The AO Foundation develops new surgical techniques, implants, and instruments under the medical guidance of independent surgeons. Responsible for the development and clinical testing of these devices as well as their educational concepts is an organization of medical-technical committees—the TK System. The interaction between industrial and medical experts cooperating according to AO Principles makes the TK System a unique institution for continuous innovation.

Tim Pohlemann and Philip Schreiterer

The AO Technical Commission (AOTK) System

History and evolution
At the AO’s very first meeting in March 1958, after testing the available osteosynthesis equipment on cadavers, it was decided to develop an AO standardized, comprehensive set of instruments and implants. Control over testing and power of decision making over the introduction of these new AO instruments and implants was given to the Technical Commission (AOTK), established in November 1961. The potential for innovation and specialization grew along with the increasing size of the AO community. Over the years, the AOTK founded subgroups, today called Expert Groups, for the different anatomical areas/clinical problems. The participation of more and more surgeons from all around the world provided the TK System with a comprehensive and diverse “voice of the practicing surgeon”, which influenced or even changed several points of view in the AO.

The highest principles
The TK System is an open forum for ideas concerning relevant clinical problems and possible solutions. Its different committees consist of surgeons (regular members and invited guests) who are the leading specialists in the relevant field. Under their clinical guidance, highly qualified engineers develop new devices. AO Research and Development (AO R&D) provides its expertise by answering research-related questions or by informing about the latest findings.

To ensure decision making according to clinical necessities, only medical members have voting rights and the chairman of each group is always a surgeon. Other than a per diem and reimbursement for travel expenses, participating surgeons receive no compensation. They are motivated by professional recognition, the chance to form friendships with respected colleagues, and the opportunity to see their ideas for improving patient care transformed into reality.

Cooperation with industry
Interaction with industrial partners is a key element of the TK System. The medical members seldom have a finished solution to a clinical problem right from the start, but rely on engineers and other specialists for design feedback, prototyping, testing, and framing the discussion in terms of manufacturing specifications.

After identifying medical needs and defining critical characteristics, the engineers work on technical solutions and present them to the surgeons. These devices are discussed, adapted, and
tested (material, mechanical, biomechanical, and/or cadaver) until a final prototype is felt to be adequate. With this design the industrial partner then obtains regulatory approvals. After FDA-approval and CE-Marking have been received, clinical evaluation starts until the device is proven to be of “AO Standard”. Only then does the responsible Expert Group propose the device to the AOTK for a final quality assurance check. Only the AOTK has the authority to release a new device, which may then be brought onto the market by Synthes. The length of time needed for developing and testing a new product depends on the degree of innovation: line extensions may take less than six months, whereas major innovations may take as long as three to four years.

It is worth repeating that only medical members have voting rights, and that all legal obligations relating to the CE mark or FDA approval have been obtained long before the AOTK decision about market release, implying that AO quality standards are higher than any existing legal requirements worldwide. This is the heart of what makes the TK system unique. Synthes deserves high credit for complying with the TK process, delegating the power to an independent body of clinicians to make decisions on the market introduction of any new product.

**Interface to education**

Depending on the complexity of the new device, teaching concepts and materials (videos, publications, course contents, etc) are defined and their production controlled by the Expert Group that was responsible during the development process. The medical content of all publications produced by the AO about these products is supervised by the Expert Group. In many courses, the TK System provides the initial faculty, since they are the only ones possessing clinical experience with the new devices at that point of time.

**The TK System today**

One of the most significant changes in recent years was the “Three Pillars” reform of 2005, which created an overall steering board, the TK Executive Board (TKEB), and three separate pillars for Trauma, Spine, and CMF. Each pillar has its own
Specialty AOTK with the power to approve new devices and Specialty Expert Groups. The greater autonomy of the Specialty pillars has encouraged more involvement from surgeons who are not AO members, and facilitated interaction with highly specialized experts in research and engineering.

Another recent focus was regionalization. Overall membership of the TK System increased to 134 surgeons worldwide, welcoming the first three members from the Middle East in 2008. A regional group was founded in Asia Pacific to adapt existing devices to the specific anatomical needs of patients in that region. Regional events such as the Experts’ Symposia, which foster open clinical exchange, were held in Europe, Asia, US, and, for the first time, Africa.

Since 2008, the TK System has assumed responsibility for clinical studies of new devices. With the support of AO Clinical Investigation and Documentation (AOCID), studies are planned by the Expert Group that developed the new device, and are approved by the AOTK.

**Involvement from idea to education**

Any surgeon can address his approach for solving a clinical problem to the TK System. After a first assessment, mainly concerning novelty, contact will be established with other innovative AO surgeons in the relevant Expert Group. In collaboration with them, the potential for the technique, possible improvements, and alternative approaches will be evaluated. If a project is started, the surgeon who proposed the idea will be involved in all further activities, such as:

- Development and non-clinical testing until final prototype
- Clinical testing in selected reference clinics
- Publication of test results/clinical evaluation
- Production of teaching concepts and materials in collaboration with AO Education
- Teaching at AO Courses
- Exchange meetings with the main clinical users, which provide clinical feedback for further improvements of the device or its handling

**Fig 5** The Spine Non-Fusion Expert Group (NFEG) in the lab.
**Fig 6** The Trauma Foot and Ankle Expert Group (FAEG) testing the hindfoot arthrodesis nail (HAN).
**Fig 7** A new navigation device gets the AO Foundation stamp of approval.
**Fig 8** CS Expert Group member Florian Gebhard teaching computer-assisted surgery.
A recent change in leadership
In January 2009, Tim Pohlemann took over the chairmanship of the TK System. In the 48 years since the inauguration of the AOTK, he is only the fourth chairman, succeeding Maurice Müller (1961–82), Stephan Perren (1982–97), and Norbert Haas (1998–2008). Tim Pohlemann is Director of the Department of Trauma, Hand and Reconstructive Surgery of the Saarland University Hospital, Homburg/Saar, Germany. He possesses vast experience gained over 16 years in the TK System, including eight years as chairman of the Pelvic Expert Group.

Challenges to the TK System
Challenges facing the TK System include increasingly restrictive regulations at hospitals, the chronic shortage of surgeons’ time, complex requirements for project coordination and information exchange, and the increasing number and variety of new products.

An increased level of evidence is required to maintain the AO’s high clinical standard, but also due to regulatory and economic changes. Together with AOCID, the TK System needs to design innovative studies and enhance clinical evaluation in order to secure highly ranked publications.

A main focus will be the identification of potential new areas. As new, even more complex technologies evolve, such as biotechnology or nanotechnology, the TK System needs to attract specialists without AO affiliation. Experience has shown that the integration of these new technologies into musculoskeletal surgery should be guided by surgeons according to clinical needs.

Summary and outlook
The TK System offers any surgeon an opportunity to realize his ideas. Innovative surgeons are provided with optimal technical support and introduced to an international network of surgeons dedicated to research, development, clinical testing, and teaching. As part of this clinical think tank he/she can provide the surgical community with continuously improved treatment options.

To learn more, please visit www.aofoundation.org/ (AO in-depth; Activities; AOTK)
A visual representation of how the TK Executive Board is organized.