

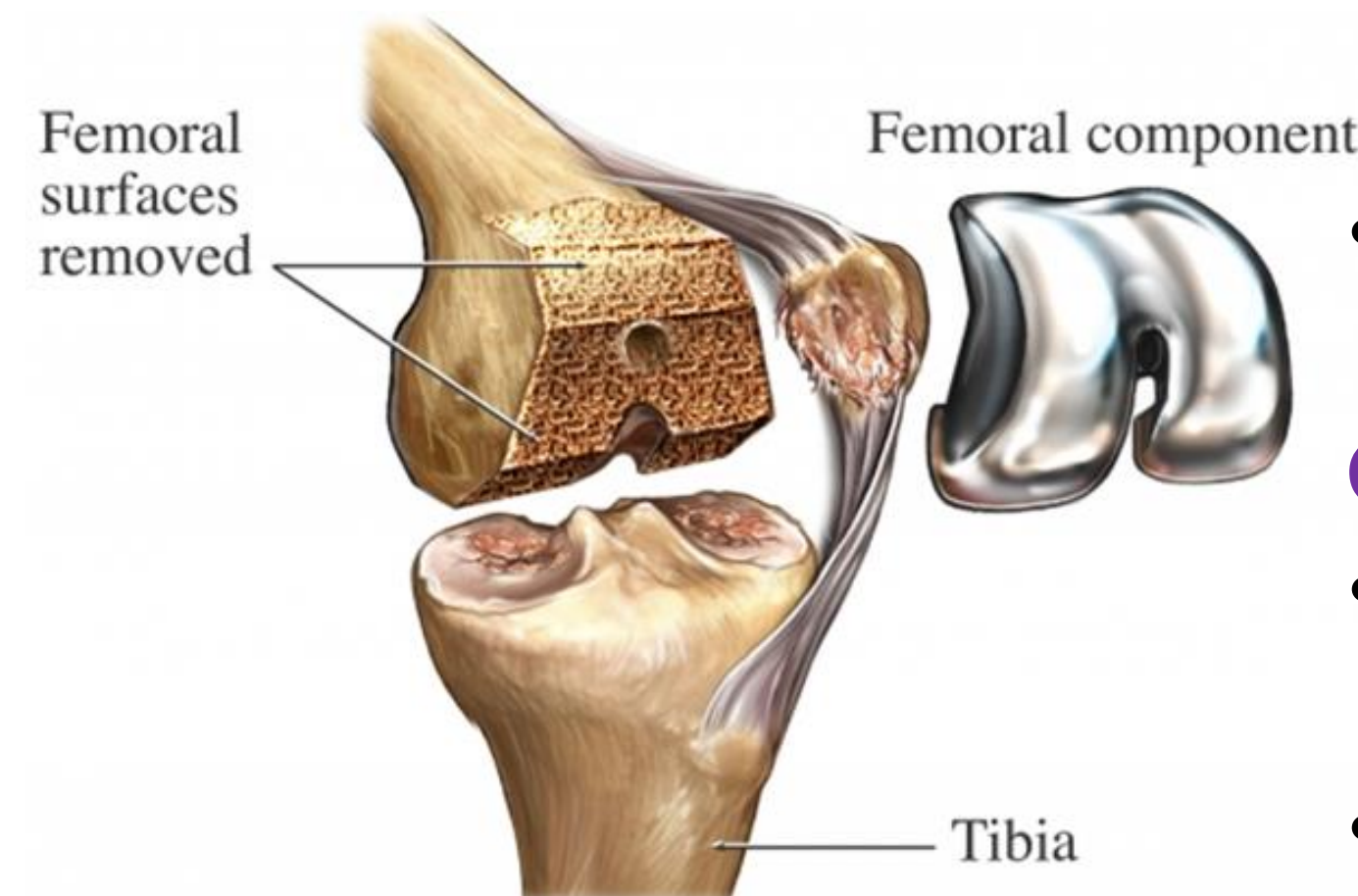
Advanced Prosthetic Removal Device for Total Knee Revision

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Objective

The objective of this project is to develop a semi-automated prototype device which reduces the removal time of a femoral component during total knee revision. Another focus will be on minimizing bone loss incurred by the patient.

Background



- Projected TKA to reach 3.48 million surgeries by 2030 [1]
- **Complications in Revision Surgery:**
 - Infections from prolonged exposure time
 - Damage to bone and tissue

Figure 1: Femoral Prosthetic Component in relation to Femur Bone and Knee Joint [2]

Engineering Specifications

- Less than 20 minutes required to remove the femoral component
- Less than 5mm of bone loss incurred by the patient
- Temperature of bone and surrounding tissue less than 55°C

Removal Method and Analysis

- Heat is applied to the femoral component surface using Silicone flexible heating elements for prosthetic removal

Deformation Analysis

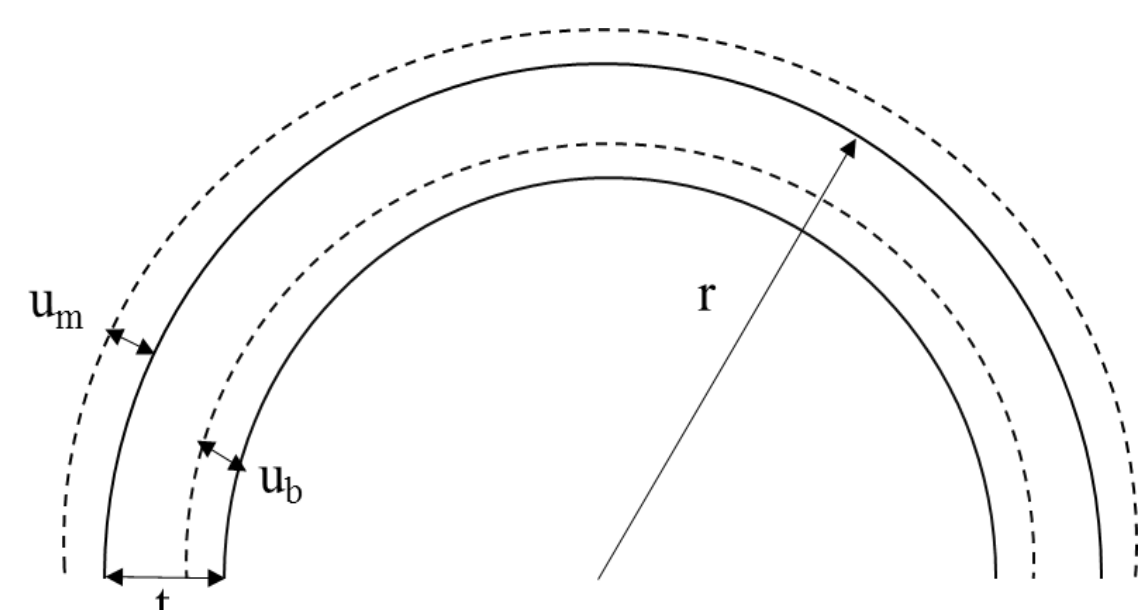


Figure 2: Model of Deformation

$$\epsilon_{tensile} = \frac{(u_{metal} - u_{bone})}{t} - \alpha_{PMMA} \Delta T_{PMMA}$$

- Calculated tensile stress on PMMA thickness from 1-5mm was 67.5-5.8MPa

Heat Transfer Analysis

- Required heating element temperature range: 121.2-135.6°C
- Potential heat loss due to free convection: 400-476W/m²

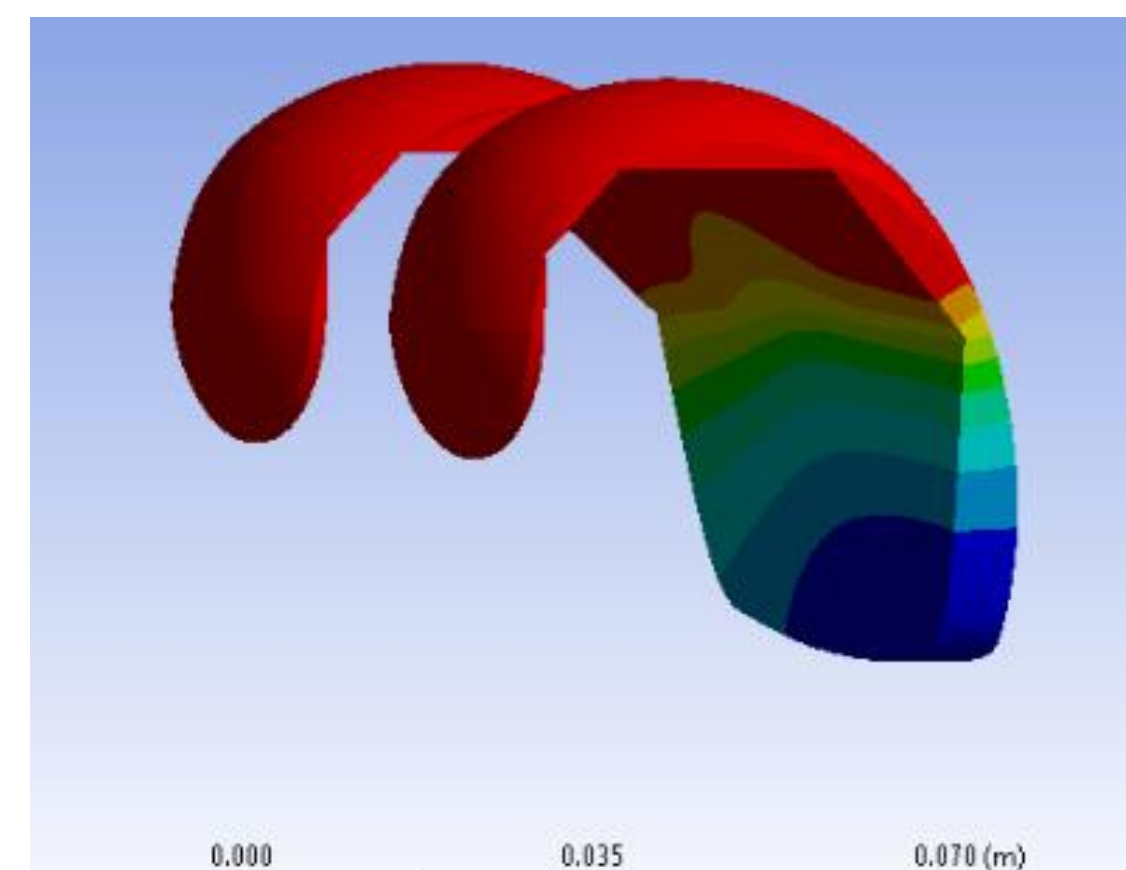


Figure 3: Thermal Distribution Through Femoral Component

ANSYS Analysis

- Transient thermal solution using 130°C surface temperature
- In 515 seconds, the underside of the component condyles reached 121°C

Manufacturing and Assembly

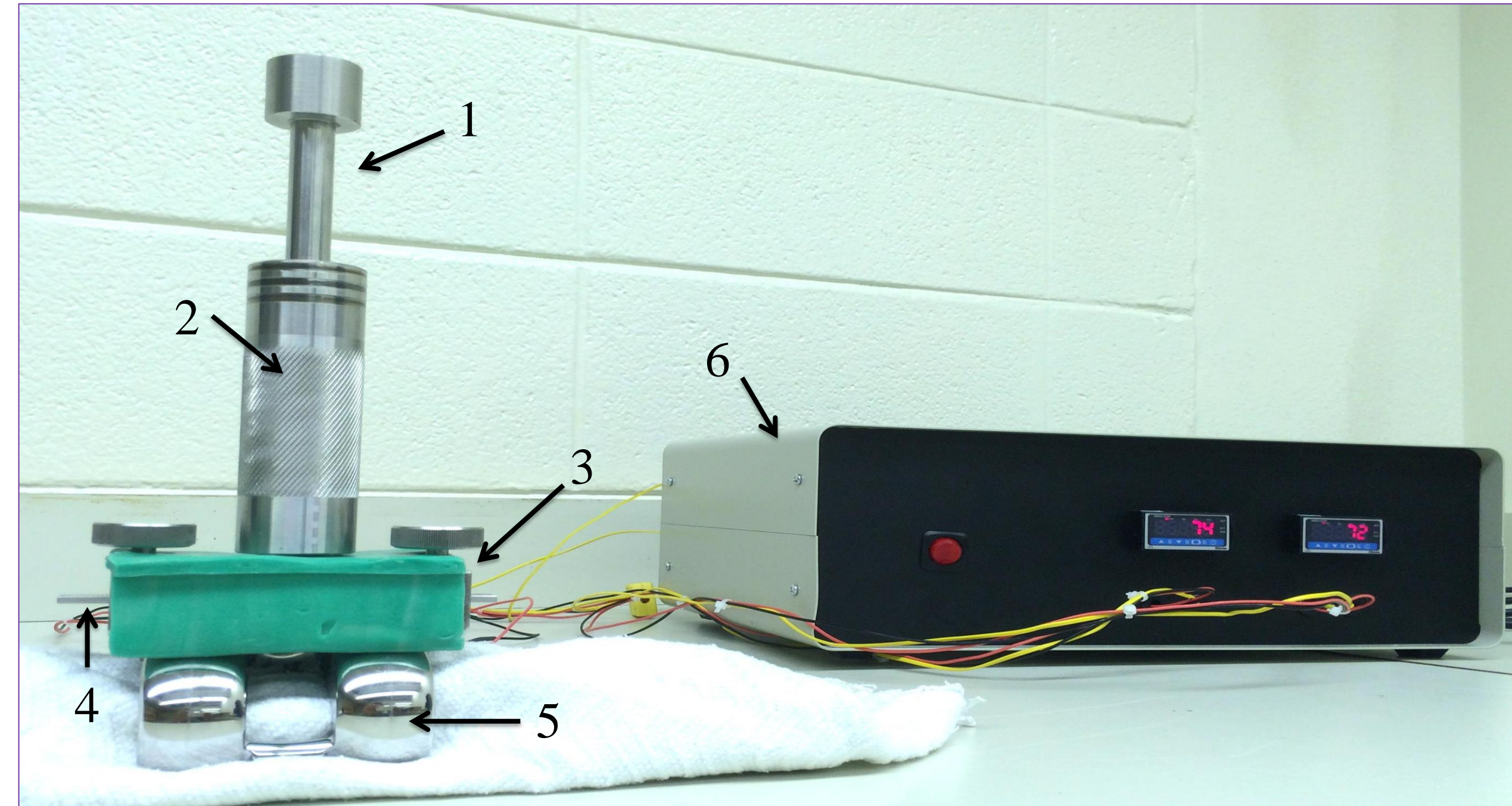


Figure 4: Prototype Device Assembly

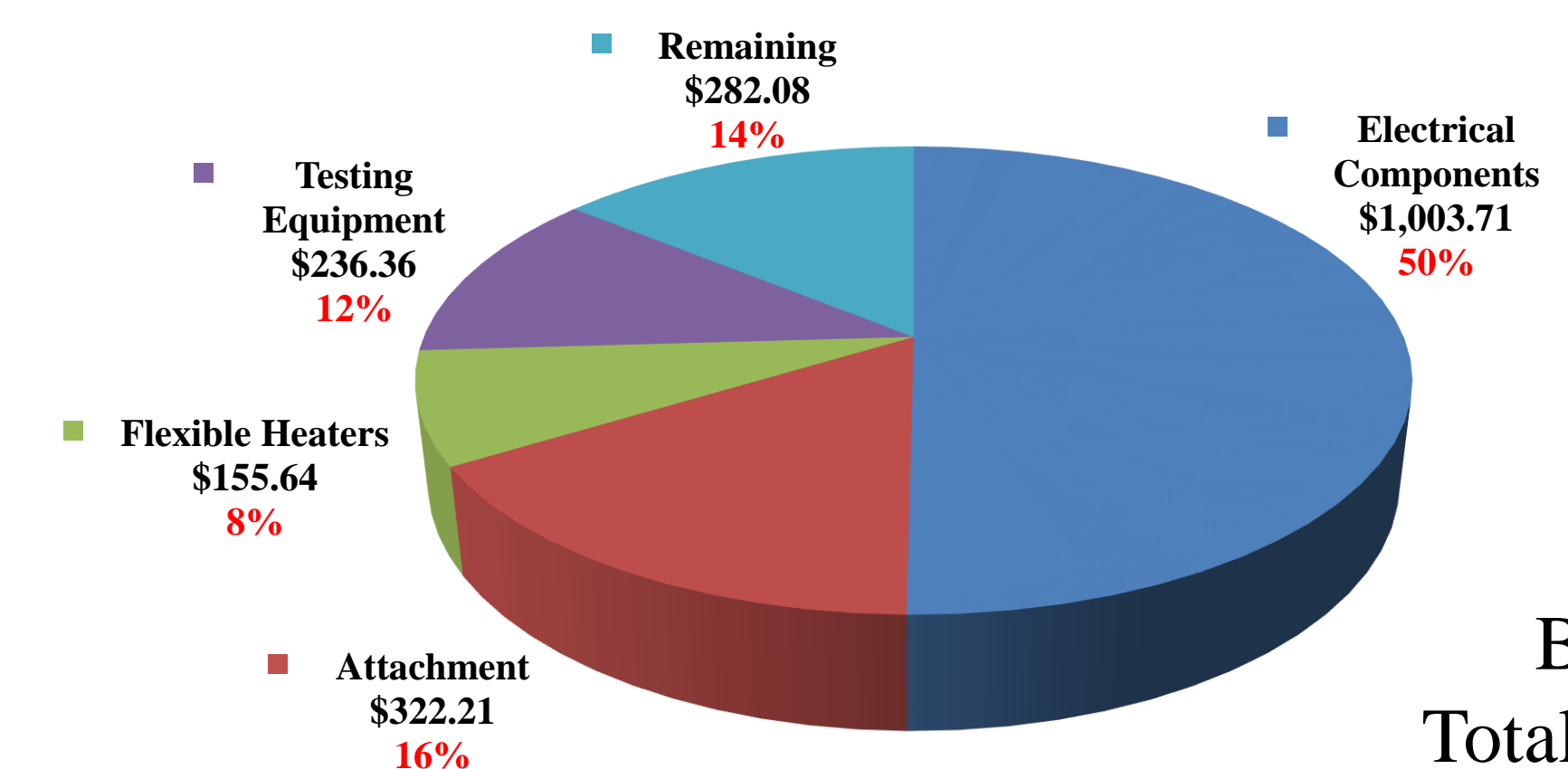
List of Components

1. Inner Slide Hammer Cylinder
2. Outer Slide Hammer Cylinder
3. Base Component with Silicone Insulation Sleeve
4. Adjustable Attachment Legs
5. Prosthetic Component with Heating Elements Attached
6. Power Supply Box with Control System

Safety

- Biocompatible and chemically inert flexible heaters
- Thermally insulated and sterilizable attachment device
- Automatic and manual shutoffs for control system

Budget and Schedule



Budget: \$2000
Total Spent: \$1717.92

Prototype Design Sept.-Dec. 2014

- Established removal method
- Incorporated slide hammer
- Detailed manufacturing and assembly drawings

Manufacturing Jan.-March 2015

- Preliminary proof of concept testing
- Machined attachment device components
- Assembled control system

Prototype Testing March-May 2015

- Bone surface temperature verification
- Separation time of implant-bone cement interface verification
- Cadaver Lab

Testing Results



Figure 5: Bone Temperature Test Apparatus

Bone Temperature at Varying PMMA Thickness

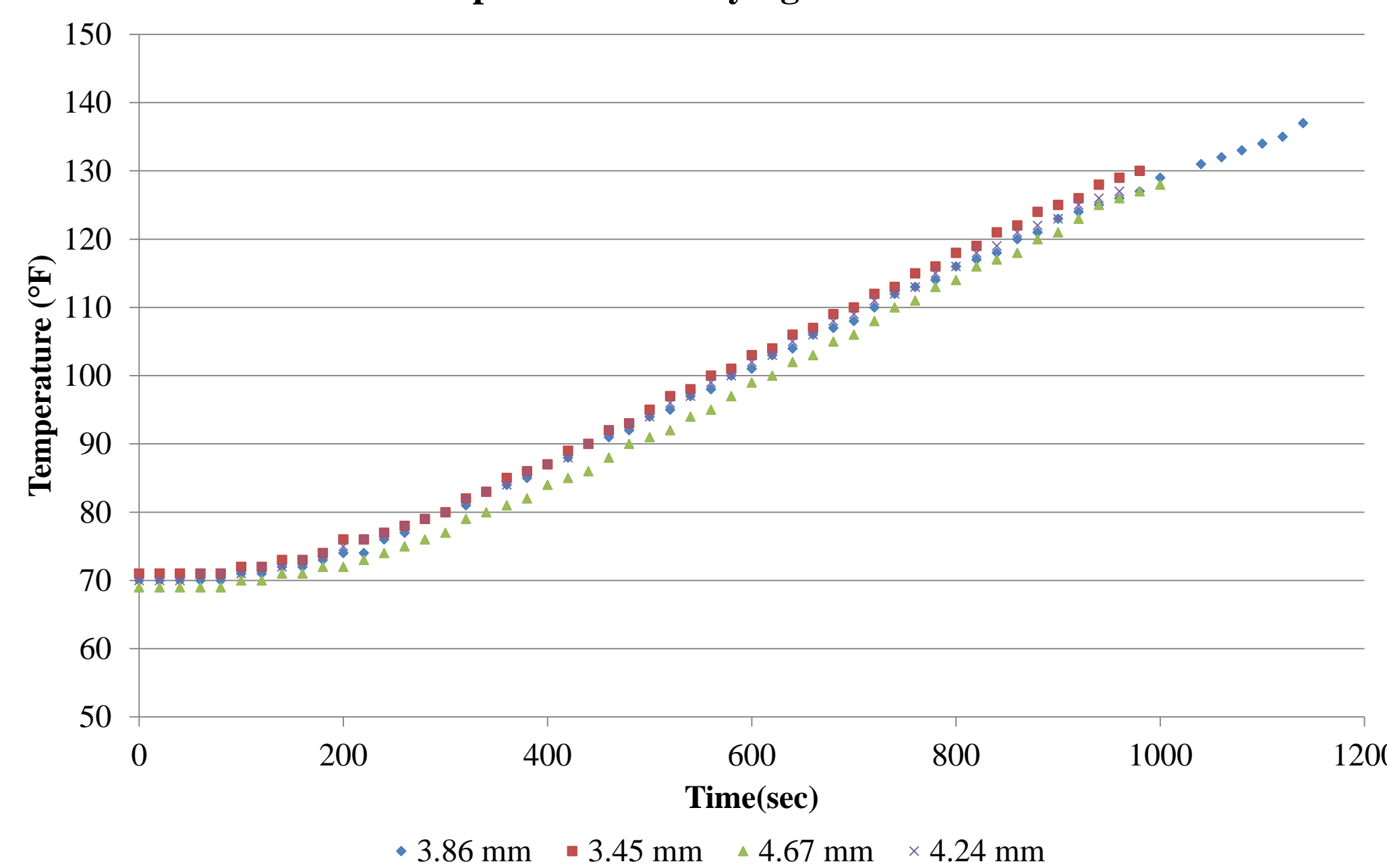


Figure 6: Graphical Results of Bone Temperature over Time during Heat Application with Varying Bone Cement Thicknesses

Protocol

- Heating elements positioned on metal surface of test sample using prototype base component
- Type K thermocouple positioned 5 mm under polyethylene surface to measure simulated bone temperature
- Ran programmed 20 minute heating cycle; team recorded bone temperature values every 20 sec
- Once bone temperature reached maximum of 55°C (131°F) removal was attempted

Results

- Five trials conducted using various bone cement thicknesses and brands of PMMA
- For cement thickness of 1-3mm removal not possible prior to reaching maximum bone temperature of 55°C (131°F)
- Cement thickness of 4-5mm removal possible for 7 of 9 samples
- Removal inhibited at times due to excessive PMMA on sides of polyethylene

Cadaver Lab: April 17th, 2015

- Orthopedic surgeon fixated prosthetic components on two cadaver knees
- Prototype was implemented for component removal
- Prosthetic was removed from both cadavers with zero bone loss in under 30 minutes

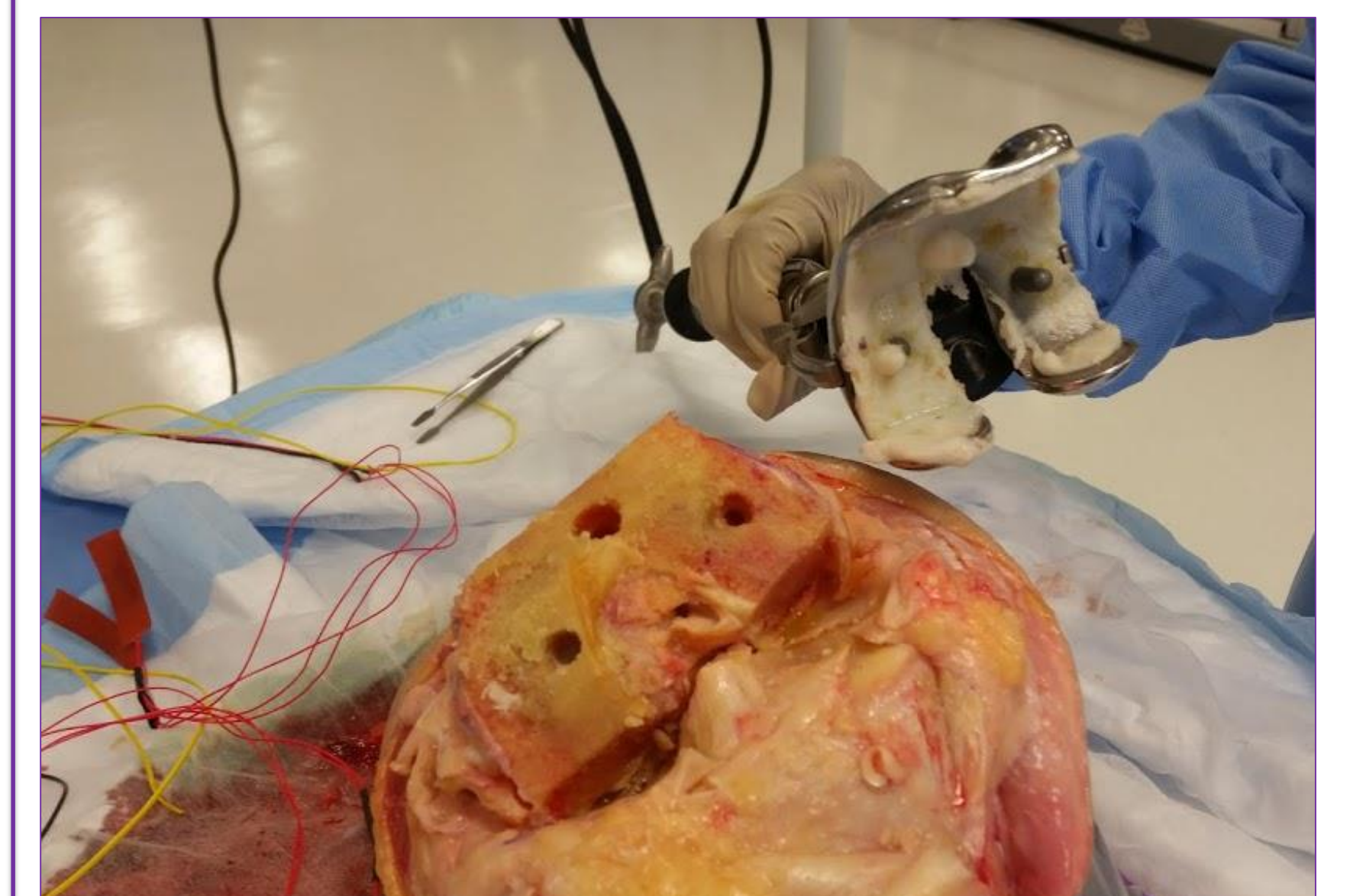


Figure 7: Prosthetic Removal after Heat Application using Prototype in Cadaver Lab