

Good long term stability with low monomer bone cement in total hip arthroplasty – A randomized RSA study



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Introduction

Lower amount of monomer in bone cement reduces the temperature during polymerization, the toxicity and the shrinkage of the cement. These advantages led to the introduction of low monomer cement in the early 90s. Cemex® cement reduces the amount of monomer needed by the removal of small particles in the powder (Fig 1a and b). For less theater pollution, a totally closed non vacuum mixing system for mixing was introduced. After intensive laboratory testing we published promising mid term results with this cement (1). We now report on the 10 year results.

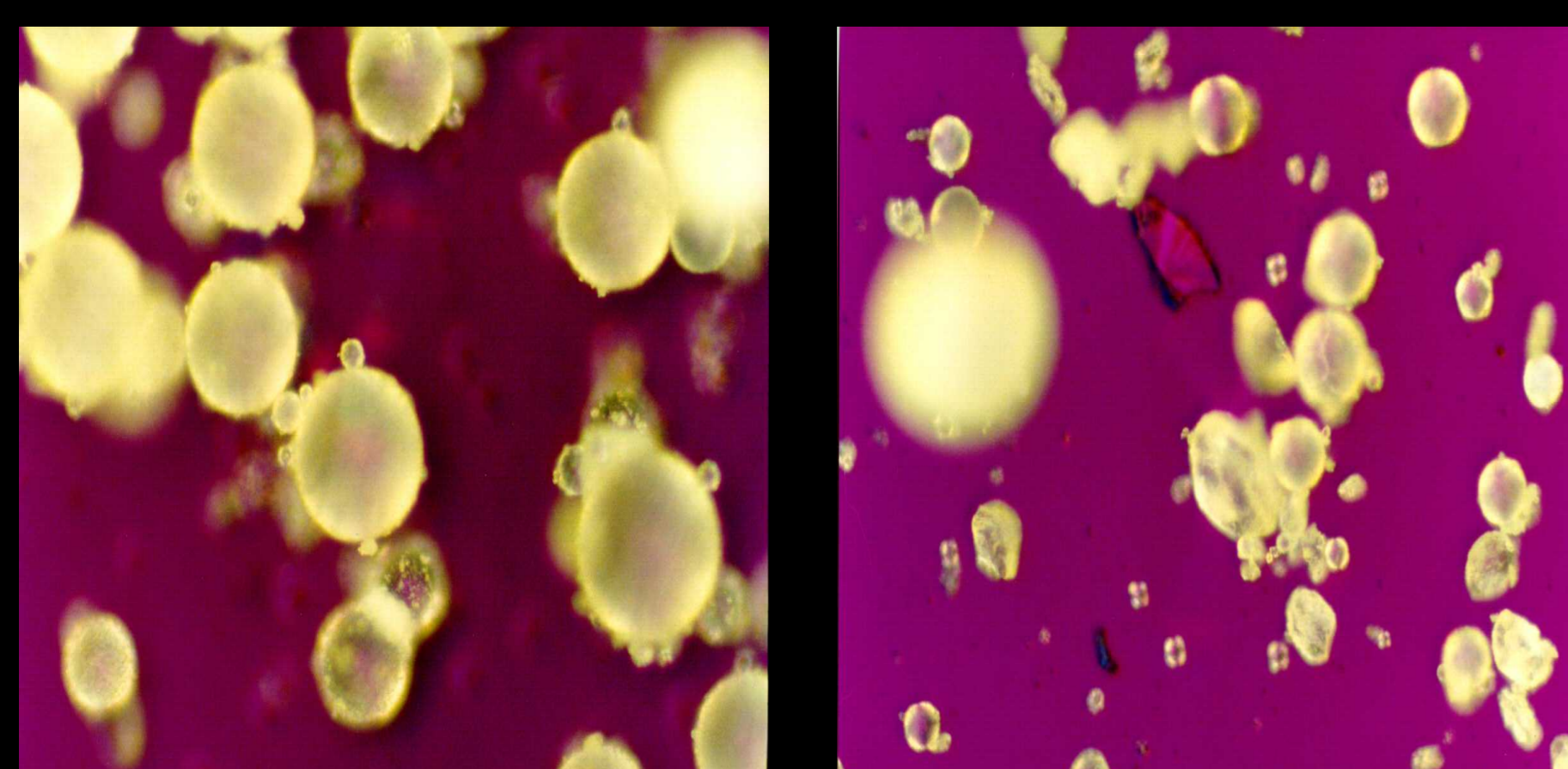
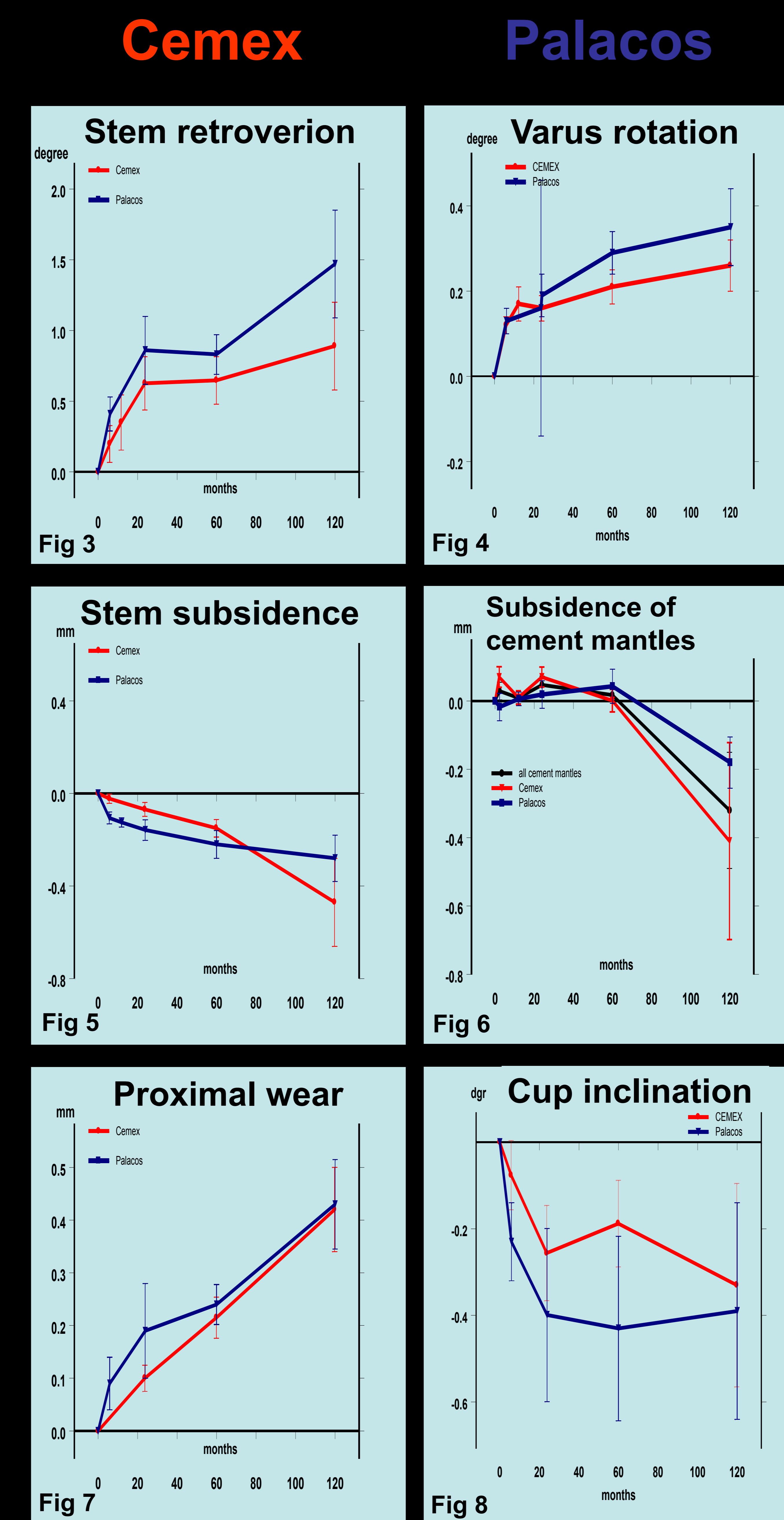


Fig 1a: Cemex b: Palacos

Materials and methods

44 patients (47 hips) with primary arthrosis of the hip were randomised to fixation with either Cemex Rx or Palacos R cement. A posterior approach and third generation cementing technique was used. The Cemex Rx cement was kept at room temperature and was mixed without vacuum using a bowl for the acetabular component and a closed disposable system (Cemex System) for the femoral component (Fig 2). The Palacos R cement was taken prechilled and was vacuum mixed. All patients received Lubinus SP2 stems made of titanium alloy with a 28 mm femoral heads made of aluminium oxide.

Tantalum markers were inserted intraoperatively. Radiostereometric (RSA) examinations were done postoperatively, after 6 months, 1, 2, 5 and 10 years. Clinical evaluation was done by HHS and a activity score. For radiographic evaluation we used conventional x-rays.



Conclusion

- **Cemex** is as stable as **Palacos**
- **Cemex** is a safe alternative for cemented implants
- “One shot mixing system” produces clinically reproducible results
- High amount of RLL with a titanium stem (Cave: Cement mantles are starting to loosen)



Fig. 2

9 patients had deceased, 4 didn't come to the follow up but were contacted by phone and 17 were available in each group at 10 years.

Results

RSA: There was no significant difference in migration between the groups in any direction (Fig 3-6). After 5 years the cement mantles started to subside in both groups (Fig 4). Annual wear was 0.04 mm (Fig 7). Cups were stable (Fig 8).

Survival: No stem was revised for aseptic loosening.

Radiography: Most RLL along the stem were in Gruen zone 2 and 6. The amount (SD) of RLL of the total interface was 40% (6,3) for Palacos and 50% (4,5) for Cemex. Interobserver reliability was 0.4.

In the cup the kappa of concordance was low (0.2). Most RLL were located in Charnley zone 1.

Clinical outcome: Activity and HHS showed no significant difference. HHS (SD) was 78 (26) for the Cemex and 84 (23) for the palacos group. The score for pain was 37 (10) for Palacos and 36 for Cemex (12).

Discussion

The high amount of RLL in both groups is probably caused by the titanium stems. Corrosion and fretting leading to revision is also seen in other series with titanium stems (2). So far there were no revision, but we recommend a close follow up after 10 years. Despite the alarming sign of RLL there is no significant difference in migration (RSA) between the cements. Both are still holding the stems fixed which might partly also be attributed to a forgiving stem shape. A learning curve with the new mixing system seems not to be a problem. Cemex had a tendency to show lower values for migration. The “one shot” mixing system performed equally well as the commonly used vacuum mixing system with Palacos and delivered clinically reproducible results. The clinical long time effects of lower monomer content with regards to toxicity and shrinkage are still unclear.

References:

(1) Nivbrant 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 Dec;72(6):572-84. (2) Thomas et al., Corrosion of cemented titanium femoral stems. J Bone Joint Surg Br. 2004 Sep;86(7):974-8.