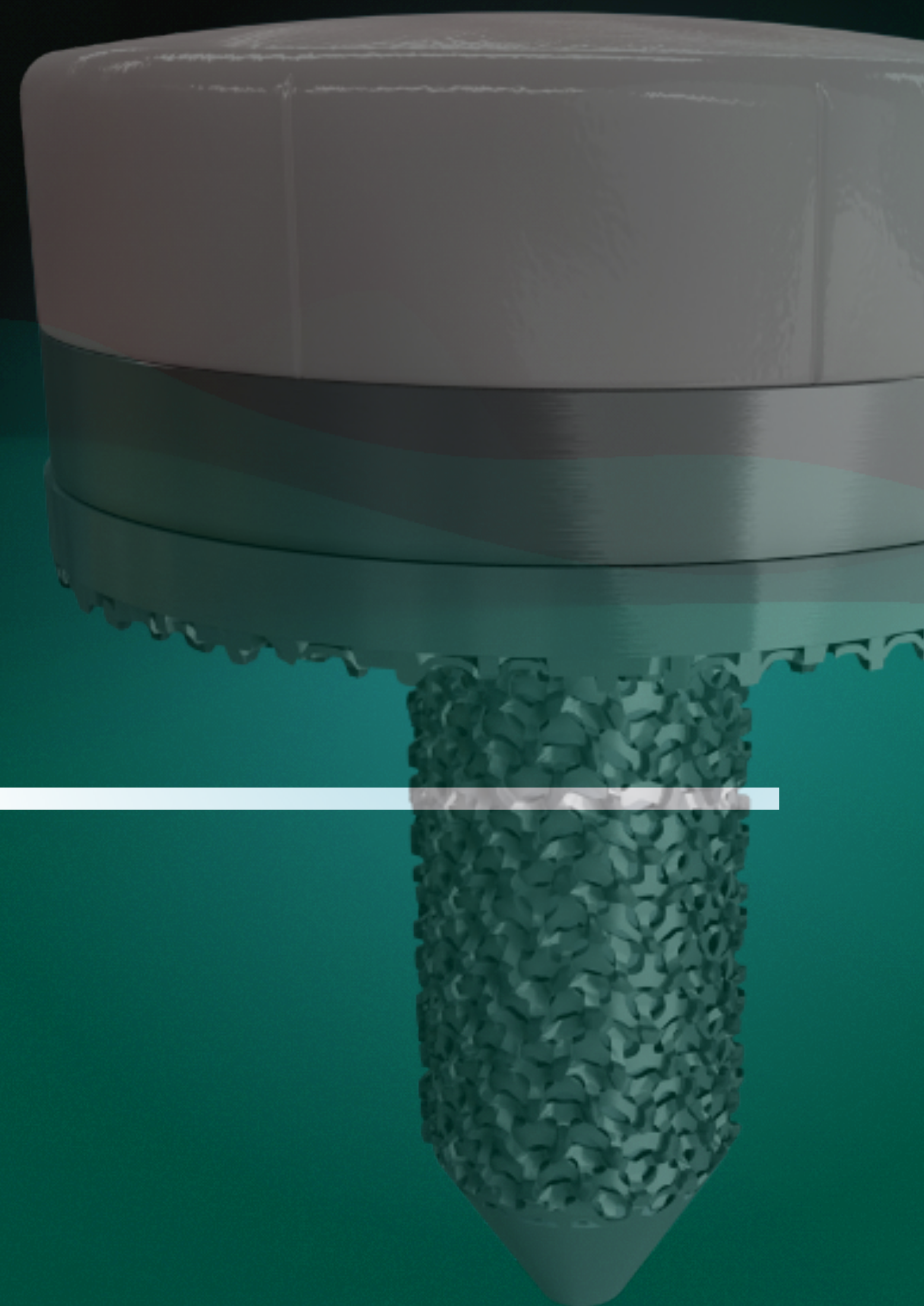




MIDWEST
ORTHOPAEDICS
AT RUSH

Evaluation of Functionality and Biocompatibility of a Novel ORMI-CFC Implant in a Sheep Knee Model: A 13-, 26- Week Study

Andrew Phillips BA¹, Erik Haneberg BS¹, Richard Danilkowicz MD¹,
Tristan Elias MD¹, Jeremiah Easley DVM², Holly Stewart VMD PhD², Ben
Gadomski PhD², James Johnson PhD², Adam Yanke MD PhD¹
Rush University Medical Center¹, Colorado State University²



Disclosures



Andrew Phillips BA, Erik Haneberg BS, Richard Danilkowicz MD, Tristan Elias MD, Jeremiah Easley DVM, Holly Stewart VMD PhD, Ben Gadomski PhD, James Johnson PhD have nothing to disclose.

Adam Yanke MD PhD has the following to disclose: AlloSource: Paid consultant, Arthrex, Inc: Research support, Icarus Medical: Stock or stock Options, JRF Ortho: Paid consultant, Organogenesis: Research support, Patient IQ: Unpaid consultant, PatientIQ: Stock or stock Options, Sparta Biomedical: Stock or stock Options; Unpaid consultant, Stryker: Paid consultant; Paid presenter or speaker

Background: Osteoarthritis



650,000,000 suffering¹

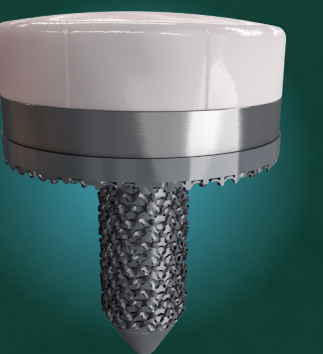
\$27,000,000,000 in cost²

1,900,000 yrs lost productivity³

1. EClinicalMedicine. 2020 Nov 26;29-30:100587. doi: 10.1016/j.eclinm.2020.100587. PMID: 34505846; PMCID: PMC7704420.

2. Arthritis Foundation. Arthritis by the Numbers. In: Atlanta, GA: Arthritis Foundation; 2019: <https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march-2019.pdf>. Accessed May 13, 2022.
<https://onlinelibrary.wiley.com/doi/full/10.1002/acr.24886>

3. Cui A, Li H, Wang D, Zhong J, Chen Y, Lu H. Global, regional prevalence, incidence and risk factors of knee osteoarthritis in population-based studies.



Background: Osteoarthritis



Biologic Treatments

Palliate

Debridement

Repair

Micro-fracture

Regenerate

MACI

Reconstruct

OCA

Does not regenerate hyaline cartilage

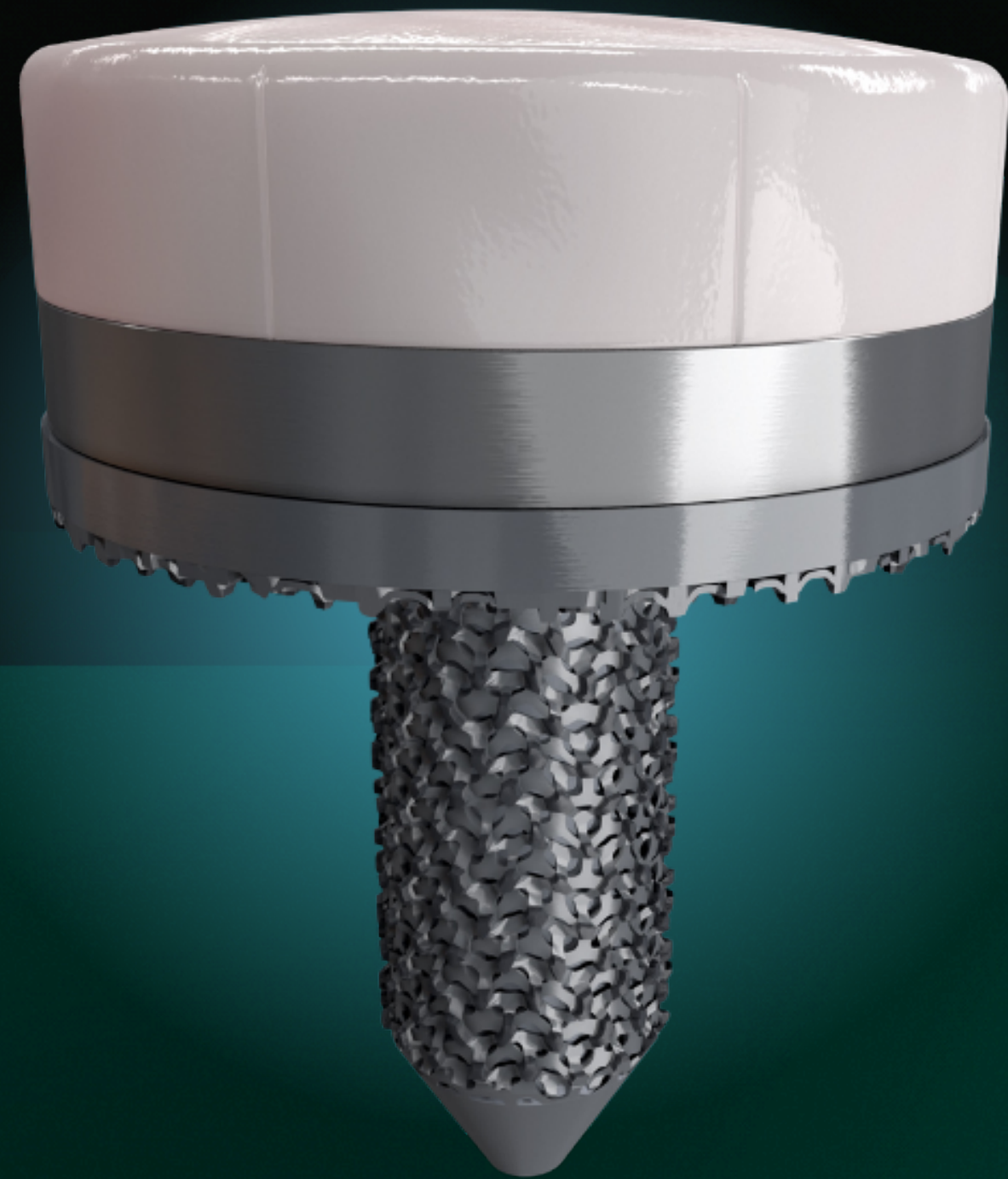
Integration Failure

Time to success up to 12 months

\$30,000 - \$40,000

\$10,000
Donor Availability

The Ormi-Circular Femoral Condyle (CFC) Implant

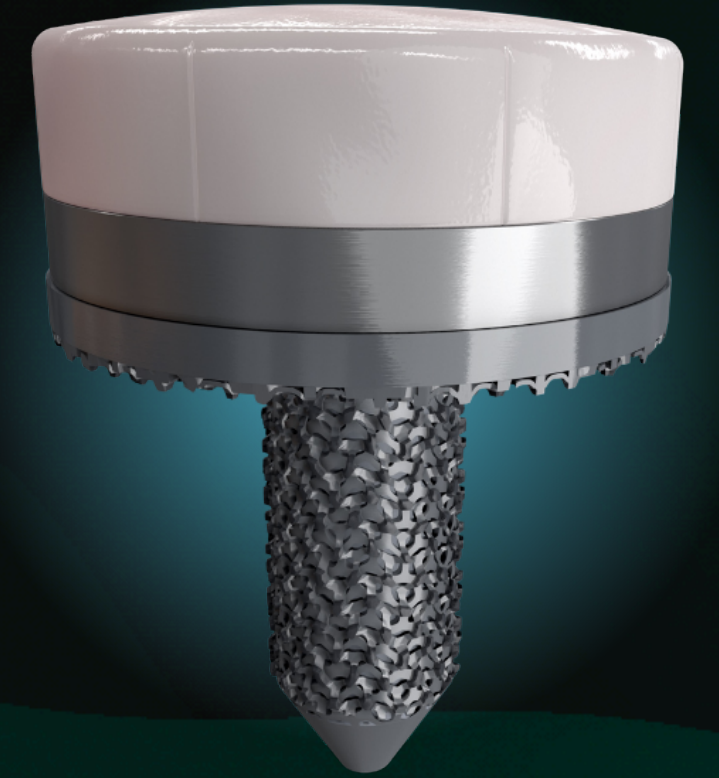


Proprietary bionic cartilage
Galene + Titanium base

Unlike cartilage regeneration technologies which *take many months*, if not years, to regrow strong cartilage, **Galene** is a bionic cartilage that meets and exceeds the properties of hyaline cartilage *day 1*.



Objectives



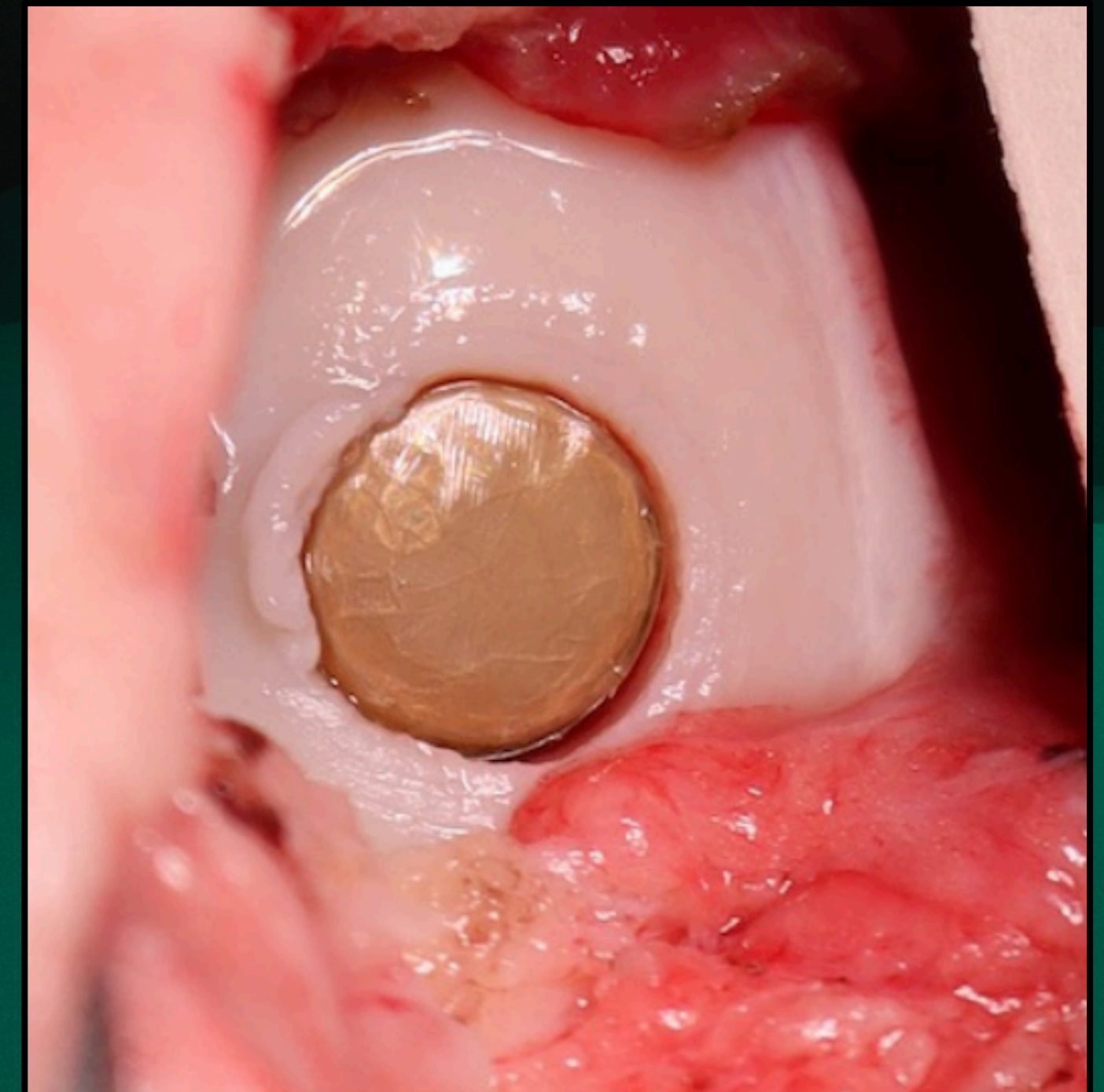
To evaluate the **safety** and **efficacy** of a novel implant device, the **Ormi-Circular Femoral Condyle (CFC)**, a non-degradable hydrogel designed to replicate articular cartilage in the knee with a titanium base to integrate with bone

Methods



12 healthy adult sheep were implanted with the Ormi-CFC on the **medial femoral condyle** of the **right hind leg**

6 sheep were sacrificed at **13 weeks**
6 sheep were sacrificed at **26 weeks**



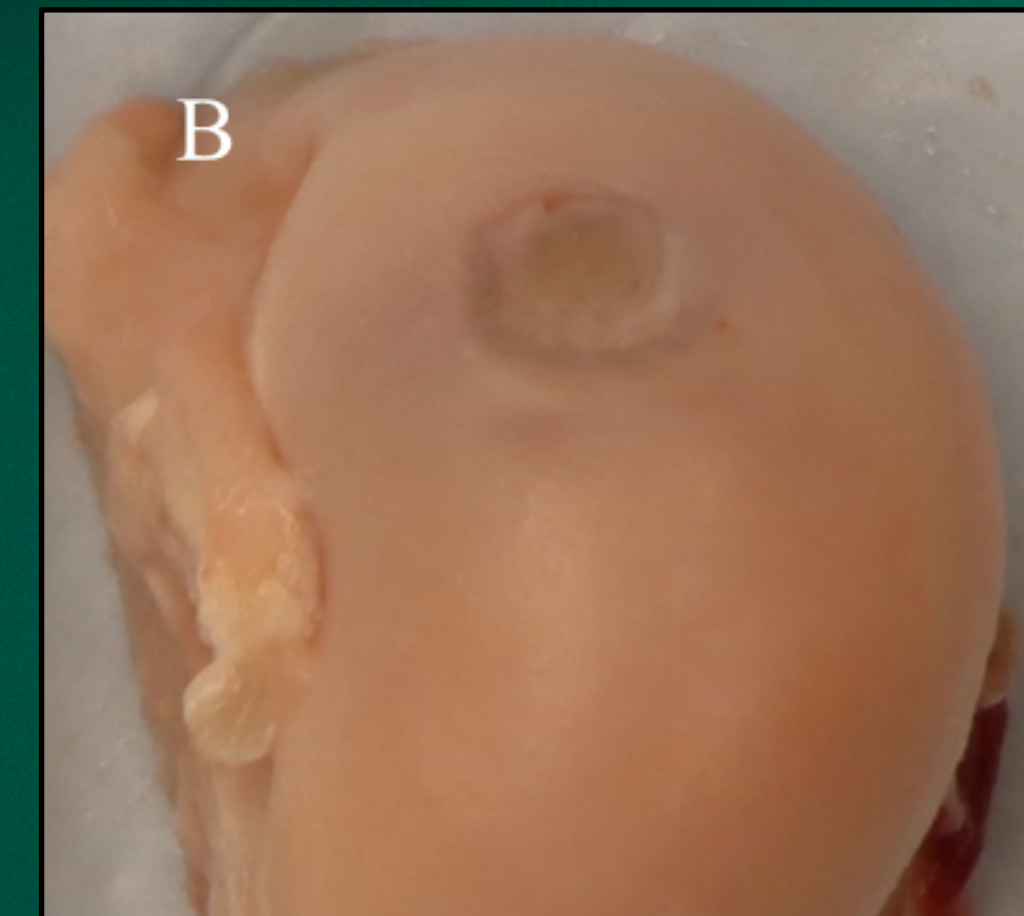
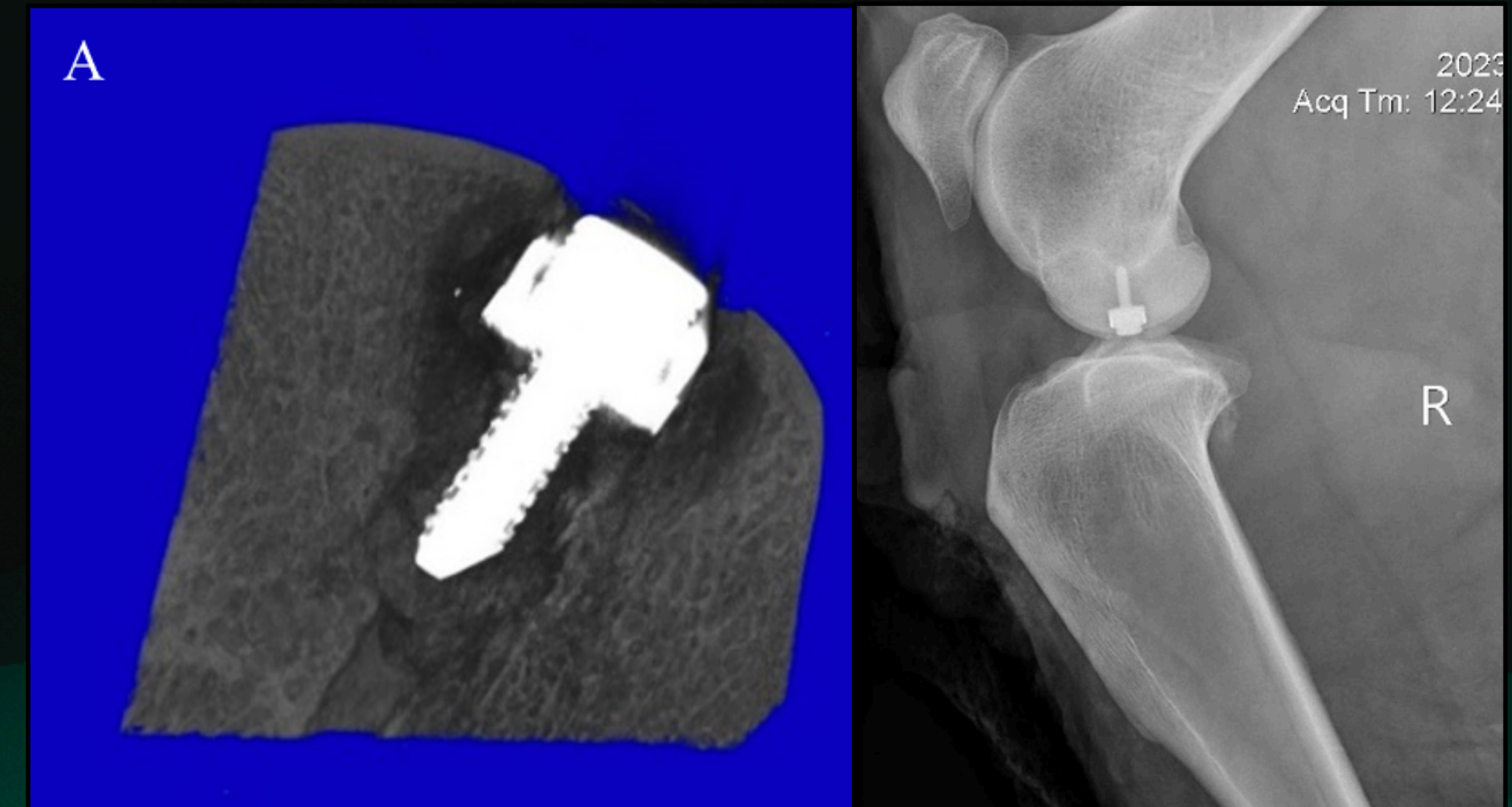
Methods



MicroCT, radiograph (a) and gross necropsy (b) was completed after sacrifice

Cartilage surfaces surrounding the implant site and contralateral leg (control) were graded with Outerbridge classification

Opposing surface wear was determined by ipsilateral tibial cartilage damage



Results

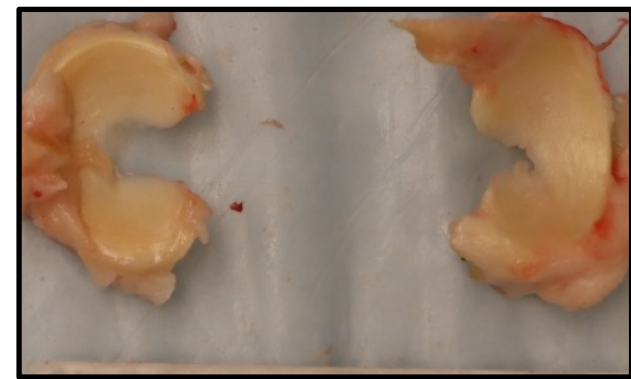
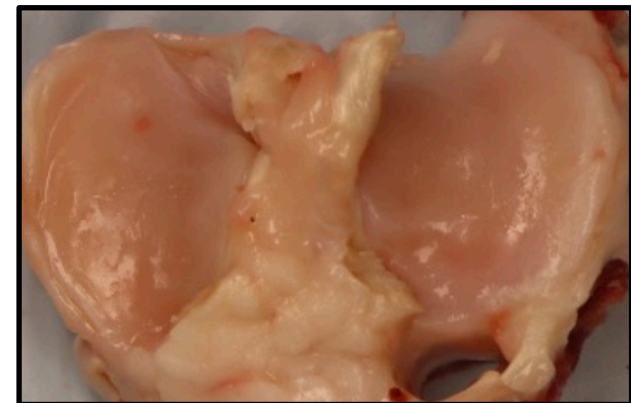


Gait lameness was not present for any sheep at the time of sacrifice

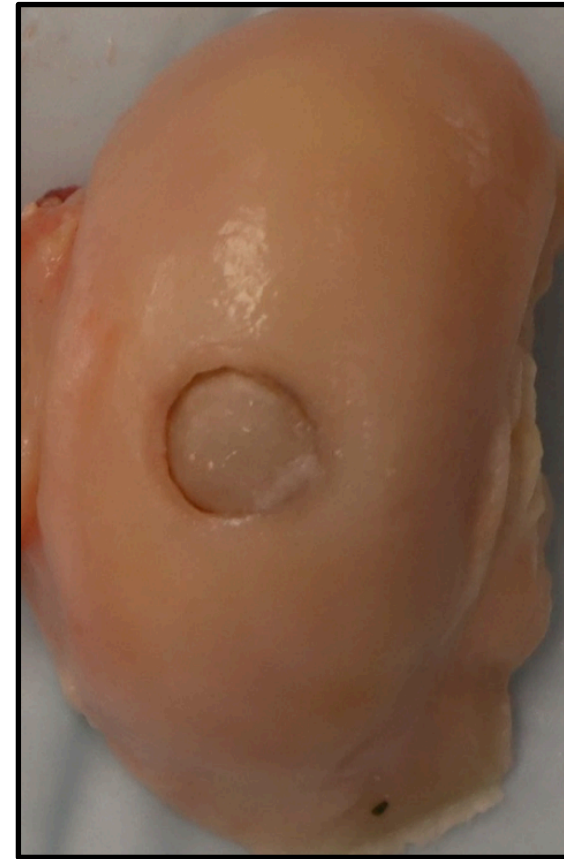
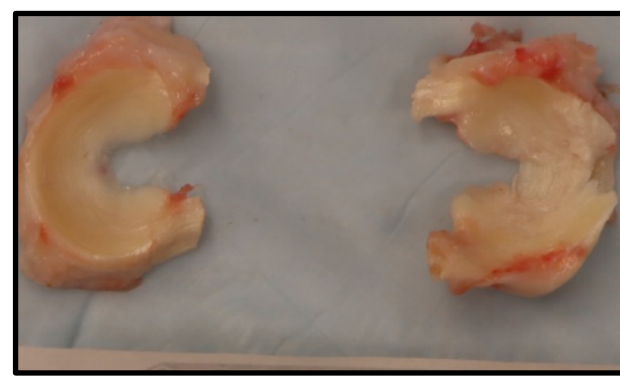
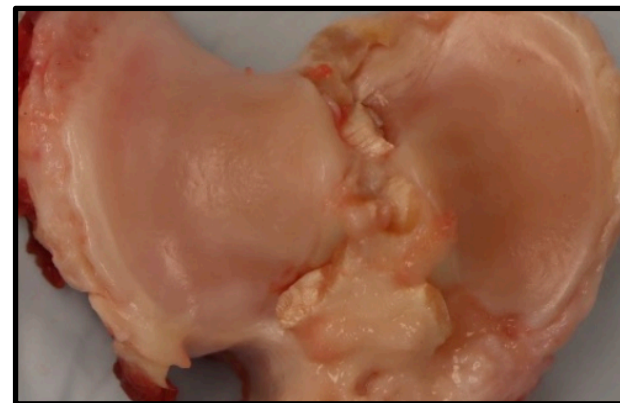
Gross Necropsy

13- week

Control

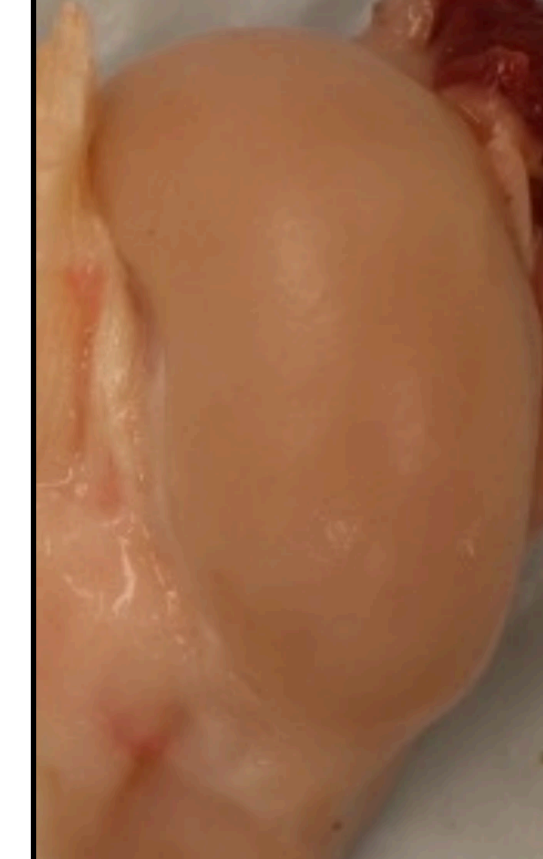
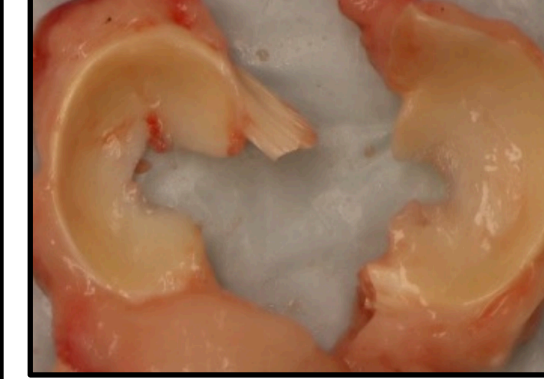
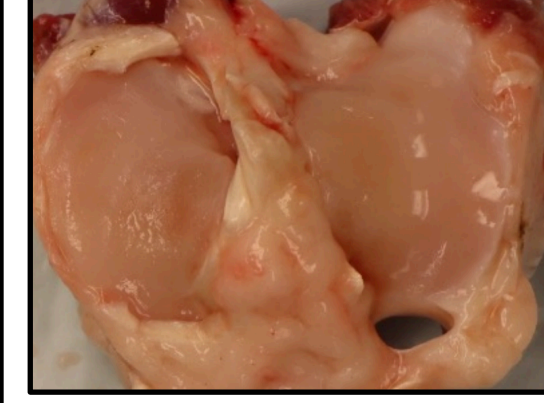


Treatment

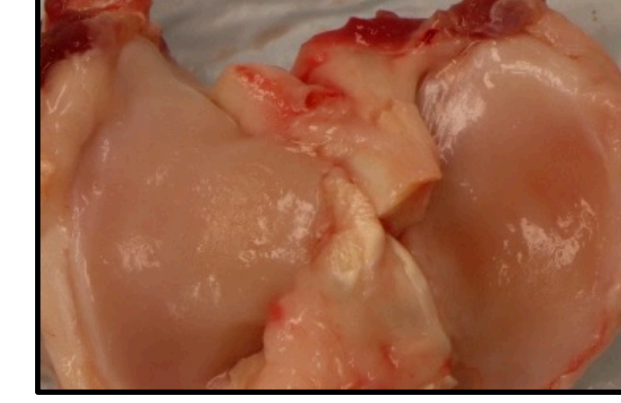


26- week

Control



Treatment



Results



Average Outerbridge classification grade

13- Week		26- Week	
Treatment	Control	Treatment	Control
1.5	1.0	0.17	0.83
p=0.20		p=0.11	

Opposing Surface Wear

Treatment		Control	
Mild	Moderate	Mild	Moderate
66.7%	16.7%	66.7%	33.3%

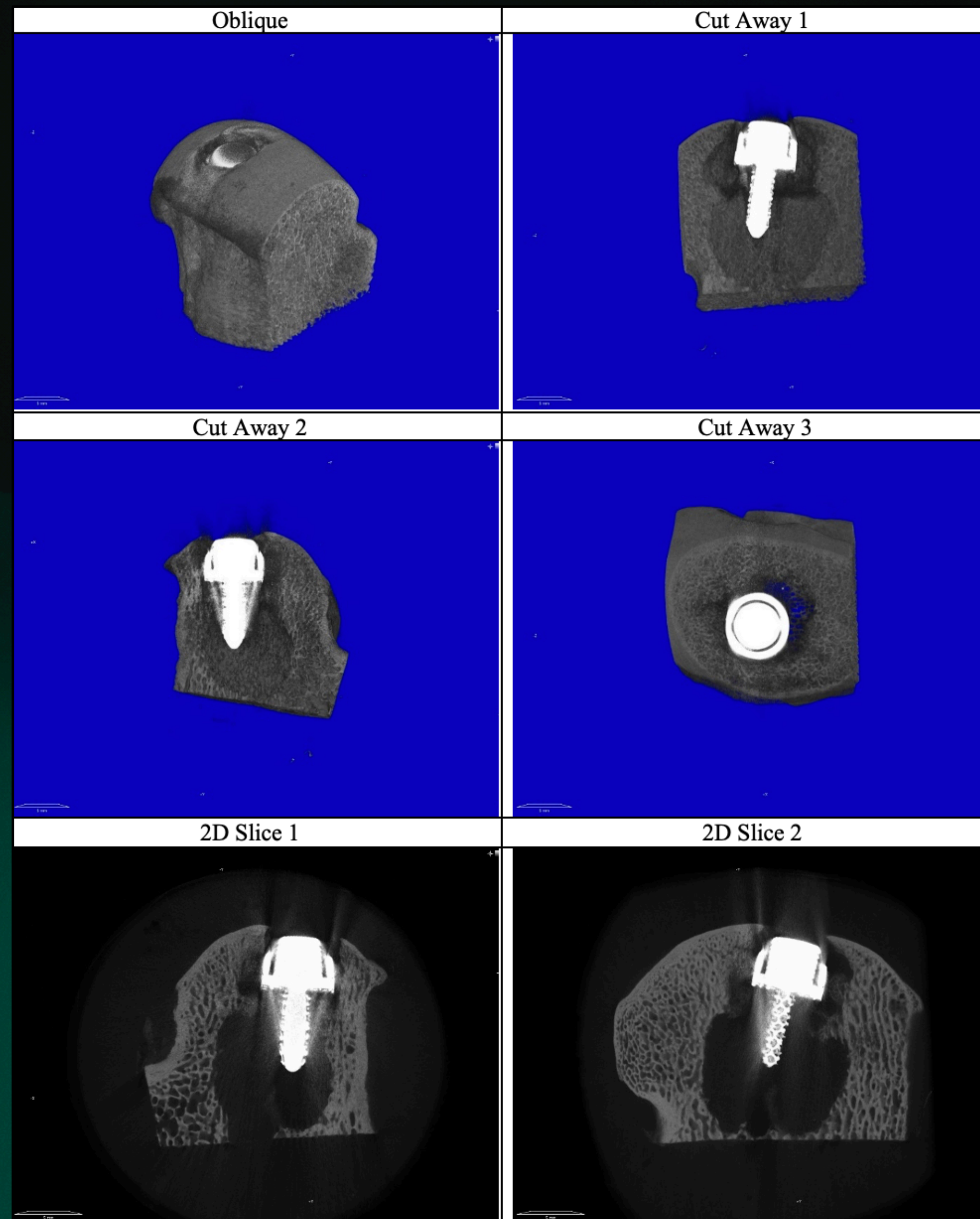
Results

Micro CT/Radiograph

No cases of:

Implant backing/
bearing failure

Subchondral sclerosis



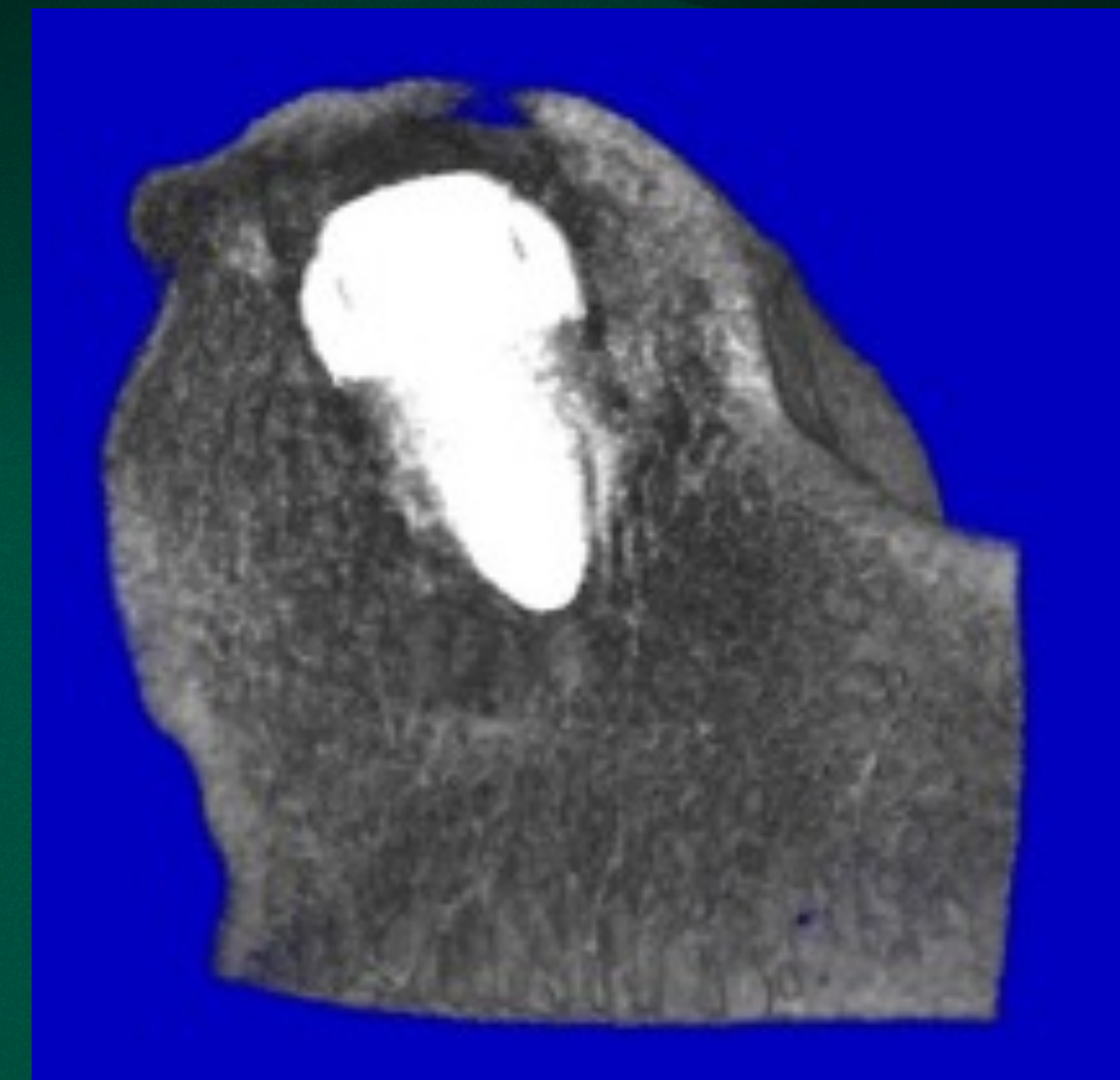
Results



Implant Subsidence

13 weeks: no sheep experienced subsidence
26 weeks: 2 sheep experienced slight
subsidence of 1-2 mm (right)

Overall % with subsidence: 16.7%
Average subsidence (when present): 1.6 mm



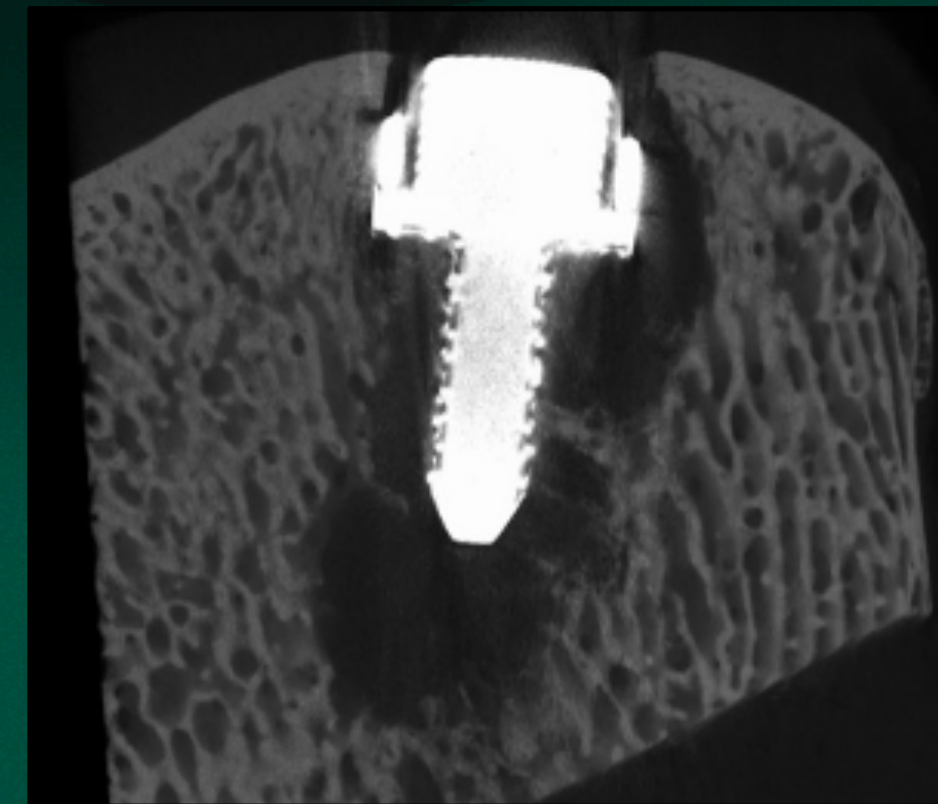
Results



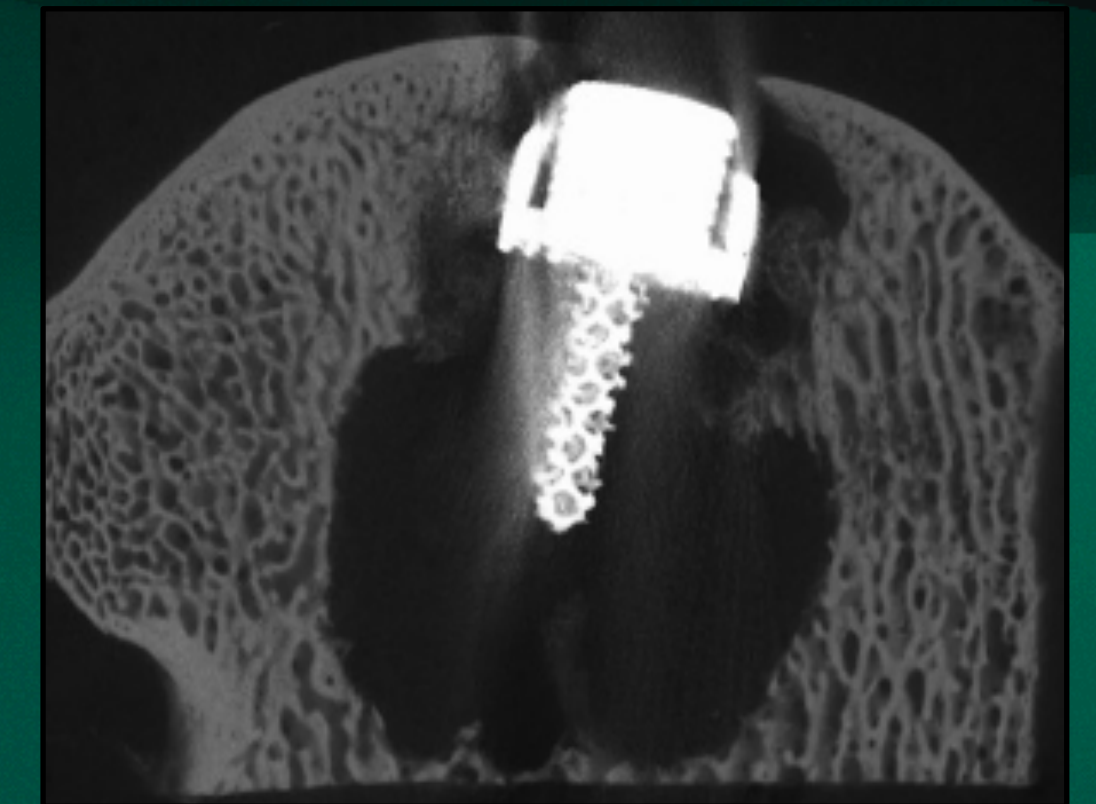
Bone Resorption (cyst formation)

Micro CT

13- Week		26- Week	
Mild	Moderate	Mild	Moderate
50.0%	66.6%	16.7%	66.6%



Mild



Moderate

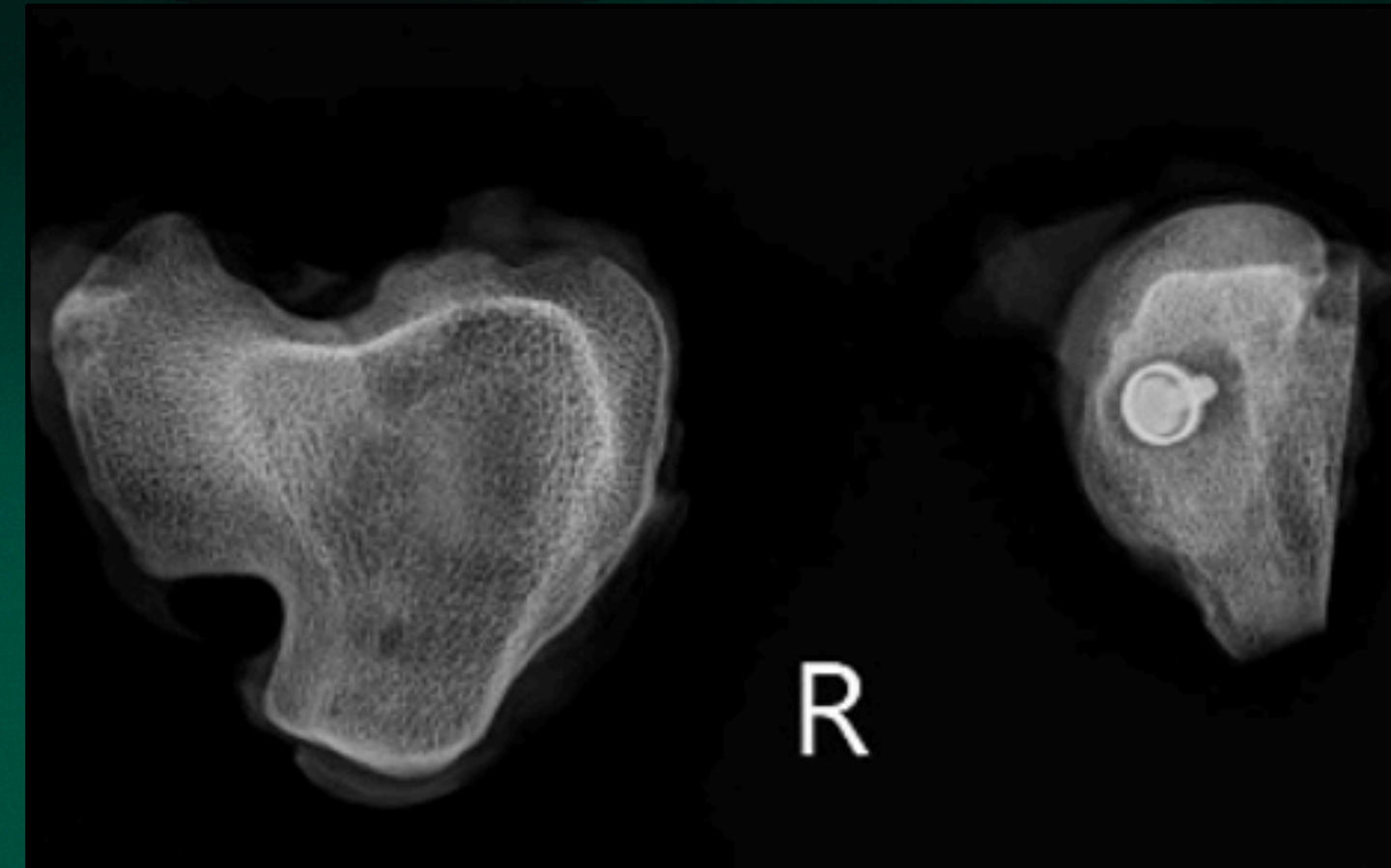
Results



Bone Resorption (cyst formation)

Radiograph

13- Week		26- Week	
Absent	Present	Absent	Present
83.3%	16.7%	66.7%	33.3%



Conclusions



The Ormi-CFC was safely implanted in 12 adult sheep

No differences seen in wear of surrounding cartilage or opposing surface wear

Micro CT analysis revealed no cases of implant failure, subchondral sclerosis, low rates of implant subsidence, but did reveal moderate bone resorption

Significance of Findings



The Ormi-CFC may serve as an alternative to current treatments of cartilage defects

Further studies must provide insight into the **effectiveness** of **Ormi-CFC** in humans as a substitute for damaged femoral cartilage



MIDWEST
ORTHOPAEDICS
AT RUSH

Evaluation of Functionality and Biocompatibility of a Novel ORMI-CFC Implant in a Sheep Knee Model: A 13-, 26- Week Study

Andrew Phillips BA¹, Erik Haneberg BS¹, Richard Danilkowicz MD¹,
Tristan Elias MD¹, Jeremiah Easley DVM², Holly Stewart VMD PhD², Ben
Gadomski PhD², James Johnson PhD², Adam Yanke MD PhD¹
Rush University Medical Center¹, Colorado State University²

   @AdamYankeMD

 www.YankeMD.com

