Clinical Performance of a Highly Cross-linked Polyethylene at 5 Years in Total Hip Arthroplasty: The Impact of Elliptical Distortion on a Clinical Wear Series

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Introduction

• Crossfire™ (Stryker, Mahwah, NJ) highly cross-linked polyethylene represents a non-re-melted, ten mega-rad material that has demonstrated 90% less wear reduction in hip simulation testing.

• Early clinical results at two years demonstrated a significant reduction in wear compared to a three mega-rad polyethylene radiated in an inert environment. Wear rates in highly cross-linked polyethylene are in the range of 10-12 microns/year (1), which requires improved precision for wear detection.

• Elliptical distortion introduced by non-hip centered radiographs in this clinical series resulted in aberrant high and low wear rates. In this study, we investigate the effect of correcting for elliptical distortion by present the five year clinical wear performance of Crossfire™ polyethylene with and without distortion correction.

Objectives

• To quantify the effect of elliptical distortion on the variance of clinical wear measurements using the F/K variance test to compare the variance of wear values with and without correction for elliptical distortion.

• To present the clinical wear performance of Crossfire™ highly cross-linked polyethylene in conjunction with a Cobalt Chrome femoral bearing at five years follow-up.

Methods

• Patients in this study consisted of 169 primary hips with Crossfire™ polyethylene and 39 hips with standard polyethylene from 4 independent institutions.

• Polyethylene wear detection was performed using computer assisted edge detection software developed at The University of Chicago, (Hip Analysis Suite - HAS ) (Figure 1a and 1b). All radiographic wear measurements were performed using two versions of the software, One version fit circles to the radiographs and did not correct for off beam elliptical distortion, and a new version of the HAS that fit ellipses to the radiographs, allowing correction of elliptical distortion.

• Wear analysis was performed by individuals trained in the use of the software.

• Wear rates were calculated by two different techniques.
  - Regression Slope Method - All wear measurements for each patient were plotted against the years since the surgical procedure. A linear regression line was then fit to this data and the slope of the line taken as the wear rate for the population.
  - The Average Wear Method - The 6 week post-operative radiograph was used as a baseline and paired with the longest follow-up for each patient. The total wear detected, divided by the follow-up interval in years represented the wear rate for each patient.

• The difference in wear rates for the standard vs. the Crossfire™ group was tested for significance at the 95% level using the Mann-Whitney non-parametric test.

Results

• Using the newest version of HAS and the regression slope method, the wear rates with bedding in included for standard and Crossfire™ polyethylene were 121 and 48 microns per year respectively p =0.0002 (Figure 2b).

• Using the average wear method the wear rates with bedding in included were calculated at 99 and 4 microns per year for standard and Crossfire™ polyethylene respectively (p = 0.028).

• The impact of elliptical distortion correction was to decrease the high and low outliers (Figure 2b), in this clinical series, which resulted in a 54.6% reduction in the standard deviation. (Std. Deviation with correction is 0.325 mm and without correction is 0.700 mm). Also Fligner-Killeen variance test shows significant difference in variance in wear rates with and without elliptical correction (p=0.032).

• The clinical performance of Crossfire™ highly cross-linked polyethylene showed significantly reduced wear (95.6) at 5-6 years follow-up compared to conventional polyethylene sterilized in a nitrogen atmosphere (p = 0.0002).

Conclusion

• Edge detection, combined with elliptical curve fitting, allowed for mathematical correction for elliptical distortion. This resulted in fewer negative and high wear values and less scatter in the regression plots. This will improve the precision and accuracy of clinical wear detection in future studies.

• The sample size required to achieve 80% power is proportional to the square of the standard deviation for wear measurements. The observed decrease in the standard deviation from 0.700 to 0.325 mm translates into (0.700/0.325)^2 = 4.5 fold less patients being required to achieve the same statistical power.

• The clinical performance of Crossfire™ highly cross-linked polyethylene showed significantly reduced wear (95.6) at 5-6 years follow-up compared to conventional polyethylene sterilized in a nitrogen atmosphere (p = 0.0002).

References
