RM Philosophy – Innovation based on clinical evidence
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First uncoated RM Classic Cup out of Polyacetal was inserted by E. Morscher in 1973.

First uncoated RM Classic Cup out of UHMWPE was implanted in 1975.
The Idea - Isoelasticity

…the main problem is the difference in **bony elasticity** encountered **between various parts of the acetabulum**


Robert Mathys Senior developed the idea of isoelasticity

Because of the poor wear characteristics of POM (Polyoxymethylene), Mathys preferred to use high density polyethylene (UHMWPE)

Surface of each cup bears shallow circular grooves to allow bone ingrowth

Two pegs to secure a firm anchoring and resist rotational forces

After extensive tests in animals, the first RM cementless hip prosthesis was inserted by E. Morscher in 1973

In **1967 Robert Mathys** conceived the **idea of an isoelastic prosthesis** made of plastic, which would anchor **into the bone without cement**
RM Philosophy – Innovation based on clinical evidence

Since the first implantation in 1973 more than 271’000 RM Classic Cups were implanted
The Beginning - RM Classic Cup

RM Classic Cup
Works even better!

10A - the highest rating
The Beginning - RM Classic Cup

10A Looks good?
94.4 %

Excellence based on more than 20 years of experience with a survival rate of 94.4% for aseptic loosening. The RM Classic Cup has a better survival rate compared to the average survival rate of the Swedish Hip Arthroplasty register for uncemented cups irrespective of talar fixation.

References:

www.mathysmedical.com
The **RM Classic Cup** is listed in the **ODEP** (Orthopaedic Data Evaluation Panel) with a **10A** NICE (National Institute for Health and Clinical Excellence) rating in the United Kingdom.

<table>
<thead>
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<td>RM CUP TiCP COATED</td>
<td>Cup</td>
<td>Cementless</td>
<td>Monobloc</td>
<td>1983</td>
<td>Yes</td>
<td>14</td>
<td>10A</td>
<td>2011</td>
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</table>

In total only 12* uncemented acetabular cups currently have a 10A rating. **RM Classic Cup is one of them!**

*Source: [http://www.supplychain.nhs.uk/odep/](http://www.supplychain.nhs.uk/odep/) (accessed on 07.08.2013)
10 A rating for uncremented cup

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<td>Smith &amp; Nephew</td>
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<td>Yes</td>
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</table>

*Source: http://www.supplychain.nhs.uk/odep/ (accessed on 30.01.2014)
10 A rating in UK today

What does 10A mean?

For 10 year benchmark products, ODEP placed products in one of four categories: 10 refers to a minimum follow-up of 10 years and A corresponds the Level A – Strong evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>Meets NICE guidance</th>
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<tr>
<td>A</td>
<td>Strong Evidence</td>
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<td>B</td>
<td>Reasonable Evidence</td>
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<td>C</td>
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<td></td>
<td>Unacceptable Evidence</td>
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</table>

Source: [http://www.supplychain.nhs.uk/odep/](http://www.supplychain.nhs.uk/odep/) (accessed on 15.05.2013)

What is the definition of Level A – Strong evidence?

- Failure rate of 10% or less
- Cohort of more than 500 joints at start of study
- All product failures identified
- Kaplan Meier survivorship at 10 years on acceptable size cohort
- Registry data or multicentre (3 or more centres including non-developing)

Source: [http://www.supplychain.nhs.uk/odep/](http://www.supplychain.nhs.uk/odep/) (accessed on 15.05.2013)
10 A rating for the RM Classic Cup & for two more

Beside the RM Classic Cup two more Mathys implants reached this rating

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Why registry data as reference?

“Worldwide joint arthroplasty registers are instrumental to **screen for complications or implant failures**”

Registry data are…..

- provided by the registries
- official available
- of high evidence
- of high acceptance
- including **survival & revision rates**
Uncemented cups were used…

at considerably lower ages
- uncemented cups: mean age 57.3±10.4 years
- cemented cups: mean age 70.7±9.5 years

more often in men
- uncemented cups: 51.4%, cemented cups: 39.2%

less frequently in secondary osteoarthritis
- uncemented cups: 17.4%, cemented cups: 19.9%

Conclusion: Uncemented cups have a somewhat reduced risk of revision for loosening/osteolysis up to an age of 69 years but are associated with other problems that lead to revision, for which reason the total revision risk shows no significant difference.
We only consider the average survival rate for uncemented cups irrespective of cause.
At 19.8 years the survival rate of the RM Classic Cup for aseptic loosening is at 94.4% which is an excellent outcome.
Medium-term results after the implantation of coated RM cups (12-year results)
Blencke BA (2005) Ortopaedics Today International

Follow up of 307 implantations in year 1990

Mean age of the patients was 67.3 years

Between 1990 and 2002, revision of implant of 13 patients
   3 isolated cup revisions, 3 isolated stem revisions, 6 complete prosthetic revisions, explanation of 1 prosthesis because of a suspected infection and re-implantation after 6 months.

11 of 224 patients required a cup revision within 12 years.
   All prosthetic cup revisions performed in the hospital were caused by aseptic indications

**Mean survival rate after 12 years for the RM Classic Cup irrespective of cause:** 96.4%

The implantation of coated RM cups has provided good medium and long-term results and has exhibited a durable fixation after a minimum follow-up of 12 years
The uncemented titanium coated monobloc Robert Mathys acetabular component. A retrospective study over 15 years
John T. et.al.(2009), EFORT Congress 3-6 June 2009, Vienna

1876 RM Classic Cups between January 1,1988 and December 31, 2001

451 patients had died unrelated to the operation during follow up
Lost of follow up were 65 patients (69 Cups) and 34 patients (48 cups) had to be revised.

Reason for revision
34 aseptic loosening, 8 infection, 2 dislocation, 2 malposition, 2 periprosthetic fractures

Cumulative survival rate of the RM Classic Cup is…
98.2 % @ 5 year  97.5% @ 10 years  96.9% @ 15 years

The RM Classic Cup has been shown to function well at up to 15 years post implantation. Its success may in part be due to the one-piece design.
The results of the titanium-coated RM acetabular component at 20 years: a long-term follow-up of an uncemented primary total hip replacement

93 consecutive primary THRs between January 1986 and July 1989

Mean age of the patients 52 years (28 to 81)
  None were lost to follow-up

At the last follow up 23 patients (26 hips) had died

14 acetabular component revisions were carried out after a mean of 12.3 years
  7 for osteolysis, 5 for loosening, 2 for infection

Mean survival rate for the RM Classic Cup irrespective of cause: 82.7%
Mean survival rate for the RM Classic Cup for aseptic loosening: 94.4%

The RM concept of a monobloc acetabular component is unique. Backside wear, which occurs between a hard metal shell and the polyethylene liner, can be avoided
The design evolution - RM Pressfit Cup
RM Philosophy – Innovation based on clinical evidence

1973 Design

1983 Coating

2002 Design

RM Classic Cup

RM Pressfit Cup
RM Pressfit Cup - Design concept

Innovation based on excellent long-term results of RM Classic Cup

UHMWPE-body to generate press-fit
Use same parameters and coating as from RM Classic Cup

Leaving the pegs away
No drilling
Short surgical technique
Easy instrumentation

Adaptation of the design
1.6 mm equatorial pressfit
No circular grooves for higher primary bone/implant contact surface
Registry data – RM Pressfit Cup

Lower revision rate of RM Pressfit Cup compared to the average of all cups documented in the registry

*The New Zealand Joint Registry Januar 1999 to December 2010
The **RM Pressfit Cup** is listed in the **ODEP** (Orthopaedic Data Evaluation Panel) with a **5A** NICE (National Institute for Health and Clinical Excellence) rating in the United Kingdom.

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Osteolysis

Osteolysis is one of the major failure mode of cemented and uncemented acetabular fixation[1]

It is a consequence of the biological reaction of bone to ultra-high-molecular-weight polyethylene (UHMWPE) wear and metallic debris[1]

The amount of UHMWPE wear is negatively correlated with the long-term survival of both cup and stem[2]

Therefore, knowledge of wear over time is an important indicator of the risk of early loosening

RM cup: Low wear, no holes in the back, good osteointegration = **Less acetabular osteolysis**
Osteolysis & wear rate in general & RM Cups

Osteolysis is infrequent when wear rates are below 0.1 mm/y and virtually absent below 0.05mm/y

Reported wear of RM Classic Cup and RM Pressfit Cup are between 0.02 and 0.09 mm/y → low risk of osteolysis
Cemented cups especially prevent the loss of cancellous bone of the acetabulum while also cortical BD loss was significantly lower … compared to the press-fit component.
## Stress shielding

<table>
<thead>
<tr>
<th>Material</th>
<th>Density (g/cm³)</th>
<th>E modulus (N/mm²)</th>
<th>Tensile strength (N/mm²)</th>
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<tr>
<td>Bone</td>
<td>0.2 – 2</td>
<td>500 – 6000</td>
<td>10 – 150</td>
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<tr>
<td>Bone cement</td>
<td>1.17</td>
<td>3000</td>
<td>47</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>0.94</td>
<td>1000</td>
<td>35</td>
</tr>
<tr>
<td>vitamys</td>
<td>0.94</td>
<td>800</td>
<td>37</td>
</tr>
<tr>
<td>Titanium</td>
<td>4.5</td>
<td>105 000</td>
<td>➢ 400</td>
</tr>
</tbody>
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Mechanical properties of polyethylene and bone cement ≈ Mechanical properties of bone

We expect the RM cup philosophy to behave as a cemented cup in terms of stress shielding
Osteolysis in long term follow up

Between 13.7 and 15.7 years after initial operation a notable number of revisions of well integrated and stable cups due to osteolysis, were reported.

Most common reason was polyethylene wear.

All heads were 32mm in diameter:
- 80 femoral heads were made of ceramic
- 13 femoral heads were made of CoCrMo alloy

Therefore, reduction in wear the future challenge for uncemented hip prosthesis.

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**Figure 1** (modified from Ihle et al., 2008 [10]) showing time course of revisions of acetabular component.
A promising solution to future challenge of wear reduction is the RM Pressfit vitamys
A promising solution to future challenge of wear reduction is the RM Pressfit vitamys.
The future - RM Pressfit vitamys Cup

RM Pressfit vitamys
Expected to work even better!

80% wear reduction with vitamys in vitro!
In hip simulator tests, according to EU-14244 vitamys proves to be one of the best substances of currently available materials. Wear rate of vitamys remained at constant low level even using different head materials and diameters.

80%
Looks good?
1–2 y
Cross-linking of UHMWPE  [ ultra high molecular weight polyethylene ]

Need to generate free radicals to enable cross-linking

Free radicals may react with oxygen

Oxidation  \( \rightarrow \) irreversible scission of molecular chains, embrittlement etc.

How to reduce the free radicals? How to prevent oxidation?
Why chose vitamin E (α-tocopherol) ?

Protects cell walls from oxidation during $O_2$ transport through these walls

Ingredient of anti-ageing crèmes, food packaging

Maximum daily amount: 400 mg

Vitamin E reacts with oxygen & slows down the ageing process
Vitamin E meets RM Pressfit

The HXLPE with highest level of mechanical properties (Type 1 according to ISO 5834-2)

Allowing articulations up to 36mm from size 52

Vitamin E reacts with oxygen and slows down the ageing process

Modulus of elasticity of the cup is 800N/mm²

~50mg Vitamin E in a RM Pressfit vitamiys cup

Improving wear performance while maintaining mechanical properties
Advantages of vitamys

Accelerated ageing through increased temperatures and oxygen content is used to simulate oxidation and ageing over many years of shelf storage.

60 days accelerated ageing under $O_2$ (70°C, 5bar) correlates to 40 years in vivo.

The in vitro testing of vitamys proved to be long-term oxidation and ageing resistant.
Clinical results and ongoing studies of vitamys

Wear rates of standard UHMWPE is strongly affected by ageing (oxidation)

Better wear resistance with vitamys
- Wear rate of vitamys is 80% lower than the standard UHMWPE

Wear rate of vitamys remained at a constant level
- Wear rate remain at a constant level using different head materials (CoCr / ceramic) and diameters (28 mm, 36 mm)

Increased wear resistance should theoretically lead to less osteolysis and thus to better long-term outcomes
Clinical results and ongoing studies of vitamys

Wear rate of vitamys is therefore predicted to remain at the same low level over its lifetime inside patients – 2 year in vivo results confirm this prediction!
Mechanical properties

Low

Wear resistance

High

UHMWPE

Cross-linked with vitamin E

Cross-linked, re-melted > 138°C

Cross-linked, annealed ≤ 138°C

vitamys, E-Poly, ECIMA

Crossfire, X3

Durasul, Longevity, Marathon
Take Home Message
RM Philosophy – Innovation based on clinical evidence

Coating

The Beginning - RM Classic Cup
- Two pegs to secure a firm anchoring and resist rotational forces
- Circular grooves to allow bone ingrowth
- Extraordinary long term results
- Backside wear can be avoided

Design

The design evolution - RM Pressfit Cup
- 1.6 mm equatorial pressfit
- No circular grooves for higher primary bone/implant contact surface
- Lower revision rate compared to the average of all cups
- Wear rate 0.09mm/y after 5 years

Material

The future - RM Pressfit vitamys Cup
- Wear rate of vitamys is 80 % lower than the standard UHMWPE
- In vitro testing proved to be long-term oxidation and ageing resistant
- Wear rate predicted to remain at the same low level over its lifetime
...together with passion!