



Materialise aMace

Personalized Acetabular Implants

Clinical Data Report

Executive summary

Acetabular bone deficiencies complicate durable reconstructions of the hip joint and increase the risk for (re-)revisions. The aMace Acetabular Revision System is indicated for use in patients with severe acetabular bone deficiencies who are undergoing primary or revision surgery and reconstruction of the acetabulum.

The system is composed of a pre-surgical 3D analysis and plan, a personalized implant, surgical guides, trial implants and anatomical bone model. The implant is a one-piece solution (integrated cup, flanges, augment) that allows to rehabilitate the hip joint by bridging the areas of acetabular bone loss.

Between May 2007 and May 2019, aMace has been used in 820 patients of whom 92% had a severe acetabular bone defect (Paprosky type III A-B) and 95% underwent a revision surgery. Evidence on the clinical outcomes for patients treated with aMace is published in literature and obtained from post-marketing surveillance.

98% Implant Survival

Published studies show a successful treatment without implant-associated revisions for 98% (59/60) of the patients at an average follow-up of 23.5 months (range 6-58 months). All patients included in the published studies had severe acetabular defects and overall, they had an average number of three prior revisions before they were treated with aMace.

Similar observations were obtained from post-marketing surveillance, showing that 96% of patients (161/168) had no revision after an average time since surgery of 26.9 months (range 1-108 months). The reasons for implant-associated revisions reported in post-marketing surveillance were infections, septic loosening, aseptic loosening and recurrent luxation.

Other complications reported in literature and post-marketing surveillance include dislocations, nerve injury, hematoma, migration and fracture; however, these were not leading to revision of the aMace implant.

Significant PROMs improvements

Published studies show 100% patient satisfaction and improvement in daily functioning and mobility for the overall majority of patients. Significant improvements in Harris Hip Scores and Oxford Hip scores were reported.

Break the revision cycle

In conclusion, aMace is leading to a sustainable reconstruction of the hip joint and high patient satisfaction in patients with severe acetabular defects, including patients with a high number of prior revisions. Post-marketing surveillance confirms that the number of revisions is limited, and the safety profile is well-known. Further data collection is being pursued to confirm the results in larger patient numbers and after longer follow-up time.



1. Introduction

National Joint Registries show that up to 27% of hip revisions are re-revisions due to a suboptimal fixation and suboptimal biomechanical reconstruction of the joint when combining standard components. Furthermore, hip re-revisions are three times more likely to fail compared to a primary acetabular revision. These failures often lead to ever enlarging bone defects which render the next revisions more and more complex and frequent.^{1,2}

Acetabular bone deficiencies can lead to pain and immobility for the patient, who will have difficulties in walking or rely on a wheelchair and permanent care. Durable reconstruction of the hip joint and fixation of an implant is complicated by acetabular bone deficiencies because the contact surface between the implant and the bone is limited.

There is currently no standard of care and high complication rates have been reported in re-revisions. Complications include aseptic loosening, infection, bone graft failures, fractures, dislocation, vascular injury, and nerve injury and usually appear within the first year after the re-revision.^{1,3} Dislocation and infection are much more common indications for re-revision than primary revision, showing the risk for instability and infection is increasing after implant failure.¹

The aMace Acetabular Revision System is indicated for use in patients with severe acetabular bone deficiencies who are undergoing primary or revision surgery and reconstruction of the acetabulum. The system is composed of a pre-surgical 3D analysis and plan, a personalized implant, surgical guides, trial implants and anatomical bone model. Pre-surgical 3D planning allows for an implant designed based on the patient's anatomy and bone quality, rather than reaming until the patient fits the implant. The personalized implant is a one-piece solution (integrated cup, flanges, augment) that allows to rehabilitate the hip joint by bridging the areas of acetabular bone loss.

2. Acetabular defect classification

The Paprosky acetabular defect classification is based on radiographic evaluation of the location and grade of bone deficiency in the acetabulum.⁴ It distinguishes six different defect types depending on the defect size, location, and the capability of the acetabular walls and anterior and posterior columns to support a cementless hemispherical press-fit cup:

- Type I with supportive elements
- Type IIA–C with partially supportive elements
- Type III A–B with non-supportive elements

Type IIIB is the most severe kind of defect, showing more than 60% of bone loss in the acetabulum and, therefore, not suitable for a standard reconstruction. Type IIIB defects can also be associated with dissociation (Figure 1)

¹ National Joint Registry Annual Report 2019 <http://www.njrcentre.org.uk/njrcentre/Reports-Publications-and-Minutes>

² Swedish Arthroplasty Register Annual Report 2017 <https://shpr.registercentrum.se/shar-in-english/the-swedish-hip-arthroplasty-register/>

³ Acetabular reconstruction in total hip arthroplasty. Shon WY, Santhanam SS, Choi JW. Hip Pelvis. 2016 Marr; 28 (1): 1-14.

⁴ Acetabular defect classification and surgical reconstruction in revision arthroplasty. A 6-year follow-up evaluation. Paprosky WG, Perona PG, Lawrence JM. J Arthroplasty. 1994 Feb;9(1):33-44.

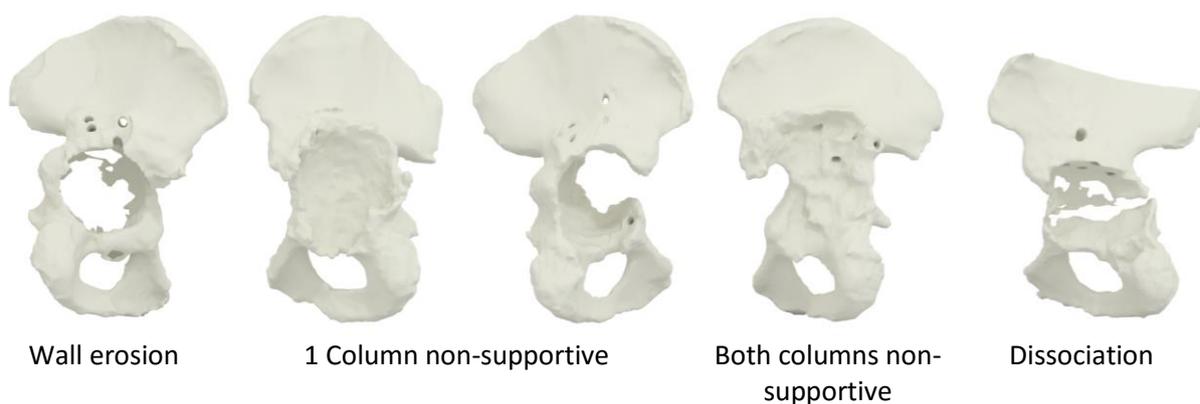


Figure 1 Visualization of the Paprosky type III patient continuum.

3. Clinical experience

Materialise aMace has been used in 820 patients between May 2007 and May 2019. Ninety-two percent of all cases presented a severe acetabular bone defects classified as Paprosky type III A-B. Materialise aMace is mostly used in revision surgeries (95% of cases) (Figure 2).

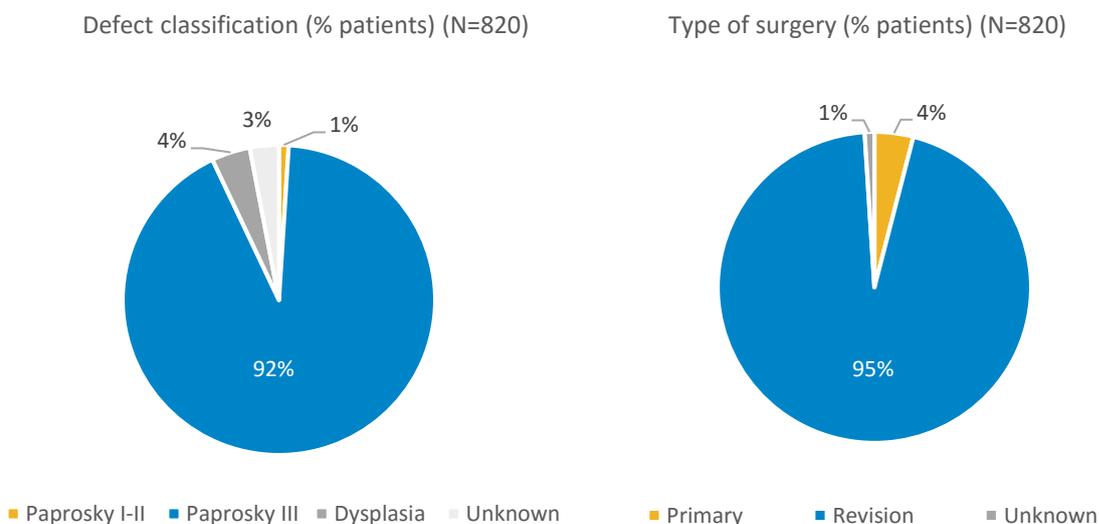


Figure 2 Defect classification and type of surgery for patients treated with aMace Acetabular Revision System.

Evidence on the clinical outcome and safety for patients treated with aMace is presented in scientific papers authored by independent researchers, and obtained from post-marketing surveillance (PMS) conducted by Materialise.

- Six peer-reviewed publications based on non-sponsored academic research report the clinical outcomes for a total number of 69 unique patients.¹⁻⁶
- A post-marketing survey was performed between July and September 2019 and asked surgeons about the number of implant-related revisions (meaning the aMace implant is removed or replaced) and complications for patients treated with aMace and not previously reported to the

company. A response rate of 18.3% was obtained (48/262 surgeons) and showed the results for 166 patients (20.6%, 166/820). Patient characteristics included in the survey were similar to the total group of patients treated with aMace when comparing the average time since surgery, age, defect classification and type of surgery (primary vs. revision).

- An internal complaints database includes post-marketing data based on voluntary reporting by the surgeon.

4. Implant survival & complications

4.1 Peer-reviewed publications

Based on the published evidence for Materialise aMace, a successful treatment without implant-associated revision was observed for 98% of the patients at an average follow-up of 23.5 months (range 6-58 months) (Table 1). All patients included in the studies for aMace had a severe acetabular defect (Paprosky type III A-B). The average number of three prior surgeries indicates that good outcomes can be achieved with aMace even if the patients are heavily pretreated.

These results are concluded based on six academic studies that are published in international peer-reviewed journals between 2013 and 2019. Table 1 summarizes the studies. Of the cases reported by Baauw et al. (2015, 2017), seven are common, meaning that the same implant case is reported in both publications. Consequently, published literature includes evidence on 69 unique patients instead of the total sum of 76 patients. Among all the patients included in the published studies, one implant-associated failure that occurred 13 months after surgery was reported by Citak et al. (2017).

Table 1 Summary of published evidence for Materialise aMace Acetabular Revision System. The implant failure rate presents the number of patients who needed implant-associated revision surgery, meaning that the aMace implant is removed or replaced. The follow-up and number of prior revisions for the total number of cases in all publications are based on the weighted average of the follow-up and prior revision reported in the individual publications.

Publication	Number of cases	Average follow-up, months (range)	Average # of prior revisions (range)	Implant failure rate, % (N)
Colen et al. (2013)	6	28.5 (10-58)	3.8 (2-7)	0% (0/6)
Baauw et al. (2015)	16*	- ⁺	1.12 (0-2) ⁺	- ⁺
Myncke et al. (2015)	22	25 (30-50)	3.1 (1-12)	0% (0/22)
Baauw et al. (2017)	12*	18 (18-39)	1.25 (0-4)	0% (0/12)
Citak et al (2017)	9	28.8 (13-47)	5 (1-8)	11% (1/9)
Goriainov et al. (2018)	11	19.5 (6-37)	2.6 (1-7)	0% (0/11)
Total	69*	23.5 (6– 58)⁺	3.0 (0-12)⁺	1.7% (1/60)⁺

* The publications from Baauw et al. have 7 patients in common. Therefore, the total number of unique patients is 69 instead of 76.

⁺ Cases included in the publication from Baauw et al. 2015 are not included in the calculation of the total implant failure rate because the follow-up was limited to 6 weeks. Therefore, these cases were also not considered in the calculation of the total average follow-up time and total average number of prior revisions. No implant failure was reported in this publication.

Table 2 shows the complications that were reported in the published studies. Complications are counted for unique patients only. Overall, dislocations were the most common complication. All dislocations were successfully treated by a liner exchange or closed reduction, without impact on the aMace implant. Myncke et al. (2015) stated that dislocations could be due to the extensive approach and the poor quality of the soft tissues in multi-operated patients and suggest using cemented dual mobility cups whenever possible to limit the strains on the bone-implant interface.

In the study from Citak et al. (2017), five patients required additional surgery without removal or replacement of the implant (reported as non-implant associated revision surgery). Additional surgery was due to hip dislocation (N = 3) and postoperative hematoma (N = 2). The patients included in this study had a very high number of prior revisions (five on average). The results from Citak et al., however, show that despite the occurrence of complications, all patients had an improvement in Harris Hip Score.

Table 2 Overview of complications reported in published evidence for Materialise aMace Acetabular Revision System.

Publication	Number of cases	Patients with complications N (%)	Dislocation	Infection	Fracture	Hematoma	Neurological complication	Screw breakage
Colen et al. (2013)	6	0 (0%)	0	0	0	0	0	0
Baauw et al. (2015)	16*	3* (18.8%)	2*	0	1	0	0	0
Myncke et al. (2015)	22	8 (36.3%)	4	1	0	1	1	1
Baauw et al. (2017)	12*	4* (33.3%)	1*	0	2*	2	0	0
Citak et al (2017)	9	5 (55.6%)	3	0	0	2	0	0
Goriainov et al. (2018)	11	1 (9%)	0	0	0	0	1	0
Total N (% of patients)	69*	19* (27.5%)	9* (13.0%)	1 (1.4%)	2* (2.9%)	5 (7.2%)	2 (2.9%)	1 (1.4%)

*The publications from Baauw et al. have seven patients in common. Therefore, the total number of unique patients is 69 instead of 76. The following complications were reported for two patients that were included in both studies: 1 fracture and 1 dislocation. These patients and complications are counted once and therefore the total number of patients with a complication as well as the total number of complications does not equal the sum.

4.2. Post-marketing surveillance

Post-marketing surveillance for implant survival shows successful treatment without revision (meaning there is no surgery leading to revision or removal of the aMace implant) for 96% of patients (161/168 patients). Post-marketing surveillance data on implant survival are based on the complaints database (2 revisions reported) and the post-marketing survey (5 revisions reported for 166 patients included). The average time since surgery for the patients included in this analysis was 26.9 months (range 1-108 months). Thirty-nine percent of these patients had the surgery more than three years ago and 10% of the patients had the surgery more than five years ago.

Reasons for revisions were infections (N=4), septic loosening (N=1), aseptic loosening (N=1) and recurrent luxation (N=1).

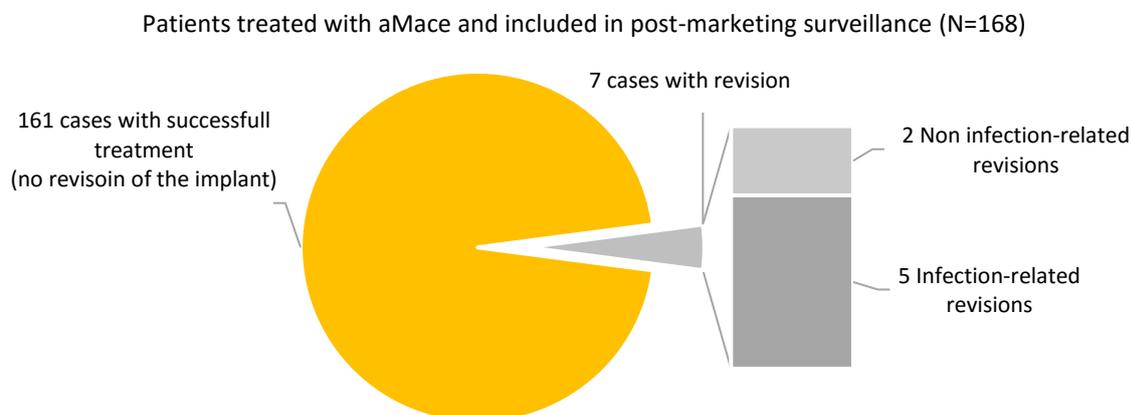


Figure 3 Implant revision for patients treated with aMace and included in post-marketing surveillance (based on survey and complaints database). PMS = post-marketing surveillance

An additional number of 13 complications not leading to a revision of the aMace implant (removal or replacement) were reported in post-marketing surveillance, resulting in a total number of 20 complications (7 complications leading to revisions and 13 complications not leading to revisions) in 20 patients. Complications not leading to revisions include infections (N=3), dislocation (N=4), nerve injury (N=2), pelvic dissociation (N=1), flange fracture (N=2) and migration (N=1).

The result from the post-marketing surveillance is consistent with the results from the literature.

5. Patient reported outcomes

Three papers showed that all patients treated with Materialise aMace were satisfied with the treatment:

- Colen *et al.* (2013) showed that all six patients were satisfied with the treatment.
- Baauw *et al.* (2017) reported that all 12 patients were satisfied with the treatment. Ten out of 12 patients find that their daily functioning has improved after the surgery. Nine out of 12 patients reported better mobility and less pain
- Myncke *et al.* (2015) showed improved patient satisfaction scores from 2.44/10 (range 0-8) to 8.53/10 (range 5-10) in 20 patients. All but one patient (19/20) would go for the same operation again if needed.

A significant improvement in patient reported outcomes was observed in two studies publications:

- The Harris Hip Score (HHS) improved significantly from 22.1 at admission (range 9-40) to 58.7 post-operatively (range 9-91) in the study published by Citak *et al.* (2017). A similar post-operative HHS was reported by Myncke *et al.* (2015).
- Goriainov *et al.* (2018) showed that all patients had an improvement in the Oxford Hip Score, and the improvement was statistically significant.

6. Conclusions

The Materialise aMace Acetabular Revision System is being used in clinical settings since 2007. Results reported in several studies shows that the Materialise aMace leads to a sustainable reconstruction of the hip joint and scores high in patient satisfaction for patients presenting severe acetabular defects and with a large number of prior revisions.

The post-marketing surveillance reports a limited number of revisions (meaning replacement or removal of the aMace implant) for patients who have the aMace implant for more than five years.

According to literature, the most critical complications related to re-revision, such as dislocations and infections, occur in the first year after surgery. Among the complications reported in the survey, dislocations were the most recurrent, but only a minimal number of complications have led to revision surgery.

The specific indication leading to re-revision surgery with aMace is unknown in many cases and, therefore, there is no view on instability risks or infection in patients who received an aMace implant. The kind of acetabular defects, the number of prior revisions, and pre-surgical HHS, however indicate that patients treated with aMace suffer from severe disease. Despite the debilitating pre-surgical conditions, significant improvements in patient-reported outcomes are still observed.

Further data collection is currently being pursued to confirm the results for a larger number of patients and present data based on a more extended follow-up period.



7. Clinical data overview

	Design	Key Points
CLINICAL	<p>Evaluation of the accuracy with which a custom-made acetabular component can be positioned</p> <p>Baauw et al. Bone Jt J 2015 (n=16)¹</p>	<ul style="list-style-type: none"> • 3 complications, no infections, no additional surgeries • 13/16 patients within Lewinnek's safe zone • 2/3 implants with deviating orientation had no complications • Encouraging results
	<p>Retrospective clinical and radiological short-term follow-up (18-39 months) study</p> <p>Baauw et al. Orthopedics 2017 (n=12)²</p>	<ul style="list-style-type: none"> • 4 complications, no infections and no additional surgeries • 92% of patients would recommend the treatment • 83% of patients report improvement in daily functioning, had better mobility and less pain • Valuable 3D analysis of the defects prior to surgery
	<p>Retrospective clinical and radiological short-term follow-up (10-58 months) study (2 surgeons)</p> <p>Citak et al. Hip Int 2017 (n=9)³</p>	<ul style="list-style-type: none"> • Case series with complex acetabular defects (average 5 previous revisions, range 2-8) • Overall implant-associated survival rate was 89% at mean follow-up of 29 months: 1 implant failure in patient with bilateral pelvic discontinuity • 5/9 non-implant related complications • Significant improvement of HHS score in 91% • The study suggests a promising future for the technique
	<p>Retrospective clinical and radiological short-term follow-up (10-58 months) study</p> <p>Colen et al. Acta Orthop Belg 2013 (n=6)⁴</p>	<ul style="list-style-type: none"> • No component removals, no revisions, no dislocations and no evidence of infection • No signs of loosening, migration or hardware breakage • All patients were satisfied with the clinical results. Good clinical outcome (HOOS score: 54-89) • 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
	<p>In-vitro and in-vivo study of 3D-printed acetabular implant with autologous skeletal stem cells</p> <p>Goriainov et al. Ren Med 2018 (n=11)⁵</p>	<ul style="list-style-type: none"> • In-vitro study shows that autologous bone marrow cells adhere on porous titanium surfaces and express osteogenic genes • Case series of 11 patients with mean follow-up of 19.5 months • no complications or need for further surgery • indications of bone formation at bone-implant interface on CT • significant improvement of Oxford Hip score
	<p>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</p> <p>Myncke et al. Acta Orthop Belg 2017 (n=20)⁶</p>	<ul style="list-style-type: none"> • Good overall experience with aMace Acetabular Revision System (mean score 8.1/10) • All surgeons would consider using the solution again • 8 complications, no radiographic signs of implant loosening and no additional surgeries • Patient satisfaction is high with almost all patients pain free • All but one patient would go for the same surgery again
TECHNICAL	<p>Comparative study between radiographic and CT-based defect analysis for periacetabular bone defects</p> <p>Horas et al. Orthopäde 2017⁷</p>	<ul style="list-style-type: none"> • Radiographic analysis often underestimates larger defects using Paprosky classification • Intra- interobserver 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.
	<p>Quantification of in vivo bone ingrowth and fixation of clinically used Ti scaffolds in adult goats</p> <p>Demol et al. J. Tissue Eng. and Reg. Med. 2012⁸</p>	<ul style="list-style-type: none"> • 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

8. Publications

Clinical

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Technical

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9. Presentations

Clinical

- P. 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. EFORT Lisbon 2019
- B. W. Wippermann. Solutions for complex hip surgery: How to get started. Materialise THINK Idea to Patient Care Webinar Series, 2018
- W. Rijnen, G. Flivik. Battle 'Acetabular revision arthroplasty; restoring bone defects with 3D-printed metal cups or bonegrafting' NOV 2018, Rotterdam, The Netherlands
- 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 Hellemond. 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. 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. AORecon 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

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- F. Gelaude for M. Mulier, M. Raaijmakers, A. Willems, T. Clijmans. Personalized implant design for acetabular revision. IMUKA 2010, Maastricht, Netherlands
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10. 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
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- H. Delpont, M. Mulier. Custom implant for Paprosky IIIb acetabular revision: a case report. E-poster #5499 @ EFORT 2012, Berlin, Germany
- H. Delpont, 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. Delpont. 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. Delpont. 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 muscoskeletal models are needed to accurately predict hip loading. Abstract @ ISB Congress 2011, Brussels, Belgium
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