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Conceptional and structural conditions for successful clinical research

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Abstract The efficiency of surgical research has again become the subject of debate. Clinical research is required to improve our understanding of surgical disorders and our ability to treat patients. This involves both experimental research (research in the test tube) and clinical research in actual patients. The surgeon must remain the expert because it is he who deals with the patient and is confronted with his problems. On the other hand, care for the patient, must always be the central issue. Here a new orientation is needed, evaluating the effectiveness of surgical research from the patient's point of view. Surgical treatment, particularly surgical research, must be adapted first to the individual patient and only secondly to the surgical disease – the problem must determine the method, not vice versa. While it is clear that a creative atmosphere, supportive structure and efficient organisation are enormously helpful, today's exaggerated attention to matters of structure and organisation are often poor substitutes for creativity and intuition. Surgical research does not refer solely to therapy research but includes methods for carrying out controlled clinical trials, establishing guidelines and scores and designing instruments for measuring outcome. Socio-economic and analyses and ethical considerations are crucial for facing such conflicts as “quality versus quantity”, “profession versus business”, “patient care versus economics costs”. Proposals for designing more effective concepts, structure and organisation for clinical research are presented here, and three models are introduced: the cooperation model, the integration model and a mixture of the two.

Key words Surgical research · Clinical research · Concept of surgical research · Structure and organisation of clinical research · Integration model · Cooperation model

Introduction

Surgical research has two basic, equally important, firm footings. These are “experimental” research (the research in the laboratory, in the test tube) and “clinical” research (the research of individual, surgical patients). The only intention is to understand the surgical patient and the surgical disease, influence it effectively, orientate that influence on the patient and evaluate the effect from the patient's point of view by asking “how are you?” [22, 28].

To achieve this objective, various important prerequisites are necessary, two of which are conception and structure. These are discussed with the focus on clinical research [27]. We have also discussed this topic previously [11, 12, 23, 25]. It is said, that conception and structure are the basis of efficient research; in fact, they are demanded! It is also said that due to nothing but planning and discussions about conception and structure, research has been degraded to pure organisation.

Instead of finding, testing and realising innovations by means of pensiveness, good ideas and creativity, research has been brought down to the level of merely organising them. Pensiveness is laughed at! The size of an institute, the number of rooms, co-workers, grants and finances, and publications are now described as and regarded as the research. The German weekly magazine *Spiegel* [20] points this out – in its typical manner – with a heading *Farbige Bilder des Grauens (Colourful Pictures of Horror)* in analysing cancer research and cancer therapy [20].

The German *Krebsforschungszentrum* in Heidelberg has a “Kuratorium”, a “Stiftungsvorstand” and a “Wissenschaftsbeirat” (special task forces with high prestige). It holds a research budget of DM 200 million, employs 1516 co-workers (657 of these are scientists and, of this number, over 50 are professors) and publishes two papers every working day. The magazine gives the world-renowned chemist Erwin Chargaff the opportunity to draw balance: “A lot has come out – thick paperworks, nice prices and medals, but where the sick are dying, hardly anything came out” [6]. After all, the institute in Heidelberg is only a

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children's playing ground compared with the "olympic centres" in the United States, such as M. D. Anderson in Houston and the National Institutes of Health (NIH) in Washington. Gigantism is borderless, but the number of publications cannot be handled anymore. The question is, what is the acceptable level? Despite all of this, however, one fact has to be mentioned: in the German *Krebsforschungszentrum*, 657 scientists are employed. In contrast, only 358 scientists are working on surgical research in German Universities [2].

Examples of the first possibility (and this has nothing to do with gigantism) included Prof. Semmelweiß, who taught us surgeons to wash our hands before operations, and Philipp Mouret, who removed – without realising it the first time – the gallbladder with the aid of a CO₂-pneumoperitoneum. Only intuition, creativity and analytical observations have been able to improve surgery, without a distinguished conception and a complicated structure being built.

A good example for the second alternative (also without showing any gigantism) is that of Prof. Heberer and Prof. Bretschneider in the 1960s. The surgeon (Heberer) realised that carrying out sophisticated operations on the beating heart was quite complicated. The *solution* was to temporarily stop the heart from beating and, to do this the surgeon asked the physiologist Bretschneider for help, which led to the "Bretschneider solution" [4]; thus, the model "experimental surgery" was born in Germany.

Clinical reality and necessity resulted in the conception and, based on this, the structure was organised. It was realised that, besides inventing a new technique, the desired advantage for the patient had to be thoroughly researched with system and method, and this had not been of so much interest prior to that time in research.

As early as 1972 an important book was published [19]. In this book (a crucial experience for me), such thoughts are presented as "what we really want to show and present is the quality of the patient's life" or "the follow-up clinic is the lab of the surgeon, or the clinician" [19]. In addition, in 1986 a small – for me almost revolutionary – book by Bryan Jennett, *High technology, medicine. Benefits and burdens*, was published [9]. In this critical but convincing book, it is described, that physicians/surgeons have to care about what they achieve and even what they cause by their own doing. A conversation with the neurosurgeon Bryan Jennett ended with the sentence "if we would be as interested in outcome measurements as we are in searching for the correct diagnosis, most surgical interventions would be changed or even dropped!" [28].

Three determining expressions for clinical research are described: (a) outcome measurement, (b) quality of life, and (c) follow-up clinic [9].

Conception

First of all, it has to be made clear that the basis of surgical research is the surgical patient; only after considering

the patient should the surgical disease be considered. Surgical disease is the fundamental orientation for the conception of surgical research and this in the above order. This and only this is the orientation for the conception of surgical research; a tight, pragmatic conception, but the correct one [27]!

The important question regarding the idea of sickness/wellness with the mechanistic and hermeneutic model will not be dealt with here; it has been discussed previously [8, 13, 27]. While stating this (my) firm believe, I already hear the well-known outcry: "One cannot do everything! One has to concentrate!" This also holds quite some truth. Research surely needs focusing and constant factors. On the other hand, surgical research lives because of a certain variety and – this is essential – from necessary flexibility. Topics of surgical research change with new questions that arise. However, flexibility has nothing at all to do with permanently jumping onto the fashion train or going with popularity.

The choice of methods is as manifold as the questions, i.e. the question determines the method; it is never the other way around. This has been pointed out many times before [23, 27] and the solution to the problem might be purely experimental, purely clinical or both. The latter is standard in surgical research. However, it is also clear that activities that work on only one or two of these tracks also mean surgical research (Prof. Goligher almost only ever performed clinical research).

The results of surgical research must prove to be effective in the patient and be as direct and quick as possible. Time pressure is strong and ruthless; a speciality of surgical research. Even though priorities must be fixed, a certain – although limited – variety is necessary and real. This is another decisive characteristic feature of surgical research. If the surgical patient, with his complex problems, determines the orientation of surgical research, the clinician/surgeon (mostly the chairman) has to decide, together with his mental milieu (if present), which questions from the clinic during a certain time period make sense, are necessary, are feasible to work on and, therefore, can or must be included as a research project. The chairman of surgery is appointed almost only for this reason. For this, there are certain prerequisites, such as instinct, good ideas, sensitivity, flexibility and, most of all, the chairman has to be open minded. Most ideas that don't fit into the old pattern are often the door to something new (change of paradigm). In particular, his own, absolutely necessary ideas complete his true competence and, therefore, produce his natural authority as a chairman of surgery.

On the a/m background, one chairman might have to deal with sepsis if his specific interest and competence centres around the pancreas. The interest of another colleague might centre around the functional and malignant diseases of the oesophagus, which he might have chosen by himself or perhaps was forced to choose because of certain circumstances. Part of his work, then, will be testing and evaluating therapy concepts based on this. For example, our group is interested in the patients in the intensive ward and, in general, in the effectiveness of the intensive ward itself. The multiply injured patient, a further topic of our inter-

est, has brought us to this; here also of course is the effectiveness of different therapies. These examples picture further aspects of the basic idea of surgical research; the choice of the clinician and the reasons for that choice. At what time patients are operated on and how these different operations will affect them are questions that have to be answered here.

The help – most of all the competence and the necessarily differing ideas – of a “real” partner on all levels is of course an ideal situation. Normally this is a grant for success; help in specific aspects is undoubtedly necessary. The extent of the help is deviating and determined by the problem. In no case must the surgeon lose direction or give management out of hand, so that, at the end, the helper sets the aims of research at a chair of surgery. From my personal point of view, this would definitely be an undesirable trend. Mostly, this comes from incompetence and indolence of the clinician, neither of which can be tolerated. Even the awful preoccupation with other organisational problems is no excuse; not even the escape into the operating theatre. It is a fact, that competence of the surgeon is based on his understanding and access to the complexity of a clinical situation. In this situation, the clinician is the absolute expert. For this reason, surgical research means a lot to clinicians.

Clinical research can possibly be described by development and testing of activities of care, better nursing care and treatment of surgical patients. This makes it clear that “looking after” and “caring” is part of surgical research, especially in clinical research. Henrik Kehlet has successfully been working on this topic for years [10]. The basis of this idea adds to the special *conception of clinical research*, as described below:

- The individual surgical patient in his complexity is the problem to solve.
 - A surgical therapy must be found and tested regarding effectiveness.
 - The surgical patient is complex, and the problems to solve are manifold.
 - Responsible for surgical research at a university is the Chairman of Surgery; he was appointed for this reason.
 - The clinician/surgeon – Chairman – chooses the topics of research.
 - Certain limitations are necessary.
 - The chosen topic – and not the existing method that one can easily handle – determines the direction of research.
 - The method may be purely experimental in the laboratory or purely clinical or both, depending on the problem to solve.
 - Flexibility is essential.
 - Clinical research is indispensable; “the follow-up clinic is the lab of the clinician”.
 - Surgical research must always be evident in the patient and as quick and direct as possible.
 - The problem with its sharply outlined basic idea determines the structure.
 - The candidate for surgical research has no time limitations; at the most it is different in its intensity.
 - The candidate must work “full-time” for 1–2 years in a purely research oriented institute; this can be a laboratory or a clinical research institute (e.g. Institute for Health System Research, Institute for Epidemiology and Biostatistics).
 - Surgical research should be performed not only at universities; this is especially true for clinical research.
- The basic idea initially contains the development and testing of the surgical trade; maybe I should even say the surgical art. The latter is hard to test. Then comes the testing of our activities in general. Of course, old and new therapy concepts are covered by that. The method for this testing is randomised controlled trials (RCTs). The controlled clinical study is the experiment. Since this sometimes is not applicable in surgery, because of various reasons, alternatives exist that have to be understood and their limitations known [27]!
- To put these *aspects of clinical research* into practice, a structure is helpful, maybe even necessary. This is follow-up and I already discussed this many years ago [21].
- The follow-up clinic is the lab of the clinician. Added to this is the necessity to develop methods to make this clinical experiment valid, to improve it, but most of all to make surgical performance safer (risk research, quality assurance, consensus conferences, decision making, etc.):
- Development and testing
 - Surgical technique
 - Surgical instruments and technology
 - Organisations structure (intensive ward, emergency system, follow-up-clinic, rehabilitation clinic)
 - Experimental and non-experimental evaluation of innovations. (therapy concepts)
 - Experimental (randomised controlled trials, RCT)
 - Non-experimental (prospective observational studies etc.)
 - Development of methodology
 - Study design
 - Consensus conference
 - Guidelines
 - Score system
 - Instruments for outcome measurement
 - Quality assurance
 - Failure analysis
 - Pre- and postoperative risk minimisation
 - Risk research
 - Decision making (structured)
 - Intuition (not structured)
 - Socio-economic analysis
 - Education and training for surgeons
 - Ethical questions
 - Primum non nocere*
 - Primum utilis esse!*
- Questions of economy and socioeconomy have gained public interest [24], an aspect clinical research has to deal with. Finally, ethics has become a desperately interesting topic:
- When am I allowed to start an innovation/operation in people?

- Am I at all allowed to practice (my first operation) on human beings?
- Can or should I stop a therapy?
- Is a certain therapy too expensive?

These are burning questions full of conflicts; they surely cannot be answered with the aid of a laboratory.

When I stated that the surgeon has his expertise mostly in clinical problems, this means that this often is the reality, but there are exceptions. These are chairmen of surgery, who are absolutely competent in heart physiology (A. Wechsler, Houston), cancer immunology (M. McKneally, Toronto) or colon physiology (L. Hultén, Göteborg), because they have been working full time in these fields and have been trained in them for a long time.

Surgical research, fundamentally, has nothing to do with research in statistics, physics, mathematics, not even in pharmacology and most of all not in molecular biology. Nevertheless, we have to not only show an understanding of these independent research fields, but have to have basic knowledge of them. It is also a fact that the surgeon, the clinician, places the decisive questions for these areas. The clinical problem is the basis here; this again comes down to the competence of the clinician. Of course it is not a platitude that, apparently, fields as far apart as mathematics, physics and chemistry have influenced and improved medicine/surgery through their outstanding research results. Examples of this are X-ray, flexible endoscopy, endoscopic surgery etc.

With regard to the basic idea of surgical research, a few more items have to be mentioned. An important aspect of a successful surgical and, in particular, academic career is the process of selection of young colleagues for surgical research. Since we have to and should train academically oriented surgeons (the emphasis is placed on surgeons) as a priority, the technical and clinical competencies are essential criteria for the selection. In surgical research, we do not necessarily train experts in histamine metabolism, but rather surgeons, who can – if necessary – understand and be able to use the facts of histamine metabolism. In addition, for this difficult but so important decision, the clinician/surgeon has the competence and responsibility. If a partner (theoretical surgeon) exists, he has part of the responsibility.

A further constant factor has to be surgeons working permanently in surgical research. It is helpful and makes sense that a surgeon who has proven surgical competence – only then – has to show that he has the necessary prerequisites for scientific understanding and interest. If this is obvious, this candidate should learn ways of thinking and problem solutions in a “theoretical” institute for 1 year or better 2 years on a full-time basis. Only after he has got to know the “world of research” will his spectrum of understanding in science be increased. This is an absolute prerequisite for an academic surgeon. With this, a further essential part of the conception of surgical research is indicated: the constant factor. Surgical research can never be temporary. Continuity is on the agenda. Only intensity is and may be different.

Research that stops after *Habilitation* (the German post-doctoral degree) or after receiving the title of a professor should not be accepted. It is requested, that surgical research should not only work towards improving things, avoiding bad and learning from mistakes, but an essential aspect of research is the obligation of every university graduate to carry out research, especially when the *Venia legendi* was received or a position at an university as a chairman has been achieved.

Structure

The conception of surgical research pictured here has to now be put into practice according to the principle “knowledge, expertise, doing”. It is no secret that a number of different factors, possibly hindering realisation, have to be taken into consideration; with energy, determination and, of course, talent and flexibility, however, these can be avoided. In general, one does not gain friends in this way and, surely, in the short term, also no impact factor.

The main influencing factors are *locality* (i.e. University of Munich, Marburg, Kiel or Cologne), the “close” vicinity (a surgical chair versus several; existing institutes for surgical research versus none), the time period, traditions, habits, and (for me) *the most important key factor, people!* In our times, this is joined by the power of administration departments showing their small-minded way of thinking with comments such as “we are not interested in visions, your ideas! Operate! – too many patients, watch the budget! Pancreas transplantations, who shall pay for all this? Insurance companies do not give us a penny for this”. To build upon understanding and help, and to hear words such as “what do you need? How can I help you” is far from reality. The opposite is true. Today, it is *en vogue* to hide behind the infamous missing resources; a repulsive cynicism!

To correspond with responsibility, the aim – the conception – may not be lost. For this, enthusiasm and trust in one’s own competence is needed, most of all at the beginning, for example, when starting a new position as a university chairman; adding to this are tenacity, toughness and, again and again, flexibility. To strive for harmony did not help me personally very much. Vision, the set targets, including sense of reality, are the true alternatives.

Many colleagues have discussed, described and lived with their experiences and positions (with differing successes and satisfaction) [1, 12, 14, 15]. Furthermore, I had the opportunity to investigate and analyse different models in different countries over the years. I was able to participate in conception and realisation at three different universities, and my detailed views on surgical research together with friends from these different countries have been described [26]. The relevant chapter in the second edition of that book is entitled *Strengthening the Research Environment* [30].

Before I point out my view on this, let me describe another reality. There were and always will be men and

women who will, despite any adversities, change or improve the world in general and the world of science in particular, without any conception or even structure, e.g. Semmelweis. "Albert Einstein needed only a kitchen table in his modest lodgings to set down the theory of relativity" [7].

The often helpless, even infantile demand of entire help is no use. This attitude, this infantile behaviour in our times is merciless and unmasked by the French philosopher Pascal Bruckner in his fascinating book *La tentation de l'innocence* – in English, "I suffer, therefore I am" [5]. However, it is obvious that a favourable, optimal environment [30] and an intellectual atmosphere will promote culture, creativity, inventiveness and an open many-sided critical observation; it will also lead young people in a positive way. The atmosphere and culture has to promote enthusiasm on the one hand and, on the other, has to transfer critical reflection and intellectual modesty [17]. The maxim here is: "We never can be sure" [17] and "Advancing through errors" [29].

The atmosphere of a mental environment and its determining effect cannot be regarded highly enough [7]. To make this plain to me, a wise, long-time friend and teacher, Wolfgang Böcher [3], told me a story from his favourite author, Antoine Saint-Exupery, from the book *Terre Des Hommes* (Chap. 4 "Human Beings"): a family is described, with a ruined mother and a strengthless father; between them sits a "hopeful, smiling, cute child with awake, shining eyes" [18]. Resumee: "Mozart is condemned to death". The environment, therefore, plays an essential part in putting surgical research into practice. In this, the structure is one part – surely an essential part – but only a part.

Structure can never compensate for incompetence, lack of character or missing conception. The above saying strikes a second note which I do not want to discuss any further: "a hound having to be carried to the hunt, put in front of the fox-hole and asked to bark has to be killed"!

It has to be clarified again that structure has to be based on the conception. The structure must allow flexibility to be able to react to urging, but also changing surgical problems. To guarantee this, the construction, the organisation and the department have to have a suitable size. The size – construction again – is determined by the basic idea and must, in no case, be sacrificed for the status mentality of the involved people. It must allow force by quick reactions and flexibility. It should not be too inflexible and, in no case, should it ossify in organisation and structure; a well-known, deadly danger of all structures. The end of it is an exclusive "administration of nothing" while waiting for retirement.

Sometimes projects develop by themselves within a structure. They were not planned or "structured", i.e. a colloquium for new experimental results. This should on no account be "structured"; it has to be cared about and nourished like a flower. The ways to Rome are different; even among religions, there is only one – as far as I know – that claims to know the only way towards salvation. Fundamentalists are, as observed daily, the worst advisors. However, it must not be forgotten that new conceptions and in-

Table 1 Neurotraumatology and neuropsychological rehabilitation in the Health Research Program 2000

Biomechanical questions	Chair of anatomy, traumatology, neurosurgery
Surgical questions	Chair of neurosurgery, surgery, traumatology
Pre-clinical treatment and logistics	Emergency system, fire department
Shock therapy, intensive care	Intensive care physicians, pharmacologists, molecular biologists, neurosurgeons, economists, psychologists
Cranio-cerebral trauma	Intensive care physicians, molecular biologists, neurosurgeons, neurologists, surgeons
Psychosomatic problems	Chair for psychosomatics and psychology, paediatric psychology
Statistics	Chair for statistics and epidemiology
Economy and socio-economy	Chair for health system research and health economy
Coordination and responsibility	Biochemical and experimental department (theoretical surgery at the II. Department for Surgery of the University of Cologne)

novations need a certain "stubbornness" and staying power to change or remove rigid, doomed traditions. History has demonstrated this in all fields of life many times. Sometimes this unfortunately almost takes a revolution. "History will punish the ones that come late!" Evolution based on understanding and insight is often a wasted effort!

Until now, we experienced this reality with the "never ending story" of the conception of *theoretical surgery*. It is another fact that a new, sensible, wise conception should be given a new name – and not only to attract attention. To put the described conception of surgical research, in general, into practice with different effectiveness, there are – according to my conviction – basically three possibilities or models:

1. Cooperation model
2. Integration model
3. Combination of both with differing focuses

Cooperation model

The cooperation model is the solution for a surgical problem – clinically or experimentally or both – in cooperation with the necessary special fields and experts. To clarify this, I would like to describe a current project focusing on *Neurotraumatology and neuropsychological rehabilitation in the Health Research Program 2000 (BMBF-01K09517. Responsible and initiators: E. Neugebauer and B. Bouillon. Volume of finances DM5 million; term 1996–2002 (= 6 years); number of co-workers 23; Table 1).*

Advantage

The strength of the cooperation model is based on the concentration of highest competence regarding a special, individual question. For every important aspect, an expert or an expert team is chosen. Here we do not deal with apprentices, but with masters in their fields who focus their complete competence on this question. So it is said; this is the basic idea. This is the ideal!

Economy – very popular nowadays – is more favourable (maybe better) and can be more favourable if existing localities and technical equipment are used by several parties. Personnel, secretaries, medico-technical assistants and nursing personnel can be exchanged and can work for the project either part time or full time. The dominating cost factor, personnel, is minimised by this. A new institution or department, or special buildings are not necessary! This is the way it is intended and promoted, and maybe it can be like this.

One less obvious advantage, although extremely important, is the exchange of knowledge. During the regularly planned discussions and meetings regarding the project, we can learn from each other; this is the ideal and the achieved results or solutions have a high degree of evidence. Publications and results (if they are completed – term of 6 years) are based on a solid basis. They receive high acceptance. Most importantly, however – not essential in this model – the advantage for the patient will hopefully show and reveal a detectable (clinically relevant) benefit! – or should only publications come from it?

At present, this kind of structure is highly respected in the world of science and even more important in the world of the sponsors (*Bundesministerium fuer Forschung und Technologie, Deutsche Forschungs Gemeinschaft, etc.*). Cooperation and bringing together clinics and experts of basic research to solve surgical problems is generally demanded and supported. It is the stated intention of the Science Ministry and the responsible persons to confront basic research with the clinical reality. With this, basic research should lose its sterility, and clinical research, which is regarded (not only in Germany) to have small effectiveness, is supposed to gain.

A further advantage of this model is the fact that, within this structure, every single institute and every expert team has their own research project within the total project. With this, autonomy and cooperation are possible at the same time. Obviously an ideal model, if only it works.

These undoubtedly existing advantages are the reasons that this structure is practised in many countries and in many universities; this is also true for Germany. Many colleagues can imagine surgical research having this structure. An aspect of this model which should not be forgotten is that the individual experts maintain their competence within their fields, within their teams, because of the autonomy and working in their own fields. In this case there is no danger in creating “the fish out of water” [27].

Disadvantage

I claim that the efficiency is indirectly proportional to the effort. It seems to me that there is a big gap between reality and imagination. The structure created with large expenditure turns into meetings, discussions, persuading people, writing protocols, fighting and helping; what is often left is pure activism. Compromises in every aspect exceed the limits of efficiency, first, because of the incompetence of the individual cooperative members. To cooperate with an institute – not turning them into opponents – incompetence has to be accepted.

Here, the parasite syndrome shows that the opportunity is taken (because one becomes needed) to jump on somebody else’s train, to also get a piece of the cake, such as financial grants or personnel. An essential negative effect of this structure is – from my point of view – the rigidity. The structure is fixed for a long term (5–10 years); this is half of a young surgeon’s career. Also, the limitation – only one subject – is, based on my idea of surgical research, a problem. Adding to this, a certain capacity is tied up for a long time.

The fact that the highly recognised economy is a misapprehension has already become reality for me. No investigation has been carried out so far regarding this question. The gigantism in the “land of unlimited possibilities” has always shocked me, for example, when I had to observe how millions or even billions of dollars were handled, argued about, and how, in 2–3 years, new institutes were produced in Toronto and Houston, new institutes for gene therapy, molecular biology and X-ray therapy, in ranges of industries as in Detroit or Wolfsburg – which makes us astonished and also concerned – seldom or never talk about sick people. The topic of discussion is: “I got the bigger grant!” The question “where is the benefit to the individual patient?” may be permitted here.

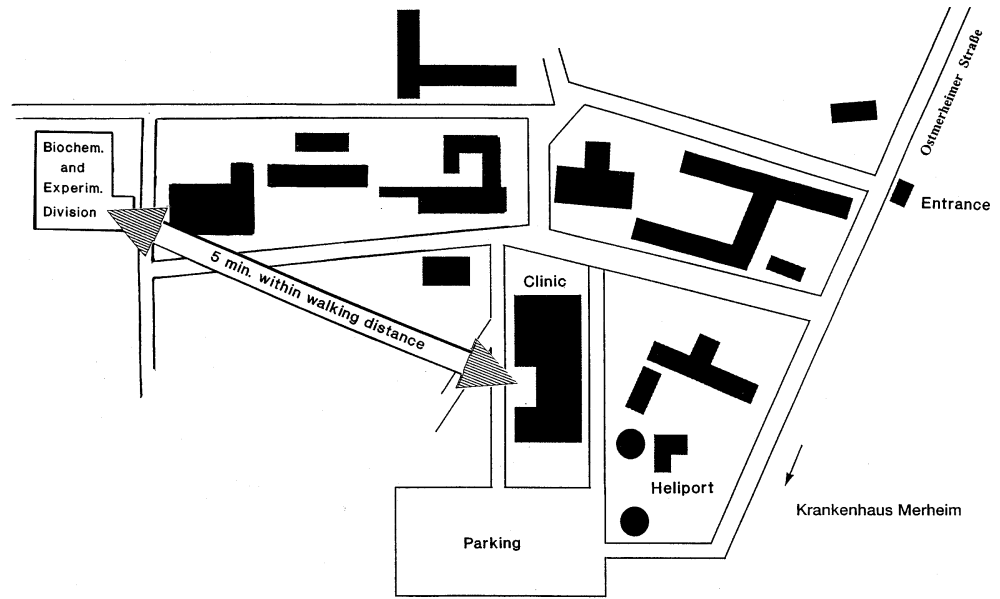
My main arguments against this model are the commitment to a single topic, the long term, the rigidity and the threatening gigantism with an enormous low grade of efficiency. For me, this model is only a supplementation, an aspect of the structure for surgical research. This model corresponds, in many aspects, to the conception of surgical research (realising experimental and clinical research) as recommended by myself. The alternative to this is the “integration model”.

Integration model

The essentials and specification of the integration model is the solution to a surgical problem – clinical, experimental or both – with the competence of experts (employed at the Second Department of Surgery) who closely and permanently cooperate with one or more clinicians (teams) [12].

“Our keyword is integration, not just frequently intended, but rarely experienced cooperation”, the credo of Wilfried Lorenz. It has to be kept in mind, that this credo is based on a person (such as W. Lorenz) with high com-

Fig. 1 Location of department for surgical research and distance from the clinic



petence, strong sovereignty and the absolute willingness to be a partner. This was and is the stated intention of the “Marburger Model” as an integration model. For this, a department or an institute is necessary, i.e. such as a department or unit for vascular surgery or traumatology can be included at a university chair. The institute for surgical research has priority and is more significant in its ranking at a university.

The experts integrated into this structure are chosen and trained according to the conception and scientific focus of the chairman’s clinic. For our focus, these are, for example, psychologists, psychosomatics, biochemists, mathematicians, information scientists who have knowledge of statistics and molecular biologists. The head of this structure form should be a physician or, even better, a surgeon. However, then he has to have a second main area, which could be physiology, statistics, epidemiology or, nowadays, molecular biology. To correspond with the position in such a conception, it is hardly possible for a non-physician to deal with the arising problems. An epidemiologist or a molecular biologist never having seen a sick person, or their fate, is not able to create surgical research competently in content; of this, I have enough examples. In addition to the professional competence, the expert’s personality and character abilities are deciding factors. Egocentrics (people having a “small-man syndrome”), former surgeons with the famous “two left thumbs”, and also hollow-chested theorists are at the end of this successful structure form also preferred by surgeons. The negative examples in our country speak for themselves.

The position of the head of a research department or an institute corresponds approximately with the position of an assistant professor in the common structure of a large clinic in terms of its hierarchy. Where the senior surgeon (nowadays often a C3 professor) is mostly occupied with problems of patients’ treatments, teaching science and the organisation of the clinic in a trustworthy representation of the chief, the head of the surgical research department is

mainly the trustworthy, responsible and loyal representative of the chairman for surgery in research. In both positions, integration has to be reality. The senior surgeon will influence the focus of research and will also choose the colleagues who will do research.

On the other hand, the head of the surgical research department will have and must have a decisive word to say regarding distribution of wards and employing new colleagues in the clinic. The continually demanded autonomy of the head of this department has its limits in loyalty, trust and in the conception of surgical research of the individual clinic. This is independent of the special position (C3 or C4). If this is not desired or if this hierarchy cannot be accepted, then there is still the possibility remains to buy stamps and apply for a position in a research institute, i.e. Max-Planck-Institute, or for a chair in molecular biology.

For optimal realisation, this form of structure needs its own facilities. To correspond to this favoured principle of integration and to constantly make it easier, the facilities are very important. Our research department is (regrettably) 5-min walking distance from the clinic. It is a nice, singular building and can be easily reached from the clinic area. This has nothing to do with gigantism. It fits just like that and was established exactly according to my conception (Fig. 1). The speciality of this department is, however, the division of the rooms. According to our conception of surgical research emphasising clinical research, we have divided the room into three main parts (Fig. 2):

1. Laboratories (seven rooms/137 m²)
2. Facilities for animals (two operating theatres, intensive ward, experimental laboratory. Also included in this building are facilities for training courses and conference rooms)
3. Follow-up clinic (four rooms/74 m²)

The latter consists of a secretarial room, a waiting zone and a room for data files. A secretary and the necessary communication techniques are also available.

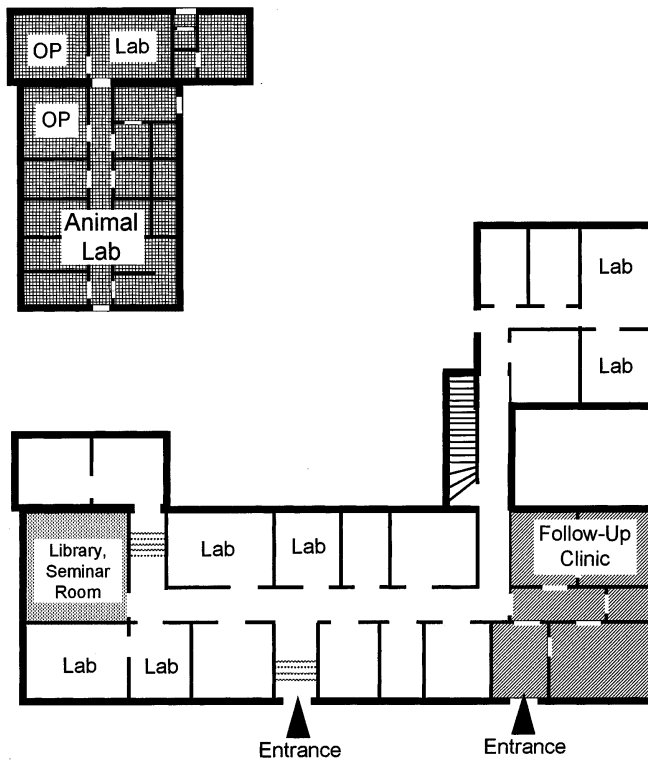


Fig. 2 Functional components according to our conception of surgical research: *I*, laboratory facilities (seven rooms, 137 m²); *II*, facilities for animal experiments and two operating theatres (36 m²) (facilities for training courses); *III*, “follow-up clinic”, four rooms (74 m²) (separate entrance, secretarial office, examination room, physician’s office); *IV*, office – library and conference room (40 m²)

The conception follow-up has nothing to do with post-examination or postoperative care (Table 2). The essential objective of a follow-up clinic is the systematic survey of clinical or paraclinical variables of a surgical patient, mostly a patient included in a controlled clinical trial. The inquired variables or measuring data have to be tested prior to usage regarding their effectiveness (true endpoint). The follow-up clinic is not for inquiring variables just because

they are easy to get, but are irrelevant for the question to be answered. There are many essential aspects of the so-called follow ups which we published many years ago. [21].

The advantages

The advantages of this model, which can differ in some details, are obvious. First, it is the structure which corresponds mostly with the realisation of the conception of surgical research, as we can and must understand it nowadays. It leads to a relief of the strain of the clinician, who definitely is, at least lately, under great pressure due to organisation, patient’s care, education and struggle for survival. Following this construction, the clinician has a quick, uncomplicated and competent help in his research work.

However, the expert, the molecular biologist, physiologist or epidemiologist, has the realistic chance to work close to reality, to learn and to use his knowledge not only in the abstraction of the laboratory or the computer. In particular, this aspect is demanded by many competent observers of the scene as a necessary impulse for surgical research. The slogan counts “research at the bed-site”, promoting clinically oriented surgical research.

A further credit point of this structure form and its variables is the possibility to quickly and competently respond to changing questions in surgical research. Furthermore, with this structure form, independence from stressed colleagues and those not willing to cooperate is gained by having competent experts within one’s own house. This highly appreciated and demanded cooperation with colleagues (necessary also for the cooperation model), however, was not always able to be detected, at least by me. The ideal of finding a competent colleague, who has the time, interest and is willing to help with the problems of a clinician, is very rare. The situations shown below are quite real and occur often; this may be referred to as the “syndrome of open doors regarding cooperative colleagues”:

Table 2 Differences between post-examination and control examination (systematic follow-up) on the example of patients with ulcus duodeni [23]

Criteria		Follow-up	Post-examination
Patient	Who?	All patients with stomach complaints	Only patients with ulcus duodeni
	How many?	All patients (at least above 90%)	Some (in general 50–60%)
	How often?	Before and every 1/2 year to 1 year after operation	Only after operation, occasionally and only once
Examiner	Who?	Group of experts, interested and experienced	Not defined (mostly only medical candidate)
	Objective?	To a great extent yes (internist or team)	Possibly not (surgeon)
	How often?	Every week, fixed date	Sporadically, irregularly
	How?	Questionnaire, pre-fixed definitions	No questionnaire, no fixed definitions
Organisation	Who?	Own secretarial office	Stressed clinician doing a side-job
	Where?	Especially facilitated rooms	Rooms not at hand or not defined, i.e. outpatient clinic or ward room

- Behind the “open door”, a colleague is found being competent, nice, interested, has time, and is willing to cooperate. The field of interest is also his or at least close to his interest
- Behind the “open door”, a colleague is found being competent, cooperative, nice, interested, highly academic, but the field of interest is far from his own interest
- Behind the “open door”, a colleague is found being competent, very successful, but egocentric; he is absolutely convinced to know the truth or the way to the truth
- Behind the “open door”, a nice colleague is found, having no problems, thinking of everything being in perfect order, but is incompetent; he is “only” nice, but nothing will ever happen at all
- Behind the “open door”, a colleague is found being ignorant, cynical, hypertrophic, knows everything better, but is truly of low level. This door, which one is better not to open, sometimes even carries a sign reading “Prof. Dr. med.”

This situation in particular has led surgeons always to try to establish the here-described “integration model”. For this, many examples exist, differing in success. Personally, I favour this system and structure form and am supported by many friends and colleagues in Canada, the United States and Great Britain [16].

Just as with the cooperation model, the other side of the coin exists here as well. It is clear – as emphasised before – that this model is based on the personality and competence of the people involved, and it is the aim of the chairman of the department and the head of the research department to create a successful integration; a job not so easy to accomplish, but very decisive. For this reason, competence and a certain character are essential prerequisites.

However, this system contains another realistic problem or even a danger, which is that physiologists, molecular biologists etc. lose competence in their own field; the problem “fish out of water” cannot be neglected. Also negative are the future perspectives of the hired experts. An able, young, competent university graduate is of course also working for his future perspectives and his career in a positive sense; a complicated and dangerous problem, which Wilfried Lorenz observed and tried to solve years ago. In the first place, the solution consists of a special education, but also of maintaining and establishing such structures and offering possibilities to achieve corresponding positions. Quite a few competence conflicts have harmed this matter, if not even destroyed the system and the future of some colleagues. Furthermore, the advantage of this model for the benefit of the patient has been discredited.

Combination of the cooperation and integration models with differing focuses

As mentioned before, a mix of these models is possible and practised. Even my example of the cooperation model is

not purely cooperative, but comes close to the mixed procedure. At the end, many of us gave our opinions on this subject. The question is “does anyone read it?”; if it is read, does anyone accept it?; if it is accepted, does anyone put it into practice?; if it is realised, is it an improvement that helps the patient?”. This is a question I have been thinking a lot about lately.

Conclusion

Surgical research has again become the subject of controversy. The issues regard its efficiency; improved concepts and structures are required. Surgical treatment means using clinical experiment toward understanding surgical disorders in the individual patient in order to prevent disease and to improve treatment. Surgical research means experimental research (research in the test tube) and clinical research for and with the individual surgical patient. That caring for the patient is not the central issue is clearly a shortcoming.

A new orientation is needed. The effectiveness of surgical research must be evaluated from the patient’s point of view. Surgical treatment, particularly surgical research, must be adapted first to the individual patient and only secondly to the surgical disease. The notion that the basic conception and the organisation of surgical research must be oriented to the surgical question – and never vice versa – is very important. As in questions of research methodology, the problem must determine the method, and not the method the problem. The ongoing debate over issues of structure and organisation clearly shows the perversion of surgical research. A fanatical search for better structure and organisation is usually an excuse for the lack of creativity and intuition. In some countries the competition for funding grants, the size of grants obtained, the number of co-workers and maintaining an impressive research facility are mistaken for research. “Einstein needed only a kitchen table in his humble lodgings to devise the theory of relativity.” Semmelweiß changed surgical techniques based merely on observation, without a large body of co-workers – many lyrics have been composed in jails. Of course, it is clear that a creative atmosphere, supportive structure and efficient organisation are enormously helpful.

This contribution presents proposals for designing more effective concepts, structure and organisation for clinical research. The concept of clinical research is a partial aspect of surgical research and sometimes cannot be separated from this, which is also not absolutely necessary. Important is that here the surgeon is the expert, because he deals with the patient and is confronted with his problems. Especially the chairman for surgery is responsible here. Appointed for research and teaching, his role should be creativity, flexibility and competence in recognising important research trends. Surgical research does not refer solely to therapy research. The new, essential tasks are in the methods for carrying out controlled clinical trials,

establishing guidelines and scores and designing instruments for measuring outcome. Here we confront elementary questions such as: “what is quality of life, sickness, health?”

Socio-economic analyses are greatly needed to prevent medicine from drifting in an utterly wrong direction. We must face such conflicts as “quality versus quantity”, “profession versus business”, “patient care versus economic costs”. We must also deal with ethical issues such as: “When may I first operate on a patient?” “When and how may we put an end to the patient’s process of death (intensive ward)?”

Structure and organisation are of course necessary for making a success of basic clinical research endeavours. There are “many ways to Rome”, and the effectiveness of the various models and organisations and structures depend on persons creatively working within them. Nevertheless, the specific conditions in the given country has a powerful effect.

The present analysis introduces three models: the cooperation model, the integration model and a mixture of the two. The advantage of the cooperation model is that here experts help surgeons with their problems. The model is favoured by public authorities because concentrating on a single aim is more promising of success. For myself, this appears an impossible dream. American gigantism is the godfather of this idea. Experience shows that experts can hardly be made interested in clinical questions since clinical research is exposed to enormous time pressure. It may be that the integration model resulted from the frustration of which speciality has its own department within the surgical clinic. Professor Heberer offers a striking example for the well-functioning of this model. He had the problem of operating on stand-still hearts and employed the physiologist Bretschneider, who developed the “Bretschneider solution” for solving Heberer’s problem. The problem in this model is maintaining and further developing the field-specific competence of the scientists. The advantage lies in having a nearby department of scientists for surgical questions.

Further models are of course possible in view of the variety of questions and the prerequisites involved. However, ensuring the important prerequisite for surgical/clinical research may not be left to chance. Responsibility for the surgical patient and for the surgery also depend on the structure and organisation, and for this the chairman for surgery is responsible. However, creativity, ideas and intuition can never be replaced by organisation and structure.

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