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A prospective randomised comparison of minor surgery in primary and secondary care. The MiSTIC trial

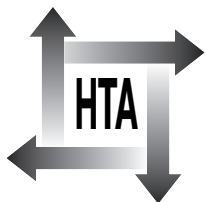
S George, P Pockney, J Primrose, H Smith, P Little, H Kinley, R Kneebone, A Lowy, B Leppard, N Jayatilleke and C McCabe



May 2008

Health Technology Assessment
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A prospective randomised comparison of minor surgery in primary and secondary care. The MiSTIC trial

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The research reported in this issue of the journal was commissioned by the HTA Programme as project number 95/25/03. The contractual start date was in May 1999. The draft report began editorial review in April 2004 and was accepted for publication in April 2007. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

A prospective randomised comparison of minor surgery in primary and secondary care. The MiSTIC trial

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Objective: To determine whether there is equivalence in the competence of GPs and hospital doctors to perform a range of elective minor surgical procedures, in terms of the safety, quality and cost of care.

Design: A prospective randomised controlled equivalence trial was undertaken in consenting patients presenting at general practices and needing minor surgery.

Setting: The study was conducted in the south of England.

Participants: Consenting patients presenting at general practices who needed minor surgery in specified categories for whom the recruiting doctor felt able to offer treatment or to be able to refer to a colleague in primary care.

Interventions: On presentation to their GP, patients were randomised to either treatment within primary care or treatment at their local hospital. Evaluation was by assessment of clinical quality and safety of outcome, supplemented by examination of patient satisfaction and cost-effectiveness.

Main outcome measures: Two independent observers assessed surgical quality by blinded assessment of wound appearance, between 6 and 8 weeks postsurgery, from photographs of wounds. Other measures included satisfaction with care, safety of surgery in terms of recognition of and appropriate treatment of skin malignancies, and resource use and implications.

Results: The 568 patients recruited (284 primary care, 284 hospital) were randomised by 82 GPs. In total, 637 skin procedures plus 17 ingrowing toenail procedures

were performed (313 primary care, 341 hospital) by 65 GPs and 60 hospital doctors. Surgical quality was assessed for 273 (87%) primary care and 316 (93%) hospital lesions. Mean visual analogue scale score in hospital was significantly higher than that in primary care [mean difference = 5.46 on 100-point scale; 95% confidence interval (CI) 0.925 to 9.99], but the clinical importance of the difference was uncertain. Hospital doctors were better at achieving complete excision of malignancies, with a difference that approached statistical significance [7/16 GP (44%) versus 15/20 hospital (75%), $\chi^2 = 3.65$, $p = 0.056$]. The proportion of patients with post-operative complications was similar in both groups. The mean cost for hospital-based minor surgery was £1222.24 and for primary care £449.74. Using postoperative complications as an outcome, both effectiveness and costs of the alternative interventions are uncertain. Using completeness of excision of malignancy as an outcome, hospital minor surgery becomes more cost-effective. The 705 skin procedures undertaken in this trial generated 491 lesions with a traceable histology report: 36 lesions (7%) from 33 individuals were malignant or premalignant. Chance-corrected agreement (kappa) between GP diagnosis of malignancy and histology was 0.45 (95% CI 0.36 to 0.54) for lesions and 0.41 (95% CI 0.32 to 0.51) for individuals affected by malignancy. Sensitivity of GPs for detection of malignant lesions was 66.7% (95% CI 50.3 to 79.8) for lesions and 63.6% (95% CI 46.7 to 77.8) for individuals affected by malignancy.

Conclusions: The quality of minor surgery carried out in general practice is not as high as that carried out in hospital, using surgical quality as the primary outcome, although the difference is not large. Patients are more satisfied if their procedure is performed in primary care, largely because of convenience. However, there are clear deficiencies in GPs' ability to recognise malignant lesions, and there may be differences in completeness of excision when compared with hospital doctors. The safety of patients is of paramount importance and this study does not demonstrate that minor surgery carried out in primary care is safe as it is currently practised. There are several alternative models of minor surgery provision worthy of consideration, including ones based in primary care that require all excised tissue to be sent for histological

examination, or that require further training of GPs to undertake the necessary work. The results of this study suggest that a hospital-based service is more cost-effective. It must be concluded that it is unsafe to leave minor surgery in the hands of doctors who have never been trained to do it. Further work is required to determine GPs' management of a range of skin conditions (including potentially life-threatening malignancies), rather than just their recognition of them. Further economic modelling work is required to look at the potential costs of training sufficient numbers of GPs and GPs with special interests to meet the demand for minor surgery safely in primary care, and of the alternative of transferring minor surgery large-scale to the hospital sector. Different models of provision need thorough testing before widespread introduction.



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List of abbreviations

CEAC	cost-effectiveness acceptability curve	MiSTIC	Minor Surgery Trial In the Community
CI	confidence interval	NA	not applicable
CONSORT	Consolidated Standards of Reporting Trials	OR	odds ratio
df	degrees of freedom	SD	standard deviation
ICER	incremental cost-effectiveness ratio	SUHT	Southampton University Hospitals Trust
IQR	interquartile range	VAS	visual analogue scale
ITT	intention-to-treat	WReN	Wessex Research Network

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.



Executive summary

Objectives

The objective of this study was to determine whether there is equivalence in the competence of GPs and hospital doctors to perform a range of elective minor surgical procedures, in terms of the safety, quality and cost of care.

The aims were:

- to conduct a randomised controlled equivalence trial of minor surgery in two settings
- to collect data on quality of surgery, patient satisfaction, patient safety and cost of procedure in two settings
- to review data from this trial and from other sources in order to consider future direction and future research in this area.

Methods

Design

This prospective randomised controlled equivalence trial was undertaken in consenting patients presenting at general practices and needing minor surgery.

Setting

The study was conducted in the south of England. At the time of this trial, minor surgery provision was provided mainly via a fee for service contract with general medical practitioners, with some serious pathology treated in hospital.

Participants

Participants were consenting patients presenting at general practices. They all needed minor surgery in specified categories and the recruiting doctor felt able to offer treatment or to be able to refer to a colleague in primary care.

Interventions

Patients were randomised, on presentation to their GP, to either treatment within primary care or treatment at their local hospital. Evaluation was by assessment of clinical quality and safety of outcome, supplemented by examination of patient satisfaction and cost-effectiveness.

Main outcome measures

The primary measure was surgical quality assessed by blinded assessment of wound appearance, between 6 and 8 weeks postsurgery, by two independent observers, using photographs of wounds. Secondary measures included satisfaction with care, which was obtained by means of a patient questionnaire; safety of surgery in terms of recognition of and appropriate treatment of skin malignancies, obtained by an examination of histological material supplied and cross-referencing with referral forms from GPs; and resource use and implications.

Results

In total, 568 patients were recruited (284 primary care, 284 hospital) and randomised by 82 GPs. Altogether, 637 skin procedures plus 17 ingrowing toenail procedures were performed (313 primary care, 341 hospital) by 65 GPs and 60 hospital doctors. Surgical quality was assessed for 273 (87%) primary care and 316 (93%) hospital lesions. Mean visual analogue scale score in hospital was significantly higher than that in primary care [mean difference = 5.46 on 100-point scale; 95% confidence interval (CI) 0.925 to 9.99], but the clinical importance of the difference was uncertain. Patients tended to be more satisfied with procedures in primary care and to report less inconvenience from their procedure. Hospital doctors were better at achieving complete excision of malignancies, with a difference that approached statistical significance [7/16 GP (44%) versus 15/20 hospital (75%), $\chi^2 = 3.65$, $p = 0.056$]. The proportion of patients with post-operative complications was similar in both groups. The mean cost for hospital-based minor surgery was £1222.24 and for primary care £449.74. Using postoperative complications as an outcome, both effectiveness and costs of the alternative interventions are uncertain. Using completeness of excision of malignancy as an outcome, hospital minor surgery becomes more cost-effective.

The 705 skin procedures undertaken in this trial generated 491 lesions with a traceable histology report: 36 lesions (7%) from 33 individuals were

malignant or premalignant. Chance-corrected agreement (kappa) between GP diagnosis of malignancy and histology was 0.45 (95% CI 0.36 to 0.54) for lesions and 0.41 (95% CI 0.32 to 0.51) for individuals affected by malignancy. Sensitivity of GPs for detection of malignant lesions was 66.7% (95% CI 50.3 to 79.8) for lesions and 63.6% (95% CI 46.7 to 77.8) for individuals affected by malignancy.

Conclusions

The quality of minor surgery carried out in general practice is not as high as that carried out in hospital, using surgical quality as the primary outcome, although the difference is not large. Patients are more satisfied if their procedure is performed in primary care, however, largely because of advantages in terms of convenience. However, there are clear deficiencies in the ability of GPs to recognise malignant lesions, and there may be differences in completeness of excision when compared with hospital doctors.

The safety of patients is of paramount importance and this study does not demonstrate that minor surgery carried out in primary care is safe as it is currently practised. There are several alternative models of minor surgery provision worthy of consideration, including ones based in primary

care that require all excised tissue to be sent for histological examination, or that require further training of GPs to undertake the necessary work. The results of this study suggest that a hospital-based service is more cost-effective, but at the moment there is not the capacity in hospitals to take on the workload of minor surgery, and it would likely be unpopular with patients if it were to happen. It must be concluded that it is unsafe to leave minor surgery in the hands of doctors who have never been trained to do it. If the capacity to undertake the work is present in primary care, then the increased costs associated with training doctors to do it must be borne.

Suggestions for further research

Further work is required to determine GPs' management of a range of skin conditions (including potentially life-threatening malignancies), rather than just their recognition of them. Further economic modelling work is required to look at the potential costs of training sufficient numbers of GPs and GPs with special interests to meet the demand for minor surgery safely in primary care, and of the alternative of transferring minor surgery large-scale to the hospital sector. Different models of provision need thorough testing before widespread introduction.

Chapter I

Introduction

Background

Minor surgery has formed part of general practice (family practice) throughout its history. Indeed, in the UK, GPs' clinics and facilities are normally referred to as their 'surgeries'. However, the range of procedures performed, the facilities and resources available, the training structures and requirements of the practising doctor, and the contractual arrangements that pertain to the doctor vary widely between and within different healthcare systems around the developed world. This study concentrates on the situation in the UK, except where the literature suggests issues that may be as relevant in their country of origin as here.

Historical context

Minor surgery offered by GPs within the NHS declined during the period from 1948, the date of inception of the NHS, to the mid-1980s.¹ This decline was ascribed to two main causes: first, the limiting contractual arrangements based on a capitation system that existed between independent GPs and commissioning health authorities; and, second, the perceived wish of patients to be treated by specialists. There was no financial incentive for GPs to undertake minor surgery, most patients were referred to secondary care (hospitals) for procedures that were provided there free of charge to the patient, and consequently the range and number of surgical procedures performed in general practice declined sharply. A few enthusiasts maintained the tradition, funded by ad hoc arrangements with their local health authorities.²⁻⁴

The 1990 contract for GPs in England and Wales specified an item-of-service payment for minor surgical procedures, which replaced an element of per capita funding and contributed to target income.⁵ The money that was directed at this initiative did not increase the total that GPs could earn, therefore, but it introduced a new incentive to perform minor surgery that reflected the prevailing political agenda of the times. The stated aim of the reforms was, in part, to try to

transfer some procedures that were being performed in secondary care to primary care. This reflected the needs of the government to reduce the political pressure that long waiting lists for hospital services were generating. It was also a reaction to several publications advocating primary care surgery as being more cost-effective, equal in quality to hospital care, and better received by patients than hospital care for some procedures. The widely held belief was that most GPs had acquired sufficient skills in minor surgical techniques during their hospital-based prequalification and postqualification training to allow them to perform a variety of procedures safely, conveniently and cost-effectively for patients.^{2,6,7}

The contract specified that in order to be able to offer minor surgery sessions a GP had to be included on the health authority's minor surgery list. A GP was able to treat his or her own patients or those of partners or group members. The types of surgical procedure for which claims could be made under the new contract are listed in *Table 1*.

This part of the 1990 contract changes was cautiously welcomed by GPs and generated debate about equipment, training and quality control.⁸⁻¹³

Within 5 years of the contract being launched, around 90% of GP principals in England and Wales were accredited by their local health authority as providers of minor surgery, and were claiming for the maximum number (60) of remunerable procedures per annum. This activity forms the vast bulk of GP-performed minor surgery in routine practice, and has therefore attracted the most attention from investigators over the years since.¹⁴⁻¹⁶

Of note in *Table 1* is that two categories of procedure for which claims could be made include procedures that do not utilise traditional surgical techniques: injections (largely of joints and around joints) and cautery (or cryosurgery). As discussed later in this report, this had implications for both the conduct of the trial and the development of GP minor surgery over the course of the 1990s.

TABLE 1 Minor surgery procedures defined in the 1990 contract

Category	Includes
Injections	Intra-articular Periarticular Varicose veins Haemorrhoids
Aspirations	Joints Cysts Bursae Hydroceles
Incisions	Abcesses Cysts Thrombosed piles
Excisions	Sebaceous cysts Lipomas Skin lesions for histology Intradermal naevi, papillomata Dermatofibromata and similar conditions Warts Removal of toenails
Curette, cautery and cryocautery	Warts and verrucae Other skin lesions
Other	Ligation of varicose veins Removal of foreign bodies Nasal cautery

Unresolved issues

Since the introduction of the 1990 contract, there has been a significant increase in the volume of

minor surgery performed in primary care, but little to suggest that care has been transferred from secondary care to the GP's premises.¹⁵ There has also been at times fierce debate about the quality and appropriateness of management decisions and clinical practices in general practice, focusing around two issues. First is the accuracy of clinical diagnosis and consequent need for histological confirmation of diagnosis. Associated with this is the second issue, the technical quality of surgery performed, discussed most often in terms of incomplete excision of malignant or premalignant conditions.^{14,17-28} These debates are still unresolved, owing to the absence of firm evidence to support either view. What evidence there is comprises descriptions of personal case series from general practice, and audits of completely or incompletely excised lesions reported by pathologists, with or without accurate diagnoses being recorded on the pathologist's request form.

Leese and colleagues examined the effect of the minor surgery contract in 1995.²⁹ In their conclusion they state, 'There are many issues which are ... still of concern and of these, lack of appropriate skills and expertise are foremost ... In effect, the issues of quality and cost effectiveness have not been sufficiently addressed.'

This study attempts to address these issues.

Chapter 2

Objective and aims of the study

Objective

The objective of this study was to determine whether there is equivalence in the competence of GPs and hospital doctors to perform a range of elective minor surgical procedures, in terms of the safety, quality and cost of care.

- To collect data on quality of surgery, patient satisfaction, patient safety and cost of procedure in two settings.
- To consider data from this trial and from other sources, to consider the implications for policy and to make recommendations for future research in this area.

Aims

The aims were:

- To conduct a randomised controlled equivalence trial of minor surgery in two settings.

Chapter 3

Methods

Design

Project structure

This study comprised a randomised, controlled equivalence trial comparing the quality of minor surgery performed by GPs and hospital doctors (surgeons and dermatologists). The primary outcome measure was clinical quality and safety of minor surgery, with secondary outcome measures of patient satisfaction and cost-effectiveness. This trial was designed to test the hypothesis that there is equivalence in the competence of GPs and surgeons to perform a range of elective minor surgical procedures. An equivalence trial has the primary objective of showing that the response to two or more treatments differs by an amount that is clinically unimportant. This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence limit of clinically acceptable difference.^{30,31} An equivalence design was decided upon because of the situation pertaining when this trial was designed, because of a lack of observational evidence that would have

allowed either an expected difference in performance in one set of practitioners over the other, or the direction of that difference, to be specified.

Figure 1 shows a range of possible results for an equivalence trial, with confidence intervals around each result. It should be noted that it is quite possible to have results where the two treatments being compared are, statistically, significantly different from each other (all results except for the central result), but are either still equivalent in clinical importance (the two results to either side of the central result) or are uncertain in importance [the two results overlapping the equivalence limits (marked $-\delta$ and $+\delta$)]. Only the two outermost results in *Figure 1* are both significant and clinically important. This makes the interpretation of equivalence trials different from that of straightforward treatment trials, but in some ways more honest: many treatment difference trials are reported as showing 'significant differences' without comment being made on the clinical importance of results.

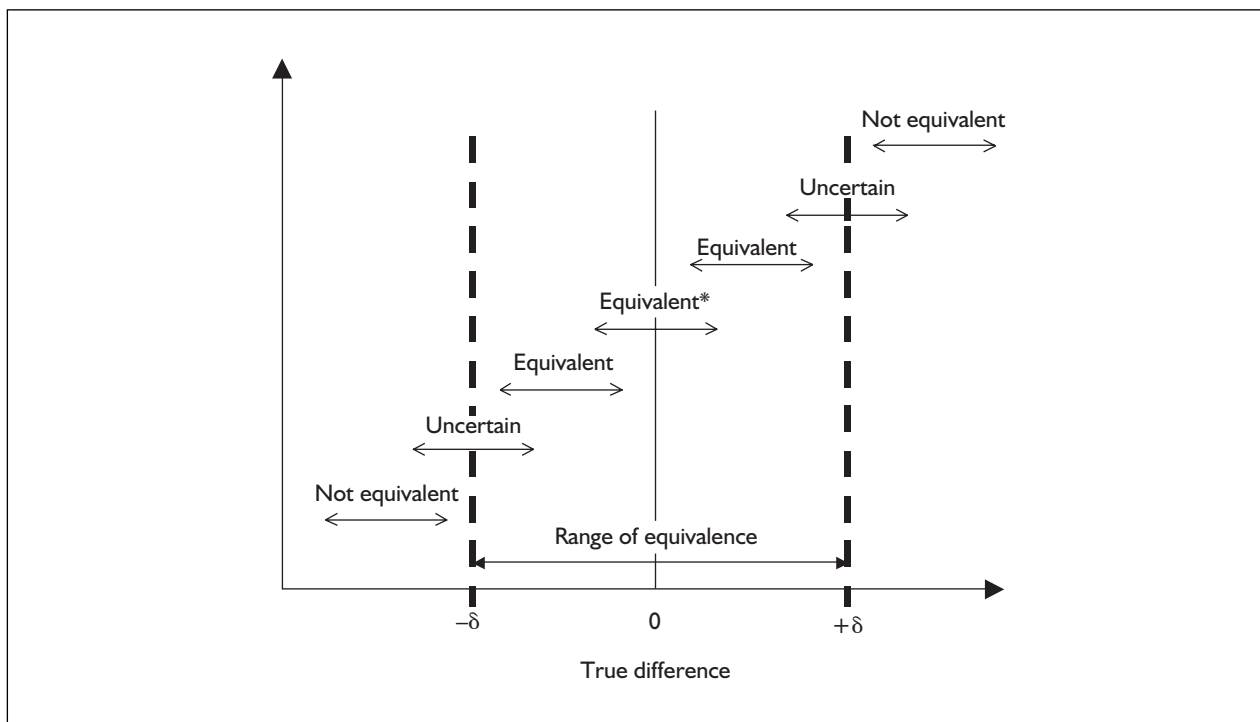


FIGURE 1 Equivalence trial: possible results

Setting

The trial was performed in South Hampshire, the geographical area lying between the New Forest and Portsmouth and surrounding Southampton.

Participants and inclusion criteria

All patients with one of a range of conditions amenable to minor surgery, who presented to one of the GPs participating in the trial and who were considered suitable for treatment by an individual GP or one of their partners, were invited to participate in the trial. The trial recruited patients over 2 years (2000–2002), from more than 40 practices throughout two health authority areas.

As discussed in Chapter 1, there are six categories of treatment attracting payment. Of these, two differ markedly from the others. The first is cautery, activity within which is largely composed of treatment for cutaneous warts, and for which a recent systematic review confirmed little evidence of benefit.³² The evidence used in this review, albeit not yet synthesised, was available in 1999/2000, when the study design was being finalised. In an equivalence trial it is possible for two treatments to be judged as equivalent in terms of effectiveness, and yet for both to be equally ineffective. This clearly compromises the interpretation of the trial result. On this basis it was decided to exclude this category of treatment from inclusion.

The second treatment category differing markedly from the others is injections, which is mainly concerned with the treatment of painful joints. Including joint injections in this trial was considered, but it was concluded that outcome measures for this category would be different from those for the other categories of treatment included and, moreover, would be specific to each joint treated. A preliminary search of the literature showed that for many joints these measures did not exist in validated form, if at all. Inclusion of joint injections would have rendered both design and interpretation of the trial very complex, therefore, and it was agreed with the HTA Programme that this category of treatment should not form part of the trial. All other categories of treatment, however, could be judged in terms of a common set of outcome measures. Included within the trial, therefore, are surgical excisions, incisions, ablations and aspirations of skin and subcutaneous lesions, injection of varicose veins, and banding of haemorrhoids.

Interventions

In formal terms the interventions were structurally rather than clinically different, and comprised

elective minor surgery for the conditions described above, delivered in either a primary care or a secondary care setting. In the primary care setting the intervention could be delivered either by the patient's own GP or by referral to a colleague within primary care. In secondary care the interventions were delivered by either surgeons or dermatologists at a variety of grades. Both interventions mimicked the situation pertaining in real life as much as possible, except for the fact that specially organised clinics were set up in the hospital arm (see below for explanation).

Sample size and outcome measures

Quality of treatment was initially defined as the absence of complications resulting from the surgery. The design of an equivalence trial and its sample size depend heavily on the expectations of the outcomes that will be achieved. There was very little in the literature regarding the complication rates that could reasonably be expected for minor operations conducted in general practice. The best available was from O' Cathain and colleagues, who conducted a non-randomised comparison of minor operations conducted in GP practices and hospitals in Rotherham in 1989.³³ They found no statistical difference in indicators of complications such as wound infection rates and other complications between the GP and hospital arms of the study. The overall rate of wound infections and other complications was 11.4% in the hospital group. This was used as the expected rate of complications for the initial sample size calculations in the present study, with a 50% each way ($\pm 5.7\%$) range of equivalence.

Using the formula proposed by Makuch and Simon, and specifying 5% significance and 90% power for sample sizes, a sample size of 653 patients in each arm was obtained.³⁰ This was considered to be a large, but achievable, recruitment target for this study. The number of GPs taking part in the study was expected to be large, as the project group had ready access to the local primary care research network of GPs [Wessex Research Network (WReN): 190 of these GPs had already expressed an interest in taking part in a study of this kind]. As each GP was believed to have up to 60 eligible patients per annum who could potentially be randomised into the trial, recruiting slightly over 1300 patients did not appear overambitious.

Secondary outcome measures were defined initially as quality of surgery, patient satisfaction and cost-effectiveness.

Protocol revision

Upon starting recruitment it quickly became obvious that the overall complication rate was not as high as that experienced by O’Cathain and colleagues in their study.³³ Details of the complications suffered by patients were collected in the questionnaire developed for this study to assess the patient experience with the treatment process. The initial estimate, based on the first 50 questionnaires received from patients, was a complication rate of less than 5%, although clearly this was an estimate with wide confidence intervals. Using the same 50% each-way equivalence limits, however, this would have inflated the required sample size to 1596 in each arm, or 3192 patients in total. Whereas the original estimate of 1306 patients needing to be randomised had seemed achievable, more than doubling that estimate did not, and the researchers decided to investigate powering the trial using other outcome measures.

Since the trial hypothesis was that there is equivalence in the competence of GPs and surgeons to perform a range of elective minor surgical procedures, the choice of outcome measure to replace complications of treatment had to remain within the sphere of operator competence. This ruled out patient satisfaction and cost, leaving wound scoring scales as the next best alternative.

Two tools are found in emergency medicine literature from the USA. Quinn and Wells describe the use and reliability of both a simple visual analogue score (VAS) and a categorical scale for the assessment of traumatic wounds, showing that both produce good interobserver and intraobserver reliability when assessing wounds using photographs.³⁴ Their categorical scale (Table 2) has been shown to produce results that show strong correlation with patients’ views of their wounds.³⁵ Although these scales and measures were developed for assessing repairs to traumatic lacerations, they have also been

validated for use in elective wounds³⁶ and it was decided to use them henceforward as primary outcome measures; they were in any case already in use as secondary outcome measures. This change in protocol was discussed with and approved by the commissioning body, the NHS HTA Programme.

The VAS has a potential score from 0 to 100 in a continuous distribution. The increased power afforded by using a continuous measure to power the trial, rather than an ordinally distributed one which would require non-parametric analysis, meant that it was the obvious choice to recalculate sample size. The mean VAS for those patients who had returned questionnaires by the time of recalculation was 50.7 [standard deviation (SD) 17.3]. Using the formula provided by Machin and colleagues³¹ for calculating sample sizes for equivalence studies utilising outcome measures with continuous distributions, and specifying 5% significance and 90% power, a sample size of 245 patients in each arm (490 in total) was obtained, with 10% each way limits of equivalence (i.e. 50.7 ± 5.07).³¹ This appeared achievable, and the trial continued using this revised sample size.

Assessment of quality of surgery

Assessment of the wound was undertaken between 6 and 8 weeks postsurgery by two blinded independent reviewers using digital photographs of each wound. This was a pragmatic time interval. The appearance of wounds has been shown to be reliably correlated at 3 months and 1 year, whereas the appearance at 5–10 days does not correlate with 1-year appearance.³⁷ However, 3 months was felt to be too long an interval to allow accurate recall of subjective impressions that the patients were to be asked about in the assessment of satisfaction, and might also have led to an unacceptably large loss to follow-up rate in the study. A time of 6–8 weeks postsurgery was felt to be an acceptable compromise. Digital photographs were taken of each wound by the trial nurse (some

TABLE 2 Criterion-based score system for assessing wounds

Distortion of skin around the scar	Score 0 if present	Score 1 if not present
Width of the scar	Score 0 if > 2 mm	Score 1 if < 2 mm
Step across scar	Score 0 if present	Score 1 if not present
Edge inversion	Score 0 if present	Score 1 if not present
Inflammation/discharge	Score 0 if present	Score 1 if not present
Overall result	Score 0 if not acceptable	Score 1 if acceptable
Total score	< 6 = suboptimal healing	6 = optimal healing

patients had more than one procedure undertaken) using a Nikon D1 digital single-lens reflex camera. It was planned that four photographs would be taken of each wound: one was taken from enough distance to allow the reviewers to orientate themselves to which part of the body had been treated; three close-up pictures were then taken, one perpendicular to the wound, one obliquely to the wound and a final picture was taken with the camera at a fixed distance from the wound. This series of photos was designed to allow the reviewer to assess the wounds using both the VAS and the categorical scale.

Photographs were judged separately by two observers, one a consultant surgeon, and one a GP with surgical training. They were both blind to the arm of the trial, and neither of them undertook any of the trial surgery. The photographs were presented to the reviewers in a specially written form program based on a Microsoft Access database, allowing simple completion (Appendix 1). The assessors judged each set of photographs using both wound scoring scales (VAS and categorical) at the same time. Their scores were combined for analysis.

Patient satisfaction

No satisfactory measure of patient satisfaction existed for this group of patients that had been validated and that contained questions on all the areas upon which data were to be gathered, and it was decided to construct a questionnaire specifically for the purpose as part of an MSc project.³⁸ A search of the literature and two group interviews with minor surgical patients generated a comprehensive list of issues to be covered within the questionnaire. From these issues items with Likert responses were formed. The literature, patient and expert opinion contributed to face and content validity. The final questionnaire used in the study forms Appendix 2.

Pathological diagnosis

Pathological diagnosis was considered important as the issue of appropriate treatment of both benign and malignant lesions was much debated in the early years after the introduction of the fee-for-service payments for minor surgery. The authors attempted to obtain a pathology report for every operation if there was one available, a detailed search being made. All the histology services for the hospitals and GP practices participating in the

study were provided by three pathology departments (Southampton University Hospitals, Salisbury District Hospital and Portsmouth Hospitals). The majority of the reports came from Southampton University Hospitals Trust (SUHT) and were obtained directly from the results service within the hospital. Those from the other centres were obtained via the GPs involved. Where missing, the individual patient records were searched at the GP practice and the hospital results service approached. Only when this process was exhausted was it assumed that a specimen had not been sent. This process was repeated several times after completion of recruitment and initial follow-up had been completed. The referring diagnosis was compared with the final report, the pathologist's report taken as being correct. For malignant lesions, completeness of excision was noted.

Analysis

As well as the effect of the trial arm upon outcome, individual operator effects have to be taken into account in both arms of the trial, and so does the effect of patients having more than one lesion removed during the trial. The resulting data set is hierarchical in nature, therefore, with three levels for variables measuring quality of surgery at lesion level (trial arm, operator, lesion) and two levels for questionnaire variables (trial arm, operator).

The primary outcome (VAS) is a continuous variable. A clinically important difference in VAS score was defined as 10% of the overall mean VAS score either way from zero (no difference). This clinically important difference was used to define an upper and a lower equivalence limit around zero. If the 95% confidence interval (CI) around the observed difference in VAS score lay completely *above* the *upper* equivalence limit, or completely *below* the *lower* equivalence limit, then the performance of the operators in the two arms was to be judged non-equivalent: if it lay entirely *between* the two equivalence limits it was to be judged equivalent: if it *straddled either* equivalence limit, the result was to be judged uncertain. The mean difference and 95% confidence intervals around it were calculated using the MIXED procedure in SPSS 14.0, with trial arm specified as a fixed effect, and operator and patient (to account for multiple lesions) as random effects. This was a per-protocol analysis, this being an equivalence trial.

For other trial outcomes no prior hypothesis was made to enable generation of equivalence limits.

Outcomes are therefore reported simply as mean differences (or differences in proportions) and confidence intervals. For these outcomes intention-to-treat (ITT) analysis was undertaken, making a worst case assumption for each missing data item. For the categorical quality scale the proportion in each trial arm achieving maximum score from both assessors on quality scale (i.e. 12/12) was calculated, as was the mean score for each trial arm on a scale comprised of adding both assessors' assessments together for each case. Scales derived from questionnaire items were treated in a similar fashion to assessed quality scales. Certain items (e.g. median distance travelled to surgery) were not amenable to multilevel adjustment and have been reported as they stand.

Training of GPs and quality of surgery

To try to estimate the effect of training on GPs' abilities to undertake minor surgery an analysis was also undertaken comparing the VAS scores from scars resulting from those who had received formal 'in-post' surgical training and those who had not. Details of amount of training undergone by GPs in surgical techniques were collected in a separate questionnaire survey. A questionnaire was distributed to all GPs in South Hampshire asking for details of jobs undertaken in surgery, dermatology or obstetrics and gynaecology, possession of FRCS (Fellow of the Royal College of Surgeons) or equivalent [e.g. Member of the Royal College of Obstetricians and Gynaecologists (MRCOG)] and attendance at other training courses. The results of the whole survey are largely not pertinent to the trial or its interpretation, and will not be presented in full. For the purposes of this analysis results of individual questions were combined to give a classification in in-post or informal training undergone. This classification was then applied to operators in the trial and their results in terms of surgical quality were compared.

Participants

General practitioners

It was originally planned to recruit members of the WReN to take part in the project. When this study was undertaken, WReN was an active organisation, primarily of GPs, promoting and developing both research ideas and projects in primary care in the Wessex region of the NHS

(Dorset, Hampshire, the Isle of Wight and Wiltshire). However, for logistic reasons, it was not possible to use this network in the way envisaged because of the organisation of hospital services in the region. The project had to be limited to the areas in which there was ready access to a hospital service for providing minor surgery to patients randomised to the hospital arm of the study. It proved impossible to persuade some hospital trusts of the benefits to them of entering the trial at all, and it was equally impossible to persuade others that they should treat patients randomised to the hospital arm but who were resident in other catchment areas. This resulted in setting the catchment area for the trial as (initially) the bulk of the Southampton and South West Hampshire health authority area. This was subsequently extended to the western areas of the Portsmouth and South East Hampshire health authority.

Hospitals

Recruiting hospitals to take part in the study was difficult. When the initial application was made to the HTA to conduct the study, the relevant senior managers in the principal hospital trust (SUHT) had agreed to support the study. However, there was a long gap between initial application for the grant and starting the project (3 years). During this time the funding arrangements for research within the NHS evolved rapidly following the adoption of the principles described by Culyer.³⁹ This review of research funding mechanisms assigned research costs, service costs and treatment costs to three separate fund-holding bodies. Definitions provided in the review were not tight enough, and this led to inevitable differences in interpretation. Lack of agreement on what constituted 'service' and 'treatment' costs, and what differentiated one from another, led to protracted discussions with SUHT, the likely major host for the hospital arm of the trial. The issue centred on the requirement to set up a special operating list for the purposes of the trial. This was necessitated by the very long hospital waiting lists for minor surgery for non-malignant skin lesions at Southampton, which would have meant that most, if not all, patients randomised to this arm would not have had a procedure undertaken within the timespan of the trial, had they been assigned to routine hospital care. Although this would have provided a definitive result as to the feasibility of undertaking all minor surgery in a hospital setting (at least under current financial constraints), it would not have answered questions relating to quality or patient experience of actually having surgery. Altogether, these delays

necessitated a 6-month extension to contract, which was agreed by the HTA.

These same problems came to the fore when attempts were made to extend the trial recruitment area to Portsmouth in 2000/01. At that time, the dermatology and general surgery consultants in Portsmouth who specialised in treating skin lesions had a waiting time of 11 months for low-grade skin cancer surgery, and had stopped offering any service for non-malignant skin lesions. In addition, internal funding arrangements for pathology services in Portsmouth meant that each lesion sent for pathological analysis would be more expensive to the clinical budgets of the operating consultants than in Southampton. Portsmouth Hospitals Trust was also in receipt of a far smaller Service Increment for Teaching and Research (SIFT-R: the research funding grant given to hospital trusts) allocation as a trust than that given to SUHT, as a result of the teaching hospital status granted to Southampton.

These problems were not as acute in the Southampton Community Health Services Trust, which runs most of the smaller scale hospitals in the Southampton district. Their waiting lists were shorter, and generally there was less pressure on each list. The overall numbers predicted to need treatment in the community trust facilities were also much smaller, only 20% of the total number of patients recruited to the hospital arm of the study. Once the practicalities had been decided of how to make appointments in the units involved, there were no significant further problems in supporting the trial in these locations. Similarly, these problems were not an issue when the armed services hospital at Haslar in Gosport was approached. Here, the practical difficulty of predicting when consultant surgeons or their teams would be available to perform procedures was more important.

The hospitals and trusts that agreed to take part in the study, finally, were the Southampton University Hospitals NHS Trust, the Southampton Community Health Services NHS Trust, and the Royal Hospital Haslar, Gosport. The community trust made available facilities at Romsey Hospital, Lymington Hospital, The Fenwick Hospital, Lyndhurst Hospital and Hythe Hospital. The university hospitals trust made available facilities at the Royal South Hants Hospital. The study was supported directly by the use of staff from academic and NHS staff in general surgery, dermatology and pathology, within all of the trusts and institutions mentioned. In terms of numbers

of hospital doctors directly involved, 59 performed procedures for the study.

Recruitment

Recruitment of patients to the trial was by GPs in their surgeries on an opportunistic basis. It was necessary initially to approach GPs to ask them to participate in the trial. All GPs in the area were contacted by letter, this being followed by a letter to their practice manager. The intention was to arrange a direct presentation with the GPs about the reasons for the study and the practical arrangements for taking part in it.

Financial issues

The challenges of negotiating Culyer funding were not the only financial issues to impact upon this trial. As described, GPs receive payment for their minor surgery activity. In the Southampton and South West Hampshire health authority area more than 90% of GPs were registered as providers of minor surgery. They were entitled to claim £25.65 for each procedure undertaken, up to a total of 60 procedures per annum (1999/2000 rates), a total of £1539 per year. Theoretically, therefore, a GP could lose a significant amount of money by taking part in the trial; if the demand for minor surgery from their patients in a year amounted to only the 60 patients on whom they would have been entitled to claim, approximately 30 would be sent to hospital for their treatment. They would not be able to claim the fee for these patients, thus losing £769.50 in fees for their practice.

In order to remove this disincentive to take part, a means had to be found to compensate the GPs for their potential loss of earnings. However, the internal rules for the NHS and for supporting clinical research meant that it was not possible simply to pay the fee for patients randomised to hospital to the GP from trial funds. A compromise was found such that GPs received a payment to cover their costs in taking part in the study; principally, the time that it took them to complete the minimal paperwork for the recruited patients. This allowed for a payment of £21.75 per patient recruited to the GP. This was funded by additional monies allocated from the National Co-ordinating Committee for the HTA Programme. This sum ensured that the GPs would receive slightly more if they recruited patients to the study than if they simply operated on them themselves, without there being such a large financial inducement that patients would be recruited who did not need operations.

Patient route through the trial

The trial process was designed to be simple and efficient for both GP and patient. GPs were given a ringbinder file with information and instructions about the trial and, within each, a number of recruitment packs. The packs contained the paperwork required to complete the recruitment of each patient, this was: a reminder of the inclusion/exclusion criteria for the study, an information leaflet for the patient, a recruitment pro forma and a sealed envelope containing the randomisation allocation to hospital or GP treatment.

When a patient presented to a participating GP with a condition suitable for randomisation, the GP asked for their informed consent for recruitment to the trial. If consent was obtained, randomisation to one or other arm of the study was performed by means of opening a sealed envelope which contained a card containing details of trial arm. Details of the patient, their diagnosis and randomisation were then faxed to the trial office. If they were randomised to hospital, the trial office arranged for treatment at an appropriate venue; if they were randomised to general practice, the GP was responsible for notifying the trial office of the date for the procedure. A special treatment list was provided by SUHT to allow rapid treatment of trial patients in the hospital sector. This clinic mimicked normal hospital service in all respects other than the time taken to be treated in it. All patients randomised to the hospital arm of the study were seen and treated within 21 days of entering the study, unless the patient opted for a later appointment. The trial office arranged and conducted all follow-up related to the trial, usually meeting the patient at a time convenient to them, in their own home, in their GP practice or in another convenient place, to enable photography and for the patient to complete the patient satisfaction questionnaire.

Randomisation

A computer-generated sequence of random allocation to hospital or general practice was obtained from the Public Health Sciences and Medical Statistics Group at the University of Southampton. The numbers were randomised in blocks of six, a detail that was withheld from the GPs using the envelopes. A series of envelopes was made up, each with a sequential number on the outside, and a sticker with 'Hospital' or 'GP' placed inside. The envelopes were manila, and

therefore it was not possible to read the allocation without opening the envelope.

The envelopes were put in sequence into the patient recruitment packs given to the GPs. Thus each GP would have, in the ringbinder, ten packs with envelope numbers that ran consecutively. Once a patient was recruited to the trial and had signed the consent form, the randomisation number was recorded by the GP on the recruitment pro forma and the GP then opened the envelope. They then recorded the treatment allocation onto the pro forma, sent this to the trial office and, if the patient was randomised to general practice, proceeded with making the arrangements for the procedure to be carried out.

The randomisation number was checked against a list kept in the trial office, to confirm that the reported randomisation was that which would be expected from that envelope, and that envelopes were being used in sequence by GPs. This system worked well during the trial. On one occasion the randomisation was not what was expected from the envelope numbers. After having checked with the GP concerned that they had been used in the correct order, the error was found to have been with putting the wrong randomisation stickers in the envelopes in that batch. That batch of recruitment packs was withdrawn from the GP involved, and a new one issued. There were no further problems of this sort with the process of randomisation.

Blinding

Clearly, it was not possible to blind patients to which arm of the trial they had been allocated. However, blinding of the two independent observers undertaking assessment of wounds was undertaken. Since all photographs of wounds were taken some 6–8 weeks after surgery, and often in the patient's own home, it was not possible to tell from them where treatment had been undertaken.

Patient withdrawal protocol

A patient could be withdrawn from the study for a number of reasons:

- At all stages within the study, the patients themselves could elect to withdraw from the trial, without compromising their ongoing care with the doctors involved in treating them.

- Patients could also be withdrawn if the condition with which they had presented had resolved, or they no longer wanted it treated.
- More complex rules had to be established for the study for lesions or conditions where the decision to treat by surgery might be questioned by the doctor asked to perform the surgery. There were two situations where this could occur. The first was where a patient was randomised to treatment in general practice, within a practice where one or two partners performed the minor operation for their colleagues. Although appropriately recruited by another GP, the operating GP had the right to decline to treat, usually on the basis that the lesion was sited in a more difficult area, for example the face or over a joint, and that therefore they were not happy to proceed. The second situation was when a patient had been randomised to hospital for treatment, and the opinion of the hospital doctor concerned was that the lesion had been misdiagnosed in general practice and needed either more radical treatment than could be offered in the clinic or day theatre concerned, or other investigation before treatment.

Record-keeping

The mainstay of the record-keeping for this study was a database written in Microsoft Access 2000 for this study. It incorporated reports that allowed tracking of patients through the study; generating due lists of operations that were pending, follow-up appointments that were pending and lists of outstanding paperwork. It also enabled monitoring of recruitment rates and sites, comparison with actual and expected randomisation, and dropout rates from the study. Most importantly, it allowed digital storage of photographs and assessment of wounds. The database and photographs were maintained on University of Southampton mainframe computers, behind electronic firewalls allowing limited access with passwords. This proved a secure and confidential way of maintaining the records. The paper record for the study was minimised, consisting of a patient recruitment pro forma, a consent form, an operation summary and, when applicable, a copy of the pathology report for each procedure. These were kept in the secure trials office in the University Department of Surgery within Southampton General Hospital.

Chapter 4

Results: quality of surgery and patient satisfaction

Potential recruitment population

It is important for the completeness of the Consolidated Standards of Reporting Trials (CONSORT) statement for a trial of this sort that an estimate is made for the total number of patients that could potentially have been recruited. From the data obtained from GPs throughout the area presented elsewhere in this report, the numbers of patients can be estimated that are treated with eligible procedures. GPs in Southampton and Portsmouth area health authorities perform an average of 20.12 (SD 28.9) excisions per year.

In total, 170 GPs agreed to take part in the study, of whom 82 referred at least one patient, although the number of patients contributed varied widely, ranging from a single patient ($n = 16$) to a maximum of 28 patients (with 41 lesions between them). The trial recruited for 2 years, but not all practices were active recruiters throughout this time. A reasonable estimate would be that they recruited for an average of 1 year.

Using these figures for 170 GPs gives an estimate of 3420 eligible patients. Repeating the calculation using only 82 GPs, the number who actually recruited any patients, gives an estimate of 1695. A pragmatic average of 2500 was made for the total number of eligible patients that might have been recruited to the study.

Recruitment

Eighty-two GPs referred one or more patients to this study: 568 patients were recruited to the trial (284 primary care, 284 hospital). The basic demography of the participants and pathology of lesions as judged by referring GPs are given in *Table 3*. The arms are similar in age, gender distribution and diagnosis. A CONSORT diagram appears in Appendix 3. Twenty-three cases in the primary care arm and 26 in the hospital arm did not attend for surgery or were excluded because they were unsuitable for surgery in primary care or ineligible to enter the trial.

Types of lesion presenting and procedure undertaken

Altogether, referrals were received for 705 lesions. There is evidence that 637 skin procedures plus 17 ingrowing toenail procedures were performed, based on the presence of photographs of the operation scar, completed questionnaires, histological samples or documentation (313 primary care, 341 hospital). Of those not receiving surgery one case died before surgery, in 17 cases the lesion resolved (e.g. 'fell off') or required only reassurance, in eight the lesion or subject was either judged unsuitable for surgery in general practice or was ineligible for the trial (three of these were referred urgently to hospital specialist surgery), and in 26 cases 'did not attend' is all that is recorded. In 589 cases assessable pictures resulted [273 primary care (87%), 316 hospital (93%)]. Sixty-five GPs undertook surgery in the primary care arm of the trial and 60 hospital surgeons or dermatologists in the hospital arm. Excisions of skin lesions were the most numerous procedures undertaken, the remaining categories making up less than 10% of the total.

VAS scores of quality of surgery

The overall VAS score across all trial subjects was 59.8, generating 10% each-way equivalence limits of ± 5.98 . The VAS score in the hospital arm was 61.22, and in the primary care arm 55.76 (mean difference 5.46, 95% CI 0.925 to 9.990). *Figure 2* shows a graphical representation of the result and makes it clear that while there is a statistically significant difference in VAS scores, it is an uncertain result rather than a non-equivalent one.

Categorical quality scores

In the hospital group 66/341 lesions (19.4%) achieved a maximum score on the categorical scale, compared with 40/313 (12.8%) in the primary care group [odds ratio (OR) 1.64, 95% CI 0.997 to 2.69].

TABLE 3 Demography of trial participants, and number of lesions referred (number where procedure performed) into the trial as diagnosed by referring doctor, by trial arm

	Hospital group (n = 284)	Primary care group (n = 284)
Mean age (years)	47.8	49.7
Number (%) of females	159 (56%)	150 (53%)
Total lesions referred (procedure performed)	369 (341)	336 (313)
Unknown/non-specific description	7 (7)	7 (7)
Eczema/dermatitis	0	0
Granuloma	5 (4)	3 (2)
Solar elastosis	0	0
Ingrowing toenail	10 (9)	8 (8)
Sebaceous gland hyperplasia	0	1 (1)
Skin tag, fibroepithelial polyp, skin polyp	21 (20)	37 (35)
Chondrodermatitis nodularis helices	0	0
Viral warts	5 (5)	7 (7)
Scars including keloid	1 (1)	1 (1)
Benign tumours including neurofibroma	14 (13)	18 (17)
Lipoma	9 (7)	10 (10)
Cysts including epidermoids	95 (90)	62 (53)
Lentigo	0	0
Seborrhoeic keratosis, seborrhoeic wart, basal cell papilloma	85 (79)	63 (53)
Melanocytic naevus	78 (72)	81 (78)
Solar keratosis	2 (2)	2 (2)
Cutaneous horn	0	1 (1)
Bowen's disease	1 (1)	0
Basal cell carcinoma	25 (21)	26 (24)
Keratoacanthoma	3 (3)	1 (1)
Squamous cell carcinoma	4 (3)	4 (4)
Malignant melanoma	1 (1)	3 (1)
Missing diagnosis/not referred by GP	3 (3)	1 (0)

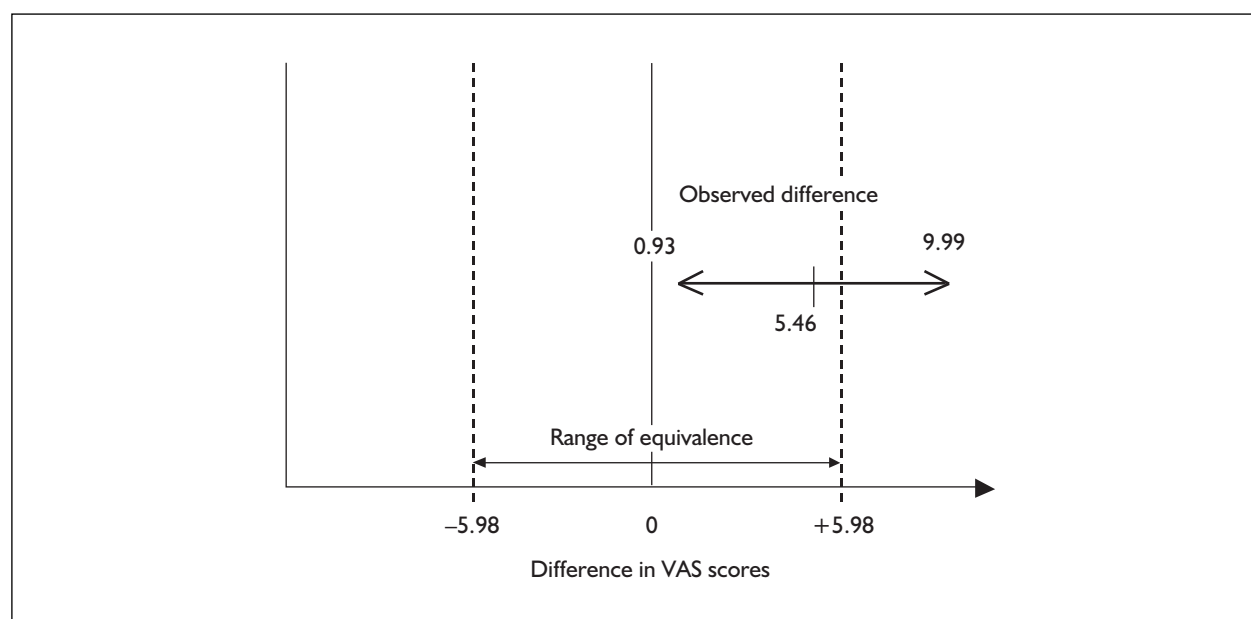


FIGURE 2 Pictorial representation of VAS score results showing observed difference with 95% CIs and equivalence range

Patient satisfaction

A total of 467 subjects returned questionnaires (228 GP arm, 239 hospital arm), although not all subjects answered all questions. *Table 4* presents patient satisfaction scores for five domains (with number of items in domain) and eight individual items in each trial arm. All scores have a maximum range from 1 to 5. For all scores a low score reflects greater patient satisfaction. There are few significant differences between arms, except in matters relating to convenience and knowing the doctor, where the primary care arm has lower scores than the hospital arm. The hospital arm scored better on provision of information following the operation.

Patient access to care

Table 4 also presents questionnaire-derived items related to access to care, which all favour treatment in primary care.

Later complications of surgery

Table 5 shows questionnaire-derived results for problems following surgery. Although postoperative wound infection was significantly lower in the hospital arm there was no difference found in the overall problem rate following surgery.

Pathology reports

Overall, 491/637 skin procedures (77%) generated a traced pathology report. Only 213/305 (70%) of GP skin procedures produced a pathology report, compared with 278/332 (84%) in the hospital arm [$\chi^2 = 17.38$, degrees of freedom (df) = 1, $p < 0.001$].

Completeness of excision of malignant lesions

Completeness of excision was achieved in 15/20 malignancies (75%) in the hospital arm and 7/16

TABLE 4 Patient satisfaction scores with mean differences and 95% CIs for the two trial arms using ITT analysis and the MIXED procedure in SPSS 14.0: ITT analysis

Domain (number of questionnaire items)	Hospital group (n = 258)	Primary care group (n = 261)	Mean difference (95% CI)
Care and courtesy ^a (4)	1.872	1.921	-0.049 (-0.322 to 0.225)
Satisfaction with wound ^a (3)	3.062	3.099	-0.037 (-0.273 to 0.198)
Privacy and comfort ^a (2)	2.327	2.466	-0.138 (-0.399 to 0.123)
Feeling that procedure was rushed ^a (2)	2.184	2.150	+0.034 (-0.228 to 0.296)
Worry that lesion was more serious than stated ^a (2)	2.050	2.182	-0.132 (-0.348 to 0.084)
Ease of making appointment (1)	2.261	2.058	+0.203 (-0.055 to 0.461)
Pain during operation (1)	2.517	2.371	+0.146 (-0.153 to 0.445)
Not kept waiting (1)	2.741	2.244	+0.496 (0.177 to 0.816)
Information following operation (1)	1.951	2.204	-0.253 (-0.478 to -0.028)
Confident to have similar operation in the future (1)	1.968	1.998	-0.030 (-0.309 to 0.249)
Importance of meeting doctor in the past (1)	3.249	2.694	+0.556 (0.290 to 0.822)
Pain in week after operation (1)	2.807	2.696	+0.111 (-0.153 to 0.375)
Wound irritating (1)	2.448	2.464	-0.016 (-0.286 to 0.255)
<i>Items not adjusted for clustering by operator</i>			
Median distance travelled to have procedure done (miles) (1)	5	2	+3 (3 to 4.25)
Median time waited after arrival and before treatment (minutes) (1)	45	10	+35 (35 to 50)
Median time taken in total (minutes) (1)	135	60	+75 (60 to 90)
Trouble parking if came by car (1)	58/214 (22.5%) (44 NA)	39/220 (14.9%) (41 NA)	9.4% (1.5 to 17.1)
A low score reflects greater patient satisfaction. NA, not applicable. ^a Domain.			

TABLE 5 Number (%) of respondents to questionnaire reporting complications of surgery in each arm, with ORs (95% CIs) calculated using logistic regression analysis adjusted for clustering by operator in Stata 9.0: ITT analysis

	Hospital group (n = 258)	GP Group (n = 261)	OR (95% CI)
Wound infection	31 (12.0)	50 (19.2)	0.58 (0.36 to 0.91)
Discomfort	62 (24.0)	58 (22.2)	1.11 (0.70 to 1.75)
Bleeding	52 (20.2)	64 (24.5)	0.78 (0.54 to 1.12)
Allergy	26 (10.1)	38 (14.6)	0.66 (0.39 to 1.12)
Other problem	53 (20.5)	70 (26.8)	0.71 (0.48 to 1.04)
No problems	116 (45.0)	123 (47.1)	0.91 (0.62 to 1.33)

(44%) in the primary care arm of the trial ($\chi^2 = 3.65$, $df = 1$, $p = 0.056$). However, two of the three cases referred for specialist surgery in this trial were malignant in character upon arrival at hospital. If the assumption is made that they received adequate excision from specialist surgical intervention, this would result in revised figures of 17/22 (77%) completely excised in the hospital arm and 7/16 (44%) in the primary care arm of the trial ($\chi^2 = 4.47$, $df = 1$, $p = 0.034$).

Training of GPs and results in terms of quality of surgery

Of the 65 GPs who undertook procedures in this trial 48 (74%) returned the questionnaire; together they carried out 278 of the 337 GP procedures

(82%). None possessed FRCS or equivalent. Twenty-six (54%) had worked for 6 months or more in a surgical or equivalent post (158 procedures) and the remainder had informal or no specific training (120 procedures). *Table 6* compares VAS scores in the two groups.

Clearly, the result, that those in the 'informal' groups score better than those in the 'in-post' group, is the opposite of what might be expected. The obvious explanation is selection bias (i.e. that those with more surgical experience are prepared to tackle more complex procedures), but without the benefit of a scoring system to allow procedures to be graded by complexity it was not possible to investigate this further. Consequently, no further analysis was undertaken comparing these groups.

TABLE 6 Comparison of VAS result in GP operators according to level of surgical experience

	In-post group (n = 158)	Informal group (n = 120)	Mean difference	95% CI for difference
Mean VAS score	52.02	60.46	-8.44	-0.426 to -16.457

Chapter 5

Economic analysis of trial

Two cost-effectiveness analyses are reported. The first uses the original primary outcome measure: absence of problems following surgery. The second uses the completeness of excision of malignancies removed.

Cost of minor surgery

Patient-level resource-use data were not collected alongside the MiSTIC trial, and in order to produce a cost-effectiveness analysis it was necessary to attach costs to each patient in the hospital and GP arms of the trial. To do this, two cost distributions were simulated, using the NHS reference costs for minor surgery in hospitals and primary care, respectively. Following convention, it was assumed that the costs were log-normally distributed. The NHS reference costs report the mean and interquartile range (IQR).⁴⁰ It is possible to extract the standard deviation from the IQR (Table 7). The mean and the standard deviation are sufficient to parameterise the log-normal distribution. The distributions are shown in Figure 3.

Monte Carlo simulation was then used to generate samples of costs. One-thousand simulations were generated for GP and hospital minor surgery costs. SPSS was then used to select randomly the appropriate number of cost observations from each sample and allocate a cost to each subject in each arm of the trial. The Monte Carlo simulations were generated using the Crystal Ball Add-in for Microsoft Excel.⁴¹

This process of generating costs draws on the between-centre variation in costs, which is described by the NHS reference costs, rather than the within-centre variation in costs that is normally captured in sample cost data. Its use for this evaluation can be thought of in terms of randomly

TABLE 7 Costs of hospital and GP-based minor surgery

	Mean cost (£)	SD
Hospital-based minor surgery	1222.24	23.24
GP-based minor surgery	449.74	47.76

sampling trusts from across the NHS to provide the care.

Incremental cost-effectiveness ratio

The primary result of cost-effectiveness analysis is the incremental cost-effectiveness ratio (ICER). This is calculated as the difference in the mean effect in each group divided by the difference in mean cost in each group.

Sensitivity analysis

It is now good practice to address explicitly the uncertainty regarding the true population values of the cost and effect parameters.⁴² Although one-way sensitivity analyses may provide some insight into the potential importance of this uncertainty, probabilistic sensitivity analysis is the most appropriate method of incorporating the uncertainty across all the parameters into the

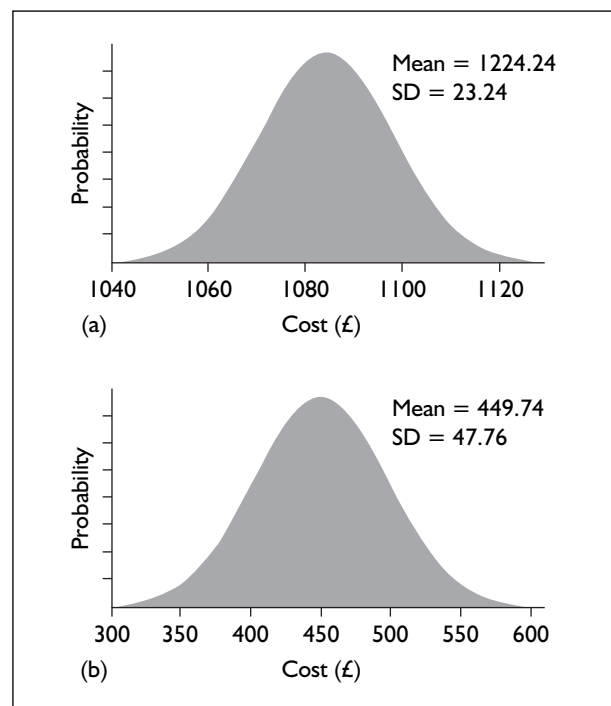


FIGURE 3 Sampling distributions for (a) hospital and (b) GP minor surgery costs

results of an economic evaluation.⁴³ Conventional frequentist analysis often uses the confidence interval to characterise uncertainty. However, a 95% confidence interval does not give you a range within which you are 95% certain the true value lies. Rather, it tells you that if you were to repeat the experiment 100 times and calculate the confidence interval on each occasion, in 95 of those analyses the true value would lie within the calculated range and on five occasions it would not. It provides no information about whether the result you are analysing is one of the 95 or one of the five. In contrast to this, the Bayesian approach to characterising uncertainty, which is taken here, gives the degree of belief or probability that something is true.

The bootstrap was used to construct probability distributions for the population mean costs and outcomes for patients treated in hospital or by GPs.⁴⁴ The basic idea of the bootstrap involves repeated random sampling with replacement from the original data sets to produce random samples of the same size as the original sample, each of which provides an estimate of the parameters of interest.⁴⁵ In this case, it was used for mean costs and mean effects. 'With replacement' means that any observation can be sampled more than once in each bootstrap sample.

Incremental costs and outcomes were calculated for each bootstrapped simulation and plotted on

the incremental cost-effectiveness plane.⁴⁶ This was repeated 10,000 times, and these 10,000 simulation results used to construct a cost-effectiveness acceptability curve (CEAC).⁴⁷ A CEAC plots the probability that an intervention is cost-effective as the decision-maker's willingness to pay for an additional unit of effect increases. In this analysis the CEAC plots the probability that hospital-based minor surgery is cost-effective compared with GP-based minor surgery, as the decision-maker's willingness to pay to avoid a missed diagnosis of malignancy increases.

Discounting

All events considered in this evaluation occurred within 1 year and therefore, by convention, discounting was not required.

Results

The mean cost (SD) for hospital-based minor surgery was £1222.24 (£23.24) and for primary care £449.74 (£47.74). The mean difference in effect between the hospital and GP surgery in terms of the patient-reported 'no problems following the operation' outcome was 0.0135 in favour of hospital surgery. The mean cost difference between hospital and GP surgery was £770.77.

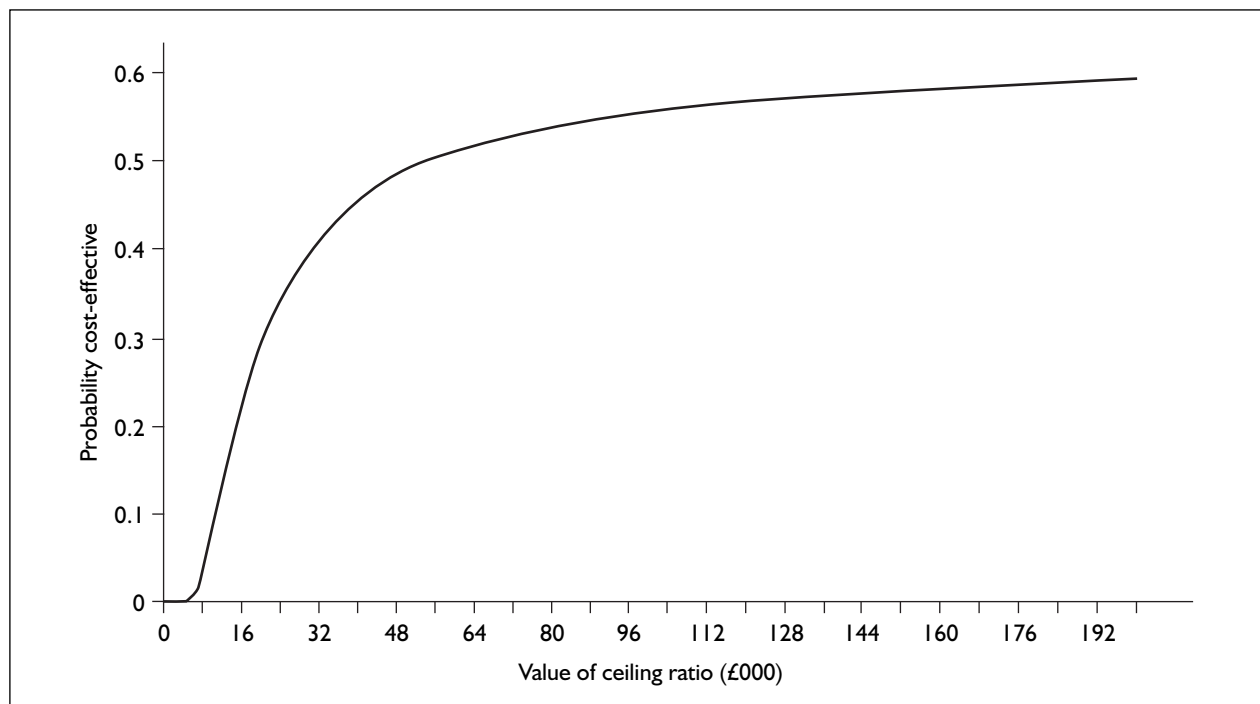


FIGURE 4 CEAC for hospital minor surgery versus primary care minor surgery: no problems after surgery outcome

The expected ICER was £13,558 per additional 'no problems following operation' for hospital surgery versus primary care surgery (SD 631,878). *Figure 4* plots the CEAC for hospital versus primary care surgery. The vertical axis indicates the probability that hospital minor surgery is cost-effective. There is no plausible willingness to pay for which primary care is expected to be cost-effective. However, there remains a large amount of uncertainty around both the expected difference in costs and outcomes using this measure of effect.

At £33,800, the mean ICER per additional complete excision is high, as is the standard

deviation (697,170). The uncertainty around the ICER is clustered around the origin, meaning that the ICER is not very stable, and small changes in either the incremental costs or effects will lead to large shifts in the ICER. The CEAC is well behaved and easy to interpret (*Figure 5*). As the value of an incomplete excision avoided approaches £13,000, the probability that hospital surgery is cost-effective becomes stable at around 90%. Given the potential health consequences of an incomplete excision of, say, a malignant melanoma, this appears a cost-effective option.

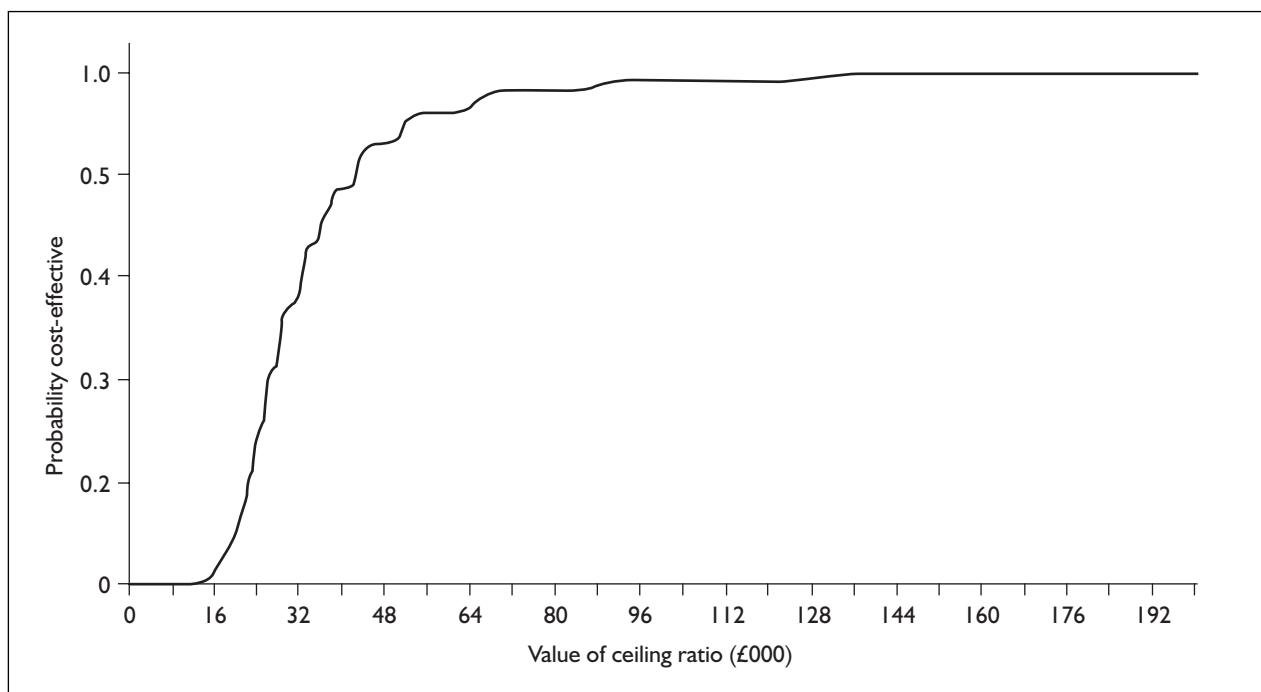


FIGURE 5 CEAC for hospital minor surgery versus primary care minor surgery: complete excision of malignancy outcome

Chapter 6

Comparison of GP diagnosis and histopathology of lesions, and performance regarding recognition of malignant lesions

This study was not powered to investigate pathological outcomes, and the resource to allow proper follow-up of clinical outcomes (e.g. survival following diagnosis of malignant melanoma) was not available. However, many procedures in this trial resulted in a pathology specimen being sent, and the decision was made to investigate the nature of lesions sent for pathology, the accuracy of their diagnosis and the completeness of excision of malignant lesions.

Data

All patients recruited to the MiSTIC trial had a GP referral form indicating a working diagnosis for the lesion concerned. Details from these were entered into a database, along with the histological diagnosis found on the histology form pertaining to the sample, where one was found. There were many diagnoses on the referral forms and pathology reports, and they were divided into 23 categories for analysis, using a classification derived from *Rook's textbook of dermatology*, Sixth edition.⁴⁸ The categories arrived at are shown in *Table 8*.

Analysis

Chance-corrected inter-rater reliability was measured using Cohen's kappa in Stata 8.0 (Stata Corp.). A kappa value greater than 0.75 is considered excellent agreement beyond chance, values below 0.40 represent poor agreement, and values between 0.40 and 0.75 represent fair to good agreement.⁴⁹ An initial comparison between GP diagnosis and histological diagnosis was undertaken across 22 of the 23 categories (ingrowing toenails were excluded from this analysis). For cases where a procedure was known to have been performed but where no histology report was recovered a sensitivity analysis was undertaken assuming, first, no agreement over missing cases and, second, complete agreement over missing cases. The 22 categories were then collapsed into two categories, benign and malignant, and kappa was recalculated. The 'malignant' category comprised three malignancies (malignant melanoma, squamous cell carcinoma and basal cell carcinoma) and one premalignant condition (Bowen's disease). Using this dichotomous categorisation the sensitivity, specificity and positive predictive value for GPs'

TABLE 8 Categories used to classify diagnoses by histology

Category	Type of skin lesion	Category	Type of skin lesion
1	Unknown	13	Cysts including epidermoids
2	Eczema/dermatitis	14	Lentigo
3	Granuloma	15	Seborrhoeic keratosis, basal cell papilloma
4	Solar elastosis	16	Naevi
5	Ingrowing toenail	17	Solar keratosis
6	Sebaceous gland hyperplasia	18	Cutaneous horn
7	Skin tags, fibroepithelial polyp, skin polyp	19 ^a	Bowen's disease
8	Chondrodermatitis nodularis helices	20 ^a	Basal cell carcinoma
9	Viral warts	21	Keratoacanthoma
10	Scars including keloids	22 ^a	Squamous cell carcinoma
11	Benign tumours including neurofibroma	23 ^a	Malignant melanoma
12	Lipoma		

^a Malignant.

recognition of skin malignancies were calculated with 95% confidence intervals. Lack of any estimate of malignancy among missing cases rendered it difficult to make assumptions that would have allowed a sensitivity analysis on the dichotomised data, and this was consequently not done.

In the group of malignancies where surgery was undertaken by the GP, cross-tabulation was used to examine whether recognition of the lesion as malignant had an effect on completeness of excision.

Results

Of 705 lesions referred into the original study, 654 can be shown to have been subject to a procedure,

17 of these being ingrowing toenails in which histology is not usually performed, and which were excluded from analysis. Overall, 491 of the 637 skin procedures (77%) generated a traceable pathology report. *Table 9* shows numbers of these cases by histological category as described by GPs, and number in each category where a histological sample was found by trial arm. In one case there was no referral from the GP, the procedure having been performed at the request of a patient with multiple lesions and in whom that lesion had not been mentioned in the referral. This lesion was excluded, leaving 490 for further analysis. The table demonstrates that the deficit in samples does not follow a random pattern; while it might be expected that skin tags would be underrepresented, shortfalls in other categories (e.g. basal cell papillomata, melanocytic naevi) are more worthy of concern.

TABLE 9 Number of cases as described by GPs on the referral form, numbers where a procedure can be shown to have been performed and numbers of those where a histological sample was found, by trial arm

GP description	Total with GP diagnosis	Total operated on	Histological sample found	
			Hospital group	Primary care group
<i>Lesions analysed</i>				
1. Unknown/non-specific description	14	14	6/7	7/7
2. Eczema/dermatitis	0	0	0/0	0/0
3. Granuloma	8	6	4/4	2/2
4. Solar elastosis	0	0	0/0	0/0
6. Sebaceous gland hyperplasia	1	1	0/0	1/1
7. Skin tag, fibroepithelial polyp, skin polyp	58	55	14/20	10/35
8. Chondrodermatitis nodularis helices	0	0	0/0	0/0
9. Viral warts	12	12	5/5	7/7
10. Scars including keloid	2	2	1/1	1/1
11. Benign tumours including neurofibroma	32	30	13/13	12/17
12. Lipoma	19	17	6/7	4/10
13. Trichilemmal cysts and epidermoids	157	143	74/90	30/53
14. Lentigo	0	0	0/0	0/0
15. Seborrhoeic keratosis, seborrhoeic wart, basal cell papilloma	148	138	57/79	43/59
16. Melanocytic naevus	159	150	66/72	62/78
17. Solar keratosis	4	4	2/2	2/2
18. Cutaneous horn	1	1	0/0	1/1
19. Bowen's disease	1	1	1/1	0/0
20. Basal cell carcinoma	51	45	21/21	23/24
21. Keratoacanthoma	4	4	3/3	1/1
22. Squamous cell carcinoma	8	7	3/3	4/4
23. Malignant melanoma	4	4	1/1	3/3
Total	683	634	277/329	213/305
<i>Lesions not analysed</i>				
5. Ingrowing toenail	18	17	0/9	0/8
No procedure undertaken or referred elsewhere		51	28	23
Not referred by GP	2	1	1/1	0/0
No data on referral form	2	2	0/2	0/0
Grand total	705	654	369	336

Table 10 shows the numbers of cases where a histological sample was found as described by GPs and as classified by histological examination (ingrowing toenails are excluded).

Agreement between GP diagnosis and histology

An overall kappa statistic of 0.42 (95% CI 0.38 to 0.45) was obtained across the whole data set using the 22-category classification (ingrowing toenails excluded). This represents moderate agreement between GP diagnosis and histological findings, but is at the lower boundary of the moderate category. The sensitivity analysis for missing data improved kappa to 0.55 (95% CI 0.51 to 0.58) if complete agreement between GP diagnosis and histology was assumed for missing cases, but it fell to 0.31 (95% CI 0.28 to 0.33) if complete disagreement was assumed.

In an attempt to improve the level of agreement, both GP referral diagnosis and histological diagnosis were collapsed into a malignant/benign classification and the analysis was redone. This resulted in a kappa of 0.45 (95% CI 0.36 to 0.54).

Even at its upper 95% confidence interval, therefore, agreement is moderate at best.

Four of the lesions (all basal cell carcinomas) were diagnosed, correctly, in the same individual. Similarly, many individuals had several benign ones. The figures can be recomputed, therefore, to reflect individuals correctly diagnosed rather than lesions, but it becomes impossible to calculate a kappa across all 22 categories as in some cases individuals had a mixture of benign and malignant lesions. Rather, they can be classified by whether or not they were judged to have one or more malignant lesions. The resulting kappa statistic, calculated on 423 individuals, is 0.41 (0.32 to 0.51). Again, even at the upper level of statistical confidence, agreement is 'moderate' at best.

Test characteristics of GPs in detecting skin malignancy

The results above can be expressed as 2×2 tables and test characteristics computed. Table 11 shows the data for individual lesions, with test characteristics computed in the footnote, and

TABLE 10 Comparison of numbers (%) in each histological category as described by GPs and as classified by histological examination (ingrowing toenails not shown)

	GP diagnosis	Histological diagnosis
1. Unknown/nonsense description	13 (2.6)	0
2. Eczema/dermatitis	0	2 (0.4)
3. Granuloma	6 (1.2)	12 (2.4)
4. Solar elastosis	0	9 (1.8)
6. Sebaceous gland hyperplasia	1 (0.2)	1 (0.2)
7. Skin tag, fibro-epithelial polyp, skin polyp	24 (4.7)	27 (5.3)
8. Chondrodermatitis nodularis helices	0	1 (0.2)
9. Viral warts	12 (2.4)	15 (2.9)
10. Scars including keloid	2 (0.4)	1 (0.2)
11. Benign tumours including neurofibroma	25 (4.9)	64 (12.6)
12. Lipoma	10 (2.0)	11 (2.2)
13. Cysts including epidermoids	104 (20.4)	72 (14.1)
14. Lentigo	0	7 (1.4)
15. Seborrhoeic keratosis, seborrhoeic wart, basal cell papilloma	100 (19.6)	93 (18.5)
16. Melanocytic naevus	128 (25.1)	134 (26.3)
17. Solar keratosis	4 (0.8)	4 (0.8)
18. Cutaneous horn	1 (0.2)	0
19. Bowen's disease	1 (0.2)	3 (0.6)
20. Basal cell carcinoma	44 (8.6)	26 (5.1)
21. Keratoacanthoma	4 (0.8)	1 (0.2)
22. Squamous cell carcinoma	7 (1.4)	5 (1.0)
23. Malignant melanoma	4 (0.8)	2 (0.4)
Total	490	490

Note that figures in the second column are not a subset of figures in the first column.

TABLE 11 Benign and malignant skin lesions as judged by histology and by GP diagnosis

	Histology malignant	Histology benign	Total
GP diagnosis malignant	24	36	60
GP diagnosis benign	12	416	428
Total	36	452	488

Sensitivity = 66.7% (52.9 to 78.00), specificity = 92.0% (89.7 to 93.9), positive predictive value = 40% (30.2 to 50.6), negative predictive value = 97.2% (95.6 to 98.2).

TABLE 12 Individuals by whether they were judged to have a malignant skin lesion as assessed by histology and by GP diagnosis

	Histology malignant	Histology benign	Total
Malignant diagnosis by GP	21	35	56
No malignant diagnosis by GP	12	355	367
Total	33	390	423

Sensitivity = 63.6% (49.3 to 75.9), specificity = 91.0% (88.3 to 93.1), positive predictive value = 37.5% (27.6 to 48.5), negative predictive value = 96.7% (94.8 to 98.0).

Table 12 is the analogous table for individuals affected with malignancy. The results do not differ by a great deal between the two analyses. They indicate that, in this population, GPs failed to recognise one-third of the skin malignancies, or slightly more than one-third of the patients with malignancies. Taking statistical uncertainty into account, the upper 95% confidence interval indicates that they miss no less than one in five. Neither of the malignant melanomas included here was diagnosed by the GP concerned: one was described as a ‘dermatofibroma’ and the other given a general description as ‘red lesion’.

Recognition of a malignancy and completeness of excision

To investigate whether recognition of malignancy improved completeness of excision, the 16 malignancies where surgery was undertaken by the GP were assessed. Six out of the 11 where the malignancy had been recognised resulted in a complete excision (55%) compared with one of the five (20%) where malignancy had not been recognised. However, the association was not statistically significant (Fisher’s exact test $p = 0.31$).

Chapter 7

Discussion

Patients are generally happier with minor surgery carried out in primary care rather than hospital and, while higher quality surgical results were achieved in the hospital arm of the trial, their clinical importance is unclear. The perceived advantages in terms of the convenience of having surgery in a local facility must be the main positive influence on increased satisfaction with the process of minor surgery, as it is clear that postoperative problems are not. However, the fact that special surgical lists were organised in the hospital arm to avoid excessive waiting for procedures might mean that hospital treatment appears more attractive than it might really be, and that the true difference may be greater than that observed. Although confined to one geographical area of the UK, the trial was population based and undertaken by a large number of practitioners in both arms, and recruitment was from a wide variety of general practices; therefore, the authors believe the results to be generalisable.

Ideally, patient-level resource utilisation and costs data would have been collected as part of the primary study, but in the absence of these data a cost data set was simulated using the cost data reported in the NHS reference cost data sets for primary and secondary care. The range of simulated values reflects the large uncertainty around the true mean cost of minor surgery in both hospital and primary care. However, many of the costs of minor surgery, from an NHS perspective, are similar in both settings: procedures in both arms were booked, typically, at 30-minute intervals within formal lists of three to four patients, and if the time allocated to each case is not fully utilised the usefulness of the intervening time in undertaking other healthcare activities is uncertain. Likewise, a pack with the necessary items for minor surgery was a requirement in both arms of the trial, and can be assumed to be equivalent. The cost differences seen are likely to be primarily attributable to differences in allocation of staffing and overhead costs in primary and secondary care.

Based on patient satisfaction, and notwithstanding small differences in surgical quality, the authors

believe it is necessary to continue providing most minor surgery in primary care. However, there are potentially worrying differences between primary care and hospital doctors in the treatment of malignancies which it may be unwise to dismiss as being due to chance. Hospital doctors send a higher proportion of skin lesions for pathological examination, and upon examination more malignant lesions are found to have been removed adequately in hospital. The difference is unlikely to be due to case-mix in the two study arms, which was very similar. In addition, using the outcome 'complete excision of malignancy', hospital minor surgery appears more effective and, acknowledging uncertainty about willingness to pay, the authors believe may be cost-effective.

Not all malignant lesions are clinically obvious at presentation, and some have potentially serious adverse outcomes if missed. In this study GPs missed one-third of malignancies, including both of the malignant melanomas. Coupled with the results of the trial it is clear that the major challenge of providing minor surgery in primary care is the potential for missed diagnosis of serious skin malignancies.

So why is this? The 1990 contract was based on the premise that doctors in practice were not using skills in minor surgery that they had acquired in medical school. However, changes in the content of medical school curricula, coupled with increased public expectations of certain procedures only being carried out by 'qualified' doctors, mean that in most UK medical schools minor surgery skills are no longer the province of the medical student nor, increasingly, of the junior doctor. The 1990 contract gave GPs a financial incentive to perform procedures, therefore, for which many of them had received little training. Perhaps it is the case that most treatment could be carried out in primary care, provided that GPs received further training in the diagnosis and management of skin lesions. A recently published trial shows that a dermatology service operated by two GPs with special interests gave results clinically indistinguishable from those obtained at a hospital outpatient clinic, although minor surgery did not form a part of the work

undertaken.⁵⁰ However, the general practice service was considerably more expensive than its hospital equivalent.⁵¹

Conclusions

Patients like the service in general practice and, while the quality of minor surgery in primary care is not as high as that in hospital, the difference is not large. However, there are possible differences between primary care and hospital doctors in the recognition and treatment of malignant lesions which mean that care needs to be taken in the development of primary care-based minor surgery. The incidence of skin malignancies is increasing, and a major limiting factor in refocusing minor surgical care into the hospital sector is limited capacity, both in terms of physical clinic and operating theatre space and in terms of medical and support staff to undertake the procedures.⁵² Recently, it has been announced that more surgical services are to be moved into primary care, and similar issues will apply as do here.⁵³ Resolution of this dilemma is not a simple matter and will extend beyond the traditional testing of two alternative interventions. The solution in this case may be not to avoid primary care minor surgery, but to improve its quality.

Recommended research

Areas for further, future study include the following:

- Further work is required to determine GPs' management of a range of skin conditions (including potentially life-threatening malignancies), rather than just their recognition of them.
- Further economic modelling work is required to look at the potential costs of training sufficient numbers of GPs and GPs with special interests (GPSIs) to meet the demand for minor surgery safely in primary care, and of the alternative of transferring minor surgery large-scale to the hospital sector.
- A series of models of different service configurations should be tested to identify the optimum service specification. Given more capacity, one such model might include community provision of services by specialist dermatologists; this might prove a safe option which is also popular with the public. Such a service might not necessarily require treatment of all cases by the dermatologist concerned; diagnosis may suffice. Another might involve testing a system in which the submission of samples resected in primary care for histological examination was made mandatory (or at least encouraged).



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Contribution of authors

Steve George (Reader in Public Health), John Primrose (Professor of Surgery), Helen Smith (Professor of Primary Care), Paul Little (Professor of Primary Care) and Adam Lowy (Epidemiologist) designed the study and obtained funding. Pete Pockney (Research Fellow), Helen Kinley (Researcher), SG, JP, HS and PL coordinated the trial on a day-to-day basis and collected data.

HK developed the patient satisfaction questionnaire with help from PL, PP and SG. JP and Roger Kneebone (Senior Lecturer in Surgical Education) assessed the quality of outcome. SG, PP, JP, RK and AL carried out an initial analysis, and SG and PP a final analysis, of the trial data. The economic evaluation was undertaken by Chris McCabe (Professor of Health Economics). PP, Nishmali Jayatilleke (medical student) and SG prepared the data for analysis of histology with help from Barbara Leppard (Consultant Dermatologist). PP and NJ analysed the histological data with help from SG. SG, PP and JP wrote the report with help from all authors.



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Appendix I

Wound assessment tool

Figure 6 is a photograph of the screen with which the assessors marked the photographs of the wounds. By clicking on the 'open photo' buttons above and to the right of each photograph, the operator could view a full-screen version of the picture. There were no details of either who the patient was or the trial arm of the

patient anywhere in the database file sent to the assessors.

When marked, the program automatically returned a file with the scores to the trial office, where it was automatically inserted into the master database. There was no manual transcription of scores.

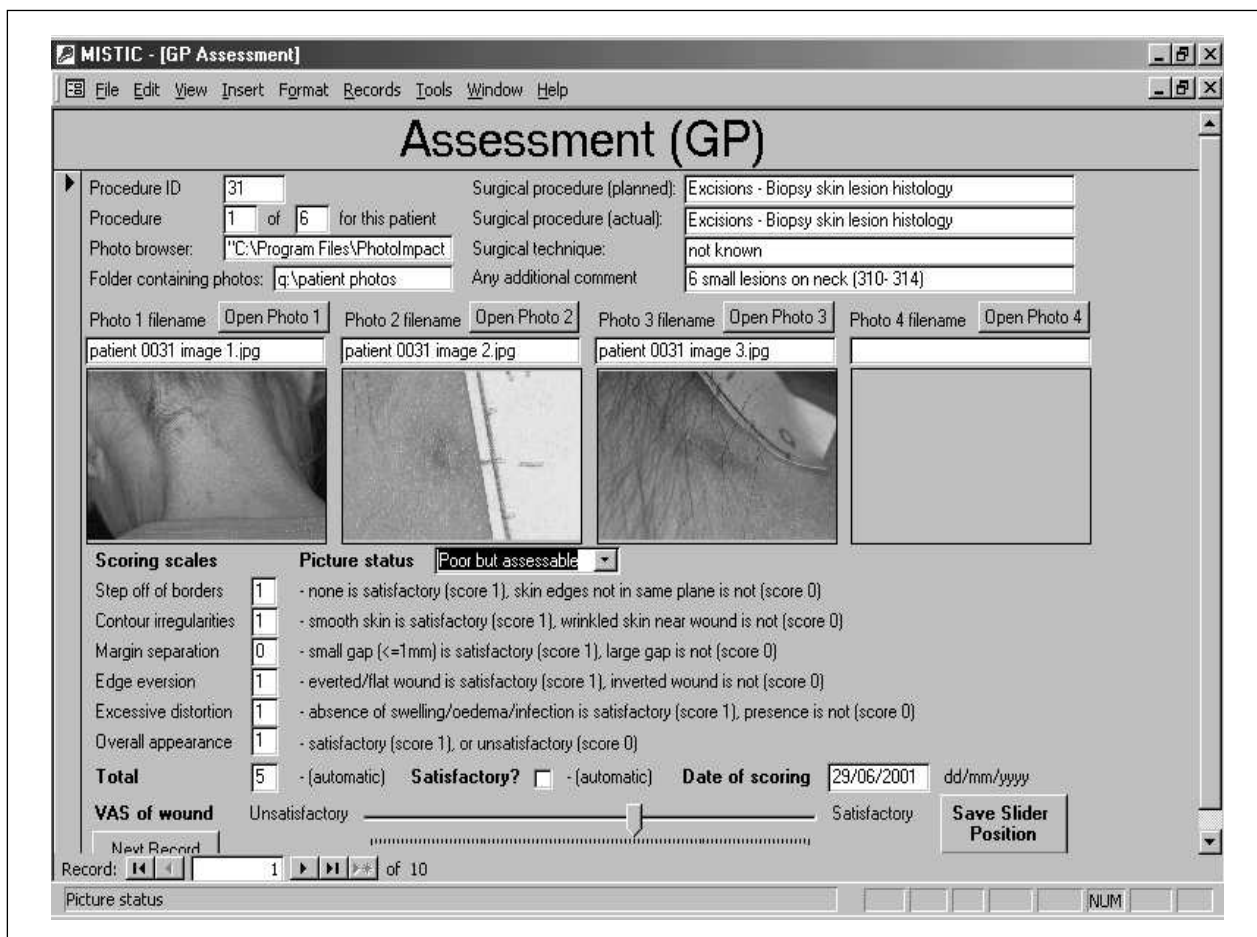


FIGURE 6 Screenshot of wound assessment tool

Appendix 2

Patient Satisfaction Questionnaire

Study No:
Site:
Date:

Minor Surgery Study – Patient Satisfaction Questionnaire

Thank you for agreeing to take part in our study of minor surgery. We would be interested to hear your experiences and what happened when you went to have your minor operation, why you had it done and what happened afterwards. Your answers will be treated as completely confidential.

Most of the questionnaire asks you to tick a box to indicate your degree of agreement with a statement.

For example, if you like to eat ice-cream you might strongly agree (or agree) with the following statement:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
<i>I like to eat ice-cream.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

On the other hand you may not like to eat ice-cream, in which case you may strongly disagree (or disagree) with the following statement.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
<i>I like to eat ice-cream.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The neutral box means you neither agree nor disagree with the statement.

If you would like to, please feel free to add comments on the back of this form.

Thank you.

I had my minor operation because:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. The problem needing the operation looked unsightly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The problem needing the operation was painful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The problem needing the operation was irritating me, for example by itching or rubbing on my clothes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I was worried that it might be something serious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. My doctor advised me to have the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Other reason why I had it done:					

I would now like to ask you what happened when you came for your minor operation.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
7. I found it easy to get an appointment for the operation at a convenient time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. When I arrived to have my operation I had a clear idea of what was going to happen.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. After I arrived for my operation I was able to wait in as much privacy as I would have liked.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. After I arrived for my operation I was able to wait in as much comfort as I would have liked.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I felt I needed more time to discuss what to expect after the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. The doctor doing the operation explained clearly what he was going to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I had every confidence in the doctor doing the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. The doctor doing my operation spent enough time with me and didn't hurry me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I experienced more pain than I expected during the operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. When I arrived for the operation I was not kept waiting very long to have it done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I felt the doctor was rushed during my operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. When I had my operation I felt I didn't have enough time with the doctor to discuss things and ask all the questions I wanted to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I felt I was treated with care and courtesy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

And now I would like to ask you what happened after your minor operation.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
20. After my operation I was told what to do if I had any problems (for example bleeding or soreness).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. I am satisfied with the way the wound looks now.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Should the need arise I would be confident to undergo a similar operation in the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I think it is important that patients having an operation have met the doctor doing it in the past.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. When I first discussed my operation with my doctor (GP) I was not aware that they were able to carry out this type of operation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Had you met the doctor doing the operation in the past?					
<input type="checkbox"/> No					
<input type="checkbox"/> Yes – details:					
<input type="checkbox"/> Not sure					
26. Did you have to take time away from paid employment in order to have your operation?					
<input type="checkbox"/> No					
<input type="checkbox"/> Yes – details:					
<input type="checkbox"/> Not applicable					
27. Did you take any time away from paid employment in the days following your operation?					
<input type="checkbox"/> No					
<input type="checkbox"/> Yes – number of days:					
<input type="checkbox"/> Not applicable					
28. Approximately how far did you have to travel from home or work to the place where you had your operation?					
..... miles					
29. If you came by car did you have trouble parking?					
<input type="checkbox"/> No					
<input type="checkbox"/> Yes – details:					
<input type="checkbox"/> Not applicable (e.g. travelled by public transport)					
30. When you arrived for your operation about how long were you kept waiting before you had it done?					
..... hrs mins					
31. Altogether about how much time did you spend in travelling, waiting for your operation, having your operation and returning home?					
..... hrs mins					

Did you experience any problems after your operation? (Please comment if appropriate).

- ³² wound infection
- ³³ discomfort greater than I expected
- ³⁴ bleeding
- ³⁵ an allergy
- ³⁶ something else, please explain:
- ³⁷ none of these

38. Since the operation have you been in contact with your GP? (Please tick all that apply).

- No, not regarding the operation.
- Yes – for the results of the operation.
- Yes – I was concerned about my wound. Please specify:

Please could you tick a box to indicate whether you agree or disagree with the following statements.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
39. I am reassured that there is nothing serious to worry about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. I think my scar looks unsightly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. In the week following the operation the wound was painful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. The wound is irritating me, for example by itching or rubbing on my clothes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. I am still worried it might have been something serious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. The appearance of the wound now is:					
<input type="checkbox"/> much better than I expected					
<input type="checkbox"/> better than I expected					
<input type="checkbox"/> about what I expected					
<input type="checkbox"/> worse than I expected					
<input type="checkbox"/> much worse than I expected					
<input type="checkbox"/> not applicable (for example, unable to see it)					
45. If you needed another similar minor operation in the future, would you prefer to have this carried out:					
<input type="checkbox"/> In a local hospital by a hospital doctor?					
<input type="checkbox"/> By your GP in his surgery?					
<input type="checkbox"/> Don't mind, either?					
<input type="checkbox"/> Not sure?					
46. If a friend or relative asked your opinion about having a similar minor operation at the place where you have just had yours, would you recommend it to them?					
<input type="checkbox"/> No					
<input type="checkbox"/> Yes					
<input type="checkbox"/> Not sure					

Thank you for your time in filling out this questionnaire.

If you would like to add any other comments about your experience that you feel are important please feel free to do so on the back of this form.

Please return the questionnaire in the enclosed FREEPOST envelope.

Appendix 3

CONSORT statement for MiSTIC trial

Paper section and topic	Item	Description	Reported on page(s)
<i>Title and Abstract</i>	1	How participants were allocated to interventions	i, iii
<i>Introduction</i>	2	Scientific background and explanation of rationale	1, 2
<i>Methods</i>			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected	6
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	6
Objectives	5	Specific objectives and hypotheses	3
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements	6–9
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	6
Randomisation – sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction	11
Randomisation – allocation concealment	9	Method used to implement the random allocation sequence, clarifying whether the sequence was concealed until interventions were assigned	11
Randomisation – implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups	11
Blinding (masking)	11	Whether or not participants, those administering the interventions and those assessing the outcomes were blinded to group assignment	8, 11–12
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	8–9
<i>Results</i>			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons	11, 13
Recruitment	14	Dates defining the periods of recruitment and follow-up	6
Baseline data	15	Baseline demographic and clinical characteristics of each group	13–16
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by 'intention-to-treat'. State the results in absolute numbers	9, 13–16
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision	13–24
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory	NA
Adverse events	19	All important adverse events or side-effects in each intervention group	NA
<i>Discussion</i>			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes	25, 26
Generalisability	21	Generalisability (external validity) of the trial findings	25
Overall evidence	22	General interpretation of the results in the context of current evidence	25, 26

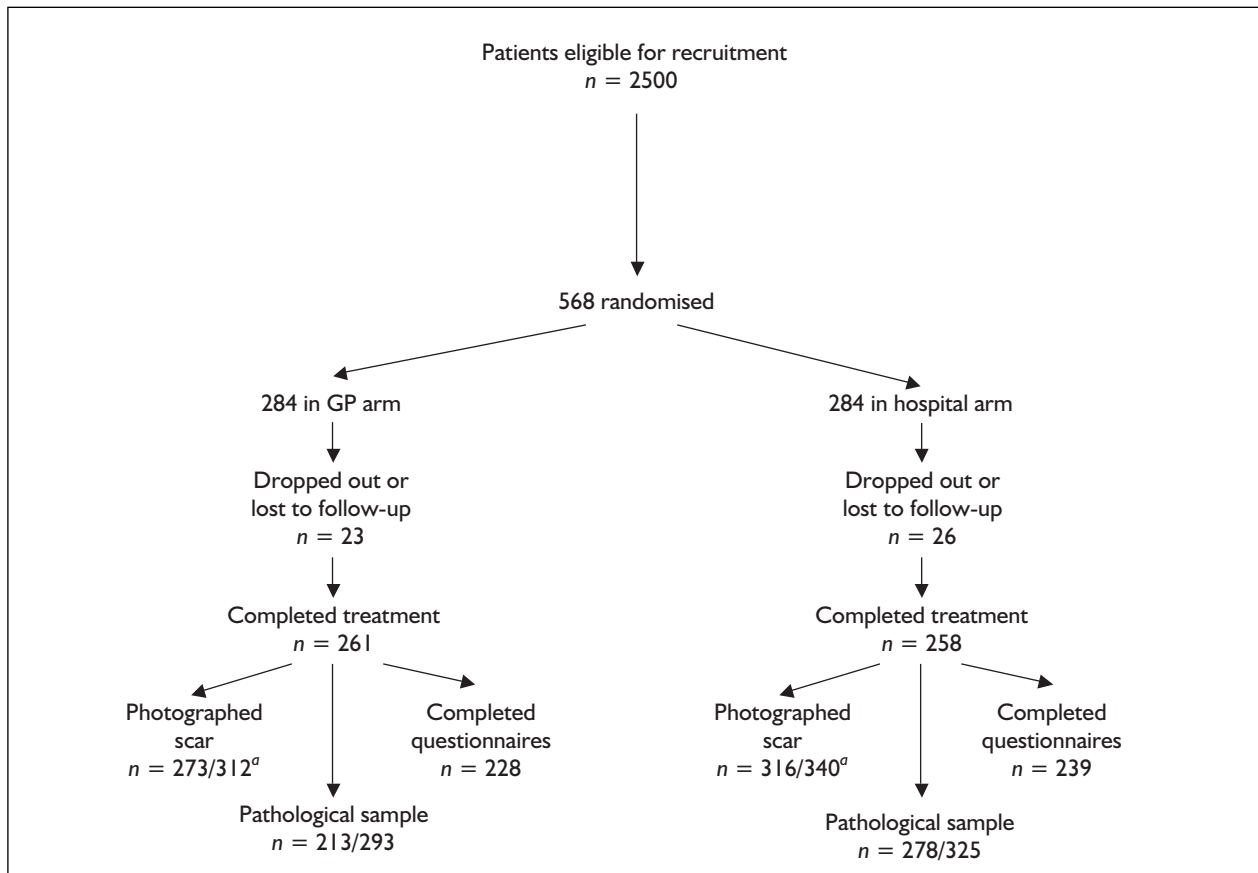


FIGURE 7 Flow diagram for MiSTIC trial. (^aIncludes ingrowing toenails).



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We look forward to hearing from you.