

Research Article

The Effects of Mixing Regime on the Bending Strength of Acrylic Bone Cement

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Abstract

Polymethylmethacrylate (PMMA) or acrylic bone cement is the most commonly used nonmetallic implant material in orthopaedic surgery. It is very extensively used in total joint replacement surgery as a means of fixation of the prosthesis to bone. PMMA is a space-filling, load-transferring material and not an adhesive. It is three times stronger in compression than tension. One of the major reasons for failure of cemented arthroplasty is aseptic loosening, which is due to the stiffness mis-match between the bone, cement and the implant. This project was designed to determine the effect of manual mixing and vacuum mixing on the bending strength of Polymethylmethacrylate bone cement. Palacos R bone cement was used in the study. Manual mixing was done using a bowl and spatula, while vacuum mixing was done in Hivac syringe mixing system under a vacuum pressure of 500mm of Mercury. Thirty rectangular cross-sectioned specimens of both manual and vacuum mixed cements were made in brass moulds. These specimens were subjected to a 3-point bending test on a Universal Testing Machine. Force-displacement graphs were obtained; the bending strength was calculated and a statistical analysis was done. The result of the study showed that vacuum mixed cement had 17.01% increase in the bending strength than the manual mixed cement with a P value < 0.001. The increase in bending strength of vacuum mixed cement is due to the reduction in porosity. The result of this study demonstrates the effectiveness of vacuum mixing of bone cement, which is one of the major factors in the final outcome of a cemented joint arthroplasty.

Introduction

Acrylic bone cement, Polymethylmethacrylate (PMMA), is widely used in many fields of medicine. Orthopaedic PMMA is a filler or cement, not an adhesive. It is a supportive material, which forms a mechanical bond between cement and bone or between cement and prosthesis. Bone cement is a material designed for fixation of prostheses, whose function is to transfer load that is compression, shear and tensile force from prosthesis to bone. PMMA has been a key factor in the advent of joint replacement as a surgical option. The intraoperative use of PMMA has not changed, despite the changes in joint replacement technology today, in spite of its problems it is still being used in joint replacement as a means of fixation of the prosthesis to bone.

The commercially available PMMA bone cement used in orthopaedic surgery is a two- component system; namely, a polymerised powder component and a liquid component of methylmethacrylate monomer. Bone cements have a tensile strength varying from 20-50MPa, compressive strength 60-117MPa, and a bending strength of 50-125MPa. The mechanical properties of the bone cement are the final deciding factors in the outcome of a cemented joint arthroplasty. The bone cement can withstand considerable compressive forces but fails more readily in tension and shear. It is about three times stronger in compression than tension. There is significant difference among the tensile, compressive, shear strength and modulus of elasticity of bone, bone cement and metallic implant. This mismatch is one of the major reasons for aseptic loosening.

Polymethylmethacrylate bone cement is used in various orthopaedics conditions; namely, joint replacements, pathological fractures and bony defects where it is subjected to significant bending. Bone cement mantle under a bending force (Fig 1) is subjected to compression on one side and tension on opposite side; it undergoes plastic deformation earlier at the tension side than the compression side. Holm (1977) observed that poor mixing techniques and inclusions in the cement reduce the bending property significantly.

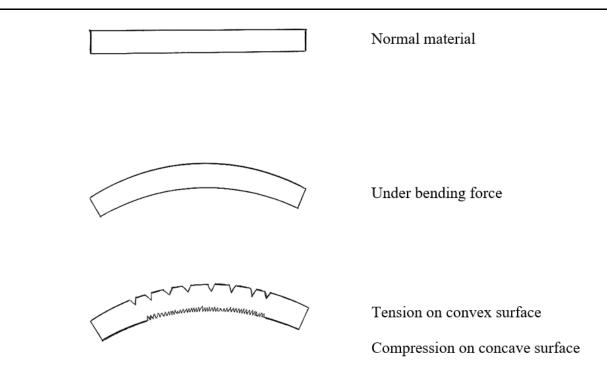


Figure 1. Cement under bending force

Mixing techniques are reported to have a role in the final outcome, because the technique is a factor which determines the quality of the cement. The pores within the cement are the source of cracking and its propagation. In order to overcome this problem, there are many modifications attempted to improve the cement. Improvements in mixing techniques are thought to have improved the long-term functions of bone cement.

The different mixing techniques available are manual mixing, mechanical mixing, centrifugation, and vacuum mixing in either bowl or syringe. Vacuum mixing in bowl (Lidgren et al. 1987) and syringe system (Dunne and Orr 2001) are reported to have improved the mechanical properties of bone cement. Titanium fibres mixed with cement result in high tensile strength and fracture toughness of bone cement in experimental study (Topoleski et al. 1992).

Aims and Objectives

The aim of the study is to determine the effects of mixing regime on the bending strength of bone cement. To achieve this, three objectives need to be fulfilled;

- I. The bone cement prepared by manual and vacuum mixing;
- II. The bending strength will be established using a strength testing machine; and
- III. Comparative statistical analysis of data will be conducted.

Brief History

Acrylic bone cement came into use after many years of intensive research and study by Otto Röhm in 1943 (www.bonecement.com). Kiaer and Jansen were the first to use bone cement in orthopaedic surgery in 1951. Judet brothers from Paris used acrylic implant in hip replacement in 1953. In 1958, Sir John Charnley first introduced a self-curing PMMA to orthopaedic surgery in his renowned low friction arthroplasty (Charnley 1970).

Polymethylmethacrylate is the most common non-metallic implant used in orthopaedics. PMMA has wide industrial application under the trade name Perspex, acrylic cement is still being used as a dental cement due to it non toxicity, dimensional stability and low water absorption.

Bone cement is a space-filling, load-transferring material and has a mechanical bonding to cancellous bone by forcing cement into the interstices. This bonding or micro-interlock should be strong enough to withstand load transfer and to prevent the generation and distribution of wear debris. The mechanical bonding of acrylic bone cement is improved by coating the implant with a layer of PMMA, texturing the surface of implant. The mechanical bond thus achieved has a significant resistance to shear force and tensile forces. As PMMA is brittle and notch sensitive, implants with sharp corners should be avoided.

Mechanical loosening of total joint replacement is the most common cause of prosthetic failure. The cause of loosening originates from failure either at the interface between cement and bone, or prosthesis and cement, or the cement mantle itself. The durability of these bonds are highly influenced by the quality of bone cement. PMMA is very solid and brittle in its polymerised state. It can withstand considerable compression, but fails more readily under tension or shear as it is three times stronger in compression than in tension. The modulus of elasticity of cement, bone and metallic implants are totally different. This stiffness mismatch can lead to aseptic loosening.

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Chemical and Physical Properties of PMMA

Acrylic bone cement is made of two components, namely, the powder and liquid;

- I. The powder is composed of polymerised methylmethacrylate in granular form, an initiator namely
 1% Di-benzoyl peroxide, and a radiopacifier either 10% barium sulphate or zirconium dioxide.
- II. The liquid is a methylmethacrylate monomer with an activator 3% N, N-dimethyl-p-toludine, and a trace of retardant to minimise the polymerisation of monomer during storage.

Other additives used are a colourant, either methylene blue or chlorophyll for optical marking of bone cement at revision, and heat stable antibiotics in powder form, either used alone or in combination of antibiotics.

Curing of PMMA

PMMA has an average molecular weight of 200,000. Depending on the manufacturer the liquid is added to powder or vice versa, polymerisation of methylmethacrylate is a slow exothermic reaction, which liberates 12-14 kcals of heat per 100 grams of typical bone cement. It goes through a series of stages from initial runny stage, through the doughy and rubbery stage to the final hardened (polymerised) stage (Table 1). The cement is used in doughy stage, when it has a low viscosity, easy to insert and pressurise cement, and to implant the prosthesis before polymerisation has occurred. Incorporation of blood and debris into cement reduces its strength and a thorough lavage and suction of cancellous bone can increase the interface between the bone and cement.

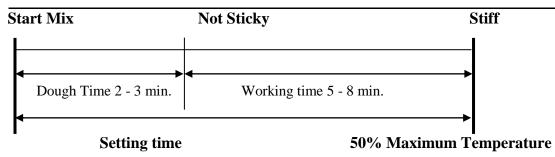


 Table 1. Curing of PMMA (Adapted from www.orthoteers.co.uk)

Polymer powder is sterilised by Gamma radiation at 2.5Mrad and liquid monomer by membrane filtration. At present, there are six commercial bone cement formulations available. They are Simplex P, Zimmer Regular, Zimmer Low Viscosity, Palacos R, CMW-1 and CMW-3. All of them vary in their properties

Mechanical Properties of PMMA

The properties of PMMA bone cement can be classified as static, viscoelastic, dynamic and rheological.

Static properties are:

- Compressive strength 60-117 MPa
- Tensile strength 25-50 MPa
- Shear strength 40-60 MPa
- Bending strength 50-125 MPa
- Young's modulus 2500-2700 MPa

Viscoelastic properties are:

- Creep
- Stress relaxation

Dynamic properties are:

- Fatigue
- Impact strength
- Fracture toughness

Rheological properties

 Flow characteristic of bone cement is important in the doughy stage, as cement must penetrate into the interstices of cancellous bone network. For easy flow a cement viscosity of less than 100 N-s/m² was required between 3 and 5 minutes after mixing.

Bone cement is brittle in nature. It is very strong in compression, weak in shear and tension. It is a viscoelastic material at body temperature. It can deform easily by creep, and creep rates reduce with time. Creep is influenced by materials environment and creep rate increases with temperature and stress. Stress relaxation occurs when it is strained to a level below that at which failure would and holding that strain. Creep resistance and stress relaxation properties of PMMA could be improved by carbon fibre reinforcement (Saha and Pal 1984). The repeated loading on the cement at a load below the critical failure load will eventually result in its failure.

There have been various modifications attempted to improve the quality of bone cement and thereby prevent loosening. New cement formulations include changing the liquid monomer, using methyl or butyl-based polymer compositions, and altering the overall composition by reinforcement.

The addition of thin fibres to PMMA based bone cement can improve its fatigue crack growth and, thus, increase its fatigue life. Fibres impede crack, because the interface between fibre and the cement matrix debonds as the propagating crack approaches it. Reinforcing the cement with fibres increase the fatigue strength and fracture toughness, but it increases the viscosity and elastic modulus. It makes the mixing and delivery by the gun difficult (Crowninshield et al. 1980). Size, composition and loading of fibres must be adjusted to avoid increase in viscosity of bone cement.

Intrusion of lower viscosity cement is much better than the higher viscosity, but the former is prone to fracture. According to Swedish and Norwegian National Hip Registry, higher viscosity bone cements have proved to offer a lower incidence of revision and aseptic loosening. The Swedish Arthroplasty Register has

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shown that antibiotic loaded cement is the most effective prophylaxis for septic complications in arthroplasty (www.bonecement.com).

The high speed mixing of nanometer barium sulphate particles provides a uniform dispersion of the radiopacifier and prevents the agglomeration in the cured nanocomposite cement (Fitz et al. 2001).

Pre-coating the prosthesis with cement particles and, thus, strengthening the bone-cement interface from aseptic loosening has shown to resist tensile stresses due to chemical bonding. Pre-chilling the liquid monomer before mixing and the addition of antibiotic decreased the compressive and tensile strength of bone cement.

EtO (Ethylene oxide) gas sterilisation and vacuum mixing improves the fracture toughness, and enhances the longevity of bone cementing. In the study 2.5Mrad Gamma radiation reduces the molecular weight, where as EtO does not alter it (Graham et al. 2000).

Derivatives of oleic acid 4-N, N dimethylaminobenzyloleate (DMAO) and oleylmethymethacrylate (OMA) when used in formulation of acrylic bone cement provided an increase in tensile properties (Vázquez et al. 2002).

Uses of PMMA

- PMMA is used a dental filling, due to its low water absorption and nontoxicity
- In thoracic surgery, as a plombage to produce lung collapse
- Used in ophthalmology for contact and intraocular lenses
- In Otology to replace ossicles
- As Cranioplast in neurosurgery
- In orthopaedic surgery bone cement is used as a filler or lute, in arthroplasty, vertebroplasty, osteoporotic bones, filling defects in tumour surgery of bone and vertebral bodies, as a delivery vehicle to carry antibiotics and chemotherapeutic agents in bone and joint infection and skeletal metastasis respectively.

Adverse Effects of PMMA

The adverse effects of PMMA are due to the high exothermic reaction during polymerisation. PMMA causes thermal necrosis of bone, impairs local circulation, and predisposes to membrane formation at bone-cement interface. Leakage of unreacted liquid monomer into the surrounding tissue results in local inflammatory reaction. Pressurization of cement results in transient hypotension and sometimes myocardial depression due to the monomer leakage.

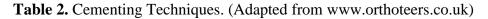
Cementing Techniques

The advent of newer cementing techniques has improved the mechanical properties of bone cement and the long-term results of cemented arthroplasty. Improved cementing techniques (First generation 1960, Second generation 1975, and Third generation 1982) have contributed to this (Table 2).

The first generation (Fig 2) resulted in clear gaps at cement bone interface and malpositioning of prosthesis. The use of a cement gun, cement centraliser and cement restrictor led to a uniform cement mantle and neutral positioning of prosthesis in the second generation cementing technique (Fig 3). The third generation cementing technique (Fig 4) involving vacuum mixing and the use of a cement pressurizer gave a strong cement-bone interface.

The optimum cement mantle thickness is ideally between 2-5mm and it should be complete with no contact between the prosthesis and the bone.

First Generation (1960)	Second Generation (1975)	Third Generation (1982)	
Hand Mixing	Hand Mixing	Vacuum Mixing	
Finger Packing	Cement Gun	Centrifuging	
No Cement Restrictor	Cement Restrictor	Cement Pressurization	
No Stem Centraliser	Stem Centraliser	Surface Changes to Implant	
No Canal Preparation	Medullary Brush	High suction and lavage	



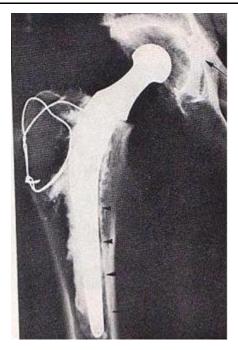


Figure 2. First generation cementing technique (x-ray of total hip replacement)

(Adapted from "Acrylic cement in orthopaedic surgery", Charnley J 1970)



Figure 3. Second generation cementing technique (x-ray of total hip replacement)



Figure 4. Third generation cementing technique (x-ray of total hip replacement)

Oishi et al. (1994), in 6-8 years old follow up of 100 patients with third generation cementing technique for the femoral component in total hip replacement found good and excellent, clinical and radiological results. The third generation cementing technique reduced the porosity, gave better intrusion of cement into the femoral canal and a better micro-interlock.

Grading of cementing technique

Barrack et al. (1992) introduced a grading of cementing technique (Table 3) purely based on the secondgeneration cementing technique and stem design. The grading of cementing technique is based on the postoperative radiological assessments. The use of cement guns and medullary plug not only allows complete filling of medullary canal but also helps in extending cement mantle 2-3 centimetres beyond the tip of prosthesis, which gives a better fixation. The improvement in cementing technique and better implant designs have vastly improved the longevity of cemented arthroplasties.

Grade A	Medullary canal completely filled with cement
Grade B	A slight radiolucency at bone-cement interface
Grade C	A radiolucency of more than 50% at bone-cement interface
Grade D	A radiolucency of more than 100% of bone-cement interface in any projection, including absence of cement distal to stem tip.

Table 3. Grading Of Cementing Techniques

Mulroy et al. (1995) observed a femoral cement mantle of less than 1mm and defects in cement mantle are associated with early loosening.

Interface Widening:

The interface widening is based on the assessment of width of bone cement interface and, assessment of location whether it is in acetabulum or femur (Fig 5a & b).

Assessment of width:

- Radiolucent zones wider than 2 mm are evidence for loosening.
- Radiolucent zones less than 1 mm are acceptable, also radiolucent zones that are less than 2 mm and are not progressive.

Assessment of location:

- Acetabular component, radiolucent zones at cement-bone interface of the infero-medial aspect (Dee-Charnley zone 3) are considered as a sign of loosening.
- Femoral component, wide lucencies about superolateral aspect of femoral component (Gruen zone1) is a strong radiological evidence of loosening.

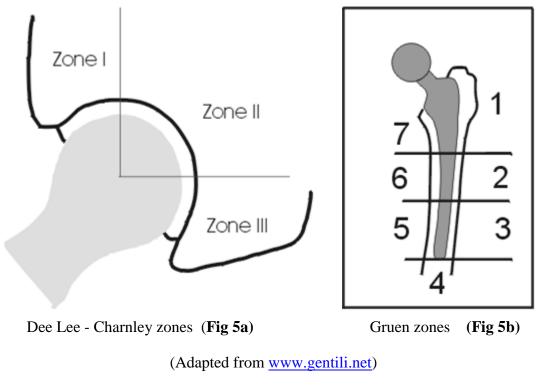


Figure 5. Interface widening

Bending Properties; Literature Review

The fatigue life of cement is dependent on the mixing technique of bone cement. The manually mixed cements have porosity ranging from 9-27 %, whereas, the cement mixed in vacuum of 500 mm mercury reduced the porosity to as low as 1 %. The pores in cement acts as stress risers that facilitate crack propagation leading to weakening of mechanical properties of bone cement.

Effects of vacuum mixing:

Various authors have conducted studies on the effects of vacuum and manual mixing of cement on its dynamic and static properties; they have concluded that vacuum mixing gave a cement of better quality.

Schreurs et al. (1988) compared four-cement preparation techniques namely hand mixing, pressurisation in a pneumatic pistol, centrifugation, and vacuum mixing on three different viscosity cements. They proved that best results were obtained with vacuum method of mixing giving a porosity reduction up to 60-80%

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when compared to hand mixing.

Lindén (1989) analysed Simplex P bone cement for its porosity by five different mixing methods, namely, manual, centrifuged manual, mechanical, centrifuged mechanical and mechanical with vacuum. He observed that mechanical mixing reduced the porosity and increased the density of bone cement. The mechanical mixing with vacuum gave optimum quality cement.

Lindén and Gillquist (1989) demonstrated that fatigue properties of three different cements CMW, Simplex P, and Zimmer LVC bone cement were better by mechanical vacuum mixing than by manual mixing. The reduction in porosity by vacuum mixing gave the cement a larger cross-section and a better load absorption.

Wang et al. (1996) observed that under vacuum mixing, high viscosity cement like Palacos R and middle viscosity cement like Simplex P had significant reduction in the number of macro and micro pores. It also increased the density of the bone cement.

Wilkinson et al. (2000) conducted a comparative study of cement produced by syringe mixing systems and a multiaxial bowl under vacuum using nonprechilled Palacos R cement. It was found that the cement produced by the syringe mixing systems had lesser micro and macro voids, higher density, better bending modulus and bending strength than the multiaxial bowl systems.

Geiger et al. (2001) did a controlled study simulating the clinical situation to assess the effect of vacuum mixing on the mechanical properties of the cement-implant construct with four different cements. Image analysis showed that vacuum mixing reduced the voids at cement-implant interface when compared with open bowl mixing. Out of the three brands used namely, Simplex, Osteobond, Zimmer Dough type and Palacos R, only Palacos R had an improvement in push out and fatigue strength with vacuum mixing.

Dunne and Orr (2001) conducted a study on the influence of mixing regimes on Palacos R cement using the third-generation mixing technique. It was found that the compressive strength, bending strength and flexural modulus improved when cement was mixed using third generation cementing technique. The reduction in the porosity by third generation mixing technique is believed to improve the mechanical properties of bone cement.

Effects of centrifuging:

Davies et al. (1986) concluded that the porosity reduction of PMMA by centrifuging improved the fatigue strength, even in presence of surface irregularities in the experimental study. He used the PMMA model to

simulate the in vivo condition while testing. The porosity reduction caused an increase in the number of cycles required for crack initiation by increasing the cross-sectional area of PMMA.

Jasty et al. (1990) on a computer assisted image analysis for the porosity of bone cements found that centrifugation for 30 seconds reduced the porosity in Simplex P, AKZ, Zimmer Regular, and CMW bone cements. However, centrifugation did not have any significant effect on LVC, Palacos R and Palacos R with gentamycin. Chilling the monomer to 0° Celsius reduced the viscosity of bone cement and did not produce any significant reduction in the porosity in either the usual mixing or centrifugation for any of the cement preparation except Simplex P. Incase of Simplex P the monomer was chilled and centrifuged for 120 seconds rather than 30 seconds to give a better porosity reduction, handling properties and an excellent fatigue strength.

Hansen and Jensen (1992) found that contemporary mixing methods like vacuum and centrifugation with or without precompression did not produce significant changes in all cements. They observed that bending strength for low viscosity cements ranged from 64-79 MPa, and was high for Palacos E when compared to other low viscosity cement mixed manually or with vacuum. As far as standard viscosity cements were concerned, the bending strength improved by 10-11% for the Palacos brands whereas others were unaffected.

Rimnac et al. (1986) concluded that centrifugation did not improve the fracture toughness of bone cement in presence of imperfections found at bone-cement interface. They came to conclusion that irregularities at the bone-cement interface are sites of fracture initiation irrespective of size or distribution of porosity in the cement. They concluded that Palacos brand cements with or without antibiotics had a better fracture toughness because of its high molecular weight.

Effect of hydroxyapatite incorporation:

Vallo et al. (1999) in a study on hydroxyapatite reinforced bone cement observed that up to a maximum of 15-weight% of hydroxyapatite the flexural modulus and fracture toughness increased. On image examination the porosity and pore size increased with increasing amounts of hydroxyapatite. Hydroxyapatite acts as rigid filler, which is supposed to enhance fracture resistance and flexural modulus.

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Effect of antibiotic addition:

The addition of antibiotic to the bone cements aid in reducing the postoperative infection. It is in the proportion of 0.5 - 2 grams of antibiotic powder per 40 grams of cement. The addition of antibiotic powder reduces the tensile and compressive strength by 5-10%.

The addition of antibiotic is said to weaken the mechanical properties of bone cement. Wright et al. (1984) conducted a study for fracture toughness of bone cement with and without gentamycin additions using Palacos and Zimmer bone cements. The results proved that fracture toughness was infact higher in both groups even after two months, than the zero-day groups, this was probably due to complete polymerisation with time.

Letters and Walsh (2000) used CMW 3 bone cement with and without gentamycin to find the effect of gentamycin addition on the bending strength and creep properties of cement. They concluded that cement with gentamycin had a reduction in the bending strength statistically, and a lower initial strain with lower percentage of strain rate. The inhibition of creep due to gentamycin addition should be taken into account in design and use of prostheses when subsidence of tapered femoral stem is desired.

Effects of fibre reinforcement:

Saha and Pal (1986) examined mechanical properties of Polymethylmethacrylate (Low viscosity cement) reinforced with Carbon fibres. They found that Carbon fibres significantly improved the bending and shear strength by 29.5% and 18.5% respectively. There was a significant reduction in exothermic temperature.

Gilbert et al. (1995) studied the mechanical properties of self-reinforced composite Polymethylmethacrylate (SRC-PMMA), a high strength, and high ductility PMMA fibres embedded in a matrix of PMMA. The flexural strength of SRC-PMMA was greater than the bone cement. The fracture toughness and fatigue strength were also significantly elevated and SRC-PMMA was found to have greater fatigue damage tolerance.

Topoleski et al. (1992) used titanium fibre (1%, 2% and 5% by volume) reinforced cement to measure the fracture toughness. They found that fracture toughness increased 56% by increasing the titanium fibre content. The surface of titanium fibre is rough and irregular indicating that a high degree of mechanical interlock between the matrix and fibre. However, the fibre content that causes an increase in the viscosity of cement makes it mixing and delivery difficult.

Effect of temperature and sterilization on bone cement:

The polymer powder is sterilized using gamma radiation, which causes a significant reduction in the molecular weight of polymer when compared to ethylene oxide sterilization. The toxicity of ethylene oxide is a factor which prevents its wide spread use. The handling properties of bone cement are dependent on operating room and bone cement temperature, high temperature reduces the working phase. High viscosity cement like Palacos R is refrigerated to $4\Box$ Celsius, which would effectively reduce its viscosity and porosity, where as a low viscosity cement like Simplex P should be used at room temperature as cooling, would adversely affect its fatigue properties.

Smeds et al. (1997) found that vacuum mixing increased the compressive strength of the three types of cements namely low, medium, and high viscosity. He however found that porosity reduction was pronounced in the low viscosity cement mixed at a temperature of 22 Celsius when compared to the high viscosity cement. The strength and density remained unchanged when high and medium viscosity cements were mixed at 6 Celsius and 22 Celsius respectively.

Graham et al. (2000) studied the effects of mixing methods, sterilization methods, and molecular weight on the fracture and fatigue properties of acrylic bone cement. Palacos R brand bone cement was used for the study, which was sterilized by Ethylene oxide gas (EtO) or Gamma irradiation with unsterilized material as control. It was found that vacuum mixing improved the fracture and fatigue resistance over hand mixing in radiation sterilized and EtO sterilized groups. A significant finding was that cement sterilized by gamma irradiation in vacuum mixing showed a decrease in the fracture and fatigue properties, it is due to the reduction in the molecular weight caused by the gamma irradiation where as the EtO sterilization doesn't alter the molecular weight. A non-ionizing sterilization and vacuum mixing gives a better mechanical performance from the cement.

Creep of acrylic bone cement:

The creep of acrylic bone cement is an important property in long-term stability and fixation of cemented joint reconstruction is concerned. Creep is a time, temperature and stress level dependent property, and at body temperature of 37oC the PMMA may undergo plastic deformation over a period of time.

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Verdonschot and Huiskes (1995) on examination of dynamic compressive creep deformation of acrylic bone cement found that there is linear relationship between the logarithmic value of number of loading cycle and creep strain. They found that compressive creep strain to exceed the elastic strain at 14×10 cycle and concluded that bone cement must creep under physiological conditions. A comparative study revealed that bone cement under a tensile load creeps quicker than a compressive load. Creep behaviour of bone cement enables subsidence of stem and reduction of stress peaks in the cement mantle.

Porosity reduction is irrelevant:

There are studies on bone cement, which argue that porosity reduction does not improve the fatigue properties of bone cement. Ling and Lee (1998) in a review article state that porosity reduction of acrylic bone cement does not improve the long-term survival total hip arthroplasty. They opined that radiostereophotogrammetry studies have proved that any implant that migrates more than 2mm at implant-bone interface in first two years after implantation is likely to fail within ten years. They also found that initial fixation of implant should provide a better mechanical interlock between implant and bony skeleton irrespective of bone cement use.

Dynamic changes in vacuum mixed cement:

Muller et al. (2002) has recognized that there is a significant dynamic volumetric change in vacuum mixed cements when compared to hand mixed cements. They have found a transient volume increase in cement volume in hand mixed cement before solidification in comparison with vacuum mixed which shows a progressive volume reduction. This volume expansion of porous cement occurs at time of micro-interlock formation and volume reduction in vacuum mixed cements can damage the micro-interlock. The volume reduction in hand mixed and vacuum mixed cements were 3.4% and 6.0% respectively. This finding they feel might have relevance to the finding of Swedish hip registry, which has shown an increase risk of early revision of vacuum mixed total hip replacements.

Apart from the above article, there is a general consensus and conclusive evidence in the literature reviewed that bone cement prepared by modern cementing technique improves material properties and is essential for the long-term survival of cemented arthroplasty.

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Methods and Materials

The study on the bending strength of bone cement was conducted in Medical Physics Laboratory at Ninewells Hospital, University of Dundee, Scotland, UK.

The methods used in the study were manual and vacuum mixing respectively. Palacos R bone cement was used for preparing the cement specimen using brass moulds and steel plates. The cement polymer and monomer belonged to the same batch. The cement was mixed at room temperature of 22° Celsius and the Palacos R cement was not prechilled before mixing.

Manual Mixing

Following steps prepared thirty specimens of bone cement;

Step 1: 20 ml of liquid monomer was taken in a plastic bowl (Fig 6), to which 40 grams of polymer powder was added. Stirring was done using a spatula, applying one stroke per second until the cement was completely wet, the average mixing time was 45 seconds for all the specimens.

Step 2: Mixed cement was poured into the brass moulds in doughy stage and pressurization was done using a mechanical press for 45 minutes. Brass moulds covered with steel plates (fig.8) are kept in a mechanical press to give uniform pressure (Fig 9).

Step 3: Defective specimens with unequal thickness, open voids, and cracks were discarded from the study.



Figure 6. Manual mixing bowl and spatula (Adapted from <u>www.bonecement.com</u>)

Vacuum Mixing

Step 1: Vacuum mixing was done using Summit HiVac syringes under a vacuum pressure of 500mm of Mercury (Fig 7), using the same ratio of bone cement as used in manual mixing. The liquid monomer was poured initially, followed by the polymer powder, these were then mixed under vacuum for about 45 seconds by longitudinal and rotation method.

Step 2: The syringe minus plunger is screwed on to ratchet cement delivery gun (Fig 10) and cement is delivered into the brass moulds. Pressurization was carried out in the same way as manual mixing.



Figure 7. Mixing syringe and vacuum system



Figure 8. Brass mould

Figure 9. Mechanical press



Figure 10: Ratchet cement gun with syringe

The cement specimens (Fig 11) obtained was kept for 48-72 hours before they were tested. Figure 12 shows cement specimen with two parallel marking which encloses the actual test segment.



Figure 11. Cement specimen

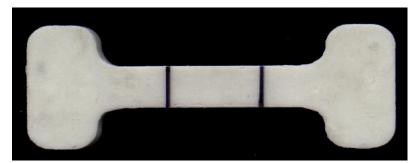


Figure 12. Cement specimen showing the test segment

The dimensions of the whole cement specimen are 80mm in length, 10mm in breadth of middle segment, 5mm in depth of the specimen (Fig 13). The dimensions of the test segment were 20mm span length; 10mm span breadth and 5mm depth of the specimen (Fig 14).

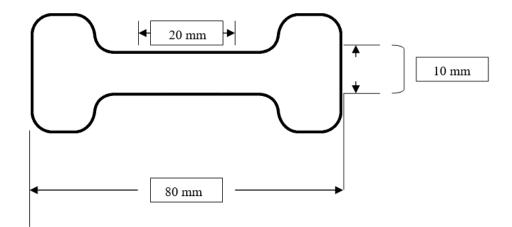


Figure 13. Dimensions of whole cement specimen

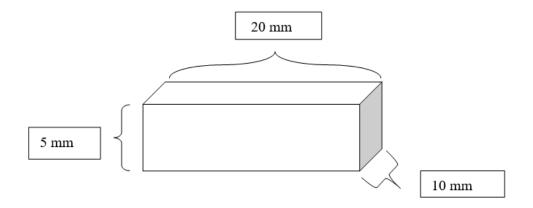


Figure 14. Dimensions of test span

Three-point bending test

The machine (Fig 15) used for testing the bending strength of the bone cement was RDP HOWDEN KN Electric Twin Screw Universal Testing Machine (RDP Group, Lamington Spa, Warwickshire, UK) Medical Physics Laboratory, Ninewells Hospital, University of Dundee, Scotland, UK.



Figure 15. Universal testing machine connected to computer

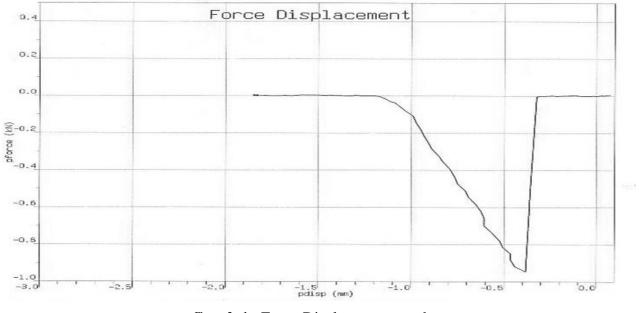
The crosshead speed was set at the rate of 20mm/minute or 0.33mm/second. Tests were conducted at room temperature of 22° Celsius. The test specimens were subjected to 3-point bending (Fig 16) and monitoring of specimens was done by a force-displacement graph on the computer screen. The software used was Pico (Cambridge, UK). A graph was recorded each time a specimen was fractured (Graph 1). All the specimens fractured in a brittle manner without any significant change in width of the specimen at fracture site (Fig 17).



Figure 16. Three-point bending test



Figure 17. Fractured cement specimen



Graph 1. Force-Displacement graph

Results

The aim of the study was to measure the effects of mixing regimes namely, manual mixing and vacuum mixing on the bending strength of bone cement.

The study group comprised of 30 specimens each of manually mixed and vacuum mixed cement respectively. The cement specimens were subjected to bending force on Universal testing machine (Fig 15) and force-displacement graph was recorded (Graph 1).

Measurement Of Bending Strength

The bending strength of a beam is dependent upon the strength of the material, the cross-sectional area and the cross-sectional shape. The bending strength was calculated using the following formula as given below.

 $M/I = \sigma/y$, where M is the bending moment which is calculated by multiplying the bending force into distance of span, I is the second moment of area which for a rectangular cross-section is calculated by, I = $bd^3/12$ (b = breadth of the span and d = depth of the span). σ (sigma) is the bending stress and, y is the displacement of extreme layer of the beam from neutral axis of the specimen. From the above formulae σ or bending stress can be calculated as follows, $\sigma = (M \times y)/I$, the bending strength derived is expressed in Mega Pascal or MPa (Dolan and Drew 2002).

The result of bending strength of manual mixed cement and vacuum mixed cement specimen, as measured on force-displacement graphs are recorded in Table 4. Values are in Kilo-Newton (KN) for bending force and Mega Pascal (MPa) for bending strength.

	Manual mixing		Vacuum mixing	
	Bending force	Bending strength	Bending force	Bending strength
1	834.86 KN	100.18 MPA	981.65 KN	117.72 MPa
2	807.33	96.82	954.12	114.50
3	807.33	96.82	944.95	113.40
4	770.64	92.48	844.03	101.29
5	750.00	84.00	699.72	83.92
6	762.38	91.49	770.64	92.48
7	880.73	105.69	972.47	116.70

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8	614.67	73.76	642.20	77.06
9	633.02	75.96	715.59	85.87
10	844.03	101.29	834.86	100.18
11	706.42	84.77	761.46	91.38
12	688.02	82.57	954.12	114.49
13	908.25	108.99	752.29	90.28
14	614.67	73.76	834.86	100.18
15	816.00	97.98	871.55	104.59
16	642.20	77.06	770.64	92.48
17	680.73	81.69	871.55	104.59
18	770.64	92.48	926.60	111.19
19	660.55	79.27	981.65	117.80
20	706.42	8477	944.95	113.40
21	706.42	84.77	724.77	86.97
22	634.86	76.18	651.37	78.16
23	678.89	81.47	706.44	84.77
24	633.94	76.07	926.60	111.19
25	762.38	91.49	853.21	102.39
26	668.25	72.99	743.11	89.17
27	577.98	69.36	798.16	95.78
28	708.25	84.99	871.55	104.59
29	651.37	78.16	752.29	90.28
30	552.00	66.27	706.42	84.77

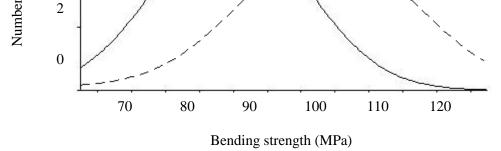
Table 4. Bending force and bending strength of cement specimens

Statistical Analysis

Statistical analysis of data was done using SPSS software. The mean bending strength was 84.68MPa for manual mixed cement and 99.05MPa for vacuum mixed cement. The standard deviation was 11.03 and 12.58 respectively for manual and vacuum method of mixing (Table 5). The data were checked for normality of distribution; an independent't' test was carried out on the data and was found to be significantly different. The P value was found to be less than 0.001.

Method	Number	Mean strength	Std. deviation	Std. error mean
Manual mixing	30	84.68 MPa	11.03	2.014
Vacuum mixing	30	99.05 MPa	12.58	2.296

Table 5. Group statistics



Graph 2 shows the difference between the bending strength of two methods, clearly the vacuum mixing gave a higher bending strength over the manual mixed specimen.

The study found that the bending strength of vacuum mixed cement was 17.01% more than manual mixed cement, which was statistically significant.

Miscellaneous Observations

The manual mixed cement specimens that had macroscopic voids and irregularities were not included in the study whereas there were no such defects in the vacuum mixed cement specimens. The thickness of specimen was measured at three different places using a micrometer and was found to be almost uniform with average thickness of 5mm.

There was no significant relationship between the minor thickness variation and the bending strength of specimens in this study.

The vacuum mixed specimens had a consistent bending strength when compared to the hand mixed specimens, which showed some variation. There was no exposure to monomer fumes in vacuum mixing and was found to be advantageous.

Discussion

Mechanical loosening has been implicated as one of the most important reasons in the failure of total joint replacement. Modern mixing techniques are a logical step in the attempt to improve the quality and durability of bone cements and there by the efficiency of total joint replacement. The aim of this study was to determine the effects of manual mixing and vacuum mixing on the bending strength of acrylic bone cement.

Vacuum mixing produced statistically significant increase in the bending strength of bone cement when compared to manual mixed cement (P value < 0.001). The study showed 17.01% increase in the bending strength of cement specimen produced by vacuum mixing.

PMMA is used for various purposes in orthopaedic surgery where it may be subjected to varying degree of bending effect. Bone cement is usually under compression; it has a compressive strength that is three times more than tensile strength. However, under dynamic loading the cement is under combination of various forces namely, compressive, tensile and shear. Hence, an improvement in the bending strength could result in a more durable implant.

This study was done using Palacos R bone cement, which is usually used in orthopaedic joint replacement surgery. Bending strength calculated was consistent with contemporary studies done by various people. Dunn and Orr (2001) showed in their study that a 9-33 % increase in bending strength by vacuum mixing.

Vacuum mixing of cement gave a uniform mix of cement, which had no macroscopic voids, whereas the manual mixed cement had voids in some of the specimens. Those specimens were promptly discarded. One of the major reasons for the early failure of manually mixed specimen was increase in the porosity induced during mixing. The source of porosity are, the air-filled spaces between polymer powder particles, air trapped between lumps of mixing material, air introduced while stirring in manual mixing and, air introduced during application of cement into bony canal. The latter situation is mainly observed in the first-generation cementing technique.

Voids produced can act as stress risers and lead to the failure of cement. Porosity reduces the cross-sectional strength of material; hence porosity reduction is mandatory to improve the dynamic and static properties of bone cement. Wixon et al. (1987) proved that vacuum mixed cement had a porosity of only 1%, when compared to 8% seen in manually mixed cement.

The cement specimen thickness in this study was 5mm, which is consistent with average thickness of 2-5mm in cemented hip arthroplasty. Ebramzadeh et al. (1994) radiologically proved that femoral stems of hip that had a 2-5mm thick mantle in the proximal region had a better outcome than stems implanted with a thinner or thicker cement mantle. Uniform quality cement gives better result and improves the performance of prosthesis stem by allowing even stress relaxation within the cement mantle.

The Hivac syringe used for vacuum mixing in this study was useful in producing cement of uniform quality. The advantage with syringe mixing system is, there is no physical contact with cement and no exposure to monomer fumes during mixing. Vacuum mixing in a bowl has the disadvantage of exposure to atmosphere during the transfer of cement into a gun while that does not occur with syringe systems. Wilkinson et al. (2000) showed that syringe-mixed cement was of greater density, better bending strength and bending modulus. These improvements are definitely helpful in reducing the mis-match between the prosthesis component and cement.

Lidgren et al. (1984) concluded that there was 15-30% increase in the flexural strength and modulus of elasticity of bone cement produced by vacuum mixing. Hansen and Jensen (1990) noted an increase of 15-30% in the bending strength of Palacos standard cement by vacuum mixing. Results of this study reinforce the effectiveness of vacuum mixing, substantiating the evidence found in the literature.

Even though vacuum mixing produces good quality cement, care should be taken while applying the cement into canal. The factors which can cause adverse problems, are poorly prepared canal, active bleeding into

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the canal and, laminations and blood entrapment introduced during curing. These problems can reduce the shear strength of bone cement interface and are purely within the control of operating surgeon. There is overwhelming evidence in the literature that advanced cementing techniques have significantly improved the long-term survival of cemented arthroplasty.

Conclusion

This study proved that vacuum mixing of acrylic bone cement produced statistically significant increase in the bending strength by 17.01% when compared to manually mixed cement.

Vacuum mixing gave better handling of cement. There was more uniformity in the quality and it was more durable. It is easily reproducible and the significant reduction in porosity gave a better bending strength. The ultimate result of cemented joint replacement surgery is better with this method.

The final outcome of any cementing technique is based on the efficacy of the same on clinical stability and longevity of joint replacement. Results of this study should lead to a long-term prospective, randomized clinical study to find out the effect of cementing technique on the performance of cement in cemented arthroplasty.

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