



A New Cementless Total Hip Arthroplasty – A Multicentre Prospective Minimum 2 Year Follow-up Clinical Outcomes Study

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Abstract

Background: Cementless implants were introduced approximately three decades ago in order to address aseptic loosening of cemented hip prostheses with the aim of early mobilisation, better functional result and bone stock preservation. The primary objective of this study is to introduce a new cementless HA coated implant and report its minimum 2 year follow up results.

Material & Method: This is a prospective, multi-centre, consecutive series, clinical outcomes study with 75 patients. Inclusion criteria for the study were age 21- 85 years, BMI <40, osteoarthritis of the hip.

Patients were operated using a standard posterolateral approach. The Paragon stem and the Global cup were implanted in a cementless method. Patients were reviewed at 6 weeks, 6 months and two years postoperative. At each visit AQoL 6D, VAS Pain, Oxford Hip Score were recorded. Post-operative X-Rays were reviewed at immediate post-operative, 6 months and two years.

Results: Mean duration of surgery was 63.1 min with range of 40-120 min. AQoL over time changed from pre-op mean 50.51 to a 2 year mean 35.06. Oxford hip score improved from pre-op mean of 19.93 (SD 8.13) to post-op 6wks mean 33.5 (SD 8.64) and plateaued at 41.3 (SD 6.75) at 6 months and 42.2(SD 6.28) at 2 years. VAS pain trajectories, showing a clear downward trend from pre-op to postoperative assessments. At a minimum 2 year clinical follow up there is a 100% survivorship of the Paragon stem and 98.7% survivorship of the total hip construct overall

for any reason.

Discussion & Conclusion: The combination of Paragon stem and Global cup incorporates proven features of successful implants. The unique feature of lateral tension grooves and progressive neck dimension with dual offset options offers promising early results with early follow up of a minimum of 2 years and is a good cementless THA option.

Background

Total hip arthroplasty is a proven procedure for treatment of end stage debilitating hip disease. Since its inception implants have undergone various modifications in design and method of fixation.

The primary objective of THA is to provide a painless, mobile, stable hip with minimal limb length discrepancy. In addition to these short term goals, efforts have been made to prolong survivorship by modifying implant morphology, fixation methods and bearing surfaces. This is particularly relevant in the younger or high demand population.

Cementless implants were introduced approximately three decades ago in order to address aseptic loosening of cemented hip prostheses [1] with the aim of early mobilisation, better functional result and bone stock preservation.

Keywords: Total hip replacement; Oxford hip score; Cementless hip ; Paragon; Early outcomes

Level of Evidence: IV

They have shown good result with combination of both cementless stem and cup [2].

Since the introduction of cementless tapered, rectangular cross-sectioned implant by Zweimuller, approximately 700,000 of this design stems have been implanted worldwide [3] and have shown good results after 15 years [4,5,6].

Biplanar wedge design was introduced to provide axial and rotational stability through the rectangular dual longitudinal taper and compaction of cancellous bone creating contact between the femoral cortex and the corners of the stem. Hydroxyapatite coating was introduced to promote bone ongrowth, providing durable secondary fixation and has shown good results in implant survivorship [7].

Cementless hemispherical Titanium press fit acetabular component design has excellent outcomes and survivorship even in more difficult patient populations [8,9,10].

This study introduces the Paragon cementless stem and Global cup (Corin, Cirencester,

UK)The Paragon stem is a monobloc, titanium, fully HA coated rectangular biplanar wedge design with compression grooves on the medial, anterior and posterior metaphyseal surfaces and unique tension grooves on the lateral metaphyseal surface. It is available in two offset options and progressive neck dimensions. TGA approval was granted in 2012.

The Global cup is a pure titanium macro ingrowth surface with a 3-dimensional dual layer of sintered HA.

The primary objective of this study is to introduce a new cementless HA coated implant and report its minimum 2 year follow up results.

Material and Methods

A prospective, multi-centre, consecutive series, clinical outcomes study was undertaken from July 2014 to March 2016. A total of 75 patients were included in the study, performed by 2 investigators at 2 different sites during the study period. 3 patients were excluded from the study due to loss to follow up. The study was approved by the ethics committee at Nepean Hospital (HREC-2019/ETH01509 ID 43890)

Inclusion criteria for the study were age 21- 85 years, BMI <40, osteoarthritis of the hip, individuals physically and mentally willing and able to comply with post-operative scheduled clinical and radiographic evaluations and rehabilitation.

Exclusion criteria were active infection in the hip joint, previous total hip replacement or hip fusion of the affected hip joint, neuromuscular or neurosensory deficiency, sys-

temic disease (i.e., moderate to severe osteoporosis, Paget's disease, renal osteodystrophy), immunologically suppressed or receiving steroids in excess of physiologic dose requirements, pregnant or scheduled for a simultaneous bilateral primary total hip arthroplasty.

Demographic details, medical history, physical review, body mass index (BMI) and laboratory investigations were collected pre-operatively. Patient reported outcomes parameters were recorded and collected prospectively.

Surgical Procedure

Patients were operated on using a standard posterolateral approach. The Paragon stem and the Global cup were implanted in a cementless method according to the manufacturer's published surgical technique (Corin Group Paragon Stem System Surgical Technique).

Implant details, operative time, operative and postoperative complications were recorded. All patients received routine antibiotic (cephazolin 3 doses) and DVT prophylaxis (rivaroxaban 10 mg daily for 30 days).

Post-operatively all the patients were mobilised from the 1st post-operative day, weight bearing as tolerated under the supervision of a physiotherapist until discharge.

Patients were reviewed at 6 weeks, 6 months and two years postoperative. At each visit AQL 6D, VAS Pain, Oxford Hip Score were recorded. Post-operative X-Rays were reviewed at immediate post-operative, 6 months and two years (Table1).

Post-operative complications, limb length discrepancies and any revisions were documented.

Finally, an AOANJRR (Australian Orthopaedic Association National Joint Replacement Registry) data analysis was requested on the patient cohort to ensure they had not had a revision procedure performed at time of write up and to determine 4 year survivorship of implant study group in the registry as compared to national data for all total hip replacement implants.

Statistical methods

Adequate sample size was selected for the study. Descriptive analyses of OHS, AQL-6D and VAS pain were performed, by tabulating the median and range (min, max), and mean and standard deviation of the scores at the pre-operative and three post-operative assessments.

Graphic representations of the data included spaghetti plots of the individual trajectories over time, box-plots, and mean and error bars (standard error of the estimated mean).

Repeated measures analysis of variance (rANOVA) was then conducted, to assess the overall within-subject changes of scores over time.

Table 1 – Table showing sequential follow up visits and parameters measured

	Pre-op	Intra-op	1 wk (hospital)	Follow-up Phase		
				6 wks (+/- 2 wks)	6 mths (+/- 1 mth)	2 yrs (+/- 2 mths)
	(Not > 2 months prior to surgery)	(Day 0)	(Day 0-7)			
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Eligibility, Consent	X	-	-	-	-	-
Patient Demographics, Medical history1, Physical examination1	X	-	-	-	-	-
Concomitant Medication	X	-	-	-	-	-
Weight, Height	X	-	-	-	-	-
Laboratory2	X	-	-	-	-	-
Leg length	X	-	-	X	-	-
Operative Details	-	X	-	-	-	-
Adverse Events / Complications	-	X	X	X	X	X
AP & Lateral Radiographs	X	-	X	X	X	X
AQoL Questionnaire, Oxford Hip Score Pain VAS	X	-	-	X	X	X

Results

Out of the 72 patients included in the study, 34 were males (47.2%) and 38 were females (52.7%) with mean age 65.1 (36.6 – 83.7). Left side in 40 cases (55.5%) and right in 32 cases (44.4%). Body mass index had a mean of 29.03 (Range 18.8-39.8, SD 4.63). The age range - sex relation and side - sex relation is depicted in graphs (figure 1,2). Bone quality was assessed as Dorr type A in 14 (19.4%), type B in 51 (70.8%) and type C in 7 (9.7 %).

Implant specifications such as stem size, cup size, liner, and head sizes are depicted in series of graphs (figure 3a, b, c, d).

Mean duration of surgery was 63.1 min with range of 40-120 min. An additional procedure was required in 8 cases. Two cases required acetabular bone grafting, three patients required repair of abductor tendons and three patients required adductor tenotomy for severe contractures.

One patient required a cerclage cable for a linear crack of the calcar at broaching. The stem remained stable and the patient progressed without complication using routine post-operative physio protocol. One acetabular cup was difficult to insert due to thread difficulties with the inserter. The cup was inserted and remained stable without further

In case of a statistically significant effect in rANOVA, post-hoc paired t-tests were performed, to test which assessments were different from other assessments. These tests were adjusted for multiple comparisons with Bonferoni correction.

The cup was inserted and remained stable without further

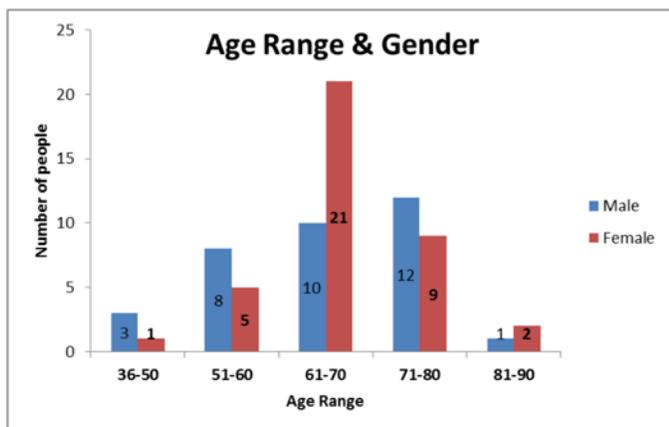


Figure 1 – Bar graph showing age range and gender

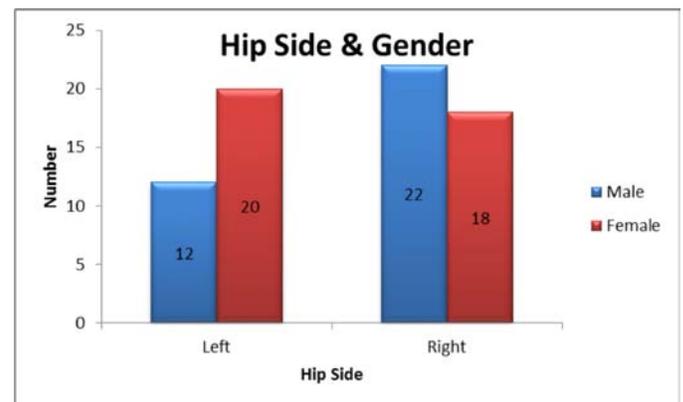


Figure 2 - Bar graph showing side and gender

Figure 3 – Series of bar graphs showing

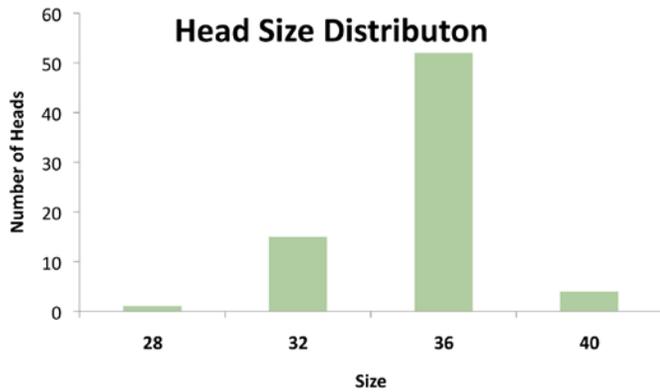


Figure 3a – femoral head size distribution

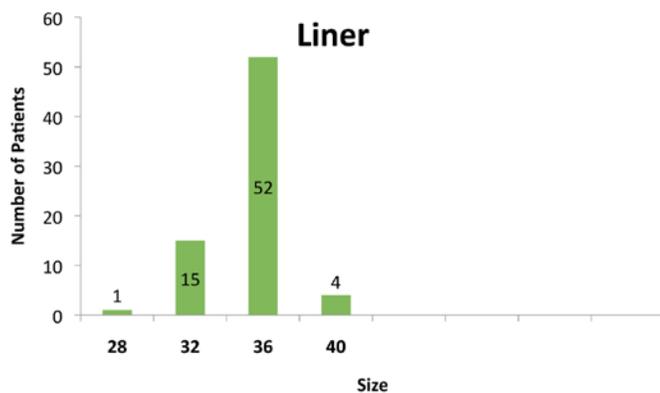


Figure 3b – Liner size distribution

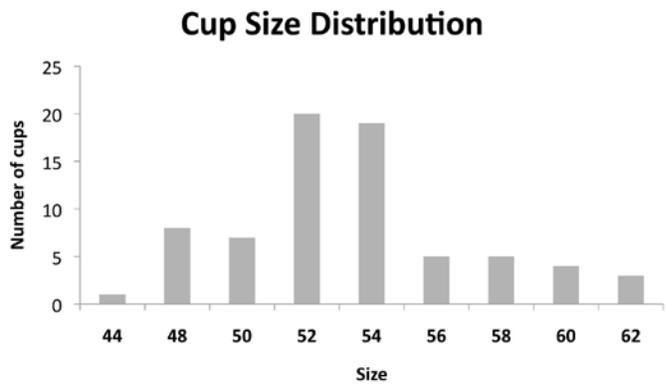


Figure 3c – Acetabulum cup size distribution

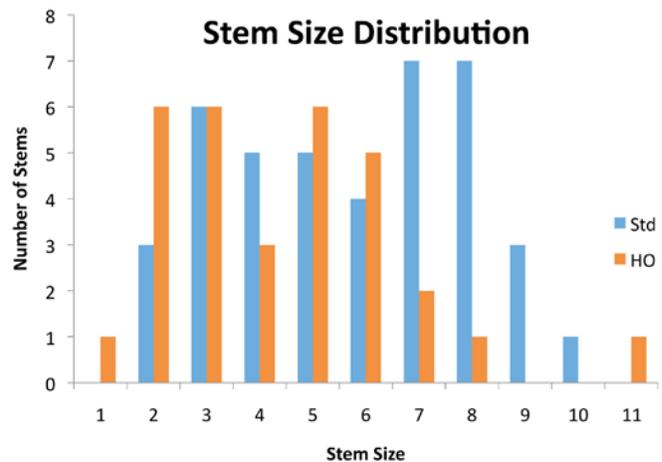


Figure 3d – Femoral stem size and offset distribution

complication.

One patient underwent a cup only revision for groin pain from psoas impingement after returning to heavy physical work within 6 weeks of surgery. The stem remained stable and left in situ. Three of the original group of patients were lost to follow-up, however no further revisions have been recorded following a data analysis by the AOANJRR. Only the one acetabular component was revised in the whole series. The revisions per 100 Observed Years of our study group is 0.40 (0.001, 2.24) as compared to 0.65 (0.64, 0.66) of all primary THAs in the registry. Also, the cumulative percentage revision rate of this implant combination in our study group at 4 years is 1.4, which is well below the average of 3 in all other THR implant combinations nationally.

Limb length at 6 weeks was equal in 65 cases (90.2%) with minimal discrepancy around 5 mm in the remaining seven cases.

Oxford Hip Score

This was measured over a period of time and is shown in table 2. Mean and error plot of individual

OHS trajectories, showing a clear upward trend from pre-op mean of 19.93 (SD 8.13 to post-op 6wks mean 33.5 (SD 8.64), 41.3 (SD 6.75) at 6 months and 42.2(SD 6.28) at 2 years. (Figure 4).

Repeated measures analysis of variance showed a statistically significant effect of time on the Oxford Hip Score, $F(3, 189) = 216.14, p < 0.0001$.

After Paired samples t-tests (with Bonferroni correction) adjusted for multiple testing, there was a statistically significant difference in the OHS from pre-op to post-op 6wks ($p < 0.0001$) and from post-op 6wks to post-op 6mths ($p < 0.0001$), but not after post-op 6mths.

Table 2 – Serial Oxford hip score mean measurement.

Time	N	Minimum	Median	Maximum	Mean	Std Dev
pre-op	72	4.00	20.00	40.00	19.93	8.13
post-op 6wks	72	9.00	35.00	47.00	33.50	8.64
post-op 6mths	72	22.00	45.00	48.00	41.83	6.75
post-op 2yrs	64	22.00	45.00	48.00	42.83	6.28

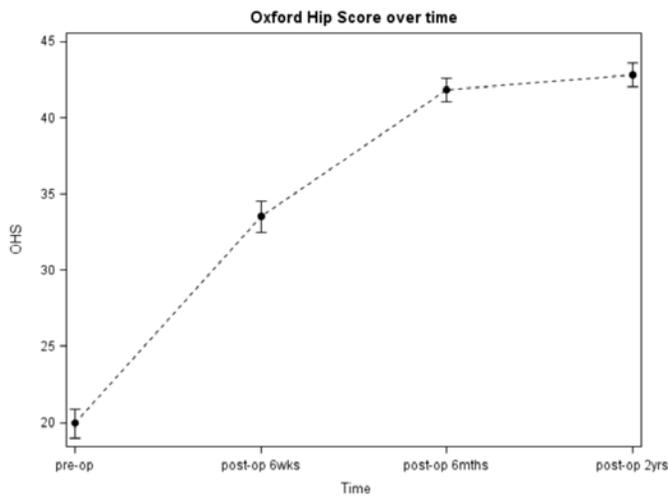


Figure 4 - Mean and error plot of individual OHS trajectories

AQoL-6D

AQoL over time changed from pre-op mean 50.51 (SD 10.80), at 6 weeks mean 38.06 (SD 9.85), at 6 months mean 34.44 (SD 9.37) and at 2 years mean 35.06 (SD 9.77).

Spaghetti plot of individual AQoL-6D trajectories, showing a general downward trend from pre-op to postoperative assessments (and a few outliers with an increase) (Figure 5).

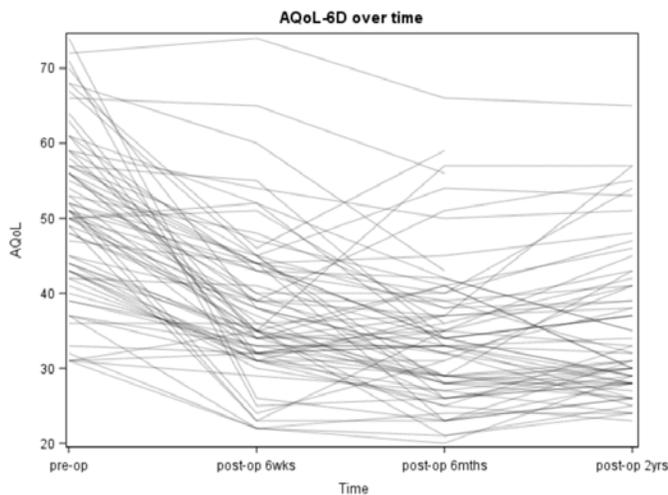


Figure 5 - Spaghetti plot of individual AQoL-6D trajectories

Box-plots of AQoL-6D, summarising the distribution of AQoL-6D at the different assessments (Figure 6).

There was a statistically significant effect of time on the AQoL-6D, $F(3, 186) = 77.80, p < 0.0001$.

After adjusting for multiple testing, there was a statistically significant difference in the AQoL-6D from pre-op to post-op 6wks and from post-op 6wks to post-op 6mths, but not after post-op 6mths.

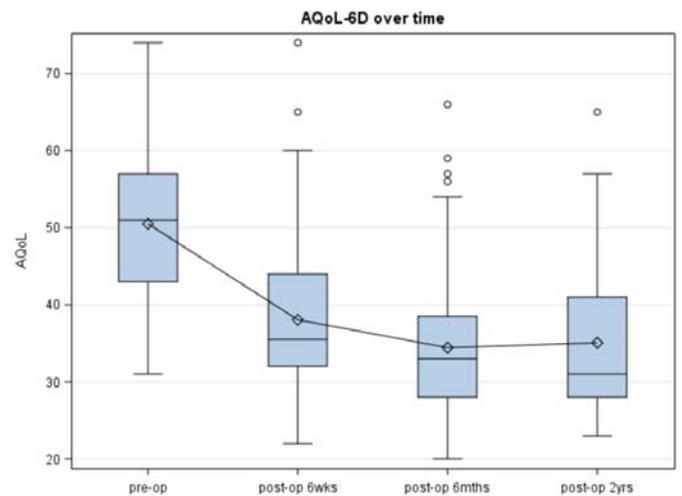


Figure 6 - Box-plots of AQoL-6D

Visual Analogue Scale for pain

VAS pain over time changed from pre-op mean 64.47 (SD 21.48), at 6 weeks mean 16.21 (SD 21.64), at 6 months mean 10.49 (SD 12.80) and at 2 years mean 14.86 (SD 21.06)

Box – plot showing VAS pain trajectories, showing a clear downward trend from pre-op to post-op 6wks and a plateau in the following postoperative assessments (and a few outliers with an increase) (Figure 7).

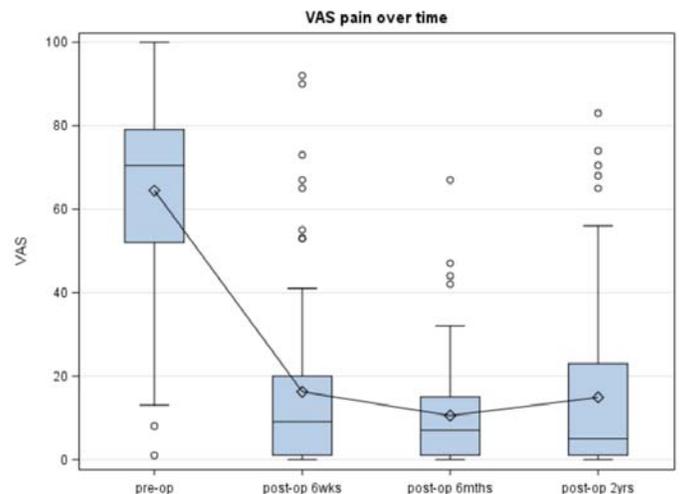


Figure 7 - Box – plot showing VAS pain trajectories

There was a statistically significant effect of time on VAS pain, $F(3, 168) = 152.49, p < 0.0001$.

After adjusting for multiple testing, there was a statistically significant difference in VAS pain from pre-op to post-op 6wks ($p < 0.0001$), but no differences in the subsequent follow-up assessments ($p < 0.1767, p = 0.4103$)

Discussion

Total hip arthroplasty designs have evolved over last few decades. Cementless femoral stem design has evolved over the last few decades with numerous features common to successful stems. Fully HA coated, dual taper, titanium ingrowth or ongrowth stems have become standard of care. Durable fixation can be expected for many years and long-term loosening is rarely seen in successful combination of stem, cup and bearing surface.



Figure 8 – Post operative X ray of Paragon and Global combination



Figure 9 – Photograph of implant showing; 9a - AP view showing Design features; 9b - Lateral view showing design features

The combination of Paragon stem and Global cup (Figure 8) incorporates proven features of successful implants. The unique feature of lateral tension grooves and progressive neck dimension with dual offset options adds potential benefits in obtaining excellent leg length and offset control, whilst minimising trochanteric osteoporosis (Figure 9 a,b).

Thigh pain has been reported in cementless stems. Gielis et al [11] compared mid-thigh pain results using short stem design vs wedge design. They reported lower rates of mid-thigh pain using short stems 14% as compared to 24% in wedge design. In our study at two year follow-up no patient complained of mid-thigh pain. This suggests that durable fixation and minimal stiffness mismatch is a feature of the clinical use of this stem.

Extensive work has been done on de-

sign to reproduce normal physiological loading of the femur and a patent design of incorporation of tension grooves on the lateral aspect of the stem to mimic lateral tensile trabeculae present around greater trochanter (Figure 10). Also, there are medial compressive grooves presently seen in many successful designs to reproduce compressive trabeculae around calcar region.

Boxy cross section of the implant along with vertical ribs on the stem provides rotational stability. Polished offset distal tip prevents distal impingement of the stem tip on cortex and subsequent thigh pain.

Periprosthetic fracture has been reported in cemented and cementless designs, with some morphological differences between the two.

Common fracture patterns in cementless stems is Vancouver 2B. To date there have been no post-operative periprosthetic fractures in this series. Colacchio et al [12] have shown better results of newer wedge design with medial curvature and lateral distal offset design in terms of periprosthetic fractures.

The Global Acetabular Cup is a cementless, press-fit, primary hip arthroplasty acetabular component. The design is a highly porous hemispherical Titanium alloy with HA coating. The Global cup is designed to engage either Delta ceramic or highly crosslinked polyethylene (HX-LPE) liners. It has a circumferential locking groove and anti-rotation feature which adds locking support for the polyethylene liner. There is provision for 3 dome screws which may be placed at surgeon discretion. Advantage of placement of screw in quadrant fashion as described by Wasielewski et al [17] is well known and provides option in special circumstances.

Eskelinen et al [13] in their study from the Finnish Arthroplasty Register reported good endurance of press-fit porous-coated cups against aseptic loosening in young patients. They have reported few cases of revision in their study due to use of ultra-high molecular weight polyethylene and not highly cross-linked polyethylene. In our study there has been no revision due to loosening. One case was revised due to psoas impingement and the new acetabular component was repositioned. This implant specifically uses either highly cross-linked polyethylene or ceramic liners. There are multiple studies which have shown good long-term results with the hemispherical design [14,15].



Figure 10 – Photograph of paragon stem showing lateral tensile grooves

In literature few designs have shown higher incidence of liner dissociation and fracture due to use of peripheral lugs or thin liner rims [18,19]. The Global cup uses a circumferential locking groove for snap-fit, along with taper design of the cup to enhance liner engagement. Similar designs have shown good results [20].

In this study, early clinical and radiological results of this implant combination are promising. The demographics of the patients in this series is consistent with general hip arthroplasty. A broad age and BMI range is represented with similar male/female distribution.

Revision rate in this study is quite low and only in 1 case there was revision required that to because of psoas tendon impingement. Overall survivorship of implant in this early result is 98.6% with revision for any reason taken as endpoint and 100% implant failure taken as end point.

Tetsunaga et al [21] in their study of early outcome of Summit stem in Japanese population has shown comparable results to our study with overall survivorship of implant as 100 percent, but in their study there are 3 patients of thigh pain, which is attributed to distal fixation of the stem. Due to optimal length of our stem and distal offset design, in this study there was no case of thigh pain.

Oxford hip score was used in this study as a measure of clinical outcome and there is marked improvement in the score from pre-operative mean of 19.3 which is severe arthritis to 42.83 at 2-year follow-up. These results are statistically significant $p < .0001$. This is consistent with other well performing implants. The point to note is that there is not much difference between the 6 month and 2-year scores. This may illustrate that overall result of the implant is good once the stem is well fixed. Although these are early results and further follow up is required.

AQoL 6d questionnaire was used to assess the improvement in quality of life. It takes approximately 2-3 minutes to complete which patients find easy [22,23]. The scores improved statistically significantly from pre-op mean of 50.51 to 34.44 at 6 months post-op and remained almost similar at 2 years. This followed the trend of Oxford hip scores and results are encouraging.

VAS is a universal method to grade amount of pain experienced by the patient. VAS score changed statistically significantly from Pre-op mean 64.47, SD 21.48 to 6 weeks post-op mean 16.21, SD 21.64. The score generally decreased over a period of time. But there were few outliers, one patient complained of pain in knee, which lead to increase in VAS score.

Our current AOANJRR data analyses obtained in September 2019, demonstrates implant combination of Paragon stem & Global cup has excellent results with 100% survival of the Paragon stem and 98.7% of Global cup at

4 years. One case of cup revision for this series was due to groin pain from psoas impingement. The cumulative percentage revision rate of this implant combination is 1.4 at 4 years, which is well below the national average of 3 for all other THR combinations.

Our study also has its shortcomings. Whilst the sample size of 72 patients is good, higher numbers and longer follow-up would enhance the validity of the results. The cases were operated on by two design surgeons and further analysis of other case series or registry data will add to broader outcomes. Third this is not a randomised controlled trial. Future studies are required which are randomised controlled trials with larger sample size, longer follow up and heterogeneous group of patients and surgeons.

Conclusion

This implant combination of the Paragon stem and the Global cup has shown promising early results with early follow up of a minimum of 2 years, with a 100% survivorship of the stem and 98.7% survivorship overall for any reason and is a good cementless option in THA.

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AUTHOR DISCLOSURES

- The authors declare that there is no conflict of interest in connection with this submitted article.

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