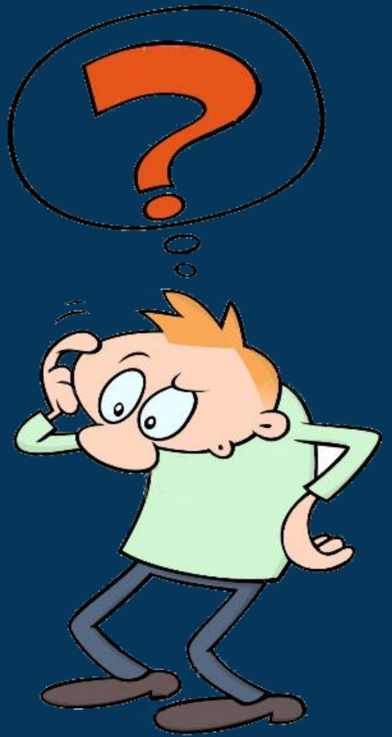
2500N OF FORCE AT 2mm DISPLACEMENT

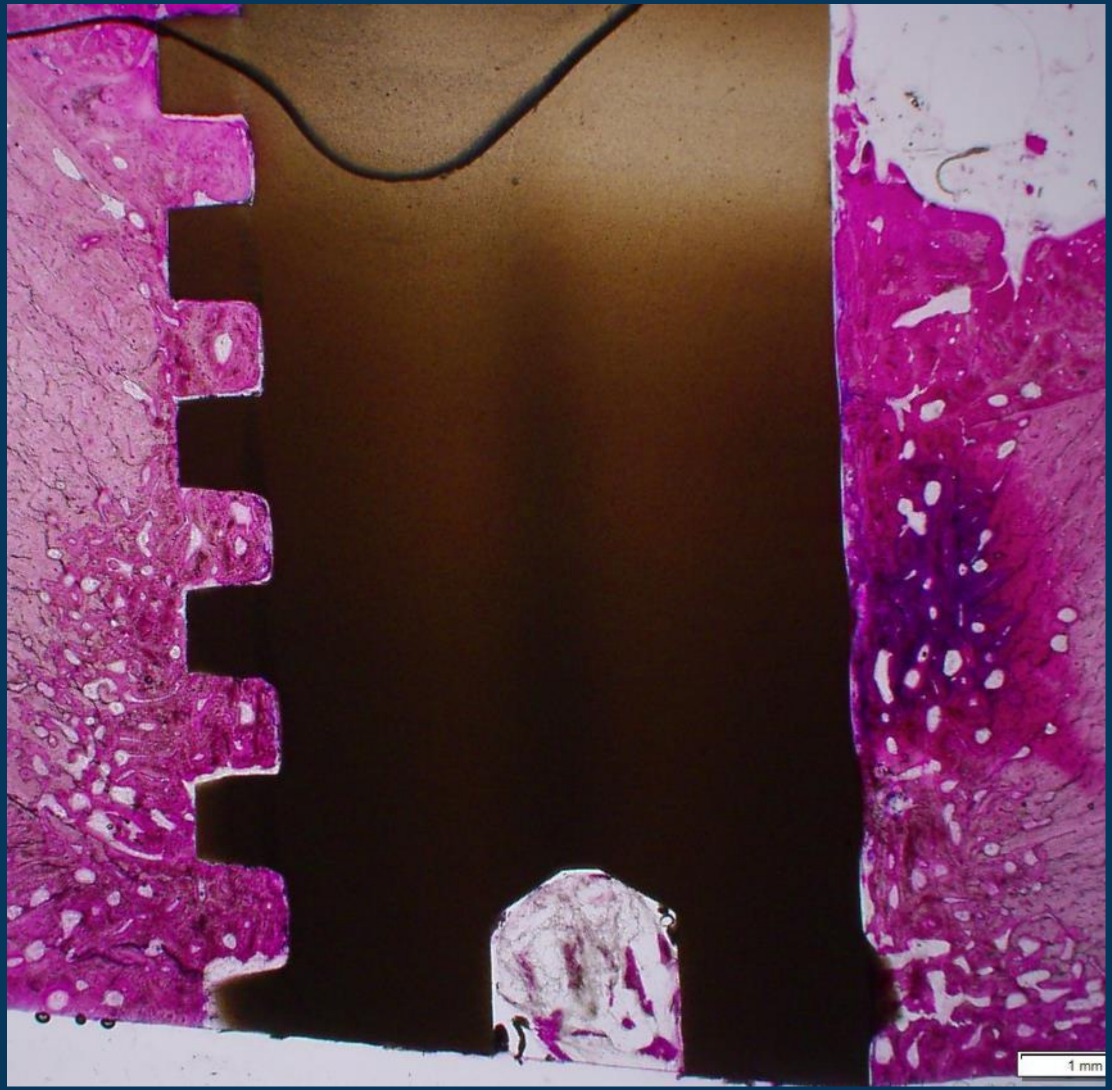
EXAMINE HISTOLOGY TO REVIEW FAILURE MODE AND DISPLACEMENT

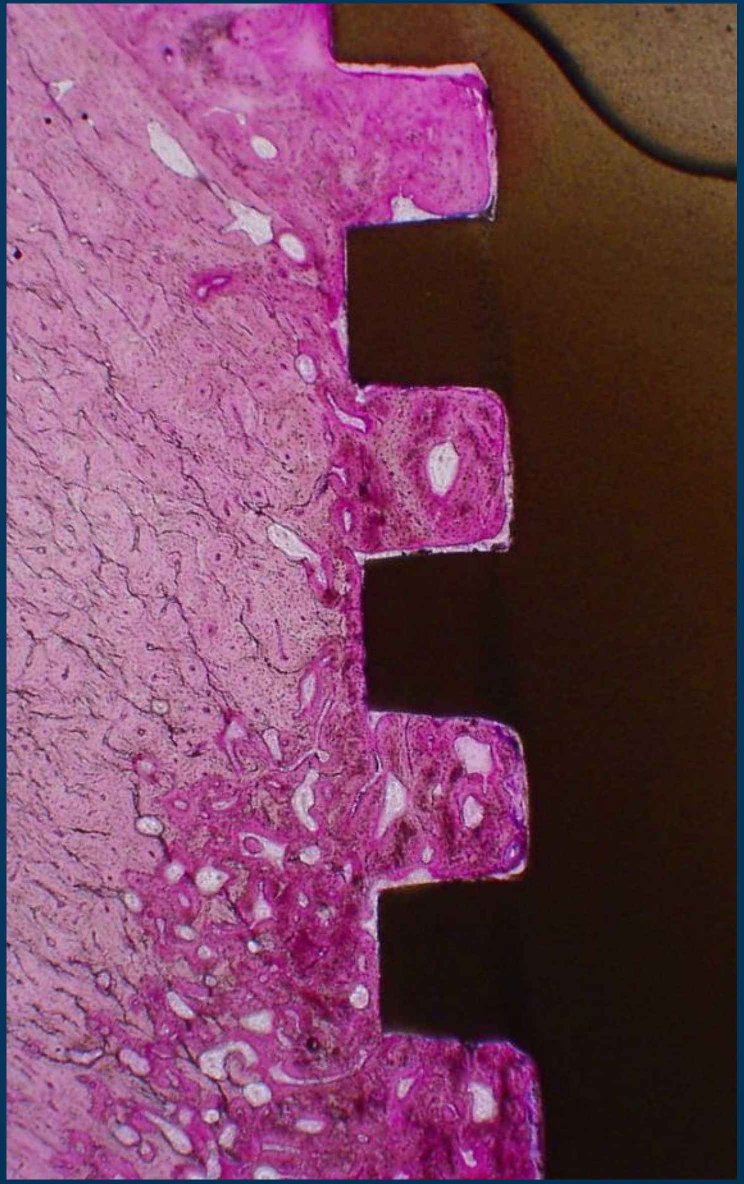


PUSHOUT TESTING: INTERFACE STRENGTH VS BULK MATERIAL PROPERTIES

HISTOLOGY SHOWED LITTLE TO NO DISPLACEMENT AT THE BONE / IMPLANT INTERFACE







PUSHOUT TESTING: INTERFACE STRENGTH VS BULK MATERIAL PROPERTIES

PRE AND POST TEST IMAGES

ULTIMATE STRENGTH OF INTERFACE WAS GREATER THAN THE STRENGTH OF THE BASE MATERIAL

PRE-TEST

POST-TEST

CONCLUSION/FUTURE WORK

CONCLUSIONS

- IN TITANIUM AND PEEK PILLARS
  - EQUIVALENT BONY IN-GROWTH
  - EQUIVALENT PUSHOUT STRENGTH
- PEEK PILLAR INTERFACE EXCEEDS STRENGTH OF PEEK MATERIAL
- DESIGNING THE INTERFACE STIFFNESS
- PILLAR MORPHOLOGY HAS LARGE VOID VOLUME: 75-85%
- PRIMARY FIXATION EVIDENCED BY BONE GROWTH
- NO INFLAMATION, LITTLE SOFT TISSUE

FUTURE WORK

- IDENTIFY CLINICAL APPLICATION: MOVE TO COMMERCIALIZATION
- IN-VIVO LOAD BEARING IMPLANT STUDIES
- BIOMECHANICAL STUDIES: INITIAL FIXATION AND DYNAMIC RESPONSE
- EXPLORE STRENGTH VS STIFFNESS NEEDS OF DIFFERENT CLINICAL APPLICATIONS