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In Vitro Performance of Eight Intramedullary Cement Restrictors in Total Hip Arthroplasty

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IN VITRO PERFORMANCE OF EIGHT INTRAMEDULLARY CEMENT RESTRICTORS IN TOTAL HIP ARTHROPLASTY

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INTRODUCTION:
Contemporary cementing techniques in total hip arthroplasty include the use of a cement restrictor to occlude the intramedullary canal. In the 80´s occlusion of the distal intramedullary canal was done with a bone plug or by sealing with bone cement. Today, with the evolvement of biomaterials in Orthopaedic surgery numerous plug designs and materials (non-resorbable, resorbable) are available. Regardless of design, however, intramedullary cement leakage and plug migration during cement and stem insertion should not occur to ensure adequate intramedullary pressures. As there are many different designs currently available it was the aim of our study to compare the stability of eight different systems (Fig. 1) with regard to biomechanical stability (distal motion of plug) and canal occlusion during standardized cement pressurization.

METHODS:
The study was divided in two different parts. Firstly, the plugs were tested in artificial bones (sawbones Mod. 1100, Sweden) to compare the plugs under identical conditions. The second part consisted of a test protocol in fresh frozen femora, which included the whole range of physiological diameters.

Fig. 1: (from upper left) REX Cement Stop™ (before insertion), REX Cement Stop™ (expanded plug), BIOSTOP G®/IMSET®, Plugin´ Tech®, EXETER™ plug, Palacos®-Plug, BUCK™ Cement Restrictor, Universal-Cement-Restrictor.

In both parts the plugs were tested in the identical set-up. After plug insertion the test specimens were fixed in a custom-made holding device. Cement was applied in a retrograde manner and the syringe with the remaining cement was mounted into a cement pressurization apparatus. A pneumatic ram pressure was then applied, which allowed to apply a defined linear pressure increase to the intramedullary canal via the cement pressurization apparatus. A pressure transducer measured the intramedullary pressure and simultaneously a linear displacement transducer was connected to the distal part of the plug in order to measure migration. The maximally achieved pressures and the distance of plug displacement were recorded for every plug. Migration was defined as displacement greater than 10 mm. Additionally cement restrictor failure was defined as a maximal pressure less than 1000 kPa due to migration, cement leakage or a combination of both. At least nine plugs of each design were tested in both parts.

RESULTS:
As the inner diameter of the sawbones was cylindrical the two rigid plugs which have to lock proximal to the isthmus of the femur could not be tested in the first part (Exeter and Palacos plug).
All plugs in the first part migrated and showed displacement of more than 10 mm. The highest maximum pressure levels were achieved with the REX Cement Stop™(max: 970 kPa, median: 466 kPa). The BUCK™ restrictor reached the lowest pressure levels(median: 121kPa).
In the fresh-frozen femora the highest median intramedullary pressures were measured with the Exeter Plug™ (1157 kPa), the Biostop G®/Imset® (1129kPa) and the REX™ (1121kPa)(Fig. 4). Figure 2 shows a typical pressure-migration graph with a decrease of the recorded pressure when the plug displacement begins. The locking device of the REX™ failed to work in one case, but the highest maximal pressure was recorded with this model (1290 kPa). Only one of the REX™ and Exeter™ plugs failed at a pressure level of 1000kPa, with migration in the REX™ and cement leakage in the Exeter™ group.
The lowest pressure levels were achieved with the Palacos® Plug (991kPa) and with the BUCK™ restrictor (690kPa). The pair wise statistical comparison of all cement restrictors showed that the Exeter Plug™ performed significantly better than the BUCK™ ($p=0.0003$) and the Palacos® Plug ($p=0.0007$) (Fig. 7). The REX™ Cement Stop reached significantly higher pressures than the BUCK™ restrictor ($p=0.0015$).

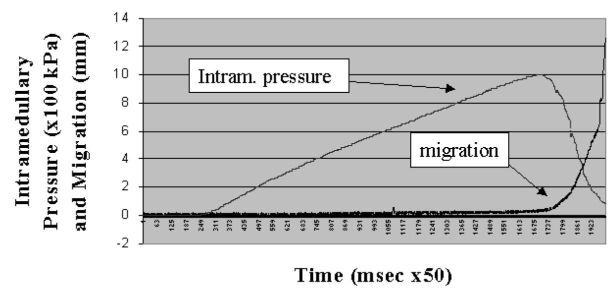

Fig 2: Typical intramedullary pressure and plug migration curve. Cement restrictor started to migrate at the pressure level of 1000 kPa.

DISCUSSION:
In conclusion, there are many different models of artificial cement restrictors available, but their performance with regard to stability and occlusion of the intramedullary cavity varies significantly. The best results in our biomechanical study were achieved with the Exeter™ plug and the expandable REX Cement Stop™, which showed the best results with high median pressure levels, a low number of migrated plugs and limited cement leakage. The REX Cement Stop™ is the only design that can be implanted below the isthmus. This cement restrictor is a safe option for all intraoperative possibilities. Soft gelatin plugs offer a reasonable performance but failure due to migration will occur if high pressure levels are generated. All other designs seem inferior and cannot be recommended. Rigid plug designs provided reliable stability (Palacos® plug, Universal Cement Restrictor) but cement leakage frequently occurred thus jeopardizing maintenance of pressure. Failing both with regard to migration and leakage, the BUCK™ yielded the poorest reliability. Appropriate plug selection is important to minimize the risk of failure due to migration or cement leakage.

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