REPORT 145

THE EFFECT OF MIXING TECHNIQUES (MANUAL, CLOSED SYSTEM, VACUUM) ON BONE CEMENT

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Introduction

Aim of the study was to compare two bone cements: Cemex®XL and Simplex®P.

The discriminating factors to evaluate an aspect of the quality of the bone cement were volume, density and porosity changes in time.

Cemex XL is also available in a closed mixing system with the brand name of Cemex® System. The Cemex System allows the preparation and delivery of bone cement.

In the human body, the bone cement is exposed to liquid. Most cement tests performed nowadays take place in a dry environment [4,5,6,7,8,9]; therefore it might be not realistic. As the authors believe that the liquid is of great influence to the material properties of the bone cement, the tests are performed for both specimens kept in a dry environment and specimens kept in physiologic water.

Three questions are addressed in this report:

- How large is the porosity of Cemex XL relative to Simplex P
- Is Cemex System proper to mix Cemex XL (In other words can differences in density and dimension change of bone cements be related to the preparation method)?
- What is the difference in dimension and density change of cement kept in a dry environment and kept in water over time?

Materials and methods

Two bone cements were used; Cemex®XL (Tecres Spa) and Simplex®P (Howmedica International). These two bone cements were hand mixed and vacuum mixed; Cemex XL was eventually prepared with Cemex®System.

Therefore 5 groups were created:

A. Cemex XL hand mixed
B. Cemex XL mixed with Cemex System
C. Cemex XL vacuum mixed
D. Simplex P hand mixed
E. Simplex P vacuum mixed

Of every group, 8 specimens were made.

Mixing techniques

The room in which all the specimens are made was kept at a constant temperature of 23 degrees, which was the recommended temperature by the manufacturers of the cements. All the specimens were made out of the same batch.

The first way was hand mixing. This means mixing by hand in a bowl, as can be seen in figure 1.

Fig. 1 Manual mixing

The spatula was turned at a frequency of 2 turns per second for 90 seconds, accordingly to the guidelines of the manufacturer of the cement.

The second way was mixing under vacuum, as can be seen in figure 2. The Optivac System was used. First the monomer is poured in the system and than the powder. Before the mixing starts, the mixing chamber is put under vacuum, which prevents air to react with the cement mix. After 10 seconds the mixing was started by pushing and turning the plunger up and down, with the chamber still under vacuum. The mixing was continued for 90 seconds.

Fig. 2 Vacuum mixing

Another way was Cemex System, which is a mixing device designed by Tecres. In figure 3 the device is shown. When this system is used, the powder and monomer are already present in the system. So it is a closed system. In this system the monomer and powder are mangled just by striking the system to the hand with a frequency of 1 strike per second, rotating it by a quarter of a turn at each strike, as indicated by the manufacturer. This striking continues for about 90 seconds.

Fig. 3 Cemex System

Test specimen preparation

After the cement was mixed, the cement was introduced in a glass test tube for curing, using a syringe in all three cases, which makes a retrograde filling fashion possible. This test tube had an internal diameter of 14.3 mm and a length of 200 mm. The bottom of the test tube was closed. After cement injection, the test tube was closed with a plunger, which had a hole to allow air to escape as the plunger was pushed down. When all the air had escaped, the glass side of the test tube closed the hole. With one batch of bone cement two test tubes could be filled. In figure 4 the filled test tube is shown.

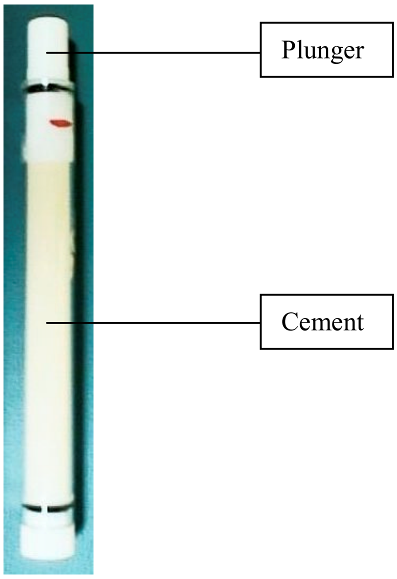

Fig. 4 Filled test tube

A force of 170 N was applied to the plunger, for 20 min (figure 5). Usually in current total hip arthroplasty, the cement is pressurized. Many studies are done to measure the pressure in the cement during pressurisation. One of these studies was done by Yee et al.. They measured pressures of about 150 psi (pounds per square inch), which equals 1.03 MPa. With our test tube diameter, a force of about 170 N has to be applied to get this pressure. The force was applied by a mass of 5,7 kg and an arm of 1:3 to the plunger.

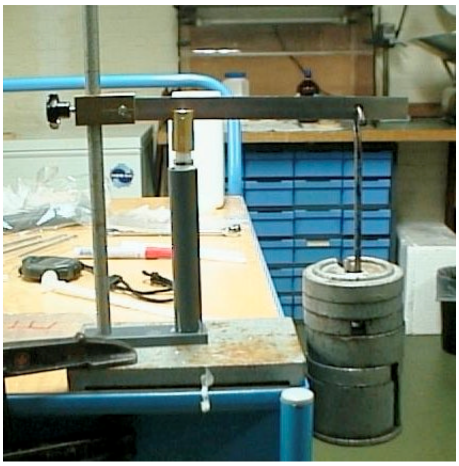

Fig. 5 Pressurizing bone cement

After pressurizing, the cement cylinder was taken out of the test tube, by breaking the glass.
After that the cement cylinders were separated into 8 specimens of 24 mm in length, the diameter of the specimens was machined to 13 mm, to get a reproducible surface/diameter.

The test

The 8 specimens were divided into two groups of 4 specimens. One group was kept in a dry constant environment. The other group was kept in physiologic water (0,9% salt water) of 37°C.
The diameter (average of 4 measurements) and the length (average of 4 measurements) were measured with a micrometer. The weight (average of 3 measurements) of both groups and the weight under water (average of 3 specimens = m_{wet}) were determined using a very accurate balance (see figure 6). Weighting under water is necessary to perform the archimedes test.

Fig. 6 The Archimedes test set-up

The cement specimen was placed in a basket made of very thin wire, which was of very little influence to the weight measured in the water (shown in figure 7). The balance was compensated for the weight of the metal basket. After that the specimen was lowered into the demineralized water very carefully (not to be confused with the physiologic water in which the specimens are kept between the measurements), so that the surface was free of air bubbles. The normal weight minus the weight measured in the water equals the upward weight of the cement specimen generated by the water (m_{upw}).

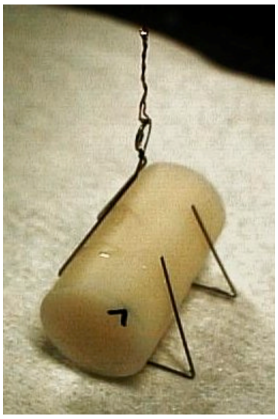

Fig. 7 Metal basket

With the weight results the increase/decrease in density and Archimedean volume of the specimens could be determined. The Archimedes' principle is the principle that proves why boats etc. float. This is done with the following formulas:

$$F_{buoyant} = p_2 A - p_1 A$$
$$F_{buoyant} = (p_2 - p_1) A$$
$$F_{buoyant} = (\rho g h) A$$
$$F_{buoyant} = \rho_{water} \cdot g \cdot V = m \cdot g \rightarrow Eureka$$

p_1 = pressure on cement specimen
p_2 = pressure inside cement specimen (air)
A = surface of cement specimen

After transposition the density of the specimens can be calculated with:

$$\rho_{specimen} = \frac{m_{dry} \cdot \rho_{water}}{m_{opw}}$$

To determine the porosity, specimens under very high pressure (139.85 MPa) were made. These specimens should have negligible porosity. When the density of these specimens is compared to the density of the specimens made in the 'normal' way, the relative porosity can be determined.

Measurements were performed four times:

1. One day after making the specimens;
2. Three days after making the specimens;
3. Two weeks after making the specimens;
4. Four weeks after making the specimens.

These times were chosen to get an idea of the saturation speed of the water.

Before the first measurement the specimens were all kept in a dry environment, after the first measurements the specimens were divided into two groups, one group for the wet environment and the other group for the dry environment.
Whether these results were significant different has to be determined with the MANOVA-test. This test is a variance analyse for repeated measurements, which indicates between which variables a significant difference can be detected. The order of significance can than be determined with the students T-test, which is a test for independent variables. As significance level, p=0.05 was chosen.

Results
The three determined values were:
1. volume; 2. density; 3. porosity.

The six groups measured were:

A. Cemex XL hand mixed
B. Cemex XL mixed with Cemex System

C. Cemex XL vacuum mixed

D. Simplex P hand mixed

E. Simplex P vacuum mixed

Volume

The volume can be calculated in two ways, with the dimension measurements or the Archimedes measurements. In figure 8, these methods are compared. As can be seen, the volume determined with the Archimedes test is always lower than the volume determined with the dimension measurements. The reason for this is because the specimens were not exactly cylindrical, so when the largest diameter is measured, a larger volume will be calculated. Another contributing factor is the voids on the surface by some of the specimens, which reduce the volume with the Archimedes measurement method. When both calculations would be the same, all the measurements should have been on the theoretical line.

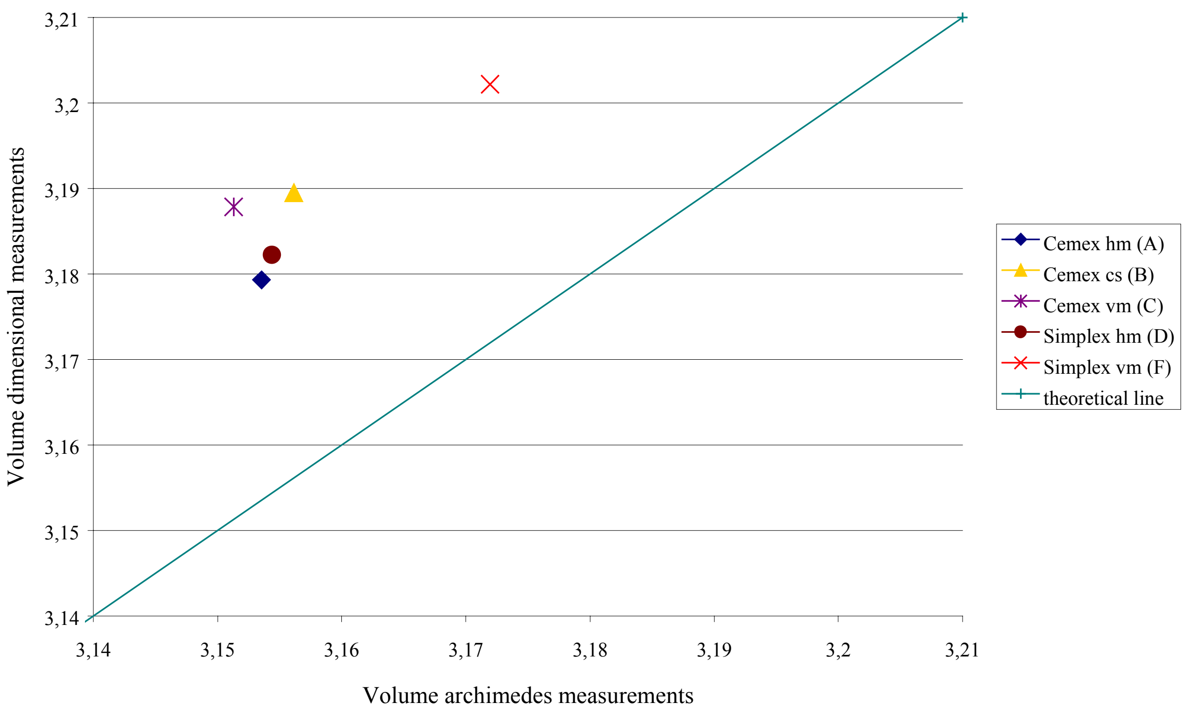

Fig. 8 Volume changes determined with Archimedes test vs. dimension measurements

To determine which method was most reliable, all the standard deviations of the 4 repeated measurements were determined. In figure 9 the standard deviations are shown.

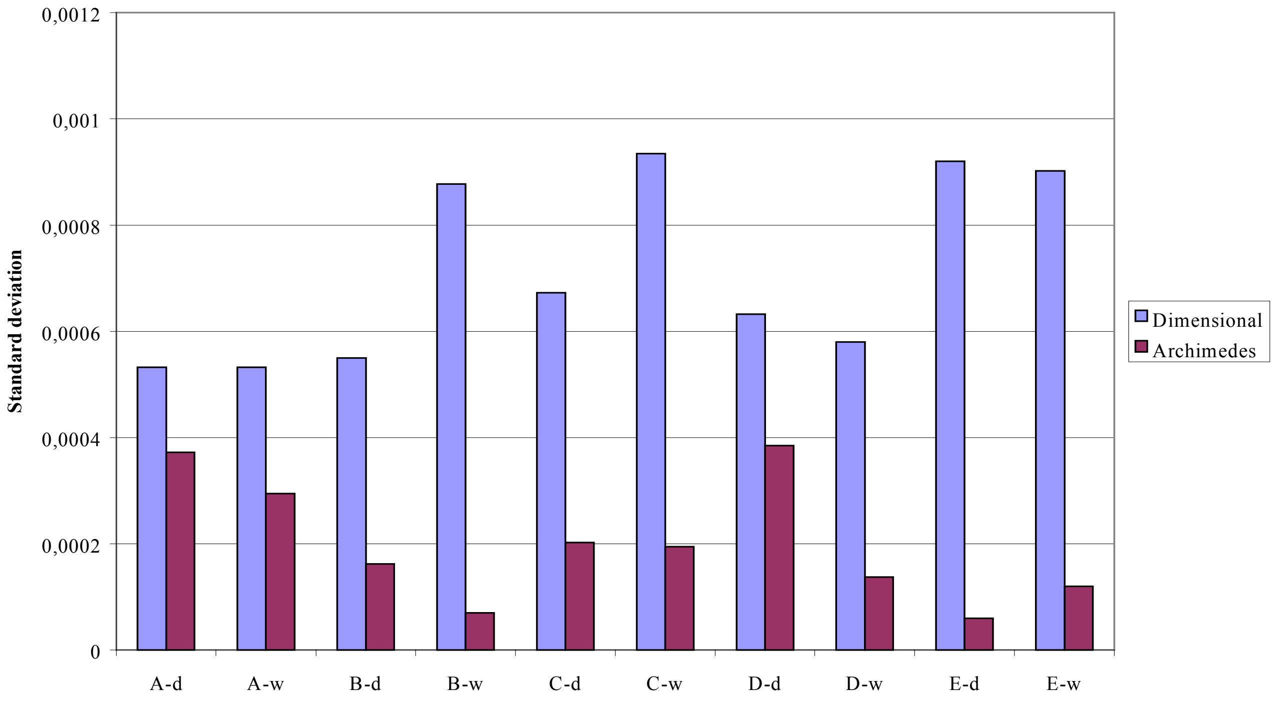

Fig. 9 Standard deviations for both measurement systems

It can be clearly seen that the reproducibility of the Archimedes measurements is much higher than the reproducibility of the dimensional measurements. Therefore only the Archimedes measurements are considered in the rest of the report.

In figure 10 the volume change percentage in time is shown for Cemex XL and Simplex P kept in both a dry and a wet environment determined with the Archimedes measurements. The first measurements are taken as the zero-measurements (0%), the reference value.

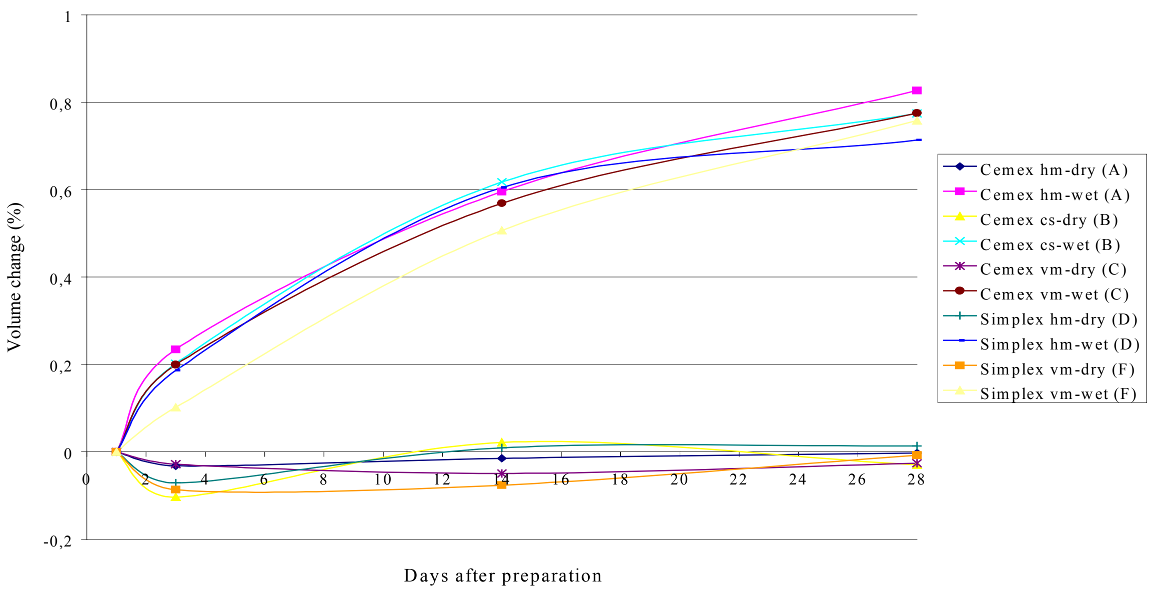

Fig. 10 Volume change of Cemex XL vs. Simplex P kept in a dry or wet environment determined with the Archimedes measurements

It can be clearly seen that the specimens kept in a wet environment have a significantly ($p << 0.001$) larger volume increase than the specimens kept in the dry environment. Between the specimens kept in a dry environment, no significant differences were detected. But when placed in water, there are significant differences, as shown in figure 11. (Left = dry; Right = wet)

	Cemex hand-mixed	Cemex System-mixed	Cemex vacuum-mixed	Simplex hand-mixed	Simplex vacuum-mixed
Cemex hand-mixed					
Cemex System-mixed					
Cemex vacuum-mixed					
Simplex hand-mixed					
Simplex vacuum-mixed					

	Cemex hand-mixed	Cemex System-mixed	Cemex vacuum-mixed	Simplex hand-mixed	Simplex vacuum-mixed
Cemex hand-mixed		H	H	H	H
Cemex System-mixed					
Cemex vacuum-mixed					
Simplex hand-mixed					
Simplex vacuum-mixed					

H = 'significantly higher when looked at from left to above'
L = 'significantly lower when looked at from left to above'

Fig. 11 Significant differences in volume between different groups for both dry and wet environment after 28 days

With regard to the volume change, there is no effect of cement type or mixing method (fig. 10 and 11), when the specimen is kept in a dry environment.

Density

The density differences between the two bone cements are large, $1.268 \cdot 10^3$ kg/m^3 (Cemex XL) to $1.239 \cdot 10^3$ kg/m^3 (Simplex P) (initial average density). A reason for this might be the larger amount of barium in Cemex XL than in Simplex P (12% vs. 10%). Initially, between the mixing methods there was just only a small variation detected ($\pm$ 0.005 $\cdot 10^3$ kg/m^3). In figure 12 the density changes of the different specimens, kept in a dry environment, are shown.

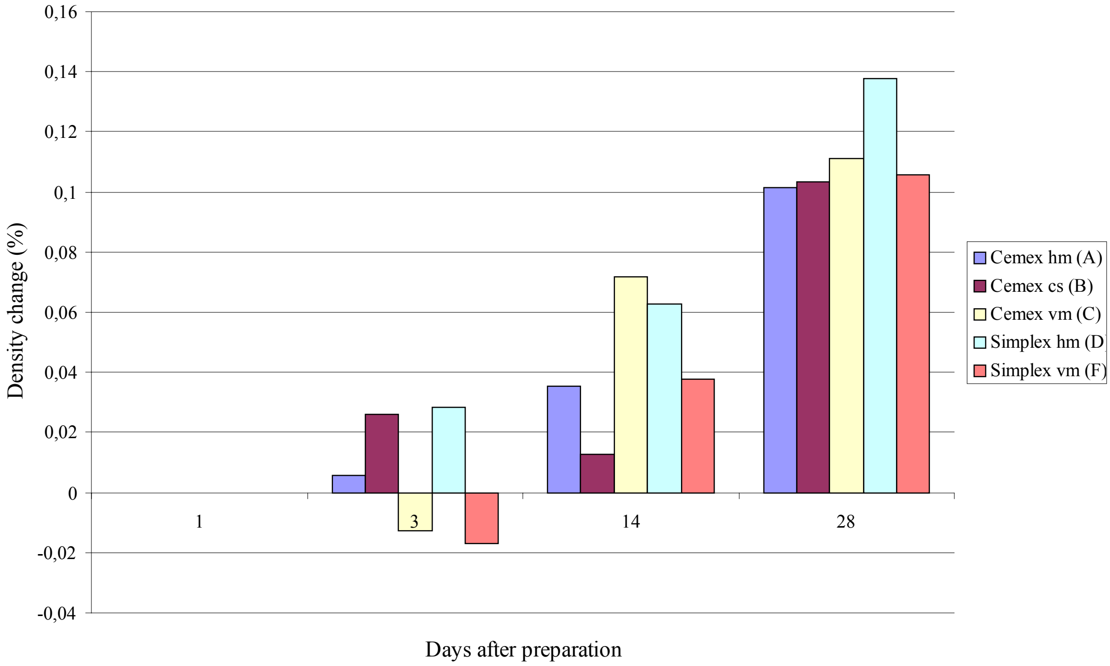

Fig. 12 Density change of Cemex XL and Simplex P kept in a dry environment

Figure 13 shows density increase of the specimens kept in water.

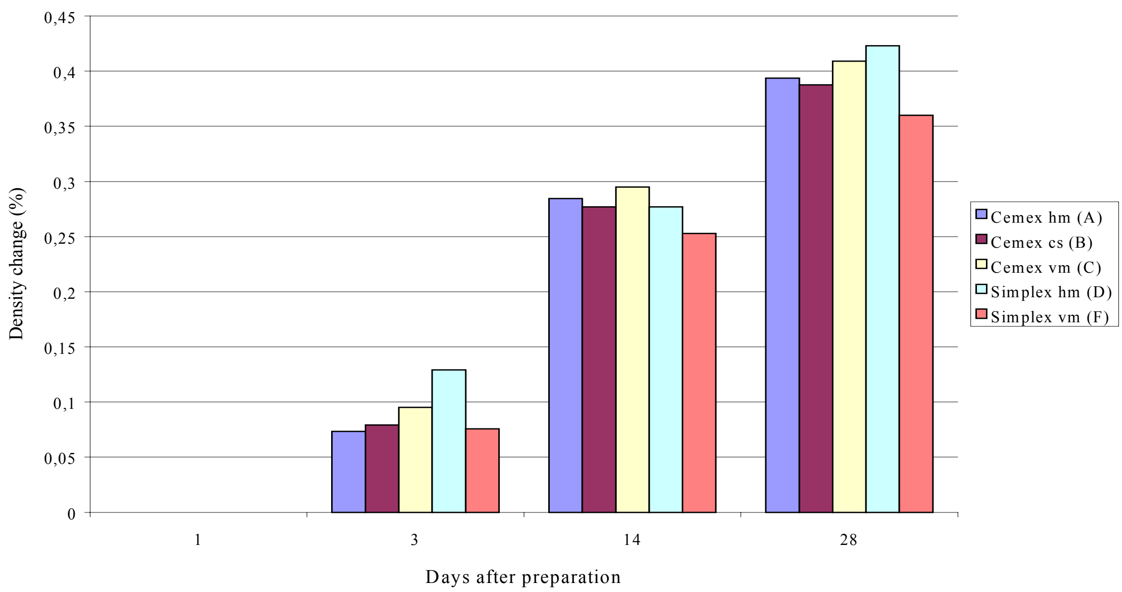

FIg. 13 Density change of Cemex XL vs. Simplex P kept in water

The significant differences are shown in figure 14.

Dry

	Cemex hand-mixed	Cemex System-mixed	Cemex vacuum-mixed	Simplex hand-mixed	Simplex vacuum-mixed
Cemex hand-mixed				L	
Cemex System-mixed					
Cemex vacuum-mixed					
Simplex hand-mixed					H
Simplex vacuum-mixed					

Wet

	Cemex hand-mixed	Cemex System-mixed	Cemex vacuum-mixed	Simplex hand-mixed	Simplex vacuum-mixed
Cemex hand-mixed				L	
Cemex System-mixed					
Cemex vacuum-mixed					H
Simplex hand-mixed					H
Simplex vacuum-mixed					

H = 'significantly higher when looked at from left to above'
L = 'significantly lower when looked at from left to above'

Fig. 14 Significant differences in density between different groups for both dry and wet environment after 28 days

Porosity

The third factor to look at was the porosity grade. This porosity grade was determined with the density of the specimens made under high pressure (which are expected to have negligible porosity). The following formula was used:

$$porosity = \frac{\rho_{high\ pressure} - \rho_{specimen}}{\rho_{high\ presssure}} \times 100\%$$

The high pressure-density of Cemex XL is $1.26799 \cdot 10^3$ kg/m^3 (average of 3 specimens). For Simplex P it is $1.24534 \cdot 10^3$ kg/m^3 (average of 2 specimens).
The results of the initial porosity of the specimens are shown in figure 15. To determine the initial porosity of all the specimens, the average of all the 8 specimens was used, because all the specimens were treated similar till the first measurements.

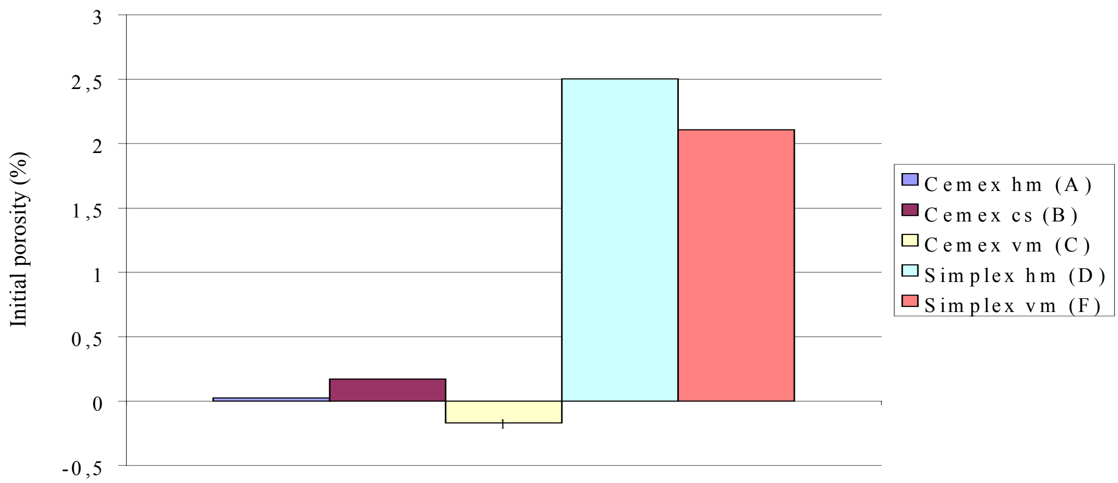

Fig. 15 Initial porosity of Cemex XL vs. Simplex P (averaged per group)

It can clearly be seen that for both the cements, the lowest porosity is created with vacuum mixing. The overall porosity of Cemex XL is lower than Simplex P. Between the HP-specimens of Cemex XL and the 'normal' specimens, there were no significant differences found. This can have three reasons, or the three mixing method are very good or the high pressure was of no influence to the porosity or the porosity is already decreased by the pressurisation during making the specimens (which would be nice). For Simplex P, mixing with Cemex System is better than hand mixing. This result is in agreement with the expectations and theory. There are some significant differences detected as can be seen in figure 16.

	Cemex hand-mixed	Cemex System-mixed	Cemex vacuum-mixed	Simplex hand-mixed	Simplex System-mixed	Simplex vacuum-mixed
Cemex hand-mixed			H	L	L	L
Cemex System-mixed			H	L	L	L
Cemex vacuum-mixed				L	L	L
Simplex hand-mixed					H	H
Simplex System-mixed						
Simplex vacuum-mixed						

H = 'significantly higher when looked at from left to above'
L = 'significantly lower when looked at from left to above'

Fig. 16 Significant differences on porosity for different groups

Conclusions

In general we have observed that Cemex had a lower porosity as compared to Simplex P.

Porosity of Cemex ranged from –0.2% (vacuum mixed) and 0.02% (hand mixed); of Simplex P ranged between 2.1%(Vacuum mixed) and 2.5% (hand mixed). These differences are significant. The negative value (Cemex XL vacuum mixed) was obtained because the porosity of the vacuum mixed specimens was found lower than the high pressure manufactured specimens assumed as "0" porosity reference.

Cemex System had a porosity of 0.2%, significantly lower than Simplex P group. This value was instead significantly higher than Cemex XL vacuum mixed.

Differences in density and volume change between Cemex System and Cemex XL vacuum mixed or Simplex P group were not significant. Within the Cemex group differences in porosity were significant only for vacuum mixed Cemex XL.

These data together with porosity results suggest that Cemex System is a proper device for mixing Cemex XL bone cement.

The environment plays an important role for dimensions stability and material density.

The dimensions increase, after 28 days at 37°C, was significant for all the wet specimens (0.8%), whereas it was not for dry specimens (at 23°C).

The density increase was not significant for the specimens kept in a dry environment whereas it was significant for the specimens kept in water (0.4 %).