

# Clinical Audit Report: Doncaster Podiatric Surgery Service

Anthony Maher. FCPodS. Specialist Registrar in Podiatric Surgery  
Anthony Wilkinson. FCPodS. Consultant Podiatric Surgeon

The department of Podiatric Surgery in Doncaster has always been keen to assess patient outcomes following surgical intervention. The standard tool for data collection in podiatric surgery within the UK is PASCOM (Podiatric Audit of Surgery and Clinical Outcomes). This system was introduced to Doncaster for routine data collection in 2004, although it was not fully implemented until September 2006. Here are presented the PASCOM data collected between September 2006 and May 2010. The department's audit processes are also considered and recommendations made for future audit practices

## AUDIT PROCESS

The audit process was built around the PASCOM audit system. PASCOM was devised by David Tollafeld in the 1990s and captured data relating to patient demographics, surgical activity, complication rates and patient satisfaction. At the time of the study, users of the system were required to enter data into a customised Microsoft Access Database. In 2010 the system was overhauled and rebranded PASCOM-10. The system is now accessible online at [www.pascom-10.com](http://www.pascom-10.com) and has a much wider scope incorporating conservative treatment, diagnoses, injection therapies, and patient-reported outcomes.

The PASCOM Microsoft Access database was used for both data entry and analysis. Additional analysis was undertaken in Microsoft Excel and with Analyse-it Version 2.2.<sup>1</sup> The audit data were initially collected in paper form and input on the database retrospectively. Prior to commencement, local approval was sought from the employing Health Trust for the introduction of clinical audit.

Three key points for data collection or activity were identified. The first point of data collection was in theatre when procedure data were collected alongside other variables (see Table 1). The second

point occurred in the post-operative phase when data relating to the post-operative recovery were collected, again in paper form.

The final point occurred at the final check or discharge appointment, which occurred at 3 months for minor procedures (e.g. hammer toe repair, nail surgery, minor soft-tissue procedures) or 6 months for major procedures (osteotomies, arthrodesis). During the final check appointment, patient satisfaction was measured with the PASCOM patient satisfaction questionnaire (PSQ-10).

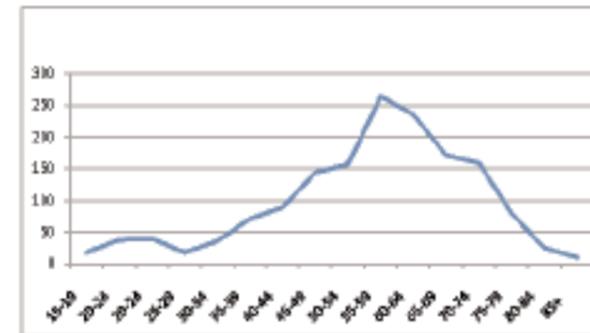
| Data Point | When  | Outcomes   |
|------------|---|--|
| 1          | Operation                                     | Demographics<br>Surgical procedure (s)<br>Anaesthesia<br>Investigations<br>Perioperative medication<br>Duration of surgery |
| 2          | Post operation (initial post operative phase) | After care<br>Dressings<br>Complications   |
| 3          | Final check (3-6 months post operation)       | Complications<br>PSQ-10  |

Table 1. Timetable for data collection using PASCOM 2000.

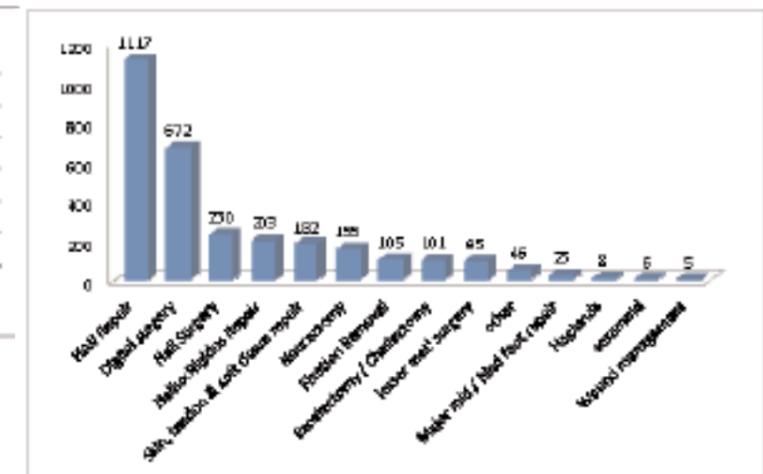
## THE DEPARTMENT

The department is led by a consultant podiatric surgeon and is also a registered training centre. During the audit period, the consultant was joined by podiatric surgical trainees and specialist registrars and a podiatrist who undertook nail surgery procedures. PASCOM does allow for analysis of outcomes for individual clinicians, though for the purposes of this study we were primarily interested in the summary data.

The department currently offers day care surgery at Mexborough Montagu



ABOVE Figure 1. Patient age range



RIGHT Figure 2. Summary of surgical activity.

Hospital. Treatment was typically provided under local anaesthesia.

## AUDIT RESULTS

### Demographics

During the audit period, 1589 patients attended for treatment and were entered into PASCOM. The majority (79.5%) of patients were female. Figure 1 demonstrates the range of age groups treated; 71.4% of patients were below retirement age. Demographic data was incomplete for a total of 35 (2.2%) patients. Missing data is discussed further in 'Lessons Learned'.

As would be expected for elective day care surgery, patients attending for treatment were for the most part systemically well or had minor well-controlled systemic disorders. Health status was summarised by the American Society of Anaesthesiologists (ASA) grading scale. ASA grades range from 1 (good health) to 6 (a brain dead patient). ASA grades 1 and 2 accounted for 98.3% of patients; only 1.7% (26) patients were graded ASA 3. As such it can be assumed that the majority of podiatric surgery patients were generally in good health with only mild systemic disorders. ASA data were missing for 4% of patients.

### Surgical activity

Figure 2 provides a summary of the surgical procedures undertaken during the audit period. A total of 2952 surgical procedures were performed on 1589 patients. The mean number of procedures per patient was 1.86. Hallux valgus and digital deformities accounted for 60.6% of surgical activity. Hallux valgus was most commonly corrected by the scarf osteotomy.

Internal fixation was routinely employed following osteotomy or

arthrodesis, to allow an early return to weight bearing. A total of 2248 fixation devices or implants were inserted during the study period. The most common form of fixation was standard AO screws, accounting for 1675 implants. Kirshner wires were also routinely applied (266). Joint replacement surgery for hallux rigidus was rarely performed, accounting for only 0.75% of procedures. The preferred implant was the Swanson-type hinged double-stemmed silicone device; 22 of these were inserted.

There was a significant failure to collect the complete PASCOM data set pertaining to surgery. As a consequence, the diagnostic imaging and revisions reports have been excluded here. Failing to record revision surgery is a significant oversight because the rate of revision surgery could be considered an indirect guide to the long-term success or failure of surgical intervention within a given department. Additionally, revision surgery is considered to be more technically demanding and at risk of further complications, potentially skewing complication rates or patient satisfaction.<sup>2</sup> An ongoing unpublished study in Doncaster, initiated in 2010, suggests that revision surgery may account for up to 15% of the surgical case load.<sup>3</sup>

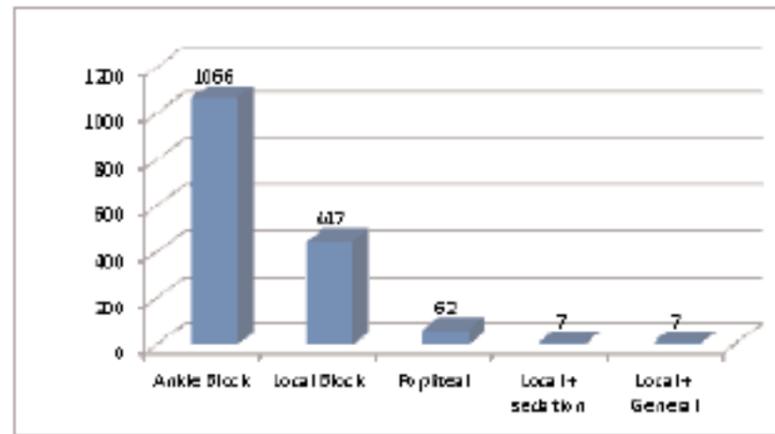
The majority of patients underwent day case surgery with local anaesthesia. By far the most common anaesthetic technique was the ankle block, accounting for 67% of all surgeries (Figure 3). Most procedures were completed under an ankle tourniquet and so there was a relative pressure on speed. Arterial tourniquets are reported to become uncomfortable at between 30 and 60 minutes following application,<sup>4,5</sup> therefore 88.3% of procedures were completed in less than 60 minutes, although it should be noted that procedure duration data were missing for 470 (29.6%) episodes.

In addition to local anaesthesia, medication was typically supplied to patients at the time of their surgery. This fell into three broad categories: analgesics, anti-inflammatory drugs and antibiotics. A total of 2724 separate entries were recorded for medication, equating to 1.7 medications supplied to each patient. The most commonly used medication was co-dramol 10/500mg, which was supplied on 921 occasions. NSAIDs were also frequently utilised in the form of either ibuprofen or diclofenac. Flucloxacillin was the most commonly used antibiotic for prophylaxis, followed by erythromycin and clindamycin.

### Post-operative data

Post-operative data collection included a note of the care received and any complications that may have developed. Unfortunately, 507 (31.9%) patients had no post-operative data collected for their episode and so for the purposes of the audit were considered lost to follow up. This can occur in a busy clinic when clinical activity takes priority over audit activity. However, such an oversight reduces the accuracy of, for example, complication reports.

Table 2 demonstrates the reported complications following podiatric surgery. Complications were recorded in clinic as and when they occurred. However, not all patients returned to the department for management of complications. Post operation, patients may call on the services of their GP or accident and emergency for treatment. Acknowledging this possibility, patients are subsequently questioned at their final check to minimise under reporting. However, it is accepted that the combination of patients lost to follow up and shared care may result in under reporting of complications.



ABOVE Figure 3. Anaesthesia

RIGHT Table 2. Complications following podiatric surgery

| Complication                       | Count      | %    |
|------------------------------------|------------|------|
| • Infection suspected (not proven) | 35         | 2.44 |
| • Pain and / or joint stiffness    | 25         | 1.75 |
| • Medication related               | 13         | 0.91 |
| • Scar line                        | 13         | 0.91 |
| • Other                            | 10         | 0.70 |
| • Complicated healing              | 8          | 0.56 |
| • Transfer metatarsalgia           | 8          | 0.56 |
| • Swelling (abnormal)              | 7          | 0.49 |
| • Fixation related                 | 6          | 0.42 |
| • Infection proven                 | 6          | 0.42 |
| • Recurrence / failed surgery      | 6          | 0.42 |
| • Cannot wear shoes (3mths+)       | 3          | 0.21 |
| • Metatarsal fracture              | 3          | 0.21 |
| • CRPS                             | 1          | 0.07 |
| • DVT (suspected)                  | 1          | 0.07 |
| • DVT (confirmed)                  | 1          | 0.07 |
| • Ischaemia                        | 1          | 0.07 |
| • Patient non compliance           | 1          | 0.07 |
| <b>TOTAL</b>                       | <b>148</b> |      |

Infection, pain and thromboembolic events are perhaps the three most significant complications that can occur following podiatric surgery, given the impact they may have on a patient's quality of life and their ability to cause ongoing morbidity.

Although the proven infection rate was 0.42%, the suspected rate was considerably higher at 2.44%. Other published audits of podiatric surgery have reported proven infection rates of between 1.3 and 2.0%.<sup>6-8</sup> The incidence of suspected infections has previously been reported at 3.3%,<sup>8</sup> while guidance from NICE (Guideline 74; Surgical Site Infection) suggests that at least 5% of patients will suffer an infection following surgery.

A proven infection is one with a microbiological confirmation following culture and sensitivity testing. A suspected infection is a wound that clinically appears infected and is treated empirically with antibiotics before swab results are available. Further to this, surgical wounds are usually closed primarily, so if there is no drainage a wound swab may not always be possible. Given that suspected infections were actively treated, we recommend emphasising this rate (2.44%) to patients, pre operation, when considering the risk of infection. Monitoring of the suspected infection rate may lead to a slight over reporting of the true infection rate.

Twenty five patients (1.75 %) suffered prolonged pain or stiffness at the site of surgery. The most significant form of post-

operative pain is Complex Regional Pain Syndrome (CRPS). This devastating complication is rare, affecting only one patient in this study (0.07%). This figure compares well with previous studies which have reported rates between 0 and 0.12% following podiatric surgery.<sup>6,7</sup>

It is accepted that podiatric surgery is a risk factor for deep vein thrombosis (DVT). In an attempt to minimise this risk we actively prophylax patients who are at increased risk. Methods employed include early mobilisation and hydration, compression stockings and heparinisation. The risk in podiatric surgery has previously been considered low with a reported incidence of 0.3%.<sup>6,8</sup> There was only one confirmed DVT in the current audit.

#### Final check appointment

The final check appointment occurred at either 3 or 6 months following surgery. This gives the clinician an opportunity to review the patient, record any delayed complications and consider the success or failure of the procedure and plan for any further treatment. Unfortunately, as with the post-operative data, there was considerable loss to follow up at final check, with data missing for 549 (34.5 %) patients. It is not possible to determine from the database if patients were truly lost to follow up (failed to attend) or whether there was a failure to implement the audit process.

#### PSQ-10

The final check appointment also offered an opportunity to assess patient

satisfaction, using the PASCOM Patient Satisfaction Questionnaire (PSQ 10).

The PSQ-10 was developed by Tollafeld & Rudge to assess surgical outcomes from the patient's perspective.<sup>8</sup> The questionnaire asks a number of questions pertinent to the patient's experience and generates a summary score, with a maximum possible of 100. This has not been formally validated, although it is a reliable measure with little degradation over time.<sup>9</sup> The scores are typically skewed, as can be seen in Figure 4. Various thresholds have been described for PSQ-10 scores, with a score above 70 considered acceptable for reconstructive forefoot surgery.<sup>10</sup> In effect the lower the score the greater the likelihood that the patient will have suffered an eventful post-operative course or less favourable outcome.

Tollafeld suggests that lower scores are more likely to trigger a complaint or even litigation.<sup>10</sup> The mean PSQ-10 score was 84.2, and the 95% confidence interval was 83.3-85.1. In a study of nine podiatric surgery departments by Tollafeld & Rudge, the mean scores ranged from 81.89 to 88.89.<sup>8</sup> In this audit, a total of 146 patients (14%) had a PSQ-10 score of below 70 and 35 (3.4%) patients had a score of below 50. It is unclear from the database why these patients had lower scores or whether further surgery was required. In summary, taking a PSQ-10 score of 70 as a benchmark, it appears that 86% of those assessed had a satisfactory outcome following podiatric surgery.

The PSQ-10 can be further analysed by reviewing answers to individual questions,

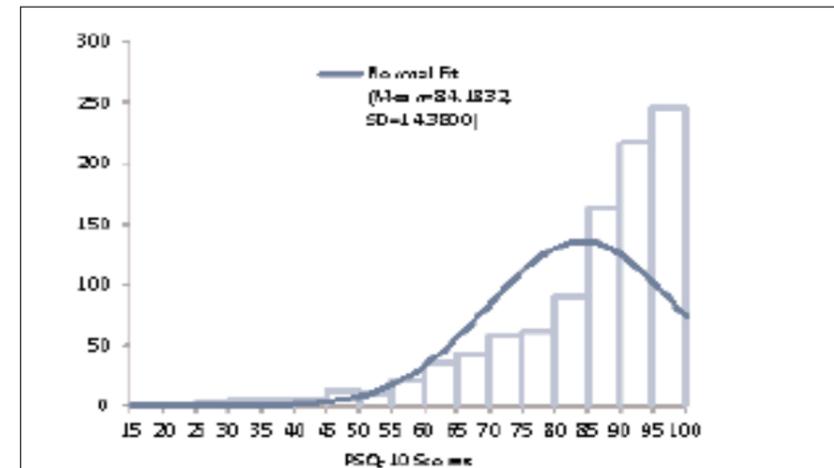


Figure 4. PSQ-10 score distribution

|  |       |   |     |
|--|-------|---|-----|
| <b>Q2 Were the risks of surgery explained?</b>                 |       | <b>Q8 How is your original problem?</b>                           |     |
| No   | 0.3%  | Deteriorated  | 1%  |
| Not sure   | 1%    | A little worse  | 3%  |
| Yes  | 96%   | The same  | 5%  |
| Not stated   | 3%    | Better  | 35% |
|  |       | Much better   | 52% |
| <b>Q4 Did you have a problem after surgery?</b>                |       | Not stated  | 4%  |
| No   | 74%   | <b>Q9 Would you have surgery under the same conditions again?</b> |     |
| Yes, minor   | 25%   | Yes   | 86% |
| Yes, major   | 1%    | No  | 7%  |
|  |       | Not Stated  | 7%  |
| <b>Q4.d How was the problem dealt with?</b>                    |       | <b>Q10 Were your aims met?</b>                                    |     |
| Poorly   | 1.9%  | Not at all  | 2%  |
| Cannot say   | 6.4%  | In part   | 15% |
| Satisfactorily   | 31.4% | Completely  | 77% |
| Excellent  | 52.6% | Not stated  | 6%  |
| Not stated   | 17.4% |   |     |
| <b>Q5 Was the pain medication adequate after your surgery?</b> |       |   |     |
| Completely ineffective   | 4%    |   |     |
| Some discomfort  | 55%   |   |     |
| Minimal pain   | 37%   |   |     |
| Not stated   | 4%    |   |     |

Table 3. PSQ summary

Table 3 presents a summary of answers to key PSQ-10 questions. Pain control was adequate for 92 % of patients, which in turn suggests that clinicians made the right decisions regarding post-operative analgesia.

Almost three quarters of patients reported no problems post operation, which is reflected in the low number of reported complications. A total of 77% of patients felt their aims had been completely met while 87% described their foot condition as better or much better. Interestingly, only 96% of patients remembered that the risks of surgery had

been explained pre operation. All patients attending for podiatric surgery in Doncaster sign duplicate copies of advice leaflets, which are then filed in their notes. Details of advice leaflets along with specific risks and benefits, are also recorded on the consent form.

#### PSQ-10: Returning to footwear

Question 6 of the PSQ-10 asks patients how long it took to return to shoes. This question has different meanings for different patients. Some may be happy with a return to trainers or soft shoes, which usually occurs at 2-3 weeks post

operation. Others may consider the question to mean 'when did you return to your normal shoes?' Despite the possible variability in interpretation, this is an important question for patients and clinicians. Poor shoe fitting is a key reason for patients to seek advice from a podiatric surgeon.

Return to footwear following surgery can also be considered an indirect marker for return to activity. By 6 weeks post operation, 58% had returned to shoes. This point coincides with bone healing and the stage at which we recommend a return to full activity levels following routine forefoot surgery. By 8 weeks, 83% were wearing shoes; 14% of patients took 6 months to return to shoes. Five patients (0.48 %) felt that they could not wear shoes at the time of questioning.

#### LESSONS LEARNED

This audit has demonstrated high levels of satisfaction with podiatric surgery performed as a day care procedure under local anaesthesia. Few patients report serious problems following surgery, and few complications were noted.

However, the significance of the missing 31.9% of patients with no follow-up data at all and the 34.5% of patients with no final check data must be considered. Difficulties in following up patients after treatment are well reported; earlier audits of podiatric surgery have reported response rates of between 38.3 and 95.8%.<sup>8,11,12</sup> The loss to follow up does weaken confidence in the results. We cannot be certain whether missing patients were satisfied with their outcome or whether they suffered complications and sought treatment elsewhere. Nonetheless, there is an emerging trend towards high levels of satisfaction.

A second problem with the current audit, particularly assessment of outcomes, was that we relied wholly on the PSQ-10 to determine the success or failure of treatment. This is not good science. The PSQ-10 was not developed as an outcome measure and is one sided (only measuring patients after treatment). A thorough audit should incorporate a validated instrument for assessing outcomes and, alongside the PSQ-10, clinicians involved in patient care should also have an opportunity to comment on the success or failure of treatment.

A third problem occurred with data collection. There was a systemic failure to collect all relevant data at the time of surgery. This most significantly affected the PASCOM reports relating to investigations, revision episodes, demographics, and duration analysis.

| Outcome  | Target               |
|--|----------------------|
| Final Check  | 6 months             |
| Loss to Follow up  | Less than 30 %       |
| PATSAT score   | >80                  |
| Proven infection rate                                      | <2%                  |
| DVT  | <0.3%                |
| CRPS   | <0.1%                |
| Improvement in MOXFQ scores (new)                          | TBC                  |
| Clinicians Analysis of Outcome (new)                       | Aims wholly met >80% |
| <b>PSQ-10</b>  |                      |
| Q6 Return to footwear by 8 weeks                           | >80%                 |
| Q2 Were the risks explained?                               | >98%                 |
| Q8 How is your original problem?                           | >85%                 |
| Q9 Would you have surgery under the same conditions again? | >85%                 |

Table 4. Benchmark targets

**MOVING FORWARD**

The current audit results will serve as benchmark for future studies against which improvements can be measured. Table 4 details the benchmark targets for future audits. The department has now adopted the latest incarnation of PASCOM

(P-10). This has a number of advantages over earlier systems. First, it is entirely web based, allowing for instant or live data inputting, so there is no longer a need to input data in paper form and transfer to a database, which was always considered a risk for errors. With the new system,

surgical data are entered by the surgeon at the time of surgery directly into the online system. Further to that, the system has inbuilt prompts and checks that attempt to minimise data loss. For example, basic demographic data must be saved before moving onto input procedure data. P-10 also has the additional advantage of being able to generate outcome reports for individual patients at the time of their final check appointment. This immediately highlights any concerns, such as low PSQ-10 scores, which can then be flagged for further assessment.

There are also a number of significant additions to P-10 over earlier versions, including a validated outcome measure in the form of the Manchester Oxford Foot Questionnaire (MOXFQ).<sup>13</sup> The current government has put a particular emphasis on ‘outcomes’ and ‘quality’ in healthcare provision,<sup>14</sup> systems such as PASCOM, which capture patient reported outcomes, are consequently invaluable in providing evidence for quality service provision.

Adopting a new audit tool was only part of the process of improving audit. Administrative systems also had to be in

place to ensure that those patients requiring final checks were offered an appointment. P-10 monitors the numbers of patients waiting for follow-up appointments and those with missing outcomes. These data are made available to clinic administrators, who can then ensure that the right numbers of clinic slots are available for every four-week period of surgery. P-10 also allows for monitoring of loss to follow up, so again we have put administrative mechanisms in place to capture these patients and limit loss. Finally all clinical and administrative staff have received training in PASCOM, and audit has been prioritised as a departmental objective.

**CONCLUSION**

This report has demonstrated the audit results for podiatric surgery over a four-year period. Overall, patients were highly satisfied with the outcome of treatment. Podiatric surgery is a safe option for the treatment of foot pathology. It is associated with a low number of complications, very little post-operative pain and a rapid return to footwear. However, the audit

system failed to follow up a significant number of patients and there was a systemic failure to collect certain data sets. As a consequence of this study, the department has overhauled its approach to audit and set key targets for data collection. We hope to publish our initial findings with the new audit system shortly.

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