INTRODUCTION:
Acrylic bone cement is still the standard in fixing orthopedic implants to bone. Several bone cements with different chemical, mechanical, and handling characteristics have appeared over the years. Vacuum mixing the cement improves the performance, and vacuum mixed Palacos R (Schering-Plough, Labo, Belgium) is one of the best performing cements according to the Norwegian and Swedish arthroplasty registers [1,2]. However, to easily be used with vacuum mixing devices, Palacos has to be cooled to 4°C prior to mixing, which make handling and logistics at the theatre cumbersome [3]. VersaBond bone cement (Smith&Nephew, Memphis, TN; USA) is a newly designed cement by the same team that originally designed Palacos. The rationale behind its design was to optimize the mixing characteristics for vacuum mixing, and obtain high dynamic strength and fatigue resistance, which has been corroborated in in vitro studies. However, a number of historical disasters and not least the extremely poor performance of Boneloc bone cement has stressed the importance to await the results of prospective randomized clinical trials before the clinical acceptance of new products and technologies. The aim of this study was to evaluate the clinical performance of VersaBond bone cement by comparing it to Palacos R in a prospective randomized trial of the tibial component in Total Knee Arthroplasty (TKA), using radiostereometric analysis (RSA).

METHODS:
59 consecutive patients (40 women, 19 men, mean age 73 [62-85] years) with 61 knees having primary gonarthrosis were operated on with a metal-backed Profix® TKA. The study was approved by The Ethics Committee of the University. Randomization between VersaBond (VB) and Palacos (P) bone cements was performed by opening of a sealed envelope during the operation. 32 knees received VB, and 29 knees received P. Two patients were operated upon bilaterally. One woman received VB in one knee and P in the other, whereas one man received P in both knees. Both cements were mixed in a vacuum chamber (Optivac®, Scimedim, Sjöbo, Sweden). Palacos was kept at 4°C before mixing, whereas VersaBond was at room temperature. Two minutes after mixing, the cement was applied to the undersurface of the implant, no cement was placed in the stem hole. When the cement was non-sticky (after approximately 4 to 5 minutes) the tibial component was positioned on to tibia and hammered against the bone and kept under pressure while the cement was setting.

Nine tantalum spheres (RSA Biomedical Innovations, Umeå, Sweden) with a diameter of 1.0 mm were spread out into the proximal tibial tray, and at 3, 6, 12, and 24 months. The patients were examined supine with the knee in 0°–15° flexion and with a weight of 1 kg at the ankle. The cement was at room temperature.

RESULTS:
At 24 months the mean migration for the 2 cements did not differ (P = 0.5 – 0.9, Mann Whitney U test) (Table 1). Anterior tilt was somewhat more common than posterior tilt in both groups (VB; 20 of 29, P; 17 of 24), whereas varus-valgus tilt was evenly distributed in both groups. The pattern of migration up to 24 months did not show any differences between the cements (Fig. 1). In 8 VersaBond knees and 6 Palacos knees the tibial component displayed continuous migration between 12 and 24 months, whereas 21 VB knees and 18 P knees were classified stable (P = 1.0, χ² test). Radiolucent lines were scant and occurred in equal frequency in both groups. In all cases the lines were thin, located at the periphery of the tibial tray, and were non-progressive.

DISCUSSION:
The rationale behind the design of VersaBond was to create a cement of equally as good properties as Palacos R, but optimized for vacuum mixing without the need for pre-chilling the cement. Recently published studies have documented favorable in vitro properties for VersaBond [4,5]. Excellent performance in in vitro studies, however, does, not guarantee excellent performance in vivo. Boneloc bone cement (Biomet, Warsaw, IN; USA) was introduced into the market showing promising properties in vitro, but soon turned out to be a disaster with very high revision rates already after short follow-up. This emphasizes the need for stepwise introduction of new cements in randomized studies using high-resolution technique before being launched for general use.

In the present study we did not find any differences between VersaBond and Palacos R in the fixation of the tibial component. Not only were the mean and median values very similar in the two cements, but was also the dispersion around the mean/median very similar. Even the distribution of outliers was almost equal in the two groups. Finally, the proportion “stable” or “continuously migrating” implants was also similar between the two cements.

The results of this study indicates that VersaBond bone cement will perform at least equally as well as Palacos R in total knee replacement.


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