The concept of a cementless isoelastic monoblock cup made of highly cross-linked polyethylene infused with vitamin E: Radiological analyses of migration and wear using EBRA and clinical outcomes at mid-term follow-up

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Abstract

Background

The newest generation of cementless titanium coated, isoelastic monoblock cup with vitamin E-blended highly cross-linked polyethylene (HXLPE) has been introduced to the market in 2009. Aim of the present study was to obtain mid-term data including the analyses of migration and wear.

Methods

The present prospective study investigated 101 primary total hip arthroplasty (THA) cases in 96 patients at a single institution. Patients were allowed full weight-bearing on the first day postoperatively. Harris hip score (HHS) as well as pain and satisfication on visual analogue scale (VAS) were assessed during a mean follow-up of 79.0 months. Migration and wear were assessed using Einzel-Bild-Roentgen-Analyse (EBRA) software. Additionally, radiological alterations in the acetabular bone and complications were documented.

Results

At mid-term follow-up (mean 79.0 months (range: 51.8 – 101.7)), 81 cases with complete clinical and radiological data were analyzed. In 42 hips utilisable EBRA measurements were obtained. HHS was 91.1 (range 38.0 – 100.0), satisfaction on VAS was 9.6 (range 6.0 – 10.0), rest pain on VAS was 0.2 (range 0.0 – 4.0), and load pain on VAS was 0.6 (range 0.0 – 9.0). Mean migration was 0.86 mm (range: 0.0 – 2.56) at 24 months and 1.34 mm (range: 0.09 – 3.14) at 5 years. Mean annual migration rate was 0.22 (range: -0.24 – 1.34). Mean total wear was 0.4 mm (range: 0.03 – 1.0). The mean annual wear rate was 0.06 mm per year (range: 0.0 – 0.17). Radiographic analysis showed osteolysis in none of the cases and no revision surgeries had to be performed.

Conclusion

Using vitamin-E blended HXLPE in cementless isoelastic monoblock cups, no signs of osteolysis were obvious and no cases of aseptic loosening occurred. There was no need of revision surgery at mid-term. Values for cup migration and wear stay well below the benchmarks which are considered predictive for potential future failure.

Trial registration

The trial registration number on ClinicalTrial.gov: NCT04322916 (retrospectively registered at 26.03.2020).

Background

Total Hip Arthroplasty (THA) is one of the most frequent operations worldwide [1]. The most challenging requirement in THA is a long implant survival. Aseptic loosening of the components is one of the most prevalent causes for revision surgery [2, 3]. In the last decades, a substantial effort has been made to avoid or prolong aseptic loosening and mechanical failure of the implants, and this will remain a major challenge in the future [4–7].

The concept of a cementless monoblock cup was initially introduced in 1983 [4, 8] (Fig. 1a). It was made of ultra-high-molecular-weight polyethylene (UHMWPE) coated by titanium. In addition to the titanium coating for primary bone fixation, two pegs provided rotational stability [9]. 20 years follow-up revealed a survival rate of 94.4% for aseptic loosening as endpoint [4].

The second generation was introduced in 2002 (Fig. 1b). It was also made of UHMWPE but has been modified by removing the 2 pegs. However, the longevity of both generations of monoblock cups was limited in the long-term because of wear and oxidative degeneration of the UHMWPE [4, 10].

The third generation of the monoblock concept, has been introduced to the market in 2009 (Fig. 1c). To improve the properties, a new generation of highly cross-linked polyethylene has been developed, which is protected from oxidation by the antioxidant vitamin E [11–13]. This new generation of polythylene promises significantly lower wear rates [2, 11–14]. However, previous studies have also shown that vitamin E-stabilized HXLPE has similar wear properties to HXLPE without vitamin E, but has improved fatigue strength and is protected from oxidative destruction [11, 15–18].

Regarding the development of osteolysis, which is known to be induced by wear of the PE and potentially causes loosening and implant failure, Dumbleton et al. defined a threshold of 0.1 mm per year, below which osteolysis is rarely observed [19].

Another major indicator for late aseptic loosening is the early migration of the cup. Several studies, using “Einzel-Bild-Roentgen-Analyse” (EBRA) [20] measurements, reported an implant migration of > 2 mm during the first 2 years being an established risk factor for implant failure, by interfering osteointegration [6, 21–25].

The primary aim of this study was to analyse the radiological outcomes of the newest generation monoblock vitamin E-blended HXLPE cup in a mid-term follow-up. Particularly, the migration pattern and wear were analyzed in order to identify potentially undesireable results at an early stage. Additionally clinical outcomes were obtained.

Methods

The present prospective observational study investigated 101 primary THA cases in 96 patients at a single institution between March 2010 and September 2011. All procedures performed were in accordance with the 1964 Helsinki Declaration. Ethical approval was obtained (FF 154/2017). All patients gave their verbal and written permission to participate prior to inclusion.

The inclusion criteria were age between 20 and 85 years and being a candidate for primary THA. The demographics of all enrolled patients are presented in Table 1.

In all cases, the RM Pressfit vitamys cup (Mathys Ltd., Bettlach, Switzerland) was used (Fig. 1c). The body of the cup is made of highly-crosslinked UHMW-PE (HXLPE) stabilized with vitamin E [5, 11, 18]. The titanium coating was developed to maintain the natural elastic properties of isoelastic polyethylene and to promote secondary stability [8, 11, 18]. Primary stability is achieved by equatorial pressfit. Optionally, up to four screws can be inserted into predefined holes in case of insufficient acetabular coverage or in soft or sclerotic bone.

The femoral components and head components used are listed as supplementary data.

All surgeries were performed using a minimally invasive, antero-lateral approach in standardized surgical technique [26]. The operations were performed by experienced consultant surgeons and the mean duration of surgery was 56.4 minutes (range 30.0 – 93.0). All patients started physiotherapy and were allowed full weight-bearing ambulation on the first day postoperatively.

The clinical and radiological follow-up included a maximum of six timepoints: preoperative, 6 weeks, 6 months, 12 months, 2 years and 5 years.

Complications and adverse events during surgery and during the follow-up were documented.

For clinical examination, the Harris Hip Score (HHS) as well as rest pain and load pain on visual analogue scales (VAS) were evaluated before surgery and during follow-up.

The radiological evaluation of osseointegration and migration of the cup was carried out on standardized anterior-posterior radiographs of the pelvis. Lucent lines and osteolysis were analyzed according to Engh et al. [27] defined in the zones described by DeLee and Charnley [28] (Fig. 2a). Heterotopic ossifications were documented according to Brooker [29].

At mid-term follow-up, a retrospective evaluation of the radiographs using EBRA was performed by one observer in order to analyse the migration pattern and detect potential wear of the polyethylene. The methology, using a software, was originally developed by Krismer et al. [20]. Basically, migration is being investigated in two orientations: horizontally (x-axis = cupx) and vertically (y-axis = cupy). Decreasing values in the horizontal direction imply medial migration, whereas increasing values in the horizontal direction imply lateral migration. In turn, increasing values in y-direction refer migration in cranial or proximal direction, hence in upward direction and decreasing y-values signify distal movement. However, given that biplanar analyses are not possible, the anteroposterior motion is discounted by the EBRA method. The overall accuracy of EBRA is validated to be within 1 mm [21]. Radiographs are only accepted by the EBRA software if all reference lines can be located accurately. Loosening was defined as total migration increase of 0.5 mm per year [30, 31]. Total cup migration was claculated as the vector summation of x and y-axis migration by the following formula using Pythagoras law:

$$\text{cupT} = \sqrt{cupx^2 + cupy^2}.$$

Besides migration, creep and wear rate were calculated using pelvic radiographs and EBRA software. A frame drawn from tangents to prominent pelvic structures defined the position of the pelvis. From the digitized points, the software calculated the best-fit circle for the femoral head or the best fitting ellipse for the contrast wire and the distances from each digitized coordinate of the implant [32]. The displacement of the head center was calculated relative to the cup center in the frontal plane (transverse and longitudinal axis) and the wear rate for each subgroup was calculated in each time interval between radiographic examinations [32]. Whereas during the first year following surgery displacement of the head center is to be considered a combination of creep and wear, the penetration of the femoral head after the first year may be defined as actual wear [2, 33].

Statistical analysis

All statistical analyses were carried using standard descriptive statistics such as mean± standard deviation (SD), median (i.e. 50% percentile) and range.

In addition, for all outcomes related to migration and wear, also 2-sided 95% confidence intervals and 25%- & 75% percentiles were provided as supplementary measures of variation. As the aim of the study was to assess migration and wear outcomes with sufficient precision, however, no explicit statistical tests were carried out. Qualitative categorical values are shown as number and percentage. All statistical analyses were performed using SAS software 9.4 (SAS Institute, Cary, North Carolina, USA).

Table 1 – Patient demographics

	Total included Mean (range)	Total with clinical and radiological FU at mid-term (range) mean
Number of hips, n	101	81
Age, years	69.4 (50.7 – 84.3)	68.0 (50.7 – 84.0)
BMI, kg/m²	27.5 (19.3 – 41.5)	27.7 (20.6 – 41.5)
Diagnosis, n (%)		
Primary osteoarthrosis	94 (93.1 %)	76 (93.8 %)
Secondary osteoarthrosis	2 (2.0 %)	1 (1.2 %)
Femoral head necrosis	3 (3.0 %)	3 (3.7 %)
Femoral neck fracture	1 (1.0 %)	0 (0.0 %)
Congenital dysplasia	1 (1.0 %)	1 (1.2 %)

Results

After five years, 12 patients are known to be deceased with the investigated implants in situ. All deaths were unrelated to the surgical procedure and did not occur within the first year postoperatively. At mid-term, four cases were lost to follow-up. In four cases only a clinical follow-up could be obtained, given that those symptom-free patients refused the preparation of a radiograph. Thus, 81 cases with complete clinical and radiological data could be analyzed (Fig. 3). The mean follow-up time was 79.0 months (range: 51.8 – 101.7).

None of the patients required a cup related revision because of aseptic loosening, nor for mechanical failure or any other reason after five years.

Intraoperatively two (2%) fissures of the femur were observed. Both of them healed uneventfully after cerclage wiring. 99 patients (98%) did not show intraoperative complications. During the early postoperative period, there were four hematomas, one femoral nerve palsy and one superficial infection which was treated successfully by antibiotic therapy. During follow-up, in two patients a periprosthetic fractures of the femoral component occurred, due to trauma, without any involvement of the acetabular component. No cup specific complications were observed.

The mean range of motion increased from a preoperative value of 92° flexion (range: 50 – 120) to 114° (range: 85 – 130). The clinical outcome is shown in Table 2.

Table 2 Clincal outcome over time

FU	Mean	SD	Median	95 % CI		Percentiles		Range	
				low	up	25%.	75%	Min	Max
VAS rest pain (pts)									
Pre-OP	5.0	3.3	5.0	4.4	5.7	2.0	8.0	0.0	10.0
6-12 weeks	1.1	1.0	1.0	0.6	1.5	0.0	2.0	0.0	3.0
6 months	0.2	0.3	0.1	-0.1	0.6	0.0	0.4	0.0	0.7
12 months	0.5	1.2	0.0	0.3	0.8	0.0	1.0	0.0	8.0
24 months	0.1	0.3	0.0	0.0	0.2	0.0	0.0	0.0	2.0
5 years	0.2	0.7	0.0	0.0	0.3	0.0	0.0	0.0	4.0
VAS load pain (pts)									
Pre-OP	7.7	2.2	8.0	7.2	8.1	6.7	9.8	1.0	10.0
6-12 weeks	1.5	1.4	1.0	0.8	2.2	0.3	2.2	0.0	4.0
6 months	0.6	0.6	0.8	-0.1	1.4	0.0	1.0	0.0	1.4
12 months	1.1	1.7	0.0	0.7	1.4	0.0	2.0	0.0	8.0
24 months	0.3	0.5	0.0	0.2	0.4	0.0	0.8	0.0	2.0
5 years	0.6	1.7	0.0	0.3	1.0	0.0	0.0	0.0	9.0
VAS satisfaction (pts)									
Pre-OP	1.7	2.0	1.0	1.4	2.1	0.0	3.0	0.0	8.0
6-12 weeks	8.8	0.8	9.0	8.5	9.2	8.5	9.1	7.3	10.0
6 months	9.5	0.5	9.4	8.9	10.1	9.2	10.0	9.0	10.0
12 months	9.2	1.4	10.0	8.9	9.5	8.8	10.0	2.0	10.0
24 months	9.7	0.5	10.0	9.6	9.8	9.5	10.0	8.0	10.0
5 years	9.6	0.9	10.0	9.4	9.8	10.0	10.0	6.0	10.0
Harris Hip Score (pts)									
Pre-OP	49.9	15.0	52.0	46.9	52.9	41.5	60.5	9.0	95.0
6-12 weeks	83.1	10.4	85.0	78.2	88.0	75.5	91.5	64.0	99.0
6 months	91.8	4.0	91.0	86.9	96.7	91.0	95.0	86.0	96.0
12 months	91.1	11.6	96.0	88.5	93.7	88.0	99.0	45.0	100.0
24 months	95.2	5.6	97.0	94.0	96.4	93.0	99.0	75.0	100.0
5 years	94.0	9.9	97.0	91.9	96.2	93.0	100.0	38.0	100.0
Flexion (°)									
Pre-OP	92.4	12.1	90.0	90.0	94.7	90.0	100.0	50.0	120.0
6-12 weeks	101.0	13.8	100.0	94.5	107.5	90.0	110.0	65.0	130.0

6 months	109.0	13.9	115.0	91.8	126.2	110.0	115.0	85.0	120.0
12 months	116.3	12.0	120.0	113.6	118.9	110.0	125.0	85.0	130.0
24 months	120.2	9.4	120.0	118.2	122.3	115.0	130.0	95.0	130.0
5 years	113.7	10.9	115.0	111.3	116.1	110.0	120.0	85.0	130.0

Before surgery, the HHS was rated with an average of 49.9 points (range: 9.0 – 95.0). At mid-term follow-up, the mean HHS was 94.0 points (range: 38.0 – 100).

Mean rest pain on VAS decreased from preoperatively 5.0 (range: 0 - 10) to 0.2 at mid-term and mean load pain on VAS decreased from preoperatively 7.7 (range: 1.0 – 10.0) to 0.6 (range: 0.7 – 9.0). Satisfaction on VAS increased from 1.7 (range: 0.0 – 8.0) to 9.5 (range: 0.9 – 10.0) after five years.

The radiographic results at mid-term follow-up are presented in Table 3.

Table 3
Radiological outcome over time

	5 years Frequency (n)	**Percent (%)**
Inclination <30° 30–34° 35–39° 40–44° 45–49° 50–54° >54°	0 1 2 7 28 36 7	0.0 1.2 2.5 8.6 34.6 44.4 8.6
Lucent lines No Yes	81 0	100.0 0.0
Osteolysis No Yes	81 0	100.0 0.0
Heterotopic Ossification No Yes Brooker I Brooker II-III Brooker IV	74 7 6 1 0	91.4 8.6 7.4 1.2 0.0

One patient showed a lucent line during follow-up, in zone 2 and partly in zone 1 (Fig. 2b). Not a single patient presented with osteolysis of the acetabulum after 5 years. Heterotopic bone formation was presented in 8.6 % (n=7) of the patients. Six patients (7.4%) showed Brooker I and one patient (1.2%) showed Brooker II.

The mean number of radiographs available for EBRA evaluation was 3.88 (range 3.0-5.0) per patient. 42 patients contributed to the EBRA analysis at mid-term follow-up.

Mean cup migration at mid-term follow-up was 1.34 mm (range: 0.09 – 3.14). The migration rate per year decreased from 0.36 mm per year (range: -3.55 – 4.02) at 12 months to 0.22 mm per year (range: -0.24 – 1.34) at 5 years (Tab. 4).

During the first year following surgery, the mean combination of creep and wear resulted in 0.17 mm (range: 0.00 - 0.67). Mean total wear at mid-term follow-up was 0.40 mm (range: 0.03 – 1.00). Mean annual wear rate at mid-term was 0.06 mm (range: 0.00 – 0.17) per year (Tab. 4). When taking into account the combination of creep and wear during the first year, the actual wear rate after the first year was 0.05 mm (range: -0.06 – 0.21) per year.

Table 4 EBRA measurements of total migration and total wear at each follow-up

	Months	*N*	*Mean*	*SD*	*Median*	*Min*	*Max*
Total Migration (mm)	0	44	0.00	0.00	0.00	0.00	0.00
	3	36	0.34	0.41	0.23	0.00	2.07
	12	50	0.80	0.71	0.56	0.00	2.81
	24	48	0.86	0.62	0.70	0.00	2.56
	60	42	1.34	0.63	1.26	0.09	3.14
Total migration rate (mm/year)							
	3	36	1.89	2.57	0.88	0.00	11.53
	12	50	0.72	0.63	0.48	0.00	2.35
	24	48	0.29	0.21	0.21	0.00	0.83
	60	42	0.21	0.10	0.19	0.01	0.47
Total wear (mm)	0	44	0.00	0.00	0.00	0.00	0.00
	3	36	0.11	0.12	0.06	0.00	0.54
	12	50	0.18	0.17	0.15	0.00	0.78
	24	48	0.28	0.17	0.26	0.00	0.68
	60	42	0.40	0.24	0.32	0.03	1.00
Total wear rate (mm/year)	3	36	0.61	0.70	0.38	0.00	2.72
	12	50	0.17	0.15	0.13	0.00	0.67
	24	48	0.09	0.05	0.09	0.00	0.26
	60	42	0.06	0.04	0.05	0.00	0.17

Discussion

The aim of the present study was to assess the mid-term radiological outcomes and in particular to investigate the migration and wear rate of the third generation of a cementless isoelastic monoblock cup with vitamin E blended HXLPE. At mid-term follow-up almost no cup-related complications could be observed and none of the investigated

implants required revision surgery. Radiologically, no direct signs of cup loosening were obvious and in none of the cases osteolysis could be observed. Clinical outcome and patient satisfaction resulted in very high scores.

Early migration is considered a predictor of aseptic loosening [5, 34], as a mean cup migration of more than 2 mm in the first two years has previously been shown to correlate significantly with aseptic loosening in the long-term [21–25, 31]. The present investigation resulted in a mean total migration of 1.34 mm at five years. Furthermore, at two years a mean migration of 0.86 mm was seen, which is far below the above mentioned 2 mm limit. Additionally loosening was defined as an overall migration increase of 0.5 mm per year [30, 31]. Our results demonstrated a migration rate of 0.22 mm per year at five years, which, again, is below the defined threshold for aseptic loosening.

To date, only few previous publications can be found regarding the newest generation of the investigated cup. Wyatt et al. [5] also analyzed cup migration, however, only few EBRA measurements (n = 13) could be included. They found a mean migration of 1.5 mm at five years, which can be confirmed by the present study. The majority of migration occurred within the first 12 weeks after surgery, thus, the authors concluded it can be explained just by the initial cup seating and all components can be considered stable thereafter [5]. The present study also shows that migration stagnates at 1-2 years postoperatively and subsequently in most cases secondary stabilization occurs. After the first two years and the onset of secondary stability, only slight further migration could be observed.

The cause of migration can be both, inadequate initial fixation with insufficient primary stability or the subsequent loss of fixation during follow-up [31, 34]. Both scenarios might indicate an increased risk of failure. In contrast, however, it has been shown that minor migration over years often remains asymptomatic [6, 34]. In the present study clinical results are excellent and no signs of failure were detected, despite minor continuous migration. Longer-term follow up will have to confirm these findings in the future.

Wyss et al. [6] investigated the second generation of the isoelastic monoblock cup (RM Pressfit, Mathys Ltd., Bettlach, Switzerland) in a mid-term follow-up. Almost the same results were found, as compared to the present study. However, in contrast to the present investigation, all surgeries were performed using a transgluteal approach, patients were only alowed partial weight bearing and flexion was initially limited to 70° [6]. It is obvious that the occurance of migration and subsequent loosening might reflect the quality of operative technique – particularly the reaming process- and implant selection [31]. Studies have also shown a correlation between cup inclination and cup diameter with early migration [22]. However, also the postoperative treatment protocol is likely to have an impact on early migration. In the present study, all surgeries were performed using the minimally-invasive anterolateral approach, theoretically making the cup positioning more challenging, potentially affecting migration. It is remarkable, that similar results are achieved in the present study compared to the investigation by Wyss et al.[6], although the postoperative treatment protocol is far more aggressive.

Besides migration, polyeythelene wear is also an indicator of aseptic loosening of endoprosthetic components, by causing osteolysis of the acetabular and femoral bone stock. Thus, this aspect has additionally been taken into account in the present investigation. It is of major interest to further improve UHMWPE in order to decrease wear and potentially increase the lifetime of acetabular components.

Previous in-vitro studies have already demonstrated that vitamin E blended HXLPE improves fatigue strength and protects against oxidative damage [11, 15, 17, 18]. The protection of HXLPE with vitamin E may lead to excellent oxidation resistance [11, 13, 15, 35], which potentially leads to a reduction of wear. Beck et al., performing a mechanical in vitro testing, found a significantly lower wear rate of vitamin E-blended HXLPE compared to standard gamma-sterilized UHMWPE [11]. This, by decreasing wear rate and oxidative degeneration may potentially result in less osteolysis, which in turn might lead to decreased rates of aseptic loosening and failure.

Early studies found that osteolysis is rarely observed in THA patients with wear below the threshold of 0.1 mm per year [19]. In the present investigation, annual wear rates were at 0.06 mm per year and thus far below this benchmark. When considering, that during the first year following surgery most of the displacement of the femoral head may be associated with creep, annual rates of actual wear are to be expected even lower. Moreover, Dumbleton et al. found that below a rate of 0.05 mm per year, osteolysis will practically not occur [19]. Earlier studies using the second generation of the isoelastic monoblock cup, showed slightly higher annual wear rates, compared to the present results. Wyss et al.[6] found 0.09 mm per year and Lafon et al.[7] found 0.07 mm per year. Rochcongar et al. recently performed a prospective randomized controlled study comparing RM Pressfit cup (UHMWPE) to RM Pressfit vitamys cup (HXLPE/VitE) and found that wear rates over the first three years following surgery were lower for the HXLPE blended with vitamin-E [2]. This might directly affect the need of late revision surgery. These results have been confirmed by a very recent randomized-controlled trial, again, comparing annual wear rates of the RM Pressfit cup (UHMWPE) to those of the RM Pressfit vitamys cup (HXLPE/VitE). At two years [36], as well as at 6 years [37] wear rates were significantly lower for the HXLPE/VitE cup than those for the UHMWPE cup.

At mid-term follow-up, in the present study, no adverse events occurred and none of the investigated cups showed signs of failure, making not a single revision surgery necessary. A sclerotic line in zone 2 can be found in some of the patients at the dome of the cup, without containing the risk of subsequent loosening. This is most probably because of the aspheric design of the cup with flattening of the dome. Osteointegration seems to be complete and stable in zone 1 and zone 3 in those cases.

Moreover, encouraging clinical results, with marked improvements in functionality and activity level, confirm earlier studies [2, 4–7, 9, 10, 14, 18] and strongly support the concept of a cementless isoelastic monoblock cup with vitamin-E blended HXLPE.

Some limitations to the present study have to be acknowledged. First is the mid-term follow-up of 5 years. Although only long-term results should be considered valid regarding the investigation of implant survival, early evaluation of radiological alterations, migration and wear, however, is helpful to identify future undisirable results. Early migration analysis using EBRA has been established in several studies providing a reference to long-term survival [5, 6, 34]. Second the method used to measure migration and wear lacks some accuracy in comparison to radiostereometric analysis (RSA) [32]. As the accuracy has been validated to be within 1 mm, results should be interpreted with caution. Nevertheless, EBRA has become a widespread scientific method without the need to implant markers intraoperatively and thus without causing intense cost and effort.

Measured wear might be greater than when using RSA, for example, due to a probable plastic cup deformation affecting the shape of the contrast wire [21, 32].

Another important limitation of this study is the EBRA software failing to evaluate all radiographs. The image requirements for EBRA measurement are quite challenging, leading to a high rate of radiographs which were not accepted by the EBRA software. Thus, in the present study, reliable results of the EBRA measurements could only be obtained in 42 out of 81 hips at mid-term. As several radiographs were taken at different time points within the follow-up period, the mean migration and wear results are reliable.

Conclusion

In the present study, using the concept of vitamin-E blended HXLPE in cementless isoelastic monoblock cups, no signs of osteolysis were obvious and no cases of aseptic loosening occurred. There was no need of revision surgery

at mid-term. Values for cup migration and wear stay well below the benchmarks which are considered predictive for future failure. Long-term data will have to confirm these findings.

Abbreviations

HXLPE: Highly cross-linked polyethylene; UHMWPE: Ultra-high-molecular-weight polyethylene; THA: total hip arthroplasty; HHS: Harris hip score; VAS: Visual analogue scale; EBRA: Einzel-Bild-Roentgen-Analyse; RSA: Radiostereometric analysis

Declarations

Ethics approval and consent to participate:

All procedures performed were in accordance with the 1964 Helsinki Declaration. Ethical approval was obtained (FF 154/2017) from the Ethics Commission of the state medical association Hessen, Frankfurt, Germany ("Ethik-Kommission bei der Landesärztekammer Hessen"). All patients gave their verbal and written permission to participate prior to inclusion. This study was funded by Mathys Ltd., Bettlach, Switzerland. KPK and PR serve as instructors for Mathys Ltd., Bettlach, Switzerland. PR also serves as medical advisor. All other authors declare that they have no competing interests.

Consent for publication

Not applicable

Availability of data and material

The dataset generated and/or analysed during the current study are not publicly available due to the high volume of data but are available from the corresponding author on reasonable request.

Competing interests

KPK and PR serve as instructors for Mathys Ltd., Bettlach, Switzerland. PR also serves as medical advisor. All other authors declare that they have no competing interests.

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Authors' contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by YA, JT, SJ and PR. The first draft of the manuscript was written by YA and KPK. JD, PD and PR were also major contributors in writing the manuscript. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Figures

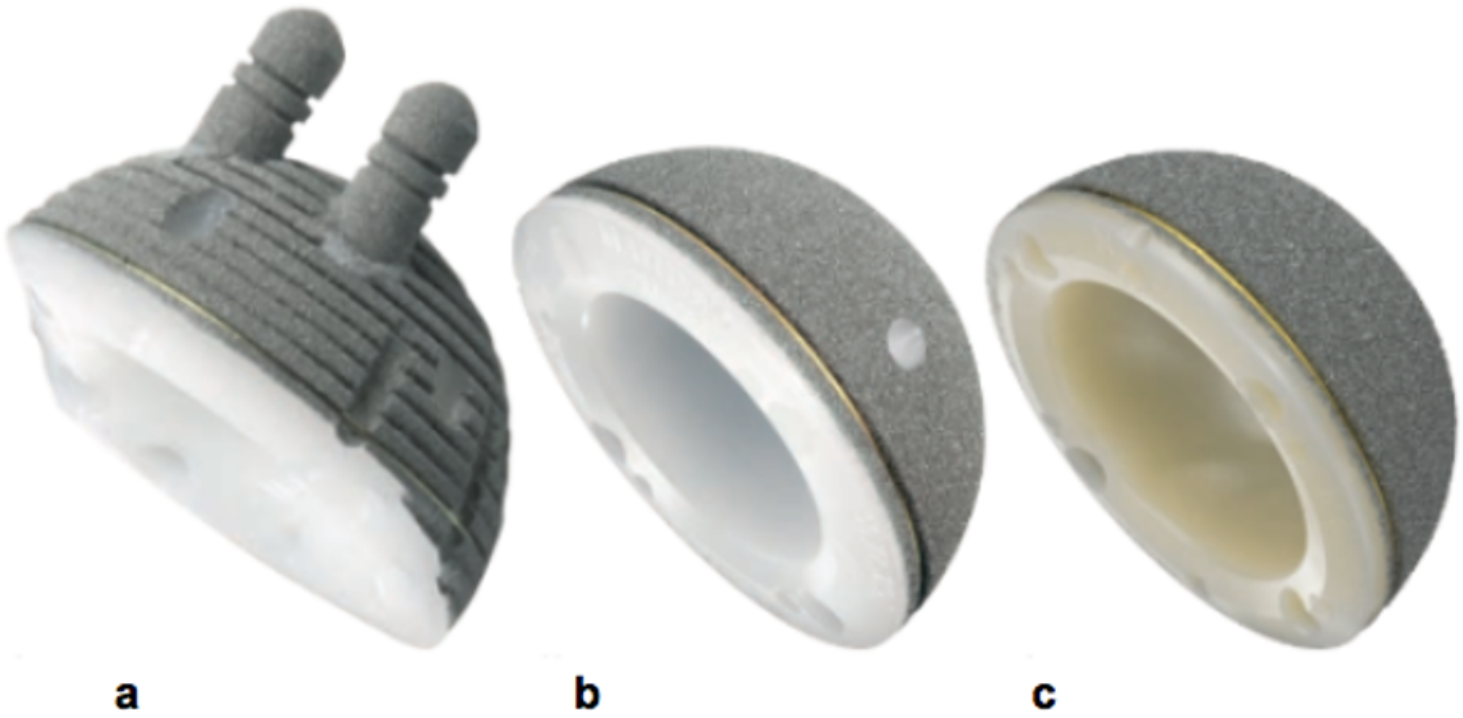

Figure 1

1a: RM Classic cup; 1b: RM Pressfit cup; 1c: RM Pressfit vitamys cup (Mathys Ltd., Bettlach, Switzerland)

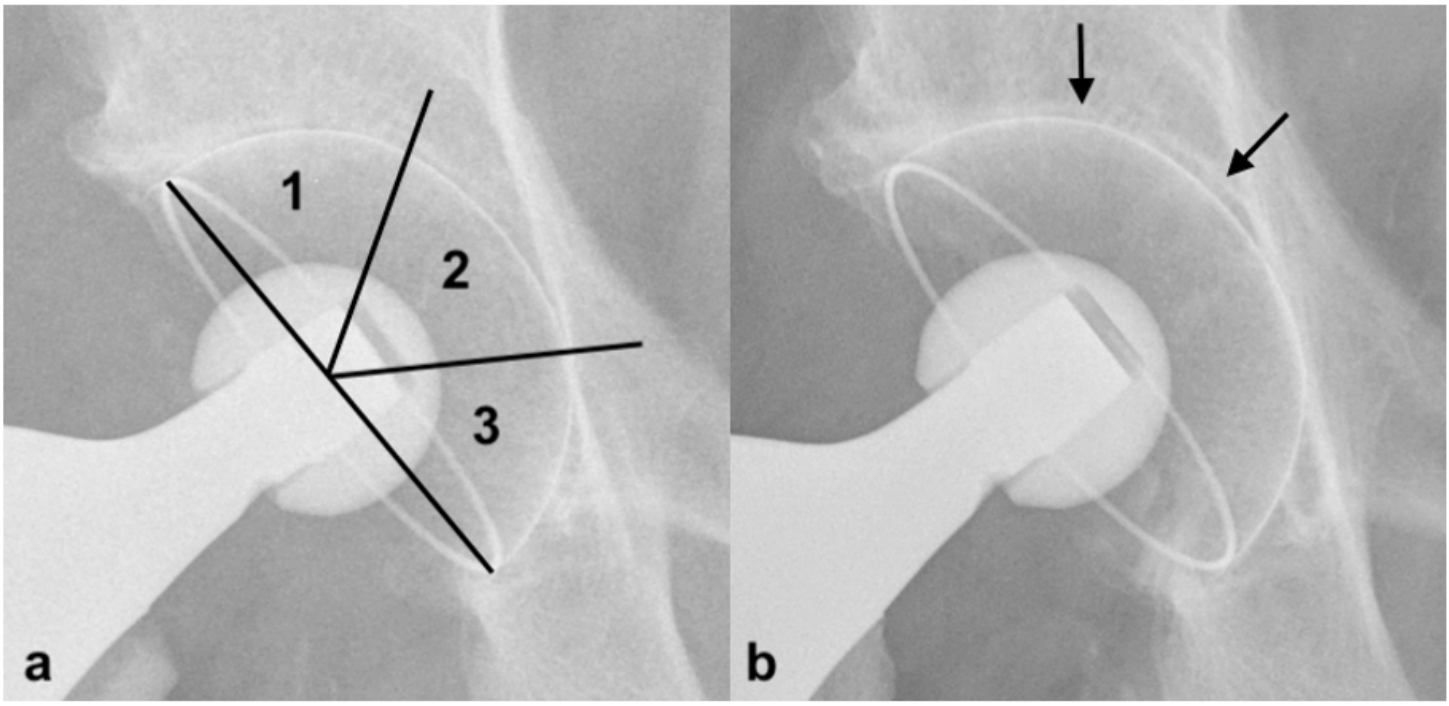

Figure 2

Radiographs of a RM Pressfit vitamys cup (Mathys Ltd. Bettlach, Switzerland) directly postoperative (a) and at 5 year follow-up (b). The patient (89-year-old male) showed signs of a sclerotic line in Zone 1 and 2.

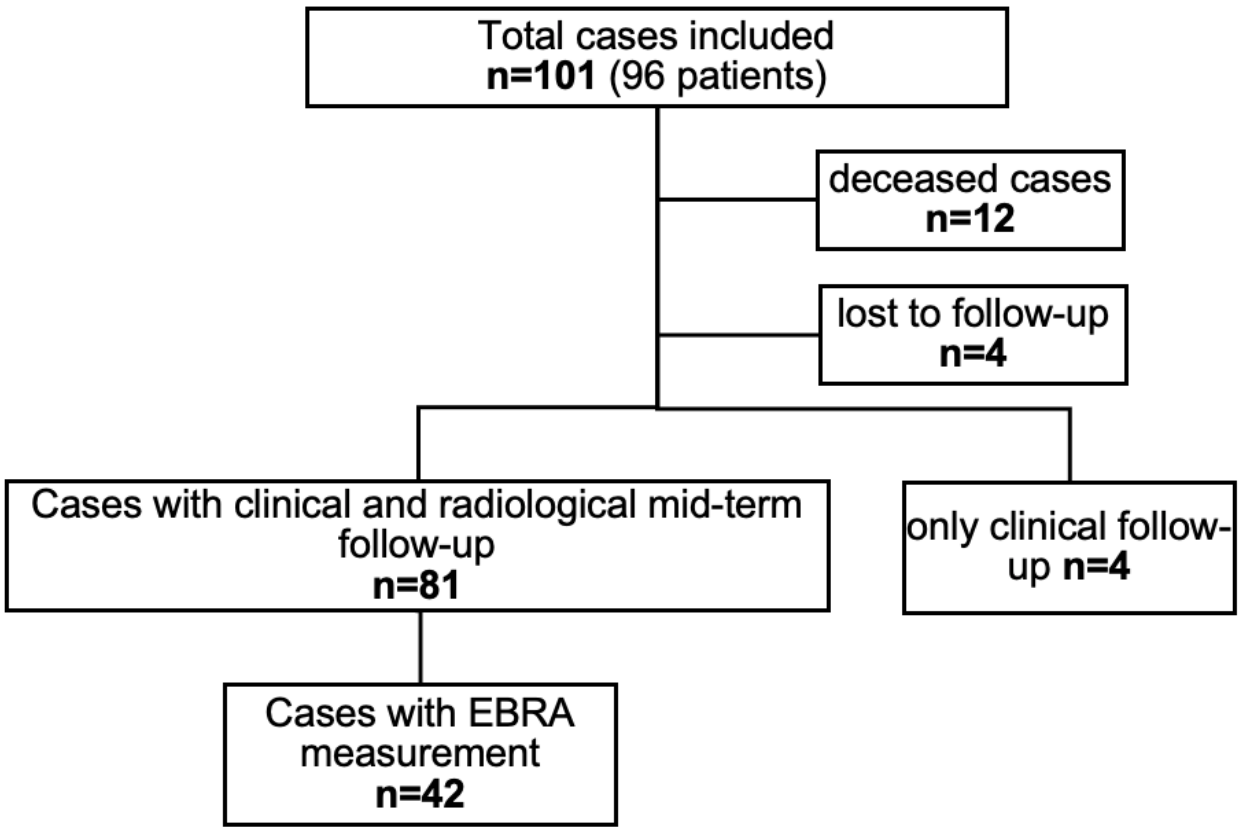

Figure 3

Flow-diagram of follow-up

Supplementary Files

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- SupplementaryData.docx
- STROBEchecklist.docx