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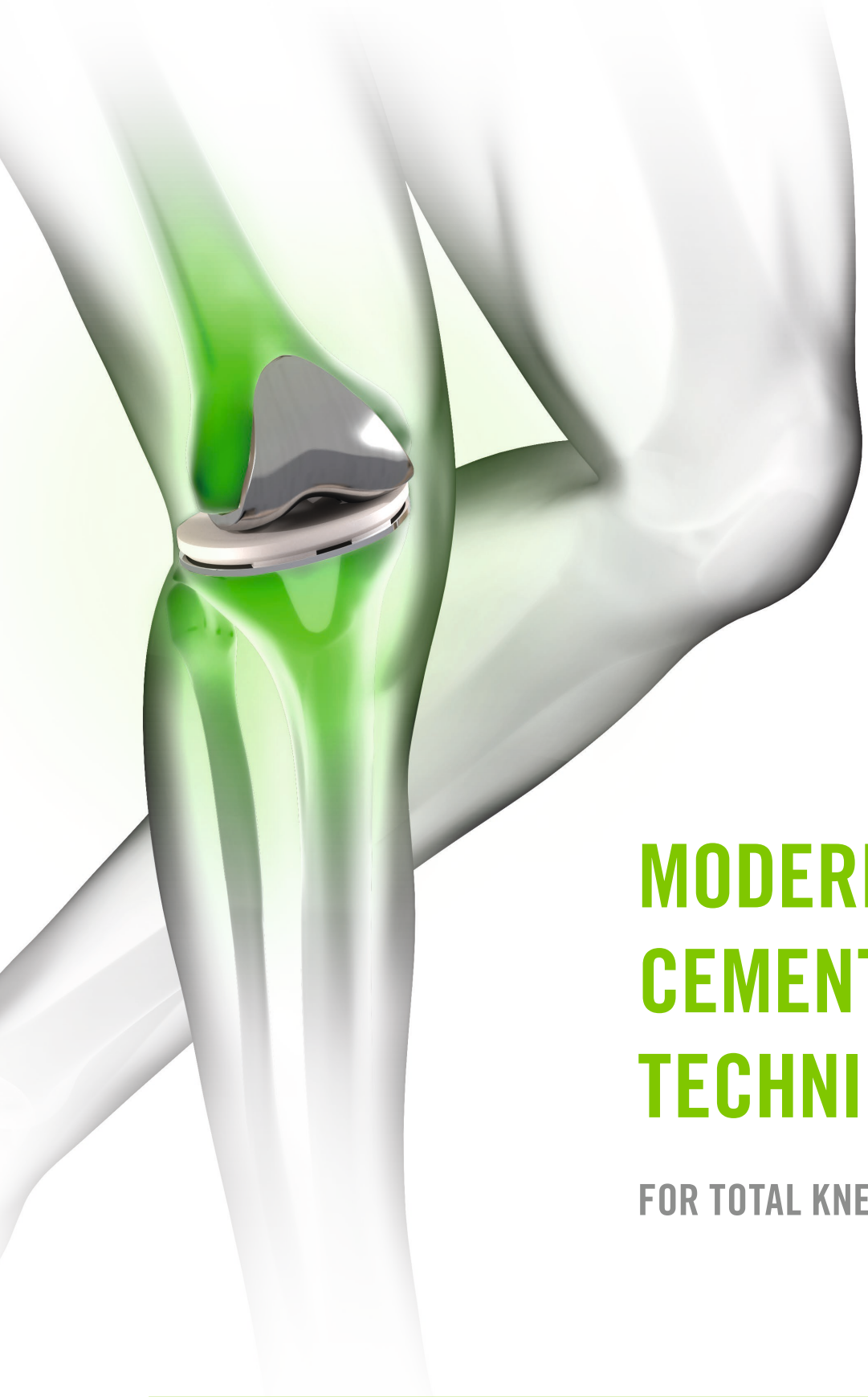
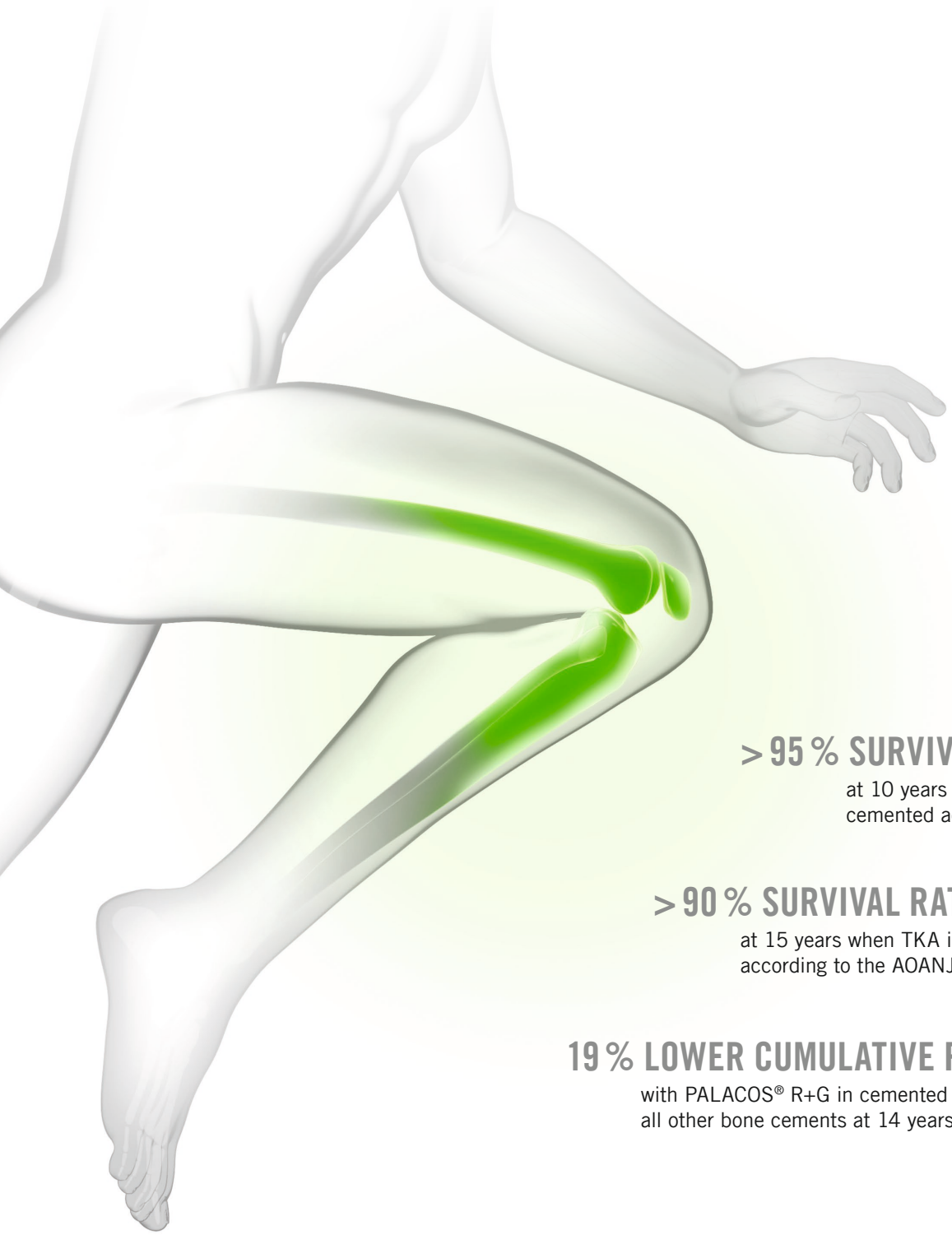
Medical



MODERN CEMENTING TECHNIQUE

FOR TOTAL KNEE ARTHROPLASTY

CEMENTED KNEE ARTHROPLASTY



> 95 % SURVIVAL RATES

at 10 years when TKA is cemented according to the NJR [1]

> 90 % SURVIVAL RATES

at 15 years when TKA is cemented according to the AOANJRR [2]

19 % LOWER CUMULATIVE REVISION RATE

with PALACOS® R+G in cemented TKA compared to all other bone cements at 14 years[3]

THE IMPORTANCE OF MODERN CEMENTING

INTRODUCTION

Total knee arthroplasty (TKA) with cemented fixation is a highly successful surgery. Both the National Joint Registry (NJR) and the Australian Orthopaedic Association National Joint Registry (AOANJRR) report greater than 95 % survival at 10 years and greater than 90 % survival at 15 years.[1,2]

When taking a closer look at the number of implant failures, aseptic loosening is the leading cause of revisions in the NJR and the AOANJRR.[1,2] In fact, the incidence of revision for cemented TKA is 34 % lower in terms of aseptic loosening than for uncemented per 1000 prosthesis-years.[1]

While historical understanding of aseptic loosening pathology was that particle wear led to macrophage activation, it is now more apparent that aseptic loosening has a multifactorial aetiology.[4] In many cases, implant design, cement, cementing technique, surgical technique, and host factors may all be important factors.[5,6]

A recent case-control study from the Hospital for Special Surgery registry suggested that cement interdigitation (< 2 mm), increasing radiolucent lines at the cement-implant interface, and varus alignment of the tibial component were associated with increased risk of early (< 3 years) aseptic loosening.[7] Additionally, another recent study showed that the contamination of the implant surface with fat or blood prior to cementation substantially weakens the bond strength.[8] These studies stress the special importance of cementing technique.

While modern cementing technique has been established in total hip replacement, the technique in total knee replacement remains controversial.[9,10] Based on a large number of research studies involving PALACOS® bone cements[11], this guide provides relevant information on modern cementing technique in TKA. It underlines the importance of an appropriate cementing technique for TKA that increases long-term implant stability and results in a better clinical outcome.

PREPARING THE BONE SURFACE

SCLEROTIC SURFACES

In areas of dense sclerotic bone, drilling supplementary holes improves the porosity of cancellous bone and appears to improve the integration of the bone cement into the bone. Importantly, greater bone porosity enables increased shear strength at the cement-bone interface.[12] The use of keyholes in sclerotic bone has been found to reduce micromotion and liftoff in cadaveric tibiae and enable equivalent fixation to bone unaffected by sclerosis.[13] In studies examining the role of keyholes, the drill bit ranged from 2.0 to 4.5 mm in size (average 3.25), and holes were drilled between 4 and 15 mm in depth (average 9.67 mm).[9] One study has examined the role of keyhole diameter on TKA patients' outcomes and concluded that a larger diameter (4.5 mm vs. 2.0 mm) was associated with greater cement interdigitation (Figure 1) and fewer radiolucent lines on x-ray one year after surgery.[14]

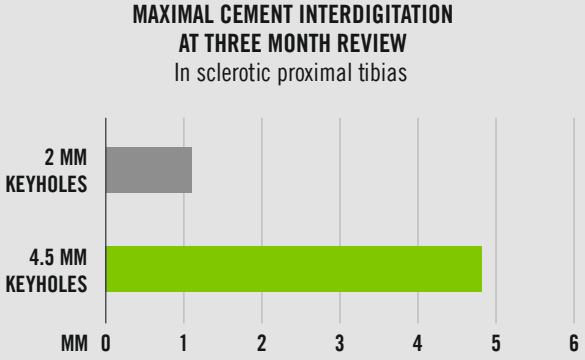


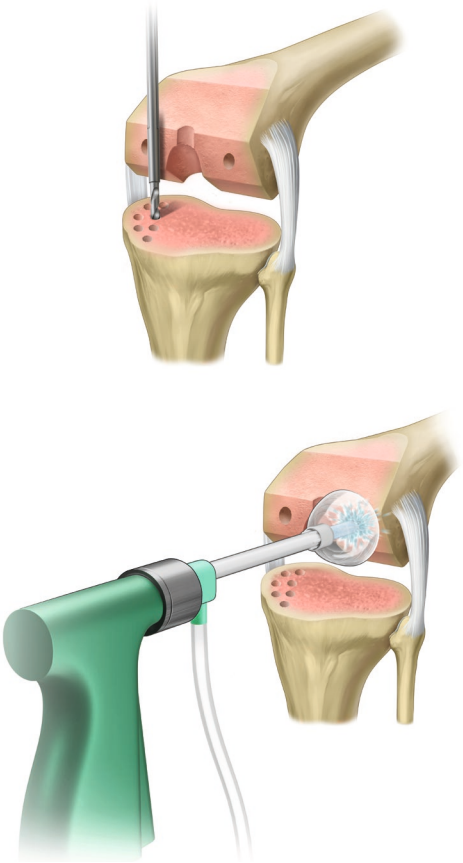
Figure 1: Adapted from 14. Ahn JH, et al. 2015.

CLEANING AND DRYING THE BONE BED

Modern cementing technique is imperative for the long-term success of a cemented endoprosthesis. Bone bed cleaning with a pulse lavage system is an essential component and first step in modern cementing technique.

All cement-receiving bone surfaces should be cleaned safely with a pulse lavage system to remove fat residues, bone debris, marrow, and blood.[15,16] This provides the basis for a stable interface between the cement and the bone due to deeper penetration of the cement into the cancellous bone bed and reduces the occurrence of radiolucent lines.[17,18]

The bone bed must be dried before applying the bone cement. A dried bone bed results in better cement penetration of the spongiosa. Cleaning and drying the bone bed are crucial for the initial stability of the components.[19] Applying vacuum suction via a cannula to the tibial metaphysis may aid in the drying and subsequent interdigitation of the cement.[20]



PREPARING THE BONE CEMENT

THE IMPORTANCE OF VACUUM MIXING

The ability of bone cement to transmit mechanical forces between the implant and the bone plays a vital role in cemented arthroplasty.[21] Since the 1990s, modern cementing technique has included vacuum mixing to achieve better mechanical properties of the bone cement. Pores at the cement-implant interface can give rise to cracks, which propagate through the cement mantle.[22,23] Additional porosity within the cement mantle will speed the growth of the cracks. Limiting the propagation of these cracks is tantamount, as they are predictive of early aseptic failure in total knee arthroplasty.[7] Vacuum mixing reduces air inclusions at the surface and in the cement matrix itself, giving rise to a stronger cement (Figure 2).[24] This improves the survival rate of the implant.[25,26]

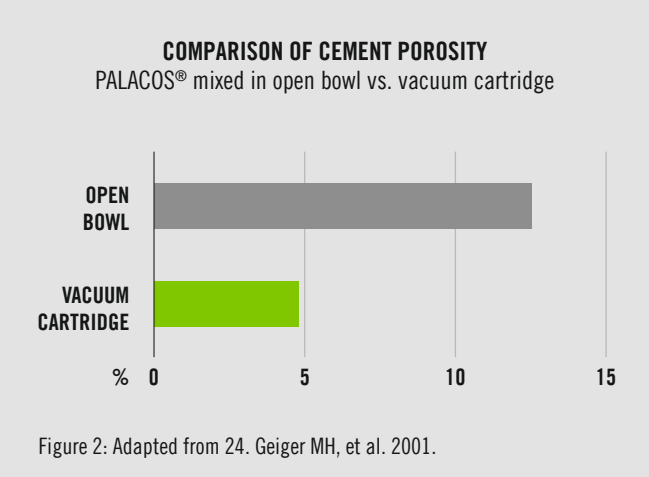


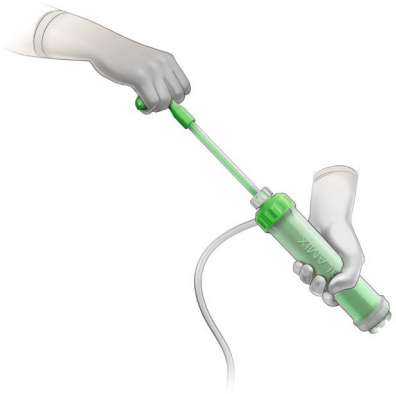
Figure 2: Adapted from 24. Geiger MH, et al. 2001.

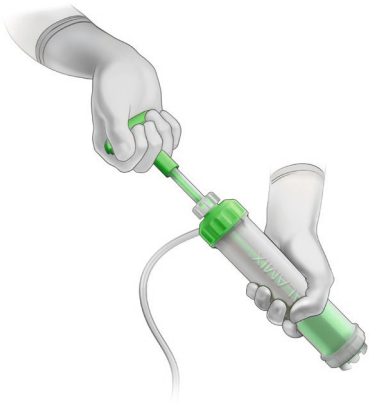
MIXING TECHNIQUE

The bone cement should be mixed in a vacuum cartridge mixing system (like PALAMIX® or PALACOS® pro) with steady up- and downward movements of the mixing rod over the cartridge's entire length at one stroke per second until a homogenous dough develops. Multiple studies have shown that cartridge mixing systems improve the density, bending modulus, porosity, and durability (as measured by the fatigue strength) of PALACOS® R bone cement[27,28] and may avoid the additional cement sampling step in open bowl systems.

PALACOS® is ready to use when a gloved "finger-test" demonstrates the cement is no longer sticky. In an early application phase, the doughy cement should be used to better penetrate the trabecula and improve the cement-implant bond strength.[8,25,29]

The polymerisation process may be negatively impacted by mixing at speeds faster than one stroke per second, mixing for longer than 30 seconds, or introducing heat during mixing. Any of these may alter the timepoint at which the surgeons should apply the cement for optimal bone interdigitation and tibial tray bone strength.[30]





CEMENT APPLICATION

TIBIAL APPLICATION

To minimise the risk of blood or fat being introduced to the cement mixture, a change of gloves is recommended before beginning application. PALACOS® should be applied to both the tray and stem of the tibial component. Applying cement only to the underside of the tray (so-called "surface cementing") reduces the push-out force required to separate the tray from the cement mantle and has been found to increase the rate of early aseptic failure.[8,31–33]

Additionally, PALACOS® should be applied down the tibial keel hole with a knee pressuriser to increase the cement's interdigitation into the tibial plateau. In total knee arthroplasty, 3 – 5 mm is considered an ideal intrusion depth.[34] Interdigitation below 3 mm is less suitable to provide adequate interlock over the life of the prosthesis due to its inability to hold up to the shear forces generated during use.[35,36] Insufficient interdigitation is also associated with greater risk of early aseptic loosening.[7] On the other hand, interdigitation beyond 5 mm may increase the risk of heat necrosis-related negative effects on osteocyte viability.[37] Using a lesser quantity of cement during application and applying cement to only one of the surfaces (implant or bone) are both associated with suboptimal interdigitation (Figure 3).[29,34]

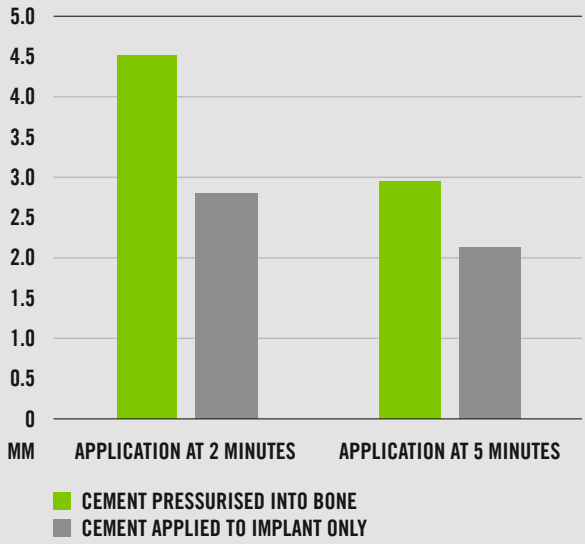
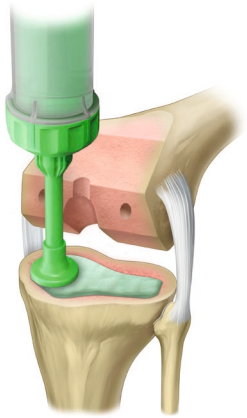
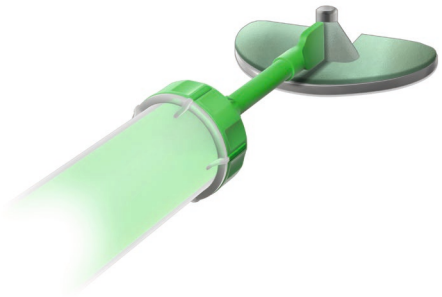


Figure 3: Adapted from 29. Pérez-Mañanes R, et al. 2012.

The implant should be inserted to the bone by driving its components into position with an appropriate impactor. The bone-cement bond can be optimised by minimising the time between applying cement to the surfaces of the tibia (bone and implant) and joining the two cement surfaces together. Prolonged time between application and joining can lead to the formation of a skin on the bone cement surface, which can reduce the cement-cement bond strength.[38] Excess bone cement should be removed carefully while it remains in the working phase.





CEMENT APPLICATION

FEMORAL APPLICATION

As with the tibia, the application of the cement to the full surface of both the distal femur bone and the femoral component leads to maximal interdigitation (Figure 4).[39] Application of the cement with a gun and pressurising tip enables increased interdigitation of the cement and limits the risk of lipid or blood contamination.[40] The implant components should be inserted into the bone and put into position with an appropriate impactor. The cement-cement bond can be optimised by minimising the time between joining the two cement surfaces (femoral component and femoral cuts).[38]

After polymerisation, the remaining cement should be removed by carefully cutting away excess cement in large fragments. Large fragments minimise the creation of micro-particulate cement debris. The remaining cement debris should be removed.

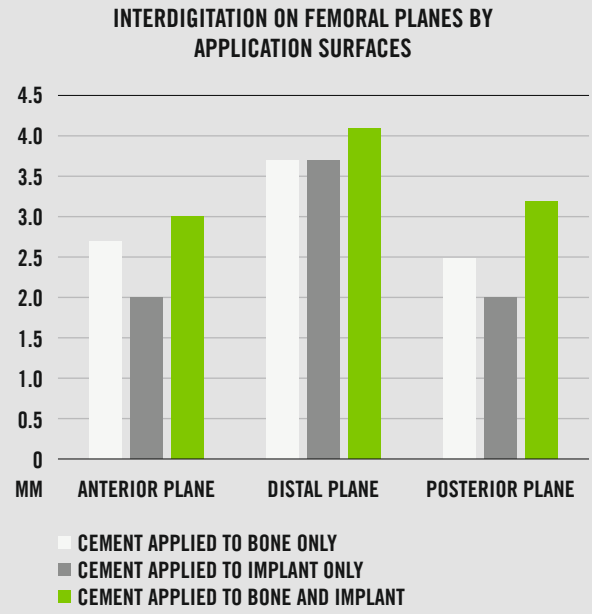


Figure 4: Adapted from 39. Vaninbroukx M, et al. 2009.

SETTING PHASE INTERVENTION

When the cement is in the setting phase, it is incredibly important not to undermine the previously performed cementing procedure. The knee should be kept immobilised and knee stability or range of motion (ROM) must not be assessed while the cement is still curing.[41] Additionally, any fluids must not be introduced into the joint space during this time (including warming agents to speed up the setting phase, cooling agents to dissipate the heat resulting from the polymerisation reaction, or povidone-iodine wash). These fluids can contaminate the cement-implant bond, cause premature elution of antibiotics from the cement, and weaken the cement's compressive strength.[42,43]

PALACOS® – DESIGNED FOR MODERN CEMENTING

All PALACOS® cements are designed to be mixed under vacuum* – preferably with cartridge vacuum mixing systems like the PALAMIX® and PALACOS® pro All-In-One-Fixation System™. Studies have shown that both hand-mixing and bowl mixing under vacuum lead to significant decreases in cement strength and durability (Figure 5).[44] All PALACOS® cements are available with added gentamicin for antibiotic prophylaxis.

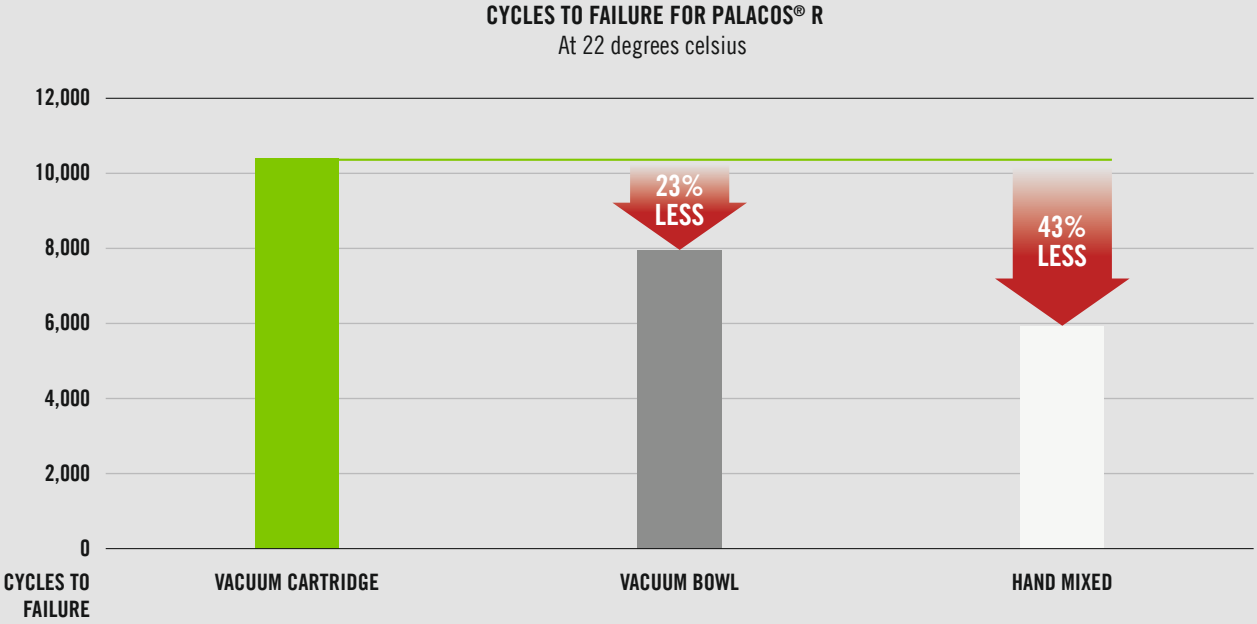


Figure 5: Adapted from 44. Dunne NJ, et al. 2003.

* Except PALACOS® fast R+G, which is not recommended for vacuum mixing due to lack of a waiting phase.

PALACOS® – YOUR ELEMENT OF SUCCESS

PALACOS® has been successfully used for over 60 years in arthroplasty for effective and permanent fixation of implants in bone. Its proven clinical use is demonstrated by more than 30 million procedures worldwide.[45]

PALACOS® R
PALACOS® R+G

A high-viscosity bone cement with reliable working properties from a proven formula.[25] Known as the gold standard in arthroplasty[46], PALACOS® R+G contains gentamicin which is eluted locally and can help to reduce the risk of infections.[47]

PALACOS® MV
PALACOS® MV+G

A medium-viscosity bone cement with excellent mechanical properties[48] and the same raw ingredients as PALACOS® R. Mixing and application of medium-viscosity bone cements is simplified by the lower initial viscosity.[49]

PALACOS® LV
PALACOS® LV+G

A low-viscosity bone cement that enables precise application even through thin nozzles, which may simplify cementing of small and medium-sized joints like the shoulder and elbow.

PALACOS® fast R+G

A high-viscosity bone cement with up to 37 % faster working times* and effective release of gentamicin.[50]

* compared to PALACOS® R+G

MIXING PORTFOLIO

PALACOS® R+G pro

The innovative PALACOS® R+G pro All-in-One Fixation System™ integrates the renowned bone cement into a ready-to-mix closed vacuum system bringing a new level of simplification and standardisation in joint replacement procedures.

- Double filtration for removal of glass particles
- 20 seconds mixing for homogenous cement
- Preloaded, completely closed system for safe and contactless cement mixing and handling
- Closed system prevents bacteria or particulate contaminants from entering the cement during mixing

PALAMIX®

Developed for use with PALACOS® cements, a vacuum mixing system like PALAMIX® is the key to their renowned workability and homogeneity.[44]

- Consistent results due to standardised mixing process
- Filling funnel with particle filter prevents glass particles from entering the bone cement
- Diverse selection of nozzles and pressurisers for flexibility in application
- Vacuum mixing for up to two pouches (2x40) with PALAMIX® uno or for up to four pouches (4x40) with PALAMIX® duo
- Bone cement can be applied directly from the mixing cartridge

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*We thank the patients and staff of all the hospitals in England, Wales, Northern Ireland and the Isle of Man who have contributed data to the National Joint Registry. We are grateful to the Healthcare Quality Improvement Partnership (HQIP), the NJR Steering Committee and staff at the NJR Centre for facilitating this work. The views expressed represent those of Heraeus Medical GmbH and do not necessarily reflect those of the NJR Steering Committee or the Health Quality Improvement Partnership (HQIP) who do not vouch for how the information is presented.

PALACOS® – THE ORIGINAL FROM HERAEUS

PALACOS® BONE CEMENTS

PRODUCT	DESCRIPTION	CONTENT
PALACOS® R	High-viscosity, radiopaque bone cement	1x40 2x40
PALACOS® R+G	High-viscosity, radiopaque bone cement containing gentamicin	2x10 1x20 2x20 1x40 2x40 1x60
PALACOS® MV	Medium-viscosity, radiopaque bone cement	1x40 2x40
PALACOS® MV+G	Medium-viscosity, radiopaque bone cement containing gentamicin	1x20 2x20 1x40 2x40 1x60
PALACOS® LV	Slow-setting, low-viscosity, radiopaque bone cement	1x40
PALACOS® LV+G	Slow-setting, low-viscosity, radiopaque bone cement containing gentamicin	1x40
PALACOS® fast R+G	Fast-setting, high-viscosity, radiopaque bone cement containing gentamicin	1x40

PALACOS® R+G PRO – READY TO MIX BONE CEMENT*

PRODUCT	DESCRIPTION	CONTENT
PALACOS® R+G pro	High-viscosity, radiopaque ready to mix bone cement containing gentamicin	Net 55 Net 75
PALACOS® R+G pro nozzle medium	Single-use, flexible, conical nozzle; length: 241 mm; ∅ 8.3–12.6 mm	10
PALACOS® R+G pro nozzle short + knee pressuriser	Single-use nozzle and knee pressuriser; length: 65.0 mm; ∅ 11.3 mm	10

*To use with PALAMIX® cement gun and PALAMIX® vacuum pump

PALAMIX® VACUUM MIXING SYSTEM WITH COLLECTION UNDER VACUUM

PRODUCT	DESCRIPTION	CONTENT
PALAMIX® uno	Vacuum mixing system with collection under vacuum for up to two pouches (2x40)	10
PALAMIX® duo	Vacuum mixing system with collection under vacuum, with two cartridges for up to four pouches (4x40)	10
PALAMIX® medium nozzle	Flexible, conical nozzle; ∅ 8.7–12.6 mm	10
PALAMIX® slim nozzle	For use with low-viscosity bone cements; ∅ 7 mm	10
PALAMIX® cement gun	Reusable cement gun	1
PALAMIX® vacuum pump	Reusable vacuum pump	1

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