The solution for a prothesis fixation

General

C~ment is a product range of bone cements that are used for the fixation of artificial joints. A bone cement fills the free space between the prosthesis and the bone and allows for an immediate and stable fixation of the surgical implant. The C~ment products distinguish themselves by convenient mixing characteristics and excellent mechanical properties.

Four types

The C~ment is manufactured in four varieties, differing with respect to viscosity and the presence or absence of Gentamicin, a prophylactic antibiotic. Standard viscosity C~ment is intended for manual use. C~ment with low viscosity is for syringe use.

	Viscosity	Antibiotics
C~ment 1	standard	No
Genta C~ment 1	standard	Yes
C~ment 3	low	No
Genta C~ment 3	low	Yes

Table 1: four types of C~ment

Mixing properties

C~ment can both be used in modern vacuum mixing systems (the two low-viscosity types) and by regular hand mixing systems. The mixing process is initiated by bringing together a polymer powder and a monomer liquid. The major component of the polymer is PMMA (see the section Technical specifications).

Advantages

- **Fast mixing**. After the monomer liquid and the polymer powder are brought together, the time to obtain a homogenous dough is only 30 to 60 seconds.
- **High precision dosage**. The dosage of the components is manufactured with great precision. This guarantees equal mixing characteristics across all batches.
- **Well-suited for vacuum mixing systems**. The low viscosity cements C~ment 3 and Genta C~ment 3 are tailor-made for these systems.
- **No air bubbles**. The resulting cement is free of agglomerates and entrapped air bubbles.

ISO standards

All the C~ment types have been tested and meet all the relevant ISO standards (ISO 5833:2002). Each criterion is discussed below.

Setting time and maximum temperature

Heat is generated when the powder and the liquid components are mixed. This heat may not be too excessive. ISO standards have to be met regarding this maximum temperature and the setting time – the time it takes the dough to reach the temperature midway between maximum and the ambient temperature. Also, the difference between the two test run values may not exceed a certain maximum. All four types of C~ment meet all these criteria. Table 2 summarizes the most important data: mean maximum temperature and mean setting time. According to the ISO standards, the maximum temperature may not exceed 90°C. The setting time must be 3 to 15 minutes for dough state usage cement and 6.5 to 15 minutes for syringe type usage cements.

As can be seen below, all C~ment types are well within these limits.

	Mean maximum temperature (°C)	Mean setting time (min:sec)
C~ment	72	8:00
Genta C~ment 1	67	8:45
C~ment 3	77	9:30
Genta C~ment 3	79	9:45

Table 2: Summary of setting time and maximum temperature test results. ISO maximum temperature: 90°C. ISO setting time: 3 to 15 minutes criterion applies to C~ment type1. ISO setting time 6.5 to 15 minutes applies to C~ment type 3.

Intrusion depth

The extent to which the cement penetrates or intrudes the trabecular bone is critical for a long lasting result. In the test, which only applies to the cements which are intended for dough usage (C~ment 1 and Genta C~ment 1), a mould with a perforated bottom face is used as a model. The perforations are cylindrical holes with a depth of 10 mm and a diameter of 1 mm. After packing and pressurizing the cement, the intrusion depth is measured. As is shown in the figure below, both C~ment 1 and Genta C~ment 1 have mean intrusion depths that are far above the ISO-required 2 mm (8.4 mm and 7.6 mm, respectively).

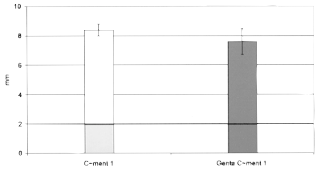

Figure 1: Intrusions of the EMCM bone cements which are intended for dough usage (standard viscosity). Also the minimal required value for the intrusion according to ISO 5833:2002 Annex D is given (thick line).

Compressive strength

To measure compressive strength, the cement is mixed manually and filled in a cylindrical mould. The cylinder is placed in a test machine, which compresses the cylindrical cement structure slowly. The maximum pressure (compressive strength) is recorded and must exceed the ISO-standard of 70 MPa. As can be seen from the below figure, the compressive strength requirement is met.

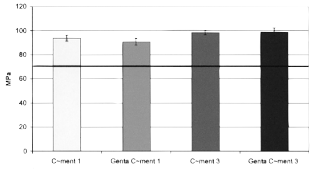

Figure 2: Compressive strengths of all EMCM bone cements Also the minimal required value for the compressive strength according to ISO 5833:2002 Annex E is given (thick line).

Bending strength and bending modulus

The bending strength determines the force that the cement sample can bear until it breaks after bending. The bending modulus measures the elasticity of the material. In other words, it measures how much the cement is deformed by stress. The bending modulus and bending strength is calculated from the deflection-versus-force curve. The higher the modulus, the less the material is deformed. As can be seen in the figure 3, all C~ment types are well above the required 50 MPa.

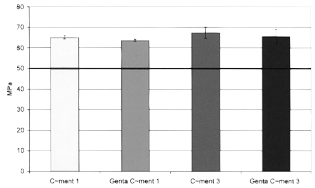

Figure 3: Bending strengths of all EMCM bone cements. Also the minimal required value for the bending strength according to ISO 5833:2002 Annex F is given (thick line).

In the below figure the bending moduli of the bone cement types are displayed. Note that all are well above the required value of the ISO standard.

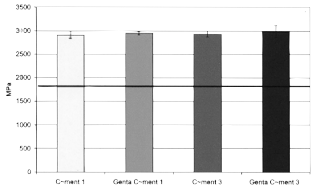

Figure 4: Bending moduli of all EMCM bone cements. Also the minimal required value for the bending modulus according to ISO 5833:2002 Annex F is given (thick line).

Technical specifications

All four cements in the C~ment range are radiopaque and sterile. They are manufactured in compliance with the EEC Guidelines 93/42/CEE, ISO 5833 :2002 and ISO13485 :2003.

The liquid component is composed of methylmethacrylate, butylmethacrylate, N, N dimethyl-p-toluidine and hydroquinone. The liquid is flammable and has a distinctive odour. It is prepared and delivered sterile by aseptic filtration.

The powder component is polymethylmethacrylate (PMMA). Benzoyl peroxide is included to initiate the polymerization. In order to obtain the required reactions and viscosities, various polymethylmethacrylates are mixed in adequate proportions. Barium sulphate is included up to 4 grams per unit and complies with the European Pharmacopoeia. The bone cement powder is sterilized by beta radiation (25 kGy).