

Comparison of various vacuum mixing systems and bone cements as regards reliability, porosity and bending strength

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Background There are several vacuum mixing systems on the market which are arbitrarily used with various bone cements in clinical work. Hardly any studies have been done on the performance and handling of these systems in combination with different cement brands.

Material and methods We therefore tested 6 vacuum mixing systems (Palamix, Summit, Cemvac, Optivac, Vacumix, MixOR) in combination with 6 cement brands (Palacos R, Simplex P, CWM 1, CWM 2000, Palamed G, VersaBond) concerning their reliability, user-friendliness, porosity and bending strength.

Results Our study indicated that each system has weak points. The preparation of the mixed cement for gun injection can present problems. If cement collection under vacuum fails, porosity is increased. Manual collection without a vacuum carries the risk of intermixing air. For comfortable and effective retrograde cement application, cement guns should have a stable connection with the cartridge and a high piston stroke. There are marked differences between the systems as regards overall porosity when all tested cements are considered (range 2–18%), and between the cements when all tested systems are considered (range 2–17%). All test samples exceeded the required bending strength of 50 MPa, according to ISO 5833. Palacos specimens showed excessive plastic deformation in the bending test.

Interpretation There are better and worse mixing system/cement combinations for a given system and a given cement. Systems with cement collection under vacuum reduce porosity best.

Implantation of a cemented hip prosthesis is a difficult procedure. Failure can occur at the bone-cement interface, the cement mantle itself (Jasty et al. 1991, James et al. 1992) or the cement-implant interface (Jasty et al. 1992, Bishop et al. 1996). Considering the cement mantle itself, the rationale for using cement mixing techniques, which reduce porosity, seems logical and is supported by in vitro studies. These studies show better mechanical properties of vacuum-mixed bone cement than the classical hand mixing method (Lidgren et al. 1984, 1987, Alkire et al. 1987, Schreurs et al. 1988, Linden 1989, Askew et al. 1990, Wang et al. 1993, 1994, Lewis and Austin 1994, Kurdy 1996, Smeds et al. 1997, Lewis 1999, Lewis 2000).

On the basis of the Swedish hip arthroplasty register it was calculated that the use of vacuum mixed bone cement lowers the risk of aseptic loosening in the mid- to long-term follow-up (Malchau et al. 2000). However, no clinical outcome studies have been published in which the mixing technique and cement porosity were evaluated and the clinical relevance of reduction in porosity has been questioned (Ling and Lee 1998, Geiger et al. 2001).

Pores and voids of different sizes in the cement are caused by air that exists in the polymer powder, intermixing air during the mixing process (Charnley 1970), boiling monomer under high vacuum conditions (Draenert 1988) and improper filling of the femoral canal. The use of a vacuum is one of the means of effectively reducing cement porosity during the mixing phase (Lidgren et al. 1984,

Table 1. Cements used, storage, processing temperature and time to gun extrusion

| Cement | stored at °C | mixed at °C | extruded after (min) |
|--|----------------|-------------|----------------------|
| Palamed G (Ch.100299, Biomet Merck, Darmstadt) | 19 | 19 | 2:30 |
| Palacos R (Ch.221196, Palacos liquid: Batch 2791, Biomet-Merck, Darmstadt) | 4 ^a | 22 | 2:30 |
| CMW1 (Lot. A014 R40 Depuy CMW, Blackpool, England) | 22 | 22 | 2:00 |
| CMW2000 (Lot. Y041 V 40, DePuy CMW, Blackpool, England) | 22 | 22 | 2:00 |
| Simplex P (Lot. 588KF 061298, Howmedica, Ireland) | 22 | 22 | 2:00 |
| VersaBond (Ch.002, Coripharm, Dieburg, distributed by Smith & Nephew) | 22 | 22 | 3:20 |

^a monomer/polymer

Table 2. Systems, mixing sequences and vacuum length used. All systems were operated with a compressed air supply of > 5 bar

| System | mixing sequence | mixing time | duration of vacuum, s | compressed air supply required, bar |
|--|--------------------|---|-----------------------|-------------------------------------|
| Palamix (Biomet Merck, Darmstadt) | polymer in monomer | 30 s vacuum build-up 15 s mixing, 15 s final evacuation | 60 | > 5 |
| Syringe System (Summit Medical, Gloucestershire, UK) | monomer in polymer | 45 s mixing | 45 | – |
| Optivac (Mebio Scandimed Dieburg, Biomet-Merck, Darmstadt) | polymer in monomer | 10 s vacuum build-up, 30 s mixing | 40 | > 5 |
| Cemvac Method (Cemvac System AB, Sweden) | polymer in monomer | 10 s vacuum build-up 15 s mixing 15 s final evacuation | 40 | 4–6 |
| VacuMix Plus (DePuy CMW, Leeds, UK) | monomer in polymer | 60 s mixing | 60 | 4–7 |
| MixOR (Smith&Nephew, Memphis) | polymer in monomer | 10 s vacuum build-up 30 s mixing | 40 | 5–10 |

Wang et al. 1996). However, the mixing result is affected by the user (Eyerer and Jin 1986) and improper technique impairs the outcome.

Several vacuum mixing systems are now commercially available, but recommendations about which cement performs best with each system are rarely given by the manufacturers. Therefore, in clinical work, various vacuum mixing systems and cement brands are arbitrarily combined, but the effectiveness of these combinations has rarely been investigated. On the basis of a recent survey in Germany on current standards in cementing technique (Breusch et al 1999), we chose 6 vacuum mixing systems, 4 commonly used and 2 recently introduced bone cements. The systems were tested as regards their user-friendliness, reliability and effectiveness in reducing porosity in combination

with the various cement brands. A four-point bending test was used as a simple mechanical test of the samples.

Material and methods

Tables 1 and 2 show the cements, systems and conditions used. The mixing sequence was done as recommended by the manufacturer of the system. All mixing procedures were performed by a single medical student (K.S.). For each system, the mixing process was tried three times under the supervision of the manufacturer to familiarize the student with it. A double pack (80 g polymer) of cement was used with the systems, except with Palamix, because it is prepacked with 60 g of

Palamed. The mixing systems were tested with the 6 different cements, which resulted in 31 ($6 \times 5 + 1$) possible combinations as Palamix can be used only with Palamed. 10 mixing procedures were carried out for each combination. The cement was filled retrogradely in a plastic tube measuring 17 mm in diameter and 120 mm in length (Greiner, Heidelberg) to simulate roughly the clinical situation. All failures or subjective shortcomings (handiness, ease of use, stability) during mixing and cement application via the cement gun supplied with the systems were recorded. To assess reliability and effectiveness of pore reduction no cement mix was excluded

Porosity

The cured cement from the plastic tubes and from the syringe nozzle was cut parallel into four 5 mm discs, respectively, with a diamond saw during continuous cooling. Standardized microradiographs were taken and scanned for image analysis (Kontron KS300, Carl Zeiss Vision GmbH). Macroporosity was measured by counting pores in categories of 1–2 mm, 3–5 mm, and > 5 mm in diameter. For each category, the number of pores was multiplied by the square of the mean pore diameter (2.25, 16 and 36 for pores 1–2 mm, 3–5 mm, and > 5 mm in diameter) with the sum giving a porosity score. Total porosity was determined by discrimination of grey shades and calculated as area of pores to total area of the disc in percentage. Microporosity was assessed in every other disc. The discs were sanded with sandpaper no. 800, stained with shoe polish and excess shoe polish was removed with a razor blade. The stained discs were viewed under a stereomicroscope (Olympus Sz6045TR 4 magnification) and digitized with a Videocamera (DXC-950P, Sony) for image analysis (Kontron KS300, Carl Zeiss Vision GmbH). Microporosity was calculated for pores < 1 mm per field as a dark area to the total area in percentage. Inhomogeneities (incomplete mixing, aggregates of contrast material) of the cement were recorded. The examiner was blinded for macro- and microporosity evaluations.

Bending strength

Bending strength was determined, according to ISO 5833. In short, cement was pressed in teflon-

coated metal molds. After setting, the cement was cut into $3.3 \times 75 \times 10$ mm test stripes and stored under dry conditions for 14 days, after which the samples were kept in 37° Ringer is solution for 48 h. The test stripes were measured with calipers and a four-point bending test was done in a material testing machine (Frank-Universal-Prüfmaschine 81816/B) at a cross-head speed of 5 mm/min. 4 specimens were tested from each cement mix.

Statistics

Means and standard deviations (SD) were calculated for the outcome values. Range (i.e., min/max-values), confidence intervals (CI) and Scheffé tests were also calculated. A two-tailed p-value equal to or less than 0.05 was considered significant. All tests were two-sided. Because of the explorative design of that study, no Alpha-adjustment was made. Data analysis was done with SPSS for Windows 11.0.1 (SPSS inc. Chicago, Illinois, USA).

Results

User-friendliness and reliability

Illustrated instructions are supplied for all systems. A CD is also available for Cemvac and a video for Optivac. Table 3 summarizes the features, user-friendliness and problems with the mixing systems.

Macroporosity

With all systems, a low total porosity can be achieved, except with the combination CMW1/VacuMix, CMW2000/Summit and CWM2000/VacuMix (see Table 4, minimum values). A significantly lower mean total porosity for all systems was found with Versabond (mean 2%), Palacos (mean 4.9%) and Palamed (mean 7%) than with CMW1 (mean 12.6%) and CMW2000 (mean 17%) cement. Simplex was in the intermediate range (mean 7.9%).

As regards the mean total porosity of all cements, Cemvac, Optivac and MixOR performed significantly better than Summit and VacuMix (Table 4). The Palamix system showed a mean total porosity in between. In the samples (Optivac, MixOr) in which the automatic collecting mechanism failed, a high total porosity was found. The porosity was

Table 3. Features, userfriendliness and problems with the mixing systems

| System | Build up | Way of mixing | Cement collection | Cement gun and extrusion | Problems | Specials |
|---------------------|--------------------------|-----------------------|---|--|--|---|
| Palamix | stable | Vertical | Dismantling of the stirring rod and collecting the cement requires multiple steps. | The cartridge can be firmly connected to the cementgun via a thread. Long extrusion times from the cement gun due to the low feeding rate | | Prepacked system for 60g of Palamed The air is evacuated separately from the components before vacuum mixing. |
| Summit | Stable | Rotational | Dismantling of the stirring rod is complicated as cement has to be manually wiped off | The cartridge can be firmly connected to the cement gun via a thread. The cement gun requires high forces for cement extrusion due to the high ratio of the plunger to the nozzle diameter | Black streaks from the seal can be intermixed into the cement. The lid was deformed during extrusion of high viscosity cements and cement can leak through the thread | |
| Cemvac | Wobbly due to its height | Vertical and twisting | Cement is collected manually while the vacuum is still applied | Firm connection to the cementgun. Easy cement extrusion from the cement gun. | Sometimes the narrow filling funnel is blocked by cementpowder and has to be freed by shaking before the cartridge is sealed with the plugging rod | The vacuum pump is switched on to suck the components into the cartridge |
| Optivac | Stable | Vertical and twisting | The cement is automatically collected under vacuum | Firm connection to the cementgun. Easy cement extrusion from cement gun | Automatic collection failed twice. With Versabond and Simplex cement monomer was sucked into the vacuum filter | Extensions are available for 120g polymer |
| VacuMix Plus | Stable | Rotational | Removal of the stirring rod is impractical as the cement has to be manually wiped off | The cementgun has a stable connection and was the most comfortable to use | The "economiser" can break early during cement extrusion with high viscosity cement and the cement cannot be fully extruded. Only 60g of the more voluminous Simplex P can be loaded into the system | A mechanism called "economiser" is built in to reduce the dead space of the nozzle. After the cement is extruded from the cartridge the driving rod breaks through the lid into the nozzle and extrudes the cement from the nozzle. It is available as a prepack for CMW1 and CMW2000 |
| MixOr | Sstable | Vertical and twisting | Cement is collected automatically under vacuum | The connection to the cement gun is not very stable. Cementgun and cartridge have to be stabilized with both hands. Low feeding rate of the cementgun | The automatic cement collection failed 7 times. With Versabond, Simplex, Palacos and Palamed cement monomer was occasionally sucked into the vacuum filter | It is the only system with an integrated barometer that shows the actual vacuum pressure. Extensions are available for 120g polymer (90g Simplex P). |

always lower in the cylinders than in the nozzles (data not shown).

The mean macropore score of all cements in each mixing system was significantly lower for Cemvac (mean 31), Optivac (mean 44) and MixOr (mean 45), as compared to the Summit (mean 81) and VacuMix (mean 84) systems. The score of the

Palamix system (mean 76) was close to that of the Summit (mean 71), VacuMix (mean 93) and MixOr (mean 72), while using Palamed. Optivac (mean 15) and Cemvac (mean 50) had significantly lower scores with the Palamed cement. Versabond (mean 14) had a significantly lower score than the other cements (Table 5).

Table 4. Data of total porosity (%) from cylinders

| | mean | SD | min.–max. | 95% CI | n |
|----------------|------|-----|---------------------|----------|----|
| VacuMix | | | | | |
| All cements | 18 | 15 | 1.5–57 | 14–22 | 60 |
| Palamed | 11 | 7.1 | 4.0–27 | 5.7–16 | 10 |
| Palacos | 5.2 | 3.0 | 1.5–11 | 3.1–7.3 | 10 |
| CWM1 | 23 | 5.1 | 16–33 | 19–27 | 10 |
| CWM2000 | 46 | 7.6 | 34–57 | 40–51 | 10 |
| SimplexP | 17 | 11 | 4.8–38 | 9.5–25 | 10 |
| Versabond | 8.0 | 4.5 | 2.8–19 | 4.8–11 | 10 |
| Summit | | | | | |
| All cements | 13 | 11 | 0.0–37 | 9.8–15 | 60 |
| Palamed | 12 | 7.7 | 1.8–25 | 6.7–18 | 10 |
| Palacos | 6.3 | 2.2 | 2.6–9.8 | 4.7–7.9 | 10 |
| CWM1 | 23 | 12 | 2.9–37 | 15–32 | 10 |
| CWM2000 | 24 | 8.0 | 13–37 | 18–30 | 10 |
| SimplexP | 9.5 | 3.9 | 2.4–14 | 6.7–12 | 10 |
| Versabond | 0.4 | 0.6 | 0.0–1.5 | –0.1–0.8 | 10 |
| MixOR | | | | | |
| All cements | 4.9 | 13 | 0.0–70 | 1.6–8.2 | 60 |
| Palamed | 4.0 | 10 | 0.0–33 ^a | –3.3–11 | 10 |
| Palacos | 8.0 | 11 | 0.2–32 ^a | 0.4–16 | 10 |
| CWM1 | 14 | 26 | 0.0–70 ^a | –4.8–32 | 10 |
| CWM2000 | 2.4 | 4.2 | 0.0–13 | –0.7–5.4 | 10 |
| SimplexP | 0.6 | 0.7 | 0.0–2.2 | 0.1–1.2 | 10 |
| Versabond | 0.6 | 1.3 | 0.0–4.2 | –0.4–1.5 | 10 |
| Cemvac | | | | | |
| All cements | 1.8 | 3.1 | 0.0–13 | 1.0–2.6 | 60 |
| Palamed | 2.8 | 3.9 | 0.0–11 | 0.0–5.6 | 10 |
| Palacos | 1.4 | 1.5 | 0.0–4.8 | 0.4–2.5 | 10 |
| CWM1 | 1.6 | 2.4 | 0.0–7.8 | –0.1–3.3 | 10 |
| CWM2000 | 1.6 | 2.7 | 0.0–7.8 | –0.3–3.6 | 10 |
| SimplexP | 3.3 | 4.9 | 0.0–13 | –0.2–6.8 | 10 |
| Versabond | 0.0 | 0.1 | 0.0–0.2 | 0.0–0.1 | 10 |
| Optivac | | | | | |
| All cements | 4.4 | 7.0 | 0.0–33 | 2.6–6.2 | 60 |
| Palamed | 0.7 | 1.0 | 0.0–3.3 | 0.1–1.4 | 10 |
| Palacos | 3.7 | 2.2 | 0.4–7.4 | 2.1–5.3 | 10 |
| CWM1 | 1.5 | 3.0 | 0.0–9.4 | –0.6–3.7 | 10 |
| CWM2000 | 11 | 6.7 | 0.5–23 | 6.5–16 | 10 |
| SimplexP | 8.5 | 12 | 0.0–33 ^a | –0.3–17 | 10 |
| Versabond | 0.8 | 1.3 | 0.0–3.7 | –0.1–1.8 | 10 |
| Palamix | | | | | |
| Palamed | 12 | 7.8 | 2.4–24 | 6.1–17 | 10 |

^a samples with vacuum failure

Microporosity

The mean microporosity was significantly lower with the Cemvac (mean 0.7), Optivac (mean 0.7) than the Summit (mean 3.5) or VacuMix (mean 2.2) systems (Table 6). All cements, even the high viscosity ones CMW1 and CMW2000, had a low microporosity with the Cemvac or Optivac system. The Palamix (mean 1.4) system gave intermediate result. In the samples (Optivac, MixOr) in which the automatic collecting mechanism failed, a high microporosity was found (Figure).

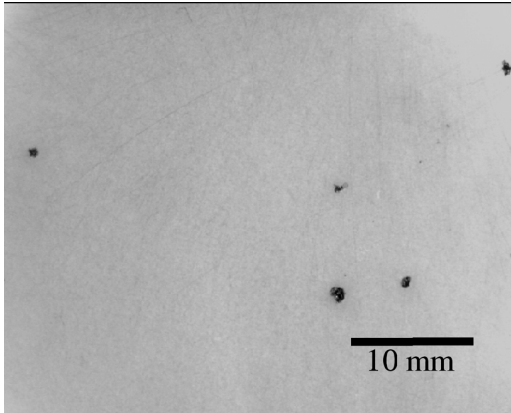
Table 5. Data concerning macropore score from cylinders

| | mean | SD | min.–max. | 95% CI | n |
|----------------|------|-----|-----------|----------|----|
| VacuMix | | | | | |
| All cements | 84 | 50 | 9.0–211 | 71–97 | 60 |
| Palamed | 93 | 33 | 48–155 | 70–117 | 10 |
| Palacos | 126 | 65 | 11–211 | 79–172 | 10 |
| CWM1 | 94 | 21 | 64–127 | 79–109 | 10 |
| CWM2000 | 58 | 32 | 25–128 | 35–80 | 10 |
| SimplexP | 109 | 47 | 50–209 | 76–142 | 10 |
| Versabond | 24 | 13 | 9.0–48 | 14–33 | 10 |
| Summit | | | | | |
| All cements | 81 | 55 | 0.0–207 | 67–95 | 60 |
| Palamed | 71 | 41 | 29–155 | 42–100 | 10 |
| Palacos | 56 | 32 | 27–134 | 33–79 | 10 |
| CWM1 | 100 | 43 | 39–161 | 69–131 | 10 |
| CWM2000 | 125 | 49 | 59–207 | 90–160 | 10 |
| SimplexP | 127 | 31 | 72–189 | 105–149 | 10 |
| Versabond | 9.3 | 13 | 0.0–38 | 0.0–19 | 10 |
| MixOR | | | | | |
| All cements | 45 | 53 | 0.0–254 | 31–59 | 60 |
| Palamed | 72 | 80 | 0.0–254 | 15–130 | 10 |
| Palacos | 77 | 67 | 9.0–230 | 29–124 | 10 |
| CWM1 | 42 | 34 | 2.3–120 | 18–66 | 10 |
| CWM2000 | 37 | 43 | 2.3–113 | 6.5–68 | 10 |
| SimplexP | 24 | 27 | 0.0–91 | 2.9–45 | 10 |
| Versabond | 18 | 25 | 0.0–71 | 0.0–35 | 10 |
| Cemvac | | | | | |
| All cements | 31 | 43 | 0.0–172 | 20–42 | 59 |
| Palamed | 50 | 52 | 0.0–142 | 12–87 | 10 |
| Palacos | 55 | 46 | 6.8–145 | 22–85 | 10 |
| CWM1 | 21 | 27 | 0.0–70 | 1.4–40 | 10 |
| CWM2000 | 11 | 17 | 0.0–55 | –1.0–24 | 10 |
| SimplexP | 47 | 55 | 4.5–172 | 7.0–86 | 10 |
| Versabond | 0.5 | 1.0 | 0.0–2.3 | –0.3–1.3 | 9 |
| Optivac | | | | | |
| All cements | 44 | 45 | 0.0–214 | 33–56 | 60 |
| Palamed | 15 | 14 | 0.0–36 | 5.7–25 | 10 |
| Palacos | 82 | 28 | 39–125 | 62–102 | 10 |
| CWM1 | 39 | 32 | 0.0–86 | 16–61 | 10 |
| CWM2000 | 50 | 52 | 4.5–154 | 13–87 | 10 |
| SimplexP | 63 | 66 | 2.3–214 | 16–110 | 10 |
| Versabond | 17 | 22 | 0.0–68 | 1.2–32 | 10 |
| Palamix | | | | | |
| Palamed | 76 | 38 | 6.8–132 | 49–103 | 10 |

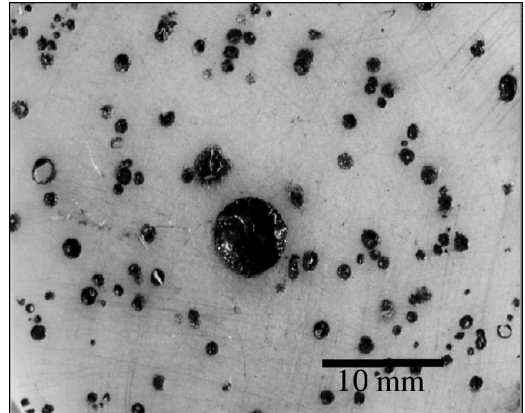
In some microradiographs, inhomogeneities indicating heterogeneous mixing were seen with the Summit and VacuMix systems. These streaks were also occasionally observed in CMW1 and Simplex P samples with the Optivac system. In the bariumsulfate-containing cements (CMW1, CMW2000, Simplex P) fine aggregates of this additive were seen. This could not be detected in the zirconiumdioxide-containing cements.

Bending strength

All test samples exceeded the required minimum



Palacos/MixOR sample with low microporosity.



Palacos/MixOR sample in which the automatic cement collection under vacuum failed.

bending strength of 50 MPa, according to ISO 5833 (Table 7). Versabond reached the highest value (mean 65 (1.1) MPa). The bending strength of Palacos (mean 57 (1.8) MPa) was significantly lower than that of other cements. This is because most of the samples did not break, but failed with plastic deformation and therefore bending strength had to be calculated with the maximal force before deformation occurred instead of the breaking force. We found a strong correlation of 0.82 between microporosity and bending strength if Palacos cement was excluded. The only significant difference in the systems was found for the Cemvac (mean 63 (2.1) MPa), as compared to the Summit (mean 60 (3.3) MPa) system.

Discussion

Several vacuum mixing systems are now commercially available and in use. We tested 6 systems in combination with 6 bone cements and we found that the cement-handling properties and quality are affected by the various vacuum mixing systems. One shortcoming of our study is that no samples were prepared by the classical hand mixing method. Evaluation of porosity is not standardized and the absolute values from various studies are not comparable. Therefore, some of the samples with a high porosity in this study may have a still lower porosity than with hand mixing.

Several factors influence the porosity for a given cement mix. These include the design and size

of the mixing vessel (Wilkinson et al. 2000), the mixing rod design (Wixson et al. 1987, Kurdy et al. 1996) and the duration and amount of vacuum applied (Draenert 1988). Alkire et al. (1987) showed that for effective porosity reduction, a minimum of about 0.5 bar is required. Wang et al. (1996) found no differences in macroporosity with a vacuum between 0.2 bar and 0.05 bar when using cement collection under a vacuum. On the other hand application of a high and prolonged vacuum results in loss of monomer by sucking it out or by boiling, which has a negative effect on wetting of the polymer, the polymerization process and on cement quality (Lidgren et al. 1987, Wixson et al. 1987, Hahn et al. 1990, Draenert et al. 1999). However, loss of monomer by boiling is minimal and does not increase porosity (Müller-Wille and Lidgren 1996). Another reason for sucking out monomer is overstuffing of the mixing cartridge, which can occur with the more voluminous cements and, therefore, the mixing cartridge should be adapted to the cement volume. Not all tested systems allow enough space for different amounts of cement. The latest research data showed that an optimal cement quality is obtained from a matched amount of cement in a suitable size of mixing system. The study was performed with various cements in different sizes of Optivac (Wang and Kjellson 2001).

All tested systems are designed to work with a compressed air supply of > 5, bar which is usually available in the operating room. We did not measure the actual vacuum during mixing but the

Table 6. Data of microporosity (%) from cylinders

| | mean | SD | min.–max. | 95% CI | n |
|----------------|------|-----|---------------------|----------|----|
| VacuMix | | | | | |
| All cements | 2.2 | 2.1 | 0.3–7.3 | 1.7–2.8 | 60 |
| Palamed | 1.2 | 0.9 | 0.5–3.7 | 0.6–1.9 | 10 |
| Palacos | 3.1 | 1.5 | 1.1–6.1 | 2.0–4.2 | 10 |
| CWM1 | 5.5 | 1.4 | 3.2–7.3 | 4.5–6.5 | 10 |
| CWM2000 | 1.7 | 1.7 | 0.5–6.1 | 0.5–2.9 | 10 |
| SimplexP | 1.1 | 1.5 | 0.3–5.4 | 0.0–2.2 | 10 |
| Versabond | 0.8 | 0.5 | 0.3–1.8 | 0.5–1.1 | 10 |
| Summit | | | | | |
| All cements | 3.6 | 2.9 | 0.3–18 | 2.8–4.3 | 60 |
| Palamed | 2.1 | 1.4 | 0.9–5.9 | 1.1–3.1 | 10 |
| Palacos | 4.1 | 1.0 | 2.5–6.3 | 3.4–4.8 | 10 |
| CWM1 | 4.7 | 1.8 | 1.5–6.9 | 3.5–6.0 | 10 |
| CWM2000 | 6.5 | 4.2 | 1.5–18 | 3.5–9.5 | 10 |
| SimplexP | 3.0 | 2.5 | 0.5–9.3 | 1.2–4.8 | 10 |
| Versabond | 0.8 | 1.1 | 0.3–3.9 | –0.1–1.6 | 10 |
| MixOR | | | | | |
| All cements | 1.9 | 3.8 | 0.2–14 | 0.9–2.9 | 60 |
| Palamed | 1.4 | 3.4 | 0.3–11 ^a | –1.0–3.8 | 10 |
| Palacos | 3.2 | 5.0 | 0.2–14 ^a | –0.4–6.8 | 10 |
| CWM1 | 2.5 | 4.7 | 0.3–12 ^a | –0.8–5.9 | 10 |
| CWM2000 | 2.7 | 5.0 | 0.3–14 | –0.9–6.3 | 10 |
| SimplexP | 0.5 | 0.4 | 0.3–1.7 | 0.2–0.8 | 10 |
| Versabond | 0.8 | 1.2 | 0.2–4.0 | 0.0–1.6 | 10 |
| Cemvac | | | | | |
| All cements | 0.7 | 1.4 | 0.0–9.6 | 0.3–1.1 | 60 |
| Palamed | 1.9 | 2.8 | 0.0–9.6 | –0.1–3.9 | 10 |
| Palacos | 0.3 | 0.1 | 0.2–0.4 | 0.2–0.3 | 10 |
| CWM1 | 0.4 | 0.7 | 0.0–2.4 | –0.1–0.9 | 10 |
| CWM2000 | 0.8 | 1.6 | 0.0–5.6 | –0.4–2.0 | 10 |
| SimplexP | 0.6 | 0.6 | 0.0–1.9 | 0.1–1.1 | 10 |
| Versabond | 0.2 | 0.1 | 0.0–0.3 | 0.1–0.3 | 10 |
| Optivac | | | | | |
| All cements | 0.7 | 1.2 | 0.0–7.1 | 0.4–1.0 | 60 |
| Palamed | 1.1 | 0.2 | 0.9–1.4 | 1.0–1.3 | 10 |
| Palacos | 0.5 | 0.3 | 0.2–1.3 | 0.2–0.7 | 10 |
| CWM1 | 0.4 | 0.2 | 0.3–0.7 | 0.3–0.5 | 10 |
| CWM2000 | 0.3 | 0.1 | 0.0–0.5 | 0.2–0.4 | 10 |
| SimplexP | 1.8 | 2.6 | 0.3–7.1 | –0.1–3.7 | 10 |
| Versabond | 0.3 | 0.1 | 0.2–0.5 | 0.3–0.4 | 10 |
| Palamix | | | | | |
| Palamed | 1.4 | 0.4 | 1.1–2.1 | 1.2–1.7 | 10 |

^a samples with vacuum failure

vacuum pressure in the systems is intended to be 0.1–0.5 bar. This pressure may vary and, indeed, the vacuum build-up was occasionally insufficient in the MixOR system, resulting in a high porosity. The reasons for this can be that the system is not air-tight or there is some malfunction of the pump. It can be assumed that this may also happen with the other systems, but is not easily recognized by the user because the MixOR system is the only one with an integrated barometer. Boiling of monomer could not be detected in any of the systems as the

Table 7. Data of bending strength (MPa) from cylinders

| | mean | SD | min.–max. | 95% CI | n |
|----------------|------|-----|-----------|--------|----|
| VacuMix | | | | | |
| All cements | 62 | 3.5 | 51–68 | 61–63 | 60 |
| Palamed | 62 | 1.2 | 61–65 | 61–63 | 10 |
| Palacos | 58 | 3.9 | 51–63 | 55–61 | 10 |
| CWM1 | 61 | 2.4 | 59–66 | 60–63 | 10 |
| CWM2000 | 63 | 2.2 | 58–65 | 61–64 | 10 |
| SimplexP | 64 | 2.1 | 61–68 | 62–65 | 10 |
| Versabond | 66 | 2.0 | 61–67 | 65–68 | 10 |
| Summit | | | | | |
| All cements | 60 | 3.9 | 49–67 | 59–61 | 60 |
| Palamed | 61 | 0.9 | 60–63 | 61–62 | 10 |
| Palacos | 54 | 1.7 | 52–57 | 53–55 | 10 |
| CWM1 | 60 | 2.4 | 56–65 | 59–62 | 10 |
| CWM2000 | 61 | 1.7 | 57–63 | 59–62 | 10 |
| SimplexP | 62 | 4.6 | 49–65 | 59–65 | 10 |
| Versabond | 64 | 2.4 | 59–67 | 62–65 | 10 |
| MixOR | | | | | |
| All cements | 62 | 3.8 | 54–73 | 61–63 | 60 |
| Palamed | 61 | 1.9 | 57–63 | 60–62 | 10 |
| Palacos | 57 | 1.9 | 54–59 | 55–58 | 10 |
| CWM1 | 62 | 2.9 | 58–66 | 60–64 | 10 |
| CWM2000 | 64 | 2.8 | 59–70 | 62–66 | 10 |
| SimplexP | 64 | 1.6 | 62–66 | 63–65 | 10 |
| Versabond | 66 | 3.6 | 61–73 | 63–68 | 10 |
| Cemvac | | | | | |
| All cements | 63 | 3.1 | 54–70 | 62–64 | 50 |
| Palamed | 64 | 2.9 | 58–68 | 62–66 | 10 |
| Palacos | 60 | 1.5 | 51–61 | 58–61 | 10 |
| CWM1 | 64 | 1.2 | 62–66 | 63–65 | 10 |
| CWM2000 | 66 | 2.0 | 63–70 | 65–67 | 10 |
| SimplexP | 63 | 3.2 | 54–66 | 61–65 | 10 |
| Versabond | – | – | – | – | 0 |
| Optivac | | | | | |
| All cements | 62 | 4.2 | 52–69 | 61–63 | 60 |
| Palamed | 64 | 4.4 | 52–69 | 61–67 | 10 |
| Palacos | 56 | 3.6 | 52–64 | 54–59 | 10 |
| CWM1 | 59 | 1.8 | 56–61 | 58–60 | 10 |
| CWM2000 | 62 | 1.4 | 59–63 | 61–63 | 10 |
| SimplexP | 65 | 1.8 | 61–68 | 64–66 | 10 |
| Versabond | 64 | 3.3 | 56–68 | 61–66 | 10 |
| Palamix | | | | | |
| Palamed | 60 | 1.5 | 56–62 | 59–61 | 10 |

cartridges are opaque with only the Summit and Optivac cartridge being more transparent.

The design of the mixing rod may also affect the mixing result (Wixson et al. 1987, Kurdy 1996). Both systems with large mixing propellers and a fixed central rotating axis (VacuMix, Summit) showed a higher porosity and some macroscopic inhomogeneities were seen in cement mixes of the Summit system at the bottom of the cartridge. Moreover, microscopic inhomogeneities were observed in some samples of the Summit, VacuMix

Table 8. Comparison of the data for total porosity between various cements used: p-values of the Scheffé test

| | Palamed | Palacos | CMW1 | CMW2000 | SimplexP | Versabond |
|------------------------|---------|---------|--------|---------|----------|-----------|
| Mixing system: VacuMix | | | | | | |
| Palamed | – | 0.7 | 0.01 | <0.001 | 0.5 | 1 |
| Palacos | – | – | <0.001 | <0.001 | 0.02 | 1 |
| CWM1 | – | – | – | <0.001 | 0.6 | 0.001 |
| CWM2000 | – | – | – | – | <0.001 | <0.001 |
| SimplexP | – | – | – | – | – | 0.1 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Summit | | | | | | |
| Palamed | – | 0.6 | 0.04 | 0.03 | 1 | 0.02 |
| Palacos | – | – | <0.001 | <0.001 | 1 | 0.6 |
| CWM1 | – | – | – | 1 | 0.005 | <0.001 |
| CWM2000 | – | – | – | – | 0.002 | <0.001 |
| SimplexP | – | – | – | – | – | 0.2 |
| Versabond | – | – | – | – | – | – |
| Mixing system: MixOR | | | | | | |
| Palamed | – | 1 | 0.7 | 1 | 1 | 1 |
| Palacos | – | – | 1 | 1 | 0.9 | 0.9 |
| CWM1 | – | – | – | 0.5 | 0.4 | 0.4 |
| CWM2000 | – | – | – | – | 1 | 1 |
| SimplexP | – | – | – | – | – | 1 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Cemvac | | | | | | |
| Palamed | – | 1 | 1 | 1 | 1 | 0.5 |
| Palacos | – | – | 1 | 1 | 0.9 | 1 |
| CWM1 | – | – | – | 1 | 0.9 | 0.9 |
| CWM2000 | – | – | – | – | 0.9 | 0.9 |
| SimplexP | – | – | – | – | – | 0.3 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Optivac | | | | | | |
| Palamed | – | 0.9 | 1 | 0.01 | 0.2 | 1 |
| Palacos | – | – | 1 | 0.2 | 0.7 | 0.9 |
| CWM1 | – | – | – | 0.03 | 0.2 | 1 |
| CWM2000 | – | – | – | – | 0.9 | 0.02 |
| SimplexP | – | – | – | – | – | 0.2 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Palamix | | | | | | |
| Palamed | – | – | – | – | – | – |

and occasionally Optivac system indicating insufficient mixing.

The major source of reintroducing air is the collection of mixed cement. The systems which are not reopened showed a lower porosity than Summit and Vacumix in which the cement has to be wiped off the mixing rod manually. Collecting the cement under vacuum especially (Wang et al. 1993, 1996) can result in a pore-free mix (MixOR, Optivac, Cemvac). However, if vacuum collection fails, the cement mix has to be rescued by manual manipulation and porosity is increased, as observed in the MixOR (not available with collection under vacuum anymore) and Optivac system. In the Palamix system, the cement cartridge is not

reopened, but the vacuum is interrupted for cement collection and this explains the intermediate result. One feature of this prepacked design is that the air in the components is removed before mixing and this appears to be an advantage (Schreurs et al. 1988, Müller-Wille et al. 1997). However, our study shows clearly that vacuum collection is the most effective measure in reducing porosity.

It is not clear why porosity is lower in the extruded cement than in the nozzle. This finding is less marked for microporosity. An explanation might be that the voids can partly escape from the cement mix if they are extruded from the nozzle. Large voids can be heard well when they burst out of the nozzle.

Table 9. Comparison of the data for microporosity between various cements used: p-values of the Scheffé test

| | Palamed | Palacos | CMW1 | CMW2000 | SimplexP | Versabond |
|------------------------|---------|---------|--------|---------|----------|-----------|
| Mixing system: VacuMix | | | | | | |
| Palamed | – | 0.1 | <0.001 | 1 | 1 | 1 |
| Palacos | – | – | 0.01 | 0.4 | 0.08 | 0.02 |
| CWM1 | – | – | – | <0.001 | <0.001 | <0.001 |
| CWM2000 | – | – | – | – | 1 | 0.8 |
| SimplexP | – | – | – | – | – | 1 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Summit | | | | | | |
| Palamed | – | 0.6 | 0.3 | 0.006 | 1 | 0.9 |
| Palacos | – | – | 1 | 0.4 | 0.9 | 0.08 |
| CWM1 | – | – | – | 0.7 | 0.7 | 0.02 |
| CWM2000 | – | – | – | – | 0.05 | <0.001 |
| SimplexP | – | – | – | – | – | 0.5 |
| Versabond | – | – | – | – | – | – |
| Mixing system: MixOR | | | | | | |
| Palamed | – | 1 | 1 | 1 | 1 | 1 |
| Palacos | – | – | 1 | 1 | 0.8 | 0.8 |
| CWM1 | – | – | – | 1 | 0.9 | 1 |
| CWM2000 | – | – | – | – | 0.9 | 0.9 |
| SimplexP | – | – | – | – | – | 1 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Cemvac | | | | | | |
| Palamed | – | 0.3 | 0.4 | 0.7 | 0.5 | 0.2 |
| Palacos | – | – | 1 | 1 | 1 | 1 |
| CWM1 | – | – | – | 1 | 1 | 1 |
| CWM2000 | – | – | – | – | 1 | 1 |
| SimplexP | – | – | – | – | – | 1 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Optivac | | | | | | |
| Palamed | – | 0.9 | 0.8 | 0.7 | 0.9 | 0.7 |
| Palacos | – | – | 1 | 1 | 0.2 | 1 |
| CWM1 | – | – | – | 1 | 0.2 | 1 |
| CWM2000 | – | – | – | – | 0.1 | 1 |
| SimplexP | – | – | – | – | – | 0.1 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Palamix | | | | | | |
| Palamed | – | – | – | – | – | – |

The volume required to pressurize cement for routine stem implantation after distal plugging of the femoral canal ranges from 30 to 70 mL (Maltry et al. 1995) and usually a double pack of cement is needed to replace cement leakage during pressurization. With Palamix, two whole sets will be needed to fill larger canals and if Simplex P is used, two packs cannot reliably fill the MixOR and Vacumix systems.

The cements in this study varied considerably in porosity when used with the different systems. The reason why a higher porosity was found in high viscosity cements is probably that it takes a longer time to evacuate bubbles from the mix. Lower-

ing the viscosity by prechilling of high viscosity cements is beneficial (Lidgren et al. 1987, Smeds et al. 1987) and has been documented for Palacos (Draenert et al. 1999). However, in our study, the viscosity at the time of mixing had only a minor effect on porosity since a pore-free mix can be obtained with high-viscosity cements in systems with vacuum collection. This has also been noted by Lewis (1999).

Bending strength does not correlate with success in vivo, but reflects a simple mechanical quality parameter of bone cements. All tested samples exceeded the required minimum of 50 MPa, according to ISO 5833, and variations were

Table 10. Comparison of the data for the macropore score between various cements used: p-values of the Scheffé test

| | Palamed | Palacos | CMW1 | CMW2000 | SimplexP | Versabond |
|------------------------|---------|---------|------|---------|----------|-----------|
| Mixing system: VacuMix | | | | | | |
| Palamed | – | 0.6 | 1 | 0.5 | 1 | 0.01 |
| Palacos | – | – | 0.6 | 0.02 | 1 | <0.001 |
| CWM1 | – | – | – | 0.5 | 1 | 0.01 |
| CWM2000 | – | – | – | – | 0.1 | 0.6 |
| SimplexP | – | – | – | – | – | 0.001 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Summit | | | | | | |
| Palamed | – | 1 | 0.7 | 0.07 | 0.06 | 0.02 |
| Palacos | – | – | 0.2 | 0.007 | 0.006 | 0.2 |
| CWM1 | – | – | – | 0.8 | 0.8 | <0.001 |
| CWM2000 | – | – | – | – | 1 | <0.001 |
| SimplexP | – | – | – | – | – | <0.001 |
| Versabond | – | – | – | – | – | – |
| Mixing system: MixOR | | | | | | |
| Palamed | – | 1 | 0.9 | 0.8 | 0.5 | 0.3 |
| Palacos | – | – | 0.8 | 0.7 | 0.4 | 0.3 |
| CWM1 | – | – | – | 1 | 1 | 1 |
| CWM2000 | – | – | – | – | 1 | 1 |
| SimplexP | – | – | – | – | – | 1 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Cemvac | | | | | | |
| Palamed | – | 1 | 0.7 | 0.4 | 1 | 0.2 |
| Palacos | – | – | 0.6 | 0.3 | 1 | 0.1 |
| CWM1 | – | – | – | 1 | 0.8 | 0.9 |
| CWM2000 | – | – | – | – | 0.5 | 1 |
| SimplexP | – | – | – | – | – | 0.3 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Optivac | | | | | | |
| Palamed | – | 0.02 | 0.9 | 0.6 | 0.2 | 1 |
| Palacos | – | – | 0.3 | 0.7 | 0.9 | 0.03 |
| CWM1 | – | – | – | 1 | 0.9 | 0.9 |
| CWM2000 | – | – | – | – | 1 | 0.6 |
| SimplexP | – | – | – | – | – | 0.3 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Palamix | | | | | | |
| Palamed | – | – | – | – | – | – |

small. Our calculated bending strengths were lower than those reported by Kühn (2000), who, however, with the same test found considerable differences (Kühn 2000). The interesting finding is that about half of the Palacos specimens did not break, but showed excessive plastic deformation. This phenomenon has been reported only by Wilkinson et al. (2000). This property might explain the excellent long-term fixation of cemented hip prostheses reported by the Swedish hip arthroplasty register when Palacos is used (Malchau et al. 2000).

In conclusion, the entire vacuum mixing process, including preparation for gun injection, follows the

principle—the lower the risk of air entrapment, the fewer pores you get.

In our opinion, the following requirements are essential: a barometer to check the actual vacuum, transparent mixing cartridges to check for macroscopic inhomogeneities, no fixed axis-rotating mixing paddles, a well-functioning mechanism to collect cement under vacuum, mixing cartridges adapted to the cement volume and an effective cement gun. So far, no commercially available system fulfills these requirements for a reliable pore-free mix, but the Cemvac and Optivac systems performed best in this study.

Table 11. Comparison of the data for bending strength between various cements used: p-values of the Scheffé test

| | Palamed | Palacos | CMW1 | CMW2000 | SimplexP | Versabond |
|------------------------|---------|---------|--------|---------|----------|-----------|
| Mixing system: VacuMix | | | | | | |
| Palamed | – | 0.008 | 1 | 1 | 0.8 | 0.04 |
| Palacos | – | – | 0.06 | 0.004 | <0.001 | <0.001 |
| CWM1 | – | – | – | 0.9 | 0.4 | 0.005 |
| CWM2000 | – | – | – | – | 0.9 | 0.09 |
| SimplexP | – | – | – | – | – | 0.5 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Summit | | | | | | |
| Palamed | – | <0.001 | 1 | 1 | 1 | 0.5 |
| Palacos | – | – | <0.001 | <0.001 | <0.001 | <0.001 |
| CWM1 | – | – | – | 1 | 0.9 | 0.1 |
| CWM2000 | – | – | – | – | 0.9 | 0.2 |
| SimplexP | – | – | – | – | – | 0.8 |
| Versabond | – | – | – | – | – | – |
| Mixing system: MixOR | | | | | | |
| Palamed | – | 0.02 | 1 | 0.4 | 0.2 | 0.008 |
| Palacos | – | – | 0.003 | <0.001 | <0.001 | <0.001 |
| CWM1 | – | – | – | 0.8 | 0.5 | 0.06 |
| CWM2000 | – | – | – | – | 1 | 0.6 |
| SimplexP | – | – | – | – | – | 0.9 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Cemvac | | | | | | |
| Palamed | – | 0.004 | 1 | 0.4 | 0.9 | – |
| Palacos | – | – | 0.005 | <0.001 | 0.04 | – |
| CWM1 | – | – | – | 0.3 | 1 | – |
| CWM2000 | – | – | – | – | 0.08 | – |
| SimplexP | – | – | – | – | – | – |
| Versabond | – | – | – | – | – | – |
| Mixing system: Optivac | | | | | | |
| Palamed | – | <0.001 | 0.03 | 0.7 | 1 | 1 |
| Palacos | – | – | 0.4 | 0.009 | <0.001 | <0.001 |
| CWM1 | – | – | – | 0.6 | 0.004 | 0.06 |
| CWM2000 | – | – | – | – | 0.3 | 0.9 |
| SimplexP | – | – | – | – | – | 0.9 |
| Versabond | – | – | – | – | – | – |
| Mixing system: Palamix | | | | | | |
| Palamed | – | – | – | – | – | – |

No competing interests declared.

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Table 12. Comparison of the data for total porosity between various mixing systems: p-values of the Scheffé test

| | VakuMix | Summit | MixOR | CemVac | OptiVac | Palamix |
|---------|---------|--------|--------|--------|---------|---------|
| VakuMix | – | 0.1 | <0.001 | <0.001 | <0.001 | 0.6 |
| Summit | – | – | 0.009 | <0.001 | 0.004 | 1 |
| MixOR | – | – | – | 0.8 | 1 | 0.6 |
| CemVac | – | – | – | – | 0.9 | 0.2 |
| OptiVac | – | – | – | – | – | 0.6 |
| Palamix | – | – | – | – | – | – |

Table 13. Comparison of the data for microporosity between various mixing systems: p-values of the Scheffé test

| | VakuMix | Summit | MixOR | CemVac | OptiVac | Palamix |
|---------|---------|--------|-------|--------|---------|---------|
| VakuMix | – | 0.1 | 1 | 0.04 | 0.05 | 1 |
| Summit | – | – | 0.02 | <0.001 | <0.001 | 0.3 |
| MixOR | – | – | – | 0.2 | 0.3 | 1 |
| CemVac | – | – | – | – | 1 | 1 |
| OptiVac | – | – | – | – | – | 1 |
| Palamix | – | – | – | – | – | – |

Table 14. Comparison of the data for the macropore score between various mixing systems: p-values of the Scheffé test

| | VakuMix | Summit | MixOR | CemVac | OptiVac | Palamix |
|---------|---------|--------|-------|--------|---------|---------|
| VakuMix | – | 1 | 0.003 | <0.001 | 0.002 | 1 |
| Summit | – | – | 0.008 | <0.001 | 0.005 | 1 |
| MixOR | – | – | – | 0.8 | 1 | 0.7 |
| CemVac | – | – | – | – | 0.8 | 0.2 |
| OptiVac | – | – | – | – | – | 0.6 |
| Palamix | – | – | – | – | – | – |

Table 15. Comparison of the data for bending strength between various mixing systems: p-values of the Scheffé test

| | VakuMix | Summit | MixOR | CemVac | OptiVac | Palamix |
|---------|---------|--------|-------|--------|---------|---------|
| VakuMix | – | 0.1 | 1 | 0.9 | 0.9 | 0.5 |
| Summit | – | – | 0.3 | 0.005 | 0.7 | 1 |
| MixOR | – | – | – | 0.7 | 1 | 0.6 |
| CemVac | – | – | – | – | 0.3 | 0.2 |
| OptiVac | – | – | – | – | – | 0.8 |
| Palamix | – | – | – | – | – | – |

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