

HXLPE with vitamin E in a monoblock pressfit cup: 2-year results from a multicentre, prospective trial

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Introduction

The RM classic cup (Figure 1a) is a monoblock polyethylene (PE) cup with good survival rates [1]. The all PE cup has a titanium (Ti) particles warm pressed into the PE giving a coating thickness of 100 - 300 µm (Figure 1d). This has no influence on the elasticity of cup and provides proven osseo-integration.

The RM cup has all the advantages of:

- Cemented cups
 - No back side wear
 - Maximum PE thickness
 - No noise, fracture, metal ions
 - Simple
 - No stress shielding
 - Cost effective
- Cementless cups
 - Biological ongrowth fixation
 - Easy to revise
 - Bone preserving



Figure 1: Evolution of the RM pressfit Vitamys cup a) RM classic cup b) RM pressfit UHMW-PE c) RM pressfit Vitamys d) Ti particles pressed into surface of PE

With increasing numbers of high demand patients undergoing THA, wear remains a fundamental issue. HXLPE with Vitamin E (Figure 1c) has demonstrated favourable abrasion resistance, regardless of head size.

Aim

To report the early (two year follow-up) results of a HXLPE monoblock pressfit cup with vitamin E

Methods

Post-marketing surveillance study:

- Multi-centre (11 institutions worldwide)
- Medium term
- Non comparative
- Prospective

Follow up:

- Pre-operatively
- Immediately post-operatively
- One year
- Two years

Outcome measures:

- Harris Hip Score (HHS)
- Radiological lysis
- Range of Movement (RoM)
- VAS Pain and Satisfaction
- Complications

Currently 890 cases are included in the study and 404 cases are at two year follow-up.

References

1. Ihle et al. J Bone Joint Surg (Br) 2008; 90-B:1284-90

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Results

The total cohort was 58% females with a mean age of 67.3 years (19 to 93) and mean BMI of 27.7 (14.6 to 53.1). All outcome measure had improved at two year follow-up (Table 1).

Table 1: Outcome measures for whole cohort pre-operatively and at two year follow up

Outcome	Pre-operatively (n=890)	Two year post-operatively (n=404)
HHS	53.5 (SD 15.4)	95.5 (SD 7.5)
VAS Satisfaction	2.6 (SD 2.0)	9.4 (SD 1.1)
VAS Load pain	7.1 (SD 1.9)	0.5 (SD 7.5)
RoM - flexion	84° (SD 17°)	107° (SD 15°)

Radiological analysis demonstrated that there were no cases of cup migration at two years (Figure 2). However there was a 4.7% incidence of radiolucency in more than two De Lee-Charnley zones. Within the total cohort there was one dislocation and 13 infections. To date five cases have been revised.



Figure 2: Radiographs showing a satisfactory RM Vitamys cup with a cementless Twinsys stem

Discussion

The concept behind this isoelastic monobloc cup is well proven. Ihle *et al.* [1] reported a 91% survival rate with revision for aseptic loosening as endpoint after 20 years. They found an increase of cup revisions after 14 to 16 years due to osteolysis. At two years, we report a low complication rate. The change from standard polyethylene to HXLPE with vitamin E has not had a negative impact at two years. The superiority of this new material will only be proven after a follow-up of 14 years or more.

Conclusions

- This implant demonstrates satisfactory clinical and radiological outcomes at two years
- Small numbers of lucent lines without clinical correlation were observed
- The use of this acetabular implant appears to be safe in the short term
- The results of the long term clinical and radiological analysis are awaited