## A Comparison of Wear of 36 mm and 28 mm Metal-on-Highly Cross-Linked Polyethylene Articulations in Primary Total Hip Replacements

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## Contents

| List of tables  | vi       |
|---|----------|
| List of figures   | viii     |
| Abstract  | X        |
| Acknowledgements  | xiii     |
| Abbreviations and glossary  | XV       |
| Chapter 1: Introduction   | 1        |
| Chapter 2: Literature review  | 3        |
| 2.1 Content of the literature review                                      | 3        |
| 2.2 Structure of the literature review                                    | 3        |
| 2.3 Research questions and limitations of the literature                  | 4        |
| 2.4 Metal-on-polyethylene total hip replacements                          | 6        |
| 2.4.1 Total hip replacement surgery                                       | 6        |
| 2.4.2 Reasons for revision  | 8        |
| 2.4.3 The role of large metal-on-HXLPE articulations                      | 8        |
| 2.5 Conventional polyethylene to cross-linked polyethylene                | 10       |
| 2.5.1 The clinical importance of wear rates of polyethylene liners        | 10       |
| 2.5.2 Defining clinically important wear rates                            | 13       |
| 2.5.3 The development and chemistry of cross-linked polyethylene          | 16       |
| 2.5.4 Proposed advantages of cross-linked polyethylene                    | 18       |
| 2.5.5 Limitations of the current literature on cross-linked polyethylene  | 19       |
| 2.6. Wear performance of total hip replacements                           | 21       |
| 2.6.1 Wear terminology and concepts                                       | 21       |
| 2.6.2 Clinical performance of first-generation cross-linked polyethylene. | 26       |
| 2.6.3 Bedding-in/creep and wear   | 27       |
| 2.6.4 Comparative studies of large and standard articulations             | 29       |
| 2.6.4.1 Bedding-in/creep  | 29       |
| 2.6.5 Studies examining wear rates of younger patients                    | 35       |
| 2.6.6 Comparative prevalence of osteolysis in short- to medium-term       | 35       |
| 2.7 Polyethylene wear   |          |
| 2.7.1 Wear of polyethylene acetabular liners                              |          |
| 2.7.2 Polyethylene wear particle generation and periprosthetic particle m | igration |
|   |          |
| 2.8 Radiographic methods of polyethylene-wear measurement                 | 41       |

| 2.8.1 A brief history of techniques and their utility                | 41       |
|--|----------|
| 2.8.2 PolyWare <sup>TM</sup>   | 46       |
| 2.8.3 Volumetric wear measurement                                    | 48       |
| 2.8.4 Two-dimensional versus three-dimensional wear measurement te   | chniques |
|  | 50       |
| 2.9 Wear interpretation and wear study design                        | 52       |
| 2.9.1 Creep and bedding-in   | 52       |
| 2.9.2 Negative wear  | 53       |
| 2.9.3 Imaging technique and quality                                  | 55       |
| 2.9.4 Clinical context of the utility of wear measurement techniques | 57       |
| 2.9.5 Reporting of wear outcomes and summary of limitations          | 58       |
| 2.10 Summary of the literature review                                | 61       |
| 2.11 Aims and hypotheses   | 62       |
| 2.11.1 Aims  | 63       |
| 2.11.2 Hypotheses  | 63       |
| Chapter 3: Methodology   | 65       |
| 3.1 Study conduct and data collection                                | 65       |
| 3.1.1 Sample population and randomised controlled trial methodology  | 65       |
| 3.1.2 Clinical and radiographic follow-up                            | 67       |
| 3.1.3 Data collection and image processing                           | 69       |
| 3.2 Data analysis  | 69       |
| 3.2.1 PolyWare <sup>TM</sup> analysis                                | 69       |
| 3.2.2 Wear analysis  | 74       |
| 3.3 Inter- and intra-observer error                                  | 81       |
| Chapter 4: Results   | 83       |
| 4.1 Cohort demographics and component positioning                    | 83       |
| 4.2 Intra-observer and inter-observer reliability                    | 87       |
| 4.3 Two-dimensional femoral head penetration across points           |          |
| 4.4 Total volumetric wear across time points                         | 90       |
| 4.5 Bedding-in/creep   | 91       |
| 4.6 Annual wear rates  | 91       |
| 4.6.1 Annual two-dimensional wear rates                              | 91       |
| 4.6.2 Annual volumetric wear rates                                   | 94       |
| 4.7 Statistical modelling of the data (mixed linear effects model)   | 99       |
| 4.8 Proportion of cohorts with elevated 2DWRs and VWRs               |          |

| 4.9 Demographic and component characteristics of patients with elevated | 2DWRs |
|---|-------|
| and VWRs  | 101   |
| Chapter 5: Discussion   |       |
| 5.1 Synthesis of results to literature and their interpretation         |       |
| 5.2 Limitations of the study and measurement technique                  | 110   |
| 5.3 Significance and future directions                                  | 113   |
| 5.4 Conclusions and implications for further research                   | 117   |
| Appendix A: Published RCT Methodology                                   | 118   |
| Appendix B: Evidence of Trial Ethics Approval and Registration          | 119   |
| Appendix C: RCT Stratification  | 120   |
| Appendix D: Statistical Modelling Tables                                | 121   |
| National and International Presentations                                | 122   |
| References  |       |

## List of tables

| Table 2.1: Examples of manufacturing differences between first-generation                    |
|--|
| moderately and highly cross-linked polyethylene used in total hip                            |
| replacements18   |
| Table 2.2: in vivo standard-sized CoCr-on-Longevity PE™ primary total hip                    |
| replacement wear studies   |
| Table 2.3: <i>in vivo</i> large CoCr-on-Longevity <sup>™</sup> HXLPE articulation (±standard |
| comparison) primary total hip replacement studies  |
| Table 2.4: The effect of different factors on cross-linked polyethylene wear                 |
| generation40   |
| Table 2.5: The effect of different factors on conventional PE wear generation41              |
| Table 2.6: Comparison of RSA and computer-assisted edge-detection techniques45               |
| Table 3.1: Variation in radiographic follow-up practices between countries                   |
| Table 4.1: Demographic characteristics and component positioning for 28 mm and               |
| 36 mm patient cohorts  |
| Table 4.2 Outer diameter of acetabular components by articulation size                       |
| Table 4.3: Type of radiograph by articulation size 86  |
| Table 4.4: Variance in 2D FHP measurement, Bland–Altman limits of agreement and              |
| coefficient of variance for intra- and inter-observer measurements                           |
| Table 4.5 Mean two-dimensional femoral head penetration ( $\pm 95\%$ CI) at different        |
| radiographic time points by articulation size90  |
| Table 4.6: Two-dimensional wear rate ( $\pm$ SD) calculated from different reference time    |
| points and methods (2 decimal places)92  |
| Table 4.7: Volumetric wear rate ( $\pm$ SD) calculated from different time points and        |
| methods by articulation size95   |
| Table 4.8: Mean wear rates ( $\pm$ SD) of 36 mm and 28 mm articulations using different      |
| radiographic time points and calculations96  |
| Table 4.9: Least square means for the effect of time on 2D FHP (mm) for 36 mm and            |
| 28 mm articulations  |
| Table 4.10: Least square means for both the effect of time (independent of                   |
| articulation size) and articulation size (independent of time) on 2D FHP (mm)                |
|  |
| Table 4.11: Proportions of 36 mm and 28 mm Cohorts with 2DWR ≥0.1 mm/yr and                  |
| VWR≥80 mm <sup>3</sup> /yr   |

| Table 4.12: Comparison of all patients with 2DWR $\geq 0.1$ mm/yr (one- year-final |    |
|--|----|
| radiograph by individual regression) compared with the overall cohort of           |    |
| patients <0.1 mm/yr1   | 03 |
| Table 4.13: Demographic and component variables of 36 mm articulations with        |    |
| VWR $\geq$ 80 mm <sup>3</sup> /yr compared with <80 mm <sup>3</sup> /yr1           | 03 |
| Table 4.14 Demographic and component variables of 28 mm articulations with VW      | 'R |
| $\geq 80 \text{ mm}^{3}/\text{yr}$ compared with $< 80 \text{ mm}^{3}/\text{yr}$   | 04 |

## List of figures

| Figure 2.1: Schematic representation on role of radiation in achieving conversion   |
|---|
| from UHMWPE to XLPE17   |
| Figure 2.2: Relationship between change in the femoral head position (A, B, C in  |
| each scenario) and the observed 2D FHP over the serial time points analysed   |
|   |
| Figure 2.3: Different modes of wear in THR articulations  |
| Figure 2.4: Wear theory proposed by Charnley and Halley (1975)  |
| Figure 2.5: Examples of point selection (smaller, thicker circles) and resultant  |
| shadow-casting (thinner, larger circles) around an articulation using   |
| PolyWare <sup>TM</sup>  |
| Figure 2.6: Display of the articulation modelling based upon data provided  |
| Figure 2.7: Implications of reporting mean wear rates only without regard to outliers   |
| exceeding the osteolysis threshold  |
| Figure 3.1: An example of a completed shadow cast following point entry and 3D  |
| model generated after entry into PolyWare <sup>™</sup> of AP and lateral points,  |
| affirming acceptable point capture71  |
| Figure 3.2: Schematic representation of the preferred process of analysing 28 mm  |
|   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>TM</sup> software<br>72<br>Figure 3.3: Schematic example of the occurrence and correction of shadow cast error<br>73<br>Figure 3.4: An example of 2D FHP (mm) outputs from 2 cycles of PolyWare <sup>TM</sup><br>analysis using the same patient radiograph sets |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>TM</sup> software<br>  |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>72<br>Figure 3.3: Schematic example of the occurrence and correction of shadow cast error<br>73<br>Figure 3.4: An example of 2D FHP (mm) outputs from 2 cycles of PolyWare <sup>™</sup><br>analysis using the same patient radiograph sets   |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |
| and 36 mm articulations in the current study using the PolyWare <sup>TM</sup> software<br>  |
| and 36 mm articulations in the current study using the PolyWare <sup>TM</sup> software<br>  |
| and 36 mm articulations in the current study using the PolyWare <sup>™</sup> software<br>   |

|        | for each cohort  | 91    |
|--------|--|-------|
|        | (1975) method with superimposed trendline through medians from 12 me | onths |
| Figure | 4.3: Scatterplot of volumetric wear over time by the Charnley and Ha | alley |

#### Abstract

Total hip replacement is one of the most frequently performed and successful surgical procedures. Its most common modes of failure identified in joint registries are dislocation in the short term and aseptic loosening associated with wear and osteolysis in the long term. Therefore, the ideal articulation would have both a low incidence of dislocation and low wear.

Metal-on-highly cross-linked polyethylene (HXLPE) articulations of 36 mm diameter have been demonstrated in a randomised controlled trial to have a significantly lower incidence of dislocation at one year postoperatively compared to 28 mm articulations. Historically, large articulations (femoral head size ≥32 mm) have been associated with increased wear rates of conventional polyethylene compared to smaller articulations. Advances in polyethylene manufacture with crosslinking for clinical use in total hip replacements has significantly reduced early wear rates compared to conventional polyethylene. This has prompted reconsideration of the ideal femoral head size to enhance the longevity of articulations.

This study aims to compare the wear of 36 mm and 28 mm metal-on-highly crosslinked polyethylene total hip replacements through a *post hoc* analysis of radiographs of patients enrolled in the randomised controlled trial referred to above. Comparison of wear rates between cohorts was undertaken by use of computer-assisted analysis (PolyWare<sup>™</sup>) of patient radiograph sets.

Radiograph sets for 326 patients, 164 with 28 mm and 162 with 36 mm articulations, were analysed. 36 mm metal-on-HXLPE articulations were found to have a statistically significant higher magnitude of bedding-in and creep at three but not twelve months when compared to the 28 mm cohort. The mean annual two-dimensional wear rate from 1 year until final radiograph was 0.00mm/yr for both

cohorts. There were no differences between 36 mm to 28 mm cohorts in mean annual volumetric wear rates or significant differences in the proportion of patients in each cohort with two-dimensional wear rates  $\geq 0.1$  mm/yr or volumetric wear rates  $\geq$  80 mm<sup>3</sup>/yr. These wear rates have previously been associated with osteolysis when using metal-on-conventional polyethylene articulations.

While the use of large articulations had been reported to be associated with comparatively greater wear rates of articulations incorporating conventional PE, this appears not to apply to large articulations incorporating HXLPE. The low wear rates measured combined with the findings of the RCT of a significantly reduced incidence of dislocation at one year of 36mm compared to 28mm articulations, support the use of 36 mm metal-on-highly cross-linked polyethylene articulations. Longer term follow-up is required to assess whether low wear rates are maintained for both 36mm cohorts and whether wear of HXLPE is associated with the development of periprosthetic osteolysis.

### Declaration

This manuscript contains no material that has been accepted for any other degree in any university. To the best of my knowledge and belief, this manuscript contains no material previously published or written by any other person, except where due reference is given in the text. I give my consent for this copy of my thesis, when deposited in the university library, being available for loan and photocopying as well as being available for access as part of the digital thesis program.

Mario G.T. Zotti MBBS (Hons) 28<sup>th</sup> August 2015

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xiii

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Violetta Zotti and my family have given an enormous amount of time, effort and compassion, which has enabled me to complete this work.

# Abbreviations and glossary

| 2D                        | two-dimensional   |
|---------------------------|---|
| 2DWR                      | two-dimensional wear rates, analogous to linear wear        |
|                           | rate  |
| 3D                        | three-dimensional   |
| annealing                 | heating followed by gradual cooling applied to a            |
|                           | material in an effort to allow recoil of polymer chains     |
|                           | and relieve internal stresses                               |
| AOA NJRR                  | Australian Orthopaedic Association National Joint           |
|                           | Replacement Registry  |
| AP                        | antero-posterior  |
| articulation              | Interface where mobility occurs between components          |
|                           | of the THR  |
| arthroplasty              | surgical modification of a native joint; in this thesis,    |
|                           | this relates to total hip arthroplasty – replacement of the |
|                           | native joint with articulating prostheses                   |
| aseptic loosening         | debonding of the component-bone interface that is not       |
|                           | the result of infection; associated with increased          |
|                           | volumes of PE wear debris                                   |
| bedding-in                | often discussed interchangeably or in combination with      |
|                           | creep, but more strictly defined as loss of surface         |
|                           | asperities left during manufacturing in the early           |
|                           | postoperative period  |
| BMI                       | body mass index   |
| CAD                       | computer-assisted design                                    |
| CAM                       | computer-assisted manufacturing                             |
| CI                        | confidence interval   |
| CoCr                      | cobalt chrome (will generally refer to the material used    |
|                           | for metal femoral heads upon PE)                            |
| conventional polyethylene | UHMWPE (non-cross-linked) utilised prior to the             |
|                           | advent of cross-linking in the late 1990s                   |
| creep                     | time-dependent deformation of a material under stress       |
|                           | that does not produce wear particles. Non-wear              |
|                           | generating process of creep and settling in of the liner    |
|                           | that dominates initial observed FHP and includes            |

|                            | bedding-in. Often discussed interchangeably with           |
|----------------------------|--|
|                            | bedding-in in the early postoperative period               |
| СТ                         | computed tomography  |
| dislocation                | an episode of disarticulation of the prosthetic joint      |
|                            | requiring reduction to restore joint mechanics             |
| e-beam                     | electron beam (method of irradiation of PE                 |
|                            | components, used exclusively by Zimmer <sup>™</sup> in PE  |
|                            | manufacture)   |
| FHP                        | femoral head penetration; FHP after creep-dominated        |
|                            | period may be referred to as steady-state linear wear      |
| HXLPE                      | highly cross-linked polyethylene                           |
| in vitro                   | studies examining subjects outside their usual context;    |
|                            | relating to articulations studied in a laboratory context. |
| in vivo                    | studies examining outcome of interest in living subject;   |
|                            | in this context, relating to study of articulations        |
|                            | implanted into patients.                                   |
| Initial radial discrepancy | the initial radius between the edge of a reduced femoral   |
|                            | head and the inner aspect of the acetabular component.     |
|                            | This discrepancy is deliberate on the part of component    |
|                            | manufacturer to ensure that manufacturing tolerances of    |
|                            | the components allow reduction.                            |
| large articulation         | greater than or equal to 32 mm articulation                |
| mg                         | milligrams   |
| mm                         | millimetres  |
| mm <sup>3</sup>            | cubic millimetres  |
| Mrad                       | megarad (equivalent to 10 kilogray doses of radiation      |
|                            | energy)  |
| negative wear              | wear measurement over serial radiographs where the         |
|                            | vector changes from the expected direction; typically a    |
|                            | wear vector away from the acetabular component             |
| osteolysis                 | resorption of bone in response to a pathology; in this     |
|                            | context caused by host response to PE wear particles       |
| osteolysis threshold       | threshold of annual wear rates in conventional PE          |
|                            | where osteolysis develops and below which osteolysis       |
|                            | is rare  |

| periprosthetic           | relates to a process occurring around a prosthetic joint   |
|--------------------------|--|
| PE                       | polyethylene   |
| phantom model            | a model of increments known to or adjusted by the          |
|                          | assessor used as a reference point to test measurement     |
|                          | tools with unknown performance                             |
| post hoc                 | retrospective examination of data following conclusion     |
|                          | of the original part of a scientific process; implies that |
|                          | the original experiment was not designed with outcome      |
|                          | of interest in mind  |
| RCT                      | randomised controlled trial                                |
| revision                 | surgery undertaken subsequent to the primary (index)       |
|                          | surgical operation replacing some or all of the            |
|                          | components to address a problem that has since             |
|                          | developed  |
| RSA                      | Roentgen stereophotogrammetric analysis                    |
| standard articulation    | articulation sized less than 32 mm                         |
| SD                       | standard deviation; square root of the variance from the   |
|                          | mean   |
| steady-state linear wear | FHP measured in the 2D plane following the bedding-        |
|                          | in period  |
| THR                      | total hip replacement (primary unless otherwise stated)    |
| TIFF                     | tagged image file format                                   |
| tribology                | the study of the interaction between bearing surfaces of   |
|                          | joints   |
| UHMWPE                   | ultra-high molecular-weight polyethylene                   |
| UK                       | United Kingdom   |
| USA                      | United States of America                                   |
| VWR                      | volumetric wear rate                                       |
| XLPE                     | cross-linked polyethylene manufactured using at least      |
|                          | 3 Mrad (i.e. includes moderately as well as highly         |
|                          | cross-linked PE)   |