

Bone Cement Matters

Simplex P Bone Cements



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is intended for healthcare professionals only.**

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Bone Cement has been used in cemented arthroplasty for over 50 years. In that time, many bone cements have been used in orthopedics. Some have stood the test of time, while others have been phased out of use by surgeons. **In that time, Simplex P has emerged as the most used bone cement in the US.**³²

The surgeon's decision to use one bone cement over another is multi-faceted. This piece discusses matters surgeons take into account in making this important choice for patient care.

Handling & Use

One matter for consideration is intra-operative handling and ease of use. Surgeons have preferences towards handling properties, and it is important to understand the effect these properties may have on patient outcomes. How do the handling characteristics effect cement interdigitation and shear strength? What can be done to produce consistent setting times?

Safety

Infection following total joint arthroplasty is a devastating complication that is very difficult to eradicate, once established.²⁶ Antibiotic bone cement allows localized delivery of the antibiotic at the cement-bone interface.²⁶ Which antibiotic is most effective against common joint arthroplasty bacteria? What are the elution profiles for different antibiotics and cements?

Implant Survivorship

The surgeon also studies the effect the bone cement will have on implant survivorship; a weak cement can cause a component to loosen. What role, for better or worse, do certain ingredients in the cement formula play? How does cement contribute to polyethylene wear and osteolysis?

All matters considered, surgeons must always rely on their clinical judgment when deciding which bone cement to use. Bone cement is an implant, and as you will read, Simplex Bone Cements demonstrate excellent survivorship.³³
Surgeons choose Simplex P over other bone cements... because Bone Cement Matters.



Viscosity Matters

Why Viscosity is Important

What is viscosity?

Viscosity describes the cement's resistance to flow. Cement is classified by which state it remains in the longest. Typically a low (LV) or high (HV) viscosity cement stays for a long time in one state. For instance, a LV cement (DePuy® 3) spends more of its working time in a low viscosity state. Therefore, if a high viscosity state is desired, the working time may be too short for the application time needed. On the other hand, HV cements (Palacos®, SmartSet HV) are thick or “doughy” immediately after mixing, and can only be used in that high viscosity state.



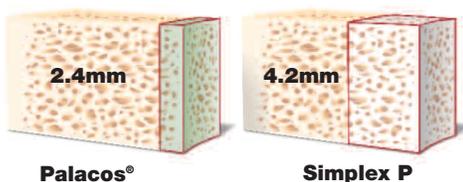
What viscosity is Simplex?

For many years Simplex P Bone Cement has been referred to as both a low and high viscosity cement in the literature. Thus in recent years, Simplex came to be known as “medium viscosity” to be able to classify the dual phases in which Simplex can be used. If delivered very early after mixing and/or if the cement storage and ambient temperature are cold, Simplex P can be used in a low or medium viscosity state. If the cement is delivered a few minutes after mixing and/or the storage temperature and ambient temperature are warm, the cement can be used in a high viscosity state.

Why is viscosity important?

Surgeons who prefer HV cement like its handling characteristics, especially when finger-packing cement for knee applications. **Viscosity affects not only how easy it is for the surgeon to handle, but also how thoroughly it penetrates the pores of cancellous bone to achieve fixation.**

The deeper cement penetrates into bone, the stronger the fixation and shear strength of the bond.¹⁷ HV cements cannot be pressurized into bone as well as medium viscosity cements. **Simplex achieves approximately 75% deeper intrusion compared to high viscosity Palacos®.**¹⁷



Porosity is air entrapped in bone cement, which can lead to mechanical failure.¹⁴ Reduction in porosity increases fatigue strength.¹⁴ **Palacos®, because of its high viscosity, may be difficult to remove air from, even with vacuum mixing.**^{8, 14, 18-21} Also, if a surgeon waits too long to apply a high viscosity cement, laminations or folds can occur in the cement mantle. A lamination could reduce cement strength.¹⁰

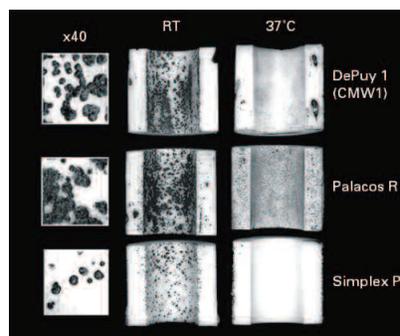


Figure 1: Longitudinal sections of the cement mantle for the different types of cements. There are pores at the cement-stem interface.

How can Simplex be used in a high viscosity state?

Here are some tips for accelerating Simplex's high viscosity state:

- 1) Store Simplex at the higher end of the recommended storage temperature range of 43-74° F.
- 2) Consider using the Stryker Revolution Mixing System. The Revolution system uses a power reamer to mix the cement. Cement setting times with this power mixing system have demonstrated quicker dough and setting times than with other Stryker cement mixers.²²
- 3) Follow the appropriate mixing instructions for the cement mixer used, and mix for slightly longer if desired. Mixing longer should speed up the chemical reaction as well as dough and setting times.
- 4) If the O.R. temperature is very cold, consider waiting to bring Simplex into the cold O.R. environment until immediately before cement mixing will begin. The longer the bone cement is in a cold environment the more it may affect the setting time.
- 5) Time your mixing to the state of viscosity required. If the goal is a high viscosity cement, begin mixing earlier to eliminate any waiting time. Do several test mixing sessions to learn what timing preference is right for various surgical situations.

In Summary:

- Simplex P Bone Cement, a dual phase cement, affords surgeons the choice of viscosity that is desired, all in one product.
- Used in a medium viscosity state, Simplex achieves approximately 75% deeper intrusion compared to high viscosity Palacos®.¹⁷
- There are techniques to accelerate the high viscosity state of Simplex, but **be aware of the concerns about high viscosity cements including poor pressurization and the presence of laminations.**^{8, 10, 14, 18-21}

CementTip

DePuy® manufactures a family of bone cement products, including some new cements with limited clinical history. By understanding the dual phases of Simplex, coupled with its excellent survivorship, surgeons can use Simplex no matter what their preference.



Consistency Matters

Controlling Setting Factors



What influences bone cement setting time?

Many factors including storage temperature, O.R. temperature, humidity, mixing conditions, mixing speed and handling of the cement influence setting time.²⁷ Operating room environments can vary widely affecting these conditions. This can all add up to a very unpredictable set time and working time in an otherwise very controlled surgical technique. **Controlling the variables can limit complications and may lead to more reproducible results.**

What can the surgeon do?

Dr. John R. Schurman of Wichita, Kansas has been able to neutralize the variability of working time and setting time of the cement by using the Simplex P *SpeedSet* product and controlling the cement environment. This has enabled him to reproduce working time and set time.

The temperature of the cement powder, monomer, bowl and mixing instruments are controlled at 73° F in a water bath at the time of setup of the case. When mixing is started, the mixing tools and cement ingredients are retrieved and mixing is done for 1 minute at 1 revolution mixing speed. The mixed-liquid cement is then set aside and, in this surgeon's experience, set time is consistently 10 minutes.

This uniform process allows Dr. Schurman to plan the mixing of cement in the procedure to eliminate waiting for the cement to dough. Operating room environmental variables no longer affect the cementing process for Dr. Schurman.

In Summary:

- There are many factors that influence bone cement setting time.
- Dr. Schurman has had success with isolating one of the variables: storage temperature.
- By storing the liquid, powder, mixer, and mixing instruments at 73°, Dr. Schurman has seen consistent 10 minute setting times using *SpeedSet*.

CementTip

Compare set times related to OR temperature and mixing system with the Bone Cement Set Time Chart (LBCT-S).



Antibiotic Selection Matters

Tobramycin vs. Gentamicin Bone Cements

Why Use Pre-blended Antibiotic Bone Cement?

Today, orthopedic companies offer bone cement pre-blended with antibiotics. Some hospitals choose to hand-blend antibiotics intra-operatively (off label). **Commercially-blended antibiotic cement demonstrated an approximate 50% increase in strength compared to hand-blended antibiotic cement.**²⁴

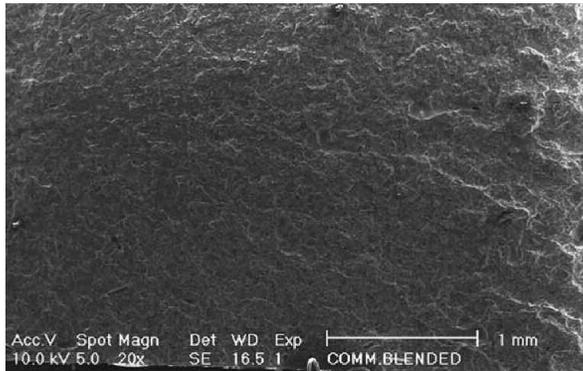


Figure 2: Simplex™ P with Tobramycin²⁴

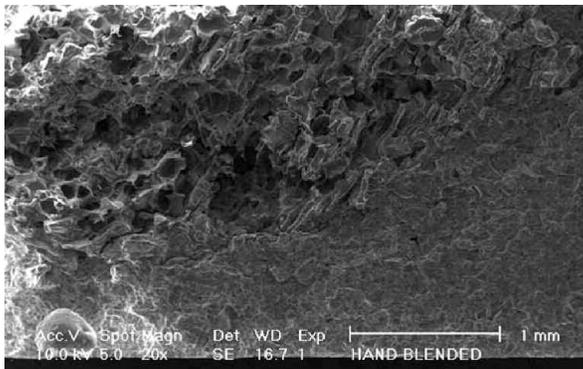


Figure 3: Hand Blended Antibiotic²⁴

Why use tobramycin over gentamicin?

Tobramycin is the antibiotic of choice for 75% of U.S. orthopedic surgeons.²⁵ Tobramycin and gentamicin are both aminoglycosides. However, tobramycin has the added benefit of superior activity against *Pseudomonas*.²⁶ **In fact, one study demonstrated that 93% of *Pseudomonas aeruginosa* bacteria isolates tested were susceptible to tobramycin, while only 81% were susceptible to gentamicin.**²⁷

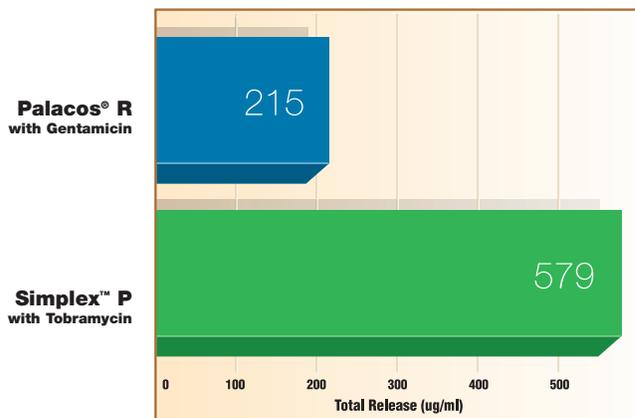
Another study, using a Kirby-Bauer susceptibility model, showed in vitro activity of Simplex with 1 gram of tobramycin against 99 strains of common orthopedic organisms.

- 24 strains of *Staphylococcus* were studied. None of the 24 strains were found to be resistant to tobramycin.²⁶
- *Enterococcus faecalis*, MRSA, MRSE, and slime producing *Staph epidermis* showed limited susceptibility to the concentrations of antibiotic released from the bone cement discs containing tobramycin.³³
- The inhibition of even the most virulent strains at the surface of the bone cement disc containing antibiotics was significant.³³

What are the elution characteristics of Simplex with Tobramycin?

Tobramycin also elutes better than gentamicin from bone cement.²⁹ **Palacos's® higher porosity contributes to its good elution profile, however porosity may have a deleterious effect on the mechanics and long-term durability of the reconstruction.**²⁸ Furthermore, Palacos® R+G contains .5g active gentamicin, compared to 1g of active antibiotic in Simplex with Tobramycin. The resulting elution characteristics can be seen in Figure 4.²⁹

Figure 4: Elution Characteristics: Tobramycin vs. Gentamicin³¹



Are there any concerns about using vancomycin prophylactically?

Surgeons who add gentamicin and vancomycin to cement to increase the antibiotic effectiveness need to be aware of the dangers of vancomycin-resistant bacteria strains, according to AAOS.³¹

AAOS Recommendation: Vancomycin should be reserved for the treatment of serious infection with beta-lactam-resistant organisms or for treatment of infection in patients with life-threatening allergy to beta-lactam antimicrobials.³¹

Simplex P with Tobramycin Bone Cement is indicated for the fixation of prostheses to living bone in the second stage of a two-stage revision for total joint arthroplasty.

Third Body Wear Matters

Barium sulfate vs. Zirconium dioxide

“The presence of macrophages at the bone-PMMA interface is a tissue reaction which no implant surgeon can lightly dismiss.”³⁴

- Sir John Charnley

What Does Barium Sulfate/Zirconium Dioxide Do?

Barium sulfate and zirconium dioxide are radiopaque additives in bone cements that make the cement visible on X-rays.

How Does Barium Sulfate Differ From Zirconium Dioxide?

Zirconium dioxide, found in Palacos[®], is grainier and shows evidence of agglomeration, or clumping.² It has also been proven to cause more third-body wear to an implant than barium sulfate, found in Simplex.¹

In Simplex P, barium sulfate is blended under special controls to allow for uniform barium sulfate dispersion that is free of clumps, even under 2000x magnification.

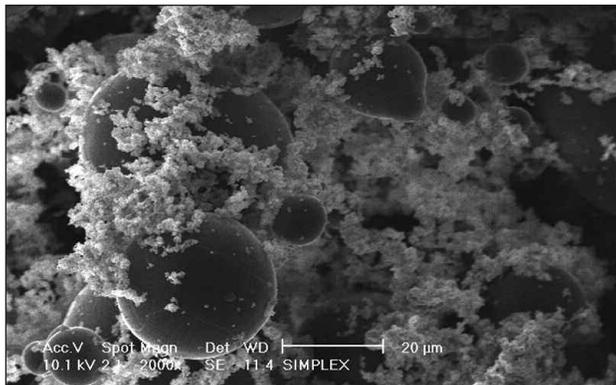


Figure 6: Simplex P Powder Mixture³⁶

Even though DePuy[®] SmartSet MV contains barium sulfate, note the clumps of the material in the mixture.



Figure 7: DePuy[®] SmartSet MV Powder Mixture³⁶

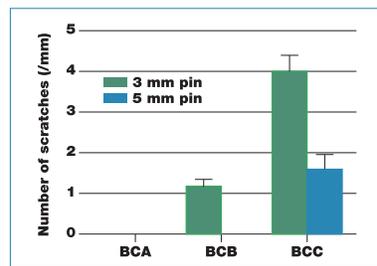
What Is Third-Body Wear?

Third-body wear occurs when abrasive particles become entrapped between primary bearing surfaces. These particles may include fragments of bone cement, polyethylene, or metallic particulates.

Granules of radiopaque agents can separate from the cement. [Fig 5]. This results in damage to the metal articulating surface and, as a consequence, a marked increase in polyethylene wear.⁴

Figure 5: Number of scratches per mm of the wear track \pm 95% confidence limits.³

Bone cement A: Bone cement without additive
 Bone cement B: Bone cement with barium sulfate
 Bone cement C: Bone cement with zirconium dioxide



What Can Third-Body Wear Lead To?

Macrophages (“big eaters”) in the body digest cellular debris. As the macrophages engulf the granules, a reaction occurs causing the macrophages to behave differently – they begin to act as osteoclasts and resorb bone, causing osteolysis.⁵

Figure 6: Radiopaque agents used in manufacturer’s bone cement.

	Zirconium dioxide	Barium sulfate
Simplex		•
Palacos [®]	•	
Osteobond	•	
Cobalt	•	
Versabond	•	
DePuy [®] 1/2/3 SmartSet MV		•
SmartSet HV	•	

In Summary:

- Barium sulfate and zirconium dioxide are added to cement by manufacturers to make them radiopaque, or visible on X-rays.
- Zirconium dioxide, found in Palacos[®] and other cements, has been proven to clump and cause more third-body wear to an implant than barium sulfate.^{1,2}

Creep Matters

Simplex Creeps Less Than High Viscosity Cements

What Is Creep?

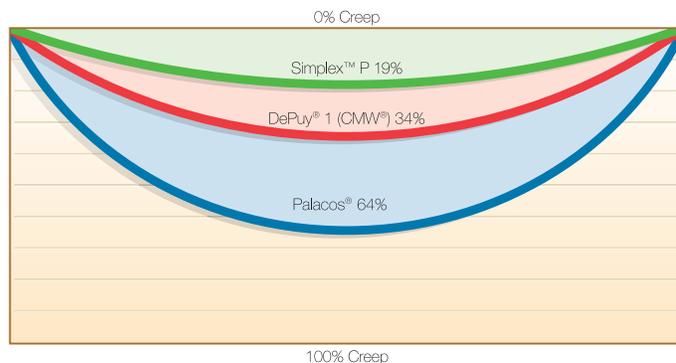
Creep, or plastic deformation, is a mechanical problem that can slowly, steadily erode long-term implant performance. Bone cement is an acrylic, and similar to other plastics, it undergoes relaxation over time.

What Causes Creep?

All bone cements creep to some degree. **Cements with higher porosity and viscosity, like Palacos® and DePuy® 1, are less resistant to creep deformation.**^{7,11} Palacos® also creeps much faster than Simplex.⁶

Figure 10:

Creep Percent Relaxation at 500 hours.⁶



Voids in cement also increase creep significantly.⁹ Therefore, surgeons should keep these points in mind to reduce the presence of voids:

- **Ensure a thorough cement mix.** The bead-flake composition of Simplex is designed to increase wettability and produce a homogeneous mixture, free of clumps.
- **Reduce cement porosity.** Vacuum mixing reduces porosity,¹⁴ and Simplex has lower porosity than Palacos®.⁸
- **Eliminate laminations.** Kneading the remaining cement not used in the procedure until it can no longer be joined smoothly, is an indicator that the working time is over. A seam indicates a lamination, or layer, which may reduce cement strength.¹⁰ Cement should not be delivered once the working time is over.

What Can Creep Lead To?

The physical behavior of bone cement has clinical significance in terms of mechanical fixation and loosening. Bone cements that creep too much may lead to component shifting, loosening, and failure.⁶

In Summary:

- All bone cements creep over time.
- Palacos® creeps much faster than Simplex.⁶
- Simplex creeps significantly less than Palacos® and DePuy® 1.

Why Bone Cement Matters

Simplex P Bone Cements



Choice of bone cement contributes to patient outcomes. No other bone cement has stronger survivorship than Simplex P.³⁴

This brochure explains how high viscosity cements like Palacos® and DePuy® 1 do not penetrate into bone as well as Simplex P.¹⁷ Greater porosity at the cement-bone interface for these cements is shown visually for these cements as well.¹²

Dr. Schurman's mixing technique for a consistent 10 minute setting time demonstrates how to control the many operating room variables. A homogenous mixture is critical to the cement strength. SEM images show how commercially blended antibiotic cement like Simplex with Tobramycin is stronger than a hand blended mix.²⁴

This brochure presented SEM images and published studies on the significant difference Simplex P's use of barium sulfate has on the uniform cement mixture as well as polyethylene wear.³

You must always rely on your clinical judgment when deciding which bone cement to use. When you select Simplex for your surgeries, you are among the most elite surgeons and hospitals in the country.³⁵

Because the patient matters, bone cement matters.

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