JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE **13** (2002) 17–22

Curing characteristics of acrylic bone cement

N. J. DUNNE[1], J. F. ORR[2]
[1]*School of Mechanical and Manufacturing Engineering, Dublin City University, Glasnevin, Dublin 9, Republic of Ireland*
[2]*School of Mechanical and Manufacturing Engineering, The Queen's University of Belfast, Stranmillis Road, Belfast, BT9 5AH, Northern Ireland*

Commercial acrylic bone cements are supplied as two components, a polymer powder and a liquid monomer. Mixing of the two components is followed by a progressive polymerization of the liquid monomer to yield a solid mass, a high level of heat being generated during this exothermic reaction. The exposure of bone to high temperatures has led to incidences of bone necrosis and tissue damage, ultimately resulting in failure of the prosthetic fixation. The aim of this study was to determine the thermal properties of two acrylic bone cements as they progress through their polymerization cycles. It was also felt that there was a need to quantify the variations in the curing characteristics as a function of preparing bone cement by different techniques, hand mixing and vacuum mixing. A number of parameters were calculated using the data gathered from the investigation: peak temperature, cure temperature, cure time, and the cumulative thermal necrosis damage index. The results show the temperature profile recorded during polymerization was lowest when the cement was prepared using the Howmedica Mix-Kit I® system: 36 °C for Palacos R® and 41 °C for CMW^{3}® respectively. When the acrylic cements were prepared in any vacuum mixing system there was evidence of an increase in the cure temperature. The main factor that contributed to this rise in temperature was an imbalance in the polymer powder : liquid monomer ratio, there was a high incidence of unmixed powder visible in the mixing barrel of some contemporary vacuum mixing devices. Observing the thermal characteristics of the polymethyl methacrylate (PMMA) bone cements assessed, it was found that particular formulations of bone cements are suited to certain mixing methodologies. It is vital that a full investigation is conducted on a cement mixing/delivery system prior to its introduction into the orthopaedic market.

1. Introduction

The exposure of bone to high temperatures has become quite common, especially with the increasing use of acrylic bone cement. With regard to total hip arthroplasty, many authors have commented on the temperature problem induced by the curing polymethyl methacrylate (PMMA) cement mass. It has been shown that three factors can affect bony tissue as a consequence implants using PMMA bone cement [1, 2]:

- Polymerization temperature of bone cement;
- Cyto-toxicity of the liquid monomer;
- Diminished vascularity of the bone due to surgical reaming of the medullary canal.

It has been cited by DiPisa *et al*. [3] that the temperature at the bone-cement interface is a function of:

- The quantity of heat produced by the bone cement;
- The rate at which the heat is produced [4];
- The thermal conductivity and thermal capacity of the bone, prosthesis and the cement [5, 6];
- The initial conditions of the bone/cement prosthesis system, including initial and ambient temperature, and preparation of the cement [7].

Polymerization temperatures range from 40 °C to 110 °C. Meyer *et al*. [8] recorded that setting bone cement never exceeded 110 °C, Revie *et al*. [9] quoted a mean exothermic temperature of 67.46 °C for an unloaded specimen, Huiskes [10] showed that interface temperatures could reach as high as 100–120 °C. *Revie et al*. [9] observed that the cement layer thickness and position of the site of measurement are two factors that influence the exothermic curing temperature. Meyer *et al*. [8] found that the maximum temperature generated was 107 °C for an cement mantle of 10 mm and 60 °C for a mantle of 3 mm. Sih *et al*. [11] showed that for a cement thickness of 1 mm the temperature was 41 °C and for 5 mm 56 °C, and for a cement thickness of 6–7 mm 60 °C. Moritz and

Henriques [12] found that when the temperature of the skin is maintained at 44 °C, the rate of injurious change exceeds that of recovery by so narrow a margin that an exposure of 6 h is required before irreversible damage is sustained at the basal cell level. At surface temperatures of 70 °C and higher the rate of injury so far exceeds that of recovery that less than 1 s is required to cause trans-epidermal necrosis. Feith [1] has shown that epidermal cell necrosis occurs after 5 s at 60 °C, after 30 s 55 °C, and after 5 min at 30 °C. Eriksson and Alberksson [13] found the temperature threshold for impaired bone regeneration to be in the range of 44–47 °C for 1 min exposure. The higher the temperature the shorter the exposure duration before thermal bone necrosis occurs. Lundskog [14] indicated that bone tissue heated at 50 °C for one minute or 47 °C for 5 min will not remain as functioning bone but will become resorbed and replaced with fat cells. Lundskog [14] also observed that bone heated to 47 °C for one minute causes a fat cell injury. This implies that 47 °C is the threshold temperature for the occurrence of morphologically evident bone tissue damage. Eriksson and Alberksson [13] observed that heating to temperatures of 60 °C or more resulted in a permanent cessation of blood flow and bone tissue necrosis, which showed no signs of repair over a follow-up period of 100 days or more.

Attempts to lower the temperature of the polymerizing bone cement and thus the degree of tissue necrosis has been investigated with varied success. Meyer *et al.* [8], found that precooling the prosthesis or the socket were of no benefit in reducing the peak curing temperature, but Larsen *et al.* [17] found a 4–5 °C drop in temperature at the bone/cement interface when using a precooled prosthesis. DiPisa *et al.* [3] observed that cooling the acetabular socket to -84 °C at operation before contact with the bone cement reduced the temperature at the bone/cement interface from 70 °C to 49 °C, this was for a cement mantle of 6 mm. A slightly reduced level of heat generation has been shown by vacuum mixing the bone cement. Lidgren *et al.* [18] and Seidel *et al.* [19] found that the maximum temperature could be lowered from 59 °C to 45 °C by cooling the bone with iced water. Meyer *et al.* [8] discovered that the maximum temperature of the curing bone cement could be lowered by reducing the ambient temperature. It was found in this study that for an ambient temperature of 4 °C the maximum temperature was 53 °C and when the ambient temperature was increased to 37 °C the maximum temperature rose to 125 °C. Haas *et al.* [20] postulated that the reaction rate and temperature as well as the polymeric chain length are influenced by the ratio of polymer powder to liquid monomer. By using the minimum liquid monomer and the maximum polymer powder, the amount of polymerization is minimized, as is the heat generated.

2. Objective

Polymethyl methacrylate bone cement, when curing, reacts exothermically and as a result temperatures may be generated during its polymerization. The aim of this investigation was to determine the temperature characteristics of various acrylic bone cements as they progress through their polymerization cycle. It was also felt that there was a need to assess the variation in the curing characteristics as a function of preparing the bone cements using different mixing techniques. Using the temperature data generated for each condition, the cumulative thermal necrosis damage was calculated with the assistance of data generated by Moritz and Henriques [12]. In addition, the cure time was also determined for each of the conditions analyzed; the cure time being defined as the time at which the acrylic bone cement reaches between 90–100% cure (Fig. 1). The cure temperature is the temperature at which the acrylic bone cement reaches between 90–100% cure. The cure temperature can be quantified using Equation 1.

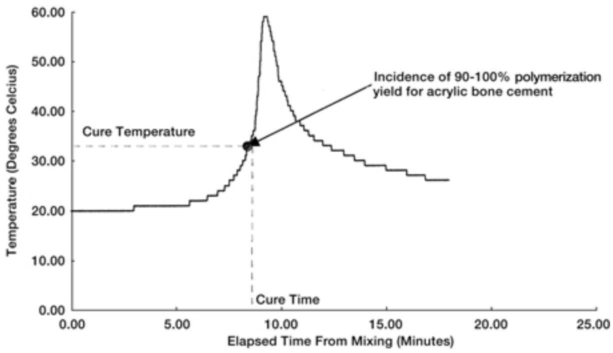

Figure 1 Continuous temperature record of curing acrylic bone cement as acquired using Labtech notebook.

$$\text{Cure temperature} = \frac{T_{\text{maximum}} + T_{\text{ambient}}}{2} \qquad (1)$$

3. Materials and methods

The thermal properties of two commercial grades of acrylic bone cements were assessed when mixed using different commercial mixing devices. The bone cements tested were:

- Palacos R® + gentamicin (normal viscosity), Schering Plough Corp., United Kingdom;
- CMW^{3}® (low viscosity), DePuy Johnson & Johnson, United Kingdom.

The mixing devices varied from a traditional spatula and bowl arrangement (first-generation) to vacuum cement mixing/delivery systems (third-generation):

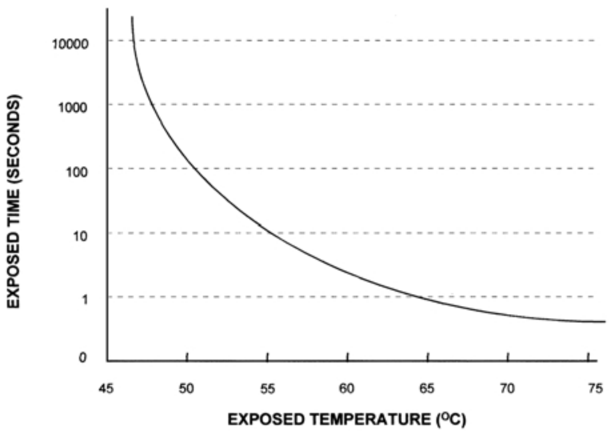

Figure 2 Results produced by Moritz and Henriques [12] showing the exposure time-exposed temperature, used to calculate the time-temperature damage threshold.

TABLE I Thermal diffusivity values illustrating the likeness between the two materials

Material	Thermal diffusivity (m^{-2} sec.$*10^{-7}$
Cancellous bone	0.90–2.50
Polypropylene	0.65–3.00

- Howmedica Mix Kit I®, Howmedica Int. Ltd., Ireland (First-Generation);
- Zimmer Osteobond® Vacuum System, Zimmer, USA (Second-Generation);
- Zimmer Quick-Vac® System, Zimmer, USA (Third-Generation);
- Cemvac®, Cemvac System Corp., Sweden (Third-Generation);
- Stryker High Vacuum Cement Injection® System, Stryker Instruments, USA (Third-Generation).

Single mixes of cement were prepared at 22 °C ambient temperature using the different mixing devices. The cement was mixed as per the manufacturers' instructions. The bone cement was stored at room temperature prior to mixing. However, it is important to note that prechilling cement in a fridge prior to use extends the cure time and reduces the cure temperature and maximum temperature [8].

The temperature characteristics were measured using a custom made piece of apparatus which simulated the femoral prosthesis-bone cement-cancellous bone interfaces. The jig comprised of two different materials, mild steel was used to replicate the femoral stem, while polypropylene was used to represent the cancellous bone. Polypropylene was employed because it mimicked the properties of the bone with respect to thermal diffusivity (Table I).

The temperature of the curing acrylic bone cement was measured using a nickel/chromium/aluminum k-type thermocouple, the measuring probe being situated at the bone cement/polypropylene interface where the level of heat produced is of the most interest and relative to bone. The temperature measurements were recorded using a data acquisition software package called Labtech notebook (Adept Scientific Ltd., UK). The package is designed to simplify laboratory and industrial data logging and monitoring. The program is user friendly, and by connecting function icons on the worksheet it can be programed to conduct any data acquisition in a short period of time. The package is able to display real time results, which can be logged to a disk and imported into a spreadsheet software package for data analysis.

The temperature information was sent to Labtech notebook through a hardware interface called Datascan 7000 measurement module, which sent the temperature results to the software package via a 25-way male to 9-way female cable that is connected to the serial port of the microcomputer.

Once the cement was mixed it was inserted into the purpose made test rig, the polypropylene plate was then put in place and the data acquisition package was enabled. Temperature data was recorded at regular intervals of one second for a time span of 30 min. Once the test procedure had ceased it was possible to assess the data recorded. From the results it was feasible to determine maximum cure temperature, cure time, and the cumulative thermal necrosis damage using Equations 1, 2 and 3 for different threshold temperatures, i.e. > 44 °C and > 55 °C. A typical plot of temperature-*vs*-time for the polymerization reaction can be seen in Fig. 1.

$$f(T) = \frac{\text{Time tissue is held at temperature } (T)}{\text{Time to thermal damage threshold for temperature } (T)} \quad (2)$$

$$\text{Cumulative thermal necrosis index} = \int_{T_1}^{T_2} f(T)\, dt \quad (3)$$

Implementing Equation 3 to calculate the necrosis index, if the summation $f(T)$ for any particular time/cure temperature plot exceeds one, then there is the possibility of irreparable damage to living tissue occurring. It should be observed that all tests related to the thermal characteristics of curing acrylic bone cement were conducted at 22 °C. Results illustrating the thermal characteristics of acrylic bone cement when mixed using various mixing systems can be observed in Tables II–VII and Figs 3–7.

TABLE II Temperature parameters determined for bone cement mixed using the Howmedica Mix-Kit I® system ($n = 6$)

Bone cement	Maximum temperature (°C)		Cure temperature (°C)		Cure time (min)	
	$\bar{X}$	R	$\bar{X}$	R	$\bar{X}$	R
Palacos R®	36.36	0.45	28.31	0.36	13.88	1.12
CMW3	40.85	0.67	27.92	0.27	22.32	0.93

TABLE III Temperature parameters determined for bone cement mixed using the Zimmer Osteobond® vacuum system ($n = 6$)

Bone cement	Maximum temperature (°C)		Cure temperature (°C)		Cure time (Min)	
	$\bar{X}$	R	$\bar{X}$	R	$\bar{X}$	R
Palacos R®	46.00	1.47	31.50	1.21	13.23	0.92
CMW3	59.00	0.21	39.50	0.34	10.63	0.45

TABLE IV Temperature parameters determined for acrylic bone cement mixed using the Zimmer Quick-Vac® system ($n = 6$)

Bone cement	Maximum temperature (°C)		Cure temperature (°C)		Cure time (Min)	
	$\bar{X}$	R	$\bar{X}$	R	$\bar{X}$	R
Palacos R®	53.34	0.75	36.96	0.67	14.82	1.45
CMW^{3}®	57.59	0.54	36.32	0.48	10.80	1.10

TABLE V Temperature parameters determined for acrylic bone cement mixed using the Cemvac® system ($n = 6$)

Bone cement	Maximum temperature (°C)		Cure temperature (°C)		Cure time (Min)	
	$\bar{X}$	R	$\bar{X}$	R	$\bar{X}$	R
Palacos R®	51.83	0.98	35.28	0.83	15.22	1.52
CMW^{3}®	39.20	1.01	28.23	0.93	18.32	1.12

TABLE VI Temperature parameters determined for acrylic bone cement mixed using the Stryker high vacuum cement injection® system ($n = 6$)

Bone cement	Maximum temperature (°C)		Cure temperature (°C)		Cure time (min)	
	$\bar{X}$	R	$\bar{X}$	R	$\bar{X}$	R
Palacos R®	44.44	0.56	30.71	0.67	15.67	1.67
CMW^{3}®	40.37	1.42	29.72	1.02	15.70	1.87

TABLE VII Illustrating the cumulative thermal necrosis index damage towards living tissue above different threshold temperature values

	Cumulative thermal necrosis damage									
	Mix-Kit I®		Osteobond®		Quick-Vac®		Cemvac®		Stryker®	
	> 44 °C	> 55 °C	> 44 °C	> 55 °C	> 44 °C	> 55 °C	> 44 °C	> 55 °C	> 44 °C	> 55 °C
Palacos R®	0.00	0.00	0.73	0.00	1.20	0.00	1.22	0.00	0.31	0.00
CMW^{3}®	0.00	0.00	1.36	0.45	0.72	0.21	0.00	0.00	0.00	0.00

4. Results and discussion

Examining the maximum temperature data for each of the mixing systems it can be observed that regardless which bone cement was mixed in the Howmedica Mix-Kit I® the peak temperatures were the lowest recorded, 36.36 °C and 40.85 °C for Palacos R® and CMW^{3}® cement respectively (Table II and Fig. 3). This is because the cement is mixed in an open bowl and as a result allowing the correct ratio of polymer powder and liquid monomer (2 : 1) to be added into the mixing bowl. It is important to note that the liquid monomer is added to the polymer powder for CMW^{3}® bone cement while the opposite occurs when mixing Palacos R® cement.

Observing the cement mixed by the Zimmer Osteobond® vacuum system (Table III and Fig. 4) it was found that Palacos R® cement generated the second lowest peak temperature, 46 °C. However, the CMW^{3}® bone cement, when mixed using this device, generated the greatest peak temperature, 59 °C. When looking at the design of the Zimmer Osteobond® vacuum system after mixing CMW^{3}® cement it was found that there was evidence of unmixed polymer powder in the groove in the bottom of the bowl. The function of this undercut is to keep the rotation of the mixing paddle eccentric. Due to this unmixed powder there is a decrease in the nominal mixing ratio because there is less polymer powder being blended with the liquid monomer, this causes an increase in the specific mass of polymerizing material and thus the

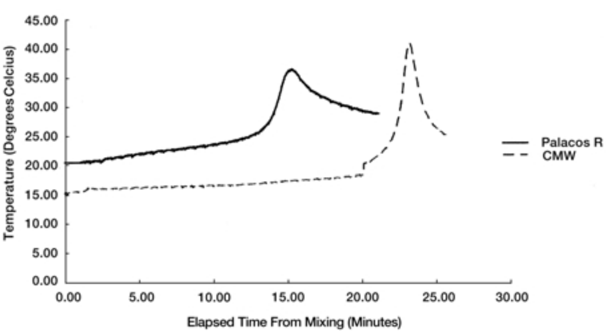

Figure 3 Temperature-*vs*-elapsed time from mixing for acrylic bone cements mixed using a Howmedica Mix-Kit I® mixing system.

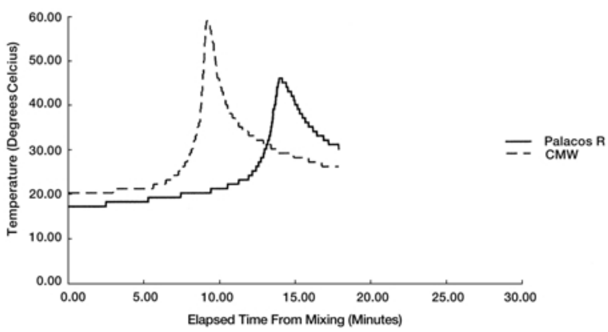

Figure 4 Temperature-*vs*-elapsed time from mixing for acrylic bone cements mixed using the Zimmer Osteobond® vacuum system.

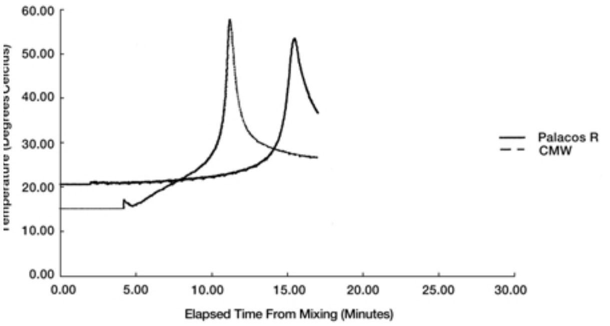

Figure 5 Temperature-*vs*-elapsed time from mixing for acrylic bone cements mixed using the Zimmer Quick-Vac® system.

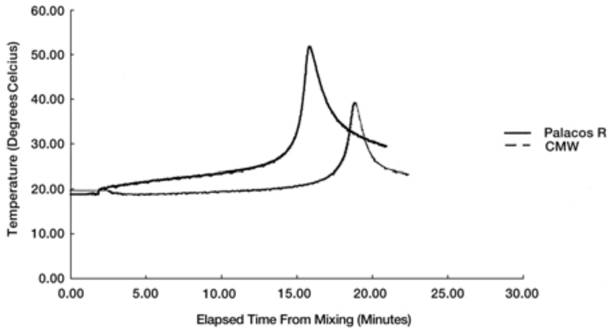

Figure 6 Temperature-*vs*-elapsed time from mixing for acrylic bone cements mixed using the Cemvac® system.

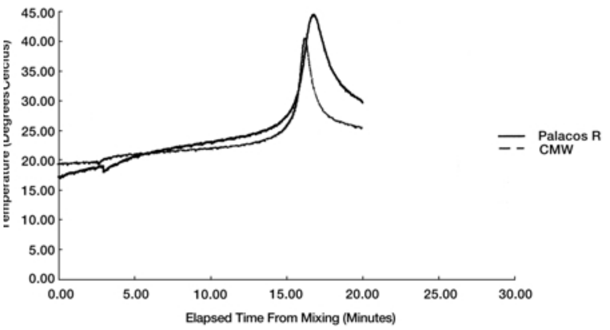

Figure 7 Temperature-*vs*-elapsed time from mixing for acrylic bone cements mixed using the Stryker high vacuum cement injection® system.

peak temperature recorded. Haas *et al*. [20] also found this to be true, they postulated that the reaction rate and temperature are influenced by the mixing ratio.

It has been quoted in literature [18, 19] that a slight reduction in the heat generated is observed when bone cement is vacuum mixed when compared to cement mixed using a second generation type device at ambient pressure. Looking at the results gathered it is noted that the maximum temperature generated during polymerization is lower for Palacos R® cement mixed using the Stryker high vacuum injection® system, 44.44 °C and CMW^3® cement mixed using the Cemvac® system and Stryker high vacuum cement injection® system, 39.20 °C and 40.37 °C respectively. The other conditions, i.e. Palacos R® mixed using the Zimmer Quick-Vac® system, the Cemvac® system and CMW^3® cement mixed using the Zimmer Quick-Vac® system yielded higher temperatures, 53.34 °C, 51.83 °C and 57.59 °C. It is reasoned that the temperatures produced are higher than in literature as a result of the difference in the powder : monomer ratio. When Palacos R® cement was mixed in the Zimmer Quick-Vac® system and the Cemvac® mix device there was evidence of unmixed polymer powder in the mixing barrel resulting in changes in the distribution of polymer powder to liquid monomer causing greater heat to be generated. The high temperature produced when CMW^3® cement is mixed in the Zimmer Quick-Vac® device is also due to the decrease in the mixing ratio, but the rationale is different. In this case the acrylic powder is added to the liquid monomer, thus a percentage of the powder coats the funnel, which is wetted from the liquid monomer.

Cure temperature is defined in Equation 1 and results from analyzing the cure temperature data, similar trends were found similar to those when observing the peak temperature results. This is because the peak temperature of the bone cement is proportional to the cure temperature. The Howmedica Mix-Kit I® mixed cements generated the lowest cure temperatures, 28.31 °C and 27.92 °C. The Zimmer Osteobond® vacuum system mixed Palacos R® and CMW^3® cement giving cure temperatures of 31.50 °C and 39.50 °C respectively. The cure temperature was considerably higher for the CMW^3® cement mixed with this device, because of the decrease in the ratio of polymer powder to liquid monomer. The cure temperature results for the other third generation vacuum systems are expected to be lower than the temperature data recorded when cement was mixed using the Zimmer Quick-Vac® device. But, again there is the problem of unmixed polymer powder, resulting in higher than normal cure temperatures being generated. The Zimmer Quick-Vac® system when mixing Palacos R® and CMW^3® cements allowed cure temperatures of 36.96 °C and 36.32 °C to be generated, the Cemvac® device for Palacos R® produced an average cure temperature of 35.28 °C.

The cure time is the time at which the acrylic bone cement reaches between 90–100% cure. From the results the following observations were made. For the mixing devices that did not fully mix the polymer powder into the liquid monomer the cure times were higher than if a homogenous mix was achieved. Using the Zimmer Osteobond® system the cure times for Palacos R® was 13.23 min and for CMW^3® cement 10.63 min. The same can be observed for the acrylic cement mixed using the Cemvac® device, Palacos R® recorded 15.22 min and CMW^3®, 18.32 min. It was also noted that for any particular mixing system that if the cure temperature was higher for certain cement then the cure time would be lower for that cement. Using the Howmedica Mix-Kit I®, Palacos R® reached between 90–100% cure at 13.88 min and CMW^3® at 22.32 min. The reason that there is such a large difference in the cure times is because the CMW^3® was mixed at 22 °C in an open bowl using a spatula and a cement temperature of approximately 15 °C was initially recorded, therefore it takes longer to reach a full state of cure. This situation occurred for all six tests. The same trends can be seen for the bone cements mixed using the Stryker high vacuum injection® system, Palacos R® 15.67 min and CMW^3® cement 17.50 min. This is an expected result as the higher the cure temperature the faster the cure time, because the rate of polymerization is increased.

A number of studies [1, 12–14] have stressed the importance of keeping the heat generated through the bone cement exothermic reaction to a minimum, as it results in a permanent cessation of blood flow and bone tissue necrosis, which show no sign of repair after 100 days or more. The cumulative thermal necrosis index is the parameter used in assessing the level of irreparable damage bone cement can cause through heat generation. Using Equations 2 and 3 and Fig. 2 the necrosis index can be determined, if the summation $f(T)$ for any specific time/temperature plot exceeds one, then is the possibility of thermal damage to the living tissue cells. The thermal necrosis index was calculated for two temperatures $> 44\,^\circ C$ and $> 55\,^\circ C$. These two temperatures were used as it has been referenced in literature that the temperature threshold for impaired bone regeneration is in the range of 44–47 °C [12, 13]. It can be observed from the results in Table VII that only three conditions produce a cumulative thermal necrosis damage of greater than one, Palacos R® cement mixed using the Zimmer Quick-Vac® and Cemvac® systems and CMW3® bone cement mixed using the Zimmer Quick-Vac® device, 1.20, 1.22 and 1.36 respectively. The reason for these index values is again because of the alteration in the proportion of liquid monomer to polymer powder, thus resulting in an increase in the level of specific heat generated during the polymerization reaction of the acrylic bone cement of uniform cement mantle.

In conclusion, it can be said that not all types of bone cement are suited to a particular mixing system. It is important that a full assessment is carried out on a mixing system before it is introduced into the orthopaedic market, ensuring that all feasible investigations have been conducted and all possible mixing conditions considered.

References

1. R. FEITH, *Acta. Orthop. Scand. Suppl.* (1975) 161.
2. J. R. WIJN DE, F. C. M. DRIESSENS and T. J. J. H. SLOFF, *J. Biomaterial Res.* **6** (1975) 99–103.
3. J. A. DIPISA, G. S. SIH and A. T. BERMAN, *Clin. Orthop. Rel. Res.* (1976) 121.
4. S. C. BAYNE, E. P. LAUTENSCHLAGER, C. L. COMPERE and R. WIDES, *J. Biomed. Mater. Res.* **9**(1) (1975) 27–34.
5. T. A. BERMAN, J. S. REID, D. R. YANICKO, C. G. SIH and M. R. ZIMMERMAN *Clinical Orthopaedics and Related Research* **186**(1) (1984) 284–292.
6. G. M. BRAUER, D. R. STEINBERGER and J. W. STANSBURY, *J. of Biomed. Mater. Res.* **20**(1) (1986) 839–852.
7. C. D. JEFFERIS, A. J. C. LEE and R. S. M. LING, *J. Bone Joint Surg.* **57-B**(4) (1975) 511–518.
8. R. MEYER, E. P. LAUTENSCHLAGER and B. K. MOORE, *ibid.* **55-A**(1) (1973) 149–158.
9. I. C. REVIE, M. E. WALLACE and J. F. ORR, *J. Engi. Medi.* **208** (1994) 45–51.
10. R. HUISKES and T. J. SLOOF, *Trans. Orthop. Res. Soc.* **6** (1981) 134.
11. G. C. SIH and G. M. CONNELLY, *J. Biomech.* **13**(1) (1980) 347–352.
12. A. R. MORITZ and F. C. HENRIQUES, *Am. J. Pathol.* **23** (1947) 695–720.
13. A. R. ERIKSSON and T. ALBERKSSON, *J. Prosthet. Dent.* **50**(1) (1983) 101–107.
14. J. LUNDSKOG, *Scand. J. Plastic Reconstr. Surg.* Suppl. (1972) 9.
15. B. MJOBERG, H. PETTERSON, R. ROSEQVIST and A. RYDHOLM, *Acta. Orthop. Scand.* **55** (1984) 597–600.
16. C. G. NELSON, E. G. KRISHNAN and J. R. NEFF, *Medical Phys.* **13**(4) (1986) 462–468.
17. S. T. LARSEN, S. FRANZEN and L. RYD, *Acta. Orthop. Scand.* **62**(2) (1991) 102–105.
18. L. LIDGREN, B. BODELIND and J. MÖLLER, *ibid.* **58**(1) (1987) 27–32.
19. H. SEIDEL, A. HEGGERT and H. PIETSCH, *Arach. Orthop. Unfallchir.* **90**(3) (1977) 251–257.
20. S. S. HAAS, G. M. BRAUER and M. A. DICKSON, *J. Bone Joint Surg.* **57-A**(3) (1975) 380–391.

Received 14 June 2000
and accepted 21 February 2001