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Research Article

Keywords: MRI, pigment, keratopigmentation, KTP, safety

Posted Date: March 27th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-9227047/v1>

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Additional Declarations: The authors declare no competing interests.

MRI Safety of Iron Oxide–Containing Pigments in Keratopigmentation

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Keywords:

Keratopigmentation; Iron oxide pigments; Magnetic resonance imaging safety; Corneal
stroma; Ocular implants

- 24 There is no conflict of interest to disclose.
- 25 We do not have any commercial interest in this presentation.
- 26 This research was not funded by any grants.
- 27

28

29 **Abstract**

30 **Purpose:**

31 To evaluate the magnetic resonance imaging (MRI) safety of iron oxide–containing
32 pigments previously used in femtosecond laser–assisted keratopigmentation (KTP).

33

34 **Methods:**

35 Twelve pigment formulations were initially screened using MRI to identify the most
36 magnetically reactive sample. Standardized pigment amounts equivalent to clinical use
37 were measured with a precision microbalance. Temperature changes were monitored
38 with fiber optic thermometry in porcine corneas with and without pigment following
39 femtosecond laser tunnel creation during a standard MRI protocol. Pigment motility was
40 assessed by suspending impregnated filter paper in MRI-safe glass jars and observing
41 potential movement within the bore. MRI sequences were analyzed for image distortion.

42

43 **Results:**

44 No measurable temperature increase was observed in pigment-containing or control
45 porcine corneas during MRI exposure. No pigment movement was detected; the
46 impregnated filter paper remained stable without displacement, deflection, or torque.
47 MRI revealed a localized signal at the pigment site, causing mild distortion limited to the
48 corneal region, with no interference in adjacent or posterior ocular structures.

49

50 **Conclusions:**

51 Iron oxide—containing pigments (Biotic Phoceia, France) used in keratopigmentation did
52 not cause heating, motility, or clinically significant imaging artifacts during MRI. Although
53 localized corneal signal distortion was noted, it did not hinder the visualization of deeper
54 eye tissues. These findings support the safety of MRI in patients with prior KTP using
55 iron oxide pigments, including those who had initial pigments implanted.

56

57

58 **Introduction**

59 Keratopigmentation (KTP), also known as corneal tattooing, has recently gained
60 popularity as a cosmetic technique to alter or enhance eye color, most often performed
61 using femtosecond laser–assisted intrastromal tunnels^{1,2}. Earlier pigment formulations
62 frequently included iron oxide, which raised safety concerns regarding magnetic
63 resonance imaging (MRI)³⁻⁵. A case reported by Nouzovská and Alió described the
64 development of corneal ectasia following an uncomplicated KTP procedure and
65 subsequent MRI exposure⁶.

66

67 While modern pigments are generally formulated without iron oxide, many patients
68 previously underwent KTP treatments with iron oxide–containing formulations,
69 prompting a need to clarify their safety. The main concerns are twofold: whether iron
70 oxide pigments might: 1) cause temperature increases from radiofrequency absorption⁷
71 and/or 2) be displaced or subjected to torque due to the main magnetic field and field
72 gradient^{8,9}. To address these issues, we conducted an experimental evaluation under
73 clinical MRI conditions.

74

75 **Materials and Methods**

76 Selection of pigment: To identify the most MRI-reactive pigment, twelve different
77 pigments were initially tested in sealed containers under MRI. The pigment producing
78 the most intense MRI signal was chosen for subsequent experiments; this was
79 assessed by gradient echo and spin echo sequences, as is routine for MRI

characterization (Figure 1, Table 1).

Both gradient echo and spin echo sequences were used. R2 is the vector sum of the distortion in the x and z directions

The containers with pigment were also tested using a strong handheld permanent magnet to select the most magnetic pigment. The 1"x1"x1" magnet used was an N52 Neodymium Cube NdFeB Rare Earth magnet with a strength of 5,900 Gauss (0.59 Tesla) and a 58-pound lift capacity (Figure 2A). The shadow around the pigment-containing containers (the MRI artifact) was assessed visually and quantified numerically. The pigment that produced the largest artifact (old honey) was selected for further testing, assuming that pigments producing a smaller artifact (containing less iron oxide) would be less reactive during the actual MRI testing.

Pigment Quantification

To mimic the clinical amount of pigment used during keratopigmentation, we standardized the load applied in each experimental condition using a pharmacy scale (A&D GF300P with a precision of 0.001g, repeatability of 0.001g, and accuracy of 0.001g). The container holding the pigment was weighed before and after immersion of the surgical applicator commonly used in human procedures. The difference between the two measurements represented the mass of pigment withdrawn in a single dip (0.028g). This process was repeated six times, and the average value was calculated to determine the standardized pigment amount. Reproducibility of the method was confirmed by performing the procedure on different occasions, producing consistent results. The same standardized quantity, corresponding to the amount typically used for

high-intensity keratopigmentation, was applied to impregnate the filter paper suspended within the MRI-safe glass jar for motility testing (Figure 2B, 2C).

MRI Artifact Acquisition:

All MRI scans were performed on a GE 3.0 Tesla Discovery MR 750 scanner [GE Healthcare; Milwaukee, WI]. An 8-channel T/R Knee Coil was used with a standard 9 cm Petri dish placed at the center of the coil and filled with water. The vial containing the pigment was secured in the center of the dish, and images were acquired in the coronal plane. Two sequences were used to assess the level of artifact, including both gradient and spin echo images as typically used in clinical settings. The 2D Fast Spoiled Gradient Echo (FSPGR) was acquired with a 12 cm x 12 cm field of view (FOV), a 512 x 512 matrix, and a 5 mm slice thickness, resulting in a spatial resolution of 0.23 mm x 0.23 mm x 5 mm. The sequence used a repetition time (TR) of 250 ms and an echo time (TE) of 2.2 ms. A Fast Spin Echo (FSE) sequence was also acquired with the same spatial resolution, a TR of 2500 ms, and a TE of 72 ms. Both sequences utilized an identical receive bandwidth of 31.25 kHz or 122 Hz/pixel and a 90° flip angle (Figure 1).

MRI Artifact Quantitation:

Measurement of the extent of the image artifact was performed in both the Right/Left (x-direction) and Superior/Inferior (z-direction) in the coronal plane. The mean signal intensity of the entire image was measured. The image intensity window was set to 0 and the level to half the mean intensity of the entire image. This technique follows the

procedure for measurements using the ACR MRI phantom¹⁰. The horizontal and vertical artifact lengths were measured at their greatest extents using ImageJ [Rasband WS;NIH]¹¹. Note that the outer diameter of the empty plastic vial containing the pigments was 18 mm, and the inner diameter of the empty vial was 16 mm.

Temperature testing:

Two isolated pig eyes were used. In one eye, KTP was performed with placement of the selected pigment (Old Honey) in a femtosecond-laser-created stromal tunnel. The control eye underwent the same tunnel creation without pigment placement. Fiber optic thermometer probes were inserted into each tunnel and connected to a calibrated recording system [Qualitrol Neoptix OmniFlex-2; Quebec, Canada]. An additional probe was placed outside the MRI coil on the table to record ambient temperature in the magnet bore. The following MRI protocol was run continuously for 20 minutes while monitoring temperature: gradient echo sequence (GRE), repetition time 18 ms (TR), echo time 7 ms (TE), flip angle 90° using the body coil for transmit. Temperatures were measured before and throughout the scan (Figure 3).

Motility testing:

A 1.0 × 1.0 cm filter paper square impregnated with the selected pigment was suspended using black 6-0 silk thread inside a sealed MRI-safe glass jar (Figure 2B, 2C). The jar with the pigment-containing filter paper was placed on the patient table and carefully moved without acceleration into the MRI bore. The position of the filter paper

was directly observed by one of the authors and recorded using a Canon Mark III camera.

Results

Temperature testing: No observable increase in temperature was detected in either the experimental or control eye during MRI exposure. Readings stayed consistent throughout the entire imaging process (Figure 4).

Motility Testing

The pigment-impregnated filter paper exhibited no measurable movement, deflection, or torque. Its position remained stable relative to pre-marked reference points throughout the experiment (Figure 2B,2C).

MRI Imaging

Cross-sectional MRI images demonstrated a localized signal at the corneal region containing the pigment tunnel. A mild image distortion (Figure 5A) compared to the control eye (Figure 5B) was observed in the corneal area itself; however, no distortion was noted in adjacent ocular tissues or in structures posterior to the cornea.

Discussion

MRI fields are known to interact with ferromagnetic materials through heating and displacement mechanisms^{8,9}. Concerns have been raised regarding keratopigmentation (KTP) pigments containing iron oxide, particularly following a case report of corneal ectasia after MRI exposure in a patient with prior KTP⁶.

Iron oxide particles have been reported to generate thermal or mechanical effects during MRI scans, and MRI-related heating has been described in cutaneous tattoos containing iron-based pigments⁷. However, consistent with our findings, Alsing et al. measured temperature changes in 11 metal-based tattoo inks in a 3.0-Tesla MRI scanner and did not observe a significant temperature rise above 0.26°C during scanning¹². Such minimal heating is not considered clinically significant and would not be expected to cause tissue injury.

In our experiments, under controlled conditions and with pigment quantities comparable to those used clinically, no measurable temperature elevation or displacement of pigment within the corneal stroma was observed. By minimizing external confounding factors, the motility testing confirmed stability of the pigment within the MRI environment. Although MRI produced a localized signal alteration at the pigment site, visualization of deeper ocular structures was preserved. The posterior pole, optic nerve, and orbital structures were not affected by corneal signal distortion (Fig. 5A).

These findings suggest that the relatively small quantity of iron oxide used in corneal pigmentation (0.028g) is unlikely to produce harmful effects in clinically utilized MRI systems, despite localized susceptibility-related image distortion. This observation is consistent with our clinical experience in patients who previously underwent KTP with

iron oxide–containing formulations (unpublished observations). The previously reported case of ectasia may therefore have been influenced by underlying biomechanical susceptibility rather than direct magnetic interaction with the pigment.

Although ex vivo data have inherent limitations in extrapolation to in vivo MRI conditions, the absence of temperature change and detectable pigment motility supports the safety profile observed in our study. Prospective evaluation during MRI procedures in patients with previously implanted iron oxide–containing pigments would further clarify clinical relevance.

Interestingly, a recent ex vivo study by Gaulier et al¹³. evaluated MRI interactions with various keratopigmentation inks using a 4.7-Tesla system and reported susceptibility artifacts and histologic pigment redistribution in iron oxide–containing formulations, particularly under spatial magnetic field gradients that are present at the entrance to the magnet bore and exposures that range up to 16 hours. Several methodological considerations are relevant when interpreting these findings clinically. The use of a 4.7T MRI system exceeds standard clinical field strengths (1.5T and 3.0T), and because magnetic susceptibility effects scale with field intensity, artifact magnitude observed at 4.7T may overestimate those encountered in routine practice. Furthermore, specimens were positioned at the entrance of the bore—where magnetic field spatial gradients are maximal, whereas patients are positioned centrally within a nominally homogeneous magnetic field where translational forces are minimized. Our study incorporated precise measurement of pigment volume and controlled intrastromal placement within a defined lamellar architecture, allowing reproducible correlation between pigment burden and MRI response. The reported obscuration of anterior ocular structures may also reflect

the use of high-iron oxide black inks and potentially substantial pigment loads within the stromal tunnel, which could exaggerate local susceptibility artifacts compared with contemporary cosmetic techniques employing lower pigment volumes or carbon-based and iron oxide-free formulations¹³.

Despite theoretical susceptibility effects and translational forces, documented clinical complications remain exceedingly rare. Taken together, the available evidence suggests that controlled pigment volume and precise intrastromal confinement under clinically relevant MRI parameters are unlikely to produce clinically significant adverse effects, consistent with the findings of the present study.

230 Figure 1: MRI images are shown of the old honey gold pigment. A) The gradient echo
231 image has distortions of 51.6 mm x 54.4 mm in x and y, while B) The spin echo image
232 yielded 45.5 mm x 57.5 mm. MRI images are shown for the new honey gold pigment.
233 C) The gradient echo image has distortions of 16.4 mm x 18.1 mm in x and y, while D)
234 The spin echo image yielded 16.2 mm x 16.4 mm.

235

236 Figure 2: A) Lifted container with iron oxide-containing pigment. B) Glass jar containing
237 pigment-impregnated filter paper to test motility. C) Recording setup of glass jar in the
238 MRI scan suite.

239

240 Figure 3: Temperature Probes placed into the tunnel of the experimental and control
241 eye.

242 Figure 4: Raw temperature in C° is shown as a function of time in the control (Probe 1)
243 and KTP (Probe 3) eyeballs for the entirety of the 20 minutes of continuous MRI
244 scanning.

245

246 Figure 5 A) Image of a porcine eye with pigment using the Fast Spin Echo MRI
247 sequence.

248 B) Image of a porcine eye without pigment using the Fast Spin Echo MRI sequence.

249

250

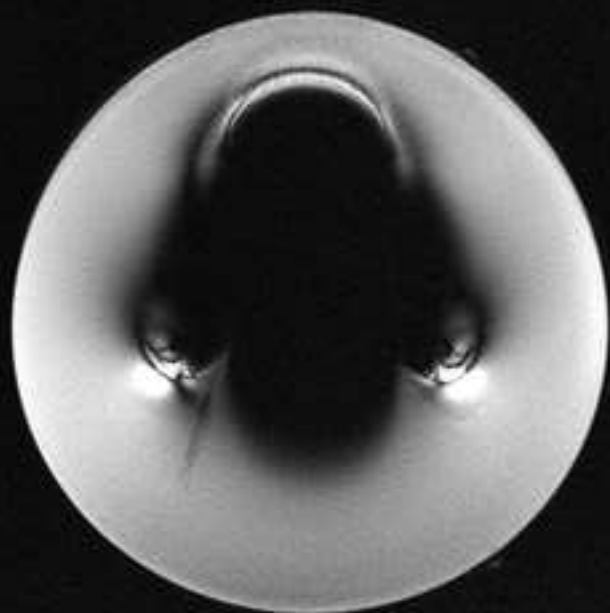
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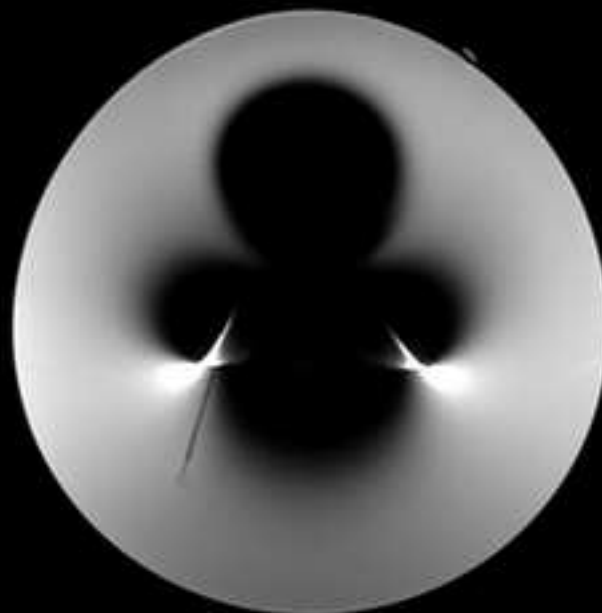
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- 285

GRADIENT ECHO				SPIN ECHO			
PIGMENT	X (mm)	Z (mm)	R² (mm)	PIGMENT	X (mm)	Z (mm)	R² (mm)
OLD HONEY GOLD	51.6	54.4	75.0	OLD HONEY GOLD	45.5	57.5	73.3
FOREST	46.4	54.4	71.5	FOREST	42.7	61.7	75.0
EMERALD GREEN	42.3	55.6	69.9	EMERALD GREEN	40.3	70.8	81.5
CHOCOLATE	43.1	49.9	65.9	CHOCOLATE	36.3	52.3	63.7
OLIVE	44.5	48.3	65.7	OLIVE	37.3	52.1	64.1
FRENCH BLUE	38.5	50.3	63.3	FRENCH BLUE	37.7	48.1	61.1
JADE	19.7	31.9	37.5	JADE	17.1	23.7	29.2
AQUA	19.2	22.9	29.9	AQUA	17.3	20	26.4
SAND	16.4	19.7	25.6	SAND	17.6	18.8	25.8
MARBRE	16.9	18.5	25.1	MARBRE	16.9	17.5	24.3
GRAY	16.6	18.3	24.7	GRAY	16.9	17.9	24.6
NEW HONEY GOLD	16.4	18.1	24.4	NEW HONEY GOLD	16.2	16.4	23.1

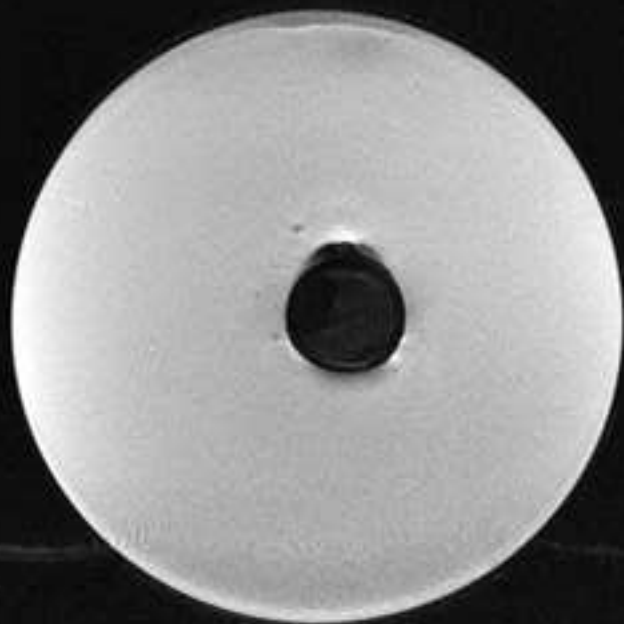
Table 1: Maximum artifact dimensions are given in mm for both x and z-directions with both gradient echo and spin echo sequences. R² is the vector sum of the distortion in the x and z directions



A)



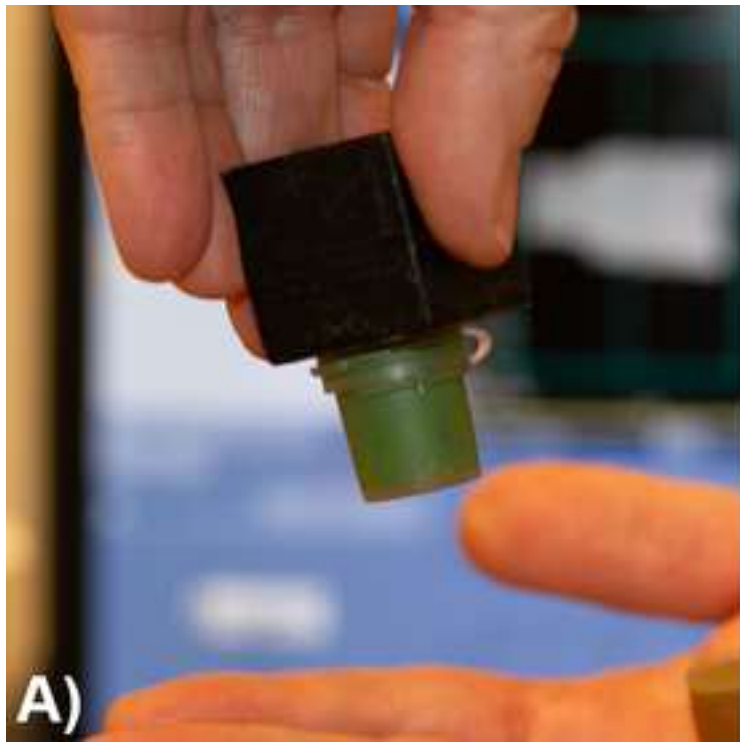
B)

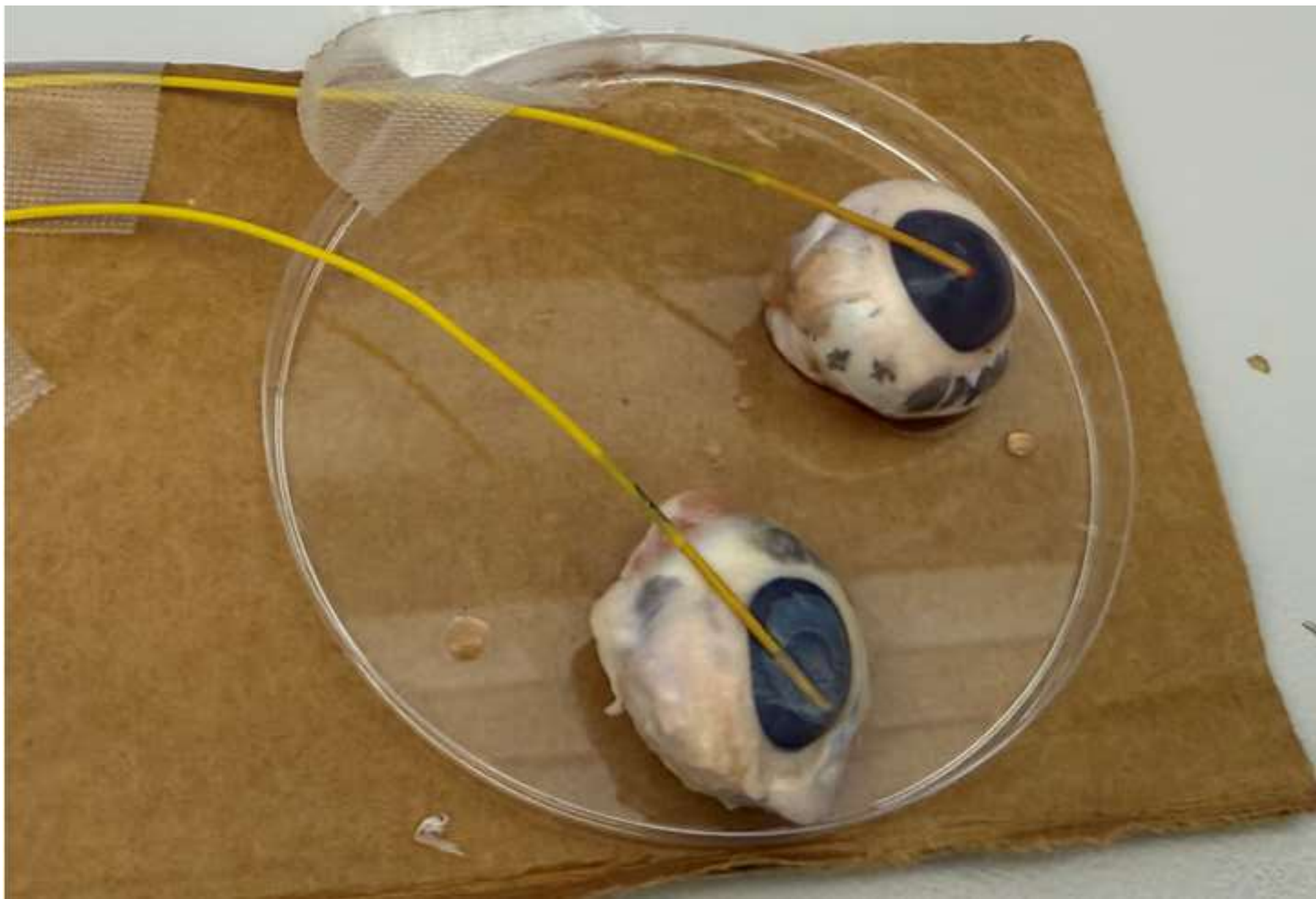


C)

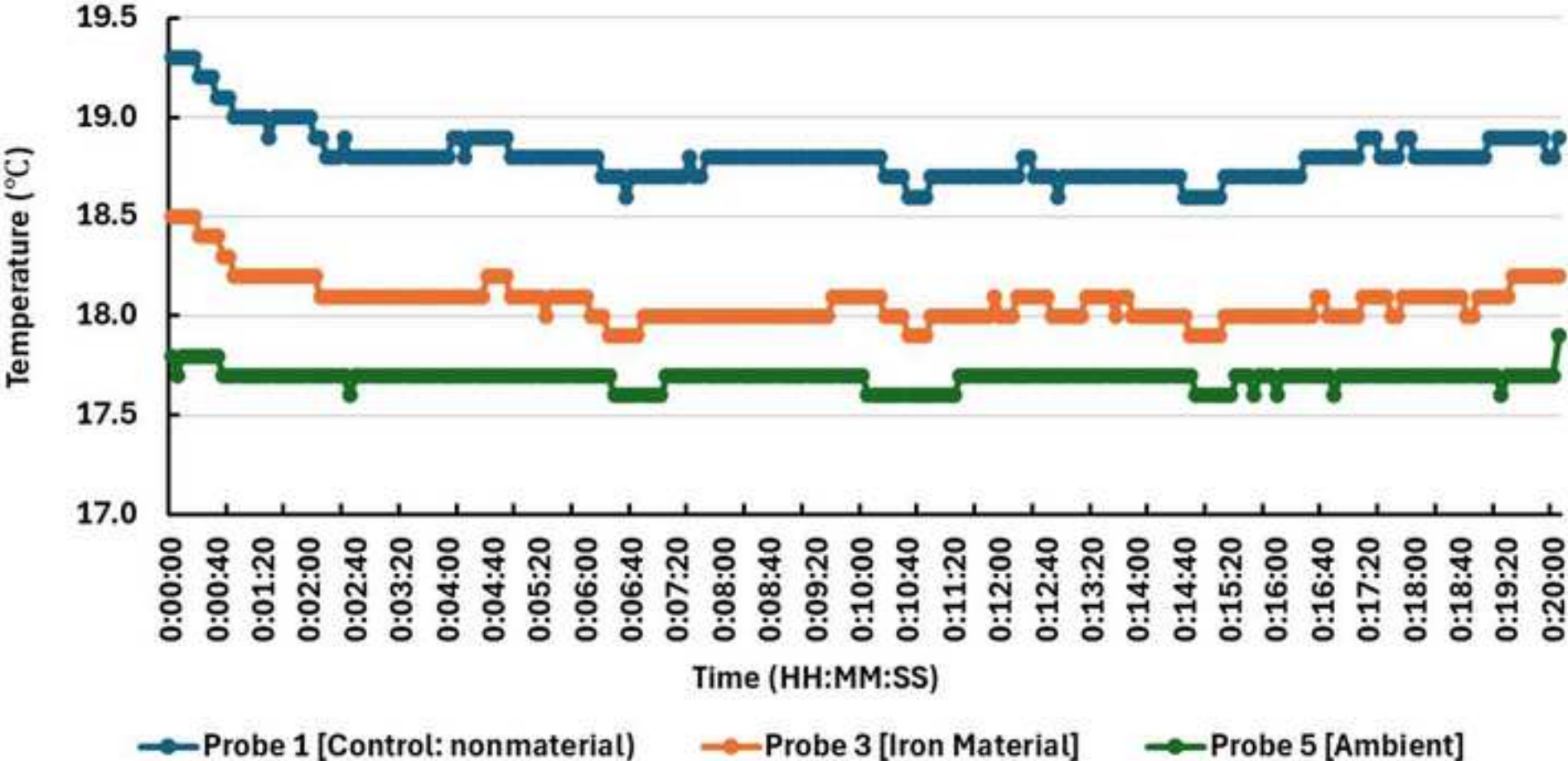


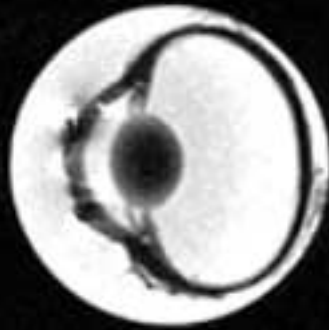
D)



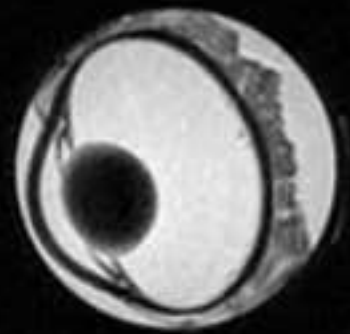


Raw Temperature Data: Pig Eye





A)



B)