Modern Cementing Technique

Biomet Bone Cement R, Refobacin® Bone Cement R, and ClearMix™ Vacuum Mixing System

ZIMMER BIOMET
Your progress. Our promise.®

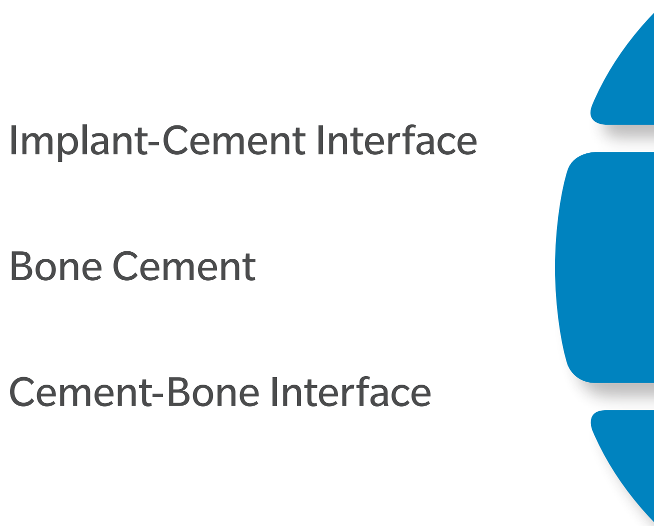
Modern Cementing Technique (MCT) for improved clinical outcome[1,2]

Modern Cementing Technique Knee (MCT Knee) addresses implant loosening and the objective is to provide long term implant stability in knee arthroplasty. It is based on scientific data,[1-26]* findings by Zimmer Biomet[27] and evidence-based techniques documented in the Swedish Hip Arthroplasty Register.[1,2]

The crucial factors in knee arthroplasty to achieve long term implant stability are to secure a strong bond and optimal interfaces, both between implant-cement and cement-bone.

Implant-Cement Interface

- Deliver the cement with a cement gun, and appropriate delivery devices, such as knee nozzles
- Apply bone cement to implant first, as early as possible in the sticky phase[4,27]
- Prevent implant-cement interface contamination by implementing a “no-touch” policy[4,27]



Bone Cement

- Use a bone cement with good mechanical and consistent handling properties
- Mix and collect the cement under vacuum to reduce cement porosity and to improve mechanical strength[8, 28]*

Cement-Bone Interface

- Perforate cancellous bone if dense or sclerotic[24]
- Clean with high pressure pulsatile lavage repeatedly until clear fluid is received in the return line[29-31]
- Deliver the cement with a cement gun and appropriate delivery devices, such as knee nozzles
- Deliver bone cement into tibial stem hole to achieve full cementation[21-23]

*Bench test results not necessarily indicative of clinical performance.

Help to secure a strong bond and optimal interfaces between Implant-Cement and Cement-Bone

IMPLANT

CEMENT

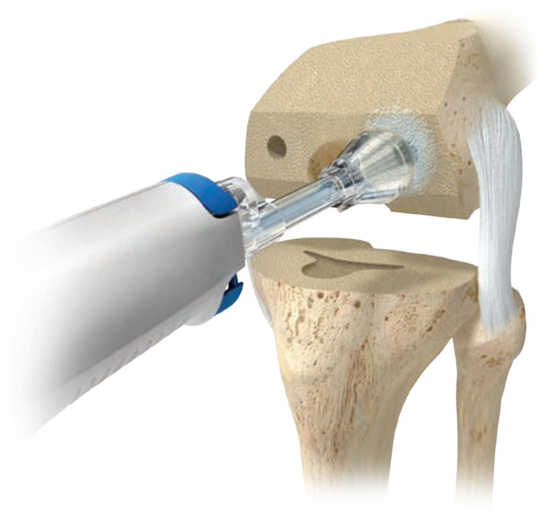
BONE

Modern Cementing Technique Key Steps

Bone Bed Preparation

Cleanse all cement-receiving bone surfaces thoroughly using high pressure pulse lavage of the entire resected bone surface in order to ensure solid cement fixation.[29-31]

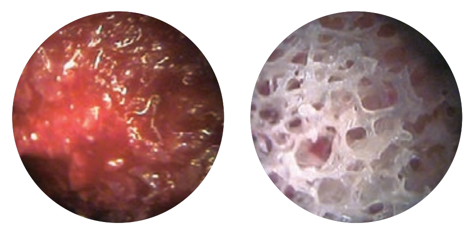
Clean repeatedly until clear fluid is received in the return line to reduce the amount of debris, blood, bacteria and fat.[29-31]



Tibia

In sclerotic bone, supplementary anchorage holes may increase the contact area between bone and cement, providing enhanced fixation.

Curette cysts and remove pericystic sclerotic walls. Depending on cyst diameter, patient age and activity level, fill bone defects with bone cement or particulate bone graft.



Before After

Femur

Contained defects can be grafted with bone taken from the cut surfaces.[32]

In sclerotic bone, drill supplementary anchorage holes.

Perform thorough pulsatile lavage of all surfaces.

Before cement application, bone surfaces should be kept dry, including the posterior aspect of the femoral condyles.

Patella

If the resected bone surface is hard and sclerotic, supplementary anchorage holes may be drilled.

Vacuum Mixing of Bone Cement

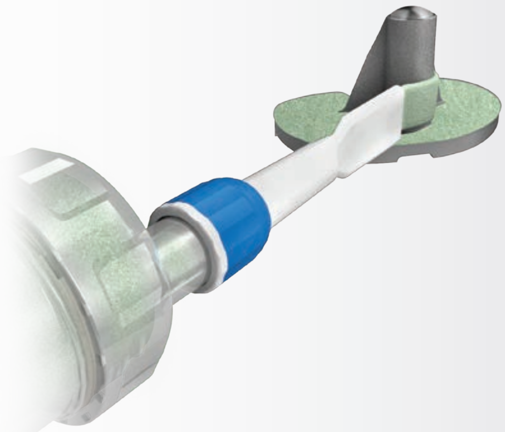
Mix cement in a closed vacuum mixing system to reduce micro and macro pores and decrease the risk of cracks in the cement.[5,7,9,33]

The handling properties of the bone cement are highly dependent on the temperatures of the cement and the operating room. Higher temperatures make for a shorter sticky and dough phases and a faster setting time.

High viscosity bone cement like Biomet Bone Cement R and Refobacin® Bone Cement R can be pre-chilled if a longer sticky and dough phase is required.

Note: Inclusions of blood and laminations in the cement mass reduces the mechanical strength of the resulting cement mantle.[34,35]

Delivery and Pressurization of Bone Cement on Implant



Start with applying the bone cement on implant as early as possible in the sticky phase.

Deliver the cement with a cement gun. Use the flat knee nozzle and apply the sticky bone cement to the implant.

Prevent implant-cement interface contamination by implementing a "no-touch" policy.

Implanting Final Components

The components may be cemented sequentially or simultaneously.

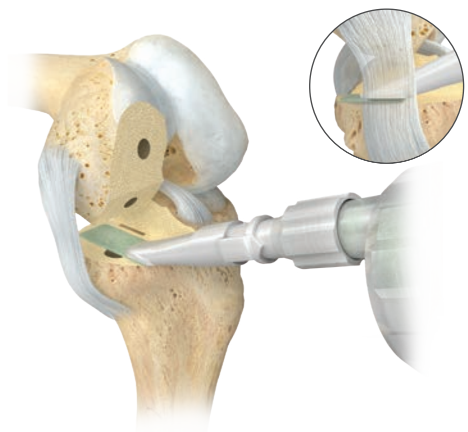
Tibia

Delivery and Pressurization of Bone Cement on Bone

Deliver the cement to a clean, dry bone bed following pulse lavage.

Use a cement gun and an adequate nozzle in order to minimize the risk of air and blood entrapment and achieve sufficient pressurization. Apply cement on bone and pressurize the cement, striving for penetration of 3-4 mm to help ensure optimal fixation and stress distribution.

Total Knee Replacement



Partial Knee Replacement

Insertion Components

To facilitate insertion, flex the knee and externally rotate the tibia. Press down on the posterior portion of the tibial component first to force excess cement anteriorly. Then press down on the anterior portion of the component with the impactor pad assembled to the Tibial Plate Impactor. Impact the tibial base plate moving from posterior to anterior until fully seated.

Remove any excess cement from posterior aspect of the tibia using a curved tonsile/ hemostat.

Total Knee Replacement

Femur

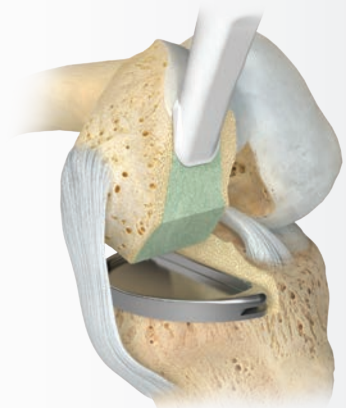
Delivery and Pressurization of Bone Cement on Bone

Deliver the cement to a clean, dry bone bed following pulse lavage.

Apply a layer of cement over the entire bone-opposing surface of the femoral component using a cement gun and an appropriate nozzle.

Pressurize the cement, striving for penetration of 3-4 mm to help ensure optimal fixation and stress distribution.

Avoid contamination of the implant-cement interface.



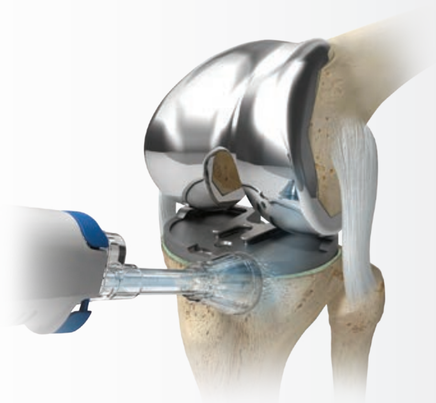
Partial Knee Replacement

Insertion Components

The components are inserted and driven into position with impactors, followed by trial liner insertion and compression with the leg lift method.

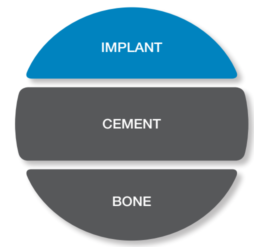
After polymerization remaining cement at implant peripheries are removed.

Cement debris is removed by high pressure pulse lavage.



Implant - Cement Interface

General Clinical Problem in Knee Arthroplasty: Tibial Loosening



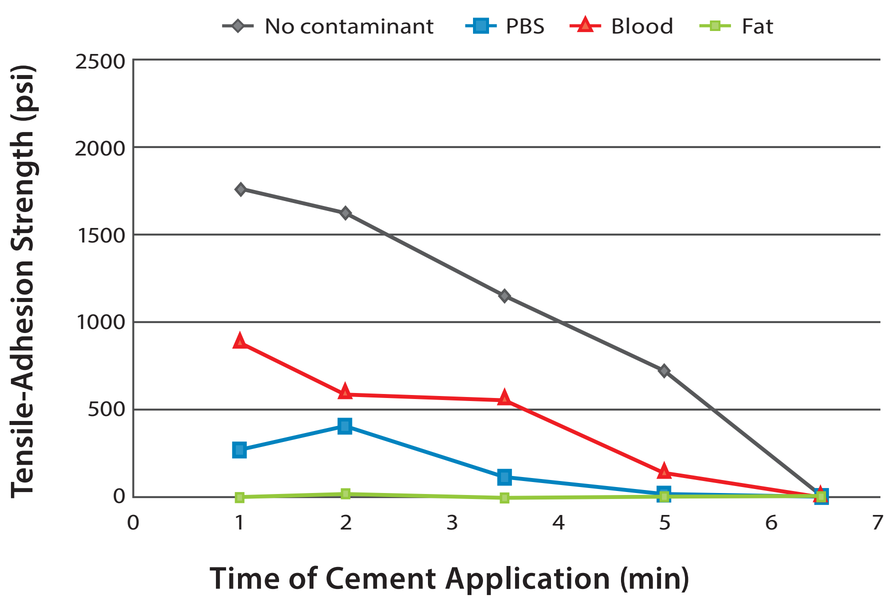
Tibial loosening between cement and implant is not limited to any particular cement brand or tibial component design. The overriding factor is the cementation technique.[4*]

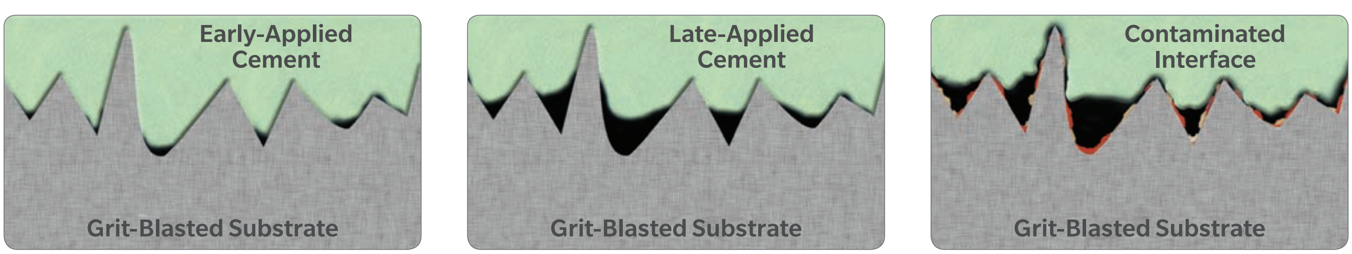
- Knee revisions in US 2017 were projected to be 94,500 with an annual growth rate of 6.2%[36]
- Aseptic loosening of cemented tibial components remain a major cause of failure. It is shown in literature to account for 24% of all knee revisions[3]
- Micro motion at the implant-cement or cement-bone interface can generate wear particles[37]

Fixation - Cement Application

Optimized micro-mechanical interlock can be achieved with early applied sticky bone cement to a non-contaminated implant surface.[27*]

Tensile-Adhesion Strength of Biomet Bone Cement R on 30 grit blast CoCr[27*]





*Lab test results not necessarily indicative of clinical performance.

Implant - Cement Interface

Independent Study with Stryker Triathlon® Tibial Trays and Simplex® and PALACOS® Bone Cements[4]*

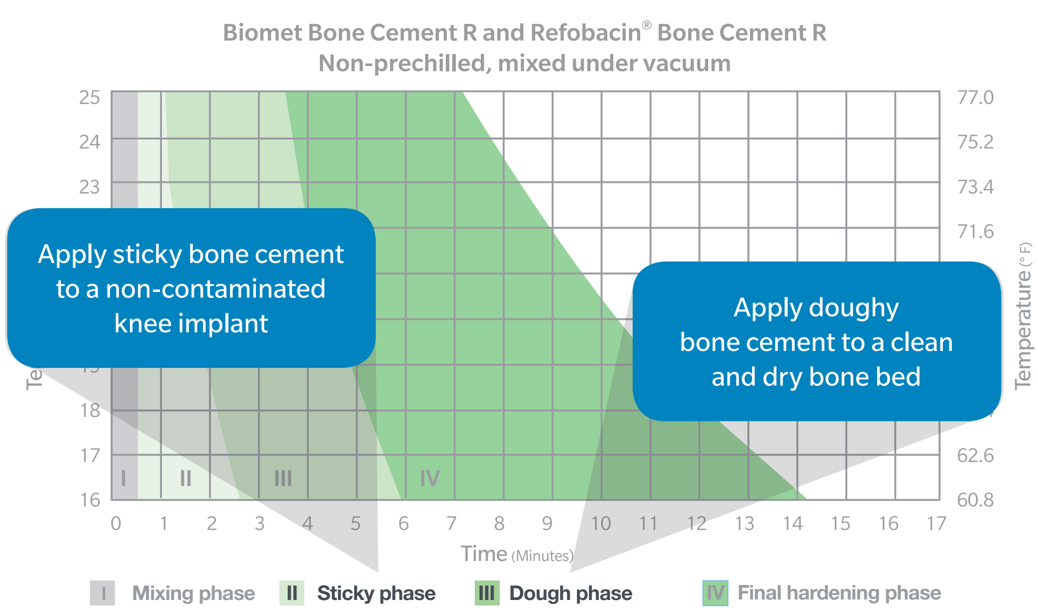
Conclusions

- Under laboratory conditions, a clean tibial tray-cement interface is strong, but much stronger when the keel is cemented
- Earlier application of the cement to metal increases bond strength while later application reduces bond strength
- Fat contamination of the tibial tray-cement interface reduces bond strength, but application of cement to the underside of the tibial tray prior to insertion substantially mitigates this

Solutions for Modern Cementing Technique Knee

Deliver the cement with a cement gun and appropriate delivery devices, as applicable. Use the flat knee nozzle and apply the bone cement to implant first, as early as possible in the sticky phase.

Flat Knee Nozzle used for early application on implant



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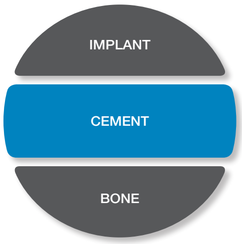
Bone Cement



Bone Cement

Polymethyl methacrylate (PMMA) bone cements fill the space between prostheses and bone, transmitting and evenly distributing loads. The main considerations are:

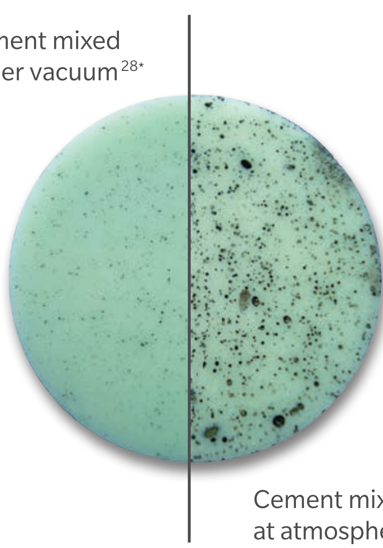
- Good mechanical properties
- Consistent handling properties

Mixing Under Vacuum

Mixing under vacuum reduces both micro and macro pores.[8]* Deliver the cement with a cement gun and nozzle suitable for the application.[10]

- Improved cement strength and fatigue life[7]
- Lower risk of aseptic loosening due to cracks in the cement[7-10]*
- Delivery of reproducible results
- Less exposure to monomer fumes[11]*

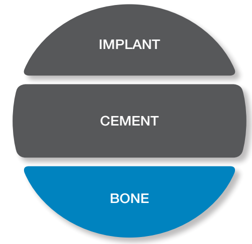
Cement mixed under vacuum[28]*



Cement mixed at atmospheric pressure[28]*

* Lab test results not necessarily indicative of clinical performance.

Cement - Bone Interface



Bone Bed Preparation

Preparation of the bone bed with a pulsative lavage system, like the Pulsavac® Plus Wound Debridement System, helps to ensure solid cement fixation. Clean repeatedly until clear fluid is received in the return line to reduce the amount of debris, blood, bacteria and fat.[29-31]

- To obtain proper cement penetration and fixation into the cancellous bone[38]
- Reduce the risk for revision due to aseptic loosening[3,18]
- Reduce the risk for fat embolism[29]

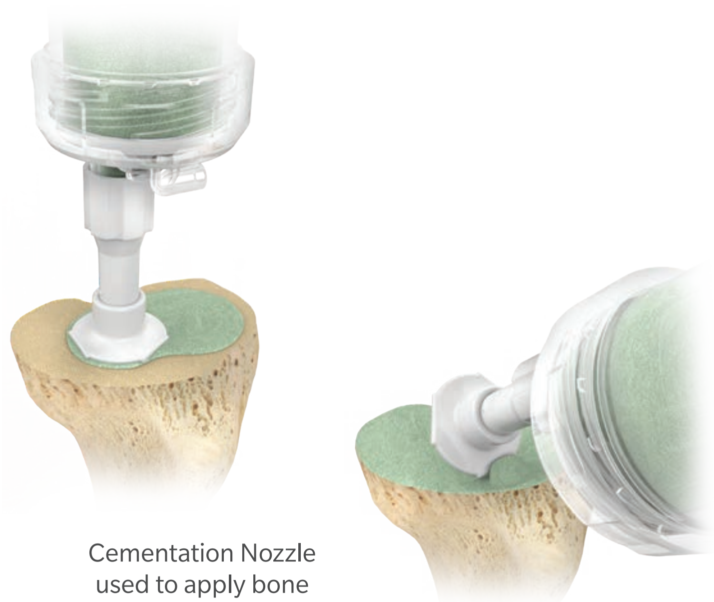
Delivery

- A uniform, deep bone cement mantle provides for optimal fixation and stress distribution[14*,15]
- Application with a cement gun and an appropriate nozzle on both tibia and femur[16-19]
- Delivery to a clean, dry bone bed following pulse lavage[7]

Pressurization

- Increases penetration into the cancellous bone[20]
- Improves interface between bone and cement[7*]

23 Degree Pressurizing Nozzle used to apply bone cement and pressurize



Cementation Nozzle used to apply bone cement and pressurize

* Lab test results not necessarily indicative of clinical performance.

Biomet Bone Cement R and Refobacin® Bone Cement R

Reliable performance

Zimmer Biomet's bone cements follow the standard specifications in all respects of material used, formulation and manufacturing methods. Bone cements from Zimmer Biomet show reliable performance based on international laboratory standard testing.[39,40]

Easy handling

Biomet Bone Cement R and Refobacin® Bone Cement R can be mixed both by hand and in a vacuum mixing system. However, Modern Cementing Technique recommends using a vacuum mixing system such as the ClearMix™ Vacuum Mixers for mixing and delivery of bone cement. This makes standardized handling easy and helps achieve a reproducible, homogeneous bone cement of the highest quality.[10,41]

Antibiotic-loaded cement - broad antibacterial spectrum

Gentamicin has proven to be the antibiotic of choice for bone cement due to its broad antibacterial coverage.[43] Refobacin® Bone Cement R includes 0.5g active gentamicin and provides high local concentrations of gentamicin over several days.[44] The protracted release of the antibiotics may protect the implant for an extended period of time, thus reducing the risk of revision.[45]

High visibility

Biomet Bone Cement R and Refobacin® Bone Cement R contain chlorophyll and the green coloring improves visualization to surrounding tissue. These cements also provide excellent visualization under post-op x-ray.

ClearMix Vacuum Mixing System

High quality vacuum mixing

ClearMix is a high performing vacuum cartridge mixing and delivery system. It allows for a standardized mixing procedure when cement is mixed, resulting in a high quality bone cement. This vacuum mixing system can be used to mix all viscosities of PMMA bone cement.

Practical and easy to use

This easy to use system requires minimal assembly. The mixing rod has a colored indicator that identifies the snap point for breaking. In addition, the vacuum line is equipped with a visual vacuum indicator to ensure proper vacuum level is present before mixing.

Safer working environment

ClearMix Vacuum Mixing System meets modern safety standards and the high demands on mixing bone cement in the OR. By drawing the monomer fumes through special filters, the ClearMix System minimizes MMA exposure of the OR staff to a level significantly lower than OSHA and NIOSH guidelines.[27]

Clear viewing

Based on customer feedback, the clear tube is important as it allows them to see the bone cement during the mixing process.

ClearMix Vacuum Mixing System

ClearMix Vacuum Mixing System is available in two different sizes

The ClearMix Vacuum Mixing System is available as single/double for 40-80g bone cement and as triple for 120g bone cement.

Knee nozzles for improved cement interfaces

Zimmer Biomet provides knee nozzles for optimal delivery and pressurization of the bone cement.

ClearMix Vacuum Mixing System

40-80g bone cement

ClearMix Triple Vacuum Mixing System

120g bone cement

Nozzle Knee Flat

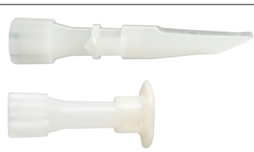
23-Degree Pressurizing Nozzle

Knee Cementation Nozzle

Ordering Information

Product	Part Number	Description	Units/Case
	110035368	**Biomet Bone Cement R 1X40**	**1**
	110034355	**Refobacin® Bone Cement R 1X40 (with Gentamicin)**	**1**

Bone Cement Mixing Systems

Product	Part Number	Description	Units/Case
	414701	**ClearMix Single/Double**	**1**
	414702	**ClearMix Single/Double**	**10**
	414703	**ClearMix Triple**	**1**
	4146	**Nozzle Knee Flat**	**5**
	110031498	**23-Degree Pressurizing Nozzle and Knee Cementation Nozzle**	**5**
	414700	**ClearMix Delivery Gun**	**1**
	00504905300	**Quik-Use® Curette**	**10**
	00504908600	**Zimmer® Vacuum Foot Pump II-Air Connector**	**1**

References

1. Malchau H, *et al*. Prognosis of Total Hip Replacement. The National Hip Arthroplasty Register 1996: 9-11.
2. Malchau H, *et al*. The Swedish Total Hip Replacement Register. *JBJS*. 84A: 2-20, 2002.
3. Austin MS, *et al*. Knee Failure Mechanisms After Total Knee Arthroplasty. *Techniques in Knee Surgery*. 3(1):55–59, 2004.
4. Kavanaugh A, *et al*. Transactions of the ORS 2014 Annual Meeting, New Orleans, LA, #1854. Factors Influencing the Initial Strength of the Tibial Tray-PMMA Cement Bond.
5. Shepard, M, *et al*. Influence of Cement Technique on the Interface Strength of Femoral Components. *Orthopaedics and Related Research*. 381:26-35, Dec 2000.
6. Keller, J, *et al*. Factors affecting surgical alloy/ bone cement interface adhesion. *Journal of Biomedical Materials Research*. Vol. 14,639-651, 1980.
7. Breusch SJ. Cementing Techniques in Total Hip Replacement: Factors Influencing Survival of Femoral Components, In Bone cements and Cementing technique ed by Walenkamp G, Murray D, Springer Verlag 2001.
8. Wang J-S, *et al*. Porosity of bone cement reduced by mixing and collecting under vacuum. *Acta Orthop Scand*. 64 (2): 143-146, 1993.
9. Wang J-S, *et al*. Bone Cement Porosity in Vacuum Mixing Systems, Bone Cements and Cementing Technique 2001, Walenkamp, Murray (Eds). Springer Verlag.
10. Dunne N-J, *et al*. Influence of the mixing techniques on the physical properties of acrylic bone cement. *Biomaterials*. 22: 1819-1826, 2001.
11. Report from SP Technical Research Institute of Sweden (2007 08 13). Airborne methyl methacrylate monomer during the use of different bone cement mixing systems.
12. Clarius M, *et al*. Pulsed lavage reduces the incidence of radiolucent lines under the tibial tray of Oxford unicompartmental knee arthroplasty. Pulsed lavage versus syringe lavage. *International Orthopaedics (SICOT)*. 33:1585-1590, 2009.
13. Christie J, *et al*. Medullary lavage reduces embolic phenomena and cardopulmanory changes during cemented hemiarthroplasty. *J Bone Joint Surg [Br]*. 77- B:456-9, 1995.
14. Walker PS, *et al*. Control of Cement Penetration in Total Knee Arthroplasty. *Clinical Orthopaedics and Related Research*. No. 185, May 1984.
15. Miller MA, *et al*. Loss of Cement-bone Interlock in Retrieved Tibial Components from Total Knee Arthroplasties. *Clinical Orthopaedics and Related Research*. 472(1):304-13, Jan 2014.
16. Ritter MA, *et al*. Radiolucency at the Bone-Cement Interface in Total Knee Replacement. The Effect of Bone-Surface reparation and Cement Technique. *J Bone Joint Surg Am*. 76(1):60-5, Jan 1994.
17. Krause WR, *et al*. Strength of the Cement-Bone Interface. *Orthopaedics and Related Research*. 163:290-299, Mar 1982.
18. Lutz MJ, *et al*. The Effect of Cement Gun and Cement Syringe Use on the Tibial Cement Mantle in Total Knee Arthroplasty. *The Journal of Arthroplasty*. Vol. 24, No. 3, 2009.
19. Yoga R, *et al*. Use of Cement Gun for Fixation of Tibia Component in Total Knee Arthroplasty. *Malaysian Orthopaedic Journal*. Vol. 3, No. 1, 2009.
20. Reading AD, *et al*. A comparison of 2 modern femoral cementing techniques: analysis by cement-bone interface pressure measurements, computerized image analysis, and static mechanical testing. *J Arthroplasty*. 15(4):479-87, Jun 2000.
21. Lombardi AV, *et al*. Surface Cementation of the Tibial Component in Total Knee Arthroplasty. Scientific Exhibit, 65th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, Lousiana. February 19-23, 1998.
22. Sisodial G, *et al*. Does Cementing Technique of the Tibial Component Influence Initial Fixation to Bone in Total Knee Arthroplasty? Full Versus Surface Cementation. *Bone Joint J*. Vol. 95-B, No. SUPP 20 6, 2013.
23. Bert JM, *et al*. Is It Necessary to Cement the Tibial Stem in Cemented Total Knee Arthroplasty? *Clinical Orthopaedics and Related Research*. 356: 73-78, 1998.
24. Miskovsky C, *et al*. The Cemented Unicondylar Knee Arthroplasty. An In Vitro Comparison of Three Cement Techniques. *Clinical Orthopaedics*. No. 284, Nov 1992.
25. Cawley DT, *et al*. Cementing techniques for the tibial component in primary total knee replacement. *Bone Joint J*. 95-B:295-300, 2013.
26. Diaz-Borjon E, *et al*. Cement Penetration Using a Tibial Punch Cement Pressurizer in Total Knee Arthroplasty. *Orthopedics*. Vol. 27, No. 5, May 2004.
27. Report Tensile-adhesion properties of Biomet Bone Cement R on 30 grit blasted CoCr, test number ATS LAB#17-25539, issued Dec 2017. Data on file at Zimmer Biomet, Internal Laboratory Testing. Laboratory testing is not necessarily indicative of clinical performance.
28. Lidgren, L, *et al*. Bone Cement Improved by Vacuum Mixing and Chilling. *Acta Orthop*. Scand. 57, 27-32, 1987.
29. Breusch SJ, *et al*. Pulmonary Embolism in Cemented Total Hip Arthroplasty. The Well-Cemented Total Hip Arthroplasty. Heidelberg, pp. 320-331, 2005.
30. Anglen JO, *et al*. The efficacy of various irrigation solutions in removing slime-producing Staphylococcus. *J Orthop Trauma*. 8(5):390-6, 1994.
31. Helmers, S, *et al*. Efficacy of Irrigation for Removal of Particulate Debris after Cemented Total Knee Arthroplasty. *Journal of Arthroplasty*. Vol. 14 No. 5, 1999.
32. Springer BD, *et al*. Conversion of failed unicompartmentel knee arthroplasty to TKA. *Clinical Orthopaedics and Related Research*. 446: 214-20, 2006.
33. Wilkinson JM, *et al*. Effect of mixing technique on the Properties of Acrylic Bone-Cement. *The Journal of Arthroplasty*. 15:663-667, 2000.
34. Flivik G, *et al*. Effects of lamination on the strength of bone cement. *Acta Orthopaedica*. 68: 55-68, 1997.
35. Saha S, *et al*. Mechanical properties of bone cement: A review. *Journal of Biomedical Materials Research*. 18: 435-462, 1984.
36. Millennium Research Group, Inc. Large-Joint Reconstructive Implants, Market Analysis, US, 2017. Millennium Research Group, M360LJ0021, p: 37, December 2016.
37. Cheng, K, *et al*. Osteolysis Caused by Tibial Component Debonding in Total Knee Arthroplasty. *Clinical Orthopaedics and Related Research*. No. 443: 333-336, 2006.
38. Kalteis T, *et al*. An experimental comparison of different devices for pulsatile high-pressure lavage and their relevance to cement intrusion into cancellous bone. *Arch Orthop Trauma Surg*. 127(10):873-7. Epub Dec 2007.
39. ISO 5833, Implants for Surgery - Acrylic Resin Cements (2002).
40. Data on file at Zimmer Biomet, Internal Laboratory Testing, Aug 2016. Laboratory testing is not necessarily indicative of clinical performance.
41. Wilkinson J.M., *et al*. Effect of mixing techniques on the Properties of Acrylic Bone-Cement. *The Journal of Arthroplasty*. 15:663-667, 2000.
42. Gehrke T, *et al*. Pharmacokinetic study of a gentamicin/clindamycin Bone Cement Used in One-Stage Revision Arthroplasty. In: Bone Cements and Cementing Technique; Walenkamp, GHIM; Murray, DW (eds); Springer Verlag Berlin Heidelberg. 127-134, 2001.
43. Kühn K-D. Bone Cements. Up-to-Date Comparison of Physical and Chemical Properties of Commercial Materials. Springer Verlag Berlin Heidelberg New York, p. 256, 2000.
44. Report Gentamicin Elution, test number 1701-019, issued Feb 2017. Data on file at Zimmer Biomet, Internal Laboratory Testing. Laboratory testing is not necessarily indicative of clinical performance.
45. Parvizi J, *et al*. Efficacy of antibiotic-impregnated cement in total hip replacement. A meta-analysis. *Acta Orthop*. 79 (3): 335-341, 2008.

For product information, including indications, contraindications, warnings, precautions, potential adverse events, and patient counseling information, see package insert and www.zimmerbiomet.com.

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