Metallic Wear Debris Isolation and Characterization:
A Postmortem TKA Study

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Introduction

- Biological reactions are associated with metal concentration which can be quantified with ICP-MS.
- Biological reactions are also dependent on particle characteristics.

Objectives

✓ Isolate metallic wear debris from cadaver TKAs using a method previously validated in animal models [1].

✓ Determine the correlation between visual scoring of tissue metallosis and isolated metallic debris.

✓ Assessed particle characteristics [2] to determine whether particles varied by patient or tissue collection location.

Methods

Device Manufacture	Device Design	Tibial Tray Material	Femoral Component Material	Cause of Death	Age of Death	Surgical Site	Gender	Estimated Implantation Time
Zimmer	Nexgen LPS	Ti Alloy	CoCr	Cancer	79	R	M	21
Depuy	LCS Mobile Bearing	CoCr	CoCr	Heart Failure	66	L	F	NA
Zimmer	Miller-Galante II	Ti Alloy	Ti Alloy	Heart Failure	65	L	M	45

Table 1: Device and patient information

Tissues digestion followed a previously-published enzymatic protocol [1] using papain and proteinase K followed by density gradient ultracentrifugation with sodium polytungstate, figure 1. Tissues were given a visual score from 1 to 5, figure 2.

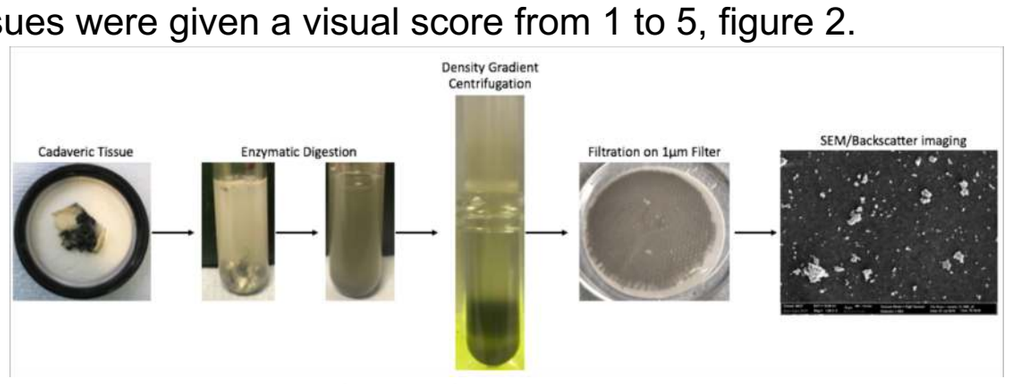


Figure 1: Outline of particle isolation protocol

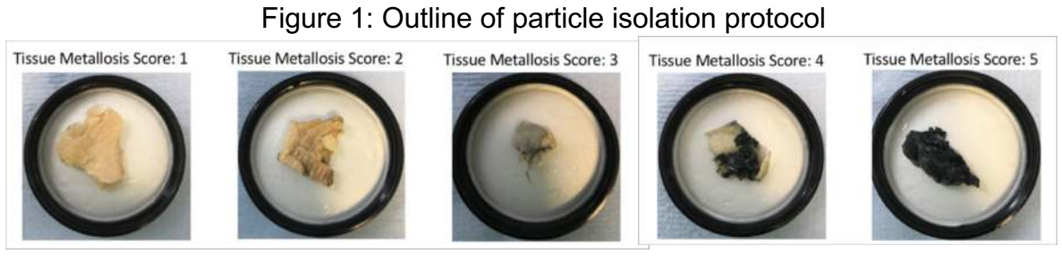
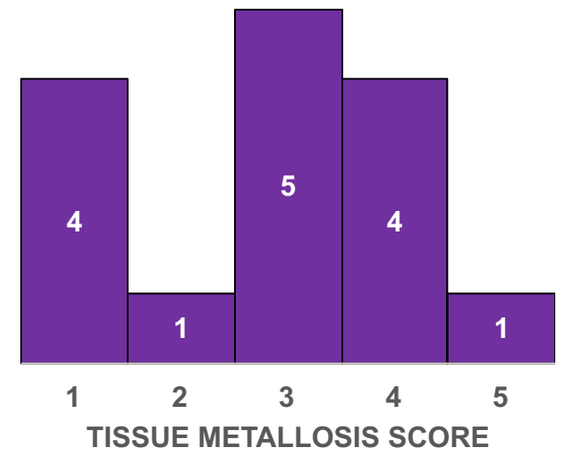


Figure 2: Description of tissue metallosis score

Sample filtration occurred using polycarbonate membranes with two pore sizes (1μm and 0.015μm). Scanning electron microscopy (SEM) images and energy dispersive X-Ray spectroscopy (EDS) was used characterize metallic debris. SEM images (N=33) were taken from the 1 μm filter of each patient at the medial gutter, lateral gutter, and inferior patella. Images were taken at 1,000x magnification and 10kV. Image processing software (ImageJ, Maryland, USA) was used to calculate particle characteristics: ECD, form factor, elongation, aspect ratio, roundness and calculated volume [2].

Results

Debris captured on the 1μm filter correlated with tissue-metal score (ρ= 0.812, $p < 0.001$). The median of the measured debris weight captured on 1 μm filters was 0.5 ± 0.6 mg (range: 0-1.9 mg).



Particle characteristics were not similar when comparing infer patella, medial gutter and lateral gutter across three patients (ECD $p = 0.004$, form factor $p < 0.0001$, elongation $p < 0.0001$, aspect ratio $p < 0.0001$, roundness $p < 0.0001$, and calculated volume $p = 0.004$).

Particle characteristic were not similar when comparing 5 sample locations (tibia, infer patella, supra patella, medial gutter, and lateral gutter) for one patient (ECD $p < 0.0001$, form factor $p < 0.0001$, elongation $p < 0.0001$, aspect ratio $p < 0.0001$, roundness $p < 0.0001$, and calculated volume $p < 0.0001$).

Device Design	Femoral Component Material	Tibial Component Material	Sample Location	ECD	FF	E	AR	R	Count
LCS Mobile Bearing	CoCr	CoCr	Infer Patella	1.59	0.83	1.23	1.43	0.74	3321
			Lateral Gutter	1.33	0.89	1.19	1.34	0.79	1271
			Medial Gutter	1.57	0.84	1.24	1.44	0.74	2341
			Super Patella	1.57	0.85	1.23	1.41	0.75	2584
			Tibia	1.88	0.83	1.23	1.43	0.75	1582
Nexgen LPS	CoCr	Ti Alloy	Infer Patella	1.68	0.81	1.28	1.55	0.71	1468
			Lateral Gutter	1.7	0.77	1.28	1.6	0.69	1157
			Medial Gutter	1.51	0.83	1.25	1.49	0.73	1640
Miller-Galante II	Ti Alloy	Ti Alloy	Infer Patella	1.6	0.8	1.29	1.56	0.7	2942
			Lateral Gutter	1.89	0.78	1.3	1.62	0.68	1957
			Medial Gutter	1.67	0.79	1.31	1.65	0.67	1195

Table 2: Average values for particle characteristics calculated from ASTM 1877 [2].

Discussion

The correlation between large particle weights (1.9 - 0.08 μm) and visual metallosis, but not smaller particle weights (40-300nm) references that the visual appearance of tissue is not a sufficient description of debris [3]. The isolated metal debris were larger than debris previously observed in THA M-o-M simulator studies [4]. Larger metal debris is less likely to be phagocytosed, but it can elicit a foreign body reaction [5]. Particle characteristics were statistically different for different sampling locations, potentially indicating different debris generating mechanisms.

SIGNIFICANCE

This study discusses isolated wear debris from postmortem TKA patients, using a model previously validated in animals. This the study discusses the connection between tissue location, and characteristics of metallic debris to attempt to illuminate the appropriate sampling region and biological reactions that could be present .

References: [1] Patel et al. Acta biomaterialia, 2018; [2] ASTM "ASTM Subcommittee F 4 (1877); [3] Ebramzadeh et al. CORR, 2015; [4] Catelas et al. Seminars in immunopathology, 2011; [5] Anderson et al. Seminars in immunology, 2008.