Materialise aMace
Patient-Specific Acetabular Implants
1. Summary

Up to 27% of hip revisions are re-revisions due to a suboptimal fixation and suboptimal biomechanical reconstruction of the joint\(^a\) when combining standard components. Furthermore, hip re-revisions are 3 times more likely to fail compared to a primary acetabular revision\(^b\). These failures often lead to ever enlarging bone defects which render the next revisions more and more complex and frequent.

Based on +10 years of technical and clinical research, the Materialise aMace Acetabular Revision System\(^c\) is designed to break this revision cycle. The following, exhaustive clinical data proves this is actually successful. About 10% of all cases by Materialise have been reported in scientific studies from Germany, United Kingdom, The Netherlands and Belgium. This representative sample shows a 98% implant survival rate at an average follow-up of 2 years (maximum 5 years)\(^1,2,3,5,6\), which is the critical time frame for implant failure of standard components according to national registries\(^1,2\).

1.1. Complications

As these are complex surgeries, complications cannot be completely avoided. Nevertheless, Materialise aMace shows high performance in terms of complications in these studies\(^1,2,3,5,6\).

- Dislocations were reported in 13% of the studied cases up to 2 years post-surgery. None led to aMace revision, all were resolved by closed reduction.
- Studies report no signs of radiological loosening up to 2 years post-surgery.
- Studies report post-operative hematomas in 6% of the cases.
- Only 2 neurological complications reported so far.
- 2 Deaths were reported, both high-risk patients, no relation with the implant was inferred.

1.2. Satisfaction

Multiple studies also show that the use of Materialise aMace results in a high patient satisfaction\(^1,3,4,6\).

- 100% of patients were satisfied with a high satisfaction score of 8.5/10.
- Almost all patients (98%) of queried patients would recommend the procedure to a family member or friend.
- The overall majority of patients (83%) reports a positive impact on their daily life after receiving an aMace implant.
- With an average follow-up time of 2.5 years post-surgery, the Harris Hip Score even improves from 22/100 (pre-surgery) to 59/100.
- Difficulty of the surgery was rated as very easy, easy or normal by 73% (16/22) of queried surgeons.

The clinical data on the use of the Materialise aMace Acetabular Revision System shows that the 3D preoperative planning combined with patient-specific instrumentation and implants, helps to provide a good fixation of the acetabular component. Therefore, Materialise aMace represents a viable solution for re-revision cases.

\(^a\) Swedish Arthroplasty Register, Annual Report 2014
\(^b\) Data UK Joint Registry
\(^c\) Materialise fully acquired the company Mobelife (which introduced the aMace Acetabular Revision System) in 2015.
## 2. Key Studies

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<tr>
<th>Design</th>
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<th>Key Points</th>
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<td>Evaluation of the accuracy with which a custom-made acetabular component can be positioned</td>
<td>Bauuw et al. Bone Jt J 2015 (n=16)</td>
<td>3 complications, no infections, no additional surgeries</td>
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<td>Retrospective clinical and radiological short-term follow-up (18-39 months) study</td>
<td>Bauuw et al. Orthopedics 2017 (n=12)</td>
<td>13/16 patients within Lewinnek’s safe zone</td>
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<td>Retrospective clinical and radiological short-term follow-up (10-58 months) study (2 surgeons)</td>
<td>Citak et al. Hip Int 2017 (n=9)</td>
<td>2/3 implants with deviating orientation had no complications, Encouraging results</td>
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<td>short-term follow-up (10-58 months) study</td>
<td>Colen et al. Acta Orthop Belg 2013 (n=6)</td>
<td>4 complications, no infections and no additional surgeries</td>
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<td>In-vitro and in-vivo study of 3D-printed acetabular implant with autologous skeletal stem cells</td>
<td>Goriainov et al. Ren Med 2018 (n=11)</td>
<td>Case series with complex acetabular defects (average 5 previous revisions, range 2-8)</td>
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<td>Early (2009-2014) Belgian (13 surgeons) retrospective clinical short-term follow-up (3-50 months) study + focus on experience with the aMace Acetabular Revision System</td>
<td>Myncke et al. Acta Orthop Belg 2017 (n=20)</td>
<td>Overall implant-associated survival rate was 89% at mean follow-up of 29 months: 1 implant failure in patient with bilateral pelvic discontinuity</td>
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<td>5/9 non-implant related complications</td>
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<td>Significant improvement of HHS score in 91%</td>
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<td>No component removals, no revisions, no dislocations and no evidence of infection</td>
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<td>No signs of loosening, migration or hardware breakage</td>
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<td>All patients were satisfied with the clinical results. Good clinical outcome (HOOS score: 54-89)</td>
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<td>Patient-specific guides and titanium porous structure with triflange design are added value in the treatment of severe acetabular bone loss and pelvic discontinuity and provide the best chances for long term stability of the implant</td>
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<td>In-vitro study shows that autologous bone marrow cells adhere on porous titanium surfaces and express osteogenic genes</td>
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<td>Significant improvement of Oxford Hip score</td>
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<td>Good overall experience with aMace Acetabular Revision System (mean score 8.1/10)</td>
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<td>All surgeons would consider using the solution again</td>
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<td>8 complications, no radiographic signs of implant loosening and no additional surgeries</td>
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<td>Patient satisfaction is high with almost all patients pain free</td>
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<td>All but one patient would go for the same surgery again</td>
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4. Technical

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| Comparative study between radiographic and CT-based defect analysis for periacetabular bone defects | Horas et al. Orthopäde 2017 | - Radiographic analysis often underestimates larger defects using Paprosky classification  
- Intra-observer reliability of radiographic analysis is low  
- Novel software tools based on CT data make it possible to anticipate volumetric bone loss, periacetabular bone quality and the intraoperative Paprosky grade in more detail. |
| Quantification of in vivo bone ingrowth and fixation of clinically used Ti scaffolds in adult goats | Demol et al. J. Tissue Eng. and Reg. Med. 2012 | - Porous Ti implants have good osseointegration characteristics  
- Titanium surface allows good bone apposition  
- The porous structure enables the bone to grow into the pores of the construct so that strong biological fixation of the implant in the bone is achieved. |

3. References

3.1. Publications

3.1.1. Clinical


3.1.2. Technical


https://www.tandfonline.com/doi/abs/10.1080/10255842.2014.890186

https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.94SUPP_XXV.ISTA2010-040


https://www.tandfonline.com/doi/full/10.3109/10929080701684762

https://www.tandfonline.com/doi/abs/10.1080/10255840600604474

3.2. Presentations

3.2.1. Clinical

• B. W. Wippermann. Solutions for complex hip surgery: How to get started. Materialise THINK Idea to Patient Care Webinar Series, 2018


• Ph. Van Overschelde. Clinical and radiological outcome up to 4 years after hip revision surgery of complex acetabular defects with the aMace custom-made acetabular cup - a retrospective study. EHS 2018, The Hague, The Netherlands

• W. Rijnen. Patient specific 3D printed acetabular cages as last resort. EHS 2018, The Hague, The Netherlands

• G.G. van Hellemondt. First experience with custom made 3D printed cups in revision. EHS 2018, The Hague, The Netherlands

• M. Baauw, Clinical results at 2-years follow-up of a 3d-printed custom-made acetabular implant for paprosky 3 defects. NOF 2018, Reykjavik, Iceland

• G. Flivik. 3D Implants, The Swedish Experience. EFR 2018, Barcelona, Spain

• G. Flivik. First experience with 3D implants. SOF 2017, Umea, Sweden

• G.G. van Hellemondt. 3D printed cups in massive acetabular deficiency. AORcon 2017, Vancouver, Canada.

• D. van der Jagt, J. Pietrzak, L. Makete. Two custom systems – comparisons, results and cost implications. Johannesburg Arthroplasty discussion group & Division of Orthopaedic Surgery University of the Witwatersrand, 2016, Johannesburg, South Africa


• T. Gehrke #101 The Custom Acetabular Component: The 3D Printed Solution. CCJR Spring Meeting, 2016, Las Vegas


• P. Van Overschelde. Complex acetabular reconstruction with custom made Mobelife implant. ICJR Middle East 2015, Dubai, United Arab Emirates


• J. Nilsson, Extreme acetabular reconstruction. BVOT Spring Symposium 2013, Antwerpen, Belgium

• M. Spruit, Custom implants for the treatment of Paprosky type IIIa and IIIb acetabular defects. BVOT Spring Symposium 2013, Antwerpen, Belgium


• M. Spruit, G. Van Hellemondt. Case specific acetabular reconstructions for challenging defects. Mobelife Symposium @ NOF 2012, Tallin, Estonia
3.2.2. Technical

- P. Tack. 3D is Here, But Can We Afford It Moving Forward? Materialise World Summit 2017, Brussels, Belgium
- F. Gelaude. Patient specific implant solutions. Regensburger Revisionssymposium 2015, Regensburg, Germany
- K. Govaers. Innovative custom technology in hip replacement. BVOT Spring Symposium 2013, Antwerpen, Belgium
- P. Vanden Berghe, J. Demol, F. Gelaude, J. Vander Sloten. Automatic reconstruction of large acetabular bone defects using statistical shape models. CORS 2013, Venice, Italy
- T. Clijmans, CT-based quantification of bone loss for refined classification of acetabular deficiencies: comparison of 30 Paprosky type IIIA-B cases. BOA Congress 2012, Manchester Central, Manchester, UK
- J. Demol, B. Lenaerts, S. Leuridan, H. Delport. Bone loss management with 3D printed metal augments: in vivo evaluation of bone ingrowth and fixation. EHS 2012, Milano, Italy
- H. Delport, M. Mulier, P. Vanderschot. Paprosky type IIb pelvic defect reconstruction by patient-specific technology. International Society for Technology in Arthroplasty (ISTA), 2011, Bruges, Belgium
- F. Gelaude for M. Mulier, M. Raaijmakers, A. Willems, T. Clijmans. Personalized implant design for acetabular revision. IMUKA 2010, Maastricht, Netherlands
- T. Clijmans. 3D image processing and pre-operative planning in orthopaedics. EHS 2010, Athens, Greece
- F. Gelaude for H. Delport, M. Mulier, P. Vanderschot. All-in-one patient-specific implant solution for severe acetabular revision – a case report. EHS 2010, Athens, Greece
- M. Raaijmakers. Surgical guides for hip joints. 33ème Journée Informelle HIS - site Ixelles 2010, Brussels, Belgium

3.3. Abstracts & Posters

- F. Gelaude, J. Demol, T. Clijmans, H. Delport. Acetabular deficiency classification by numbers: overview of 40 Paprosky type IIIA-B cases. Abstract n° 32465 @ Combined 33rd SICOT & 17th PAOA Orthopaedic World Conference 2012, Dubai, United Arab Emirates
- J. Demol, B. Lenaerts, S. Leuridan, S. De Boodt, H. Delport. Osseointegration of personalized 3D printed metal augments for the management of severe acetabular bone loss. Abstract n° 32461 @ Combined 33rd SICOT & 17th PAOA Orthopaedic World Conference 2012,Dubai, United Arab Emirates
- W. Bartels, J. Demol, F. Gelaude, J. Vander Sloten, I. Jonkers. Patient-specific musculoskeletal models can predict the impact of acetabular reconstruction on hip muscle length. Abstract n° 32471 @ Combined 33rd SICOT & 17th PAOA Orthopaedic World Conference 2012,Dubai, United Arab Emirates
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- W. Bartels, J. Demol, F. Gelaude, J. Vander Sloten, I. Jonkers. Simulation tool for predicting the impact of acetabulum reconstruction on hip muscles. Abstract @ NOF 2012
- T. Clijmans for F. Gelaude, J. Demol, H. Delport. Computerised quantification of the degree of bone loss in 30 Paprosky type IIIA-B cases: comparision and relevance to classification. Abstract @ NOF 2012
- B. Lenaerts for J. Demol, S. Leuridan, H. Delport. Bone ingrowth in porous titanium bone augments in in vivo goat model: customization and functionalization. Abstract @ NOF 2012
- H. Delport, M. Mulier. Custom implant for Paprosky IIIb acetabular revision: a case report. E-poster #5499 @ EFORT 2012, Berlin, Germany
- H. Delport, M. Mulier. Extreme acetabular reconstruction: Solving the impossible requires innovative techniques. A Case illustration. E-poster @ EHS 2012, Milano, Italy
- F. Gelaude, J. Demol, T. Clijmans, H. Delport. CT-based acetabular deficiency classification by numbers: illustration on 50 Paprosky type IIIA-B cases. E-poster @ EHS 2012, Milano, Italy
- T. Clijmans, F. Gelaude, J. Demol, H. Delport. Refined classification of acetabular deficiencies using CT-based quantification of the amount of bone loss: overview of 30 Paprosky type IIIA-B cases. Abstract FM 84 @ SGOT 2012, Basel, Switzerland
- B. Lenaerts, J. Demol, S. Leuridan, H. Delport. Management of acetabular bone loss with 3D printed metal augments: in vivo bone ingrowth and fixation. Abstract FM 1 @ SGOT 2012, Basel, Switzerland
- F. Gelaude, T. Clijmans, H. Delport. 3-dimensional quantitative classification of acetabular defects: Total radial Acetabular Bone Loss (TrABL). E-poster @ 30. Jahrestagung der Österreichischen Gesellschaft für Orthopädie und Orthopädische Chirurgie, 2011, Linz, Austria
- W. Bartels, G. Lenaerts, M. Mulier, G. Van der Perre, J. Vander Sloten, I. Jonkers. Subject-specific muscoskeletal models are needed to accurately predict hip loading. Abstract @ ISB Congress 2011, Brussels, Belgium
- H. Delport, M. Mulier, T. Clijmans, F. Gelaude. Bone and joint implant fixation personlized. Poster @ International Society for Technology in Arthroplasty (ISTA), 2011, Bruges, Belgium
- T. Clijmans, M. Mulier, P. Broos, F. Gelaude. Custom pelvis salvage surgery planning and implantology for better functionality. Poster @ EMSOS 2010, Birmingham, UK
- A. Willems, M. Mulier, M. Raaijmakers, T. Clijmans, F. Gelaude. Reconstruction of complex acetabular deficiencies with patient-specifically designed and evaluated implants. Poster S3 @ EORS 2010, Davos, Switzerland
- P. Broos, T. Clijmans, J. Dille, J. Vander Sloten, F. Gelaude. Contribution of 3D image processing and pre-operative planning to orthopaedic health care. Poster 26306 @ 7th SICOT/SIRO Annual International Conference & SOF Ortopediveckan 2010, Gothenburg, Sweden
- M. Mulier, M. Raaijmakers, F. Gelaude, A. Willems, T. Clijmans. Severe acetabular revision surgery: a personalized approach. Poster 26290 @ 7th SICOT/SIRO Annual International Conference & SOF Ortopediveckan 2010, Gothenburg, Sweden
- M. Raaijmakers, K. De Smedt, F. Gelaude, T. Clijmans, F. Stockmans, M. Mulier. Patient-Specific guide technology in orthopaedics. Poster 26263 @ 7th SICOT/SIRO Annual International Conference & SOF Ortopediveckan 2010, Gothenburg, Sweden
- F. Gelaude, T. Clijmans, B. Lauwers, J. Vander Sloten. A database for muscle attachment regions: femur and pelvis. Poster @ Computer assisted radiology and surgery conference (CARS) 2006, Osaka, Japan