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# A critical assessment of a new evaluation tool for podiatric surgical outcome analysis

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**ABSTRACT**

Systematic, large-scale collection of surgical outcome data is uncommon in podiatric surgery, owing to the relatively small size of the speciality and lack of highly-developed data capture systems at provider level. This remains the case, despite an increasing need for high-quality data to support clinical audit, clinical governance and evidence-based practice. This paper reports the findings of a system designed to address these needs. Evolving from a small-scale outcome measurement project, the methodology was later used to compare practice across a number of centres. The system seeks to describe key features of surgical episodes, which can then be correlated with outcomes and patient satisfaction indicators.

These data were collected by nine podiatric surgical teams in England between 1997 and 2001. The purpose of the paper is primarily to describe the data collection process and discuss the methodological issues underlying this kind of exercise. Space does not permit detailed statistical analyses of the findings.

## INTRODUCTION

The subject of this paper is a framework devised by podiatric surgeons to assist in outcome measurement and clinical audit. Known by the acronym PASCOM, (podiatric audit of surgery and clinical outcome measurement) the project seeks to provide a structured framework in which to collect and compare data relating to the characteristics, outcome and patient experiences of foot surgery performed by podiatrists.

Whilst it has been referred to in a number of sources[1-5], this is the first time a detailed account of the project has been published.

The aim of this paper is to introduce the data set, illustrate the ways in which the data can be used and discuss some of the problems in its implementation. It will argue that this approach has provided a valuable opportunity to scrutinise a large number of foot surgery outcomes for the first time, as it allows outcome data to be correlated with a range of other variables. It will explore how robust this approach is likely to be when used to support activities such as evidence-based practice and clinical governance. Space does not permit in-depth analysis of the information collected. The project team plans to follow this article by a series of smaller papers examining selected aspects of the data in greater detail.

## BACKGROUND

The origins of PASCOM can be traced back to an outcome measurement project undertaken at Nene College in 1994.[3]

Shortly after its completion, the clinical lead for this project started a Podiatric Surgery service in a Community Health Trust in the West Midlands, where he continued to use this methodology for monitoring outcomes.

At unit level, the most useful feature of the system was the ability to isolate cohorts of episodes, using a range of predetermined process or outcome criteria, for further scrutiny by the team. This could then support reflective practice, clinical audit[5] and risk management.

At the same time, comparative outcome measures were being developed in many areas of the NHS. One application of these was the High Level Performance indicator system[6] in which a number of process and outcome indicators were applied to geographical populations or service providers. A key feature of this approach was the ability to compare a (limited) range of clinical outcome data between settings.

Initiatives like this were largely applied to common conditions, often drawing heavily on data from acute providers. However, with the advent of clinical governance, all clinical professions were encouraged to develop ways of measuring, monitoring and assuring quality.[7] For clinicians who provide highly-specialised interventions in relatively low volumes, it is difficult to obtain data to do this. In podiatric surgery, this was exacerbated by services being mainly located in Community Health Trusts, which often did not have IT systems that routinely recorded clinically relevant information. At an early stage of the project it was realised that, if adopted across a number of clinical settings, PASCOM may provide a solution to some of these problems.

Since 1997, a small working group of podiatric surgeons have been collaborating in developing the PASCOM dataset. It was decided that a small number of centres would support the project either by piloting data collection in their own units or by providing advice and assistance at regularly convened working parties, or a combination of both.

The information presented here must still be regarded to all intents and purposes as pilot data, as minor changes to the data set are still being implemented and, as will be described in the discussion section, there are still areas where improvements in data quality need to be made.

## METHODOLOGY

The data set consists of three distinct sections. Firstly, details of the treatment carried out were collected. Next, the post-operative

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progress of the patient is summarised with particular reference to any adverse post-operative sequellae. Finally, the patient is asked questions on a range of issues relating to their treatment and its outcome using a postal survey.

Information on all three sections was collected on colour-coded paper proformas. The responses were transcribed onto a bespoke database application based on Microsoft Access.

## Surgical Episode Data

A proforma is raised at the start of a surgical episode. This notes the date of birth of the patient and a health status indicator. This latter measure is the American Society of Anaesthesiologists physical status (ASA-PS) scale (Table 1).[8] It was designed to indicate health status prior to surgery and has become widespread in many surgical specialties since its introduction in 1941. In PASCOM, ASA-PS acts as a case mix indicator which is sensitive enough to highlight the presence of chronic co-morbidity but is also quick and simple to apply.

The date of the operation is noted, which is the chronological start-point of the pathway. An alphanumeric code is used to identify the surgeon and centre. This is so that teams can compare their own data to that of their peers but maintain confidentiality if they wish. Diagnostic tests are also recorded, again using a pre-agreed coding system.

Next, a list of all the individual surgical procedures used in the episode in question are recorded. All operations were coded using a system that maps to the Office of Population Census and Statistics version 4 classification (OPCS4).[9] The reason OPCS4 was not used directly was that some procedures have variants for which there is no OPCS subdivision.

Medication associated with the episode is also recorded, selected from a predetermined list of drugs known to be used in podiatric settings. The type and number of any fixations or implants used during the procedure were also recorded, again chosen from a list of possible alternatives. The type of anaesthetic used was recorded. Three options were available in the pilot data set: local, local with sedation and general. In most cases, local anaesthetic was the only means available to teams, although increasingly the option of offering sedation or general anaesthetic is becoming available.

During the course of the project it was necessary to update the proforma at regular intervals to incorporate drugs, implants or techniques that were introduced into practice. This was done by feedback to a working party that periodically issued updated proformas to contributors.

## Outcome of treatment

Six months after treatment, the sequellae of surgery and other events in the post-operative pathway are captured in a casenote review. The dates of follow-up contacts are noted, along with any post-operative diagnostic investigations.

The episode can be flagged with any of 32 possible sequellae together with a presentation date. Some are relatively common and would be expected to appear in a proportion of a typical caseload. Others are more serious, their avoidance being essential to a successful outcome. Detailed guidance was given in the project manual as to the criteria the surgeon should apply when determining the presence or absence of any of these. In addition to these 32 possible sequellae, an 'other' category was provided.

An important component of outcome is the extent to which a patient requires further services after treatment. Most will have an uneventful recovery and discharge well within the six-month period. However some may still be under active clinical management, for example in the case of those who undergo staged surgery. Also some patients with enduring conditions may have been referred on to other specialties. The options available to capture these data are listed in Table 2. A flag has been provided which indicates when a patient has had an unplanned return to the care of the podiatrist between discharge and outcome review.

| Grade | Definition |
|---|---|
| ASA 1 | No physical, organic, psychological or biochemical disease. |
| ASA 2 | Mild disease under control; e.g. mild diabetes, slightly limiting angina, essential hypertension, anaemia. |
| ASA 3 | Severe systemic disturbance, limiting heart disease, diabetes with vascular complications/ healed myocardial infarction, pulmonary insufficiency. Use for stable marked disease and polypharmacy. |
| ASA 4 | Cardiac insufficiency, active heart disease, advanced pulmonary disease, hepatic, renal and endocrine insufficiency. Only suitable for local anaesthetic not general. |
| ASA 5 | Moribund patient with low chance of survival e.g. burst abdominal aneurysm. |

**Table 1. American Society of Anaesthesiologists physical status scale.**

| Service Use |
|---|
| Full discharge from Podiatry |
| Further surgery planned |
| Orthoses |
| Hospital admission unplanned |
| Revision of this episode planned |
| Sent to medical agency (not primary care) |
| Referred to GP |
| Referred to Chiropody |
| Referred to physiotherapy |
| Post discharge return |

**Table 2. PASCOM Post Operative Service Use Data Set.**

Lastly, the clinician is asked to state whether the aims of treatment have been met. Three simple categories are offered: wholly met, partly met or not met. More recently, a fourth option of 'lost to follow up' was added to the proforma. This covers situations where there has been insufficient post-operative patient contact to assess outcome, usually owing to non-attendance.

## Patient Satisfaction Questionnaire (PSQ-10)

The third and final part of the process is to explore the patient's perceptions of their treatment. In the original Nene College study, a postal questionnaire was used. Although the wording of some of the questions has been modified, this was the instrument that was used in PASCOM.

Centres were asked to send questionnaires to patients six months after surgery. Unfortunately no guidance was given on dealing with non-responders at the beginning of the project, which may have led to the instrument being applied differently in these cases.

The questionnaire starts by asking the patient to articulate their own expectations of treatment. The other questions are in fixed-response format and ask the patient to relate both fact and opinion about their treatment and recovery.

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Early on in the project, it had been suggested that a scoring method be applied to the questionnaire results. Clearly an overall 'satisfaction score' offers a potentially simple measure with which to compare centres, although devising a system which is sufficiently sensitive to variations in outcome is difficult. The marking scheme applied to the instrument was devised, with each response being given a score. The minimum possible total score is zero and the maximum is one hundred. This marking schedule is shown in Table 3. As well as overall score, it is hoped that responses to individual questions could be applied to various cohorts in the study, to examine how they correlated to clinical features of the cases.

## STATISTICAL ANALYSIS

Ninety-five percent confidence intervals (CIs) have been applied to mean ASA scores. The incidence of outcome also had 95% CIs calculated using the Wilson score method with continuity adjustment.[10] It

| Question | Response | Score |
|---|---|---|
| Q1. Briefly state what you expected to gain from treatment | Free text response | |
| Q2. Were the risks and complications of surgery explained to you before you had your operation? | Yes | 5 |
| | Not sure | 2 |
| | No | 0 |
| Q3. Did you know what do if you had a problem after your operation? | Yes | 5 |
| | Not sure | 2 |
| | No | 0 |
| Q4. Did you have a problem after your operation? | No problem | 15 |
| | Yes, | 6 |
| | Yes, a major problem | 0 |
| Q4a When you had your problem, how did you seek help? | Waited until next appointment | 4 |
| | Verbal advice from podiatrist | 4 |
| | Obtained earlier review appointment | 3 |
| | I called out the podiatrist | 2 |
| | Called out GP | 0 |
| | Went to casualty | 0 |
| | Other | 0 |
| Q4b. Overall how would you say your problem was dealt with? | Excellent | 5 |
| | Satisfactorily | 3 |
| | Poorly | 0 |
| | Still under management | 0 |
| Q5. After the operation, how effective was your pain control? | Excellent minimal pain | 15 |
| | Some pain but I coped | 10 |
| | Completely ineffective | 0 |
| Q6. When could you get back into your shoes? | By 2 weeks | 10 |
| | By 4 weeks | 10 |
| | By 6 weeks | 8 |
| | By 8 weeks | 6 |
| | By 12 weeks | 4 |
| | By 6 months | 3 |
| | 6 months and over | 0 |
| Q7. Do you still have discomfort arising from your original foot condition? | No discomfort at all | 10 |
| | Occasional twinges | 8 |
| | Standing for a long period | 6 |
| | When standing | 0 |
| | At rest | 0 |
| Q8. How would you describe your original foot condition since treatment? | Deteriorated | 0 |
| | A little worse | 0 |
| | The same | 0 |
| | Better | 7 |
| | Much better | 10 |
| Q9 Would you be prepared to have surgery performed under the same conditions again? | Yes | 15 |
| | No | 0 |
| Q10. Were the original expectations that you stated at the beginning of this questionnaire met? | Yes | 15 |
| | In part | 10 |
| | No | 0 |

**Table 3. PSQ-10: Questions, responses and scores.**

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| Centre | ONS Classification | Episodes Submitted | Outcome data submitted | % | PSQ-10 data submitted | % |
|---|---|---|---|---|---|---|
| 1 | Urban manufacturing | 1009 | 426 | 42.2 | 386 | 38.3 |
| 2 | Mining and industrial: coalfields | 341 | 312 | 91.5 | 302 | 88.6 |
| 3 | Rural areas: mixed urban and rural | 270 | 149 | 55.2 | 76 | 28.1 |
| 4 | Not applicable – private provider | 199 | 128 | 64.3 | 33 | 16.6 |
| 5 | Inner London | 150 | 105 | 70.0 | 42 | 28.0 |
| 6 | Inner London | 104 | 104 | 100.0 | 54 | 51.9 |
| 7 | Urban centres mixed economy | 101 | 100 | 99.0 | 94 | 93.1 |
| 8 | Prospering areas: growth area | 71 | 70 | 98.6 | 68 | 95.8 |
| 9 | Mining and industrial: coalfields | 80 | 78 | 97.5 | 58 | 72.5 |
| Total | | 2325 | 1464 | 63.0 | 1113 | 47.9 |

**Table 4. Summary of data submitted.**

should be noted that these give asymmetric intervals around '*p*'.

The PSQ-10 scores were highly skewed, consequently a non-parametric ranking method was used to examine variances; in this case the Kruskal-Wallis rank test.

## RESULTS

### Case mix

The participating centres differed in terms of the area they serve, the health of their client populations and the interventions that they offer their service users. These were described using an Office of National Statistics (ONS) area classification, often used in the NHS to describe Health Authority Populations. For the purposes of this study, the classification applies to the principal Health Authority served by the centre.

The timescale over which the data was collected did vary from centre to centre. Some centres sent operation data as soon as they had it and sent in whatever outcome data they were able to obtain. Other centres only sent in episodes where a complete or nearly complete set of surgical, outcome and patient satisfaction data was available. As can be seen from Table 4, this affected the completeness of data from one centre to another. The implications of this upon the comparability of centres are discussed later in the paper.

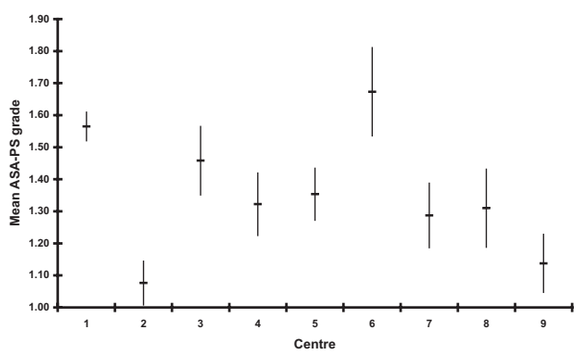


**Figure 1. Mean ASA Scores with 95% confidence intervals.**

The ASA grade of treated patients differs between centres. In three centres, over half of the submitted episodes involved patients with an ASA score of more than one.

ASA-PS capture was very good, with most centres having 100% reporting, although some were missing from early submissions from centre 1, where the overall capture was 63.3%

At 95% CI, it would appear that there are significant differences between samples, centres 1 and 6 having caseloads with markedly higher ASA-PS scores, and centres 2 and 9 having relatively low scores (Figure 1).

## SURGICAL PROCEDURES

A further indication of the differences in case mix was the way in which the samples differed in terms of range of surgical techniques used and the number of individual procedures performed in each episode. One centre submitted audited episodes containing 51 different procedure types, whereas one submitted data with sixteen. The mean number of procedures per episode varied from 1.46 to 2.14.

It is important to illustrate the variation in the types of cases the centres submitted to the project. One way to do this is to look at the most common operations performed. Table 5 lists the five most common procedures per centre. As was stated earlier, each procedure was given a numeric code which could be subdivided into procedure variations. For the purposes of this analysis, procedures of a particular generic type were aggregated. For example Austin capital osteotomies (code 7.1) and Mitchell capital osteotomies (code 7.3) along with any other variants are all classified as simply capital osteotomies.

In Table 5, each of the procedures are calculated as a percentage of the total number of procedures carried out by the centre. In all centres except for centres 4 and 5, lesser arthroplasty was the most commonly performed intervention in the cases submitted.

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## OTHER TREATMENT VARIABLES

The three other dimensions of treatment captured by the dataset are diagnostic services, drugs and the use of fixations and implants. These are important treatment variables and capturing them in this way will facilitate exploring their relationship with outcomes. Also, interesting variations in these aspects of treatment were observed. However for the sake of brevity, just summary data on fixations and implants are presented here.

Table 6 shows the percentage of episodes in each centre where any given fixation or implant was used. The uppermost row shows the proportion of episodes in which none were used. As can be seen there is considerable variation in the extent of their use.

So far, we have summarised the data that describe the kinds of surgery performed. However the most important feature of this data set is the ability to match episodes to outcomes. Clinical sequellae reported post-operatively are summarised in the Table 7. Only those sequellae observed in more than 1% of all cases are

| Centre | No. of procedures | Procedures performed | % of all procedures |
|---|---|---|---|
| 1 | 309 | Lesser arthroplasty | 17.4 |
| | 287 | Capital osteotomy | 16.2 |
| | 105 | Hallux osteotomy | 5.9 |
| | 104 | Neurectomy | 5.9 |
| | 100 | Hardware removal | 5.6 |
| 2 | 177 | Lesser arthroplasty | 27.4 |
| | 154 | Hallux osteotomy | 23.8 |
| | 143 | Capital osteotomy | 22.1 |
| | 28 | Lesser metatarsal osteotomy | 4.3 |
| | 25 | Hardware removal | 3.9 |
| 3 | 97 | Lesser arthroplasty | 21.0 |
| | 85 | Capital osteotomy | 18.4 |
| | 36 | 1st ray excisional arthroplasty | 7.8 |
| | 26 | Lesser amputation | 5.6 |
| | 24 | Hallux osteotomy | 5.2 |
| 4 | 64 | Capital osteotomy | 15.1 |
| | 62 | Lesser arthroplasty | 14.6 |
| | 38 | Nail ablation | 8.9 |
| | 36 | Neurectomy | 8.5 |
| | 28 | Hardware removal | 6.6 |
| 5 | 69 | Greater amputation | 21.5 |
| | 68 | Lesser arthroplasty | 21.2 |
| | 42 | Capital osteotomy | 13.1 |
| | 24 | Lesser metatarsal osteotomy | 7.5 |
| | 19 | Hardware removal | 5.9 |
| 6 | 49 | Lesser arthroplasty | 30.1 |
| | 20 | Capital osteotomy | 12.3 |
| | 15 | Hallux osteotomy | 9.2 |
| | 11 | 1st ray excisional arthroplasty | 6.7 |
| | 10 | Biopsy of skin | 6.1 |
| 7 | 49 | Lesser arthroplasty | 26.2 |
| | 45 | Hallux osteotomy | 24.1 |
| | 41 | Capital osteotomy | 21.9 |
| | 14 | Lesser metatarsal osteotomy | 7.5 |
| | 7 | Whole cheilectomy | 3.7 |
| 8 | 54 | Lesser arthroplasty | 51.9 |
| | 19 | Lesser metatarsal osteotomy | 18.3 |
| | 12 | Capital osteotomy | 11.5 |
| | 3 | Hallux osteotomy | 2.9 |
| | 2 | Multiple metatarsal osteotomy | 1.9 |
| 9 | 26 | Capital osteotomy | 18.1 |
| | 19 | Lesser arthrodesis | 13.2 |
| | 14 | Lesser metatarsal osteotomy | 9.2 |
| | 13 | Hallux osteotomy | 9.0 |
| | 10 | Neurectomy | 6.9 |
| | 10 | Tendon lengthening | 6.9 |
| | 10 | Prosthetic joint implant | 6.9 |

**Table 5. Five most commonly-performed procedures per centre.**

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shown here. The methodological implications of comparing small reported incidences are dealt with later in the paper.

Each outcome is expressed as a percentage of all the episodes for that centre where both operative data and follow-up data were made available.

It was anticipated that a number of sequellae would appear so infrequently that separate classification would not usefully add to the dataset, so an 'other' category was provided. However the range of these rarer sequellae is such that, when added together, they account for the largest problem group.

Note that these data show the incidence of each clinical feature as a proportion of all the episodes. When added to the percentage of episodes where no problems were reported, the total may exceed 100% as some episodes had several sequellae associated with them.

There does appear to be variation between centres, particularly in more commonly-occurring outcomes such as infections. Also in centre 1, we see a greater range of reported outcomes as would be expected owing to the greater range of procedures performed there. Confidence interval calculations did not suggest that any of these variations were significant, possible reasons for this are highlighted in the discussion section below.

It was also assumed that there would be variation between cohorts undergoing certain procedures. More complex and invasive procedures were expected to be associated with a higher incidence of adverse outcomes.

Two common procedures were picked to demonstrate this point, capital osteotomies and lesser arthroplasties. These were chosen because both are quite common, and one is more invasive with more potential for the development of a range of sequellae.

Lesser arthroplasties are often done in combination with other more invasive procedures in some centres. These episodes were excluded from the lesser arthroplasty cohort, although multiple arthroplasties were left in. This reduced the potential sample size, but ensured that these were reasonably homogeneous in terms of the degree of invasiveness. For the capital osteotomy cohort, episodes which contained other procedures as well as osteotomies were included. This appears anomalous, but the aim here is not to compare outcomes of the two procedures *per se* but to explore how the sensitive the system is at detecting differences between cohorts where demonstrably different procedures were used. As expected, differences emerged but surprisingly not to a statistically significant degree (Table 8).

## PATIENT SATISFACTION RESULTS

The following tables summarise the results of the PSQ-10s submitted with the surgical data. Results from only a few of the questions are included here.

In all of the following tables the number of responses are expressed as a percentage of the number of questionnaires returned for each centre. The first collection of tables summarise all of the survey data collected.

The responses from question 4 (Table 9) are interesting as they allow comparison between patient perceptions of post-operative complications with those of clinicians.

The responses to question 5 (Table 10) allow comparison of patient's perception of post operative pain to be compared not just to different procedures, but also to different analgesic prescribing practices.

The time taken to return to the patient's usual footware (Table 11) is an important dimension of outcome. The responses to the questions in tables 12 and 13 concern patient perceptions of outcome.

These responses can be obtained for cohorts defined by any of the variables in the dataset. Analysis of them does highlight some differences between centres. Further work is needed to determine to what extent this variation is due to process rather than case mix. For example, we could look at the responses to individual questions by different procedure cohorts.

It was hoped that applying a simple scoring system may offer a useful shorthand measure to signal differences in patient-perceived experience of treatment to another.

It soon became apparent that the scoring system applied to the instrument clustered scores toward the maximum for patients who were generally satisfied, with scores rapidly falling off for those reporting a less favourable experience. Also the mean scores show a remarkable consistency across centres. This raised questions about the overall sensitivity of PSQ-10, but with the application of a non-parametric ranking test for significant differences, we find that they do differ across centres (Table 14).

If we draw cohorts based upon the procedures used earlier, we can see that differences emerge here too. Again, Kruskal-Wallis analysis suggests these are significantly different results (Table 15).

Note that the sample sizes are different to the cohorts selected to examine sequellae, as this example uses cases where the PSQ-10 has been returned, rather than those for which the clinical follow-up proforma has been submitted.

## DISCUSSION

There is a range of methodological issues associated with this project that must be highlighted. Firstly, in projects such as this it is necessary to ensure that data are collected in a consistent manner across settings. Even in this pilot, this has not always been the case. There has been some sampling variation; some centres submitting all of the surgical data that they could collect to the project over a given period, followed by whatever follow-up data and survey responses that they could retrieve. Other centres batched their returns, only submitting data where all or nearly all of the follow-up and survey data was available. This latter approach may result in these episodes being self-selecting.

There may have been different criteria applied to determining the presence of some of the sequellae despite issuing a guidance manual with unequivocal definitions of all of the items in the data set. For example, it may be that variations in infection rate are due to centres differently interpreting the definitions of infection provided in the project manual. There have been no systematic audits of data quality against original records to check this.

Another problem is the interpretation of variance. Routine observation of practice and variances in outcome is an important quality control technique. All other things being equal, high incidences of adverse sequellae will be associated with certain causal factors. However, specialties such as podiatry, whose practice is largely safe and effective, have a real problem using this method. The incidences of many sequellae are so small, that very large samples will be needed to obtain the required statistical power to highlight cohorts that have significantly different outcomes. This is a common problem with analysis of incidence of uncommon outcomes, which has been encountered in performance measurement initiatives in other specialties, such as cardiology.[11,12] Also this raises the complex issue (not debated here) as to the extent to which variation which has no statistical significance is clinically significant and vice versa.

If significant variance is found, it should be determined whether this is just due to differences in case mix or because centres are using different treatment processes. However the case mix indicators captured by PASCOM are currently quite limited. The ASA-PS grade may offer a useful measure, and certainly there appear to be marked differences in mean scores for the centres concerned. There is little literature on ASA-PS relevant to podiatry.

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| | Centre | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Fixation | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| None used | 57.6% | 45.7% | 60.0% | 56.8% | 50.7% | 73.1% | 39.6% | 78.9% | 32.5% |
| Staple | 4.6% | 0.3% | 12.2% | 7.0% | 0.7% | nil | nil | nil | nil |
| Wire external | 7.0% | 0.3% | 8.1% | 9.0% | Nil | nil | nil | nil | 18.8% |
| Wire internal n.o.c * | 3.7% | nil | 5.9% | 1.5% | Nil | nil | nil | nil | nil |
| Wire internal threaded | 21.5% | 46.3% | 14.1% | 15.6% | 2.7% | 19.2% | 53.5% | 21.1% | nil |
| Wire internal smooth | 2.0% | 1.5% | 2.2% | 5.5% | 31.3% | 9.6% | 3.0% | nil | nil |
| Screw n.o.c* | 4.8% | 0.3% | 13.3% | 6.0% | 0.7% | nil | nil | nil | nil |
| Screw A.O | 9.8% | 34.0% | 7.0% | 13.6% | 38.7% | 11.5% | 40.6% | nil | nil |
| Screw M3X | 11.8% | 2.6% | Nil | 7.5% | Nil | nil | 5.0% | nil | 48.8% |
| Screw cannulated | 0.2% | 0.3% | 0.4% | 0.5% | Nil | nil | nil | nil | 2.5% |
| Joint n.o.c* | nil | nil | Nil | nil | 1.3% | nil | nil | nil | nil |
| Joint swanson one-part. | 0.8% | nil | 1.1% | 3.5% | Nil | nil | nil | nil | nil |
| Plate | 2.8% | 0.3% | 0.4% | 2.5% | 1.3% | 1.0% | nil | nil | 10.0% |
| Drain | 0.7% | 0.3% | 0.4% | nil | 6.0% | nil | nil | nil | nil |
| Anchor screw | 0.5% | nil | Nil | 0.5% | 0.7% | nil | nil | nil | nil |

**Table 6. Percentage of episodes where fixations and implants were used.**

| Procedure | Centres | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | All |
| Avascular necrosis | 0.2% | nil | nil | nil | nil | nil | nil | nil | nil | 0.1% |
| Bone union delay | 0.2% | nil | nil | 0.8% | nil | nil | nil | nil | 1.3% | 0.2% |
| Callus development | 1.4% | nil | 0.7% | 1.6% | nil | 1.0% | nil | nil | nil | 0.7% |
| D.V.T | 0.5% | 0.3% | nil | nil | 1.0% | nil | 1.0% | nil | nil | 0.3% |
| Digital periostitis | 0.5% | nil | nil | 1.6% | nil | 1.9% | nil | nil | nil | 0.4% |
| Fixation movement | 1.2% | 1.6% | 1.3% | 5.5% | nil | nil | nil | 2.9% | 1.3% | 1.5% |
| Fixation problem other | 0.5% | nil | 0.7% | nil | 1.0% | nil | 1.0% | 1.4% | nil | 0.4% |
| Fracture of fixation | 0.2% | nil | nil | nil | nil | nil | nil | nil | nil | 0.1% |
| Incision line healing | 4.0% | 0.3% | 2.0% | 7.0% | nil | 4.8% | 2.0% | 4.3% | nil | 2.7% |
| Infection proven | 1.4% | 3.2% | 0.7% | 2.3% | 2.9% | nil | 2.0% | nil | 6.4% | 2.0% |
| Infection suspected | 2.1% | 4.2% | 1.3% | 3.9% | 2.9% | 2.9% | 6.0% | 5.7% | 5.1% | 3.3% |
| Joint pain increased | 1.6% | 0.3% | 1.3% | 1.6% | nil | 2.9% | nil | 1.4% | 2.6% | 1.2% |
| Medication side effect | 0.7% | nil | 0.7% | 3.1% | 1.9% | 1.9% | 2.0% | nil | nil | 1.0% |
| Metatarsal fracture | nil | 0.6% | nil | nil | 1.0% | nil | nil | nil | nil | 0.2% |
| Motor power loss | nil | nil | 0.7% | nil | 1.0% | nil | nil | nil | nil | 0.1% |
| No shoes at six months | 0.2% | nil | nil | 0.8% | nil | nil | nil | nil | nil | 0.1% |
| Other | 3.1% | 1.3% | 1.3% | 3.9% | 12.4% | 6.7% | nil | 1.4% | 3.8% | 3.3% |
| Pain around site of surgery | 1.6% | 0.3% | 3.4% | 3.9% | 2.9% | 11.5% | nil | 1nil | 3.8% | 2.9% |
| Patient non compliance | 1.6% | nil | 0.7% | 4.7% | 1.0% | 1.9% | nil | 2.9% | nil | 1.3% |
| PONV | 1.6% | nil | nil | 2.3% | 1.9% | nil | nil | nil | nil | 0.8% |
| Poor healing | 0.7% | nil | 0.7% | 1.6% | nil | nil | nil | nil | nil | 0.4% |
| Poor pain control | 4.2% | 0.3% | 1.3% | 1.6% | 1.9% | 2.9% | 2.0% | 2.9% | 3.8% | 2.4% |
| Recurrence | 4.0% | 0.3% | nil | 2.3% | nil | 1.0% | nil | 2.9% | nil | 1.6% |
| Scar line | 1.4% | 5.1% | 6.0% | 0.8% | 1.0% | 3.8% | nil | 2.9% | 1.3% | 2.7% |
| Sensory loss (large) | nil | nil | 0.7% | nil | nil | nil | nil | nil | nil | 0.1% |
| Sensory loss (small) | 0.9% | 1.0% | nil | 1.6% | nil | 2.9% | nil | 2.9% | nil | 1.0% |
| Skin necrosis | nil | nil | nil | 0.8% | nil | nil | nil | nil | nil | 0.1% |
| Stitch problem | 0.5% | 0.6% | nil | nil | 1.0% | 1.0% | nil | nil | nil | 0.4% |
| Stump neuroma | 1.2% | nil | nil | nil | nil | nil | nil | nil | nil | 0.3% |
| Swelling at six months | 1.6% | 1.3% | 2.7% | 4.7% | nil | nil | 3.0% | 1.4% | 2.6% | 1.8% |
| Transfer metatarsalgia | 1.9% | 0.3% | 3.4% | 1.6% | nil | 1.0% | nil | nil | nil | 1.2% |

**Table 7. Percentage incidence in reported clinical sequellae in all episodes.**

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| | Capital osteotomy cohort n=168 | | | Lesser artroplasty cohort n=119 | | |
|---|---|---|---|---|---|---|
| Sequellae | Incidence | LCI | UCI | Incidence | LCI | UCI |
| Avascular necrosis | 0.84% | 0.04% | 5.28% | nil | 0.00% | 2.79% |
| Bone union delay | 0.84% | 0.04% | 5.28% | nil | 0.00% | 2.79% |
| Callus development | 0.01% | 0.07% | 3.91% | 0.60% | 0.03% | 3.77% |
| D.V.T | nil | 0.00% | 3.90% | nil | 0.00% | 2.79% |
| Digital periostitis | nil | 0.00% | 3.90% | 1.19% | 0.21% | 4.68% |
| Fixation movement | 4.20% | 1.56% | 10.02% | nil | 0.00% | 2.79% |
| Fixation problem other | 0.01% | 0.07% | 3.91% | nil | 0.00% | 2.79% |
| Fracture of fixation | nil | 0.00% | 3.90% | nil | 0.00% | 2.79% |
| Incision line healing | 3.36% | 1.08% | 8.90% | 1.19% | 0.21% | 4.68% |
| Infection proven | 0.84% | 0.04% | 5.28% | 1.19% | 0.21% | 4.68% |
| Infection suspected | 3.36% | 1.08% | 8.90% | 4.17% | 1.84% | 8.73% |
| Joint pain increased | 2.52% | 0.65% | 7.74% | 0.60% | 0.03% | 3.77% |
| Medication side effect | 0.84% | 0.04% | 5.28% | 1.19% | 0.21% | 4.68% |
| Metatarsal fracture | nil | 0.00% | 3.90% | nil | 0.00% | 2.79% |
| Motor power loss | 0.84% | 0.04% | 5.28% | nil | 0.00% | 2.79% |
| No shoes at six months | nil | 0.00% | 3.90% | 0.60% | 0.03% | 3.77% |
| Other | 0.84% | 0.04% | 5.28% | 1.79% | 0.46% | 5.54% |
| Pain around site of surgery | 3.36% | 1.08% | 8.90% | 3.57% | 1.46% | 7.96% |
| Patient non compliance | 2.52% | 0.65% | 7.74% | 0.60% | 0.03% | 3.77% |
| PONV | 2.52% | 0.65% | 7.74% | nil | 0.00% | 2.79% |
| Poor healing | nil | 0.00% | 3.90% | nil | 0.00% | 2.79% |
| Poor pain control | 5.88% | 2.60% | 12.18% | nil | 0.00% | 2.79% |
| Recurrence | nil | 0.00% | 3.90% | 0.60% | 0.03% | 3.77% |
| Scar line | 1.68% | 0.29% | 6.54% | 4.76% | 2.23% | 9.49% |
| Sensory loss (large) | 0.84% | 0.04% | 5.28% | nil | 0.00% | 2.79% |
| Sensory loss (small) | nil | 0.00% | 3.90% | 0.60% | 0.03% | 3.77% |
| Skin necrosis | nil | 0.00% | 3.90% | nil | 0.00% | 2.79% |
| Stich problem | 0.84% | 0.04% | 5.28% | 1.79% | 0.46% | 5.54% |
| Stump neuroma | nil | 0.00% | 3.90% | nil | 0.00% | 2.79% |
| Swelling at six months | 1.68% | 0.29% | 6.54% | 1.79% | 0.46% | 5.54% |
| Transfere metatarsalgia | 4.20% | 1.56% | 10.02% | nil | 0.00% | 2.79% |

**Table 8. Reported sequellae; capital osteotomy cohort compared to lesser arthroplasty cohort.**

| | All | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| No problem | 70.2% | 66.3% | 74.5% | 72.4% | 75.8% | 64.3% | 77.8% | 76.6% | 66.7% | 62.1% |
| Yes minor problem | 24.6% | 26.9% | 23.8% | 25.0% | 18.2% | 33.3% | 13.0% | 22.3% | 17.9% | 34.5% |
| Yes major problem | 4.1% | 6.7% | 1.7% | 2.6% | 6.1% | 2.4% | 9.3% | 1.1% | 2.6% | 3.4% |

**Table 9. (Q4) Did you have a problem after your operation?**

| | All | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Excellent /minimal pain | 35.8% | 39.6% | 37.7% | 42.1% | 39.4% | 31.0% | 35.2% | 23.4% | 23.1% | 32.8% |
| Some pain | 53.9% | 53.4% | 52.0% | 43.4% | 51.5% | 61.9% | 57.4% | 60.6% | 57.7% | 60.3% |
| Completely ineffective | 7.6% | 6.2% | 7.9% | 14.5% | 9.1% | 7.1% | 3.7% | 13.8% | 3.8% | 5.2% |
| Not stated | 1.5% | 0.8% | 2.3% | Nil | nil | nil | 3.7% | 2.1% | 2.6% | 1.7% |

**Table 10. (Q5) After the operation, how effective was your pain control?**

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| | All | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| By 2 weeks | 15.6% | 7.3% | 26.5% | 3.9% | 12.1% | 4.8% | 14.8% | 38.3% | 14.1% | 6.9% |
| By 4 weeks | 23.4% | 23.3% | 31.8% | 19.7% | 18.2% | 16.7% | 16.7% | 26.6% | 12.8% | 10.3% |
| By 6 weeks | 24.1% | 26.4% | 17.5% | 34.2% | 21.2% | 28.6% | 22.2% | 17.0% | 20.5% | 46.6% |
| By 8 weeks | 22.3% | 26.2% | 14.2% | 26.3% | 27.3% | 31.0% | 35.2% | 8.5% | 29.5% | 25.9% |
| By 12 weeks | 0.5% | 0.8% | nil | Nil | nil | 2.4% | Nil | 1.1% | 1.3% | nil |
| By 6 months | 7.4% | 10.4% | 4.0% | 9.2% | 9.1% | 11.9% | 7.4% | 5.3% | 1.3% | 10.3% |
| After 6 months | 2.8% | 3.6% | 2.0% | 5.3% | 12.1% | 2.4% | 1.9% | nil | 1.3% | nil |
| Still can't wear | 0.6% | 0.8% | 0.3% | Nil | nil | Nil | Nil | nil | 3.8% | nil |
| Not stated | 2.1% | 1.3% | 3.6% | 1.3% | nil | 2.4% | 1.9% | 3.2% | 2.6% | nil |

**Table 11. (Q6) When could you get back into your shoes?**

| | All | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Much better | 66.0% | 54.1% | 80.5% | 75.0% | 69.7% | 40.5% | 70.4% | 81.9% | 51.3% | 67.2% |
| Better | 23.1% | 28.0% | 14.6% | 19.7% | 24.2% | 52.4% | 24.1% | 16.0% | 26.9% | 24.1% |
| The same | 3.1% | 7.0% | 1.0% | 1.3% | 3.0% | nil | nil | nil | 2.6% | 1.7% |
| A little worse | 2.6% | 4.1% | 1.3% | 1.3% | nil | 4.8% | 1.9% | nil | 3.8% | 3.4% |
| Deteriorated | 2.1% | 4.9% | nil | nil | nil | nil | 1.9% | 2.1% | nil | 3.4% |
| Not stated | 2.0% | 1.8% | 2.6% | 2.6% | 3.0% | 2.4% | 1.9% | nil | 2.6% | nil |

**Table 12. (Q8) How would you describe your original foot condition since treatment?**

| | All | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Yes | 85.7% | 79.8% | 92.1% | 94.7% | 90.9% | 83.3% | 81.5% | 95.7% | 80.8% | 77.6% |
| In part | 5.3% | 9.1% | 2.3% | 1.3% | 3.0% | 4.8% | 5.6% | Nil | 1.3% | 17.2% |
| No | 5.4% | 9.1% | 3.0% | 2.6% | 6.1% | 4.8% | 7.4% | 3.2% | 1.3% | 5.2% |
| Not stated | 2.4% | 2.1% | 2.6% | 1.3% | Nil | 7.1% | 5.6% | 1.1% | 3.8% | Nil |

**Table 13. (Q10) Were the original expectations that you stated at the beginning of this questionnaire met?**

| Centre | n | mean score | Mean rank |
|---|---|---|---|
| 1 | 386 | 81.89 | 497.91 |
| 2 | 302 | 88.89 | 645.01 |
| 3 | 76 | 87.23 | 588.65 |
| 4 | 33 | 85.85 | 577.65 |
| 5 | 42 | 82.17 | 447.96 |
| 6 | 54 | 84.42 | 544.12 |
| 7 | 94 | 88.35 | 608.07 |
| 8 | 68 | 84.53 | 532.07 |
| 9 | 58 | 83.10 | 465.11 |
| Total | 1113 | | |

$X^2 = 49.13$, $p<0.001$

**Table 14. Mean PSQ-10 scores and Kruskal-Wallis rank test results for PSQ-10 responses, all centres.**

| Group | N | Mean score | mean rank |
|---|---|---|---|
| Lesser arthroplasty (only) | 143 | 90.31 | 306.56 |
| Capital osteotomy (all) | 361 | 84.21 | 231.09 |
| Total | 504 | | |

$X^2 = 27.59$, $p<0.001$

**Table 15. Kruskal-Wallis rank test results for mean PSQ-10 scores, lesser arthroplasty cohort vs. capital osteotomy cohort.**

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Some evidence from orthopaedics suggests ASA-PS is a good predictor of a range of serious post-operative sequellae, but doubts have been expressed as to its sensitivity to less severe adverse outcomes.[13,14] The relationship between ASA-PS and outcome is something which will be explored in greater detail during the course of the project.

Arguably the most important case mix indicator is that of diagnosis, which is conspicuously absent from the current data set. The reason for this is that when the Nene college project was run, the range of surgical techniques in the sample was relatively small and the operations themselves were reasonably robust indicators of the patient's main presenting complaint. To an extent this still holds true, for example a patient undergoing a neurectomy will clearly have a diagnosis of neuroma. However there was no scope for recording significant co-morbidities such as arthritis or diabetes, or indeed to reflect different stages in advancement of a given pathology The project team are currently working methods of capturing these data.

The discussion of variance is to some degree academic. Sequellae appear to vary across the centres, but not to a statistically significant degree, despite significant variations in case mix. We can also tell that there is considerable process variation by looking at the type of surgery employed, the varying use of fixations and implants (Table 6) and the prescribing of drugs (data not presented here). Even when we abandon looking for variation between centres and compare large cohorts undergoing very different types of surgery, we still see no significant variation. So why is this? There are a number of possible reasons.

As has been stated, the incidences of the sequellae in question are very small. This means that any variation will have to be detected across large samples to be considered significant. We also must consider the possibility that some of the variations in process or case-mix may be simply too marginal to affect outcome greatly. The extent to which this is the case will become clearer as more data are submitted.

As even a casual observer of the clinical statistics literature will be aware, there are controversies concerning the interpretation of variance and what significance actually is. This analysis has followed the very conventional 95% route, but there are some authorities which persuasively argue that this is insufficient to provide hard evidence of real process variation.[15]

Also we must consider that various factors could be cancelling each other out. For example, less effective interventions may be being performed on relatively healthier patients in one centre giving a similar sequellae profile to another centre using more effective treatment on patients with more advanced or complex disease. This would require the use of a multi-level approach to analysis to investigate.

The causal factors of the scarcest sequellae will probably never be elucidated using this (or any other) system. However, with more data it may be possible to build risk-adjustment models for the more common problems, such as post-operative infection.

There are some other methodological issues with the survey questionnaire. This instrument was borrowed (largely intact) from the Nene college work. The individual questions were not tested for face validity and sensitivity at the time. Analysis of variance using the scoring system is complicated by the tendency for the scores to cluster near the upper end of the scale. Despite these apparent drawbacks, PSQ-10 appears to have more sensitivity to variation in centre or process than the incidence of sequellae. This is understandable, as it is influenced by a greater range of factors than purely the pathological ones which determine clinical outcome.

This analysis has highlighted future priorities of the project. Some development of the data set is needed. The need for better case mix measures has been highlighted earlier. Also, the system does have the flexibility to 'bolt on' a range of pre and post measures that can be correlated with treatment variables.

These could consist of specialist measures such as the American Orthopaedic Foot and Ankle Society rating scales,[16] which has been used successfully in the US, or possibly more generic functional or health profile measures. In the short-term however, the project team have two aims. Firstly, to see what PASCOM can offer in the detailed examination of particular processes or outcomes and secondly, to re-examine cross-centre variance using multi-level analysis techniques.

## CONCLUSION

So what can a project like PASCOM contribute to podiatry? At first sight, the methodological problems appear very limiting in a project that seeks to provide a system for systematically comparing treatment variables and outcome, particularly compared to other methods such as case controlled studies.

However, case-controlled studies belong in a family of tools and techniques designed to address specific prior research questions. PASCOM should be seen as routinely collected data in thinking about how it can be used. It has much in common with data set ssuch as Hospital Episode Statistics (HES). However, whereas HES must support managerial and organisational data as well as providing clinically useful information, this data set is designed for clinical needs from the outset. Routinely collected data should be seen as the starting point for the collection and analysis of clinical evidence. As David Sackett, a pioneer of evidence-based medicine (EBM) points out, the first stage of EBM practice is the formulation of answerable clinical questions.[17] Work like this, through examining variance, can suggest what some of these questions should be. This could prompt further study, either of the cohorts already selected or through prospective research, perhaps using case-controlled methods which could account for confounding factors.

Secondly, it represents the largest published body of outcome data relating to foot surgery in the UK. Not only does this contribute to the clinical evidence base, it also has implications for informed consent. An important component of consent is the patient obtaining a realistic assessment of what they can expect from treatment. Data such as these can assist the practitioner in assessing the probability of a successful outcome.

Thirdly, the project offers some unique development opportunities for the future. The development of a podiatric data set in itself is arguably a worthwhile achievement. Having developed it, there are a significant (and growing) number of podiatrists who are all collecting information the same way, who work collaboratively and can discuss outcomes freely and frankly. These are essential prerequisites to any large-scale scrutiny of clinical outcomes.

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