



In search of evidence-based plastic surgery: the problems faced by the specialty

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SUMMARY. Recently, there has been significant interest both from government and medical practitioners in the discipline of evidence-based medicine. In this article we discuss the problems faced by the plastic surgeon when trying to ensure that practice is evidence-based and highlight some of the reasons behind these difficulties. With the rapid growth of the Internet we also outline its use to access high quality information for the plastic surgeon.
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The Government White Paper: *The new NHS – modern, dependable* was published in December 1997 and has initiated the biggest changes in the NHS since its birth in 1948. The Prime Minister writes in the foreword, ‘For the first time the need to ensure that high quality care is spread throughout the service will be taken seriously. National standards of care will be guaranteed.’¹

To ensure this, the White Paper sets out three areas for action: national standards and guidelines for services and treatments; local measures to enable NHS staff to take responsibility for improving quality; and the establishment of a new Commission for Health Improvement.

The Government followed this up with the Health Service circular, *A first class service: quality in the new NHS*, in July 1998.² This stated that a new special health authority, the National Institute for Clinical Excellence (NICE), will promote clinical and cost-effectiveness through guidance and audit. The NICE will appraise therapeutic interventions, and produce and disseminate clear, authoritative information throughout the NHS – including guidelines for the management of certain diseases and conditions, and guidance on the appropriate use of particular novel interventions.³

The NICE will cover the English and Welsh NHS. The Clinical Resource and Audit Group and the Clinical Standards Board will perform the same functions in Scotland. Northern Ireland is currently in consultation about its own organisation.⁴

A new system of Clinical Governance in NHS Trusts will ensure that clinical standards are met, and that processes are in place to ensure continuous improvement, backed by a new statutory duty for quality in NHS Trusts.¹ The essence of this is that Chief Executives are now personally responsible for the quality of clinical services within their trusts.⁵

Consequently, modern NHS consultants are now being asked to produce evidence that they are performing current best practice, i.e. evidence-based medicine (EBM).

What is evidence-based medicine?

The essence of EBM is the integration of individual clinical expertise with the best available external clinical evidence from systematic research.⁶ It requires the clinician to be aware of the available external evidence and to be able to critically appraise and apply it correctly.⁷

Professor David L. Sackett, the Director of the NHS Research and Development Centre for Evidence-Based Medicine in Oxford states:

Good doctors use both individual clinical expertise and the best available external evidence and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, practice risks becoming rapidly out of date, to the detriment of patients.⁸

He goes on to say that EBM is:

a process of life-long, self-directed learning in which caring for our own patients creates the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues, and in which we:

1. convert these information needs into answerable questions;
2. track down, with maximum efficiency, the best evidence with which to answer them (whether from the clinical examination, the diagnostic laboratory, from research evidence or other sources);
3. critically appraise that evidence for its validity (closeness to the truth) and usefulness (clinical applicability);
4. apply the results of this appraisal in our clinical practice; and
5. evaluate our performance.⁸

Appraising the evidence

In order to help clinicians make decisions, the evidence must be critically appraised. This process aims to inform the clinician about how much 'weight' to give each piece of information.

Attempts have been made to rank the validity of evidence about prevention, diagnosis, therapy and harm into levels. These 'levels' were originally defined in 1979⁹ and evolved to provide the basis of clinical recommendations on the use of antithrombotic agents.^{10,11}

They are under constant development as new types of trial and studies are developed and even have a website on the Internet,¹² which is updated periodically to give the most up-to-date advice.

The randomised control trial (RCT) has been called the 'Gold standard' for evidence and the levels reflect this.^{6,8,13}

- Level 1 – consists of RCTs and systematic reviews of all RCT data including meta-analyses;
- Level 2 – consists of cohort studies and their systematic reviews;
- Level 3 – consists of case-control studies and their systematic reviews;
- Level 4 – consists of case-series;
- Level 5 – consists of expert opinion without explicit critical appraisal, or based on physiology, bench research or 'first principles'.

Depending on which level the evidence is categorised into, a 'grade of recommendation' is then given to it. For example, level 1 is given an A and is known as the 'best evidence'. Levels 2 and 3 are given a B, level 4 is given a C and level 5, a D.¹²

Where to find the evidence

To practise EBM at its best we need to be able to track down all of the level 1 information and apply it effectively.

With over two million new articles published every year in the medical literature as a whole it takes a lot of time to trawl through it, in order to find what is actually relevant to our own practice.

Places to search for the evidence include:

Journals

Evidence-based medicine journals. The journal *Evidence-Based Medicine* published by the BMJ Publishing Group and the American College of Physicians¹⁴ surveys a wide range of international medical journals (at least 70) to identify key research papers that are scientifically valid and relevant to practice. Consequently, it contains lots of level 1 'best evidence'. Unfortunately, it does not cover plastic surgery.

Plastic surgery journals. There is very little level 1 evidence in the plastic surgical literature. The reasons for this will be discussed later in this article.

Databases of systematic reviews

Most hospital medical libraries have access to the Cochrane Library on CD-ROM or it may be accessed via the Internet.¹⁵ This contains the Cochrane Database of Systematic Reviews (mainly of RCTs), a Database of Abstracts of Reviews of Effectiveness and a Controlled Clinical Trials Registry. Unfortunately, even this extensive database contains little information of relevance to surgery and even less to plastic surgery.

Using the Cochrane Database, the Royal College of Surgeons of England have assembled a list of systematic reviews (relevant to surgery) which can be accessed via the Internet at their evidence-based surgery website.^{16,17} These reviews can be searched by surgical specialty. Plastic surgery is notable by its absence. At the time of writing, of the 89 reviews currently listed (Issue 1, 1999), none are relevant to plastic surgery.

The Internet

The Internet has the potential to be an extremely useful resource when searching for evidence. Examples of evidence-based resources are listed in Table 1. Other useful websites include those of:

Medical databases and search engines. These websites will search for high quality biomedical Internet resources that have been appraised for scientific rigour. A good example is OMNI (Organising Medical Networked Information).¹⁸

Learned societies. Many learned societies have developed websites which give access to evidence-based resources. The Royal College of Surgeons of England has assembled an Internet site, which provides links to resources that will support evidence-based surgery.¹⁶

To the same end, many plastic surgery organisations are developing websites. The World Plastic Surgery site run by the International Confederation for Plastic, Reconstructive and Aesthetic Surgery (IPRAS)¹⁹ contains links to each member country's website.

The British Association of Plastic Surgeons website²⁰ has links to several evidence-based medicine resources.

Electronic journals. The evidence-based medicine journal *Bandolier*, published by the NHS Research and Development Centre in Oxford²¹ can be accessed free via the Internet.²² This provides systematic reviews of medical topics. Unfortunately, it has published very few articles on plastic surgery topics.

The evidence-based journal *ACP Journal Club*, published by the American College of Physicians – American Society of Internal Medicine regularly reviews more than 100 journals and selects published articles which are then summarised in 'value added' abstracts and commented on by clinical experts.²³

The first 'paper' plastic surgical journal to go online was the *Canadian Journal of Plastic Surgery*.²⁴ The electronic form contains some of the original articles, which may be viewed for free. Other 'paper' journals such as *Plastic and Reconstructive Surgery*²⁵ give free access to recent articles in abstract form. The *British*

Table 1 Websites of some useful evidence-based resources

Bandolier Home Page
http://www.jr2.ox.ac.uk/bandolier
NHS Research and Development Centre for Evidence-Based Medicine
http://cebm.jr2.ox.ac.uk
NHS Centre for Reviews and Dissemination
http://www.york.ac.uk/inst/crd/welcome.htm
Canadian Centres for Health Evidence
http://www.cche.net/
Cochrane Collaboration Home Page
http://hiru.mcmaster.ca/cochrane/default.htm
Cochrane Effective Practice and Organisation of Care Group
http://www.abdn.ac.uk/public_health/hsru/epoc/index.htm
Clinical Effectiveness Unit – Royal College of Surgeons of England
http://www.rcseng.ac.uk/public/ceu/clinieff.htm
Clinical evidence '99
http://www.evidence.org
Evidence-Based Surgery website – Royal College of Surgeons of England
http://www.rcseng.ac.uk/public/infores/reso_ir.htm
National Institute for Clinical Excellence (NICE)
http://www.nice.org.uk/
Netting the evidence – A SCHARR Introduction to Evidence-Based Practice on the Internet
http://www.shef.ac.uk/~scharr/ir/netting.html
NHS health technology assessment
http://www.hta.nhsweb.nhs.uk/
TRIP searchable database of evidence based resources
http://www.ceres.uwcm.ac.uk/frameset.cfm?section=trip

*Journal of Plastic Surgery*²⁶ has a website where the latest contents pages may be viewed but at present no articles are available.

There are also 'experimental' free journals, which do not have a paper equivalent. At the time of writing, we could find four:

1. The Electronic Journal of Hand Surgery;²⁷
2. International Journal of Plastic and Aesthetic Surgery;²⁸
3. The OnLine Journal of Plastic and Reconstructive Surgery;²⁹
4. Update in Plastic Surgery.³⁰

Discussion groups. In addition to the rapid dissemination of information the Internet can act as a forum for those interested in particular research areas, to discuss ideas and collaborate on research. These fora are known as discussion groups and mailing lists, e.g. Mailbase serves the academic community and has some lists on topics relevant to the plastic surgeon, such as hand surgery.³¹

National Electronic Library for Health. Currently the NHS is constructing the National Electronic Library for Health,³² which will provide access to useful articles and perhaps some journals. It will focus on those resources that synthesize knowledge and assure quality of their content in clear and explicit ways. Access will be via NHSnet or the Internet.

Why is there so little level 1 evidence in surgery?

After exhaustive searching of these resources we have found that the surgical literature is poor in comparison to the medical literature in the amount of level 1 evidence available.

Level 1 evidence and well conducted RCTs do exist in surgery. For example, Majeed et al published a randomised, prospective, single-blind comparison of laparoscopic versus small-incision cholecystectomy in 1996.³³

Unfortunately across all areas of surgery only 3–9% of clinical study designs are RCTs.^{34,35} This has led to attacks on the validity of a large proportion of surgical research which has been dubbed a 'comic opera'.³⁶

Plastic surgery is no different from other branches of surgery in the lack of RCTs and most of the evidence published in plastic surgical journals may be classified into levels 3, 4 and 5.

Level 1 evidence in plastic surgery does exist, but is generally confined to non-plastic surgery journals and concerns non-operative interventions. For example, the Cochrane Injuries Group published a systematic review of RCTs of the administration of human albumin to critically ill patients, in 1998.³⁷ This was of relevance to all plastic surgeons who treat burn injuries since it suggested that there was an increase in mortality of 6% in critically ill patients who had been treated with human albumin, compared with patients who had received either crystalloids or no treatment. The authors rightly acknowledged that the results should be interpreted with caution because the review was based on small trials with small numbers of deaths. After much controversy and debate, an Expert Working Party (EWP) of the Committee on Safety of Medicines was set up to examine these findings. The EWP concluded that there was not enough evidence of harm to warrant removal of albumin from the market.³⁸ The final conclusion drawn was that the only way to determine the true effect of albumin on mortality is for a large, purpose-designed, rigorous RCT to be performed.

Given the widespread acceptance of RCTs and systematic reviews as 'best evidence', why are there so few of them in the surgical literature? Why are the RCTs that are of relevance to us published in non-plastic surgical journals? And why do they tend to concentrate on non-operative interventions?

The reasons include:

Not all surgical procedures are suitable for trials

Solomon and McLeod performed a search of the surgical literature to identify a sample of treatment evaluation questions involving surgical operations. They found that methodological issues would have prevented an RCT in only 2% of cases. However, they found that RCTs can be performed to evaluate only 40% of treatment questions involving surgical procedures, even in an ideal situation, with unlimited resources and availability of clinical cases.³⁹

A major barrier identified was that the disease incidence was not common enough to be able to perform an RCT, even if all the patients with the disease were included in the study. This may be a problem in some areas of plastic surgery. However, areas such as skin cancer treatment are eminently suitable.

Patient preference as a barrier to RCTs

This is a complex and poorly understood problem which may affect all RCTs.⁴⁰ Some patients fear becoming a 'guinea pig'⁴¹ and do not want to participate in trials. Angell reported that although different treatments were not believed to differ in terms of their efficacy, they often differed markedly in terms of their impact on the patient's life.⁴² For example, a study of determinants of patient non-participation in RCTs for the treatment of sarcomas reported that 25% of patients with soft tissue sarcoma would not accept randomisation to amputation versus limb-sparing surgery plus irradiation. However they would all accept randomisation to receive or not receive immunotherapy with BCG.⁴³ Randomisation to surgery when this is seen as an irreversible treatment of greater magnitude is difficult for patients to accept.⁴⁴

Patient preference is a highly significant variable in plastic surgery especially for non-malignant conditions where aesthetic concerns are often to the fore. For example, a professional young woman may opt to attempt reconstruction of a severed digit whereas a male manual labourer may prefer terminalisation to enable early return to work. Patient preference affects motivation and it may be difficult to distinguish between a treatment that failed due to its own inherent ineffectiveness and another that failed because it was not targeted towards the correct patients.⁴² Motivation in many areas of plastic surgery, especially hand surgery, correlates well with effective outcomes.

Almost all reconstructive surgery has a 'price to pay' from the donor site and it is up to an individual patient, guided by their plastic surgeon, to decide whether they are prepared to pay that price. Since our operations are judged on the aesthetic result, as well as the functional one, randomisation between different

procedures may prove difficult to accept for both the patient and the surgeon. Cultural and societal influences may also play a part in the patient's decision-making process.

Operations are different from medicines

It has been argued that RCTs are inherently more difficult to perform in surgery as opposed to medicine because of the fundamental differences between operations and drugs.⁴⁵

It is a difficult problem to standardise the treatment in surgery as the individual skill and experience of the surgeon will affect the outcome.^{46,47} Moreover, in surgery for uncommon conditions, where multicentre trials may be required to obtain sufficient numbers of patients, this becomes an important variable.⁴⁸

Lack of enthusiasm by surgeons

It has been suggested that the lack of participation in clinical trials may be related to lack of interest by surgeons and that they see little need for RCTs.^{34,49} Surgeons are inherently most often interested in the technical aspects of their specialty and happiest when they are in the operating room.⁴⁹ Thus, surgical journals are often weighted towards new and novel techniques.

Plastic surgery has advanced and expanded rapidly over the last 30 years and is concerned with the restoration of form and function.⁵⁰ The diagnostic challenge is not the attraction to the surgeon – that is often simple. The real challenge is in the perfection of new surgical techniques to achieve our aims; consequently our journals have a large proportion of articles about new techniques.

Also, 'the modality of treatment used by the surgeon is definitive and applied based on experience and known facts as to results. This does not lend well to a trial-and-error approach to management of most surgical pathologic conditions.'⁴⁹

Furthermore, it has been suggested that clinical research lacks the same esteem that basic research affords in academic surgery.^{34,49} A large proportion of MD theses are science-based rather than clinically based.

Funding

The funding for clinical trials is often difficult to obtain.^{44,49} Many RCTs comparing drug therapies are financed by the pharmaceutical industry. There is a financial incentive to provide evidence that a newly developed drug is better than current therapy. The money to finance trials of new operations may be more difficult to obtain.⁴⁴

A recent study found that 83% of consultant urologists in the UK, responding to a questionnaire, felt that there was insufficient advice and information available for trainees about the availability and preparation of grant applications.⁵¹ It may be that there are funding opportunities available but at present these are not being exploited by surgeons.

The number of papers written by trainees

At the current time, in order to be seriously considered for a Specialist Registrar post in plastic surgery and ultimately for a Consultant post, each candidate must produce a list of publications in peer-reviewed journals.⁵² Consequently, the journals receive a large number of papers written by trainees. Often, trainees do not have the time and funding for RCTs and publish case series and new techniques. Thus, since journals can only publish what they are sent, there are less RCTs as a proportion of the total number of papers published.

The way forward for plastic surgery

Plastic surgery has historically been concerned with refining surgical technique and surgical innovation. As we enter the new millennium, the specialty faces an identity crisis, as areas that have traditionally been pioneered by our specialty are threatened with takeover by others, e.g. breast reconstruction to breast surgeons, and cleft lip and palate to maxillofacial surgeons.

Professor P. Bell states that initially new techniques must be reported, then other surgeons must learn the technique and publish their own experience with it. Feasibility studies should be carried out and audited by others. It is then that we should embark upon multicentred RCTs.⁵³

The Academy of Medical Royal Colleges set up the Safety and Efficacy Register of New Intervention Procedures (SERNIP) in 1996.⁵⁴ A similar register has also been set up in Australia: ASERNIP-S.⁵⁵ The idea is that these will suggest which procedures are suitable candidates for RCTs by establishing a mechanism for collecting data on the safety and efficacy of selected new surgical procedures. This would attempt to evaluate whether a new procedure should be studied more fully prior to its introduction into everyday clinical practice. Currently, notification of a new procedure is voluntary.

We should try to perform RCTs to answer clinically important questions. Areas of our specialty that may be more amenable to trials include burns research and the study of treatments for melanoma (e.g. the Melanoma Study Group Trial of 1 cm versus 3 cm excision margins).

In order to establish valid conclusions, RCTs must be properly conducted. As the Cochrane Injuries Group found, many of the RCTs in the general medical literature are of poor quality and have low power, often due to inadequate size.³⁷ This problem is becoming increasingly obvious as more systematic reviews are published. Surgical journals also have this problem. Haines reviewed the *Journal of Neurosurgery* for articles evaluating therapeutic manoeuvres and found that only 2.1% were controlled trials. Moreover, only 1 out of the 18 found met the criteria for a satisfactory RCT.⁵⁶

In order to improve the quality of trials and to ensure that trials are carried out properly, the CONSORT (Consolidated Standards of Reporting Trials)

statement was published.⁵⁷ This describes 21 different items that should be included in the methods section of an RCT and has been encouraged by the *Lancet*,⁵⁸ the *British Medical Journal*⁵⁹ and the *Journal of the American Medical Association*.⁶⁰ In order to improve surgical RCTs, the surgical scientific community has been urged to take this seriously.⁶¹

It is clear that not all questions will be answered by RCTs. In those cases Pollock has suggested that the answers we seek may have to be found by reliance on complete, accurate and, above all, honest audit.⁶²

The natural result of an increase in level 1 evidence will be the publication of national evidence-based guidelines.⁶³⁻⁶⁵ At present, the US Agency for Health Care Policy and Research provides evidence-based clinical practice guidelines on the Internet via the National Guideline Clearinghouse.⁶⁶ In Britain, clinical guidelines constitute an ambitious national plan⁶⁷ to get evidence into practice.⁶⁸

The National Institute for Clinical Excellence (NICE) has been given the task of producing these new guidelines.^{3,65} In a recent interview, Sir Michael Rawlins, the chairman of NICE, was quoted as saying, 'ideally, doctors will go to work with the British National Formulary in one pocket and a copy of NICE guidelines in the other.'⁶⁴ But, as Richard Smith, the Editor of the *British Medical Journal*, has written, 'guidelines that covered every eventuality would be carried in a wheelbarrow not a pocket'.⁴

Currently, some evidence-based guidelines may be accessed via the Scottish Intercollegiate Guidelines Network,⁶⁹ the NICE website⁶⁵ and St George's Health Care Evaluation Unit Guidelines Appraisal Project⁷⁰ (which assesses the quality of existing guidelines for the NHS Executive).

Some are worried about 'cookbook' medicine⁶ or that our professional decisions will be overruled, such as in France with the introduction of mandatory practice guidelines.⁷¹ Others worry about whether breaking guidelines, using clinical judgement, will leave us open to litigation should some untoward outcome prevail.^{63,64,72}

Evidence-based plastic surgery

To criticise the evidence base for surgical specialties as not being as good as the evidence base for medical ones, as demonstrated by the lack of RCTs, is to misunderstand the differences and consequent problems which we have discussed.

A recent study of inpatient General Surgery concluded that current practice is evidence-based, but the proportion of surgical treatments supported by RCT evidence is much smaller than that found in general medicine.⁷³

The lack of level 1 evidence in plastic surgery does not mean that we cannot strive to practise EBM. Professor Sackett states that EBM is not restricted to RCTs and meta-analyses: 'If no randomised trial has been carried out for our patient's predicament, we follow the trail to the next best external evidence and work from there.'⁶

Plastic surgeons should strive to practise evidence-based plastic surgery. At present this will mean relying on predominantly level 3, 4 and 5 evidence. With the future use of well designed RCTs and with help in performing systematic reviews by our EBM colleagues, we can improve the quality of some of our evidence. Moreover, by increasing our critical appraisal skills we can make best use of the current evidence.⁴⁵

We hope that the introduction of NICE will help to encourage further development of the evidence base for plastic surgery and improve the quality of the evidence produced. This may involve increasing the number of RCTs in some areas of the specialty. Moreover, it will certainly require the Government to fulfil their aims of consultant expansion.

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