

# Clinical Data Summary

## Materialise aMace Acetabular Revision System

The clinical data on the use of the Materialise aMace Acetabular Revision System<sup>1</sup> shows that the preoperative planning combined with patient-specific instrumentation and implants, produced by additive manufacturing technologies (plastic and metal), helps to provide a good fixation of the acetabular component. Therefore, aMace represents a viable solution for revision cases with large bone defects.

	Design	Publication	Key Points
Clinical	Retrospective clinical and radiological short-term follow-up (18-39 months) study	<b>Baauw et al.</b> Orthopedics 2017 (n=12) <sup>3</sup>	<ul style="list-style-type: none"> <li>• 4 complications, no infections and no additional surgeries</li> <li>• 92% of patients would recommend the treatment</li> <li>• 83% of patients report improvement in daily functioning, had better mobility and less pain</li> <li>• Valuable 3D analysis of the defects prior to surgery</li> </ul>
	Retrospective clinical and radiological short-term follow-up (10-58 months) study	<b>Colen et al.</b> Acta Orthop Belg 2013 (n=6) <sup>5</sup>	<ul style="list-style-type: none"> <li>• No component removals, no revisions, no dislocations and no evidence of infection</li> <li>• No signs of loosening, migration or hardware breakage</li> <li>• All patients were satisfied with the clinical results. Good clinical outcome (HOOS score: 54-89)</li> <li>• 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</li> </ul>
	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	<b>Myncke et al.</b> Acta Orthop Belg 2017 (n=20) <sup>2</sup>	<ul style="list-style-type: none"> <li>• Good overall experience with aMace Acetabular Revision System (mean score 8.1/10)</li> <li>• All surgeons would consider using the solution again in a similar case</li> <li>• 8 complications, no radiographic signs of implant loosening and no additional surgeries</li> <li>• Patient satisfaction is high with almost all patients pain free</li> <li>• All but one patient would go for the same surgery again</li> </ul>
	Retrospective clinical and radiological short-term follow-up (10-58 months) study (2 surgeons)	<b>Citak et al.</b> Hip Int 2017 (n=9) <sup>1</sup>	<ul style="list-style-type: none"> <li>• Case series with complex acetabular defects (average 5 previous revisions, range 2-8)</li> <li>• Overall implant-associated survival rate was 89% at mean follow-up of 29 months: 1 implant failure in patient with bilateral pelvic discontinuity</li> <li>• 5/9 non-implant related complications</li> <li>• Significant improvement of HHS score in 91%</li> <li>• The study suggests a promising future for the technique</li> </ul>
	Evaluation of the accuracy with which a custom-made acetabular component can be positioned	<b>Baauw et al.</b> Bone Jt J 2015 (n=16) <sup>4</sup>	<ul style="list-style-type: none"> <li>• 3 complications, no infections, no additional surgeries</li> <li>• 13/16 patients within Lewinnek's safe zone</li> <li>• 2/3 implants with deviating orientation had no complications</li> <li>• Encouraging results</li> </ul>

<sup>1</sup> Materialise fully acquired the company Mobelife (which introduced the aMace Acetabular Revision System) in 2015.

Technical	Comparative study between radiographic and CT-based defect analysis for periacetabular bone defects	<b>Horas et al.</b> Orthopäde 2017 <sup>6</sup>	<ul style="list-style-type: none"> <li>• Radiographic analysis often underestimates larger defects using Paprosky classification</li> <li>• Intra- interobserver reliability of radiographic analysis is low</li> <li>• 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.</li> </ul>
	Quantification of in vivo bone ingrowth and fixation of clinically used Ti scaffolds in adult goats	<b>Demol et al.</b> J. Tissue Eng. and Reg. Med. 2012 <sup>7</sup>	<ul style="list-style-type: none"> <li>• Porous Ti implants have good osseointegration characteristics</li> <li>• Titanium surface allows good bone apposition</li> <li>• 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</li> </ul>

## 1 Publications

### Clinical

1. M. Citak, L. Kochsiek, T. Gehrke, C. Haasper, E. M. Suero, H. Mau. Preliminary results of a 3D-printed acetabular component in the management of extensive defects. *Hip Int* 2017; 4:0  
<https://www.ncbi.nlm.nih.gov/pubmed/29218689>
2. Myncke I, van Schaik D, Scheerlinck T. Custom-made triflanged acetabular components in the treatment of major acetabular defects. Short-term results and clinical experience. *Acta Orthop Belg* 2017;83:341-350.  
<http://www.actaorthopaedica.be/acta/article.asp?lang=en&navid=4&id=15844&mod=Acta>
3. Baauw M, van Hellemond GG, Spruit M. A custom-made acetabular implant for Paprosky type 3 defects. *Orthopedics* 2017;40(1):195-198.  
<https://www.ncbi.nlm.nih.gov/pubmed/27610701>
4. Baauw M, van Hellemond GG, van Hooff ML, Spruit M. The accuracy of positioning of a custom-made implant within a large acetabular defect at revision arthroplasty of the hip. *Bone Jt J* 2015;97-B:780-5.  
<https://www.ncbi.nlm.nih.gov/pubmed/26033057>
5. Colen S, Harake R, De Haan J, Mulier M. A modified custom-made triflanged acetabular reconstruction ring (MCTARR) for revision hip arthroplasty with severe acetabular defects. *Acta Orthop Belg* 2013;79:71-5.  
<https://www.ncbi.nlm.nih.gov/pubmed/23547519>

### Technical

6. K. Horas, J. Arnholdt, A. F. Steinert, M. Hoberg, M. Rudert, B.M. Holzapfel. Acetabular defect classification in times of 3D imaging and patient-specific treatment protocols. *Orthopäde* 2017; 46(2):168-178.  
<https://www.ncbi.nlm.nih.gov/pubmed/28078371>
- P. Vanden Berghe. Design of Custom Implants – Patient-specific analysis and evaluation. Doctoral thesis 2017, Faculty of Engineering, K.U. Leuven, Leuven, Belgium
- P. Vanden Berghe, J. Demol, F. Gelaude, J. Vander Sloten. Virtual anatomical reconstruction of large acetabular bone defects using a statistical shape model. *Computer Methods in Biomechanics and Biomedical Engineering* 2017;20(6):577-586  
<https://www.ncbi.nlm.nih.gov/pubmed/27957883>

- P. Vanden Berghe, J. Demol, F. Gelaude, J. Vander Sloten. Automatic reconstruction of large acetabular bone defects using statistical shape models. *Orthopaedic Proceedings* 2014; 96-B; 11. [https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.96BSUPP\\_11.CORS2013-051](https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.96BSUPP_11.CORS2013-051)
- M. Van Parys, E. Audenaert, C. Pattyn. Threedimensional imaging and applications in the orthopaedic practise: state of affairs (original title: Driedimensionale beeldvorming en toepassingen in de orthopedische praktijk: een stand van zaken.) 2014; *Tijdschr. voor Geneeskunde*; 70 (5):233-242.
- W. Bartels, J. Demol, F. Gelaude, I. Jonkers, J. Vander Sloten. Computed tomography-based joint locations affect calculation of joint moments during gait when compared to scaling approaches. *Computer Methods in Biomechanics and Biomedical Engineering*, 2014:1238-1251 <https://www.tandfonline.com/doi/abs/10.1080/10255842.2014.890186>
- Delpont H, Mulier M, Gelaude F, Clijmans T. Complex acetabular revision using computer-aided planning for patient-specific implant and guide. *J Bone Joint Surg* 2012;94-B:40 [https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.94BSUPP\\_XXV.ISTA2010-040](https://online.boneandjoint.org.uk/doi/abs/10.1302/1358-992X.94BSUPP_XXV.ISTA2010-040)
- W. Bartels, J. Vander Sloten, I. Jonkers. Sensitivity analysis of hip joint centre estimation based on three-dimensional CT scans. *Computer Methods in Biomechanics and Biomedical Engineering* 2012, Vol. 15(5):539-546. <https://www.tandfonline.com/doi/abs/10.1080/10255842.2010.548323>
7. J. Demol, B. Lenaerts, S. Leuridan, S. De Boodt, P. Delpont. Bone ingrowth and biological fixation of selective laser melted porous scaffolds for the reconstruction of severe bone defects. *Journal of Tissue Engineering and Regenerative Medicine* 2012, 6 (Suppl 1), 401.
- W. Bartels, *Biomechanical Modeling of the Lower Limb for Pre-Operative Planning*. Doctoral thesis 2011, Faculty of Engineering, K.U.Leuven, Leuven, Belgium, 300 pages
- F. Gelaude, T. Clijmans, H. Delpont, Quantitative computerized assessment of the degree of acetabular bone deficiency: Total radial Acetabular Bone Loss (TrABL). *Advances in Orthopedics* 2011; Article ID 494382, 12 pages <https://www.hindawi.com/journals/aorth/2011/494382/>
- G. Lenaerts, W. Bartels, F. Gelaude, M. Mulier, A. Spaepen, G. Van der Perre, I. Jonkers. Subject-specific hip geometry and hip joint centre location affects calculated contact forces at the hip during gait. *J Biomech* 2009; 42:1246-1251. <https://www.ncbi.nlm.nih.gov/pubmed/19464012>
- F. Gelaude, J. Vander Sloten, B. Lauwers. Accuracy assessment of CT-based outer surface femur meshes. *Computer Aided Surgery* 2008; 13(4):188-199. <https://www.ncbi.nlm.nih.gov/pubmed/18622793>
- F. Gelaude 2007, *Medische beelden: concrete steun bij complexe bekkenchirurgie*. Het Ingenieursblad (HIB) (Koninklijke Vlaamse Ingenieursvereniging) 2007(2): 34-39.
- F. Gelaude, *Computer-aided planning of bone reconstructive surgery: optimization of implant design through automation, integration and biomechanical validation*. Doctoral thesis 2007, Faculty of Engineering, K.U.Leuven, Leuven, Belgium, 375 pages.
- F. Gelaude, T. Clijmans, P.L. Broos, B. Lauwers, J. Vander Sloten. Computer-aided planning of reconstructive surgery of the innominate bone: automated correction proposals. *Computer Aided Surgery* 2007; 12(5):286-294. <https://www.tandfonline.com/doi/full/10.3109/10929080701684762>
- F. Gelaude, J. Vander Sloten, B. Lauwers. Semi-automated segmentation and visualisation of outer bone cortex from medical images, *Computer Methods in Biomechanics and Biomedical Engineering* 2006; 9(1):65-77. <https://www.tandfonline.com/doi/abs/10.1080/10255840600604474>

## 2 Presentations

### Clinical

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

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

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

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

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

G. Flivik. Challenging acetabular revisions – a truly patient-matched solution.  
CCJR Winter meeting, 2016, Orlando, Florida, US

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

S. Weidert, Patient-specific Implant for Post-Traumatic Acetabular Defect Reconstruction.  
Materialise THINK Medical 3D Printing Webinars, 2016.

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

H. Mau, S. Luck, T. Gehrke. Versorgung ausgedehnter acetabulärer Defekte mit Individualimplantaten.  
Endoprothetik 2015, Berlin, Germany

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. Challenging acetabular revision: Detailed analysis and patient specific approach. Early results.  
Orthopaedic Revision Forum. Challenges in the Hip. 2013, Leuven, Belgium

J. Vuorinen, T. Suutarinen. Challenging pelvic defect reconstruction by patient-specific technology.  
Mobelife Symposium @ NOF 2012, Tallin, Estonia

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

## 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 Revisionsposium 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. Delpport. Bone loss management with 3D printed metal augments: in vivo evaluation of bone ingrowth and fixation  
EHS 2012, Milano, Italy

J. Vander Sloten. Engineering for health: the case of patient-specific implants.  
Mobelife Symposium @ NOF 2012, Tallin, Estonia

J. Demol, A. Soares, B. Lenaerts, S. Leuridan, S. de Boodt, H. Delpport. In vivo biological fixation of selective laser melted bone scaffolds. 6B.6  
EORS 2012, Amsterdam, Netherlands

H. Delpport, M. Mulier, P. Vanderschot. Treatment of Paprosky IIIb acetabular deficiencies with personalised implants: a case report.  
30. Jahrestagung der Österreichischen Gesellschaft für Orthopädie und Orthopädische Chirurgie, 2011, Linz, Austria

H. Delpport, M. Mulier, P. Vanderschot. Paprosky type IIIb 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. Delpport, M. Mulier, P. Vanderschot. All-in-one patient-specific implant solution for severe acetabular revision – a case report.  
EHS 2010, Athens, Greece

H. Delpport, M. Mulier, T. Clijmans, F. Gelaude. Complex acetabular revision using computer-aided planning for patient-specific implant and guide.  
International Society for Technology in Arthroplasty (ISTA), 2010, Dubai

M. Raaijmakers. Surgical guides for hip joints.  
33ème Journée Informelle HIS - site Ixelles 2010, Brussels, Belgium

### 3 Abstracts & Posters

J. Demol, A. Soares, B. Lenaerts, S. Leuridan, S. De Boodt, H. Delpport. Custom metal augments produced by selective laser melting for the reconstruction of severe bone defects: in vivo evaluation of bone ingrowth and biological fixation.  
Poster @ EFFORT 2013

F. Gelaude, J. Demol, T. Clijmans, H. Delpport. 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. Delpport. 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

J. Demol, A. Soares, B. Lenaerts, S. Leuridan, S. De Boodt, H.P. Delpport. Bone ingrowth and biological fixation of selective laser melted porous scaffolds for the reconstruction of severe bone defects.  
Poster @ TERMIS World Congress 2012 "Tissue Engineering and Regenerative Medicine". 2012, Vienne, Austria  
Journal of Tissue Engineering and Regenerative Medicine 2012: 6(Suppl.1):401

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. Delpport. Computerised quantification of the degree of bone loss in 30 Paprosky type IIIA-B cases: comparison and relevance to classification  
Abstract @ NOF 2012

B. Lenaerts for J. Demol, S. Leuridan, H. Delpport. Bone ingrowth in porous titanium bone augments in in vivo goat model: customization and functionalization.  
Abstract @ NOF 2012

H. Delpport, M. Mulier. Custom implant for Paprosky IIIb acetabular revision: a case report.  
E-poster #5499 @ EFORT 2012, Berlin, Germany

H. Delpport, 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. Delpport. 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. Delpport. 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 64 @ SGOT 2012, Basel, Switzerland

B. Lenaerts, J. Demol, S. Leuridan, H. Delpont. 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. Delpont. 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 musculoskeletal models are needed to accurately predict hip loading.  
Abstract @ ISB Congress 2011, Brussels, Belgium

H. Delpont, M. Mulier, T. Clijmans, F. Gelaude. Bone and joint implant fixation personalized.  
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 53 @ 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/SIROT 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/SIROT 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/SIROT Annual International Conference & SOF Ortopediveckan 2010, Gothenburg, Sweden

F. Gelaude, W. Bartels, P. Bertrand, P.L. Broos, B. Lauwers, G. Van der Perre, J. Vander Sloten. Inter-subject variability of hip moment arms.  
Poster @ Symposium 'Prediction and evaluation of THR performance: can we plan success?'"  
Proceedings of Symposium 'Prediction and evaluation of THR performance: can we plan success?' 2007, Leuven, Belgium: 37-38.

F. Gelaude, P.L. Broos, M. Mulier, B. Vandenbroucke, J-P. Kruth, B. Lauwers, J. Vander Sloten. Treatment of massive acetabular defects with excessive bone loss: from automated computer-based reconstruction proposal to biomechanically justified defect-filling Triflange Cup implant.  
Poster 72 @ Proceedings of the International Society for Computer Assisted Orthopaedic Surgery (CAOS) 2007, Heidelberg, Germany: 514-517.

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