Hi-Fatigue G Bone Cement and Hi-Fatigue Bone Cement

Evidence

Consistent and Reliable Performance[1-3*]

Bone cement is a key component in orthopaedic surgery, primarily used for the fixation of joint implants. For that reason, bone cements must present certain characteristics that are both important for handling by the user, and relevant for stable fixation of the implant in the bone.

Hi-Fatigue Bone Cement (non-antibiotic) and Hi-Fatigue G Bone Cement (with antibiotic) are high viscosity bone cements that have been on the market since 2008. Hi-Fatigue G Bone Cement includes Gentamicin, which has shown to be the antibiotic of choice due to its broad antibacterial spectrum.

The clinical and laboratory data presented in this brochure confirms the consistent and reliable performance of the Hi-Fatigue Bone Cement including:

- Strong support for good long-term implant survival[1]
- Mechanical properties well exceeding internationals standards[2*]
- High fatigue strength after long term cyclic exposure[3*]

* Laboratory test results not necessarily indicative of clinical performance.

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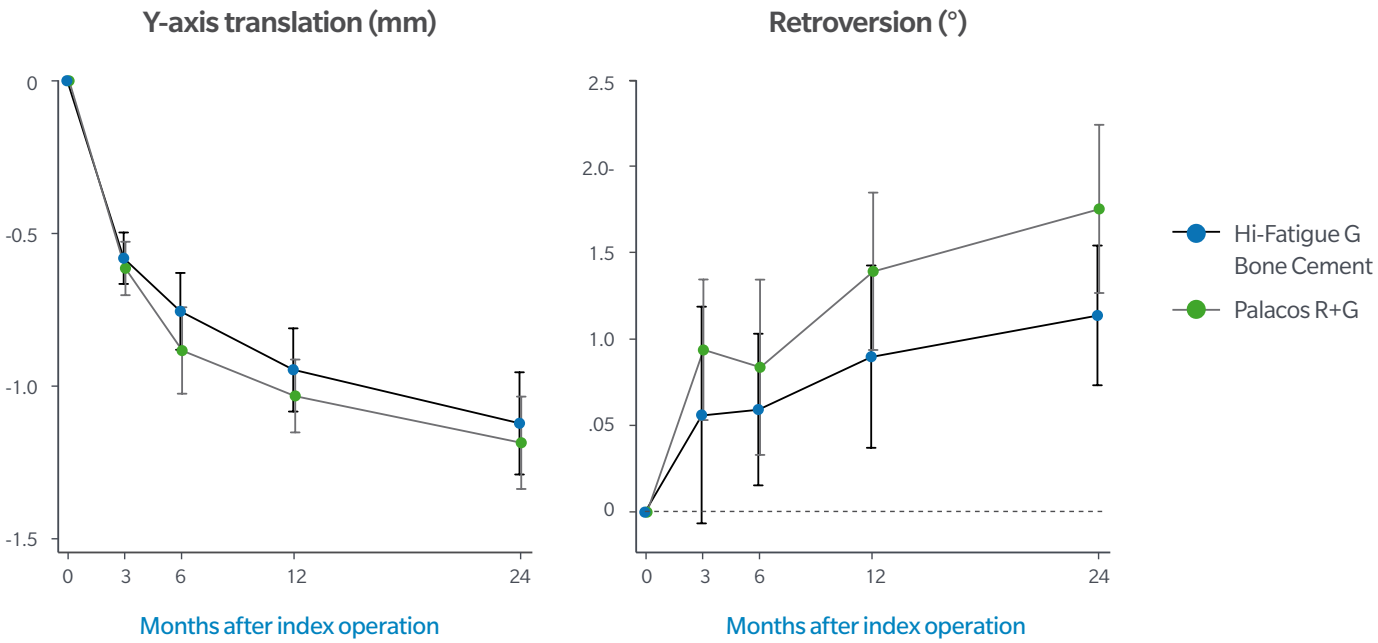
Clinically Proven with Reliable Results[1]

In a 2-year RSA study, Jørgensen et al. evaluated long-term fixation in hip stem arthroplasty when using Hi-Fatigue G Bone Cement compared to Palacos® R+G.[1]

Since stem subsidence and retroversion, i.e. the stem migration, have shown to be good predictors of implant survival, the stem location was measured at 3 months, 6 months, 1 year and 2 years after surgery using radiostereometry (RSA). The randomized controlled trial included 52 patient with a mean age of 76 years.[1]

Key findings of the study were equivalent hip stem fixation and clinical results for the two bone cements used. Until the 2-years' follow up, similar and generally low migration of the stem was found, indicating good long-term survival with both bone cements. Both Hi-Fatigue G Bone Cement and Palacos R+G showed good cement distribution (whiteout), but Palacos R+G was more often classified with slight radiolucency (n = 10) than Hi-Fatigue G Bone Cement (n = 1). In addition, at 2 years' follow-up, there had been no revisions due to aseptic implant loosening.[1]

Based on the results, the authors conclude that similar long-term results (>2 years) for fixation of the CPT® stem with Hi-Fatigue G Bone Cement and Palacos R+G bone cements could be expected.[1]



Laboratory Testing Results

International Standards

Following the implantation of a cemented endoprosthesis, bone cement is subjected to high mechanical stress. The mechanical properties, strength and stiffness of the bone cement are therefore tested, e.g. compressive strength, bending strength and bending modulus, according to international standards - ISO 5833 and ASTM F451-16.[4, 5]

Methods

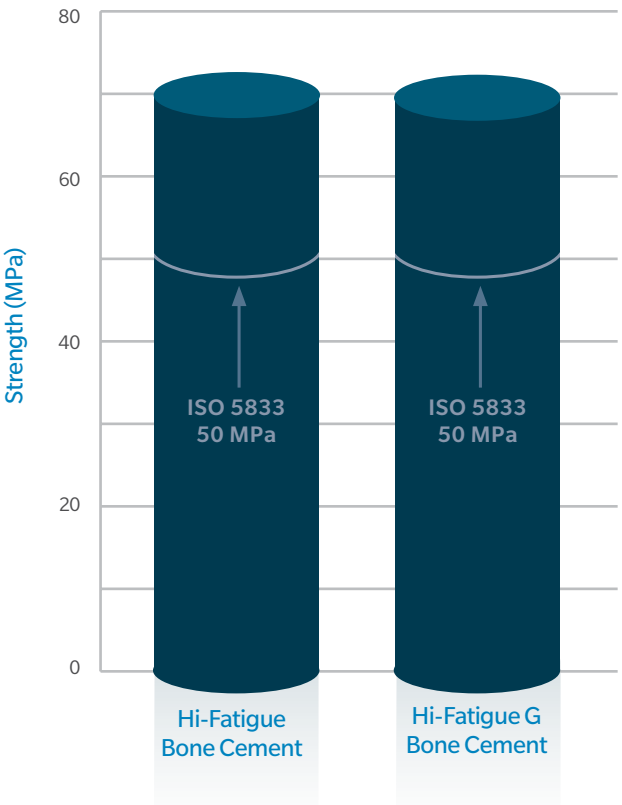
In a study performed by OSARTIS GmbH (legal manufacturer), the Hi-Fatigue Bone Cement and Hi-Fatigue G Bone Cement were tested in regards to mechanical properties.[2*]

For the determination of mechanical stability, the bone cement is filled into defined molds. With these molds the samples for testing are performed; cement stripes for testing of strength and bending modulus and cylinders for testing of compressive strength. These samples are then tested in the testing machine for bending and compression strength, respectively.

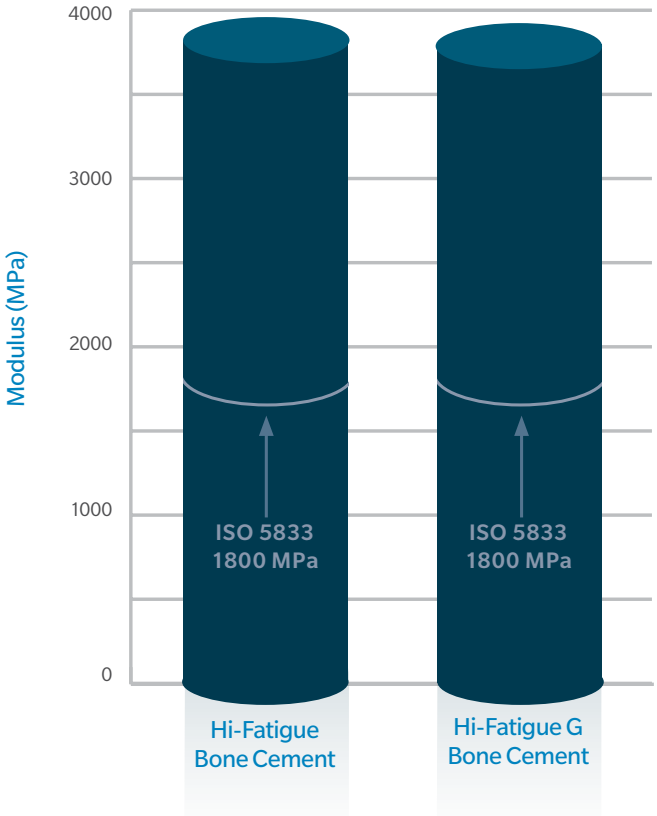
* Laboratory test results not necessarily indicative of clinical performance.

Mechanical Stability

Bending Strength

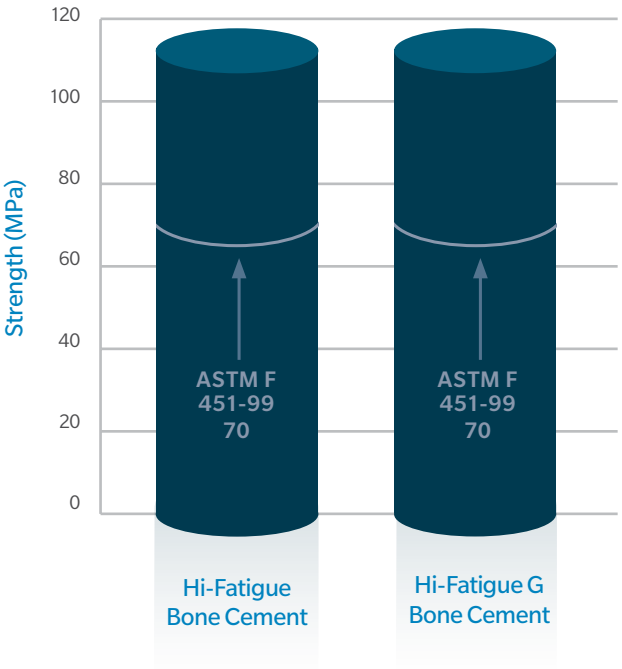


Bending Modulus



The minimum standard for bending strength of 50 MPa and the minimum standard for bending modulus of 1800 MPa as specified by ISO 5833 were fulfilled and exceeded by both the Hi-Fatigue Bone Cement and the Hi-Fatigue G Bone Cement.[2*]

Compressive Strength



The minimum standard for compressive strength of 70 MPa, as specified by ASTM F451-16 and ISO 5833, were fulfilled and exceeded by both the Hi-Fatigue Bone Cement and the Hi-Fatigue G Bone Cement.[2*]

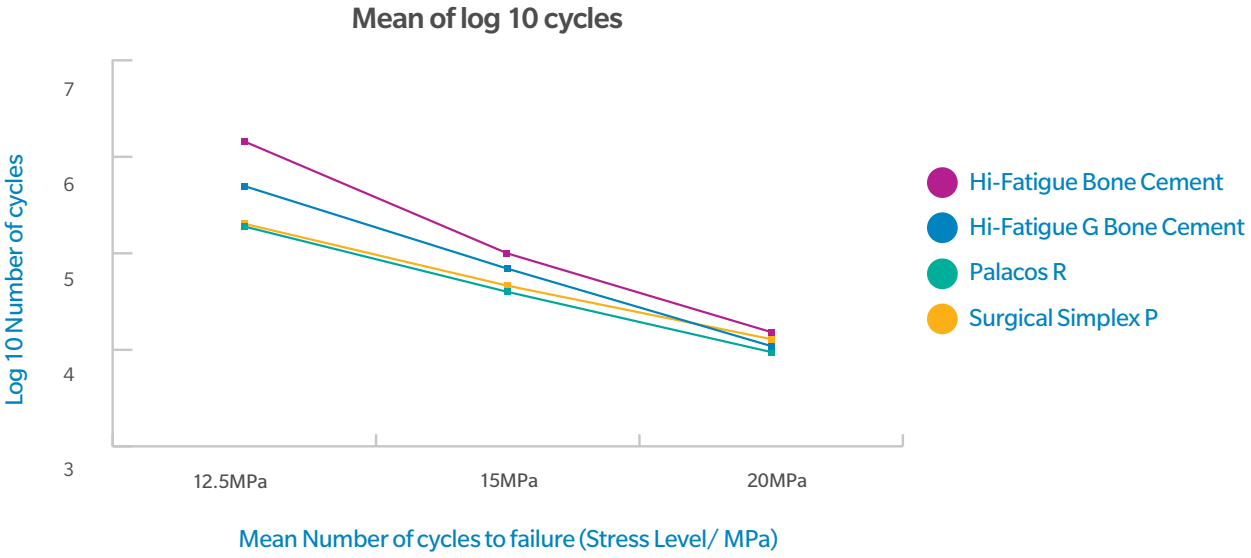
* Laboratory test results not necessarily indicative of clinical performance.

Fatigue Performance

In a laboratory testing performed by Tanner, *et al.*, the fatigue properties of Hi-Fatigue Bone Cement and Hi-Fatigue G Bone Cement were tested and evaluated. The bone cements Palacos® R and Surgical Simplex® P were used as control specimens.[3*]

All tests were run to fracture of the specimen or five million load cycles, which ever occurred first. For each stress level eight specimens of each cement were tested.[3*]

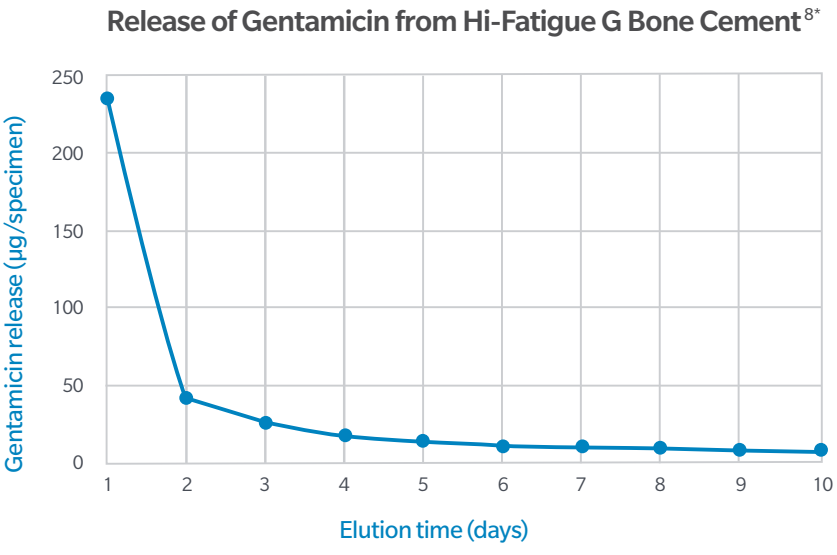
The study concludes that at physiological stress levels Hi-Fatigue Bone Cement and Hi-Fatigue G Bone Cement have similar or longer fatigue lives than the two control cements tested, Palacos R and Surgical Simplex P.[3*]



Antibiotic Elution

By using antibiotic-loaded bone cement, high local concentrations of antibiotics can be administered in the surrounding of the implant, preventing germs from settling.[6,7] The protracted release of the antibiotic protects the implant for an extended period of time, thus reducing the risk of revisions.[7]

Hi-Fatigue G Bone Cement provides high local concentrations of gentamicin over several days.[8*] In addition, Hi-Fatigue G Bone Cement has shown a high initial burst with rapid decline *in vivo*. The serum concentrations never exceeded toxic levels, which confirmed the effectiveness and safety of the gentamicin release.[9]



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Notes

References

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