INTRODUCTION:
Large wear rate reductions have been shown for crosslinked polyethylene (PE) in simulations and short- to mid-term clinical wear studies. However, concerns persist about the long-term performance of crosslinked PE, especially for annealed variants which shall be more prone to oxidative degradation and thus late accelerating wear than remelted alternatives due their higher level of residual free radicals. While it has become generally accepted that crosslinked PE effectively reduces wear volumes, concerns persist to whether the particles may be more numerous and of higher osteolytic potential due to their smaller sizes and different shapes as reported in literature. This may (over-) compensate any reductions in wear volume and produce more osteolysis in-vivo.

Weap particle induced osteolysis develops slowly and becomes visible on 2D x-rays only at a certain severity and due to the cup projection only partially so that hidden cysts may persist. Thus statistically powerful evidence to whether crosslinked PE does not only reduce wear volumes but also causes less osteolysis requires a long-term follow-up and ideally CT or oblique x-rays to detect all cysts. Long term studies are still scarce because most crosslinked PE was only introduced ca. 10yrs ago. This study is a yet rare long-term (14yrs) prospectively randomized comparison of conventional to crosslinked PE investigating whether the wear reduction is maintained in the long-term and if reduced osteolysis becomes evident using quantitative CT analysis.

METHODS:
In a prospective study 48 patients indicated for primary, unilateral THA (Stryker ABG-II, 28mm CoCr heads) were randomized to either receive a first generation moderately crosslinked PE (Stryker Duration: 30kGy, gamma irradiation in N2, annealed for free radical removal and crosslinking) or a then conventional, now ‘historic’ PE (30kGy, gamma irradiation in air). The elevated crosslink level of Duration versus the conventional PE was validated via the “load-at-break” of a small punch test (84.1N vs 70.7N= +13.1N) showing an equivalent gain as comparison of conventional to crosslinked PE investigating whether the wear reduction was maintained in the long-term and if reduced osteolysis becomes evident using quantitative CT analysis.

RESULTS:
Thirty-one patients (18 conventional, 13 Duration) were left for analysis (eight deaths and 9 lost to follow-up). At 14yrs the total linear head penetration was sign. lower with Duration (0.85 ±0.27mm, range: 0.4-1.2mm) than conventional PE (1.66 ±0.83, range: 0.4-3.3mm, p<0.01). Also the annual wear rate was significantly (p=0.005) lower for Duration (0.064 ±0.020mm/yr) than conventional PE (0.124 ±0.063mm/yr). This reduction (+49%) compared well to the original simulator prediction (-45%) and even increased with time (-30% at 5yrs, -38% at 8yrs, -42% at 10yrs, Fig. 2). In the Duration group no patient (0%) had a wear rate above the >0.1mm/yr (osteolysis threshold) compared to 11 (61%) in the conventional group (p<0.01, Fig. 3).

Patients with radiographic signs of acetabular osteolysis (cysts) on the AP x-ray were less frequent in the Duration (4/13= 31%) than in conventional group (13/18= 72%, p= 0.023). This difference became even more pronounced when also the lateral view was evaluated and the affected DeLee-Charnley zones were counted (7 vs 22, p= 0.017).

DISCUSSION:
At 14yrs long-term FU the annual wear rate of a first generation moderately crosslinked PE did not increase but in fact it decreased so that the relative wear reduction over conventional (now ‘historic’) PE did not deteriorate but increased. With Duration PE, also the incidence and the severity of osteolysis was significantly less. Thus no clinical evidence of PE degradation or the elevated osteolytic potential of its wear debris was found for this first generation moderately crosslinked and annealed PE at 14yrs in-vivo. These results must still be confirmed for newer generations of highly crosslinked PE.

REFERENCES: