CEMEX®

Advancing the Ordinary

Cemex | Cemex Genta | Cemex System | Cemex Accessories | Cemex Automatic Mixer

Exactech® *Surgeon focused. Patient driven.™*

Committed to a Common Purpose

Exactech started with a dream shared by orthopaedic surgeon Bill Petty, MD, his wife Betty, and biomedical engineer Gary Miller, PhD. Drs. Miller and Petty had worked with several orthopaedic companies and thought they saw some things they could do differently, and better.

They wanted to make a difference in the quality of care provided to patients suffering from injuries or arthritic disease.

The Pettys and Dr. Miller made the first step toward realizing their vision by incorporating Exactech in 1985.

Since that time, we have leveraged our founding principles to look at clinical challenges through the eyes of a surgeon. It's all about working together, focusing on your needs and then engineering innovative solutions that improve patient outcomes for hip, knee and extremities surgery utilizing Advanced Surgical Technologies like **Cemex Bone Cement.**

Stable leadership for 30+ years

Fast-growing orthopaedic device company

Distribution in more than 30 countries

Innovative bone and joint products

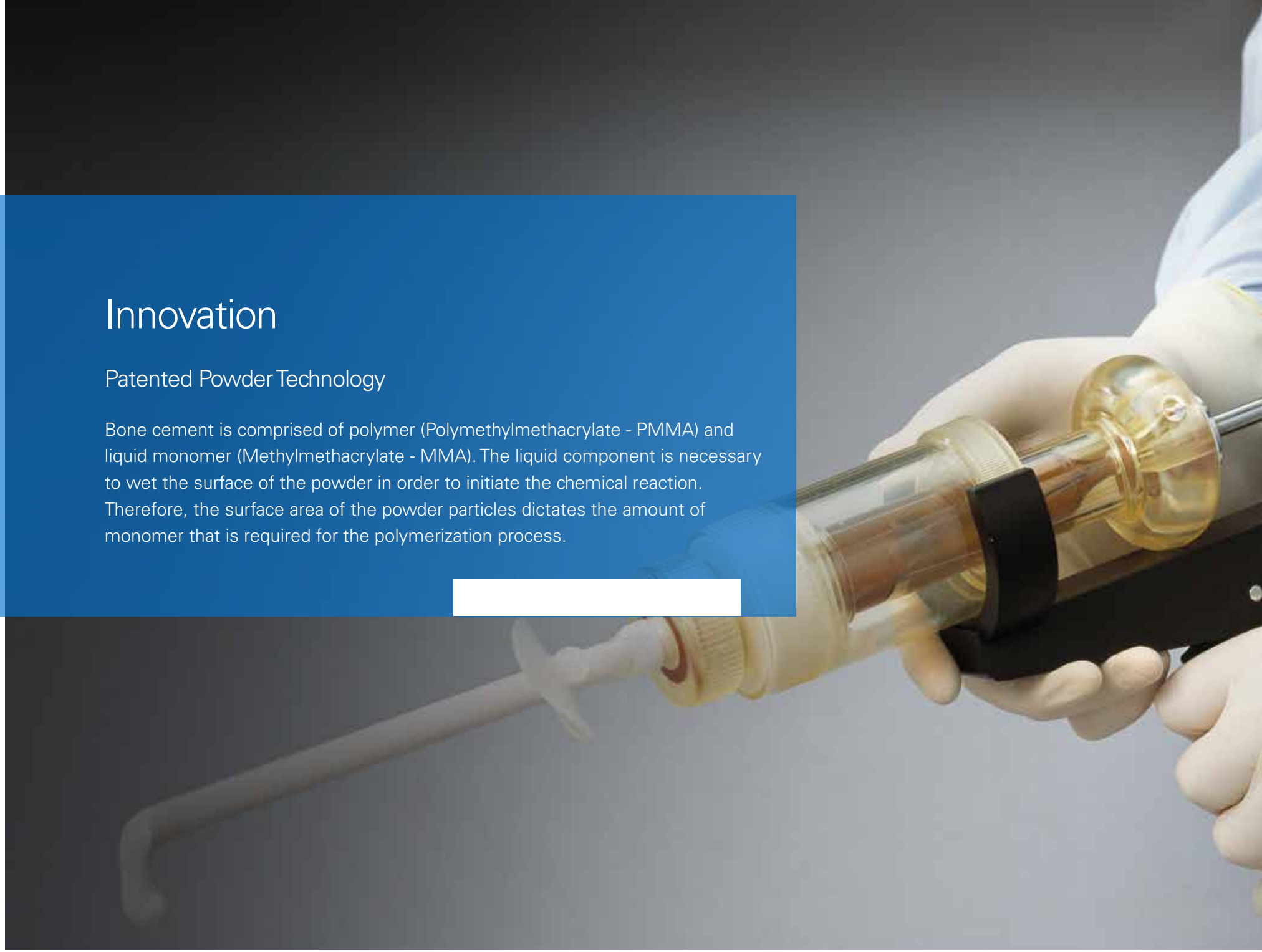
The Cemex Advantage

Cemex® is a clinically proven bone cement with long-term success in the fixation of joints.[1] Cemex features a unique self-contained delivery system that integrates both the bone cement powder and liquid into an enclosed mixing system while offering surgeons and operating room personnel safety, simplicity and reliability.

Innovation

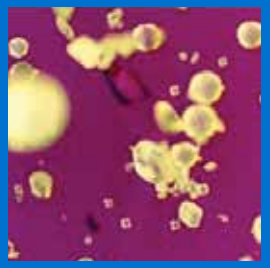
Patented Powder Technology

Bone cement is comprised of polymer (Polymethylmethacrylate - PMMA) and liquid monomer (Methylmethacrylate - MMA). The liquid component is necessary to wet the surface of the powder in order to initiate the chemical reaction. Therefore, the surface area of the powder particles dictates the amount of monomer that is required for the polymerization process.

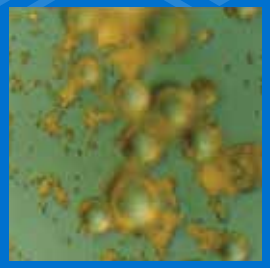


Consistent Particles

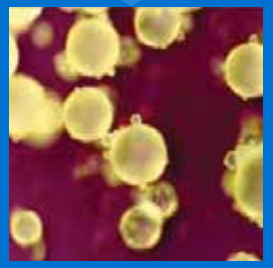
Thanks to a patented process, Cemex powder particles are consistent in shape and size. The powder has few microparticles and has nearly no irregularities when compared to other commercially available cements (see particle comparison).[2] These characteristics result in uniform spheres that yield decreased total surface area. This feature means less monomer is needed to create the cement. Therefore, we were able to develop Cemex with a 3:1 powder to monomer ratio. Because monomer is the more dangerous component, using less monomer decreases risks to patients and O.R. staff. By comparison, the best-selling bone cements on the market utilize a 2:1 powder to monomer ratio and polymerize at higher temperatures.[3]



2:1 Cement Spherical–irregular
12.7×10^{-2} m^2/cm^3



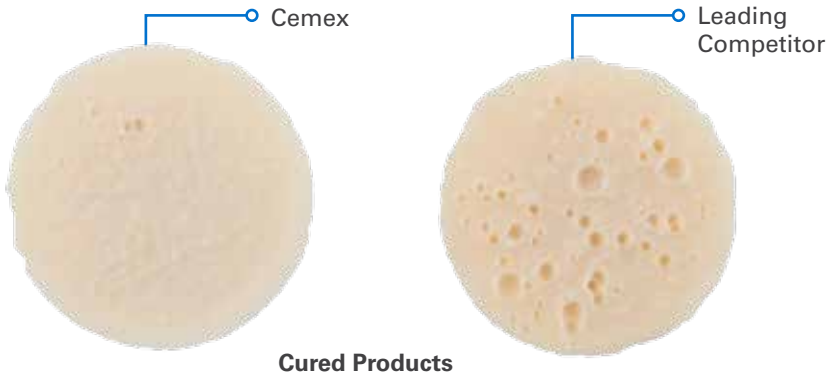
2:1 Cement Spherical–many micro particles
12.2×10^{-2} m^2/cm^3



3:1 Cemex Spherical–uniform; few micro particles
6.1×10^{-2} m^2/cm^3

Air and Porosity

The consistency in shape and size of the patented powder particles produces a more dense structure that traps less air, removing the need to vacuum mix Cemex.



Cured Products

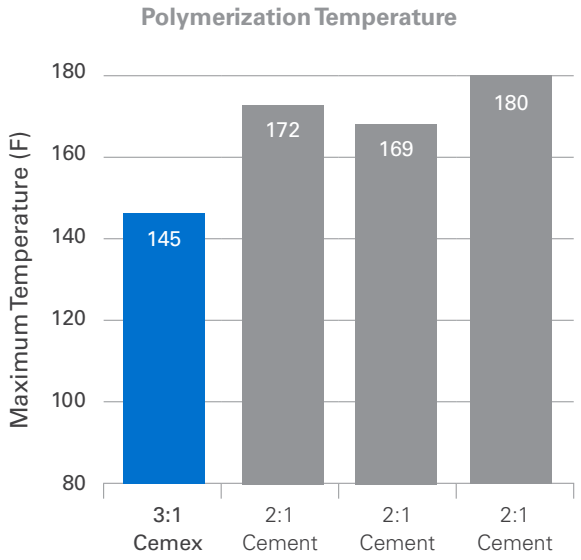
Side-by-side comparison depicts 40g of dry powder. Leading competitor traps twice as much air or volume necessitating the need for vacuum mixing.

Less Monomer

The more liquid bone cement contains, the more toxic it is to patients, surgeons and O.R. staff directly mixing and applying the bone cement. Cemex uses one-third less liquid than best-selling competitive bone cements, exposing the patient to reduced levels of toxic monomer.[4]

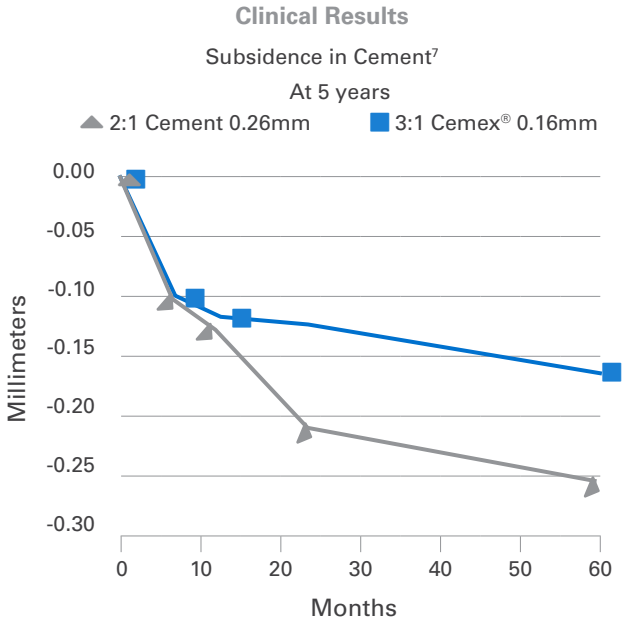
LOWER MAXIMUM POLYMERIZATION TEMPERATURE

Cemex has been shown to produce 20 percent less heat than other commercially available formulations.[3] Every gram of monomer (liquid component) generates energy equal to 130 Kcal.[5] Because of its unique powder component, Cemex requires about 30 percent less liquid than other bone cements, thereby substantially reducing the maximum temperature reached during the chemical reaction.[3,4] The reduced polymerization temperature may reduce the potential for bone and tissue necrosis.[6]



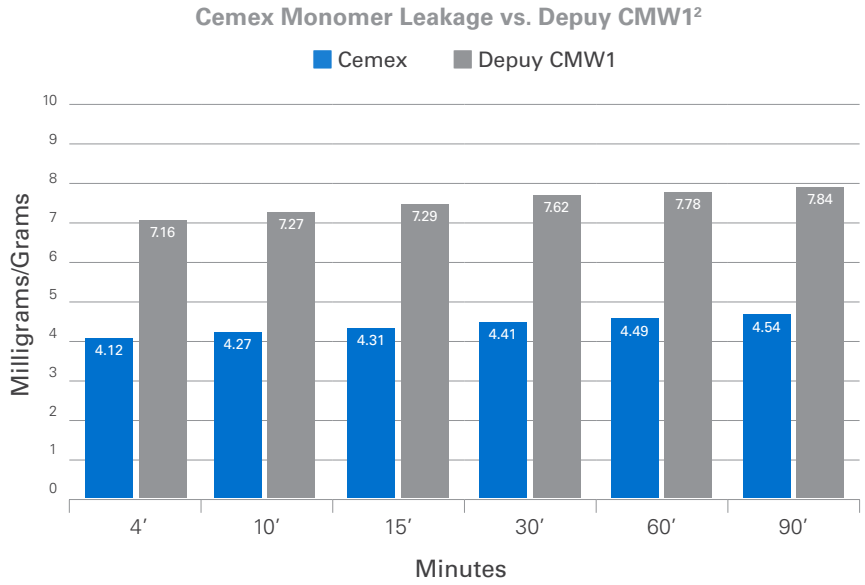
LESS SHRINKAGE

When cement hardens, one of the effects of the chemical reaction is that the cement contracts or "shrinks". This shrinkage is proportional to the amount of liquid present in the cement mixture.[7] By using less liquid than other commercially available formulations, Cemex shrinks 67 percent less than its competitors.[8] The shrinkage phenomena is most clearly evidenced with the loosening of the prosthesis and early implant failure. Bone cement with less monomer minimizes the shrinkage phenomena and the likelihood of a revision.[7]



REDUCED MONOMER LEAKAGE

Leakage occurs when the uncured toxic monomer from the bone cement "leaks" into the patient, potentially causing hypotension and systemic toxicity.[9] Therefore, the cementation phase can be a critical point during the procedure for the surgical staff considering the potential patient complications. Cemex offers a PMMA bone cement with less monomer that inherently reduces the leakage to patients.



Safety, Simplicity and Reliability

Self-Contained Mixing and Delivery System

Cemex System is unique because of its pre-loaded liquid and powder components. It features a self-contained delivery system that has been clinically proven in Europe for many years.[1] By integrating the bone cement powder and liquid into an enclosed mixing system, Cemex offers safety, simplicity and reliability in bone cement with several advantages.

Cemex System is a combined bone cement mixing and delivery system. With no bags to open, no complicated mixing system and no hoses, cement preparation time is minimized. In just a few simple steps performed by one person, the cement is ready to use.

**A detailed diagram of the Cemex System can be found on the back page of this brochure.*

Minimized Contamination

If the technique is followed, the operator should never come into contact with the material during polymerization stages, which eliminates the intrusion of foreign particles (e.g. glass) or bacteria from entering the cement during mixing. Cemex is designed to provide safety through minimized contamination risk.

Reduced Toxic Vapors

The enclosed system minimizes the release of toxic vapors into the operating room environment—not to mention that Cemex already has 33 percent less monomer than its competitors. Cemex System, combined with the reduced monomer Cemex, is designed to offer the surgical staff a safe solution for mixing and delivering cement.

Compact Mixing and Delivery System

Cemex System is an all-in-one, self-contained system that includes the bone cement, mixing components and delivery method. This simple System removes the necessity for bulky mixing and delivery products, reducing shelf space and biohazard waste.

Automatic Mixer

The Cemex® Automatic Mixer is the first and only fully-automatic bone cement mixer. This revolutionary device removes the human element from the mixing process of cementation, which is the most critical phase for a successful cement product. The Cemex Automatic Mixer attempts to deliver an optimal mix for every application. These results are further enhanced using Cemex System and the Cemex Automatic Mixer together. Cemex System is truly advancing the ordinary and delivering simplicity to the cementation process.

Clinical Success

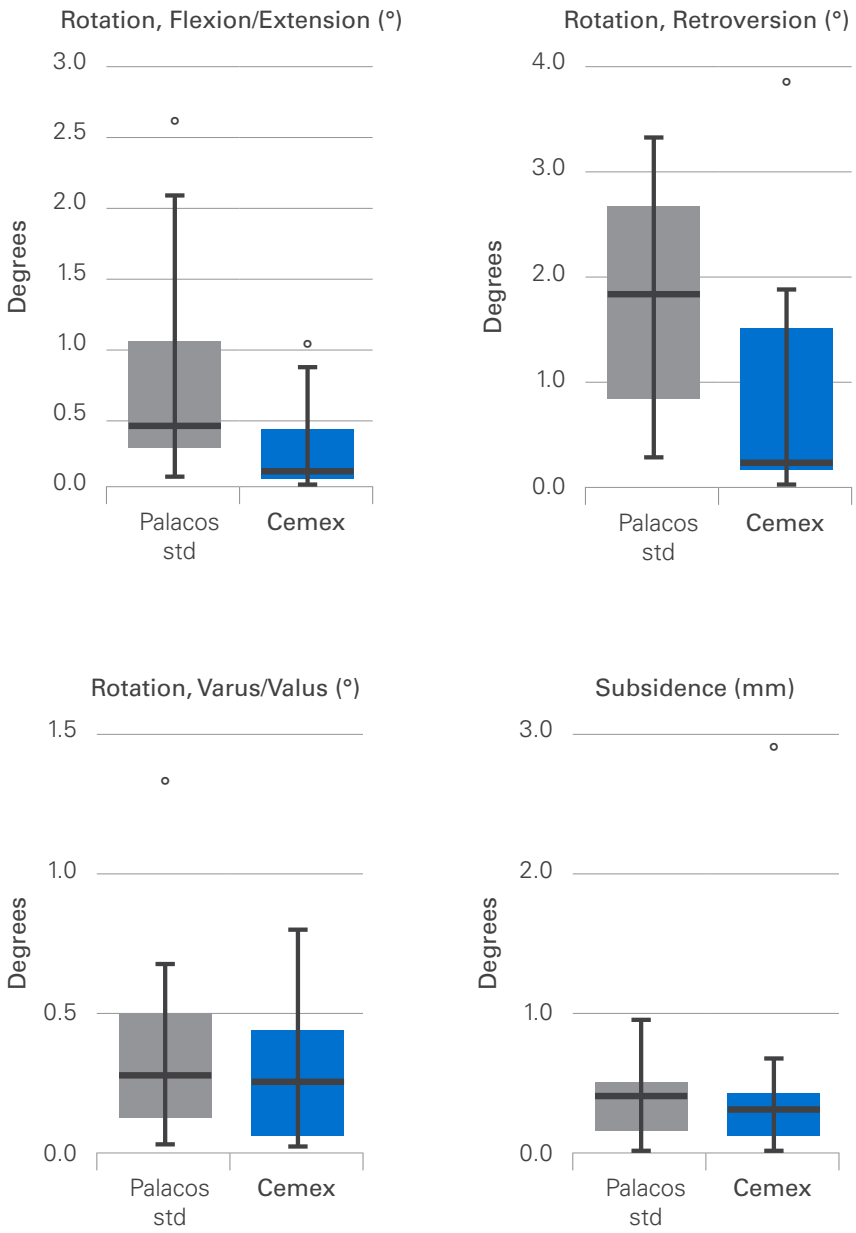
Cemex System has been successfully used in Europe for more than 25 years[1,10] and has shown good clinical results in the Swedish Hip and Knee Registry.[11,12] Cemex Bone Cement showed no statistically significant differences in a head-to-head prospective randomized, controlled Radiosteriometric Analysis (RSA) study using Palacos as the control.[1]

Patients were examined using RSA tantalum markers, Harris hip score, and conventional radiographs to evaluate cement performance and patient outcomes. The results are summarized in the following:

"At 10 years, 33 hips could be evaluated clinically and 30 hips could be evaluated with RSA (16 Cemex and 14 Palacos). 9 patients had died and 4 patients were too old or infirm to be investigated. Except for 1 hip that was revised for infection after less than 5 years, no further hips were revised before the 10-year follow-up. There were no statistically significant clinical differences between the groups. The Cemex cement had magnitudes of migration similar to or sometimes lower than those of Palacos cement."[1]

– Söderlund P, et al.

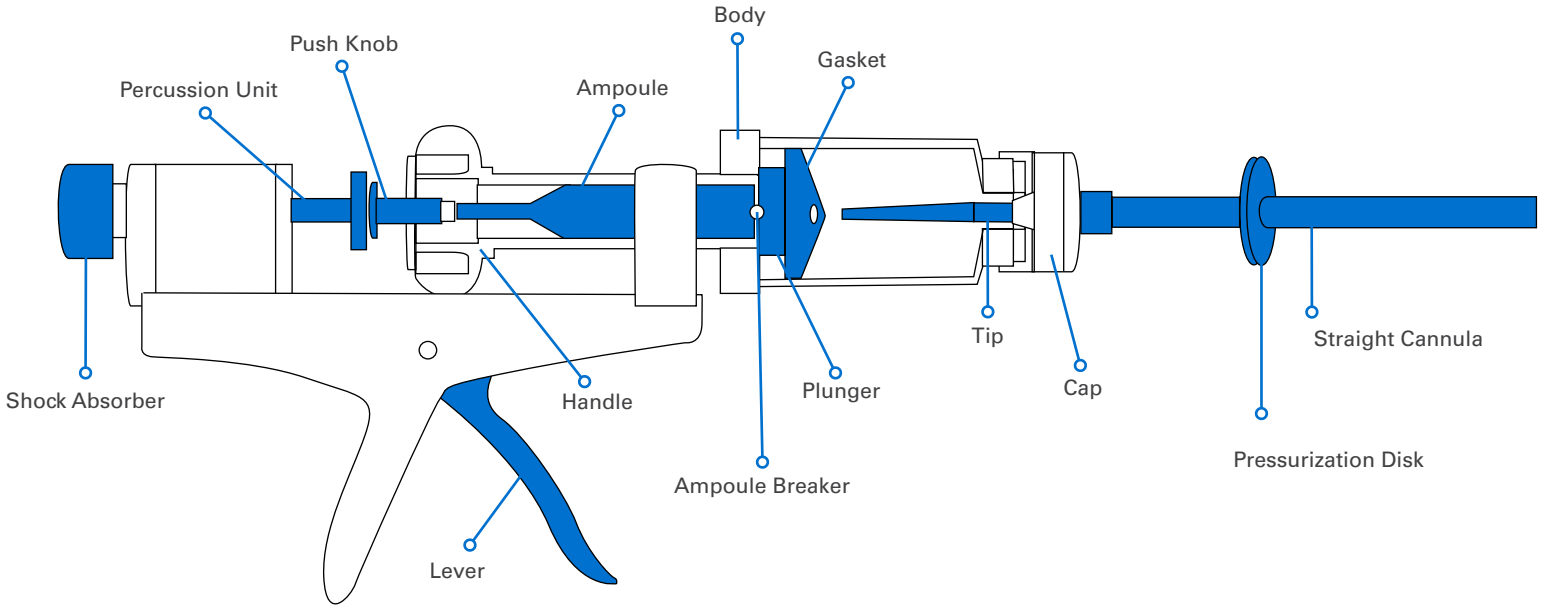
10-Year Follow-Up of Femoral Rotation[1]



Advancing the Ordinary

We continue to work together to focus on the needs of surgeons and their staff. Cemex Bone Cement's innovative low monomer formulation has been proven to support long-term fixation of joints.[1] Cemex features a unique self-contained delivery system that integrates both the bone cement powder and liquid into an enclosed mixing system while offering surgeons and operating room personnel safety, simplicity and reliability

Cemex truly is Advancing the Ordinary.



Cemex® System Diagram

References

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