Planning
The incidence of proximal humeral fractures has greatly increased over the last several years, most likely due to an increasing elderly population with osteoporosis. An end to this exponential increase in the frequency of these fractures is unforeseeable. As a result, the surgical treatment of displaced fractures, especially in the elderly, is becoming more important than ever. With the development of angular stable plate fixation a new tool for the treatment of proximal humeral fractures—the Philos plate providing enhanced purchase in osteoporotic cancellous bone—has been created. Therefore, a decrease in the occurrence of previously known complications such as secondary loss of reduction, pseudarthrosis, screw and plate loosening, and avascular head necrosis is anticipated. A prospective case series planned by CID in conjunction with a number of trauma shoulder surgeons was undertaken to evaluate complications and functional outcome after ORIF with the Philos plate. The developed study protocol involved perioperative assessment to obtain clinical and radiological information at baseline, as well as at three, six, and twelve month follow-up visits. As functional outcome measurements, the Constant, Neer, and DASH scores were chosen. In each participating clinic, the local ethics committee granted approval to conduct the study.

Monitoring
From September 2002 until March 2005, 157 patients with 158 proximal humeral fractures were recruited at eight trauma units in Germany (Kaiserslautern, Rosenheim, Tübingen), Sweden (Stockholm) and Switzerland (Chur, Davos, Fribourg, Lucerne). Each clinic assessed their patients at baseline and follow-up visits using the respective standardized questionnaire complete with x-rays (AP and Neer’s view). Data were collected at the CID office in Davos and entered into a database, checked for integrity and prepared for further analysis. Due to conscientious monitoring, follow-up rates of 88%, 82%, and 84% were attained at the three, six, and twelve month follow-up examinations, respectively.

Statistical analysis and publication process during a fellowship at CID
To achieve an ideal exchange between statisticians and clinicians, Felix Brunner had the opportunity to play a chief role in the data analysis during a fellowship at CID: this exchange turned out to be inspiring for all parties involved. During this fellowship, the members of the CID staff taught him the necessary epidemiological and statistical concepts, and as a surgeon from a participating center, he could contribute his clinical knowledge to the analytical process. This interaction of a clinician with scientists facilitated the communication between CID and the principal investigator of the study. As well as the usual statistics regarding demographic and functional outcome parameters, they particularly focused on the analysis of reported complications. Together with the principal investigator, all information and x-rays from patients with reported complications were reviewed. Any complication was
defined if its occurrence was implant or nonimplant related (eg, surgical technique, general surgical complication, result of the trauma), and complication risks were also calculated. By the end of the study, Felix Brunner was able to successfully conduct all the statistical analyses, as well as compose a manuscript for publication.

Results and comments
Reflecting on the typical study population with proximal humeral fractures, the mean patient age was 65 years and three-quarters were female. In addition, 75% of the patients sustained a low energy trauma, mostly due to a simple fall. According to the Müller AO Classification, 25%, 39%, and 37% of the fractures were observed as Type A (2 part), B (3 part), and C (4 part or valgus impacted) fractures, respectively. In total, 71 complications in 53 patients led to 39 unplanned reoperations within one year. Main problems involved primary screw perforations of the articular surface due to erroneous placement of ‘too long’ screws (n = 22), followed by soft tissue complications (eg, frozen shoulder, impingement) (n = 15), secondary screw perforation due to impaction of the humeral head (n = 13), and avascular head necrosis (n = 13). Patients were at a 9% risk of sustaining an implant-related complication. This risk increased to 36% for a nonimplant-related complication. In patients over 60 years of age, the complication risk was almost doubled (relative risk 1.9, p = 0.02), whereas patients with Type B and C fractures were at a 1.8 times higher risk of experiencing any complication compared to patients with Type A fractures (p = 0.05). After one year, the functional outcome using the Constant score achieved a mean of 72 points (SD 15.2), and on average 87% (SD 16.6%) of the score of the contralateral, healthy shoulder.

Our results are comparable with published and congress communicated results of other case series evaluating the Philos plate. Excellent primary stability can be achieved and previously feared complications (ie, loss of reduction, implant loosening, AVN) have either become a rarity or did not appear in our study (pseudarthrosis). Although complications due to surgical technique (particularly those of primary screw perforations) occurred and overshadowed the good anatomical and functional outcome obtained in all performed trials, future reflection regarding screw length measuring techniques must become a priority for surgeons and developers.

Overall, we strongly believe that multicenter studies like ours—performed in various clinics of different care level—better reflect the clinical reality compared to single center evaluations of an implant. Therefore, we encourage CID and clinicians to continue designing multicenter studies, even though they are more demanding in consideration of the design, monitoring, and analysis procedures. But with the help of CID staff, these challenges are both fun and accomplishable.