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Evaluation of Prepacked Bone Cement Mixing Systems in Arthroplasty: Implications for Intraoperative Hygiene and Contamination Risk

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Abstract

In cemented endoprosthetics, closed prepacked mixing systems represent the most advanced generation of cementing technology. (1) Background: The purpose of the present study is to evaluate four approved prepacked systems—Palacos® R+G pro, SmartMix™ Cemvac GHV, Optipac® Refobacin and Cemex® System Genta—with a focus on practical handling and intraoperative hygiene. (2) Method: The systems were evaluated according to established standard test methods for bone cements (ISO 5833), including dough time, setting time, additional mechanical tests and the level of system closure. (3) Results: The results show that all systems are safe to use and meet the general requirements, but there are relevant differences in terms of intraoperative hygiene. The Palacos R+G pro system shows significantly shorter doughing and setting times, which helps to minimize wound exposure during surgery and thus significantly reduces the overall operating time and the risk of bacterial contamination. Two of the systems cannot be classified as completely closed "pre-packaged systems." In two cases, the system must be temporarily opened before mixing to insert the mixing element, which may result in a temporary but clinically relevant impairment of sterility and a corresponding potential risk of contamination. (4) Conclusion: From a hygienic point of view, systems that remain completely closed throughout the entire preparation process can offer advantages in terms of infection prevention. This was the case for all systems tested. Short handling times, reduced exposure of the surgical site and a shorter overall duration of the procedure could further improve intraoperative safety and reduce the risk of contamination. In terms of intraoperative hygiene, the Palacos R+G pro system achieved the best results compared to the three other systems tested due to its rapid readiness for use and comparatively short setting time (according to ISO 5833). Cemex System Genta performed worst in this respect due to its late doughing time and setting time.

Keywords: prepacked cement systems; surgical site contamination; doughing and setting time; infection prevention; intraoperative hygiene

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1. Introduction

PMMA bone cements are used in orthopedics to fix artificial joints. Controlled mixing under strong hygiene conditions can be performed in different ways: open mixing, open vacuum mixing and closed vacuum mixing [1,2]. In recent years, hygiene, safety and simpler surgical techniques for mixing and applying cement with accessories have been significantly improved. The term "Modern Cementing Technique" (MCT) is now considered the "state of the art" [2,3]. MCT improves safety, hygiene and reproducibility of cement in the operation theater [2,4,5].

MCT includes pulse lavage, mixing under vacuum, distal femoral closure and proximal femoral sealing. Especially mixing under vacuum is achieved by using modern vacuum cement mixing systems [3,6,7]. Using an external vacuum source removes air from the cartridge of the mixing system and thus also from the cement dough. This results in a reduced porosity by minimizing micro- and macro-pores and an increased density of the cement paste, thus increasing its mechanical strength [2,8,9]. Most mixing systems for bone cements are also equipped with a mixing geometry in the form of a mixing paddle that helps to homogenize the Polymethylmethacrylate (PMMA) powder and the Methylmethacrylate (MMA) liquid [2,10]. The homogeneity of the bone cement and thus the correct ratio of bone cement powder to monomer liquid, therefore, have a significant influence on the mechanical properties [11]. According to several studies, the production of homogeneous, standardized mixtures of bone cement mixtures by well-trained users in modern vacuum mixing systems under controlled hygiene conditions contributes significantly to sustainable surgical results and the long-term stability of the implant [4,12,13].

Open mixing has the disadvantage that MMA fumes are easily released and can lead to contamination of the material by airborne germs and air particles [14]. In addition, bone cements can also be contaminated with substances such as saline solution, blood and bone fragments, which are commonly found in the operating room environment [15].

Using completely closed systems ("prepacked" systems), the user has no direct contact with cement and speeds up the entire cementing process. In addition, the user saves several manual steps, such as opening powder bags and ampoules, which not only accelerates the entire cementing process but also reduces the duration the surgical site remains open. This contributes to improved operating room hygiene by minimizing the risk of contamination through airborne particles and reducing unnecessary handling of sterile components [16,17].

Although pre-filled vacuum mixing systems have advantages compared to open vacuum mixing systems, there is currently little literature comparing the available pre-filled mixing systems [18]. Most investigations are limited to the bone cement itself, regardless of the mixing variant in a pre-filled mixing system [19]. Kühn in 2014 [2] described three representatives of prepacked systems, compared them with regard to some key parameters and handling properties and found differences. Changes in mechanical and handling properties after using the Cemex System Genta ready-mix system in terms of the setting properties of the hardened material, compared with an open mixing system, showed a higher compressive strength compared to Simplex P [20]. Various standardized test standards are used to ensure that the systems examined are comparable. The most important standard for bone cements is ISO 5833 "Implants for surgery—Acrylic resin cements" [21]. In addition to the mechanical properties of the hardened bone cements, this standard also tests the handling properties and readiness for use of this material. These handling properties in particular have a significant influence on how long the cementing process takes and therefore also have a direct influence on possible contamination of the open surgical site [2].

A comprehensive study of these pre-packaged mixing systems, comparing them directly with the most important parameters and standards for bone cements, does not currently exist. In the context of this work, four established prepacked mixing systems are examined and evaluated for these properties, with a primary focus on their impact on operating room hygiene.

2. Materials and Methods

The following systems were investigated: Cemex® System Genta [22] (Tecres S.p.A., 37066 Sommacampagna (VR), Italy), Palacos® R+G pro [23] (Heraeus Medical GmbH, 61273 Wehrheim, Germany), Optipac® Refobacin [24] (Zimmer Biomet, Warsaw, IN 46580, USA) and SmartMix™Cemvac™ GHV [25] (Johnson & Johnson, New Brunswick, NJ 08933, USA) (Figure 1). All mixing systems were handled according to the manufacturers' instructions for use.

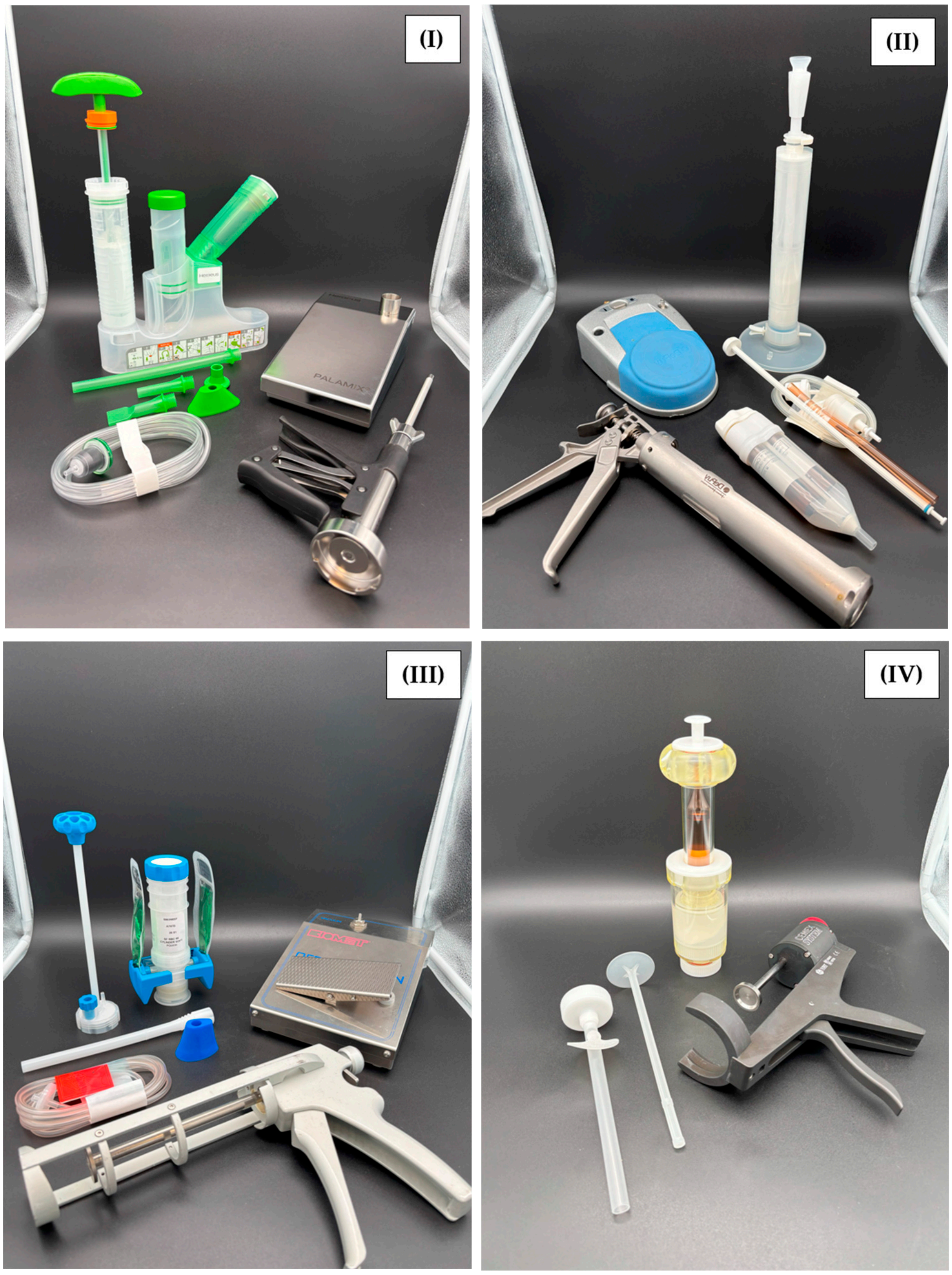

Figure 1. Four tested prepacked mixing systems: Palacos® R+G pro (**I**); SmartMix™Cemvac™ GHV (**II**); Optipac® Refobacin (**III**); Cemex® System Genta (**IV**).

2.1. Statistic

The number of tests and statistical evaluation was chosen in accordance with the requirements of the ISO 5833 [21] standard used. The number of tested systems is summarized in Table 1. The mean and standard deviation were calculated for the elution data. Statistical significance was assessed using a one-way ANOVA followed by Tukey's multiple-comparison test, which compares all possible pairs of mean values. A p-value of 0.05 was considered statistically significant. All analyses were performed using BioRender software (July 2025, BioRender Inc., Toronto, ON, Canada).

Table 1. Summary of mean values, ANOVA results, mixing systems and sample sizes for the test methods examined.

Test Method	Sample Number	Cemex® System Genta	Palacos® R+G Pro	Optipac® Refobacin	SmartMix™ Cemvac™ GHV	F-Statistic	p-Value
Visual inspection	–	+	+	+	+	–	–
ISO doughing time [s]	$n = 2$	225.0	100.0	215.0	162.5	234.19	0.0001
ISO intrusion [mm]	$n = 4$	9.53	4.44	3.71	0.75	42.84	0.0000
ISO setting time [s]	$n = 2$	582.5	440.0	535.0	587.5	48.28	0.0013
ISO maximum temperature [°C]	$n = 2$	52.20	70.95	64.18	63.45	5.46	0.0672
ISO compressive strength [MPa])	$n = 5$	89.5	84.2	84.4	84.9	2.77	0.0755
ISO bending modulus [MPa]	$n = 5$	2569.2	2644.0	2508.2	2598.8	6.52	0.0044
ISO bending strength [MPa]	$n = 5$	64.8	65.3	63.3	63.4	1.82	0.1843
Internal pressure during mixing [mbar]	$n = 3$	999.5	94.0	164.5	105.0	1420.41	0.0000

2.2. Test of Doughing Time (ISO 5833)

The doughing time refers to the moment when the dough is no longer sticky and can be processed without a syringe. According to ISO 5833 [21], the test is to be carried out with a latex glove commonly used in dentistry. Mixing is carried out according to the manufacturer's instructions. After 1 min, the cement dough is touched with a gloved finger at 15 s intervals. As soon as the cement no longer sticks to the glove, the test is finished. A double determination of a single cement mixture is to be carried out from the test ($n = 2$, according to ISO 5833, see Table 1).

2.3. Test of Intrusion (ISO 5833)

To determine the intrusion depth according to ISO 5833 [21], the PMMA cement is mixed, and after the doughing time of the cement is reached, the dough is put into a specific mold with a perforated bottom with four holes with a diameter of 1 mm. One minute (±10 s) after doughing time, a force of 49 ± 1 N is applied. After the cement dough has set, the extent of intrusion into the perforations is measured, and the mean value in mm is calculated ($n = 4$, according to ISO 5833, see Table 1).

2.4. Test of Setting Time and Setting Temperature (ISO 5833)

The maximum temperature and setting time of cement are tested adiabatically according to ISO 5833 [21]. For the test, the mixed cement dough is placed in a flat, round Teflon mold as soon as the doughing time is reached. Then a precisely fitting round punch, which is provided with holes through which the excess dough can pass, is pressed into the mold as far as it will go. This leaves a "dough cylinder" with a diameter of 60 mm and a height of 6 mm in the mold. In its center is the soldered tip of a thermocouple; the wires are routed through a small central hole in the bottom of the mold to the outside and to the measuring instrument. The maximum temperature (at the turning point) and the setting time in the area of the steep rise are read from the setting curve (temperature/time) (n = 2, according to ISO 5833, see Table 1).

2.5. Test of Compressive Strength (ISO 5833)

To determine the compressive strength, 6 cylindrical samples with a diameter of 6 mm and a height of 12 mm are produced in a metal mold in accordance with the standard. Testing is carried out on the dry test specimen between two compression stamps. The machine applies an increasing force to the test piece at a rate between 19.8 mm/min and 25.6 mm/min until the test piece breaks or the 2% proof stress reaches the upper proof stress. At this point, the internal pressure in N is measured and converted into MPa [21] (n = 5, according to ISO 5833, see Table 1).

2.6. Test of Bending Modulus and Bending Strength (ISO 5833)

The bending modulus and the bending strength are determined by a combined measurement [21]. For this purpose, 6 rectangular samples with the dimensions 3.3 × 75.0 × 10.0 mm are produced. The test is carried out using a four-point test stand with a distance of 60 mm between the outer and 20 mm between the inner load points at a constant crosshead speed of 5 mm/min. The test is continued until failure to calculate the flexural strength. The flexural modulus is calculated from the difference in deflection under 15 N and 50 N loads (n = 5, according to ISO 5833, see Table 1).

2.7. Test of Vacuum Tightness and Internal Pressure of the Mixing Systems

For systems with an external vacuum connection, a special vacuum hose configuration was used. One hose is connected to the vacuum pump, a second to the barometer and a third to the mixing system. Figure 2 shows a detailed representation of these connections using the Palacos® R+G pro system as an example (three tested systems are used, n = 3, see Table 1).

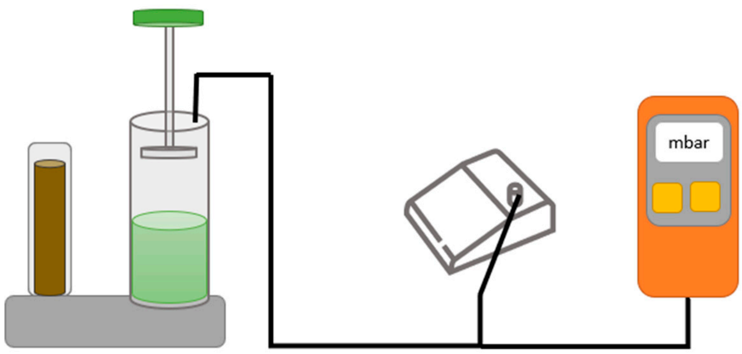

Figure 2. Measurement setup internal pressure of Heraeus PALACOS R+G® pro, Zimmer Optipac® and SmartMix™Cemvac™.

The Cemex system works without an external vacuum connection, which requires a different approach to connecting the barometer to measure the internal pressure. To enable measurement of internal pressure in the Cemex system, a direct connection to the barometer was achieved by drilling a hole in the protective cap (see Figure 3).

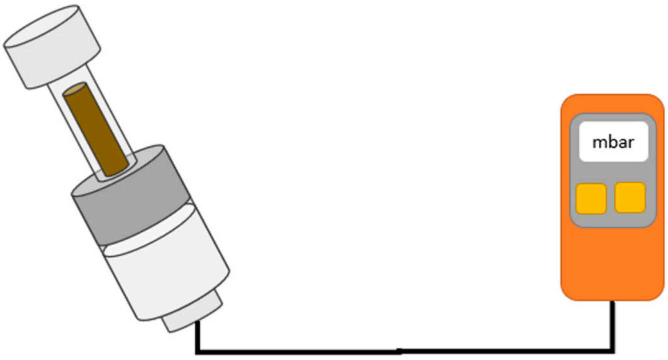

Figure 3. Measurement setup internal pressure of Tecres CEMEX®.

3. Results

3.1. Doughing Time (ISO 5833)

The doughing time of all tested systems meets the requirement of ISO 5833 [21] of ≤300 s. The values for all systems are between 100 and 225 s and show significant differences between five groups (see Table 2). Palacos R+G pro is the system that is ready for use the quickest, with a preparation time of approx. 100 s. SmartMix Cemvac GHV reaches tack-free properties after approx. 165 s, followed by Optipac Refobacin after approx. 210 s. Cemex System Genta has the latest dough formation time of 225 s (Figure 4).

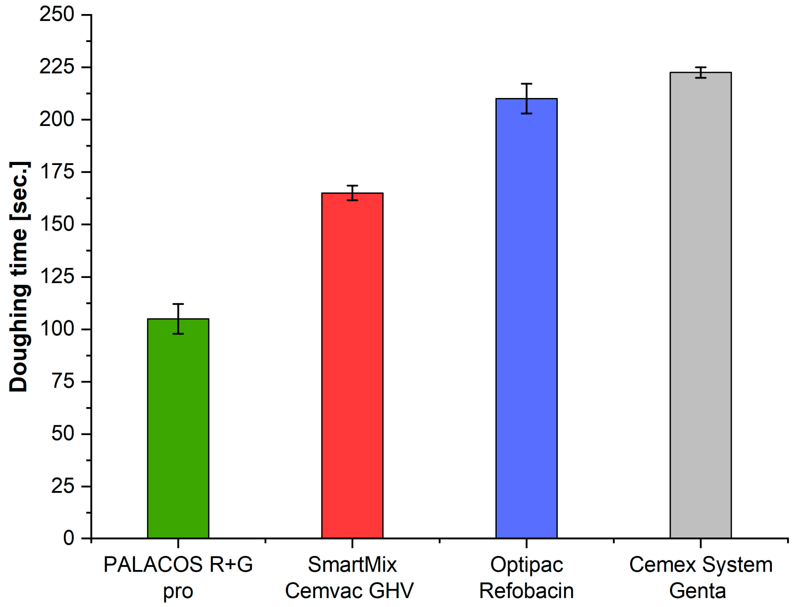

Figure 4. ISO 5833 doughing time in seconds of 4 tested cementing systems (requirement ISO 5833 ≤ 300 s) [21].

Table 2. Summary of significant and insignificant group differences identified by Tukey–HSD ($p < 0.05$).

Test Method	Significant Group Difference Comparisons ($p < 0.05$)
ISO doughing time	Cemex–Palacos ($p = 0.0001$), Cemex–SmartMix ($p = 0.0010$), Optipac–Palacos ($p = 0.0001$), Optipac–SmartMix ($p = 0.0020$), Palacos–SmartMix ($p = 0.0010$)
ISO intrusion	Cemex–Optipac ($p = 0.0000$), Cemex–Palacos ($p = 0.0002$), Cemex–SmartMix ($p = 0.0000$), Optipac–SmartMix ($p = 0.0128$), Palacos–SmartMix ($p = 0.0026$)

Table 2. *Cont.*

Test Method	**Significant Group Difference Comparisons ($p < 0.05$)**
ISO setting time	Cemex–Palacos ($p = 0.0018$), Optipac–Palacos ($p = 0.0083$), Palacos–SmartMix ($p = 0.0016$)
ISO maximum temperature	None—(all $p > 0.05$)
ISO compressive strength	None—(all $p > 0.05$)
ISO bending modulus	Optipac–Palacos ($p = 0.0028$), Optipac–SmartMix ($p = 0.0489$)
ISO bending strength	None—(all $p > 0.05$)
Internal pressure during mixing	Cemex–Optipac ($p = 0.0000$), Cemex–Palacos ($p = 0.0000$), Cemex–SmartMix ($p = 0.0000$), Optipac–Palacos ($p = 0.0117$), Optipac–SmartMix ($p = 0.0286$)

3.2. Intrusion (ISO 5833)

The tested systems show significant differences between five groups (see Table 2) in determining intrusion. Palacos R+G pro achieves an intrusion of approx. 4.5 mm. Optipac Refobacin achieves approx. 4 mm. SmartMix Cemvac GHV shows very low intrusion (<2 mm). Cemex System Genta has the highest intrusion at approx. 10 mm (Figure 5).

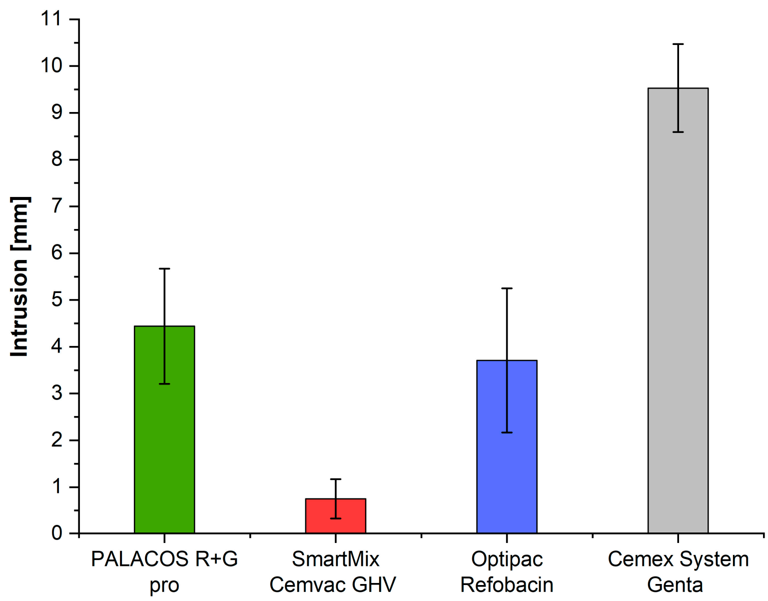

Figure 5. ISO 5833 intrusion in mm of 4 tested cement intrusion sticks (requirement ISO 5833 $\geq$ 2 mm) [21].

3.3. Setting Time (ISO 5833)

For the setting time, the four systems tested meet the ISO 5833 requirement of 3 to 15 min. The values for all systems are between 7.15 and 9.45 min and show some significant differences between three groups (see Table 2). Palacos R+G pro has the shortest setting time at 7.15 min, followed by Optipac Refobacin at 9 min. Cemex System Genta and SmartMix Cemvac GHV have a comparable setting time of 9.45 min each (Figure 6).

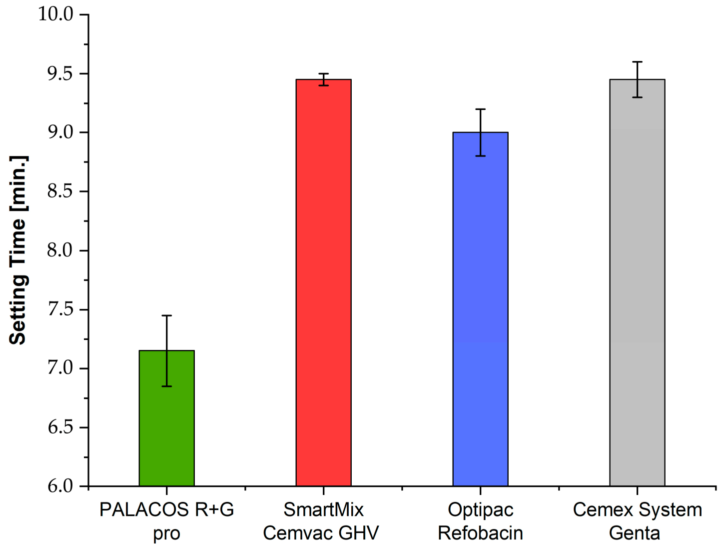

Figure 6. ISO 5833 setting time in minutes of 4 tested cementing systems (requirement ISO 5833 3 to 15 min) [21].

3.4. Setting Temperature (ISO 5833)

The setting temperature of the tested systems was clearly below the requirement of ISO 5833 [21] of ≤90 °C. There were no significant differences between the tested systems (see Table 2). At 69 °C, Palacos R+G pro has the highest curing temperature. At 52 °C, Cemex System Genta has the lowest. At 63–64 °C, SmartMix Cemvac GHV and Optipac Refobacin are at a comparable level. The standard deviation of the results is greatest for Optipac and Cemex (Figure 7).

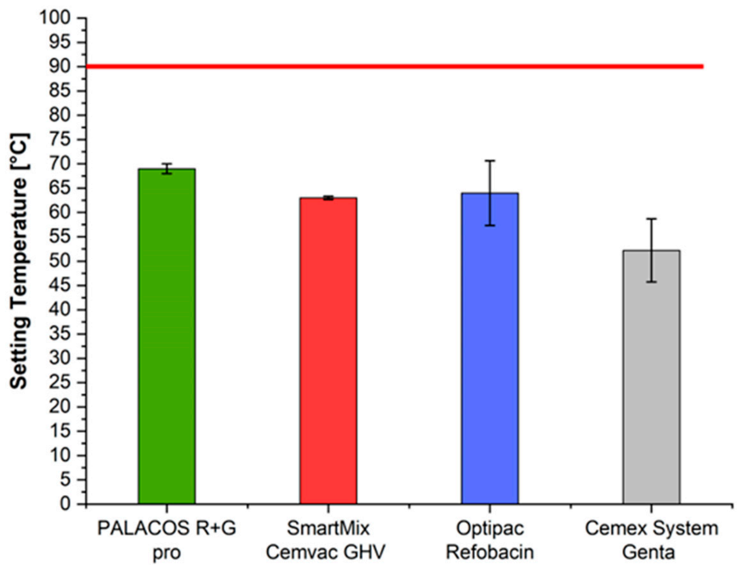

Figure 7. ISO 5833 setting temperature in °C of 4 tested cementing systems (red = requirement ISO 5833 ≤ 90 °C) [21].

3.5. Compressive Strength (ISO 5833)

Concerning ISO compression, all systems tested meet the requirement of ISO 5833 [21] of ≥70 MPa. The values for all systems are between 84 and 89 MPa. There were no significant differences between the tested systems (see Table 2). At approx. 89 MPa, the Cemex Genta system has the highest flexural modulus. All other systems have a compressive strength of approx. 84 MPa (Figure 8).

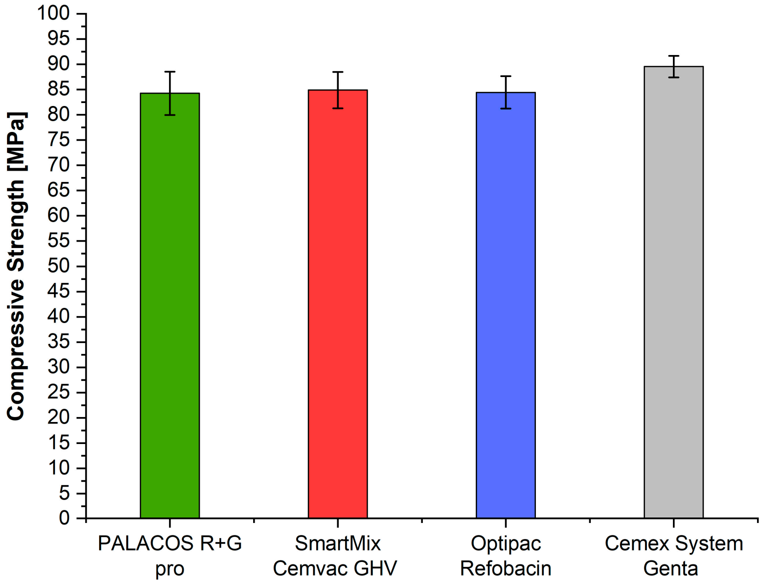

Figure 8. ISO 5833 compressive strength in MPa of 4 tested cementing systems (requirement ISO 5833 ≥ 70 MPa) [21].

3.6. Bending Modulus (ISO 5833)

All tested systems meet the requirement of ISO 5833 [21] of ≥1800 MPa. The values for all systems are between 2500 and 2700 MPa. The results show no significant deviations between two groups (see Table 2). The Cemex Genta system has the highest bending modulus at approx. 2700 MPa. Optipac Refobacin has the lowest bending modulus at approx. 2500 MPa (Figure 9).

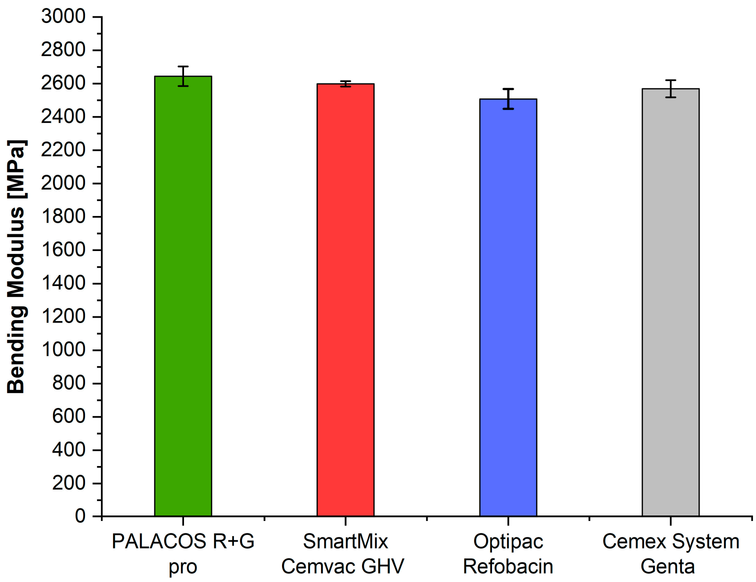

Figure 9. ISO 5833 bending modulus in MPa of 4 tested cementing systems (requirement ISO 5833 ≥ 1800 MPa) [21].

3.7. Bending Strength (ISO 5833)

Each of the four systems tested meets the ISO 5833 [21] requirement of ≥ 50 MPa. The values for all the systems are between 60 and 65 MPa. There were no significant differences between the tested systems (see Table 2). Palacos R+G pro has the highest bending strength at approx. 65 MPa. Optipac Refobacin has the lowest bending strength at approx. 60 MPa. The standard deviation of Cemex Genta is high compared to the other systems tested (Figure 10).

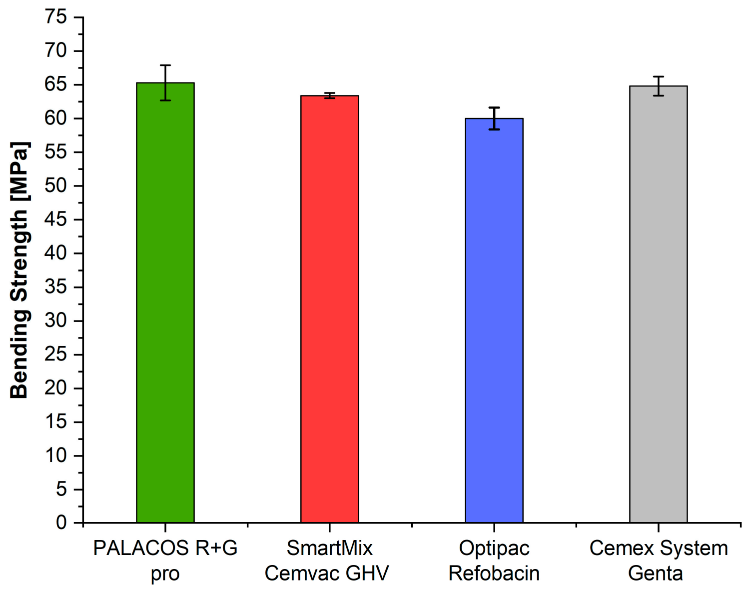

Figure 10. ISO 5833 bending strength in MPa of 4 tested cementing systems (requirement ISO 5833 $\geq$ 50 MPa) [21].

3.8. Vacuum Level

There are significant differences between the four groups (see Table 2) of the tested systems during the mixing process. Palacos R+G pro offers the most effective vacuum build-up of approx. 919 mbar. Optipac Refobacin achieves a value of 908 mbar, while SmartMix Cemvac GHV achieves a value of approx. 848 mbar. Cemex System Genta showed no vacuum build-up during the mixing process and the highest standard deviation (Figure 11).

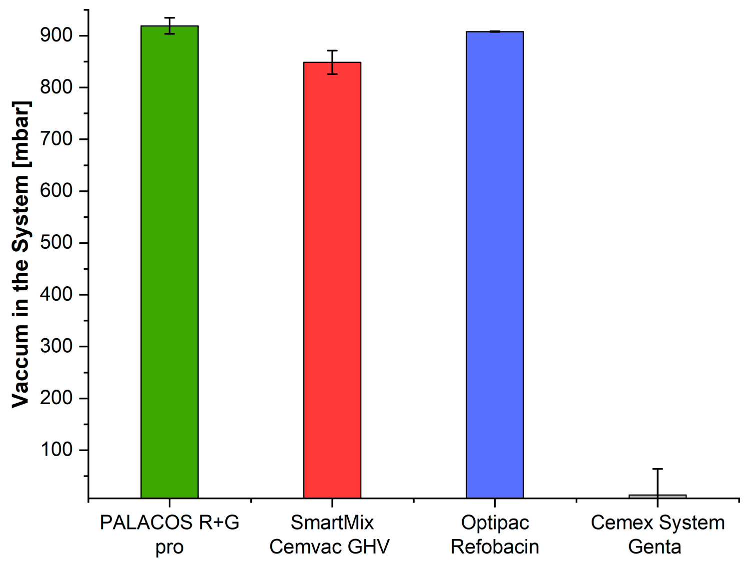

Figure 11. Vacuum level during the mixing process in the 4 tested cementing systems in mbar.

4. Discussion

Testing of four established prepacked mixing systems showed that all systems meet the standards for acrylic bone cements. The systems are safe under surgical conditions, contribute to MCT and thus lead to good cementing results. Cementing prepacked systems significantly reduced the risks of contamination of the cement dough during mixing and application. In addition, only very small amounts of MMA were detected in the operation room, far below all legal requirements [14,26]. Direct contact with allergens such as MMA, BPO or antibiotics no longer occurred [2].

Nevertheless, some differences were observed while using such systems.

4.1. System Design

Note: Only completely closed systems meet all hygiene requirements regarding sterility.

Although the four systems tested are classified as "pre-packaged systems" by the manufacturers, there are significant differences in how they work. For example, the Palacos R+G pro system [23] and the Optipac Refobacin system [24] use an external vacuum connection, whereby the monomer is transferred under vacuum, and the cement is mixed under vacuum conditions to ensure a homogeneous result. However, with the Optipac system—as with the SmartMix Chemvac system [25]—the gas-permeable cap required for sterilization with ethylene oxide gas (EO) must first be removed and replaced with the mixing element. This temporarily opens the system, meaning that these are not truly closed pre-packaged systems. From a clinical perspective, this step introduces a potential risk of contamination [2,16,17], as the cement components are briefly exposed to the environment [14]. In contrast, Palacos R+G pro and Cemex System Genta [22] have an integrated gas cap, allowing the system to remain closed throughout. SmartMix Chemvac also features a vacuum connection, but in this case, the monomer is transferred by gravity. After the system is closed, the cement is mixed under vacuum in a separate step. The Cemex system from Tecres is a special case. The system works without an external vacuum or mixing paddle. The viscosity of the bone cement is very low, presumably because this is the only way to achieve a homogeneous cement paste by shaking without a mixing paddle. Instead, the monomer is transferred via a pumping mechanism. As shown in Figure 11, no measurable vacuum build-up occurred during the process. However, insufficient vacuum during mixing may lead to increased air entrapment in the cement, potentially compromising its mechanical stability [7,9,27]. Furthermore, systems without an internal mixing paddle may result in less homogeneous cement, which could negatively affect implant fixation [12].

4.2. Processing and Working Times

Note: Short doughing and setting time minimizes the risk of contamination.

Processing and working properties play a crucial role in the use of bone cement, with key factors including the ISO doughing time and setting time [1,2,5,28]. These parameters influence not only the efficiency of the application process but also intraoperative hygiene. Our investigations (Figure 4) show that the Palacos R+G pro system has a significantly (Table 2) shorter doughing time and a shorter setting time compared to the three other products tested. This results in noticeable time savings during cementation.

Longer processing times, on the other hand, mean that the surgical site remains open for longer, which increases the risk of microbial contamination from the air, especially with open mixing systems [17]. A late doughing time can also make handling more difficult when cementing knee implants [29] and delay wound closure. The choice of a cement with optimized processing times is therefore not only important for efficiency reasons but also to minimize the risk of infection.

The Cemex system provides an example of the challenges involved in application. According to the instructions for use [22], the cement is ready for use when a convex meniscus remains stable in the nozzle for 5 s, which is achieved after approximately 120 s. At this point, however, the cement still sticks to the glove, indicating low viscosity. Although the cement appears to be non-sticky, fine threads remain (Figure 12), which is a typical characteristic of low-viscosity products [2] such as Palacos Low Viscosity. If ISO

5833 [21] was strictly applied, according to which no cement should adhere to the glove, the Cemex Genta system would only be ready for use after about 6 min and thus outside the specification for medium- to high-viscosity cements. This delay could be due to both the cement formulation and the lack of a mixing paddle in the Cemex system, which results in a lower shear rate during mixing [12].

Figure 12. For low-viscosity cements, typical formation of threads on the glove (left Cemex System Genta; right Palacos LV hand-mixed).

4.3. Intrusion Depth

Note: The optimum intrusion depth for bone cement is between 3 and 5 mm.

According to register studies of Malchau et al., 2002 [30], an optimal cement penetration depth of 3 to 5 mm into the cancellous bone is recommended to ensure permanent implant fixation and reduce the risk of aseptic loosening. Less than 2 mm increases the risk of micro-movement and loosening. More than 5 mm does not provide any relevant additional stability but increases the risk of possible thermal damage due to the increased cement thickness [29–31]. Of the systems tested, Palacos R+G pro and the Refobacin Optipac system are within this optimal range. SmartMix Cemvac shows significantly lower intrusion < 2 mm. The Cemex System Genta, on the other hand, shows significantly higher intrusion of approx. 10 mm. These differences are also due to the different initial viscosities [2], which are also reflected in the doughing time (see Figure 4).

4.4. Setting Temperature

Note: In vivo, the curing temperatures are significantly lower; curing measurement according to ISO 5833 in vitro is only used for reproducible comparison.

The ISO 5833 [21] standard for bone cements specifies a maximum curing temperature of 90 °C for bone cements. This limit is significantly higher than the in vitro temperature during the operation, which is approximately 46 °C [32]. This disparity is attributed to the cooling effect of the metal implant, a good heat conductor. In his review article, Soradi describes that temperatures above 50 °C are considered potentially harmful to bone tissue, as protein denaturation begins at this temperature, leading to damage to osteocytes [31]. At temperatures above 70 °C, the risk of irreversible thermal necrosis is very high. The standard test according to ISO 5833 is carried out without metal contact in a standardized Teflon mold [21]. This means that less heat is dissipated, and the results of the standard test are in the range of 50–70 °C. Even if the standard deviates significantly from the in vivo procedure, the results in the closed Teflon mold are more comparable. As described by Biehl [32], protein coagulation is therefore not to be expected in any of the cement mixing. The Cemex® system reaches a smaller maximum temperature under in vitro ISO test conditions due to its 3:1 powder–liquid ratio [22].

4.5. Mechanical Properties

Note: Good mechanical properties stabilize the implant in the bone.

In order to ensure a complete overview of the standard applied, not only the processing properties described in ISO 5833 were tested, but also the mechanical tests relevant for acrylic bone cement were carried out in accordance with the applicable standards [21].

Note: Bending strength is the most sensitive mechanical property according to ISO 5833.

The bending strength describes the maximum tension that a material can resist before it fails during bending. The bending modulus quantifies how much a material deforms under tension and serves as an indicator of the material's stiffness. A higher modulus means that the cement deforms less under tension. The tendency that Palacos R+G pro showed good bending strength is often published [2,3,33,34]. Lower ISO bending strength for Cemex was also found in Dunne, 2008 [35]. The absolute results and standard deviations are within the usual methodical variations resulting from the preparation of the test specimens [2,5]. However, the deviation of the results obtained with the Cemex system is greatest in both tests, which in turn could be attributed to the lack of mixing geometry.

Note: High ISO 5833 compression and modulus might be a disadvantage because of a lack of stiffness.

The mechanical properties of compressive strength also meet the specifications of the standard of at least 70 MPa for all systems. As can be seen in Figure 8, the compressive strength of the Cemex system is about 5% higher than that of the other systems. The higher-pressure results of the Cemex system compared to other mixing systems were also confirmed in a previous study [20]. On the other hand, Thaher et al., 2018 [36], found that Palacos R+G showed significantly better compression before and after aging specimens in phosphate-buffered saline solution (PBS) at 37 °C for 3 months. According to Thaher, Palacos R+G was always within the ISO specification after aging, while Cemex was not. The combination of high compressive strength and high bending modulus, as observed in the Cemex Genta cement system, seems to have a detrimental effect on the functional objective of the cement as an elastic load transmitter between the implant and the cancellous bone. Bone cements must have elastic properties to dampen impulses caused by the movement of a prosthesis and to soften their transmission to the bone. If bone cement lacks these elastic properties, it cannot serve as a mechanical buffer. This lack of local transmission or damping of impulses can ultimately cause the entire bone cement mass to move or fracture, possibly leading to implant loosening [2,5,37].

The relevance of a stable compressive strength in bone cements is also explained in the work of Karpiński [38]. In this work, various additives (e.g., ceramic, glass or carbon particles) were added to the cements to improve their biological interaction, such as osteointegration and the effects of cement on bone tissue. The higher compressive strength of the Cemex system observed during the mechanical testing could be due to its very low initial viscosity [39]. The lower viscosity of Cemex System Genta at the time of pressing the cement into the holes of the mold to produce the test specimens allowed better compression than higher-viscosity bone cements [2,5]. This viscosity could be because of the different surface of the polymer powder in Cemex bone cement® [22], as the swelling process depends strongly on the quality of the polymer beads. Another reason could be the use of styrene copolymers in Cemex cements [40].

4.6. Vacuum Level

Note: Low vacuum level means more pores in the bone cement.

As described, the MCT and the mixing of bone cement under vacuum led to a significant improvement in cemented arthroplasty [19,20]. The results clearly show that an external vacuum connection is necessary to generate a vacuum in the mixing cartridge. A pumping motion such as that used in the Tecres Cemex Genta system [22] is not sufficient to create a vacuum in the system. Palacos R+G pro, Optipac Refobacin and SmartMix Cemvac GHV, on the other hand, show a very good vacuum < 200 mbar in the cartridge thanks to the external vacuum connection and the use of a foot pump. The vacuum build-up and vacuum tightness are best with Palacos R+G pro at <100 mbar. As Optipac Refobacin requires bags to be emptied for the MMA transfers, vacuum is required from this step onwards. Palacos R+G pro and SmartMix Cemvac GHV do not require a vacuum for the MMA transfer. The vacuum is only started once the powder and liquid have been combined [2,40].

5. Conclusions

Closed systems offer a significant hygiene advantage. They reduce the risk of contamination [2,16] and minimize MMA vapor exposure [14].

All tested systems fulfilled the ISO 5833 [21]. Significant differences were observed in ISO doughing and setting times.

Optipac and the SmartMix system are not completely closed systems due to their ethylene oxide sterilization.

Only the Palacos R+G pro system showed a significantly reduced mixing time (approx. 100 s) and a reduced setting time of approx. 7 min.

Clinical recommendations:

- Use safe, standard-compliant and approved systems.
- Use closed systems that are safe from a hygiene perspective.
- Closed prepacked systems are mainly recommended for primary surgery.
- When selecting systems, ensure that the cement contained is ready for use quickly (short doughing time) and has a comparatively fast setting time.

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Conflicts of Interest: C.P. and M.Z. are employees of Heraeus Medical GmbH. The mixing systems tested were selected impartially. All commercially available prepacked systems were considered, without any special pre-selection or influence. The relevant standards for bone cements were fully taken into account without restrictions when applying the test methods. P.S.R. and K.D.K. declare that they have no conflicts of interest in connection with the manuscript and that their contributions were made on an academic basis.

Abbreviations

The following abbreviations are used in this manuscript:

MCT	Modern Cementing Technique
PMMA	Polymethylmethacrylate
MMA	Methylmethacrylate
EO	Ethylene Oxide
ISO	International Organization for Standardization

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