

O 671 PRECLINICAL AND CLINICAL EVALUATION OF POLYETHYLENE WEAR

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Purpose of the study: Despite excellent fixation wear will jeopardise the long-term results of cementless fixation of hip joint prostheses. Reducing Polyethylene wear and consequently osteolysis will help in reducing the risk of aseptic loosening.

Material and methods: Cross-linked Polyethylene was developed by sterilisation in nitrogen and annealing to promote further crosslinking. Preclinical testing was performed on 28 mm acetabular cups on hip wear simulators. Crosslinked inserts were compared to controls sterilised to the same dose but in air and without annealing. A randomised single-blinded clinical study was initiated at three medical centres. A total of 74 inserts (35 conventional and 39 crosslinked) were followed for a minimum of two years post-operatively. Wear was measured yearly using a previously validated two-dimensional algorithm using digital filtering and edge detection performed by a blinded observer.

Result: A thirty to forty percent reduction in wear rate was observed for the cross-linked Polyethylene vis-à-vis the control insert. At two years the patients receiving a conventional insert were observed to have a volumetric wear rate of $94 \pm 78 \text{ mm}^3/\text{a}$. The patients receiving the crosslinked inserts were observed to have a volumetric wear rate of $54 \pm 70 \text{ mm}^3/\text{a}$. The wear rates were statistically different from one another ($p < 0.05$). The ratio of volumetric wear observed in vivo closely bounded the ratio observed using the wear simulator.

Conclusion: These data indicate that Polyethylene wear can be significantly reduced by sterilisation crosslinking in the laboratory and is also relevant for the clinical outcome.