RCT comparing radiological, clinical and function scores after 5 years follow-up of the uncemented Symax and Omnifit hip prosthesis.

INTRODUCTION:
Uncemented total hip replacement has excellent survival rates, even in young patients. However survival is still not indefinite.[1-2] New hip stems are still being designed in order to improve clinical survival and functional outcomes such as range of motion (ROM). A recent new hip stem design is the uncemented Symax hip stem which combines an anatomical proximal stem section with larger offset and side specific neck features, a decreased neck diameter and a straight distal section with a posterior chamfer. It was hypothesized that the proximal stem and neck section leads to less frequent dislocations and an extended range of motion, while the distal chamfer avoids distal stem tip impingement. For implant fixation the Symax stem is coated with a biomimetic electrochemically deposited BONIT-HA coating on top of a Titanium Plasma Spray (TPS) layer. It was hypothesized that this improves bone-implant anchorage and osseointegration. The neck and distal stem of the Symax stem are treated with a special DOTIZE® anodization surface treatment to prevent bone apposition in these sections of the prosthesis.

METHODS:
In a prospective randomized study we compared short term (5 yrs) radiological, clinical and functional results of 25 uncemented Symax hip stems (Stryker) versus 25 more traditional straight tapered uncemented Omnifit hip stems (Stryker).

The same two surgeons performed all surgeries using the posterolateral approach without osteotomy of the greater trochanter. Patients were treated with 24 hours intravenous antibiotic prophylaxis, DVT prophylaxis during 6 weeks and prophylaxis against heterotopic ossifications with an NSAID for 14 days. Patients were allowed full weight bearing from day 1. Standard AP X-rays of the pelvis and lateral X-rays of the affected hip were made during follow-up. Radiological evaluation for all Gruen zones [5] was performed direct post-operative and after 1 and 5 years by one evaluator who assessed implant position, implant migration and implant fixation according to Engh [3] and a Modified Engh Score[4]. ROM was measured with patients in supine position and for rotations the hip and knee were flexed 90°. The Harris Hip Score (HHS) and Oxford Hip Score (OHS) as well as complications were recorded during follow-up consultation. ROM and patient questionnaires were evaluated pre-operative and post-operative after 6 weeks, 3 months, 6 months, 1 year and yearly till 5 years. Institutional METC approval and informed consent were obtained for all study patients prior to surgery.

RESULTS:
At 5 year evaluation no patients had died. One patient was excluded because of protocol violation with the allocated Omnifit stem. 1 patient was revised due to recurrent dislocations, 1 patient refused follow-up and 1 patient was lost to follow-up due to relocation. Therefore 46 patients were eligible for assessment at 5 years follow-up. X-rays showed stable implants without subsidence or migration. There was no progressive radiographic loosening in either group. No differences were found for stem fixation between the Symax and Omnifit hip stem according to the Engh and Modified Engh Score after 1 and 5 years. After 5 years the Symax group showed significantly more reactive line formation in Gruen zone 5 and 12, respectively p < 0.001 and p < 0.05.
The Symax hip stem group showed a statistical significantly larger ROM at 5 year follow-up in all directions p < 0.001 starting from 2 years follow-up.

The HHS improved from pre-op to direct post-op and maintained high scores during follow-up for both hips. The HHS was significantly better for Symax after 4 and 5 years, respectively p < 0.005 and p < 0.001. The OHS improved from pre-operative to postoperative for both hips, but no differences were seen between Symax and Omnifit.

No differences in occurrence of complications were found between both groups. Mid thigh pain and dislocations were seen in both groups in a comparable amount. One revision for recurrent dislocations in an incomppliant patient in the Symax group led to survival rates for any reason of 96% in Symax and 100% in Omnifit after 5 years. With aseptic loosening as an end-point both hips showed survival rates of 100% after 5 years follow-up.

DISCUSSION:
No differences in radiological bone remodeling were observed between both hips. However Engh Score and Modified Engh Score are not designed for proximally HA coated uncemented prostheses, for it leads paradoxically to lower scores. New scoring lists are required for proper evaluation of these types of uncemented prostheses in future.

After 5 years the Symax stem showed more distal reactive line formation in Gruen zones 5 and 12. The so called ‘windshield-wiper’-sign was observed. This sign becomes visible because of proximal fixation and distal discrepancy between the stiffness of the femur and the prosthesis. The design of the Symax stem favours better proximal fixation and no or very little distal bone apposition which explains this observation. Initial signs of bone remodeling point towards good osseointegration which may result in good long-term clinical survival.

Geometry of the Symax stem leads to an extended range of motion in all directions even though when larger femoral head sizes were more commonly used in the Omnifit group. Survival rates of both hips are good to excellent after this short term follow-up study. Continued clinical follow-up in this study is warranted to assess long-term clinical survivorship. In general the uncemented Symax hip stem has proven to be a safe total hip prosthesis with better outcomes in terms of ROM and function as compared to the clinically well established Omnifit hip stem.

REFERENCES:
5. Gruen TA et al. CORR 1979 141:17-27

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