GUIDANCE FOR

CEMENTING TOTAL KNEE REPLACEMENTS

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Cementing Total Knee Replacements

1.0 Introduction

The survivorship of Total Knee Replacement (TKR) is dependent on, among other factors, the cementing technique used.[1] Early attempts to use acrylic cement in orthopaedic surgery may have failed due to a misunderstanding around how the cement functions.[2] Cement achieves a mechanical bond to the bone by penetrating into the pores of the cancellous bone where it hardens, forming a micro-interlock; modern cementing techniques aim to improve this micro-interlock.

There are different cement considerations for TKR and Total Hip Replacement (THR). However, like in THR surgery, knee implants are known to fail at the cement-bone interface or at the cement-implant interface. Failure at the cement-bone interface may appear as radiolucent lines and is usually attributed to poor penetration of the cement into the bone.[3] Failure for the cement-implant interface may be due to the poor interfacial strength of the cement to the implant.[4]

2.0 Definitions

Dough time – the change in physical condition of the cement identified by an increase in cement viscosity (becoming less runny), a change to a dull appearance, and reduced tackiness against surgical gloves.

Working time – sometimes referred to as "dough state" – the appropriate period of time for implanting the cement for a given ambient temperature according to its specific instructions for use (package insert).

Ambient temperature – the temperature of the surrounding environment in the operating room.

Working time/temperature chart – a chart contained in the instructions for use (package insert) that defines the available working time for a given ambient temperature.

Final pressurization – the final application of pressure to securely seat the implant within the bone cement by means of bringing the knee, with the implant, into extension and holding it there until the cement cures.

Cement setting or curing time – is the time when the cement hardens.

Tibial Preparation Instruments; Clearance – these instruments provide clearance around the implant for a cement mantle. Thus removing a larger diameter of bone than the implant.

Tibial Preparation Instruments; Non Clearance – commonly known as Line To Line instruments, removes the same diameter of bone as the implant.

3.0 General Cementation Principles

3.1 Cement Viscosity

Following mixing, all bone cements reach a higher viscosity state (dough state) and Medium Viscosity (MV) cements reach that higher dough state somewhat later than High Viscosity (HV) cements. In doing so MV cement is sometimes classified as having dual phases i.e. low viscosity (prior to reaching its dough state) and MV (once the dough state has been reached).

HV cements reach dough state quickly after mixing, and therefore do not have a low viscosity state. Care should be taken to use the HV cement immediately from the start of its dough time, to optimize its working time. The optimum time for cement application to the metal implant in TKR surgery, is just before the cement has reached this dough state (i.e. while the cement is tacky) to aid adherence to the implant. For HV cements, the cement should be used as soon after mixing as practical.

- Application of the cement to the roughened implant surface early in the dough state has been demonstrated to increase the fixation strength of the cement to the implant.[4] It is therefore a general principle that cement should be applied to the components early in the dough state; in some cases this will be several minutes before actual implantation into the bone.[4]
- Using the cement too early prior to the dough state may lead to poor pressurization and reduced penetration.[5]
- Using the cement too late in the dough state may reduce the flow of the cement into the bone and reduce penetration; it may also reduce the interfacial strength of the cement with the implant.[4]

The behavior of cement is strongly temperature sensitive; increasing the cement's temperature will speed up the curing of the cement, however it will result in an earlier dough-time and significantly reduced available working time.

■ **NOTE:** **The user should refer to the specific instructions for use (package insert) for the timing and usage chart before preparing the cement.**

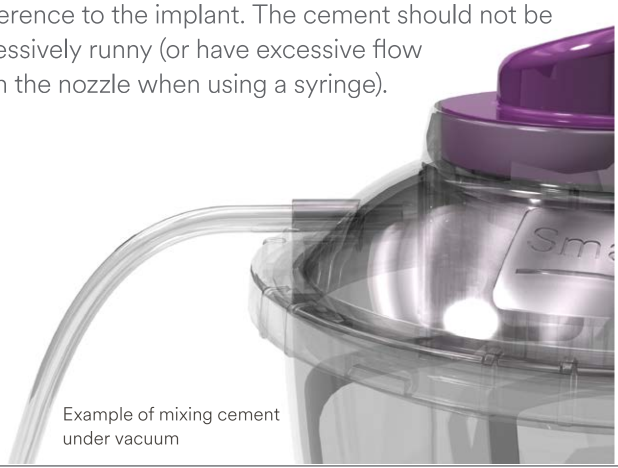
■ **NOTE:** **Pre-warming powder or liquid beyond the temperature range stated in the instructions for use (package insert) is not recommended as it increases the risk of the cement being used too late in its working time phase.**

■ **NOTE:** **Heating MV cements will reduce the dough time (time to achieve dough state), however, heating HV cements will not only reduce its tackiness, but will also reduce the available working time.**

■ **NOTE:** **When using a High Viscosity bone cement, it is advised to firmly apply the cement onto the implant early in its working phase by using a suitable cement gun, syringe, or spatula to encourage prime adhesion to the implant.**

3.2 Preparing Cement

When mixing cement, all of the powder must be mixed with all of the liquid to ensure that the cement behaves as intended. The cement is ready to apply to the metal implant in TKR, just before the cement has reached its dough state (i.e. while the cement is still tacky) to aid adherence to the implant. The cement should not be excessively runny (or have excessive flow from the nozzle when using a syringe).



Example of mixing cement under vacuum

- Voids in the cement can reduce the strength of the cured cement[6]; mixing in a vacuum system reduces the inclusion of air voids[7] with the added benefit of reducing exposure to monomer fumes for OR staff.

■ **NOTE:** **Mixing under vacuum can impact the setting time and reference should be made to the instructions for use (package insert) for the relevant product.**

3.3 Working with Cement

The mixed cement in its working phase is incompatible with water and so aqueous liquids, such as saline or blood, will reduce its bonding strength.[8,9]
Blood laminations in the cement can reduce the mechanical strength of the cement.[9] It is recommended to use clean gloves when cementing and all implant surfaces should be clean and dry. The use of a haemostatic agent (e.g. a solution containing H202) has been suggested to reduce the amount of blood and debris trapped within the trabecular bone-cement interface and may assist in reducing the risk of blood laminations.[10]

4.0 Cementation in TKR Surgery

Because of the high range of complex movement in the knee following TKR, the cement mantle is subject to a wide range of forces. Although cement is strong in compression, the shear strength of the cement-bone interface is dependent on the depth of penetration. The strength of this interface is therefore dependent on tibial preparation, cementation technique, and an ideal depth of cement penetration into the bone of 3-4 mm has been proposed.[11,12]

■ **NOTE:** **The choice of Tibial Preparation instruments can also impact the fixation of the tibial component. If a surgeon prefers simultaneous cementation during TKA and is assessing ligamentous stability and ROM during cementing curing, then designs with a 'No Clearance' tibial preparation are recommended. Stress and movement of the knee during the cement curing phase is not recommended, due to the inherent risk of motion with regard to lipid infiltration and degradation of tibial tray fixation strength.[23]**

Example of drilling keying holes in sclerotic tibial bone

Examples of knee nozzles

65˚ Flanged Knee Nozzle

90˚ Flanged Knee Nozzle

90˚ Knee Nozzle

4.1 Preparation of the Bone Surfaces

Washing all the bone surfaces (e.g. with pulsatile lavage) to remove loose bone, blood, fat, and marrow also exposes the porous bone and helps to achieve penetration of bone cement[13] resulting in a stronger interlock at the bone-cement interface.[14] The bone and implant should be dried prior to applying the cement; this may be achieved by drying in various ways including using an absorbent pad, such as a dry sponge, suction, or a carbon dioxide jet.

- In areas of dense or sclerotic bone, drilling keying holes in the bone may assist in creating a greater degree of cement interdigitation.[15]

4.2 Cement Application

A number of application techniques have been used to improve cement penetration:

- Cement can be syringed under pressure, by seating the nozzle directly onto the cut bone surface and syringing the cement into the cancellous bone structure. A purposefully designed tibial syringe applicator may be attached to the nozzle to facilitate this. Syringing cement in this way may provide an improved peripheral seal to retard later ingress of osteolytic micro-particulate debris into the bone, particularly at the periphery of the tibia.[16]
- In its dough state, MV cement and HV cement may be pressurized digitally, or by hand, into the bone surface.[17]
- Once the implant has been seated, an impactor can be used to help pressurize the cement.

A thin layer of cement may not be sufficient to achieve good penetration into the bone. Sufficient cement must be applied and two mixes of standard (40g) packs of cement are often used in cementing the femoral and tibial components of a TKR to provide an adequate layer to facilitate cement pressurization. One 20g pack of cement is sufficient when cementing the patella alone.

Example of one standard 40g pack of cement

4.3 Implantation

■ **NOTE: The surgeon should follow the implant system's surgical technique guidelines for applying cement to the knee components.**

During implantation, cement must flow from around the periphery of the implant to generate an adequate seal between the implant and bone; this is important in preventing later ingress of osteolytic particles and debris. However, it is extremely important to remove excess cement from around the implant. By using the cement according to the instructions for use (working time for a given ambient temperature) and by watching for the changes indicating initiation of the dough state, the cement will be in the appropriate portion of the dough state for both implantation and cleanup. Cement in the dough state can be pulled cleanly away from the bone. MV cements applied early in their low viscosity state can be more difficult to clean off the bone and soft tissues.

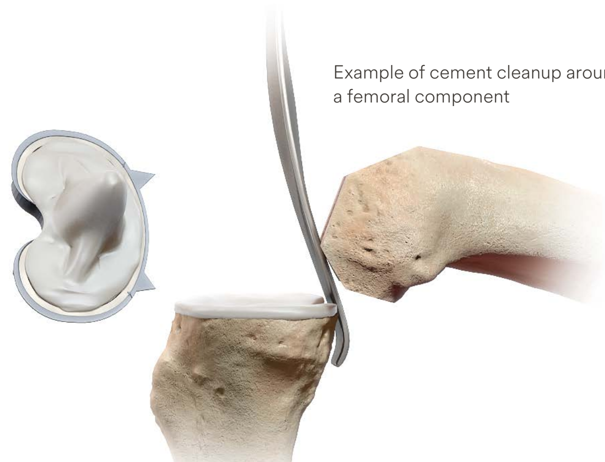
- Care must be taken not to pull cement from under the edge of the implant in order to ensure the edges remain sealed.
- Excess cement or cement debris not removed may scratch the implant and may lead to polyethylene wear debris.[18]

4.3.1 Tibial Cementation

Generally the tibial component is cemented into place first and an impactor used to pressurize the cement. A number of different cementing techniques are known to be used. MV cement is sometimes applied soon after mixing and is poured onto the bone before its dough state is reached[19], and the implant is seated onto the cement once it has reached the dough state, at which time it has sufficient viscosity to pressurize into the bone. Alternatively, in the same way that the HV cement is frequently used, MV cement may be applied to the bone after it has reached its dough state. In this latter case a thick layer of cement should be applied to both the bone and implant surfaces.

■ **NOTE: The surgeon should follow the implant system's surgical technique guidelines for applying cement to the tibial stem base.**

- If applying doughy cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.[20]



Example of cement cleanup around a femoral component

Summary of Best Practice Recommendations From Recent Research

■ **NOTE: To improve tibial tray-cement bond strength:**

1. Thoroughly dry off the entire tibial interface (plateau and keel).
2. Apply cement to the keel as well as the plateau.
3. Apply cement to the component soon after mixing (while the cement is tacky).[22]
4. Intra-operative knee motion prior to curing of the cement introduces lipid contamination at the implant-cement interface. This adversely affects tibial fixation strength, and should be avoided.[23]
5. If a surgeon prefers simultaneous cementation during TKA and is assessing ligamentous stability and ROM during cementing curing, then designs with a 'No Clearance' tibial preparation are recommended. Stress and movement of the knee during the cement curing phase is not recommended, due to the inherent risk of motion with regard to lipid infiltration and degradation of tibial tray fixation strength.[23]

4.3.2 Femoral Cementation

Example of applying cement onto the back of the femoral implant

A thick bed of cement may be placed onto the back of the implant or directly onto the exposed bone surface. An impactor is used to pressurize the cement. Good levels of penetration can be achieved by applying cement to the anterior and distal bone surfaces, and to the posterior flanges of the prosthesis prior to implantation.[21]

- Retained posterior cement may prevent full flexion and generate debris so care must be taken to ensure posterior cleanout; despite the difficult access. Posterior extrusion may be reduced by applying posterior cement to the implant, rather than to the bone.
- For cementing a PS box, the general recommendation is to apply the cement to the implant, specifically the side walls of the PS box only, not to the top of the box; unless otherwise specified in the surgical technique.

■ **NOTE:** Care should be taken to remove excess cement or cement debris which may scratch the implant which may lead to polyethylene wear debris.[18]

Example of cement cleanup around a femoral component

■ **NOTE:** Do not allow the femur to rest onto the freshly cemented tibia. Pressure on the back part of the tibia can cause the tibia to lift off anteriorly.

4.3.3 Patella Cementation

If applying cement to the bone it should be pressed sufficiently into the bone surface and peg holes prior to introducing the patella implant. Alternatively, a thick bed of cement can be applied to the implant. A clamp is then used to fully pressurize the cement.

Example of using a patella clamp

5.0 Final Pressurization and Cleaning

Once all components are implanted, extending the leg will further pressurize the cement while waiting for the cement to harden.

■ **NOTE:** If the distribution of forces is unequal during final pressurization, the implants may move or cement may not penetrate into the cancellous bone equally in all zones[3] resulting in radiolucent lines and potentially early failure.

■ **NOTE:** This step will extrude excess cement: the knee must be examined and any extruded cement carefully removed.

■ **NOTE:** Care should be taken to apply bone cement to the patellar implant while the bone cement is in its working time, or dough phase.

■ **NOTE:** Keep the patella under compression, using the patella clamp, until the cement has fully hardened.

■ **NOTE:** Keep the leg in full extension. Do not flex or hyper-extend the knee while the cement is curing.

6.0 Summary and Conclusion

The following is a summary of recommended TKR cementing practices:

- Drill keyholes especially in areas of dense or sclerotic bone.
- Thoroughly wash all bone surfaces before cementing.
- Keep all surfaces clean and dry, including gloves, bone, and implant surfaces. Do not apply saline to the cement surface.
- Mix the cement under vacuum.
- Use the cement within its working time.
- Do not preheat the powder or liquid, especially with HV type cements, as this may impact the available working time. Follow the appropriate instructions for use on cement preparation.
- If a surgeon prefers simultaneous cementation during TKA and is assessing ligamentous stability and ROM during cementing curing, then designs with a 'No Clearance' tibial preparation are recommended. Stress and movement of the knee during the cement curing phase is not recommended, due to the inherent risk of motion with regard to lipid infiltration and degradation of tibial tray fixation strength.[23]
- Pressurize the cement by compression; use a thick layer of cement and impaction.
- Ensure that cement around the periphery of the implant has been well pressurized into the bone.
- Remove all extruded cement around the implant, making sure the implant is sealed by cement around its edges.
- Hold the cemented components under compression until the cement is finally set. Ensure that tibio-femoral compressive forces are perpendicular to the tibial axis. Curing in high flexion or hyper-extension may cause tilting of the tibial tray.

7.0 Ordering Information

SMARTSET™ HV Bone Cement

Cat. No.	Description
3092020	SMARTSET HV Bone Cement, 20g
3092040	SMARTSET HV Bone Cement, 40g

SMARTSET™ GHV Bone Cement

Cat. No.	Description
3095020	SMARTSET GHV GENTAMICIN Bone Cement, 20g
3095040	SMARTSET GHV GENTAMICIN Bone Cement, 40g

SMARTSET™ MV Endurance Bone Cement

Cat. No.	Description
3102020	SMARTSET MV ENDURANCE Bone Cement, 20g
3102040	SMARTSET MV ENDURANCE Bone Cement, 40g

SMARTSET™ GMV Endurance Bone Cement

Cat. No.	Description
3105040	SMARTSET GMV ENDURANCE GENTAMICIN Bone Cement, 40g

DePuy CMW™ 1 Bone Cement

Cat. No.	Description
3312020	DePuy CMW 1 Bone Cement, 20g
3312040	DePuy CMW 1 Bone Cement, 40g

DePuy CMW™ 1 Gentamicin Bone Cement

Cat. No.	Description
3315020	DePuy CMW 1 GENTAMICIN Bone Cement, 20g
3315040	DePuy CMW 1 GENTAMICIN Bone Cement, 40g

DePuy CMW™ 2 Bone Cement

Cat. No.	Description
3322020	DePuy CMW 2 Bone Cement, 20g
3322040	DePuy CMW 2 Bone Cement, 40g

DePuy CMW™ 2 Gentamicin Bone Cement

Cat. No.	Description
3325020	DePuy CMW 2 GENTAMICIN Bone Cement, 20g
3325040	DePuy CMW 2 GENTAMICIN Bone Cement, 40g

DePuy CMW™ 3 Bone Cement

Cat. No.	Description
3332020	DePuy CMW 3 Bone Cement, 20g
3332040	DePuy CMW 3 Bone Cement, 40g

DePuy CMW™ 3 Gentamicin Bone Cement

Cat. No.	Description
3335020	DePuy CMW 3 GENTAMICIN Bone Cement, 20g
3335040	DePuy CMW 3 GENTAMICIN Bone Cement, 40g

8.0 References

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Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

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