

Incorporation of screwless press-fit acetabular cups and disappearance of polar gaps

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ABSTRACT

Background: Uncemented press-fit acetabular cups without screws rely on the elastic recoil of the bone for its primary stability and tend to leave polar gaps with its use. The clinical significance of these gaps and the functional outcome of the patients with polar gaps is evaluated in this study.

Methods: This comparative analysis was done on 224 cementless primary THA using Deltamotion® Hip System from January 2010 to December 2017. Patients were divided into two groups based on the presence or absence of polar gaps on immediate post-operative radiographs. Patients were observed for their clinical, radiological and functional outcomes with regular follow ups. At each follow-up, patients' clinical outcome was evaluated using the Harris Hip Score (HHS) and Patient Reported Outcome Measures (PROMs).

Results: 14 of 224 patients (6.25%) demonstrated polar gaps in their immediate post-operative radiographs. No statistically significant difference was noted in the final mean HHS between the two groups. The polar gaps ranged from 0.5 to 1.8 mm (mean-1.09 mm). None of the patients showed progression of the polar gaps. All patients showed bony ingrowth into the gaps at a mean of 8.57 months.

Conclusion: The presence of polar gaps in the immediate post-operative radiographs are not of a major clinical significance provided a secure peripheral fit is achieved intra-operatively. The functional outcome and rehabilitation in such patients is at par with that seen in the patients without polar gaps. Disappearance of these polar gaps is a rule rather than an exception.

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1. Introduction

Total Hip Arthroplasty (THA) is a well established orthopaedic procedure for the control of pain and debility associated with avascular necrosis of femoral heads and hip arthritis. With an increase in the number of young patients being diagnosed with such debilitating hip conditions during their productive years of life, the use of THA in them is on the rise.¹ The use of cemented prosthesis in such young active individuals has led to early failure and higher revision rates.^{2–4} Hence since its inception in 1983, uncemented fixation has gained popularity for young patients.⁵

Higher physical activity in young patients necessitates use of prosthesis with a greater range of motion. Limited range of motion

is a norm with conventional THA. Hence the use of large head prosthesis is of utmost importance in young patients to ensure optimum functional benefits of the surgery.⁹

Early aseptic loosening and higher revision rates are seen in uncemented acetabular cup as compared to the uncemented femoral stem.⁶ Lack of primary stability and increased micro motion at the bone metal interface is attributed to the early failure.⁷ Such a fixation leads to poor bone ingrowth and higher fibrous tissue at the interface. Cups with fixation fins and pegs were introduced initially to achieve primary stability. These however led to inadequate seating of the cup in the acetabulum.¹¹

Trans-iliac screw fixation or press fit cup implantation have been two main techniques to achieve the primary stability of the acetabular cup. The former is however associated with complications like iliac medial wall penetration, vascular injuries, fretting wear, third party wear, outer polyethylene surface wear and screw fractures.⁸ These complications can be obviated with a press fit unscrewed cup.

Press fit cups rely on the elastic recoil of the bone for its primary

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stability. There are reported incidences of polar gaps with the use of press fit cups.^{6,10} These cups usually show a good peripheral fit but some gap between the bone metal interface at the dome.

The clinical significance of these gaps, their effects on the primary stability of the acetabular cups and the outcome in terms of patient function is unknown. The effects of these gaps on loosening are not well understood. It is due to this reason that the use of press-fit cups without supplementary fixation is still not very popular. Through this paper we aim answer these questions and determine the significance of these polar gaps. We also aim to determine the short term and mid term outcomes of these hip replacement.

2. Material and methods

This retrospective analysis was done on 224 cementless primary THA using Deltamotion® Hip System. These cases were performed at a single tertiary care centre in Mumbai, India by a single surgeon from January 2010 to December 2017. All cases requiring primary THA for varied reasons in whom Deltamotion® Hip System was used were included in the study. Patients followed up for less than 12 months were excluded.

Patients were divided into two groups based on the presence or absence of polar gaps seen on the immediate post-operative radiographs. These cases were observed for their clinical, radiological and functional outcomes with regular follow up on a monthly basis for the first two years and annually thereafter. In presence of radiological evidence of cup loosening immediate revision surgery was done.

The surgery was performed using the Hardinge antero-lateral approach. After determining the adequate cup size by trialling, the Deltamotion® cup, which is a titanium alloy shell with a pre-assembled CeramTec BIOLOX® delta ceramic liner (DePuy, Synthes) was press-fit into the acetabulum without any supplementary fixation. The acetabulum was reamed to one mm less than the final cup implanted. The stability of the cup was determined by complete absence of horizontal, vertical or rotational movements ensuring a tight peripheral fit. The Biolox Delta (DePuy, Synthes) femoral head and the uncemented Corail® femoral stems (DePuy, Synthes) were used for all cases. The femoral head size was determined as given in Table 1.

Post-operatively patients were made to sit up, stand and walk with a walker on the same day of surgery provided the patients were medically fit. Hip exercises and stair climbing were initiated from the next day and patients were discharged between days three and five post-operatively.

At each follow-up, the patients' clinical outcome was evaluated using the Harris Hip Score (HHS) which was graded as given in Table 2. The patients' ability to squat and sit cross-legged was assessed using Patient Reported Outcome Measures (PROMs).

Standard true size antero-posterior view of pelvis with both hips and frog leg lateral views were obtained at each follow-up and were evaluated using IMPAX PACS tools. Acetabular cup positioning,

Table 2

Grading of the patients according to the post-operative Harris Hip Score on the final follow-up.

Grading	HHS
Excellent	90–100
Good	80–90
Fair	70–80
Poor	<70

polar gap measurements, changes in the cup position and osteolysis around the cup were noted. The criteria for radiographic failure included: radiolucencies greater than 2 mm in any zone, cup migration more than 4 mm or change of inclination more than 4° compared to the immediate post-operative radiograph or radiographic evidence of osteolysis around the implant.

A close radiographic assessment of the polar gaps was done at each follow-up. Any increase in the gap size was noted. Loosening or migration of the cup was recorded. Any evidence of the bony ingrowth into the gap was checked for in the radiographs.

The data was analysed using the SAS statistical software, Version 10 (SAS Institute Inc.). The continuous variables were summarized using number of observations, mean and standard deviation with ranges. Categorical values were described in terms of frequencies and percentages. The change in average pre and post-operative HHS was estimated by student t-test. All p-values were reported based on two-sided significance test and all the statistical tests were interpreted at 5% of significance level.

3. Results

Of the 224 patients included in the study, 14 patients (6.25%) demonstrated polar gaps in their immediate post-operative radiographs. The demographics of patients in both the groups are shown in Table 3.

Avascular necrosis of the femoral head was the most common indication for surgery accounting for 64.28% cases followed by ankylosing spondylitis (18.30%), rheumatoid arthritis (14.29%) and fracture neck of femur (3.13%).

The median prosthesis sizes used in this study were as follows; femoral head size, acetabulum cup size and femoral stem size 40 mm, 52 mm and 9 mm respectively. Using large size heads the range of motion achieved in all our patients was 120° flexion, 10° extension, 25° adduction, 40° abduction, 20° internal rotation and 40° external rotation. All the patients were able to squat and sit cross-legged comfortably.

The mean HHS was recorded pre-operatively and post-operatively at six weeks and at the final follow-up. These values are shown the following graph (Fig. 1).

The polar gaps seen in all 14 of our patients ranged from 0.5 to 1.8 mm with a mean of 1.09 mm. The distribution of these gaps in the patients is shown in Fig. 2.

In our series, none of the patients showed any progression of the polar gaps, on the contrary all patients showed bony ingrowth into the gaps as demonstrated by disappearance of the gap in the

Table 1

Corresponding sizes of the acetabular cups and femoral heads for the Deltamotion® Hip System.

Acetabular component size (in mm)	Corresponding femoral head size (in mm)
42 and 44	32
46 and 48	36
50 and 52	40
54 and 56	44
58 and above	48

Table 3

Comparative demographics of the patients seen in the current study.

Demographics	Polar gap group	No gap group
Number of cases	14	210
Males:Females	5:9	143:67
Mean age	51.29	50.98
Right hip involvement	57.14%	55.24%
Follow up duration (months)	67.86 (40–94)	58.92 (14–89)

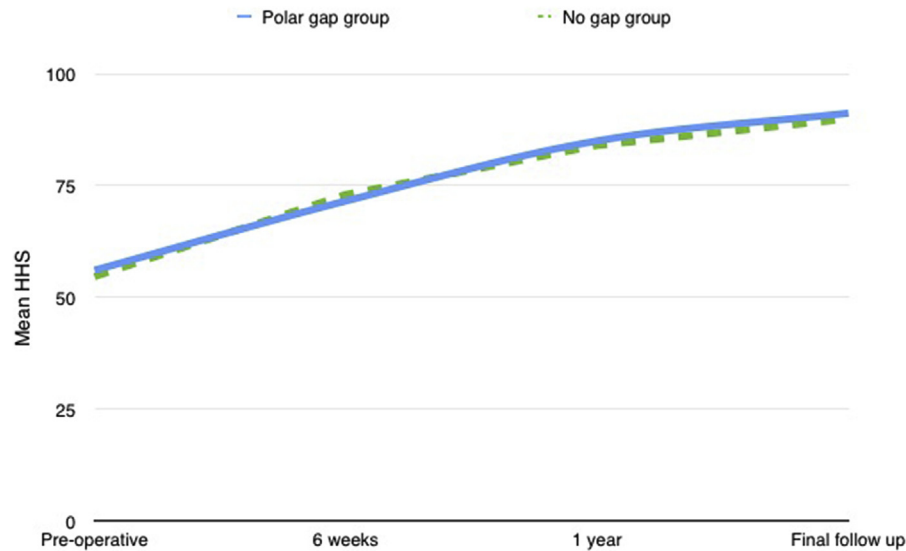


Fig. 1. Graph comparing the HHS of the polar gap and the no gap groups.

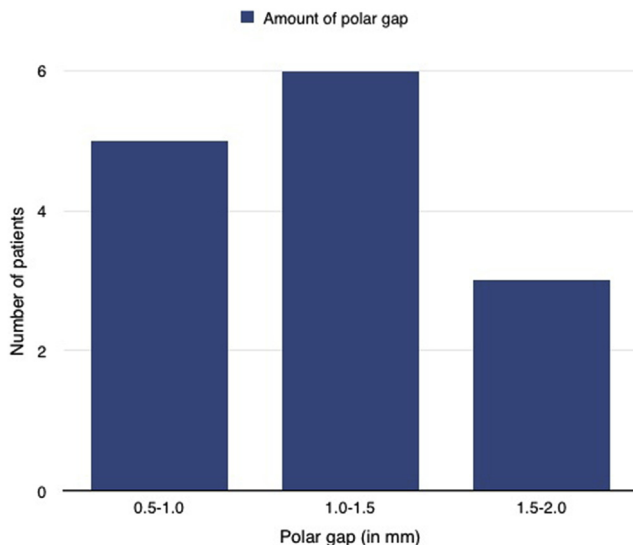


Fig. 2. Bar diagram showing the distribution of the polar gaps in the patients.

follow-up radiographs. The time required for complete obliteration of the polar gap ranged from 5 to 14 months with 8.57 months being the mean duration. Complete bony ingrowth was seen in four patients (28.57%) within the first six months and in 13 patients at the end of one year (92.86%). Only one patient (7.14%) showed complete bony ingrowth at 14 months.

No patients showed any evidence of cup loosening or migration. No functional deterioration was observed in any case and none of the prostheses were revised.

Given below are the radiological images of representative patients from our series (Figs. 3 and 4).

4. Discussion

Restriction of the hip range of motion is a major concern for young patients following a THA. The use of large head THA prostheses are capable of restoring a near full range of hip motion.⁹ Total hip prosthesis like Deltamotion[®] by the virtue of a ceramic

lined metal backed acetabular cup eliminates the need of an extra liner allowing a larger size head to be used. The trade-off to this however, is the lack of holes in the cup through which the bottoming-out of the cup can be assessed intra-operatively. The polar gaps occurring due to the press fit insertion technique and the cup geometry hence cannot be assessed due to lack of screw holes.

This mid-term retrospective comparative study was conducted to determine the functional significance of these polar gaps and to observe if any bony ingrowth occurs in these gaps. In our study, the incidence of polar gaps was found to be 6.25%. The outcome of these patients was compared to the outcome of patients in whom we used the same implant and no polar gaps were seen.

As the horizontal, vertical and torsional stability of the cup was ensured intra-operatively, the patients with polar gaps were mobilised on day one post-operatively. The post-operative mobilisation or physiotherapy protocol was the same in both groups. The hip range of motion achieved by patients in both the groups was similar. These findings suggest that peripherally stable cups with polar gaps do not indicate a loose or an improperly fitted implant nor do they affect the functional outcome of patients in any way.

In a patient specific finite element model study by O'Rourke et al.⁶, CT scan models of 103 cadaveric hemipelvises were matched with models of Pinnacle[®] acetabular cups. Polar gaps were found in all the hemipelvic models ranging from 284 to 1112 μ m. A regression analysis of these polar gaps and the composite peak micro-motion occurring during the gait cycle indicated no relationship between the two suggesting that polar gaps did not indicate a loose implant. This is in accordance with the findings in the current study.

Table 4 compares the HHS of both groups in this study and the HHS seen in the study by Schmalzried et al.⁸ and Pepe M et al.¹⁴. The evaluation of the pre-operative and the post-operative HHS demonstrated a significant improvement (p value-0.001) in the HHS post-operatively in both the groups. There was a steady improvement in the HHS from the 6th week follow up to the last follow up signifying sustainable results over a mid-term (>5years follow-up). No significant difference was seen in the HHS between the two groups. The six week HHS seen in this study was better than that seen in the series published by Pepe M et al.¹⁴ who have reported a six week mean HHS for screwless uncemented acetabulum of 60. The scores seen in the study by Schmalzried et al.⁸ were

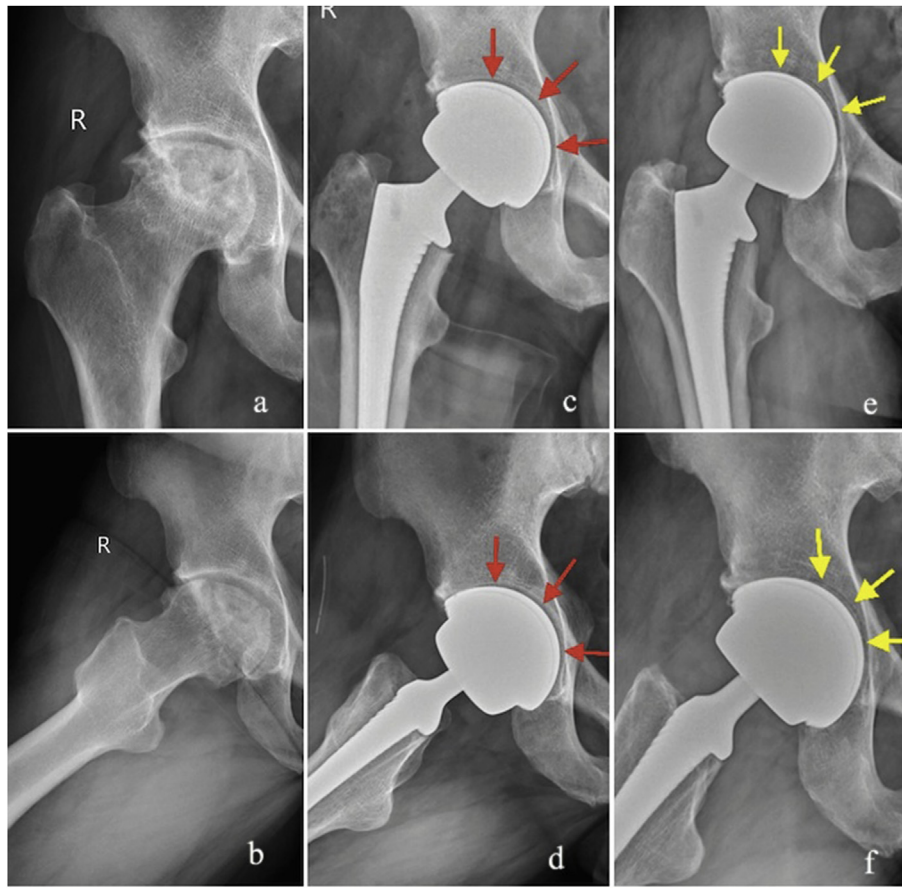


Fig. 3. Radiographic images of a representative patient (a) pre-operative AP view (b) pre-operative frog leg lateral view (c) immediate post-operative AP view (red arrows showing dome gap) (d) immediate post-operative frog leg lateral view (red arrows showing dome gap) (e) 10 month post-operative AP view (yellow arrows showing bony ingrowth into the gaps) (f) 10 month post-operative frog leg lateral view (yellow arrows showing bony ingrowth into the gaps).

comparable to the current study.

Polar gaps seen in this study ranged from 0.5 to 1.8 mm with 1.09 mm being the mean gap size. In an animal study carried out by Sandborn et al.¹² they found that the initial apposition was not necessary for bony ingrowth onto a porous coated implant. They also concluded that gaps up to 2 mm disappeared eventually by bone ingrowth into the implant. In accordance to their study, the polar gaps seen initially on the post-operative radiographs in this study disappeared with subsequent follow-up.

A five year radiological analysis of press-fit screwless Harris Galante porous acetabular cup by Schmalzried et al.⁸ indicated a 36.07% incidence of polar gaps which is a bigger incidence than 6.25% reported in this study. According to them, these gaps were not associated with progressive radiolucencies. Gaps in this study disappeared only in 34.09% patients while we report a 100% disappearance of these gaps. The time taken for these to disappear was 2 years while the current study showed that all gaps but one disappeared by the end of one year and one gap disappeared by the 14th month.

In a long term follow-up study by Udomkiat et al.¹³ 110 primary total hips done using uncemented screwless acetabulum press-fit into the socket were analysed. 34% hips showed polar gaps on the initial post-operative radiographs which decreased over time. These gaps were not associated with progressive radiolucencies. Their study however does not evaluate functional outcomes of the patients with polar gaps compared to patients without polar gaps.

F.Y. Ng et al.¹⁰ in their study on the effects of cement-less

acetabular component inserted without screws on immediate weight bearing found polar gaps in 29.73% hips (22 of 74 hips) of which all but one disappeared at the final follow up. These gaps were not associated with radiolucent lines or implant migration at subsequent follow-up. Their study is limited by lack of direct comparison with patients who did not show polar gaps on the immediate post-operative radiographs.

This study is unique in terms of being the only study focusing on the functional outcome of patients with polar gaps and a direct comparison with the patients without such gaps in whom same implant has been used and were operated by the same surgeon. Our study has a short coming in terms of it being a mid-term analysis. A long term study on prosthesis loosening due to polar gaps remains to be seen.

5. Conclusion

Based on our current study and the review of literature we conclude that presence of polar gaps seen in the immediate post-operative radiographs are not of a major clinical significance provided a secure peripheral fit is achieved intra-operatively. With a good operative technique the incidence of these gaps can be minimised though not eliminated. The functional outcome in such patients is at par with that seen in the patients without polar gaps and such an outcome is sustainable over a mid-term follow up. These patients do not need any alterations in their post-operative rehabilitation protocol. Disappearance of these polar gaps is a

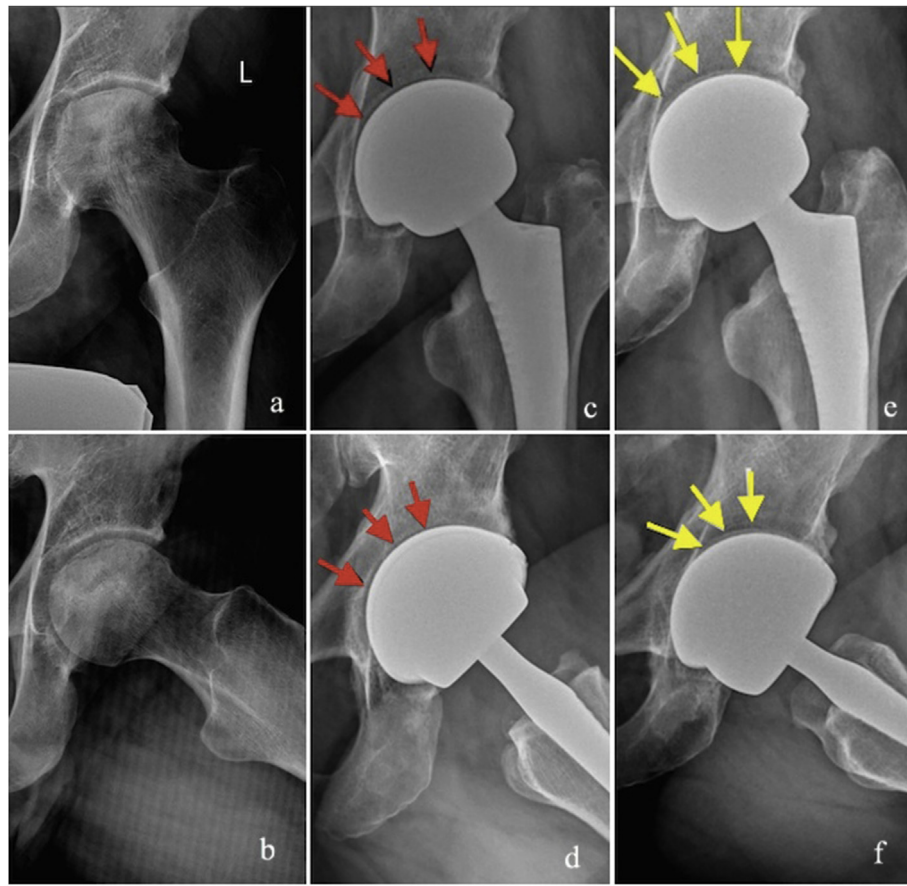


Fig. 4. Radiographic images of a representative patient (a) pre-operative AP view (b) pre-operative frog leg lateral view (c) immediate post-operative AP view (red arrows showing dome gap) (d) immediate post-operative frog leg lateral view (red arrows showing dome gap) (e) Nine month post-operative AP view (yellow arrows showing bony ingrowth into the gaps) (f) Nine month post-operative frog leg lateral view (yellow arrows showing bony ingrowth into the gaps).

Table 4

Comparison of Harris Hip Scores at six weeks and at final follow up.

Harris Hip Scores	Polar gap group	No gap group	Schmalzried et al. ⁸	Pepe Met al ¹⁴
Pre-operative	56.07 ± 6.31	54.66 ± 6.42	51	35
Post-operative (six weeks)	71.56 ± 5.02	73.01 ± 4.89		60
Post-operative (last follow-up)	91.22 ± 4.04	89.95 ± 4.32	92	85

rule rather than an exception. Thus polar gaps are of no clinical significance to the patients provided the cups have a good peripheral fit and are torsionally stable. Such prostheses provide the benefits of a large head and a near-normal range of motion post-operatively which is a great advantage for young active patients.

Disclosure

No conflict of interest to be disclosed.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jcot.2018.11.012>.

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