Clinical evaluation of a novel press-fit acetabular cup using “Ein-Bild-Roentgen-Analysis” (EBRA): A positive short-term prognosis

B.A. Ishaque^{a,*}, J. Wiecek^a, C.A. Fonseca Ulloa^b, J.B. Seeger^a, G.A. Ahmed^a, M. Rickert^a, A. Jahnke^b

^a Department of Orthopaedics and Orthopaedic Surgery, University Hospital Giessen and Marburg (UKGM), Klinikstrasse 33, 35392, Giessen, Germany

^b Laboratory of Biomechanics, Justus-Liebig-University Giessen, Klinikstrasse 29, 35392, Giessen, Germany

ARTICLE INFO

Keywords:

Total hip arthroplasty
Acetabular cups
Press-fit system
Migration
Ein-Bild-Roentgen-Analysis (EBRA)
Epidemiologic factors

ABSTRACT

Introduction: Demographic change and demand for high quality of life lead to increasing implantation numbers. Aim of this study was to compare the Plasmakit® cup to Allofit® and Plasmacup®.

Methods: The study included 174 patients who had received 33 Plasmacup®, 68 Allofit® and 73 Plasmakit® cup implants. These were reviewed postoperatively, after 6 months control and after 12 months.

Results: No significant progressive migration could be discovered in any of the cup systems. At each follow-up the cups showed nearly constant values.

Conclusions: All examined acetabular cups showed excellent migration behavior within the first 12 postoperative months.

1. Introduction

Demographic change and demand for high quality of life lead to increasing implantation numbers with over 1,000,000 primary total hip replacements worldwide.¹ At the same time, however, the number of replacement surgeries mostly due to aseptic loosening is increasing,² which in turn raises the demands for a more bone-saving primary surgery to achieve a better clinical outcome even after revision.³ Due to the high revision rate of 75.3%,² it is absolutely necessary for manufacturers to constantly improve their implants. These improvements may result from the development of novel anchoring mechanisms, novel bioactive coatings, new surface structures as well as from novel prosthetic designs. Then, in order to quantify the advantages and disadvantages of these newly developed – in this case – acetabular cup systems, *in vitro* primary stability analyses may be conducted prior to market launch to obtain statements about primary cup stability^{4–6} and to determine its prospective longevity. Though, such preclinical *in vitro* studies are often more expensive and labor-intensive than clinical trials.

So, very often new implants are directly used in everyday clinical practice immediately after their approval without having been tested preclinically in *in vitro* studies, since in accordance with EU Directive 93/42/EEC the technical characteristics of the implant are known and existing clinical data are sufficiently available. Thus, a renewed clinical trial often is considered superfluous. Ultimately, early statements

concerning a positive clinical outcome can usually only be confirmed by time-consuming retrospective or prospective clinical studies in which early migration behavior of the acetabular component is measured. One validated relatively cost-efficient and quick clinical method for early prediction of future performance of acetabular cup systems is the “Ein Bild Roentgen Analyse” (EBRA).^{7–9} Therefore, the objective of this retrospective clinical study was to compare the migration behavior of the more recent Plasmakit® cup, introduced in 2012, to the cup systems Allofit® and Plasmacup® with a longer market presence via EBRA-CUP within a short-term radiological follow-up period of 12 months as it is to be expected that the biologic integration of the cup implant into the bone occurred prior to the one-year control.¹⁰ Besides, we exploratively investigated predefined possible migration influencing epidemiologic factors like age, sex, bearing couple, indication for surgery, cup/stem combination or body mass index.

2. Patients and methods

2.1. Demographic data

After receipt of a positive ethics committee vote (file number 06/16), between January 2007 and December 2014, 300 patients which were treated with a total hip replacement (THR) were recruited continuously. Inclusion criteria were at least three consecutive

* Corresponding author.

E-mail address: Bernd.Ishaque@ortho.med.uni-giessen.de (B.A. Ishaque).

<https://doi.org/10.1016/j.jor.2020.03.059>

Received 25 March 2020; Accepted 28 March 2020

Available online 30 March 2020

0972-978X/ © 2020 Professor P K Surendran Memorial Education Foundation. Published by Elsevier B.V. All rights reserved.

Fig. 1. Illustration of the examined acetabular cups Allofit® (left), Plasmacup® (middle) and Plasmafit® (right).

radiographic follow-up examinations, in the form of plain anterior-posterior X-ray images of the entire pelvis for at least 12 months.

2.2. Implants

The cementless press-fit acetabular cups examined in this study have on the one hand already been established for decades (Plasmacup® (BBraun, Aesculap, Tuttlingen, Germany) and the Allofit® cup (Zimmer Germany GmbH, Freiburg, Germany)) and on the other hand only been used since 2012 (Plasmafit® cup (BBraun, Aesculap, Tuttlingen, Germany)). The implants used were exclusively press-fit cups causing an equatorial press-fit situation which results in primary stability. The Allofit® cup has a macrosurface structure of wrought titanium alloy (Protasul®-Ti). The Plasmacup® cup has a microsurface structure made of a Plasmapore® coating with a porosity of 40%. By contrast, the Plasmafit® cup consists of a macro and micro surface structure. Here, too, we find a Plasmapore® coating with a porosity of 50% and a fine-tooth geometry (Fig. 1).

2.3. Radiological examination

After surgery, the collective was followed-up at times t_1 = postoperatively, t_2 = 6 months control and t_3 = 12 months control and X-rays of the pelvic area were taken. EBRA.CUP (University Innsbruck, Innsbruck, Austria)¹¹ was used to measure any progression of the anteversion and inclination angles of the acetabular cups. Reference points here were anatomical landmarks such as the foramina obturata, the symphysis joint, the transition from the last lumbar vertebral body to the first sacral vertebral body and the lateral boundary of the opening of the lesser pelvis. The prosthetic head served as calibration point. Progressive migration behavior of the cup components depending on the anteversion and the inclination angles were then calculated by the system using the marked ellipse (red arrow, Fig. 2).

This measuring method is based on a comparability algorithm of the geometric evaluation of the anatomical landmarks and their projections in a series of images which correspond to the observation period. Images of the series which are not considered comparable by the program are excluded by the program itself.¹² The EBRA-CUP software indicates an accuracy of ≈ 1 mm.^{9,13,14}

2.4. Statistics

Data are presented as mean values with respective standard deviations. A possible progressive migration behavior of the acetabular cups was determined via the difference (Δ) in terms of inclination (ΔI) and anteversion (ΔA) angles between follow-up controls t_1 and t_3 . Statistical evaluation was performed using SPSS Version 22.0 (IBM Corporation, New York, USA). In order to analyse a possible loosening behavior of the individual cups over the 12-month study period and to correlate them with the epidemiologic factors, a MANOVA (multivariate analysis of variance) was applied. A p-value < 0.05 was considered statistically significant. Pairwise comparisons of the three

Fig. 2. Entire view of the pelvis in the EBRA-CUP software with marked landmarks and marking of the hip prosthesis.

follow-up dates and the epidemiologic factors were investigated with the LSD Post-HOC test and the alpha level was adjusted based on multiple testing by means of the Bonferroni correction.

3. Results

From initially 300 patients, 227 patients could not be included due to lack of follow-up, ineligible views of the entire pelvis, treatment on both sides or due to programmatic exclusion. Therefore, the study included 177 patients, 86 women whose mean age was 61.9 ± 8.7 years (40–77 years) and 88 men whose age was 56.9 ± 10.6 years (18–78 years). 33 patients received a Plasmacup® cup, 68 patients received an Allofit® cup and 73 patients a Plasmafit® cup. The mean age of the patients was 59.4 ± 10 years (18–78 years).

3.1. Epidemiological factors

The predominant indication for surgery was primary coxarthrosis with 68.4%. Secondary coxarthrosis due to prior hip dysplasia applied to 14.9% of the patients and for 6.9% of the patients femoral head necrosis was the indication for surgery. 0.6% of the indications were due to epiphysiolysis capitis femoris and 9.2% to various other diseases, such as morbus Perthes. 55.2% of the bearing couples were ceramic on ceramic (CoC) and 44.8% ceramic on polyethylene (CoP). The age distribution for Plasmacup® was 55.2 ± 10.1 years (18–71 years), for Allofit® the average age was 64.4 ± 8.5 years (42–78 years) and for the Plasmafit® cup on average 56.6 ± 9.4 years (29–77 years). The body mass index showed the largest proportion of patients, 69 patients, in the range of pre-obesity (39.7%). Despite no known bias regarding

Fig. 3. Anteversion angles at follow-ups t_1 , t_2 and t_3 .

the BMI, the Allofit® cup was most frequently implanted in the higher BMI classifications (BMI > 30). The Plasmafit® cup was primarily used in the ranges of normal weight (BMI 18.5–24.9) and in the pre-obesity patients (BMI 25–29.9). None of the selected epidemiologic factors did significantly affect the migration behavior of the three acetabular cups during any of the follow-up controls t_1 – t_3 (p-value > 0.05).

3.2. Migration behavior

As already described, the anteversion and inclination angles served for migration analysis of the individual cups. The results indicate relative differences concerning the mean values for the anteversion angles, but not concerning the inclination angles of the individual cups (Fig. 2). For the Plasmafit® cup, the anteversion angle remained averaged at $17.3^\circ \pm 6.2^\circ$ (range: 4.5° – 38.7°) at all follow-ups. For the Allofit® at $26.6^\circ \pm 6.2^\circ$ (range: 5.8° – 39.7°) and for the Plasmacup® cup at $11.4^\circ \pm 4.9^\circ$ (6.4° – 31.8°). Thus, the general mean anteversion angle was $19.7^\circ \pm 8.3^\circ$ (range: 4.5° – 39.7°) (Fig. 3).

The inclination angles for all three cups remained almost unchanged at an average of $41.1^\circ \pm 6.1^\circ$ within a range of 26.1° – 60.7° (Fig. 4).

Fig. 4. Inclination angles at follow-ups t_1 , t_2 and t_3 .

Table 1

List of the ΔI and ΔA as well as the associated p-values regarding the three examined press-fit cup systems.

cup	ΔA t1/t3	p-value	ΔI t1/t3	p-value
Plasmacup®	-0.1 ± 1.7	1.00	0.6 ± 2.8	0.73
Allofit®	-0.2 ± 1.7	1.00	0.2 ± 2.6	0.74
Plasmafit®	-0.3 ± 1.2	0.38	0.0 ± 1.6	1.00

In none of the three hip cups examined, an increased change or progression of the inclination angle or the anteversion angle could be demonstrated for any follow-up examination. The Plasmacup® cup inclination angle remained nearly unchanged with ΔI t1/t3 of only $0.6^\circ \pm 2.8^\circ$ and for ΔA t1/t3 of only $-0.1^\circ \pm 1.7^\circ$. The Allofit® cup showed a ΔI t1/t3 of $0.2^\circ \pm 2.6^\circ$ and a ΔA t1/t3 of $-0.2^\circ \pm 1.7^\circ$. The Plasmafit® cup had a ΔI t1/t3 of $-0.02^\circ \pm 1.6^\circ$ and ΔA t1/t3 of $-0.3^\circ \pm 1.2^\circ$ (Table 1).

4. Discussion

Cementless acetabular cup systems have been clinically established for years. Nevertheless, early loosening often occurs which is promoted by an increased migration of the acetabular systems. EBRA helps identify early loosening and make quick statements about possible future performance e.g. in order to evaluate new acetabular systems. Within the framework of this study, possible progressive inclination as well as anteversion migration of two well established cementless acetabular cup systems and a more recent one were radiologically examined in the first 12 months and compared with each other using EBRA. In addition, possible influencing epidemiological factors of the collective on the migration behavior of the acetabular cups were taken into account correlatively. EBRA was chosen because this method has proven to be sufficiently precise^{12,15} and uncomplicated due to the X-ray images of the pelvic overview images taken as part of the follow-up examination. At the same time, EBRA provides good short-term predictive power for early loosening of the cup systems.^{12,13}

Generally, pre-clinical *in vitro* and *in vivo* studies should be raised for testing newly approved acetabular prostheses especially when it comes to discovering possible advantages or disadvantages of different surfaces on the primary stability and the supposed related resulting secondary stability - i.e. osseointegration - of the acetabular cups. The Plasmacup® has a microsurface structure, the Allofit® a macrosurface structure with a tooth geometry and the novel Plasmafit® cup is a combination of both surface textures and could therefore be regarded as hybrid between the Allofit® and the Plasmacup® cup. In a former *in vitro* study of the working group Jahnke et al. 4 three different acetabular cups with different surface qualities were compared for their primary stability. For this purpose, the cups were implanted in a simplified spherical bone model as well as in an anatomical artificial bone model. Taking into account the resulting frictional moments of CoC and CoP bearings, the relative micromotions between cup and bone were determined and primary stability of the three cups was compared. It could be shown that the respective cup wall thickness and the surface quality of the cups had a significant influence on the primary stability of the cup systems examined.

Another *in vitro* study by Le Cann et al.¹⁶ likewise considered the question of the influence of micro- and macroporosity on primary stability. It could be shown that equatorial macroporosity generally has a negative influence on primary press-fit, but is indispensable for osseointegration, i.e., secondary stability. The key message of this study was that microporosity, thanks to less bone injury, provides better conditions for primary stability. However, some macroporosity is essential for achieving secondary stability, i.e., osseointegration.

In contrast to above mentioned *in vitro* studies,^{4,16} we were unable to demonstrate any short-term difference between the influences of the

different surface structures on the migration of the examined acetabular cups.

In a clinical *in vivo* study by Ilchman et al.,¹⁷ the influence of a roughened surface of a threaded cup and the possible connection between roughness and early aseptic loosening of the cup was examined using EBRA. The Authors found a high rate of aseptic loosening in the examined collective, but no connection between surface roughness and loosening of the cup could be demonstrated. This finding also coincides with the results of our study. The examined cup systems all have a different surface with different roughness values and structures. Nevertheless, we could not prove any migration of the cups within the first 12 months and the cups remained stable in their initial positions - regardless of their initial, partly non-physiological and irregular anteversion angle malposition. Literature specifies $45^\circ \pm 5^\circ$ for inclination and $15^\circ \pm 10^\circ$ for anteversion.¹⁸ If we look at the different anteversion angles of the respective acetabular cups examined, we find that the Allofit® cup was primarily implanted with a relatively unphysiologically high anteversion angle, followed by the Plasmacup® cup and the Plasmacup® which were implanted in an optimized manner according to values found in literature. These different anteversion angles could result from different insertion guides and the associated different curvatures of the used implantation sets. Nevertheless, during the investigation period, the actual anteversion angles and their possible “malorientation” did not show any negative influence on the course of the cup migration. These results coincide with the results of a certain study in which no influence of malorientation of acetabular cups influenced the migration or led to any early aseptic loosening.¹⁷

At no follow-up control, postoperatively, at the 6-month or 12-month follow-up, any significant value of progressive migration nor any correlation between migration and any of the examined epidemiological factors were found (p-value > 0.05). It appears that the primary stability of the cups, bone quality, anatomical reconstruction¹⁷ and the associated implantation expertise of the surgeon might have a greater impact on the anchoring behavior of the cup systems.

The large number of implantations of the two already established cups, Allofit® and Plasmacup®, is justified by long-term studies.^{19,20} To date, neither clinical *in vivo* nor experimental *in vitro* studies have been carried out to examine the characteristics and the associated future performance of the relatively novel Plasmacup® cup but our first short-term results permit to expect good long-term results compared to the already established cup systems.

A major limitation of this study is the short follow-up time, although osseointegration and any migration of the cup should already have occurred at the 12-month postoperative follow-up.¹⁰ Another limiting factor is the evaluation of CoC bearing couples by means of the EBRA-Cup software because of possible obscuration. However, it was possible to counteract this limitation by contrasting in the best possible manner. Furthermore, there were many exclusions within the collective due to the algorithm-controlled exclusion process within the EBRA software. Nevertheless, due to the continuous recruitment and support of our collective, we consider the results to be meaningful and robust.

5. Conclusion

This study analyzes the migration behavior of the more recent Plasmacup® cup system and compares it with that of the already established Allofit® and Plasmacup® press-fit cup systems. There was no evidence for short-term aseptic loosening in any cup system. Neither do any epidemiologic factors such as age, sex, indication for surgery, cup/stem combination, bearing couple, and body mass index seem to influence the migration behavior of the cup systems. The EBRA method appears to be a fast and reliable tool for providing early predictions about the possible performance of acetabular cups and could therefore be used to provide rapid *in vivo* results certifying recently introduced acetabular cup systems. Though, subsequent long-term studies have to be carried out to confirm our short-term prognosis.

Level of evidence

2b

Ethics approval and consent to participate

IRB approval was obtained and informed, written consent from all patients (or their parents/guardians).

Consent for publication

Not applicable

Funding

We thank Aesculap AG (B Braun, Aesculap, Tuttlingen, Germany) for the financial support for the EBRA software costs.

Authors' contributions

BAI, JBS, MR, GAA, and AJ conceptualized, analysed and interpreted the patient data and were major contributors in writing the manuscript. JW, CAFU performed the data curation, the statistics as well as the discussion. All authors read and approved the final manuscript.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declaration of competing interest

The Authors declare that there is no conflict of interest.

Acknowledgements

Not applicable.

References

- Pivec R, Johnson AJ, Mears SC, Mont MA. Hip arthroplasty. *Lancet*. 2012;380(9855):1768–1777. [https://doi.org/10.1016/S0140-6736\(12\)60607-2](https://doi.org/10.1016/S0140-6736(12)60607-2).
- Malchau H, Herberts P, Eisler T, Garellick G, Söderman P. The Swedish total hip replacement register. *J Bone Joint Surg Am*. 2002;84 A Suppl 2:2–20.
- Wittenberg RH, Steffen R, Windhagen H, Bücking P, Wilcke A. Five-year results of a cementless short-hip-stem prosthesis. *Orthop Rev (Pavia)*. 2013;5(1):e4. <https://doi.org/10.4081/or.2013.e4>.
- Jahnke A, Bott CC, Fonseca Ulloa CA, et al. In vitro examination of the primary stability of three press-fit acetabular cups under consideration of two different bearing couples. *Med Eng Phys*. 2019;67:49–54. <https://doi.org/10.1016/j.medengphys.2019.03.008>.
- Bürkner A, Fottner A, Lichtinger T, et al. Primary stability of cementless threaded acetabular cups at first implantation and in the case of revision regarding micro-motions as indicators. *Biomed Tech (Berl)*. 2012;57(3):169–174. <https://doi.org/10.1515/bmt-2011-0066>.
- Jahnke A, Schroeder S, Fonseca Ulloa CA, Ahmed GA, Ishaque BA, Rickert M. Effect of bearing friction torques on the primary stability of press-fit acetabular cups: a novel in vitro method. *J Orthop Res*. 2018;36(10):2745–2753. <https://doi.org/10.1002/jor.24041>.
- Krismer M, Biedermann R, Stöckl B, Fischer M, Bauer R, Haid C. The prediction of failure of the stem in THR by measurement of early migration using EBRA-FCA. Einzel-Bild-Röntgen-Analyse-femoral component analysis. *J Bone Joint Surg Br*. 1999;81(2):273–280. <https://doi.org/10.1302/0301-620X.81b2.8840>.
- Nunag P, Deakin AH, Oburu E, Sarungi M. Two-year radiologic assessment of the Trident Peripheral Self-Locking cup using EBRA. *Hip Int*. 2012;22(5):511–515. <https://doi.org/10.5301/HIP.2012.9744>.
- Kim YS, Abrahams JM, Callary SA, et al. Proximal translation of 1 mm within the first two years of revision total hip arthroplasty correctly predicts whether or not an acetabular component is loose in 80% of cases: a case-control study with confirmed intra-operative outcomes. *Bone Joint Lett J*. 2017;99-B(4):465–474. <https://doi.org/10.1302/0301-620X.99B4.BJJ-2016-0805.R1>.
- Wolf O, Mattsson P, Milbrink J, Larsson S, Mallmin H. Periprosthetic bone mineral

- density and fixation of the uncemented CLS stem related to different weight bearing regimes: a randomized study using DXA and RSA in 38 patients followed for 5 years. *Acta Orthop*. 2010;81(3):286–291. <https://doi.org/10.3109/17453674.2010.487238>.
11. Krismmer M, Tschupik JP, Bauer R, et al. Einzel-Bild-Röntgen-Analyse (EBRA) zur Messung der Migration von Hüftendoprothesen. *Orthopade*. 1997;26(3):229–236. <https://doi.org/10.1007/PL00003378>.
 12. Krismmer M, Stöckl B, Fischer M, Bauer R, Mayrhofer P, Ogon M. Early migration predicts late aseptic failure of hip sockets. *J Bone Joint Surg Br*. 1996;78(3):422–426.
 13. Abrahams JM, Callary SA, Won Jang S, Hewitt J, Howie DW, Solomon LB. Accuracy of EBRA-cup measurements after reconstruction of severe acetabular defects at revision THR. *J Orthop Res*. 2020. <https://doi.org/10.1002/jor.24623>.
 14. Ilchmann T, Franzén H, Mjöberg B, Wingstrand H. Measurement accuracy in acetabular cup migration. *J Arthroplasty*. 1992;7(2):121–127. [https://doi.org/10.1016/0883-5403\(92\)90004-A](https://doi.org/10.1016/0883-5403(92)90004-A).
 15. Ilchmann T, Kesteris U, Wingstrand H. EBRA improves the accuracy of radiographic analysis of acetabular cup migration. *Acta Orthop Scand*. 1998;69(2):119–124. <https://doi.org/10.3109/17453679809117610>.
 16. Le Cann S, Galland A, Rosa B, et al. Does surface roughness influence the primary stability of acetabular cups? A numerical and experimental biomechanical evaluation. *Med Eng Phys*. 2014;36(9):1185–1190. <https://doi.org/10.1016/j.medengphy.2014.07.003>.
 17. Ilchmann T, Neher S, Maurer F, Weise K. Modes of failure of a threaded acetabular cup : a radiographic study with EBRA of 42 revised cups. *Int Orthop*. 2007;31(2):211–216. <https://doi.org/10.1007/s00264-006-0155-2>.
 18. Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. *J Bone Joint Surg Am*. 1978;60(2):217–220.
 19. Streit MR, Weiss S, Andreas F, et al. 10-year results of the uncemented Allofit press-fit cup in young patients. *Acta Orthop*. 2014;85(4):368–374. <https://doi.org/10.3109/17453674.2014.925351>.
 20. Wilkinson JM, Gordon A, Stockley I. Experiences with the Plasmacup—early stability, wear, remodelling, and outcome. *Int Orthop*. 2003;27(Suppl 1):S16–S19.