

***In vitro* heat transfer from epoxy polymer and poly(methyl methacrylate) to fixation pins: recommendations to avoid tissue damage in free-form external skeletal fixation**

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ABSTRACT: External skeletal fixation has been used for the management of fractures of many types of bone. The use of polymeric free-form connecting bars in external fixators has become widely used in veterinary orthopaedics because of its versatile forms of frame construction and its relative low costs. Determining thermal-transfer to trans fixation pins during polymerisation of poly(methyl methacrylate) and epoxy putty polymers used for free-form external skeletal fixation connecting bars is important for avoiding temperatures of more than 47 °C, which would cause thermal soft tissue injury. Therefore, thermal transfer to trans fixation pins was measured *in vitro* during the polymerisation phase of these polymers. We used trocar-pointed pins of different diameters that punctured one wall of a connecting tube, resulting in the tip of the trocar-pointed pin reaching the centre of the tube. The FLUKE® VT02 infrared digital camera was then used to measure heat transfer to the pins at 1 or 2 cm from poly(methyl methacrylate) or epoxy putty. The polymerisation temperatures of these polymers yield a potentially dangerous level of heat for soft and hard tissue. This was observed in almost all the experimental conditions tested. On the other hand, epoxy putty transfer to the pins did not cause the temperature to reach 47 °C at any time or in any of the setups examined. Poly(methyl methacrylate) did reach more than 47 °C and remained at that level for more than 1 min at 1 cm from the polymer. This acrylate exhibited polymerisation temperatures higher than epoxy and its heat transfer to the pins was potentially dangerous if used at less than 1 cm from soft or hard tissue.

Keywords: epoxy putty; bone necrosis; exothermic polymerisation; infrared digital image

List of abbreviations

AP = alkaline phosphatase, **EPOX** = epoxy putty, **ESF** = external skeletal fixation, **FOV** = field of view, **FPA** = focal plane array, **HTI** = highest temperature interval, **IR** = infra, **PMMA** = poly(methyl methacrylate), **Tmax** = maximum polymerisation temperature

External skeletal fixation (ESF) has been used for the management of fractures of different severities in many different types of bone. This technique involves a process of bone structure alignment and stabilisation, with pins that attach the bone fragments to an external stiff frame (Roe 2005). The use of external fixators for the treatment of open fractures, non-union, arthrodesis and growth deformity corrective surgery are commonly used in

veterinary orthopaedics (Ozsoy and Altunatmaz 2003; Theyse et al. 2005; Rahal et al. 2006; Seibert et al. 2011; Cappellari et al. 2014; Arias et al. 2015). This system consists of an extracorporeal frame and fixation elements – either pins or small-diameter wires – that stabilise the engaged bone segments that are connected with clamps to steel, aluminium or reinforced carbon-fibre connecting bars (Tyagi et al. 2014). These devices provide rigid skeletal fixa-

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tion while permitting access to soft tissue injuries during fracture healing. The use of polymeric free-form connecting bars in external fixators has become widely used in veterinary orthopaedics (Okrasinski et al. 1991; Willer et al. 1991; Egger 1992; Roe and Keo 1997; Davis et al. 1998; De La Puerta et al. 2008).

This free-form type of fixation has the advantage that pin direction and diameter do not need to be influenced by the connecting bar location or by the clamp size, respectively (Roe and Keo 1997).

Poly(methyl methacrylate) (PMMA) is the most widely used polymer to be applied as a connecting bar (Preininger et al. 2012). This polymer has not only been used for these purposes, but also as hip implant cement (Gemmill et al. 2012; Roe et al. 2012; Song et al. 2013), for vertebral fixation and fusion (Sanders et al. 2004; Aikawa et al. 2013; Hettlich et al. 2013) and in maxillofacial surgery (Cook et al. 2001). This is due to the low cost of materials, the simplicity of the technique and its adaptability to a wide variety of pin diameters when compared with the clamp and rod device. An acrylic connecting bar can easily be contoured to the shape of the body and allows the surgeon to place trans-cortical pins in different planes (Shahar 2000; Alam et al. 2006). The PMMA hardens *in situ* through an exothermic polymerisation process, which takes about 10 minutes. This process can affect surrounding soft (Martinez et al. 1997) and hard tissue (Feith 1975; DiPisa et al. 1976; Li et al. 2003; Radev et al. 2009; Tyagi et al. 2014) by means of heat necrosis, when preventive actions are not taken.

Studies on PMMA made by Preininger showed that measurements of polymerisation temperature yielded maximum PMMA surface temperatures ranging from 101 °C to 110 °C and a two-minute-plateau of > 100 °C (Preininger et al. 2012). Previous studies exploring the fixation pin conductivity of heat from PMMA polymerisation have suggested a 1-cm safety margin to the tissue when the polymer is used as free-form ESF (Williams et al. 1997).

Previous studies have also reported deleterious effects on soft tissue with temperatures of 47 °C after one minute of exposure; one minute of 70 °C would have the same effect on bone tissue by means of denaturation of alkaline phosphatase (AP) enzyme (Matthews and Hirsch 1972; Rhinelanders et al. 1979; Eriksson et al. 1982; Eriksson and Albrektsson 1983; Berman et al. 1984; Eriksson and Albrektsson 1984; Eriksson et al. 1984). Eriksson explored the minimum amount of heat needed to

produce bone damage using a thermal chamber for intravital microscopy of heated bone tissue. They showed that a temperature of only 50 °C for one minute is sufficient to produce bone tissue damage (Eriksson et al. 1982; Eriksson and Albrektsson 1983; Eriksson and Albrektsson 1984; Eriksson et al. 1984).

Epoxy putty (EPOX) has been compared to PMMA with respect to its biomechanical properties when used in free-form external skeletal fixation (Roe and Keo 1997; Goldberg et al. 2005; Tyagi et al. 2014). These studies showed a similar strength and greater apparent modulus of EPOX when compared with the PMMA (Roe and Keo 1997), making it a good alternative for free-form external fixation.

The purpose of this study was to determine the maximum heat of polymerisation generated by PMMA and EPOX and to assess biologically dangerous thermal transfer levels along stainless steel trans fixation pins of different diameters in a controlled *in vitro* environment.

MATERIAL AND METHODS

Study design. *In vitro* type I ESF were created using one 4.7 mm × 100 mm or a 2.7 mm × 100 mm trocar-pointed Steinmann intramedullary pin. These were placed perpendicularly to the bench and were suspended with a clamp holder fixed to a stand. Pieces of a tube were punctured in one wall such that the tip of the trocar-pointed pin reached the centre of the tube (Figure 1). These tubes were composed of anaesthesia aerosol hose (Hudson RCI[®], Teleflex Medical, Research Triangle Park, USA) of 21 mm inner-diameter. Two different length of tubing filled with 33 cm³ and 17 cm³ of polymer as connecting bars, were used. Dental acrylic PMMA (Marche[®], Santiago, Chile) and EPOX (POXILINA[®] 10 minutes, Akapol S.A., Buenos Aires, Argentina) were used and compared. The polymers were weighed and mixed as recommended by the manufacturer and used to fill the tubes of anaesthesia.

The temperature of the polymer was measured using a digital thermometer (Thermistor HI 93503, HANNA INSTRUMENTS, Woonsocket, USA) at the centre of the tube (Figure 1). The pin's temperature of dissipation during polymerisation was measured using *in situ* tele-thermographic measurements (Preininger et al. 2012) with an infrared

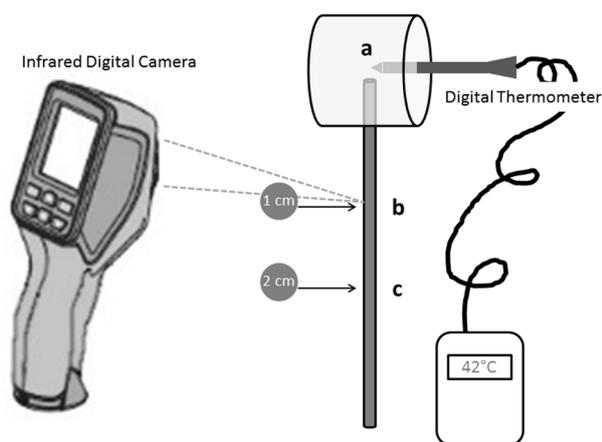


Figure 1. Basic diagram of the experimental thermal-measurement setup. An infrared digital camera was used to measure the thermal transfer to *in vitro* type I external skeletal fixators. Thermal measurement of polymerisation temperatures was performed in the middle of the polymers with a digital thermometer (a). Heat transfer measurement-point at 1 cm (b). Heat transfer measurement-point at 2 cm (c)

digital camera (FLUKE® VT02, Everett, USA) at 1 and 2 cm of the anaesthesia tube (Figure 1). This technology has been used to measure *in situ* polymerisation of PMMA *in vivo* and *in ex vivo* settings to measure differences in bone temperature generated during dental implant site preparation (Lucchiari et al. 2016). In this last publication, the accuracy of the temperature measurements recorded with the IR thermometer as well as that of the imaging and optical data was tested and contrasted by taking a series of measurements with a thermocouple (a method widely described in the literature) with a contact probe (FLUKE® 51, Everett, USA) inserted in the bone marrow. The authors concluded that IR imaging was a relatively inexpensive tool, easier to use and more accurate than a thermocouple. This technology has been recommended for the standardisation of experiments that measure bone temperatures (Mohlhenrich et al. 2015).

Resolution. The resolution of the infrared digital camera was 80×80 pixels, with a thermal sensitivity of $< 0.1 \text{ }^\circ\text{C}$ ($0.18 \text{ }^\circ\text{F}$), field of view (FOV) of $17^\circ \times 17^\circ$, minimum focus distance of 0.6 m (2 ft.), spatial resolution (IFOV) of 3.7 mrad and image frequency of 9 Hz; focus-free mode was used.

Detector data. The focal plane array (FPA) detector type was used with an uncooled microbolometer and a spectral range of $7.5\text{--}13 \text{ }\mu\text{m}$.

Measurements. Temperature measurement for this model of infrared camera ranges from $-20 \text{ }^\circ\text{C}$ to $+250 \text{ }^\circ\text{C}$ ($-4 \text{ }^\circ\text{F}$ to $+482 \text{ }^\circ\text{F}$), with an accuracy of $\pm 2 \text{ }^\circ\text{C}$ ($\pm 3.6 \text{ }^\circ\text{F}$) or $\pm 2\%$ of reading. Background temperature was set in the menu of the VT02 to $24 \text{ }^\circ\text{C}$ and emissivity to 0.28ϵ , which corresponds to Type 316 polished surgical stainless steel at a temperature of $45 \text{ }^\circ\text{C}$ ($75 \text{ }^\circ\text{F}$). These parameters are given by the manufacturer as the emissivity values of common materials.

The camera was fix-mounted at 20 cm from the Steinmann intramedullary pin and the central-point aim-marker pointing to the desired measuring site. The PMMA and EPOX used in these experiments both hardened within 10 minutes. Thus, values were recorded every 30 seconds for each measurement point for a total time of 11 minutes. These measurements were taken for the two different quantities of PMMA and EPOX, with the two classes of Steinmann pins, in five repetitions each (Table 1).

Statistical analysis. For each treatment (polymer type, polymer quantity and tube diameter), five measurements were considered to represent the highest temperature interval (HTI). This interval was considered as the time when the maximum polymerisation temperatures (T_{max}) was recorded, $\pm 30 \text{ s}$ and $\pm 60 \text{ s}$. These measurements of HTI were performed at 1 cm and 2 cm from the polymer. Non-parametric Kruskal-Wallis ANOVA and *a posteriori* pair comparison tests were used to identify differences among treatments (Conover 1999).

RESULTS

Polymerisation temperatures

T_{max} values in the centre of the polymer for PMMA and EPOX are showed in Table 2. A poten-

Table 1. Temperature measurements of poly(methyl methacrylate) and epoxy putty

Volume of polymer	Type of pins	Points of temperature measurement (cm)	Number of repetitions for each point
17 cm ³	2.7 mm	0; 1 and 2	5
	4.7 mm	0; 1 and 2	5
33 cm ³	2.7 mm	0; 1 and 2	5
	4.7 mm	0; 1 and 2	5

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Table 2. Average highest temperature interval (HTI) in degrees Celsius (°C) for each experimental setup with epoxy putty (EPOX) and poly(methyl methacrylate) (PMMA), 1 cm from the polymer

Setup	Average HTI	SD
EPOX 4.7 × 17	31.7	0.94 ^a
EPOX 2.7 × 33	31.7	0.94 ^a
EPOX 2.7 × 17	28.3	1.62 ^a
EPOX 4.7 × 33	37.6	2.62 ^c
PMMA 2.7 × 17	46.4	8.07 ^d
PMMA 4.7 × 33	49.6	7.53 ^d
PMMA 4.7 × 17	48.8	6.75 ^d
PMMA 2.7 × 33	47.0	5.58 ^d

Different letters indicate significant differences between the mean results of the setups ($P < 0.05$)

tially dangerous level of heat transfer to soft tissue (temperatures over 47 °C) and hard tissue (temperatures over 50 °C) was observed with almost all the tested experimental setups. The Tmax of the PMMA measurements reached temperatures well over the 80 °C (Figure 2), while the EPOX did not

reach 60 °C at the peak of the exothermic reaction of polymerisation (Figure 3).

Heat transfer from polymer to the pins

Significant differences were found in the HTI ($H = 154.49, P < 0.05$, and $H = 153.94, P < 0.05$; for measurements at 1 cm and 2 cm from polymer, respectively). For measurements taken at 1 cm from the polymer, all treatments with PMMA had significantly higher temperatures than those with EPOX. No differences were observed for all setups of PMMA, with average heat transfer temperatures being in the soft tissue damage range. All temperatures observed with EPOX were at least 10 °C lower than the soft tissue damage range. The lowest temperatures were obtained with the EPOX 4.7 mm × 17 cm³ setup (Table 2). For measurements performed at 2 cm from the polymer, the same pattern was observed, but with all HTI average temperatures well below the soft tissue damage range. All setups based on PMMA polymer had significant higher temperatures when compared

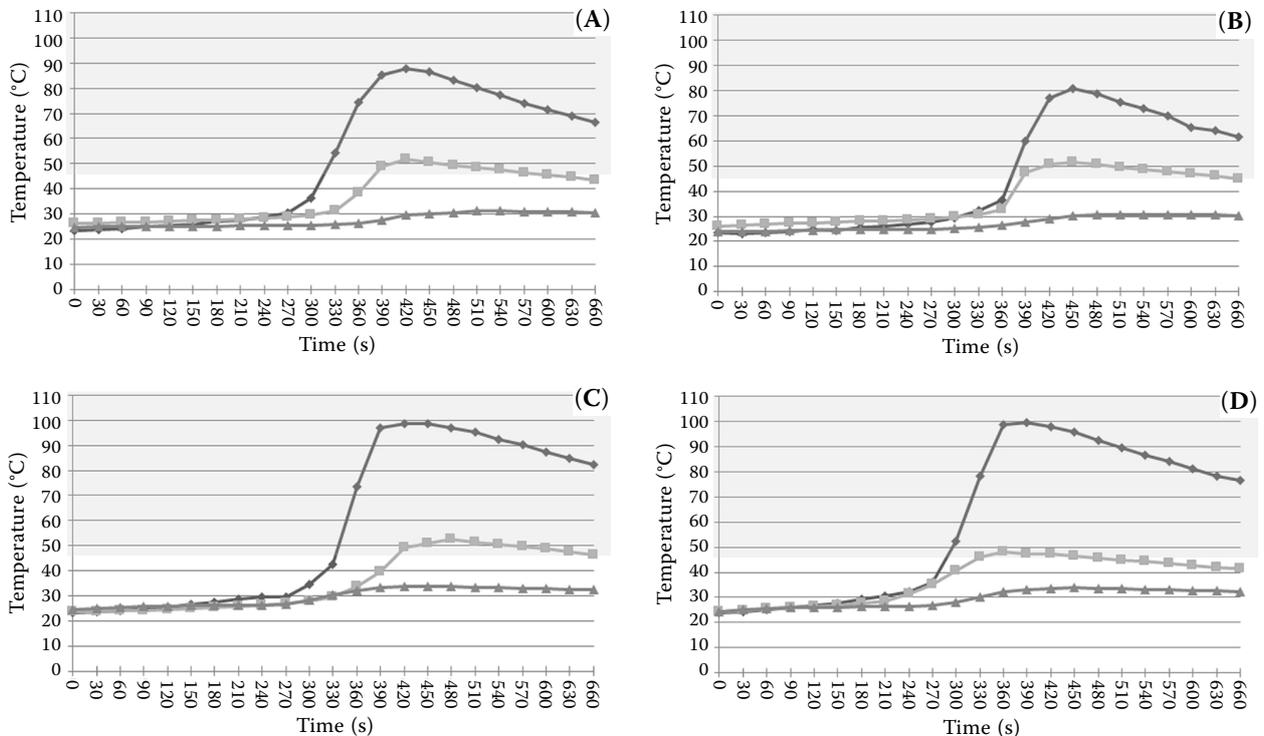


Figure 2. Mean measurements of poly(methyl methacrylate) polymer temperatures and heat transfer in the 11-minute polymerisation reaction. Graphs represent the 17 and 33 cm³ polymer volume setups with 2.7 and 4.7 mm Steinmann intramedullary pins. Lines show temperatures at the centre of the polymer (◆), 1 cm (■) and 2 cm (▲) from the Steinmann pin

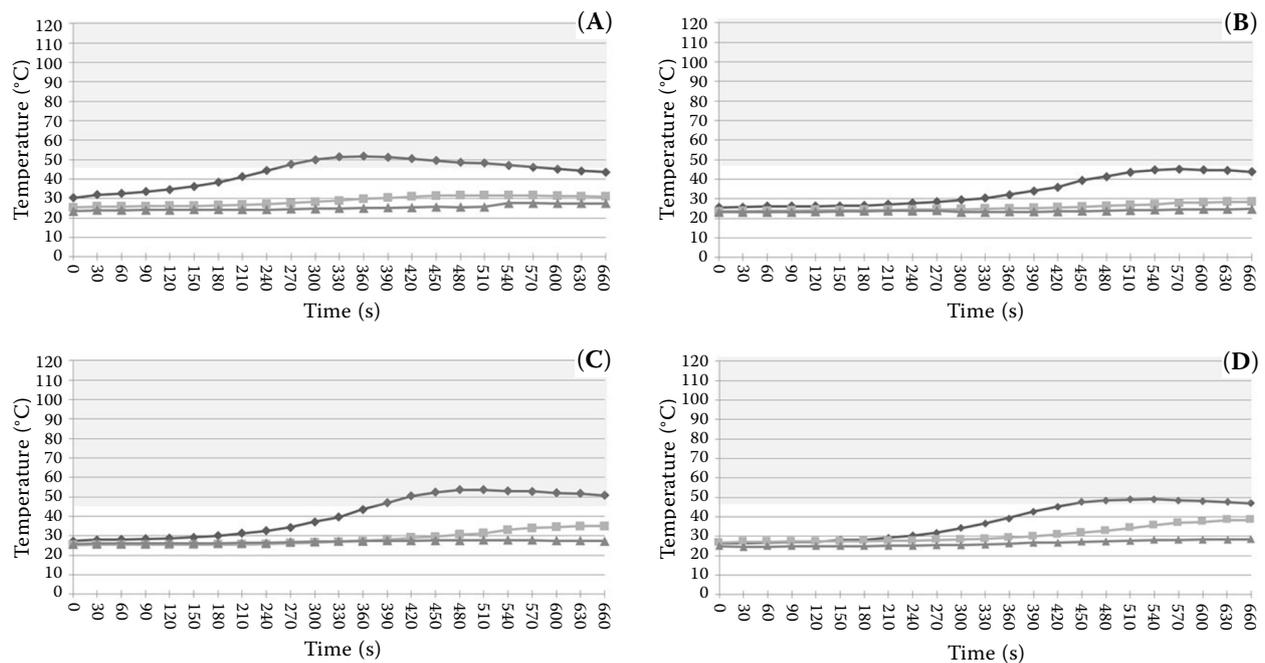


Figure 3. Mean measurements of epoxy polymer temperatures and heat transfer during the 11-minute polymerisation reaction. Graphs represent the 17 cm³ polymer volume setup with 2.7 mm Steinmann intramedullary pins (A), 17 cm³ polymer volume setup with 4.7 mm Steinmann intramedullary pins (B), 33 cm³ polymer volume setup with 2.7 Steinmann intramedullary pins (C) and 33 cm³ polymer volume setup with 4.7 mm Steinmann intramedullary pins (D). Lines show temperatures at the centre of the polymer (◆), 1 cm (■) and 2 cm (▲) from the Steinmann pin

to EPOX setups, and PMMA 4.7 mm × 33 cm³ and 2.7 mm × 33 cm³ showed the highest temperatures. The lowest temperature, meanwhile, was recorded with EPOX 4.7 mm × 17 cm³ (Table 3).

DISCUSSION

The EPOX results show that the heat transfer from the polymerising putty to the pins did not reach 47 °C at any time and with any of the experimental setups tested (Figure 3), regardless of the amount of EPOX or the diameter of the pin used. This means that both bone and nerve tissue would not undergo irreversible injury and cell death, because they would not be exposed to temperatures over 47 °C for 1 to 2 minutes, as described by Goldberg (Goldberg et al. 2005) and others before him (Matthews and Hirsch 1972; Xu and Pollock 1994).

The PMMA results demonstrate that, at 1 cm from the polymer, in all of the tested experimental setups a temperature of 47 °C was reached and maintained for more than 1 min. However, only three of the four experimental conditions (both

of the 17 cm³ polymer volumes and the 33 cm³ with 2.7 mm pin) reached a temperature of 50 °C for more than 1 min. This has been described as the minimal condition necessary for bone damage to occur (Eriksson and Albrektsson 1983; Eriksson and Albrektsson 1984; Eriksson et al. 1984) (Figure 2). This differs from the recom-

Table 3. Average highest temperature interval (HTI) in degrees Celsius (°C) for each experimental setup with epoxy putty (EPOX) and poly(methyl methacrylate) (PMMA), 2 cm from the polymer

Setup	Average HTI	SD
EPOX 4.7 × 17	27.5	0.65 ^a
EPOX 2.7 × 33	27.5	0.65 ^b
EPOX 2.7 × 17	25.1	1.66 ^b
EPOX 4.7 × 33	28.6	2.47 ^b
PMMA 4.7 × 17	31.1	1.62 ^c
PMMA 2.7 × 17	33.5	1.21 ^c
PMMA 4.7 × 33	30.7	0.73 ^d
PMMA 2.7 × 33	33.5	1.34 ^d

Different letters indicate significant differences between the mean results of the setups ($P < 0.05$)

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recommendations given by Martinez et al. (1997) and Williams et al. (1997), who proposed the 10 mm mark as the safety limit.

On the other hand, *in vitro* PMMA transfer at 2 cm from the polymer resulted in safe temperatures, far lower than the 47 °C level necessary for tissue damage. In the literature, temperature increases elicited by the drilling of bone as well as K-wire and Steinmann pin insertion are associated with far higher temperatures (Pandey and Panda 2013). Elevation of temperature through this mechanism is much more likely to cause tissue damage and implant loosening (Matthews and Hirsch 1972; Berman et al. 1984; Lucchiari et al. 2016).

In conclusion, epoxy putty is a versatile, inexpensive and safe polymer that is suitable for use in free-form external skeletal fixation, because the exothermic polymerisation process does not transfer enough heat to the fixation pins to affect soft or hard tissue at 1 cm from the polymer.

PMMA, on the other hand, exhibits polymerisation temperatures that are higher than those of Epoxy. The transfer of heat to the pins is also higher. Nonetheless, this thermal transfer is only dangerous when soft or hard tissue is in contact with the fixation pins at less than 2 cm from the polymer.

Based on the results of this study, distances of at least 1 cm from the EPOX polymer and at least 2 cm from the PMMA polymer are recommended.

Finally, it seems highly unlikely that the transfer of heat from the polymerisation of both EPOX and PMMA through the trans fixation pins would elicit bone necrosis and implant loosening, since they are fastened to the bone at distances that normally exceed 2 cm from the polymer.

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