INTRODUCTION:
Total knee arthroplasty (TKA) has become a standard operative procedure to relieve pain and restore function in patients with osteoarthritis. Polyethylene (Pe) mobile bearing (MB) inserts have been developed to minimize implant wear, prolong prosthesis survival and evoke less anterior knee pain due to better self-alignment. The aim of this study was to compare the clinical, radiological and functional outcome results of the Scorpio PS TKA prosthesis with either a mobile (MB) or fixed bearing (FB) Pe insert. We hypothesized that the MB group would perform better over time in clinical and functional outcome as well as showing a reduction in anterior knee pain occurrence.

METHODS:
In a prospective, randomised, single centre, multi surgeon clinical study a total of 100 patients were enrolled at the Maastricht University Medical Centre equally divided between MB and FB groups. A standard surgical protocol was used for implanting the Scorpio knee prosthesis with either an MB or FB insert. Post-op rehabilitation was standardized and unrelated to insert type. Patients were assessed pre-op and after 3-6-12-24 months post-op. RAND-36 and Knee Society Score (KSS), were assessed as well as pain measurement during functional testing (chair rise and stair climb) using Visual Analogue Scale (VAS) scale. X-rays were assessed for implant positioning, migration, radiolucent lines and patella tilt (using a Skyline view in 30-60 and 90 degrees). Statistical analysis was performed using SPSS 16.0. The differences in various parameters between study groups were evaluated using unpaired student t-test. Repeated measures test were used to evaluate the results within each group over time. Significance was determined p<0.05. Institutional ethical committee approval and informed consent were obtained for all study patients.

RESULTS:
Chair rise (CRT) and Stair climb tests (SCT)
Both tests both groups showed a statistical significant decrease of VAS pain score over time (p<0.01). No significant differences were seen between both groups at any time point. Results did show the MB group to have less pain the first postoperative year in both CRT and SCT tests.

Range of motion
No statistically significant differences were found in total ROM between the two groups. The MB group showed a non-significant larger total ROM in all follow up months compared to the FB group. Repeated measurement tests showed significant differences over time in the FB group (p<0.01).

KSS and RAND 36 questionnaires
Repeated measures tests showed a significant improvement over time for both groups for KSS and most RAND 36 sub scores. There were no significant differences between groups at any given follow up moment. KSS score, both function and pain sub scores showed a significant improvement over time in both groups (p<0.01) 8 out of 9 RAND 36 subdivisions showed the MB group to score non significantly better the first postoperative year. After one year the differences disappeared.

DISCUSSION:
This randomised clinical trial compared the radiological results, anterior knee pain, ROM, KSS and RAND 36 questionnaire outcomes of the Scorpio PS TKA prosthesis with either a MB or FB Pe insert after a 2 year follow up. One theoretical advantage of the MB prosthesis is improved functional performance of the knee. Our hypothesis, that the MB prostheses would provide a better ROM and less anterior knee pain, was not confirmed by the results. In our study the MB group showed less decrease in ROM immediately post-op. This phenomenon was also seen by Harrington et al. The MB prosthesis regained its ROM after surgery earlier than the FB implants. This difference could potentially be attributed to the implant design and its kinematics. This advantage did not persist and the FB group slowly leveled.

Another proposed advantage of the mobile bearing design is that it allows self-alignment of the tibia under the femur. It has been hypothesized that this could improve patello-femoral tracking and diminish patello-femoral pain. No significant differences in patellar tilt were found in our study. We did find a tendency of MB prostheses having less tilt in 30, 60 and 90 degrees flexion, partly confirming the hypothesis of self-alignment of the mobile bearing prosthesis.

In terms of KSS and RAND 36 questionnaires no statistically significant differences were observed. The MB group scored non significantly better compared to the fixed group the first year post op only. Garling’s RSA study challenged the theoretical advantages of MB prostheses by in vivo measured movements. They observed limitation of axial rotation of the MB prosthesis over time. Hypothetically this can be caused by fibrous tissue formation. Fibrous tissue can be formed around prosthetic components, at the edge of the mobile bearing insert articulating surfaces limiting movement freedom. The MB group showed a non significant tendency to perform better in terms of ROM the first 6 months post-op, KSS function score and most of RAND 36 subdivisions the first year post-op. After 2 years follow up all these advantages were gone. Potentially the disappearance of the advantages is caused by mobile bearing fixation by any reason. If it can be confirmed that due to insert fixation MB prosthesis loose movement freedom unfavourable long term survival might be a result. Because the MB then acts in a mechanical environment where it was not designed to function.

In conclusion, our study does not show any clear advantages in terms of function, pain, ROM, general health, radiological evaluation. KSS and RAND 36 of MB compared with FB TKA at a follow-up of 2 years. The claims on wear reduction and prolonged implant survival of mobile bearing designs could so far not been waylaid or proven in our study.

We will continue to evaluate our study population again at 5 years (and longer) follow up to assess whether differences between MB and FB change again over time and if using an MB has added clinical value for the patient. Based on our current results we recommend the use of a fixed bearing insert for TKA procedures.