# **Originalarbeit**

Obere Extremität 2020 · 15:28-34 https://doi.org/10.1007/s11678-020-00558-0 Received: 6 December 2019 Accepted: 15 January 2020 Published online: 8 February 2020 © The Author(s) 2020



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# Outcome after operative revision of clavicular nonunions

# Clinical and radiographic results

Fractures of the clavicle are common and account for around 3% of all adult fractures [5]. The incidence ranges from 64 to 71/100,000 per year [10, 23]. Historically, midshaft clavicular fractures have been treated nonoperatively with good functional outcomes. A major complication of conservative therapy is the relatively high nonunion rate, which is reported to be 15-20% in some studies [32, 33].

In the past decade, randomized control trials have been conducted to compare operative and nonoperative therapy of midshaft clavicular fractures. A recent meta-study concludes that surgical treatment significantly reduces the nonunion rate, shortens the time to union, and, despite a slightly higher incidence of complications, leads to better shoulder functional scores in both short- and longterm follow-up [9]. Although other studies state that there is still no consensus on treatment, there has been an overall paradigm shift towards operative therapy with open reduction and plate fixation [18, 27, 29]. However, the problem of nonunion remains after both conservative and operative management.

Less is known about the results after revision of clavicular nonunions, regardless of whether the initial therapy was operative or nonoperative. Nonunion is either atrophic or hypertrophic. Most studies report a higher rate of atrophic nonunions (see Table 5). The surgical procedure usually includes a resection of the nonunion (decortication according to Judet) and (angular stable) plating combined with autologous bone grafting [20, 28]. Bony union can reliably be achieved with this technique [6, 25]. McKnight et al. compared the surgical management of midshaft clavicular nonunions with that of acute fractures and found an increased risk of short-term complications such as wound infections [21]. Long-term results are scarce. O'Conner et al. found a higher level of disability according to assessment with the Disabilities of Arm, Shoulder, and Hand (DASH) questionnaire in the operated group compared with the normal population after a mean follow-up of 42.1 months [24].

The aim of the present study was therefore to examine the clinical and radiographic results after operative revision of clavicular nonunions in a multicenter study. We hypothesized that the functional results would be similar to the noninjured side and that radiographic fracture union could be achieved in the majority of the cases.

#### **Methods**

# Study design and patient cohort

Two level-1 trauma centers in northwestern Germany conducted a retrospective analysis of patients with clavicular nonunion who needed revision surgery during the past 10 years. The study was approved by the local ethics committees (2019-159-f-S/8688\_BO\_S\_2019). All patients who underwent operative revision for clavicular nonunion in these two hospitals were included. Patients

<b>Table 1</b> Epidemiological data of the cohort					
Total patients	n=31				
Age (years)	52.3 ± 15.2 (range: 32–84)				
Male vs. female	12 (38.7%) vs. 19 (61.3%)				
Body weight (kg)	80.4 ± 22.1 (range: 51–160)				
Right- vs. left- handed	29 (93.5%) vs. 2 (6.5%)				

Table 2   Mean values of active range of motion						
Movement	Injured side	Noninjured side	p			
Anteversion	162 ± 22°	170 ± 4°	0.0953 (ns)			
Retroversion	39 ± 5°	$40 \pm 4^{\circ}$	0.9993 (ns)			
Abduction	163 ± 30°	174±10°	0.0064 (**)			
Adduction	$37 \pm 8^{\circ}$	39±7°	0.9746 (ns)			
External rotation <sup>a</sup>	83 ± 13°	85 ± 8°	0.9692 (ns)			
Internal rotation <sup>a</sup>	73 ± 11°	75 ± 9°	0.9939 (ns)			
<i>ns</i> Nonsignificant, **significant <sup>a</sup> ln 90° abduction						

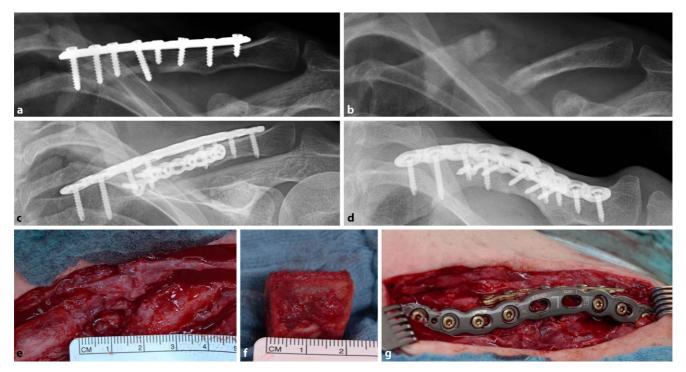


Fig. 1 A Case of a 35-year-old male patient who had a mountain bike accident. Presentation 6 months after trauma to our department with two previous operations after medial implant loosening (a). Complete removal of the material was necessaryafter verification of a septic nonunion (b). After antibiotic therapy, surgical revision was performed (c). Intraoperatively, a 2-cmbony defect was seen (e). Accordingly, an autologous bone graft from the iliac crest (f) was combined with double plating (g). X-rays 1 year postoperatively show complete union of the defect (d)

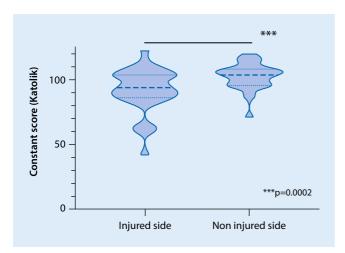


Fig. 2 ◀ Age-and gender-adjusted Constant score according to Katolik for the injured and noninjured shoul-

with a record of pre-existing shoulder conditions (e.g., osteoarthritis), earlier operations at the injured side, or regular immunosuppressive medication were excluded. This was a two-center retrospective cohort study with a level III of evidence.

#### Outcome assessment

All patients underwent a structured clinical and radiological assessment. The clinical interview included a survey of the relevant epidemiological data, preexisting illness, and individual course of treatment. Risk factors such as smoking, diabetes, and osteoporosis (when explicitly stated as a diagnosis in the patient reports) were also recorded. Pain was assessed using the Visual Analog Scale (VAS). The major outcome parameter was functional assessment using the age- and gender-adjusted Constant score according to Katolik [14].

For the radiographic follow-up, the major outcome parameter was fracture union on conventional X-rays of the clavicular in two planes (anteroposterior [ap] and tangential). This was defined by three continuous cortices. Technical aspects, such as the plate type and length as well as usage of conventional and angular stable screws, were also recorded. Furthermore, the usage of autologous bone grafting was noted. This was harvested either from the iliac crest or from the resected hypertrophic nonunion itself (decorticated bone was cleaned from soft tissue, reduced to small chips, and used for bone grafting). Additionally, complications such as wound site infections with re-operation and the occurrence of paresthesia were examined.

# Statistical analysis

Data were collected in a Microsoft Excel data sheet. Mean and standard deviations were calculated where applicable. Statistical analysis was performed with GraphPad (GraphPad Prism 8.3.0, San Diego, CA, USA). Welch's t test and two-

#### Abstract · Zusammenfassung

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# Outcome after operative revision of clavicular nonunions. Clinical and radiographic results

Background. Over the past decade, the treatment of midshaft clavicular fractures has increasingly shifted from conservative to operative therapy. The overall results seem to be better with surgery, although the problem of nonunion remains. The aim of this study was to report the functional results after operative revision of clavicular nonunions in two German level-1 trauma centers.

Methods. All patients who underwent surgery for clavicular nonunions during the past 10 years were invited for a structured clinical follow-up examination. The major functional outcome parameter was the age- and

gender-adjusted Constant score. Additionally, radiographic fracture union was assessed with the available X-rays. Complications such as wound site infections were also monitored. Results. In total, 31 patients were available for assessment. The mean follow-up rate was  $69.7 \pm 31.2$  months. The mean age of the patients was  $52.3 \pm 15.2$  years. The nonunion was classified as atrophic in 26 cases and hypertrophic in five. A total of 25 (80.6%) patients were treated with angular stable plating combined with autologous bone grafting from the iliac crest. The ageand gender-adjusted Constant score was

significantly decreased compared with the noninjured side (82.2  $\pm$  17.1 vs. 95.6  $\pm$  10). Radiographic union was achieved in 30 of the 31 patients (96.8%). Complications with need for surgical revision were recorded for two patients.

Conclusion. Surgery for clavicular nonunion is a safe and well-established procedure, which leads to radiographic union and good functional results for the majority of cases.

#### **Keywords**

Clavicle · Clavicle fracture · Constant score · Revision surgery · Radiographic union

# Ergebnisse nach operativer Revision von Klavikulapseudarthrosen. Klinische und radiologische

#### Zusammenfassung

Hintergrund. Die Behandlung von Klavikulaschaftfrakturen hat sich aufgrund der Studienergebnisse der letzten Jahre zunehmend von der konservativen zur operativen Therapie gewandelt. Eine der Hauptkomplikationen bleibt jedoch weiterhin die Pseudarthrose. Das Ziel dieser Studie war es, funktionelle Ergebnisse nach operativer Revision in 2 Level-1-Traumazentren zu untersuchen.

Material und Methoden. Es wurden alle Patienten zu einer Nachuntersuchung eingeladen, die in einem Zeitraum von 10 Jahren an den beiden Kliniken mit einer Klavikulapseudarthrose operativ behandelt wurden. Der Hauptparameter für das funktionelle Outcome war der modifizierte

Constant-Score. Zusätzlich wurde anhand der verfügbaren Röntgenbilder die knöcherne Konsolidierung erfasst. Komplikationen wie Wundinfektionen wurde ebenfalls dokumentiert.

Ergebnisse. Es konnten 31 Patienten nachuntersucht werden. Das durchschnittliche Follow-up war 69,7 ± 31,2 Monate. Das durchschnittliche Patientenalter lag bei  $52.3 \pm 15.2$  Jahren. Die Pseudarthrose wurde in 26 Fällen als atroph und in 5 Fällen als hypertroph klassifiziert. Bei 25 Patienten (80,6%) erfolgte eine autologe Spongiosaplastik vom Beckenkamm mit winkelstabiler Plattenosteosynthese. Der alters- und geschlechtsadjustierte Constant-Score war signifikant geringer als auf der gesunden

Gegenseite (82,2  $\pm$  17,1 vs. 95,6  $\pm$  10). Eine Konsolidierung im Röntgenbild wurde in 30 von 31 Fällen festgestellt. Revisionspflichtige Komplikationen zeigten sich in

Schlussfolgerung. Die operative Therapie einer Klavikulapseudarthrose ist ein sicheres und etabliertes Verfahren, welches gute Konsolidierungsraten zeigt und in den meisten Fällen zu guten funktionellen Ergebnissen führt.

#### Schlüsselwörter

Klavikula · Klavikula-Fraktur · Constant  $Score \cdot Revisionschirurgie \cdot Radiologische$ Konsolidierung

way ANOVA were used with Sidak's multiple comparisons test and significance was set at p < 0.05.

#### Results

A total of 31 patients from the two centers were available for follow-up. No patients had to be excluded because of the exclusion criteria defined earlier.

#### Epidemiological data

The data of 31 patients were analyzed for this study. General epidemiologic data of the cohort are summarized in • Table 1.

#### Initial treatment

The etiology was a mono-trauma of the clavicle in 28 (90.3%) patients, and only three (9.7%) patients suffered a polytrauma. In 18 (58.1%) patients the left side was injured; 14 of the 31 (45.1%) patients were treated in a primarily conservative manner, of whom four (28.6%) had to undergo surgery later than 42 days after trauma owing to secondary dislocation. For 17 patients, surgery was performed primarily within 6.6 ± 8.2 days (range: 0-35). The mean operation time was  $53.3 \pm 15.8 \,\text{min}$  (range: 37–80) but these data were only available for six of the operated patients. In summary, ten (32.6%) patients were treated conservatively prior to revision surgery while 21 (67.7%) patients underwent primary surgery or conversion to surgery. In seven (33.3%) surgically treated patients an angular stable plate was used, while an elastic stable intramedullary nail (ESIN) was

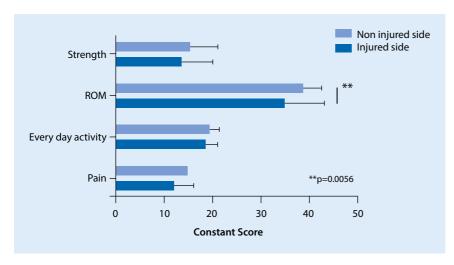


Fig. 3 ▲ The different outcome categories for the Constant score. ROM range of motion

inserted in three (13%) patients (no information on fixation material in 11 patients, 52.4%). The mean plate length was  $7.6 \pm 2.3$  holes (range: 6-10).

#### Revision surgery

Data on revision surgery were available for all 31 patients. The mean time from trauma to revision was 19.9 ± 20 months (range: 4-107). The nonunion was classified as atrophic in 26 (83.9%) patients and hypertrophic in five (16.1%) patients. The mean radiographic distance of the nonunion gap was 10.9 ± 6.6 mm. A loss of reduction in the operated cohort was noted in 16 (76.2%) cases while an implant breakage was present in five (23.8%) patients. The number of previously conducted operations prior to the revision surgery in one of the two hospitals ranged from 1 to 3 with a mean of  $1.38 \pm 0.59$ operations per patient. In nine (42.9%) cases the implants were already removed.

The mean operating time of the revision was  $96.3 \pm 35.9$  min (range: 49-174). A straight angular stable plate was used in 19 cases (61.3%), while a pre-contoured plate was utilized in 8 (25.8%) cases. The mean plate length was  $8.7 \pm 1.4$  holes with an average of 7.5 ± 1.2 screws per plate  $(4.3 \pm 2.5 \text{ conventional screws}/3.2 \pm 3)$ locking screws). In 25 (80.6%) patients, autologous bone grafting was used, either from the iliac crest (54.8%) or from the resected nonunion (25.8%). Representative X-rays and intraoperative

images from a study patient are shown in **Fig. 1**.

### Clinical outcome

The clinical survey and assessment were conducted with a mean follow-up of  $69.7 \pm 31.2$  months. Eight (25.8%) of the patients reported active smoking, while 17 (54.8%) stated no pre-existing illnesses. None of the patients had a history of osteoporosis or diabetes. The active range of motion is summarized in ■ **Table 2**. In total, 29 (93.5%) patients could return to their previous work and 28 (90.3%) could return to sport. A total of 26 (83.9%) patients were able to conduct overhead work after revision surgery. Moreover, 27 (87.1%) of the patients answered the question: "Were you satisfied with revision surgery?" with "Yes" and the same number of patients would opt for revision surgery again.

Pain at rest measured with the VAS for the injured side was  $0.5 \pm 1.5$  (range: 0-7) while stress-induced pain was  $1.7 \pm 2.7$ (range: 0-8). Eight (25.8%) patients had tenderness on palpation, three (9.7%) patients reported taking regular pain medication, and five (16.1%) patients regularly received physiotherapy. Two patients had to be re-operated because of a postoperative complication (infection), vielding a complication rate of 6.5%: one patient was from the primarily conservative and the other from the primarily operated group. At the time of followup, 19 (61.3%) patients had their implants

removed. A total of 20 (64.5%) patients reported paresthesia above or ventral of the clavicle. The total number of operations for all patients was 2.54 ± 0.87 (range: 1-4).

#### Constant score

The analysis of the age-adjusted Constant score according to Katolik et al. [14] showed a difference between the injured and noninjured side ( Fig. 2). The breakdown of the different categories within the Constant score revealed a significant difference in the range of motion. The other categories also showed a tendency toward lower scores for the injured side, although these differences were not significant ( Fig. 3).

#### Radiological outcome

The mean radiological follow-up after revision surgery was  $49 \pm 30$  months (range: 2-120). Fracture union was seen in 30 (96.8%) patients while no implant breakage, loosening, or loss of reposition were detected. Ossifications were present in 23 (74.2%) patients.

# Initial treatment: nonoperative vs. operative

A total of ten patients underwent nonoperative treatment, while 21 were operated on (initial treatment before revision surgery). We compared these groups in terms of the major outcome criteria. Epidemiological data are summarized in ■ Table 3. The conservative group included significantly more smokers.

The main clinical and functional outcome parameters are summarized in ■ Table 4. Apart from the number of operations, no significant differences were detected. There were also no differences in all of the other aforementioned parameters (data not shown).

#### **Discussion**

The most important finding of our study is that revision surgery of clavicular nonunions can lead to satisfying midterm functional outcomes. The great majority of patients were satisfied with

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Epidemiological data of conservative vs. operative treatment groups (initial treatment before revision surgery) Conservative Operative р Total patients n = 10n = 21Male 0.3732a 5 14 5 7 **Female** 5 3 Smoker 0.0336° 0.2423<sup>b</sup> Age (years)  $57 \pm 15.4$  $50 \pm 14.2$ 0.8005<sup>b</sup> Body weight (kg)  $81.8 \pm 19$  $79.8 \pm 22.9$ **bold values** significant <sup>a</sup>Chi-square test bWelch's **t** test

	Conservative	Operative	p
Primary treatment	10	21	-
Nonunion			
Hypertrophic	3	2	0.1473°
Atrophic	7	19	0.1473°
Revision surgery			
Time until revision (months)	$14.8\pm8.2$	$22.4 \pm 22.8$	0.1865 <sup>b</sup>
Operations until revision	0	$1.4\pm0.6$	0.0001 <sup>b</sup>
Operation time (min)	91.2 ± 36.2	$98.8 \pm 34.6$	0.5866 <sup>b</sup>
Clinical outcome			
Age-adjusted Constant score of the injured side	91.5 ± 16.6	93.1 ± 17.2	0.8069 <sup>b</sup>
Radiological outcome			
Bony union	10	20	0.483ª
Complications			
Re-operation because of wound complication	1	1	0.99 <sup>b</sup>
Total operations	$1.7 \pm 0.46$	$2.95 \pm 0.46$	0.0001 <sup>b</sup>
Clavicular paresthesia	5	15	0.2438 <sup>a</sup>
bold values significant <sup>a</sup> Chi-square test <sup>b</sup> Welch's t test			

the revision surgery and were able to return to work and sport. Radiographic union was reached in 30 out of 31 patients and the overall complication rate was low.

Longer-term follow up data on the functional outcome after surgical treatment of clavicular nonunions in large cohorts are rarely reported. We identified a total of 15 studies over the past 25 years that included the assessment of functional results through either the Constant or DASH score ( Table 5).

In summary, the majority of the available studies are retrospective analyses with limited cohort sizes. Rollo et al. presented a larger study population with

57 consecutive cases [26]. Although we were not able to significantly increase the cohort size compared with the available literature, we report the results of two different study centers. Interestingly, our cohort is older on average than any of the aforementioned studies  $(52.3 \pm 15.2 \text{ years})$ . The clinical followup and the rate between atrophic and hypertrophic nonunions are comparable to those in the literature. Furthermore, similar to the available functional outcome assessment data, the Constant score is significantly decreased compared with the noninjured side (95.6 vs. 82.2). The difference is greater than the accepted threshold for the minimal clinically important difference for the Constant score [17]. Additionally, the range of motion for abduction was decreased in our study. Nevertheless, bony union was achieved in 96.8% of the cases and only two complications requiring revision surgery were recorded.

Additionally, our study provides detailed information on the technical aspects of the surgical revision. Huang et al. reported a mean operation time of 96 min, which is comparable to our data and longer than the average operation time for the initial fixation of a clavicular fracture in our cohort (96.3  $\pm$  35.9 vs. 53.3  $\pm$  15.8 min; p = 0.0002; [11]). Also, the plate length seems to be longer in the revision case compared with the initial surgery (8.1  $\pm$  1.2 vs. 8.7  $\pm$  1.4).

The comparison between initially nonoperative and operative treatment revealed no difference in the outcome measures. Interestingly, significantly more smokers were seen in the conservative cohort. This is in line with studies that identified smoking as an independent risk factor for the development of a nonunion [12].

The case presented in Fig. 1 is a good example of a typical failure of primary clavicular fracture fixation and secondary development of complications like infection and nonunion. In these cases, in which stability of the fixation seems to be the major issue, double plating is a good option to increase the overall fixation stability [15, 22].

#### Limitations

There are several inherent limitations to our study. Firstly, this is a retrospective cohort analysis solely reporting functional and radiographic outcomes. Like other comparable studies published previously, we were not able to recruit a larger cohort, although we did manage (for the first time) to report results from two centers. In addition, the indication for the index therapy (conservative vs. operative) remained unclear and was based on the decision of the treating surgeon. Similarly, the surgeon decided on the need for a bone graft in the revision situation. Therefore, the revision procedures were not standardized.

Author	Year	n	Mean age (years)	Follow-up (months)	Atrophic vs. hypertrophic	Constant score	DASH score	Union rate (%)	Compli- cation
Olsen et al. [25]	1995	15	34	24.8	9 vs. 6	87.9	NA	94	None
Bradbury et al. [3]	1996	32	NA	72	21 vs. 10	85	NA	97	1
Wentz et al. [31]	1999	22	18-33	NA	19 vs. 3	97	NA	100	None
Kabak et al. [13]	2004	33	39.3/43.6	44.2	NA	NA	14.8/6.7	100/87.5	6
O'Conner [24]	2004	24	38	42.1	14 vs. 10	NA	a	92	2
Endrizzi et al. [7]	2008	45	38.7	NA	NA	NA	14.6	93	3
Khan et al. [16]	2008	11	NA	36	4 vs. 5	NA	24	100	2
Huang et al. [11]	2009	21	32	65.7	17 vs. 4	91	NA	100	1
Baker et al. [1]	2010	15	39	12	NA	NA	14.5	100	None
Stufkens et al. [30]	2010	21	48.2	30	NA	NA	22.8	100	2
Faraud et al. [8]	2014	21	47	41	16 vs. 5	84	17	90	6
Beirer et al. [2]	2017	11	44	27	NA	82	NA	100	1
Rollo et al. [26]	2017	57	35	42	35 vs. 22	NA	16.7	98	1
Chen W. et al. [4]	2018	17	44	38.5	8 vs. 9	75.5	19.9	100	None
Marsalli et al. [19]	2019	14	44.9	77	NA	87.5	NA	86	2

NA not available <sup>a</sup>No single value stated

# **Practical conclusion**

- Operative treatment for clavicular nonunion with iliac bone grafting and plate fixation is a well-established and safe procedure.
- Radiographic union and good functional outcomes can regularly be achieved.
- Our study showed that this also applies to an older patient cohort.
- In order to compare outcome measures between initial conservative and operative treatment, significantly larger cohorts are needed.

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Funding. Open Access funding provided by Projekt DEAL.

# **Compliance with ethical** guidelines

Conflict of interest. P.A. Michel, B. Schliemann. M.J. Raschke, J.C. Katthagen, L.F. Heilmann, F. Dyrna, F. Sax, M. Warnhoff, H. Lill and R.-O. Dey Hazra declare that they have no competing interests.

All procedures performed in studies involving human participants or on human tissue were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975 (in its most recently amended version). The ethics committee of the Westfaelische Wilhelms University (2019-159-f-S) as well as the ethics committee of the medical school of Hannover (8688\_BO\_S\_2019) approved the study. Informed consent was obtained from all individual participants included in the study.

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#### Dank an die Gutachter

Allen Experten und Expertinnen, die im Jahr 2019 Manuskripte für die Obere Extremität begutachtet haben, danken wir sehr herzlich für ihre konstruktive und gewissenhafte Arbeit. Durch ihre Expertise und ihr Engagement im Rahmen des Peer-Review-Verfahrens tragen sie ganz wesentlich dazu bei, die hohe Qualität der Zeitschrift zu sichern.

PD Dr. Knut Beitzel, München Prof. Dr. Sepp Braun, Innsbruck Prof. Dr. Ulrich-H. Brunner, Hausham PD Dr. Klaus Burkhart, Pforzheim Dr. Alexander Ellwein, Hannover Dr. Christian Gerhardt, Karlsruhe Prof. Dr. Thorsten Gühring, Pforzheim Dr. Michael Hackl, Köln Prof. Dr. Pierre Hepp, Leipzig Prof. Dr. Philip Kasten, Tübingen PD Dr. Christoph Katthagen, Münster Dr. Rolf Michael Krifter, Salzburg Prof. Dr. Lars Lehmann, Karlsruhe Dr. Petra Magosch, Heidelberg PD Dr. Frank Martetschläger, München PD Dr. Frieder Mauch, Stuttgart PD Dr. Philipp Moroder, Berlin Prof. Dr. Andreas Niemeier, Hamburg PD Dr. Ben Ockert, München PD Dr. Thilo Patzer, Düsseldorf Prof. Dr. Patric Raiss, München PD Dr. Marc Schnetzke, Ludwigshafen Prof. Dr. Dominik Seybold, Düsseldorf PD Dr. Sebastian Siebenlist, München Prof. Dr. Mark Tauber, München Dr. Markus Wambacher, Innsbruck PD Dr. Kilian Wegmann, Köln Prof. Dr. Mathias Wellmann, Hannover PD Dr. Andreas Werner, Hamburg