

bonepreservation

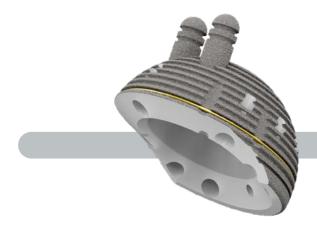
optimys – ceramic head – RM Pressfit vitamys Results you can rely on

CLINICAL RESULTS

40 years of history

With the RM cup family, Mathys has 40 years of clinical experience with uncemented isoelastic monoblock cups and expertise in titanium particle coating for cementless application.

EXPERIENCE

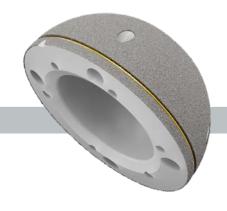


1983

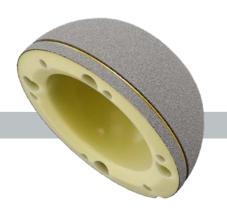
RM Classic Cup

DESIGN

MATERIAL



2002



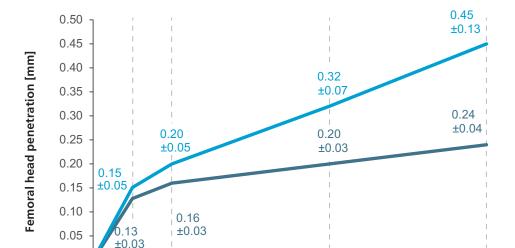
2009

RM Pressfit Cup

Significantly reduced wear

According to a study using radiostereometric analysis (RSA), the RM Pressfit vitamys cup made of highly cross-linked and vitamin-E-enriched polyethylene vitamys demonstrates significantly lower femoral head penetration compared to a cup with conventional polyethylene (UHMWPE). ¹ These results have been confirmed by Massier et al. ² The wear rate is independent of cup inclination, cup size ¹ or head size ³. The RM Pressfit vitamys cup shows a high potential for prevention of osteolysis and implant loosening. ^{1,2} The wear rate is only one-fifth of the critical value established as leading to osteolysis or implant loosening. ²

Creep and wear behavior of UHMWPE (light blue line) and vitamys (blue line) over time 1



2

Years after surgery

4

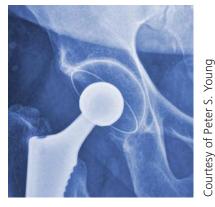
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Optimised bone preservation

After an initial adaption phase, the osseous changes around the optimys stem remain stable for at least five years after surgery. ⁴ The greatest changes were in Gruen zones 1, 2 and 7. ⁵ The RM Pressfit vitamys cup shows excellent primary stability due to its equatorial pressfit design. ⁶ Two years after implantation, the initially reduced acetabular bone mineral density was on the way back to normal levels, stimulated by the medial pelvic loading. ^{4–6}



PreoperativeOsteoarthritic hip joint



Two years postoperativeOsseointegration with pronounced medial trabeculae around the cup



Excellent reconstruction

In vitro – tested

In a surgical planning study, it was shown that the optimys stem can be used to reconstruct neutral hip positions as well as coxa valga and coxa vara with regard to offset and leg length. ⁷

In vivo - confirmed

The in vitro results have been confirmed by Kutzner et al. ⁸ for a variety of anatomies. The total femoro-acetabular offset was increased by 2.1 mm, while the acetabular offset was reduced by 3.7 mm, and the femoral offset gained by 5.8 mm. Thanks to its design and the possibilities for individual positioning, the optimys stem allows effective prevention of loss of total offset. ⁸ Optimal offset restoration may improve the functional outcome. This could particularly benefit the younger patient population, who expect more from their implant in their more active lifestyle. ⁹

From the patients' perspective, implantation of the Mathys bonepreservation system results in high satisfaction and leads to clinically relevant pain reduction. 10, 11

Visual analogue scale (VAS) for **satisfaction**



Visual analogue scale (VAS) for **pain**





50 % better sleep and more sport

A 50 % improvement of sleep quality and physical function can be expected after implantation of the optimys stem. ¹²

After implantation of the optimys stem, 50 % of the patients that would not do sport before surgery started becoming active after the operation. ¹³ 91 % of the patients who had been active in sports before surgery returned to their sports after implantation of the Mathys bonepreservation system. ¹⁴

Superior survival in registries

German Arthroplasty Registry (EPRD) 15

In the German Arthroplasty Registry, the RM Pressfit vitamys cup and the optimys stem perform significantly better than all cementless total hip arthroplasties (benchmark) do, with a revision rate of 2.2 % after 8 years compared to the benchmark with 4.3 %.

Revision rate at the respective time after implantation of the RM Pressfit vitamys cup and the optimys stem; revision rate in % incl. 95 % confidence interval in brackets. Only time points with at least 40 cases under observation are listed.

Hip system	1 year	2 years	5 years	8 years
Benchmark	2.7 (2.6–2.8)	3.1 (3.1–3.2)	3.7 (3.6–3.8)	4.3 (4.2–4.4)
RM Pressfit vitamys & optimys	1.7 (1.5–1.9)	1.9 (1.7–2.2)	2.2 (1.9–2.5)	2.2 (1.9–2.5)

Swiss Implant Registry (SIRIS) 16

The Mathys bonepreservation system shows excellent performance in the Swiss Implant Registry. It stands out with below-average long-term revision rates. At ten years, the revision rate is significantly better with 2.9 % for the RM Pressfit vitamys cup in combination with the optimys stem compared to all total hip arthroplasties (benchmark), which have a revision rate of 5.3 %.

Revision rate at the respective time after implantation of the RM Pressfit vitamys cup and the optimys stem; revision rate in % incl. 95 % confidence interval in brackets.

Hip system	1 year	3 years	5 years	8 years	10 years
Benchmark	2.3 (2.2–2.4)	3.2 (3.1–3.3)	3.8 (3.7–3.9)	4.4 (4.3–4.5)	5.3 (5.1–5.5)
RM Pressfit vitamys & optimys	1.8 (1.6–2.0)	2.2 (2.0–2.5)	2.4 (2.2–2.7)	2.6 (2.3–2.9)	2.9 (2.3–3.6)

The excellent long-term results from the German and the Swiss arthroplasty registries are supported by excellent mid-term results in the Australian (AOANJRR), Dutch (LROI) and New Zealand (NZJR) joint replacement registries at mid-term. 17-19

Proven – 20-year registry data

In their recent study, Foxall-Smith and co-workers analysed the New Zealand Joint Registry data for the RM cup designs. ²⁰ Data from 1998 to 2018 were included. All implant designs were safe. Use of larger heads resulted in fewer revisions due to dislocation.

Revision rate as revisions per 100 observed component years; revision rate in % incl. 95 % confidence interval in brackets. The source for the benchmark value is the Annual Report from the New Zealand Joint Registry 2019.²¹

Implant type	Number	Component years	Revision rate	
Benchmark	135,461	972,138	0.72 (0.70-0.73)	
RM Classic	1321	12,959	0.62 (0.49-0.76)	
RM Pressfit	6006	37,028	0.57 (0.49–0.65)	
RM Pressfit vitamys	4574	14,032	0.58 (0.46-0.72)	

Excellent mid- to long-term survival

The RM cup family stands out with excellent long-term survival rates.



RM Classic 94 % at 20 years (aseptic cup loosening) 22



RM Pressfit vitamys 98.9 % at 9 years 11 100 % at 5 years 1



optimys 98.4% at 6 years 10

Very strong clinical evidence

Orthopaedic Data Evaluation Panel (ODEP) 23

The Orthopaedic Data Evaluation Panel (ODEP) lists the optimys stem with 7 years of very strong evidence, the RM Pressfit vitamys cup with 10 years of very strong evidence and the RM Pressfit cup even with 13 years of very strong evidence. The clinical success of the RM Classic bevelled cup is rated with 13 years of strong evidence.

ODEP 13A

RM Classic bevelled

ODEP 13A*

RM Pressfit

ODEP 10A*

RM Pressfit vitamys

ODEP **7A***

optimys

Glossary

Confidence interval

The confidence interval is a value range that describes the uncertainty surrounding a calculated parameter. A 95 % confidence interval is most commonly used. This means a probability of 95 % that an interval is obtained that comprises the unknown expected value. The minimum and maximum values of the confidence interval are called the lower and upper confidence limit, respectively.

Estimation of survival and revision rates

The survival and revision rates of implants in registries and scientific publications are often calculated by means of the Kaplan-Meier estimation. In the Kaplan-Meier estimation, the time to the first implant revision corresponds to the survival rate. The cumulative revision rate at a certain point in time, e.g. after 5 years, is the complement (in terms of probability) of the Kaplan-Meier survival calculation at that point in time. If a patient is deceased or the implant is in the patient at the time the database is closed (data export), the data will be censored at that time.

ODEP

ODEP is an acronym meaning «Orthopaedic Data Evaluation Panel». It is an independent panel of experts drawn mainly from British surgeons but also including some non-clinical experts with many years of industry experience.

The panel was established by the National Health Purchasing and Supply Agency (PASA, later replaced by SCCL – the Supply Chain Coordination Limited).

The numbers indicate the number of years of clinical evidence. The letter represents the clinical evidence of the data provided by the manufacturer.

Further information can be found at http://www.odep.org.uk/ODEPExplained.aspx

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