Smith+Nephew

RALLY◊ Bone Cement: an effective bone cement with intra-operative flexibility to meet surgical needs

Summary

- RALLY Bone Cement has highly similar mechanical properties to Cemex™[1]
  - Cemex™ has demonstrated reduced porosity and shrinkage compared with leading bone cements[2,3]
  - Cemex™ has also demonstrated similar implant fixation results to other leading bone cements, up to 10 years after hip arthroplasty[4–6]

The role and importance of bone cement

Bone cement is used frequently during total hip and knee arthroplasties for implant fixation.[7] Bone cement transmits load through the joint replacement into the surrounding bones and muscles, and a strong bone-cement interface is important to reduce prosthetic migration and prevent subsequent failure of the joint replacement.[7] Joint replacement failure necessitates revision surgery, which carries a high cost and burden on both patients and healthcare professionals.[8,9]

Cemex™ and RALLY Bone Cement

Cemex™ (Tecres, Sommacampagna, Verona, Italy) is a bone cement which has been in use for over 30 years in orthopaedic surgery.[10] Cemex™ is effective and reliable, and has excellent mechanical performance and long-term clinical performance.[1–6,10] RALLY Bone Cement has been more recently developed by Tecres and is available in several different formulations, including All-in-One and hand-mixed versions, medium viscosity (MV) and high viscosity (HV) formulations, and antibiotic-containing (AB) and non-antibiotic-containing (non-AB) formulations,[11] all of which are highly similar to Cemex™, with comparable mechanical properties.[1]

RALLY Bone Cement has similar mechanical properties to Cemex™ and meets the International Organization for Standardization (ISO) 5833 criteria

RALLY Bone Cement has demonstrated highly similar dynamic mechanical properties to Cemex™ in mechanical testing of MV AB and HV AB (both hand-mixed and All-in-One) formulations (Figure 1). These properties include creep and fatigue, which are important to ensure a strong bone-cement interface and reduce the risk of arthroplasty failure and subsequent joint revisions.[1,7]

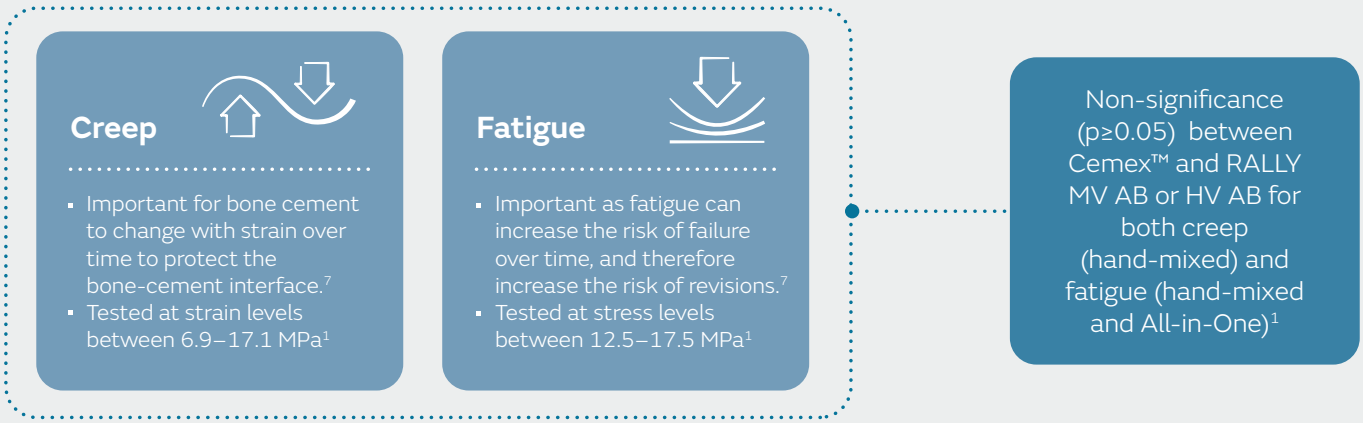

*Figure 1. RALLY Bone Cement has similar dynamic mechanical properties to Cemex™**

*Non-AB formulations of RALLY Bone Cement were not tested. Non-AB bone cements are generally stronger than AB bone cements. Abbreviations: AB = antibiotic; HV = high viscosity; MPa = megapascal; MV = medium viscosity.

✚ Evidence in focus

The ISO 5833 criteria are an international standard that specify the requirements for bone cement to meet for use in clinical practice, including the requirements for static mechanical properties - compression strength, bending strength, and bending modulus.[7] RALLY◊ Bone Cement MV AB and HV AB (both hand-mixed and All-in-One formulations) exceed the ISO 5833 acceptance criteria for static mechanical properties (Figure 2).[1] This demonstrates that RALLY Bone Cement has passed the international quality control standards for properties which contribute to the long-term performance of bone cement.[7]

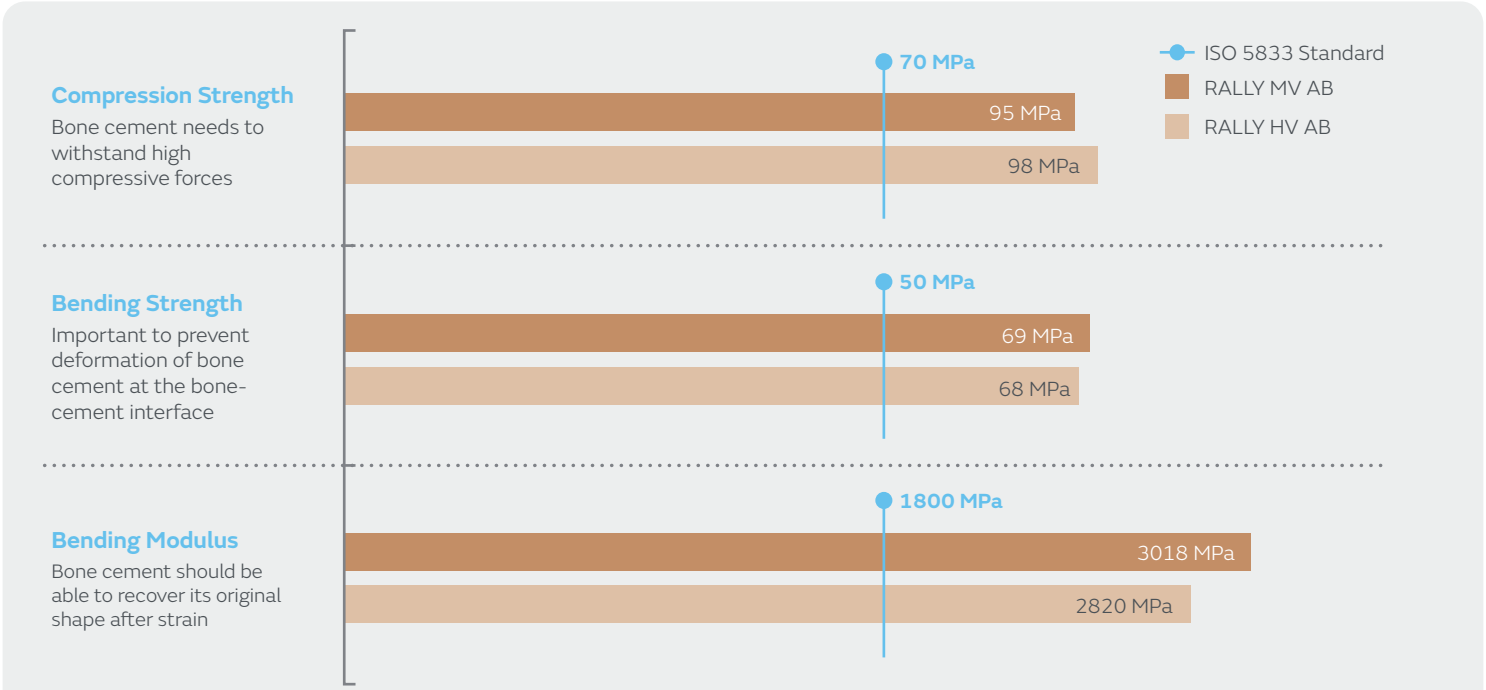

*Figure 2. All RALLY Bone Cement formulations satisfy the ISO 5833 acceptance criteria[1]**

Data shown for RALLY Bone Cement hand-mixed formulations - RALLY Bone Cement All-in-One formulations also satisfy the ISO 5833 criteria. *Non-AB formulations of RALLY Bone Cement were not tested. Non-AB bone cements are generally stronger than AB bone cements. Abbreviations: AB = antibiotic; HV = high viscosity; ISO = International Organization for Standardization; MV = medium viscosity.

Cemex™ performs well relative to other leading products

Porosity and shrinkage are important factors when considering bone cement, as higher porosity and/or shrinkage makes crack formation in the bone-cement interface more likely, which increases the risk of implant failure and subsequent revision surgery.[12,13] In comparative studies, Cemex™ demonstrated reduced porosity compared to Simplex™ P (Stryker, Kalamazoo, Michigan, USA),[3] and reduced shrinkage compared to CMW™ 1 and 3 (DePuy, Warsaw, Indiana, USA) (Figure 3).[2]

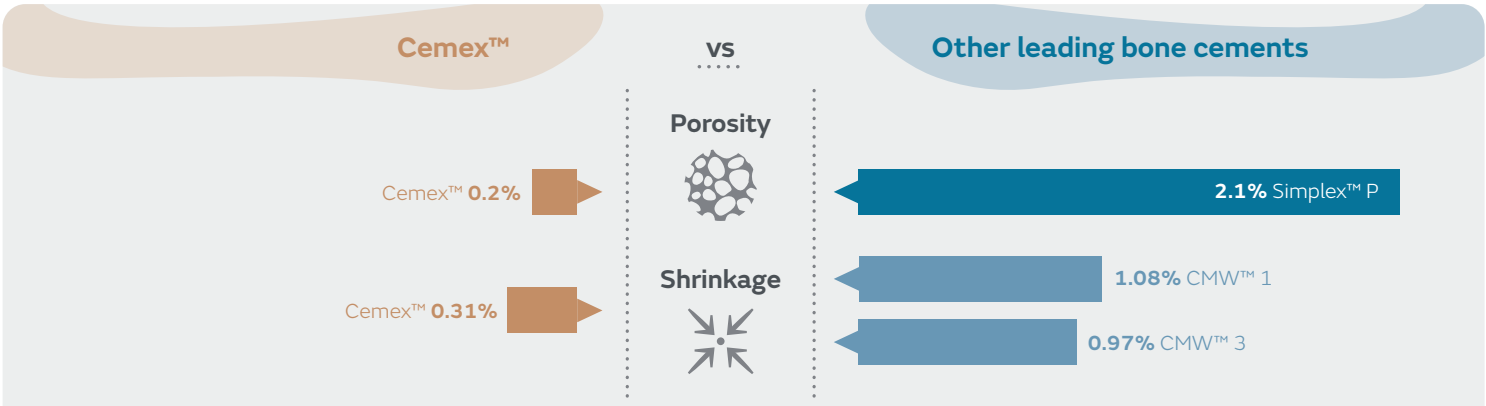

Figure 3. Porosity and shrinkage of Cemex™ compared to other leading bone cements[2,3]

Data were included based on how cements would be prepared clinically (vacuum-mixed cement for other leading bone cements and non-vacuum-mixed for Cemex™).

✚ Evidence in focus

Cemex™ has also demonstrated similar clinical results to other leading bone cements over an extended timescale.[4–6] Cemex™ demonstrated no significant difference relative to Palacos™ (Heraeus, Hanau, Hesse, Germany) when considering clinical performance, including stem migration, head penetration and 3D wear, five and 10 years after hip arthroplasty (Figure 4).[4–6]

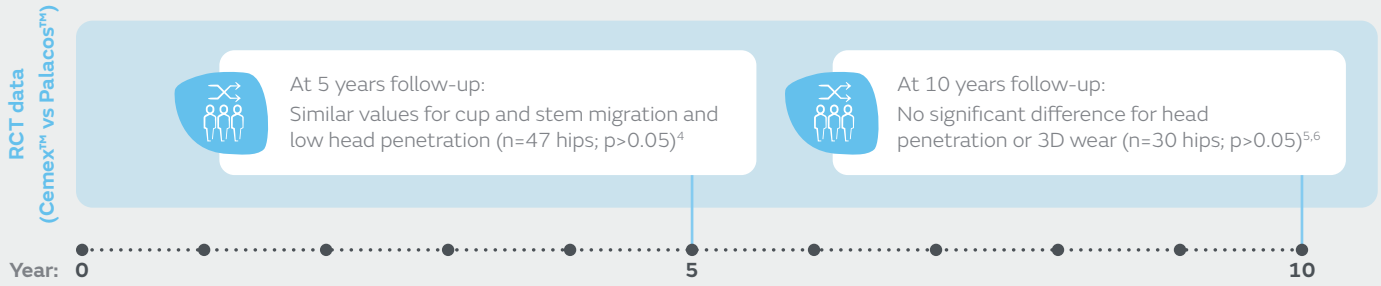

Figure 4. Cemex™ performs equally as well as other leading bone cements when measuring long-term clinical outcomes for hip arthroplasty (stem migration, head penetration and 3D wear)

Abbreviations: RCT = randomised controlled trial.

Key characteristics of RALLY◊ Bone Cement

RALLY Bone Cement has several key characteristics that are important for both the performance of bone cement, and the ease of use for surgeons – reliability, visibility and consistency (Figure 5).[11] These key features are possessed by all variations of RALLY Bone Cement, including All-in-One and hand-mixed versions, MV and HV formulations, and AB and non-AB formulations. This allows surgeons intra-operative flexibility whilst conducting total hip or knee arthroplasty.[11]

Reliability

- High compressive and bending strengths
- Long time to fatigue failure and low porosity, even with hand-mixing

Visibility

- Green colour for visibility
- Barium sulphate for radiopacity

Consistency

- Easy-to-mix, whether hand or vacuum mixing
- Smooth consistency from initial mixing to final implantation
- Unique All-in-One vacuum mixing device - 70g of cement components pre-loaded in a mixing and dispensing device

Figure 5. Key characteristics of RALLY Bone Cement[11]

Conclusions

RALLY Bone Cement and Cemex™, which has reduced shrinkage and porosity and equivalent implant fixation relative to other leading bone cements,[2–6] have highly similar mechanical properties.[1] In conjunction to having similar properties to Cemex™, all RALLY Bone Cement formulations meet the international standard for bone cement (ISO 5833 acceptance criteria)[1,7] and have specific features including green pigmentation and radiopacity for visibility, providing flexibility for surgeons.[11]

References:

1. Smith+Nephew 2022. Technical Memo. Mechanical Properties of RALLY AB Bone Cement. TM-22-029A revision A. **2.** Trieu H, Morris L. Comparative measurement of shrinkage of 5 commercial cements prepared under vacuum mixing. In: Grassi FA, Soffiatti R, eds. *Bone Cements in the Year 2000: State of the Art and Prospects.* Varese, Italy: 2000:23. **3.** Verdonschot N, De Groes S. The effect of mixing techniques (manual, closed system, vacuum) upon bone cement. In: Pipino F, eds. *Bone Cement and Cemented Fixation of Implants. 40 Years of Clinical Practice and Prospective for the Future.* Italy: Tecres; 2001:99–107. **4.** Nivbrant B, Kärrholm J, Röhrl S, et al. Bone cement with reduced proportion of monomer in total hip arthroplasty: Preclinical evaluation and randomized study of 47 cases with 5 years' follow-up. *Acta Orthop Scand.* 2001;72:572–584. **5.** Söderlund P, Dahl J, Röhrl S, et al. 10-year results of a new low-monomer cement: Follow-up of a randomized RSA study. *Acta Orthop.* 2012;83:604–608. **6.** Dahl J, Söderlund P, Nivbrant B, et al. Less wear with aluminium-oxide heads than cobalt-chrome heads with ultra high molecular weight cemented polyethylene cups: A ten-year follow-up with radiostereometry. *Int Orthop.* 2012;36:485–490. **7.** Lee C. Properties of bone cement: the mechanical properties of PMMA bone cement. In: Breusch S, Malchau H, eds. *The Well-Cemented Total Hip Arthroplasty: Theory and Practice.* Berlin, Germany: *Springer*; 2005:60–66. **8.** Kallala RF, Vanhegan IS, Ibrahim MS, et al. Financial analysis of revision knee surgery based on NHS tariffs and hospital costs: does it pay to provide a revision service? *Bone Joint J.* 2015;97-B:197–201. **9.** Vanhegan IS, Malik AK, Jayakumar P, et al. A financial analysis of revision hip arthroplasty: the economic burden in relation to the national tariff. *J Bone Joint Surg Br.* 2012;94-B:619–623. **10.** Exactech. Cemex© Bone Cement. Available from: https://www.exac.com/bone-cement/. Accessed December 11, 2020. **11.** Smith+Nephew. RALLY Bone Cement. Available from: https://www.smith-nephew.com/professional/products/all-products/rally/. Accessed December 14, 2020. **12.** Dunne NJ, Orr JF, Mushipe MT, et al. The relationship between porosity and fatigue characteristics of bone cements. *Biomaterials.* 2003;24:239–245. **13.** Orr JF, Dunne NJ, Quinn JC. Shrinkage stresses in bone cement. *Biomaterials.* 2003;24:2933–2940.

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