# The Adverse impact of bone cement injection to lower vertebral body on proximal disc in terms of polymerization temperature

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# The Adverse impact of bone cement injection to lower vertebral body on proximal disc in terms of polymerization temperature

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**This certifies that the Master's Thesis of Wooseok Jung is approved**

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# ABSTRACT

## The Adverse impact of bone cement injection to lower vertebral body on proximal disc in terms of polymerization temperature

Introduction:

Bone cement, particularly polymethyl methacrylate (PMMA), is commonly used in spinal procedures such as vertebroplasty, kyphoplasty and cement augmented screw to reduce probability of proximal junctional failure. While PMMA provides mechanical stabilization and pain relief, the exothermic polymerization reaction can lead to significant temperature increases, potentially affecting adjacent structures such as proximal disc. This study investigates the polymerization temperature of PMMA in relation to its effects on the proximal intervertebral disc, using both human and porcine cadaver specimens.

Materials and Methods:

The study involved four porcine cadavers and one human cadaver. The polymerization temperature was measured at various locations within the vertebral body and proximal disc(anterior, middle, posterior) using K-type thermocouples. Two porcine cadavers were experimented in air, the remaining two were tested in a water bath at 37°C reflecting body temperature, and one human cadaver was tested in air. A bi-pedicular approach was used for PMMA injection, and temperature measurements were taken at one-minute intervals for ten minutes post-injection.

Results:

In porcine cadavers, in the air, average peak temperature at the middle of the disc was 57.1°C and in warm bath, it was 48.2°C. In human cadavers, the average of peak temperature at the disc center measured 52.1°C. Near the PLL, the average peak temperature was 27.1°C and negative correlation was observed between distance from the cement and temperature.

Discussion:

This study demonstrates that the insertion of PMMA bone cement can raise the temperature of the adjacent intervertebral disc to a critical threshold of 50°C, with the effect depending on the distance from the cement. Temperatures near adjacent nerves did not exceed 50°C, suggesting minimal impact on nerves, though this may vary by proximity.

Key limitations include the thermometer's margin of error (±1°C), differences between experimental and in vivo conditions such as body temperature (35–40°C) and blood flow (e.g., Batson's plexus), and the avascular nature of intervertebral discs. Individual variations in muscle and soft tissue distribution and differences in cement quantity and distribution between vertebrae also influence heat diffusion.

Conclusions:

The study concludes that clinicians should be aware of the exothermic reactions associated with PMMA injection, as they can significantly impact the temperature of adjacent structures, potentially leading to adverse effects such as proximal disc degeneration.

Key words : proximal disc; vertebroplasty; bone cement; pmma; degeneration; proximal junctional failure

# I. INTRODUCTION

## 1.1. Research background

Bone cement, such as polymethyl methacrylate(PMMA), is widely used in spinal procedures like vertebroplasty, kyphoplasty and cement-augmented screws in clinical practice[1, 2].
PMMA is an acrylic polymer that forms through the combination of two sterile components : a liquid monomer (MMA) and a powdered co-polymer made of MMA and styrene. When these components are mixed, the liquid monomer polymerizes around the pre-polymerized powder particles, resulting in solid PMMA. This process generates heat due to an exothermic reaction and also bone cement augmentation was known to enhance the vertebrae's resistance to stress loading. The mixture's physical and chemical characteristics are influenced by PMMA and various additives.[3-5]
Due to the physical and chemical properties of bone cement, it is primarily employed for its positive effects, such as mechanical stabilization and pain reduction from its chemical neurolytic effect[3, 4, 6-13]. We usually consider negative effect of bone cement such as cement leakage through spinal canal and pulmonary embolism, however, in many clinical cases, the negative impact of the exothermic reaction that occurs during the polymerization process of bone cement is often overlooked. [10]
Previous studies have reported that the peak temperature during bone cement polymerization can even exceed 100°C[9]. While many studies have explored this exothermic reaction, these studies measured temperature mainly from bone by isolating the disc and soft tissues from cadavers, and no research has measured the peak temperature in the clinically significant proximal disc. [6, 8, 9, 13-16],
Temperature elevation near the spinal cord can be a main concern and beyond the effects on adjacent nerves that we usually consider carefully, the clinical importance of the impact of cement on the proximal disc lies in the increasing trend of fusion surgery over the past decade. This rise in frequency has led to concerns among spine surgeons about adjacent segment disease associated with fusion procedures. [17, 18]
While some studies suggest that the use of cement in the upper instrumented vertebra, or even in vertebrae more proximal, can help prevent adjacent segment disease, other clinical studies indicate that cement insertion may contribute to the degeneration of the proximal disc[2, 19].
This study aims to experimentally analyze the effect of cement polymerization temperature in relation to these findings using human cadever and pig cadever which is most similar with human spine.

## 1.2. Constitutes of intervertebral disc

The intervertebral disc is composed of three distinct regions: the outer annulus fibrosus, the inner nucleus pulposus, and the superior and inferior cartilaginous endplates. The annulus fibrosus consists of concentric lamellae made of fibrocartilage that are rich in type I collagen, providing structural strength. In contrast, the nucleus pulposus is a less structured, jelly-like substance, abundant in type II collagen and proteoglycans. The cartilaginous endplates, similar in composition to articular cartilage, serve to anchor the annulus fibrosus and nucleus pulposus to the adjacent vertebral bodies. Together, these three regions form a complex structure that imparts the biomechanical properties necessary for spinal stability, while also allowing for movement, such as flexion, extension, and rotation, particularly in the anterior portion of the spine.

The cells within the nucleus pulposus primarily consist of notochordal and chondrocyte-like cells. In the intervertebral disc of a healthy adult, these cells account for only about 1% of the total volume, dispersed throughout a substantial extracellular matrix. While nucleus pulposus cells typically produce only type II collagen in alginate bead cultures, annulus fibrosus cells are capable of synthesizing both type I and type II collagen.

## 1.3. Critical temperature

Mild temperature increases (41–45°C) for 30 minutes can cause cellular damage, but this damage is typically reversible and non-lethal. Within this temperature range, heat-induced physiological effects may include an acceleration of metabolism or cellular processes, enzyme inactivation, rupture of cell membranes, and a delayed increase in blood flow and vessel permeability. However, when temperatures exceed 45°C or are sustained for a longer duration, cellular repair mechanisms fail due to protein denaturation or an inability to cope with the accumulating damage. This results in complete cell death and tissue necrosis, which typically manifests within 3 to 5 days.

Exposure to temperatures between 42–45°C is frequently used as an adjunct in radiation therapy for cancer and is being explored for enhancing gene therapy and immunotherapy. Temperatures around 50°C are being studied for inducing beneficial physical changes in tissues, such as controlled thermal coagulation to "tighten" ligaments and joint capsules, tissue reshaping, and selective thermal coagulation for destroying both malignant and benign tumors. Exposure to high temperatures (50°C) causes irreversible denaturation of cellular proteins and changes in tissue structure, leading to immediate thermal coagulation of the tissue[20].

Since the likelihood of thermal injury to osteocytes and chondrocytes is influenced by both temperature and duration of exposure, these variables were considered when assessing the potential for cell necrosis and apoptosis. The literature analyzes the effects of temperature and duration on bone and cartilage, noting that exposure to 45°C for 15 minutes can induce partial death of cartilage, while 50°C for 5 minutes can result in the death of over 50% of chondrocytes. Additionally, exposure to 50°C for 1 minute can cause partial necrosis of bone[14].

Thermal coagulation of soft tissues requires temperatures exceeding 50°C, and collagen subjected to temperatures greater than 60 to 65°C for several minutes will undergo coagulation necrosis.

For mammalian collagens, the shrinkage temperature remains fairly constant at around 65-67°C. However, for fish and invertebrate collagens, it can vary significantly, ranging between 35 and 55°C. Similarly, the denaturation temperature of collagen molecules in solution is relatively stable for mammals, around 39-40°C, but it fluctuates between 5°C and 30°C in fish. The difference between the shrinkage temperature and the denaturation temperature in solution is consistently about 27°C across most species.[21]

# II. Materials and methods

## 1. Materials

1.1. Four pig cadevers

1.2. One human cadever

1.3. C-arm(GEMSS health care Co., Ltd, Paju si, Kyunggi do)

1.4. Thermal bath with 5L water(37°C ± 1°C)

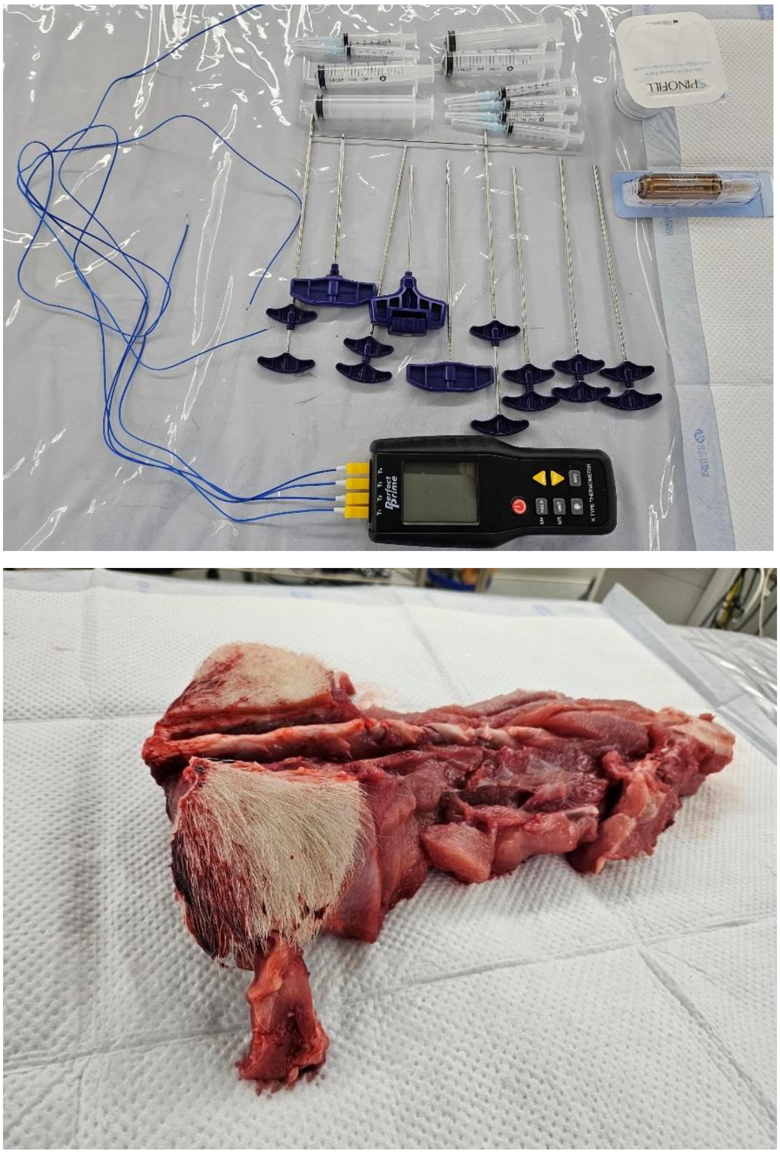
1.5. 4-channel thermometer(PerfectPrime, New York, NY 10013, U.S.A)

1.6. K-type thermocouples(PerfectPrime, New York, NY 10013, U.S.A)

1.7. PMMA cement(Injecta Inc., Gunpo si, Kyunggi do)

1.8. Vertebroplasty needle(Imedicom Co., Ltd., Gunpo si, Kyunggi do)

1.9. 20cc syringes, 2cc syringes(Korea vaccine Co., Ltd, Song pa gu, Seoul)



<Figure 1> Experimental materials(Thermometers, Kyphoplasty set, Syringes, PMMA cement, Pig cadaver)

## 2. Methods

### 2.1. Porcine spines

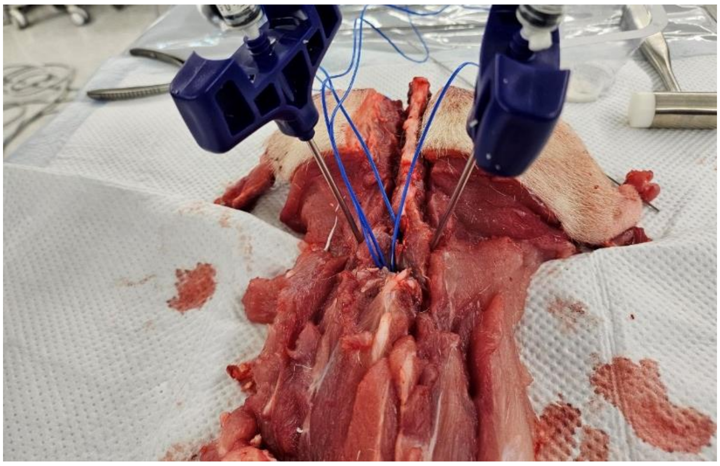
Four porcine spines, known for their structural and dimensional similarity to human spines, were prepared for the experiment[22]. The porcine spines were sourced from animals weighing an average of 46 kg, with all spines dissected while preserving the intervertebral discs.

Since external temperature and humidity could affect the experiment, it was conducted in a controlled environment with humidity levels between 50-60% and a temperature range of 24-27°C.

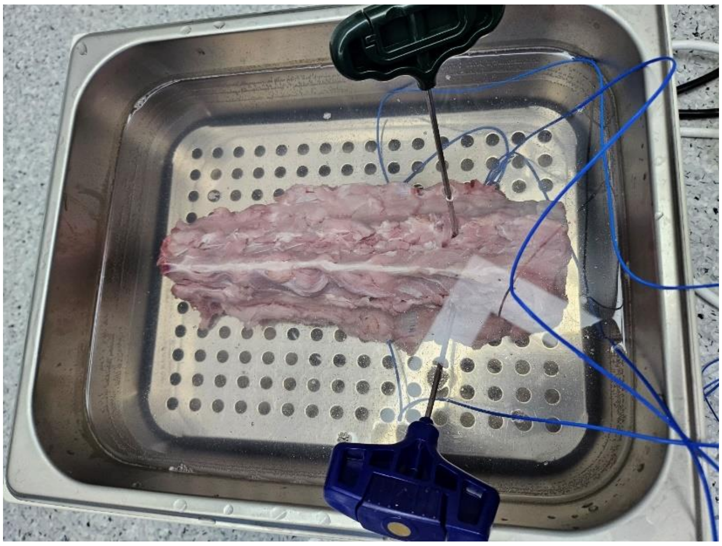
One 4-channel thermometer and four K-type thermocouples were prepared to measure the polymerization temperature and vertebroplasty needle.

Among 4 channels, 1st channel was inserted in the middle of vertebral body(bone cement insertion site), 2nd channel in the anterior part of proximal disc, 3rd channel in the middle part of proximal disc and 4th channel was inserted in the posterior part of proximal disc.

Two specimens were positioned in the air and the other two specimens were positioned in an 5L water bath at 37°C ± 1°C. The temperature was kept constant by help of a heating plate on the bottom of water bath.



<Figure 2> Pig cadaver in the air



<Figure 3> Pig cadaver in the warm bath

After thoroughly mixing the liquid MMA monomer with the powdered MMA-styrene co-polymer, the mixture was transferred into a 20cc syringe. The cement injection was initiated using the standard method, which begins at the appropriate viscosity after 7 minutes from the start of mixing.

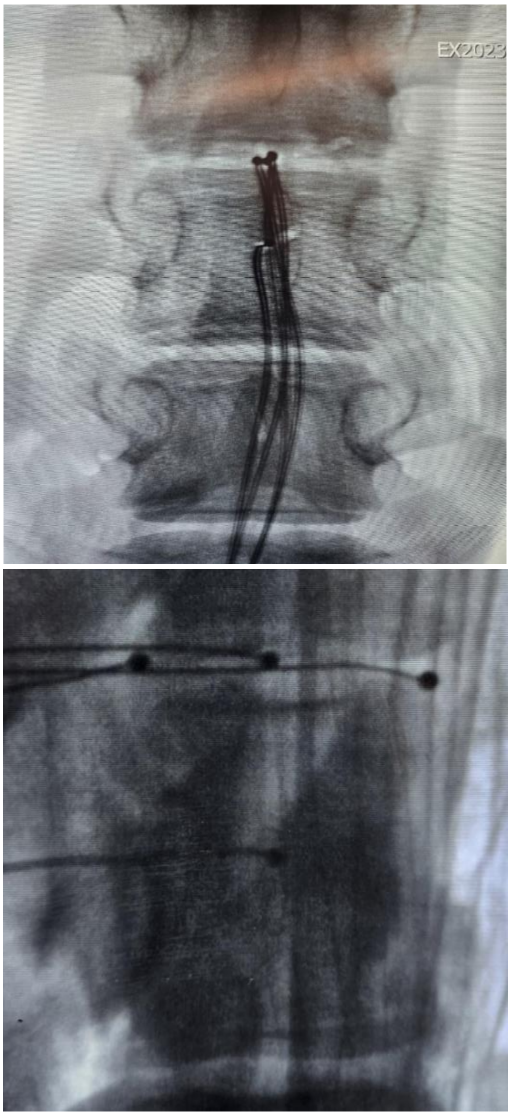
The solvent was poured in completely and mixed for 30 seconds, followed by a 30-second rest. The mixture was then transferred into a 20cc syringe, rested for another minute, and subsequently moved into a 2cc syringe. After resting for 5 minutes, injection began when the cement formed a long thread-like consistency as the syringe plunger was pushed.

In vertebroplasty, there are two approaches: the unipedicular and the bipedicular approach[19]. In this experiment, the bipedicular approach was used, with 4cc of PMMA injected per pedicle, totaling 8cc.

Vertebroplasty was done at twenty vertebral bodies(L1,L2,L3,L4,L5 for each vertebral column) and five measurements were excluded because they were not performed correctly due to extravasation in any direction.Total fifteen measurements of porcine spine were included in this experiment.

After the full insertion of 8cc of PMMA, temperature measurements were taken at four different locations at 1-minute intervals for a duration of 10 minutes.

All the procedures mentioned above were performed under C-arm guidance.




<Figure 4> Location of thermocouples in pig cadaver

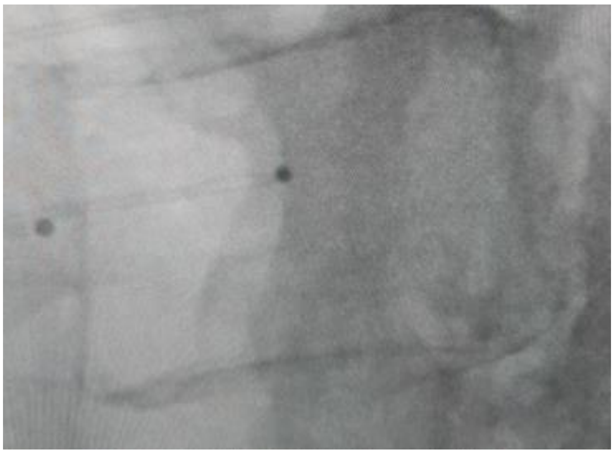
## 2.2. Human spines

The human cadaver used was that of an 89-year-old female who passed away from end-stage renal disease.

Since external temperature and humidity could affect the experiment, it was conducted in a controlled environment with humidity levels between 50-60% and a temperature range of 24-27°C and specimen was positioned in the air.

Two 4-channel thermometer and five K-type thermocouples were prepared to measure the polymerization temperature and vertebroplasty needle.

Among 5 channels, 1st channel was inserted in the middle of vertebral body(bone cement insertion site), 2nd channel in the anterior part of proximal disc, 3rd channel in the middle part of proximal disc, 4th channel was inserted in the posterior part of proximal disc and 5th channel was inserted at the location of posterior longitudinal ligament(PLL). The temperature near the PLL was measured to reflect the temperature at the anterior wall of spinal canal.



<Figure 5> Additional location of thermocouples in human cadaver

In this experiment, the bi-pedicular approach was used, with 4cc of PMMA injected per pedicle, totaling 8cc.

Vertebroplasty was done at seven vertebral bodies(T11, T12, L1, L2, L3, L4, L5) and all measurements were successfully done without extravasation of bone cement.

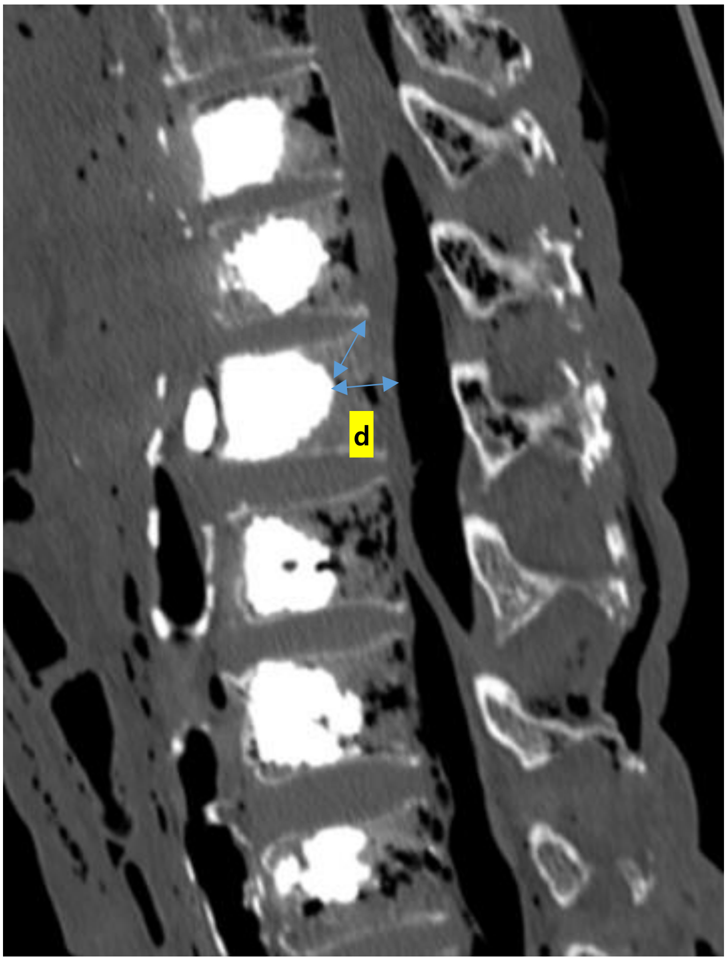
After the full insertion of 8cc of PMMA, temperature measurements were taken at four different locations at 1-minute intervals for a duration of 10 minutes.

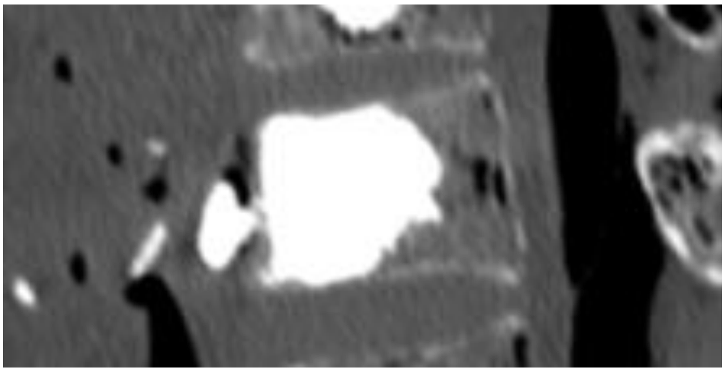
All the procedures mentioned above were performed under C-arm guidance.

### 2.3. CT scan

After inserting PMMA cement into the vertebrae of pigs and humans, we measured the shortest distances from the cement to the anterior, middle, and posterior regions of the disc, as well as to the PLL (posterior longitudinal ligament) area in human vertebrae, in order to analyze the correlation between these distances.

The relationship between temperature and distance was statistically analyzed using Pearson correlation analysis.





.<Figure6> CT scans of human cadaver after PMMA insertion

# III. Results

When the experiment was conducted without a water bath on porcine cadavers, the average core temperature was 81.2°C, while the temperature at the middle of the disc was 57.1°C, with a standard deviation of 11.7°C.

<Table 1> Average Temperatures in Porcine cadaver in the air

| Core | Disc anterior | Disc middle | Disc posterior |
|---|---|---|---|
| 81.2°C (±8.3) | 41.4°C (±7.7) | 57.1°C (±11.7) | 38.4°C (±7.0) |

In contrast, when performed within a water bath, the core temperature of the vertebral body was 66.1°C, and the disc middle measured at 48.2°C, with a standard deviation of 6.3°C.

<Table 2> Average Temperatures in Porcine cadaver in the warm bath

| Core | Disc anterior | Disc middle | Disc posterior |
|---|---|---|---|
| 66.1°C (±3.5) | 42.8 °C (±4.7) | 48.2°C (±6.3) | 40.5°C (±3.5) |

In human cadavers, the average core temperature was 77°C, while the temperature at the disc center measured 52.1°C.

<Table 3> Average Temperatures in Human Cadaver

| Core | Disc anterior | Disc middle | Disc posterior | PLL |
|---|---|---|---|---|
| 77.5°C(±13.4) | 46.7°C(±5.1) | 52.2°C(±10.9) | 29.6°C(±3.8) | 27.1°C(±5.2) |

On porcine cadavers in the air, among the nine vertebrae examined, eight discs reached temperatures exceeding 50°C, whereas, within the water bath, only three out of six vertebrae reached temperatures above 50°C.

In the air, 6 out of 9 discs maintained a temperature above 50°C for more than 1 minute, while in the water bath, 2 out of 6 discs maintained a temperature above 50°C for more than 1 minute.

In human cadavers, among seven vertebra, six proximal discs exceeded 50°C. Among them, 5 discs maintained a temperature above 50°C for more than 1 minute. Near the PLL, the temperature was significantly lower, reaching only average temperature 27.1°C, indicating minimal heat increase in this area near nerve.

<Table 4> Percentage of Discs with Temperatures Above 50°C

| Porcine, air | Porcine, warm bath | Human cadaver |
|---|---|---|
| 8/9(87.5%) | 3/6(50%) | 6/7(85.7%) |

When analyzing temperature according to distance, in porcine cadavers exposed to air, 34.8% of the areas within 0-5 mm from the cement reached temperatures above 50°C, while no areas beyond 5 mm surpassed 50°C. Similarly, in the water bath group, 30.8% of areas within 5 mm exceeded 50°C, but no areas beyond 5 mm did.

In human cadavers, 53.3% of areas within 5 mm from the cement reached temperatures over 50°C, while no areas beyond 5 mm reached such temperatures. The relationship between distance and temperature showed a negative correlation and was statistically significant by Pearson correlation analysis($P<.001$).

<Table 5> Percentage of Discs with Temperatures Above 50°C

| | Porcine, air | Porcine, warm bath | Human cadaver |
|---|---|---|---|
| 0-5mm | 8/23(34.8%) | 4/13(30.8%) | 8/15(53.3%) |
| >5mm | 0/4(0%) | 0/5(0%) | 0/13(0%) |

# IV. Discussion

The results of this experiment indicate that the insertion of PMMA bone cement can elevate the temperature of the adjacent intervertebral disc to critical temperature of 50°C , and this effect is related to the distance from the cement.

Since the temperature did not exceed 50°C in the vicinity of adjacent nerves, we can estimate that the impact on the nerves is minimal; however, it may vary depending on the distance from the cement.

There are some limitations in the study. The margin of error for the thermometer (±1°C) could be a limiting factor and in living human bodies, not only are the temperatures typically between 35-40°C, but there may also be differences in the movement of substances or heat through blood vessels, such as Batson's plexus, compared to experimental conditions. Also, the temperature can vary depending on the amount of bone cement.

When inserting the thermometer, additional holes need to be created. While this may seem to reflect the heat dissipation influenced by blood supply in bone, it is important to reconsider its impact on the disc, which is a characteristic avascular structure.

The amount and distribution of muscle and soft tissue can vary between individuals, potentially affecting the degree of heat diffusion.

In vertebroplasty, the pattern of cement distribution varies between vertebrae. Even when comparing temperatures based on proximity, it should be considered that the quantity of cement might still be low despite the close distance.

Additionally, as mentioned earlier, the disc is composed of various elements, each with a different critical temperature. The range of temperatures reported in the literature varies, and critical temperatures may differ across individuals, so it is important to recognize that in vivo conditions may not directly align with experimental results.[14, 20, 21, 23]

Comparing the use of a water bath and the absence of one, the peak temperature was lower when a water bath was used. This is likely due to the higher specific heat capacity of water compared to air or vapor. Factors such as the water temperature and its mineral content could alter the specific heat capacity, which may influence the observed temperatures[24-26]. Although average peak temperature of proximal disc(in warm bath) didn’t exceed 50°C, it exceeded 45°C in which cellular repair mechanisms fail due to protein denaturation or an inability to cope with the accumulating damage[20].

The differences in temperature changes observed between porcine and human spines are likely due to structural differences, even though they are similar. Additionally, when we typically perform vertebroplasty or insert cement-augmented screws, we are often dealing with elderly osteoporotic patients, which may further contribute to differences compared to porcine cadavers. The human cadaver used in this experiment was a female patient, 89 years old, with end-stage renal disease. Although we could not directly measure bone density, there is a high likelihood that she was osteoporotic, and the results are expected to be similar to those of the usual target population for bone cement use.

Despite these limitations, efforts were made to reduce bias by standardizing factors that could affect the experimental results, such as temperature, humidity, and the approach (unipedicular versus bi-pedicular approach)[27, 28].

For future studies, I would like to explore disc degeneration at the cellular level through in vivo animal experiments to further substantiate the findings in comparison to other study.[29]

# V. Conclusions

This experiment demonstrates that the insertion of bone cement into the vertebral body can elevate the temperature of the proximal adjacent disc to levels exceeding the critical temperature. Therefore, clinicians should fully consider the potential negative effects of the exothermic reaction of bone cement before surgery.

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Abstract in Korean

## 골시멘트의 척추체로의 주입이 상위 추간판에 미치는 중합온도 관점에서의 부정적 영향

서론:
PMMA와 같은 골시멘트는 척추성형술, 후만 성형술이나 근위 인접 분절 퇴행을 예방하기 위한 시멘트 보강 나사 등 척추 분야에서 널리 사용되고 있다. 골시멘트는 기계적 안정화나 통증 완화와 같은 긍정적 측면을 기대하고 사용하게 되지만, 골시멘트의 중합 과정에서 높은 온도의 발열 반응이 일어나고, 이는 근위 추간판과 같은 인접 구조에도 온도 상승을 유발할 수 있다. 본 연구는 인간 및 돼지 사체를 사용하여 PMMA의 주입 후 나타나는 온도 상승을 근위 추간판에서 측정함으로써 근위 추간판에 미치는 영향을 조사하고자 하였다.

재료 및 방법:
본 연구는 돼지 사체 4구와 인간 사체 1구를 대상으로 하였다. K형 열전대를 사용하여 척추체와 근위 추간판의 다양한 위치(앞, 중간, 뒤)에서 중합 온도를 측정하였다. 돼지 사체 2 구는 공기 중에서, 나머지 2 구는 인체의 온도를 반영하기 위한 37° C의 수조에서 실험을 진행하였고, 인간 사체 1구는 공기중에서 측정하였다. 골시멘트 주입은 양측 척추경 접근법(bi-pedicular approach)이 사용되었으며, 주입 후 10분 동안 1분 간격으로 온도를 측정하였다.

결과:
돼지 사체에서 공기 중에서 실험하였을 때 근위 추간판의 최고온도의 평균은 57.1° C였으며, 항온 수조에서는 48.2° C로 측정되었다. 인간 사체의 경우, 근위 추간판 최고 온도의 평균은 52.1° C로 나타났고, 후종인대에서의 최고 온도의 평균은 27.1° C로 측정되었다. 온도 측정 지점과 골시멘트 사이의 거리와 온도 간에는 음의 상관관계가 관찰되었다.

토론:
이 연구는 골시멘트의 삽입이 인접 추간판의 온도를 50° C의 임계 수준까지 상승시킬 수 있음을 보여주며, 이는 시멘트로부터의 거리와 관련이 있음을 확인할 수 있었다. 거리에 따라 달라질 수 있지만, 후종인대의 온도를 고려하였을 때 신경에

미치는 온도의 영향은 적을 것으로 사료된다.
이 실험의 제한점으로는 온도계의 오차 범위(±1° C), 실험 조건과 in vivo(생체 내) 조건의 차이, 개개인 간의 근육과 연부 조직 분포의 차이, 시멘트 분포의 차이가 열 확산에 영향을 미칠 수 있으나 조건 통제에 어려움이 있다는 것이다.

결론:
본 연구는 PMMA 중합 때 발생하는 발열 반응이 인접 구조의 온도에 상당한 영향을 미칠 수 있으며, 이는 근위 추간판의 퇴행을 유발할 가능성이 있다.

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**핵심되는 말** : 추간판; 척추성형술; 골시멘트; 퇴행; 근위 인접분절 퇴행