Progress in Surgery

VOLUME ONE

EDITED BY

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Preface

Progress in surgery, as indeed in most branches of medicine, is a continuing process consisting of rapid change often interspersed with more leisurely periods of consolidation. It becomes of constant concern, therefore, both to surgeons-in-training, as well as to established consultants, to ensure that their approach to patient management keeps pace with innovation. In this new series, aspects of clinical surgery and of surgical science which can truly be said to represent major areas of *Progress in Surgery* are reviewed. Many of the topics chosen are common surgical conditions which still stimulate controversy and provide dilemmas in decision making. Of particular note in this regard are prophylaxis in surgical sepsis (Mr Alan Pollock), the management of solitary thyroid nodules (Mr Clifford Talbot) and head injury management (Mr John Pickard). Other topics reviewed represent relatively new trends in surgical management which have enhanced progress and improved patient care. For example, staplers in colorectal surgery (Mr R.J. Heald), computers and surgical audit (Mr Alan Taylor) and ileo-anal anastomosis in inflammatory bowel disease (Mr Norman Williams and Professor David Johnston). Further chapters review in depth developments and progress in surgery for myocardial ischaemia (Sir Keith Ross), transplantation (Professor Peter Morris), by-pass graft for peripheral vascular disease (Mr Charles McCollum), mastalgia (Mr David Webster), vagotomy (Mr T.V. Taylor), rectal prolapse (Mr Michael Keighley), and portal hypertension (Mr Magnus McLaren). Each author has been asked to review the recent advances in progress in their subject and to include their personal views. It is hoped that the in-depth analysis of these topics will be of especial interest to surgical trainees during the approach to the Final Fellowship examinations.

I would like to thank all the contributors for giving of their time in writing the reviews and the staff of Churchill Livingstone for their co-operation. I hope the reader enjoys the contributions as much as I have enjoyed assembling them.

Southampton, 1985 I.T.

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Contents

Surgery on trial

It has been estimated that between the cradle and the grave (or perhaps between the womb and the tomb) some 90% of the population of most Western countries will require some form of operative procedure. Indeed in the UK alone over 2 million procedures are performed each year. It is hardly surprising therefore that the practice of surgery in any form generates such intense media interest. Rarely a week passes without either an entire documentary or at the very least a news comment on television regarding some operative innovation, some development or para-surgical dilemma exposed to its fullest extent. Surgery has indeed become a newsworthy topic of interest to all. However, it is important to remember that this respectability for the practice of surgery has not always been so. Indeed, it is a relatively recent phenomenon. Just over 100 years ago it was described by Joseph Lister as: 'This bloody and butcherly department of the healing art'. It is said that it was safer to be a soldier on the field of Waterloo than to be a patient in a large London hospital in 1840. In those days surgery had little to offer in treatment and surgeons could do very little, except dress wounds and carry out amazingly slick amputations. Investigation was non-existent and treatment minimal. The doctors opinion was all that there was.

50 years ago a surgeon was absolutely delighted to see his patient leave the operating theatre alive. Over the last 50 years major advances, in the non-surgical fields of aseptic techniques, blood transfusions, physiology and especially modern anaesthesia have enabled the surgeon the relative freedom to advance and concentrate on surgical science, practice and technique. Cardiac surgery, neurosurgery, transplantation and indeed every branch of each surgical discipline has developed and expanded due to major breakthroughs in these non-surgical disciplines.

In the days when surgeons were predominantly, and quite rightly, involved in ensuring postoperative survival, both clinical and basic scientific research played very little part in a surgeons training.

There were, of course, notable exceptions—predominantly John Hunter who still remains the patron saint of surgical research. He appreciated the need for research and clinical investigation and indeed conducted

careful and worthwhile studies into many different fields. He was particularly able to stimulate those about him and made many important contributions.

However, until relatively recently surgical research had been generally regarded as the prerogative of a somewhat eccentric band of hardy individuals and of having little relevance to routine 'bread and butter surgical practice. Anecdotal evidence of a new treatment or technique was usually sufficient to have it accepted into general surgical practice—particularly if it was advocated by a noteworthy personality. Below are listed operative procedures which were performed in hundreds, if not thousands, of patients to no avail whatsoever. They were introduced without proper assessment and on the basis of anecdotal evidence only. Many were not only of no benefit but distinctly dangerous.

—Sympathectomy for hypertension
—Gastropexy for 'dropped stomach'
—Nephropexy for 'dropped kidney'
—Prophylactic portacaval shunt
—Colon bypass for hepatic encephalopathy

Over the last 30–40 years, however, there has been a more tolerant realisation of the value of careful assessment of surgical results and of surgical research. It is now accepted that before any surgical technique, treatment or patient management is accepted, careful studies must be initiated to confirm their efficacy.

SURGICAL TRAINING

The training of a surgeon demands the acquisition of scientific knowledge and clinical judgement as well as technical ability. A slick operator whose judgement is shaky will carry out unnecessary operations. In addition if he has not been exposed to on-going research or clinical investigation during his training he may not be in a position to take full advantage of developments which will occur during his consultant years.

There is no doubt that with adequate training programmes such as exist throughout the UK today, the acquisition of technical skills can be obtained in a far less arduous and lengthy period than is demanded at present. All surgeons-in-training will confirm this. However, clinical judgement and wisdom take a little longer to acquire. It is not possible to be dogmatic on the ideal length of training for a young surgeon. Some require longer periods than others and indeed various specialties demand a longer period of training than others.

Most consultant surgeons will admit that their own research experience has resulted in the adoption of a more critical attitude to clinical problems generally. This can only improve the standard of clinical care for the individual patient and the current demand with regard to surgical audit

and assessing cost-effectiveness of particular operations are but an example of this attitude. A present generation of practising surgeons trained in part in critical assessment of all that they do has resulted in overall better surgical care. This is why training in research and in evaluation techniques are an essential part of surgical education.

PROSPECTIVE CLINICAL TRIALS IN SURGERY

Surgery and its results must always be carefully evaluated and judged. Confirmation of effective therapy requires objective assessment.

How do we assess prospectively and in a scientific manner the results of surgical treatment? Some of the terms used when describing prospective clinical trials are both emotive and frequently misleading, e.g. random treatment, control patients etc. It is not surprising therefore that misunderstandings may arise. All these terms and considerations are aspects of two major ethical dilemmas. These are:

1. Fully informed consent
2. Randomisation.

No one doubts the need to obtain informed consent from a patient prior to undertaking elective or emergency surgery. This is important and required by law. How well it is achieved, however, is a different matter. Nevertheless, if a patient requires any form of surgery informed consent must be sought and obtained. Similarly, if a patient is to be included in a non-therapeutic research investigation which is unlikely to be of direct benefit to the individual then informed consent is also essential.

In 1964 the World Medical Association drew up a code of ethics on human experimentation. The code, known as the Declaration of Helsinki, was revised in 1975. The declaration under the heading 'Basic Principles' declares:

> 'In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is at liberty to withdraw his or her consent to participation at any time. The doctor should obtain the subject's freely-given informed consent, preferably in writing. There should be no modification of this basic right to information and consent. The doctor may advise and suggest, but in an informed situation.'

This declaration was specifically related to non-therapeutic clinical research and is generally accepted.

The question of fully informed consent prior to including a patient in a clinical trial involving alternative forms of surgical therapy, however, is a much more difficult subject, and by no means as clear cut. Should a patient be informed of randomisation procedures in the determining of therapy? As is often the case in such ethical dilemmas there is no simple

answer and no generalisation that can be applied to all types of clinical trials in surgery. There are, in my view, three types of clinical trials in surgery, each of which require different considerations.

Standard treatment A v. Standard treatment B

Surgeons are individuals and endeavour to treat patients to the best of their ability but this is frequently coloured by previous experience as well as by individual preference. There are often different approaches to the same problem. For example, surgeon A may carry out an operative procedure using a one layer anastomosis to join two ends of bowel together, whereas surgeon B, such as myself, may prefer an anastomosis using two layers of sutures. Similarly in the preoperative preparation of a patient for colonic surgery there are several ways in which the bowel can be prepared in order to reduce faecal contamination. Accordingly, one surgeon may prefer bowel preparation A, simply because he has used it for many years, whereas surgeon B may prefer a different form of bowel preparation. These are all standard treatments, but it is desirable to determine which is the most effective form of therapy to avoid complications in the post-operative period (an example of audit). A patient having fulfilled the criteria for inclusion in the study would be randomised to receive either of these treatments and the outcome assessed to determine which is the most effective. Under these circumstances is informed consent really required? The clinician may wish to mention to the patient the nature of the treatment to be given, but should he specifically seek informed consent? There would, in the majority of patients, be a good deal of anxiety and doubt generated which could result in loss of confidence and even misunderstanding between patient and doctor. In my view fully informed consent for inclusion in this type of trial, where two forms of standard treatment are being compared, is not only unnecessary but may be distressing to the patient. How can a standard treatment be unethical or require fully informed consent merely because it is included in the context of a clinical trial? Most patients are not interested in hearing about the alternative forms of standard therapy and really would prefer to rely entirely upon the doctors discretion and simply ask him to get on with it.

Standard treatment v. New treatment

If medical practice and particularly surgical therapy are to progress it is important to continually evaluate new forms of therapy when they become available. In order to carry out evaluations of this type it is of necessity desirable to compare a new form of treatment with the standard available treatment whose outcome is well known. In other words a new or different approach to treatment is compared with the standard form of treatment which is the best available and which acts as the 'gold standard'. Under these circumstances it would seem essential for the doctor to obtain fully

informed consent from the patient before carrying out randomisation. However, this frequently presents very serious problems. Let me give you an example:

It has been estimated that over 1.5 million women have had operations for breast cancer in the United Kingdom alone over the last 50 years. And yet, the question of which is the most effective form of local therapy for breast cancer still remains unsolved.

If a woman presents with a relatively small and localised carcinoma of the breast, many surgeons in this country, and I am one of them, would recommend a mastectomy with removal of the associated axillary lymph nodes. Recently, however, there has been a suggestion, and it is no more than a suggestion, that this relatively mutilating, ablative procedure may be no more effective in improving overall survival than a wide local excision and radiotherapy. In order to determine whether this lesser procedure is as satisfactory as mastectomy it is necessary to conduct a large controlled trial comparing the two procedures.

Such a study is being coordinated by the Cancer Research Campaign on a multi-centre basis to try and answer the question, 'is "lumpectomy" as good as mastectomy in the surgical management of early breast cancer?' Women with early breast cancer are randomised either to undergo mastectomy or 'lumpectomy' with radiotherapy. Trials of this type create a number of very difficult problems.

1. Although it is necessary to obtain fully informed consent before including a woman in the study this is more difficult than it may sound. Most women would obviously prefer removal of a lump to removal of the breast. However, when it is explained that randomisation will occur to determine which treatment she will receive in order that we can determine which is the most effective form of therapy for future generations of patients, this may create some confusion in her mind. The confusion will be added to when it is explained that we do not know whether 'lumpectomy' is as good as mastectomy as an effective form of therapy. Many women will opt on this basis to have simple 'lumpectomy' and therefore any form of clinical trial may be invalid due to selection of patients.

2. However one may consider the problem, it is unlikely that simple removal of the lump can be any better in terms of long term survival and avoidance of local recurrence than removal of the entire breast. Therefore 'lumpectomy' may be as good as, but is unlikely to be better than, simple mastectomy. If it is shown that 'lumpectomy' is not as good as, as it may well not be, then we run into the problems of prescribing a treatment which is not the optimum.

This brief description of a very complex clinical trial may give some indication of the difficulties which surgeons face when considering whether their patients should be included in such studies of new treatments.

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The problems related to informed consent should be carried out on a one-to-one basis. It is important to try and determine whether the patient wishes to be involved in the decision making process. Many patients express a strong preference to leave it entirely up to the doctor and under these circumstances it may be irrelevant for the patient to know that formal randomisation plays a part in the decision making process. It is important to remember that many treatment decisions outside clinical trials have a large informal random element. A patient may go to a doctor with a sore throat or chest infection and the doctor may mentally randomise a treatment for the patient, for example, he may decide on one of two different antibiotics but the patient would clearly be astonished if before prescribing an antibiotic he was offered the chance of receiving fully informed consent. In general terms, however, when a standard treatment is compared with a new form of treatment, patient consent should be sought and there should be as formal a discussion as possible commensurate with the patients understanding.

In my view, all new techniques must be evaluated with the existing best-buy therapies in a proper randomised, controlled trial setting. We are all aware of anecdotal evidence suggesting a new treatment has cured, for example, a cancer on a one-off basis and this clearly influences patients and doctors alike as well as certain television presenters. But surely it must remain the responsibility of doctors to properly and accurately assess new therapies before they become generally available. This is necessary not only to confirm an effective form of therapy but also to ensure that side-effects are few.

Standard treatment v. Standard treatment + adjuvant therapy

Large bowel cancer is showing a gradual increase in incidence throughout the Western world. The number of patients dying with large bowel cancer each year is also showing a gradual rise. The standard form of treatment for large bowel cancer is surgical. Unfortunately, however, surgery alone has failed to improve the overall prognosis for this disease over the last 20 years. Surgery is, of course, safer now than previously but the chances of a patient being cured by surgical therapy alone is no better now than it was 20 years ago.

There are two reasons for this. The first is related to the extent of disease at the time of presentation. Dukes A tumours have an excellent prognosis (90% 5-year survival) compared to Dukes B (60%) and Dukes C (25%). However the majority of patients present with Dukes B and C tumours.

Another reason is that surgery alone fails to effect the metastasising potential of large bowel cancer. Spread of the tumour to distant sites—particularly to the liver—is common. Liver metastases develop by the

invasion of the tumour into adjacent blood vessels and passage to the liver through the portal vein.

A number of techniques have therefore been suggested over recent years in order to combine resection of the tumour with either adjuvant chemotherapy or adjuvant radiotherapy and even adjuvant immunotherapy. We have been involved in such a trial in which cytotoxic chemotherapy (5-Fluorouracil), is given directly into the portal venous circulation via the obliterated umbilical vein for the first 7 postoperative days in an attempt to destroy malignant cells which enter the portal circulation. The trial involves randomising patients with primary carcinoma of the colon and rectum but without liver metastases at the time of treatment into two groups. Group 1 receives standard treatment which is surgical resection of the tumour, and group 2 receives this plus adjuvant cytotoxic therapy directly into the portal venous circulation.

By their very nature these trials can be particularly worrying since the concept is based on the premise that micrometastases are present in patients at the time of initial presentation and that in the case of colorectal cancer they may well be present within the portal circulation. However, we know that only half the patients will eventually develop metastases and therefore 50% of the patients will be receiving cytotoxic agents totally unnecessarily since these patients will not develop further problems following surgery alone. Unfortunately, it is as yet not possible to select which patients will develop recurrence. If this were possible then only those patients at risk would, of necessity, receive additional cytotoxic therapy.

Accordingly, in this form of clinical trial some patients are receiving dangerous therapy which will be of no benefit to them and may induce a number of serious side-effects. In addition, patients included in these trials must be followed-up very carefully for many years.

Although it would appear necessary to obtain fully informed consent prior to including a patient in such a study, to a certain extent this depends upon when randomisation occurs. If randomisation occurs in the preoperative period then fully informed consent for all patients may be unnecessary. However, when randomisation occurs intraoperatively, fully informed consent from all patients is necessary.

If patients are randomised preoperatively to receive one of two forms of therapy; one being a standard therapy, for example surgery alone in large bowel cancer (A) and the other the experimental treatment, for example, resection and adjuvant therapy in colorectal cancer (B), then those receiving A are receiving the best standard form of therapy available and clearly it is not essential for informed consent to be obtained from this group of patients. Patients randomised to receive the experimental form of treatment (B) should be informed before undertaking treatment. On receiving fully informed consent those patients who do not agree to

the 'new' treatment can be transferred to Group A and will receive the standard form of therapy only, whereas those who do agree to receive the experimental form of therapy can remain in Group B (Zelen, 1976). This model is always feasible in adjuvant trials following surgery when pre-operative randomisation is obtained.

Conduct of clinical trials in surgery

Clinical trials are now a recognised and important aspect of surgical research. It is important that they be conducted in as careful and precise a manner as possible so that the information obtained can be used to determine the optimum form of treatment for future generations of patients. These are scientific experiments in which the laboratory has been transferred to the bedside. They are difficult to conduct and create pressure upon the surgeon to ensure that all aspects of the protocol are satisfactory. The clinical dilemmas are also significant—my own personal approach to undertaking trials is as follows:

1. Examine very carefully study designs; check references and read all the relevant literature; do not enter any form of clinical trial which involves particular conditions for which the individual does not have a large fund of experience.
2. It is important not to enter patients into trials where aims are not clear and where it is felt that the design is poor. In this regard it is extremely important to obtain the assistance and help of a statistician.
3. Discuss in detail with medical colleagues for further opinions on the protocol.
4. It is important to submit all protocols to the local ethical committee for approval; although acceptance by an ethical committee should not relieve a doctor of his duties in ensuring that the trials are properly conducted.

Objections to prospective trials

Are randomised clinical trials the only method of determining whether or not two methods of procedure yield comparable or different results? It can be argued, as indeed many distinguished surgeons have, that there are insurmountable difficulties in conducting trials in surgical practice and alternatives to the randomised clinical trial in surgery should be sought to obtain reliable knowledge.

If a clinical trial is to be successful, particularly a surgical trial, then the many variables which exist must be reduced to a minimum. This means that all the clinicians involved in the study must stick rigidly to a predetermined protocol. This clearly may involve some sacrifice of clinical freedom to ensure that the trial is properly conducted. If a clinician is not prepared to adhere strictly to these criteria then he should not take part in the study since the results which will eventually be obtained are likely to be misleading.

I have discussed some of the ethical problems involved in the correct conduct of clinical trials—some surgeons undoubtedly feel unable to take part because of their general unease in randomisation of patients to alternative forms of therapy.

Importance of clinical trials in research

With the imposition determined by financial restraint and by our greater awareness of the need for careful evaluation, clinical trials and research in general have become more rather than less important. This is the time for more investment in clinical research, not less. When resources are scarce a greater proportion of them should be channelled into evaluation. There is a danger also that the recent undue emphasis on highlighting ethical difficulties will detract from the pursuance of improving patient care.

If a doctor qualifies at the age of 24 and enters a surgical training programme immediately he will spend the best part of 40 years in surgical practice as a trainee and consultant. Is it not reasonable that 1 or 2 of these years should involve a period of formal training in research and assessment techniques? Only by doing so will surgeons carry through their career the habit of inquiry and scepticism which is essential if high standards are to be maintained in the restricted financial atmosphere that lies ahead. This is why we must encourage and not denigrate the needs for research in our training programmes. Rigidity and inflexibility must be avoided. The ability to audit and criticise technique and treatment are essential in all branches of medicine but this is particularly so for surgical practice.

Our surgical predecessors were predominantly concerned with obtaining a live patient after an operation. They succeeded in this task admirably. Surgery is now safe. Unexpected postoperative death is fortunately an extremely rare occurrence. Our skills must now be devoted to improving the quality of life for decades after any procedure. Only by placing surgery on trial can we be confident that the tremendous progress initiated by the surgical giants of the past will be maintained for the benefit of patients in the future.

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The present position of prophylaxis in surgical sepsis

Whatever the aim of the surgeon, be it to remove diseased tissues, to repair damaged tissues, to restore blood flow to ischaemic tissues, or to replace tissues or organs whose function has failed, his best efforts may be thwarted by infection.

The prophylaxis of surgical infections can be considered under five headings:

—Prevention of exogenous contamination
—Prevention of endogenous contamination
—Prevention of infection if contamination is inevitable
—Prevention of sepsis if infection is inevitable
—Prevention of death if sepsis is inevitable

I will, however, limit myself to discussion of the first three, the last two being inextricably bound up with treatment.

THE PREVENTION OF EXOGENOUS CONTAMINATION—OPERATING THEATRE

Except when prostheses are to be inserted, the aseptic practices established a century ago are adequate. Brewer (1915) reported that their observance resulted in an infection rate in clean wounds of 1.5% and commented, 'Many years ago I established the custom of giving a prize to the house surgeon on whose service of 6 months no clean case became infected'.

Routine autoclaving of instruments and linen, together with improved antiseptics (particularly chlorhexidine-detergent and alcoholic chlorhexidine for the 'surgical scrub', and activated glutaraldehyde for heat-intolerant instruments) should mean that exogenous bacteria can be introduced into a wound only through the air. It is tempting to blame contamination on bacteria from the patient's own skin which, even when it is prepared with an antiseptic, does not remain sterile for long. On the analogy of rubber gloves for the surgical team, some surgeons have advocated isolating the patient's skin from the wound by using a plastic

adhesive drape. There is, however, no evidence from random control trials that this practice is of any value.

The air in a plenum-ventilated operating theatre is sterile while it is empty but, if you let people come in and move about and then use a slit sampler or expose some settle plates, you will find that the air has become laden with bacteria. Fortunately most of these are of low virulence; they come from skin scales shed by the theatre staff and *Staphylococcus epidermidis* predominates. At the end of all abdominal operations it is my practice to swab the subcutaneous tissue and immediately place the swab in cooked meat broth in an incubator in the operating theatre suite. *S. epidermidis* is such a common finding, and its presence so rarely predictive of subsequent wound infection in abdominal surgery, that I ignore it in classifying the degree of wound contamination. In a recent series of 464 consecutive abdominal operations I found endogenous (enterobacterial) contamination of the wound before skin closure in 200 (43%). In the remaining 264 the subcutaneous swab showed no growth in 136 (52%) and *S. epidermidis* in 128 (48%).

Staphylococcus aureus is much more pathogenic. It is rarely discovered on settle plates, but people with skin diseases—including acne—should be investigated and, if shown to shed *S. aureus*, should be excluded from operating theatres.

The special case of prosthetic implants

The development of successful prosthetic replacements of arteries and joints has called for a re-evaluation of traditional aseptic practices and a move towards the absolute sterility practised in pharmaceutical and microbiological departments. Charnley pioneered this change when he introduced vertical laminar flow ventilation and the wearing of impermeable exhaust-ventilated suits. In an audit of consecutive patients undergoing total hip replacement he found that these measures were associated with a fall in the deep infection rate from 8.9% in 1958 to 0.9% in 1968. At the same time, however, he altered other aspects of technique and the value of ultraclean air remained 'not proven' until the Medical Research Council multi-centre random control trial (Lidwell et al, 1982). In this series of 8055 total hip or knee replacement operations there were 86 failures (1.1%) due to deep infection, from 68 of which organisms were recovered (Lidwell et al, 1983). *S. aureus* was responsible for 27, other skin bacteria for 26 and intestinal bacteria for 15. This trial showed the additive effect of three prophylactic measures (laminar flow ventilation, body exhaust suits and antibiotics). The deep infection rate ranged from 3.4% in patients operated on in plenum-ventilated operating theatres and not given antibiotics, to 0.3% in those whose operations were done in laminar flow theatres in which the staff wore impermeable exhaust-ventilated suits and the patients received prophylactic antibiotics.

The total sterility demanded by microbiologists and pharmacists is

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