Patient-reported outcomes: a new direction for podiatric surgery?

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As a relatively new specialty, podiatric surgery has found audit and service evaluation vital to its continued development. Over the years, a number of departments have published the results of these audits and in doing so have steadily built the evidence base for podiatric surgery.

As the profession developed through the latter part of the 20th Century, so the process of clinical audit evolved. Published audits of podiatric surgery over the years have demonstrated clinical effectiveness, high levels of patient satisfaction and few serious complications.[1-5]

The introduction of computerised systems such as PASCOM in 1996 allowed for the rapid collection of clinical outcomes data at a local and national level.[6] Subsequent reports from PASCOM were generated on an annual basis and made available to Fellows of the College of Podiatry. Reports have been used for peer review and as a means of demonstrating the clinical effectiveness and quality of podiatric surgery in the UK. As an audit tool though, PASCOM had a weakness; it failed to include a validated measure of health outcomes. As such, more recent reviews of surgical procedures and service delivery have relied on alternative instruments such as clinical rating scales or measures of health-related quality of life (HRQOL).

But why do we audit?

Audit of podiatric surgery determines the quality of treatment provided. Quality can be measured through, for example, monitoring of complication rates, satisfaction rates, clinical outcomes, patient outcomes and waiting lists. Other reasons for audit include reflective practice, safety assessments and performance indicators.

As we head into the second decade of the 21st Century, audit is becoming an increasingly important aspect of clinical practice. Lord Darzi's report in 2008 'High Quality Care for All' can be seen as a significant milestone in the development of an audit culture within the NHS.[7] Darzi firmly established 'quality' as a theme in healthcare provision, with the focus placed squarely on patient outcomes. As a result, the quality of services and even individual procedures are judged by the effect they have on patients.

This drive for quality sits alongside the initiatives of NICE, which aim to couple quality and cost-effectiveness in determining which interventions should be supported or funded within the NHS.[8] In his review, Lord Darzi suggested that quality (of service provision) should be a factor in determining service evaluation, funding and provision.

This is further supported by the World Class Commissioning handbook, which recommends preferentially commissioning services that are evidence based.[9] The devolution of commissioning duties to a local level over the next few years is likely to ensure that quality remains a key consideration.

So what evidence do we need to support the provision of podiatric surgery services? In the early days, simple audits of surgical procedures were the norm. However, the goal posts have now significantly shifted towards more robust tools such as Patient Reported Outcomes (PROMs). Amongst others, PROMS have been suggested by Darzi as a measure to determine hospital funding. In December 2008 the Department of Health (DoH) published a document on the 'routine collection of PROMs'.[10] As of April last year, a small number of services were mandated to collect PROMs data pre and post intervention. These data are now being collected and analysed at a national level, with results being fed back to Hospital Trusts.

The project developed by the DoH is at present somewhat limited but, when read alongside Darzi's report, it could be interpreted as highlighting the direction the DoH wishes to take in the future evaluation and funding of services and procedures. Surely it can only be a matter of time before the DoH requests PROMs information from all public sector healthcare providers.

These judgements regarding quality and the use of PROMs were made under the last government. The general election bought a change of government but there is a continued emphasis on quality healthcare provision as judged by patient outcomes. Andrew Lansley MP, Secretary of State for Health, has placed the improvement of patient outcomes at the top of his ministerial agenda.[11]

What are PROMs?

Outcome measures can be defined as 'an instrument, device or method that provide data on the quantity or quality of the result'.[12] Such a definition has its routes within the applied sciences, and refers to the outcome of experiments. In its most simplistic terms, an outcome measure provides a scale for measuring the effect of an intervention (before and after). We routinely utilise outcome measures in clinical practice, perhaps without realising. An example of this would be the visual analogue scale (VAS).

However, the term 'outcome measure' is most typically applied to some form of questionnaire completed either by the clinician or the patient.[13] Perhaps the most recognised outcome measure in healthcare

is the Shortform 36 (SF-36) and its many variants published by the Rand group in North America.[13] Long-standing outcome measures that lower-limb specialists may be familiar with include the foot function index (FFI),[14] Foot health status questionnaire (FHSQ)[15] and more recently the Manchester Oxford Foot questionnaire (MOXFQ).[16] These measures and many others like them are now collectively referred to as PROMs.

What PROMs have in common is that they all measure health-related quality of life. This term suggests that health is only a single (albeit important) component of quality of life. Quality of life may be considered a rather subjective measure, hence the application of techniques learnt in psychology that led to the development of clinimetric testing. The second half of the 20th Century saw the development of numerous clinimetric tests. All shared a desire to measure health-related quality of life. The interest was spurred on by governments and health insurance companies keen to determine the most appropriate treatments or those treatments with the greatest impact on HRQOL.[13]

Measures of HRQOL can be divided into three broad categories: generic; disease specific; and anatomical. The generic scales such as the SF-36 and EQ-5D provide a snapshot of a patient's overall health status and how that impacts on the patient's quality of life. Concerns have been raised over the broad nature of questionnaires such as the SF-36 which has led researchers to develop measures specific to diseases or anatomical regions.[17] Anatomical or regional scales are of relevance to podiatric surgeons who typically treat diseases specific to the foot. These localised pathologies may have a direct and measurable impact on the patient's perspective of their health or their quality of life.

Podiatric surgery and PROMs

It is fair to say that patient-reported outcomes are not routinely collected by UK podiatric surgeons. A recently published long-term follow up of hallux valgus surgery highlighted the weakness of current studies in failing to utilise PROMs.[18] The Cochrane review of hallux valgus interventions also highlighted the lack of PROMs data in research studies, noting that only one study included in their review asked patients if they were better following surgery.[19]

Clinical research is becoming more and more difficult to progress in a realistic timeframe because of ethical and administrative constraints. The DoH support for PROMs, however, will facilitate case series audit and, with careful selection of the audit tool, will allow multiple centres to compare their patient-reported outcomes. For all those with even a passing interest in summarising the outcomes of their surgical care, PROMS represent a practical, quick and easily administered format for providing clear and understandable data.

In the private sector, PROMS are also vital to clinical governance and monitoring of quality. They may also provide a validated measure of pathology prior to surgery, which is a vital defence in case of litigation. Additionally, the division of the provider and commissioning arms of PCTs in England and Wales has led to an opportunity for private sector organisations to provide NHS services. Such organisations will in all likelihood be required to produce PROMS data.

Which PROM should I use?

The sheer wealth of available measures makes this a difficult question to answer. The choice is largely a personal one based on prior experience. The DoH appears to favour the EQ-5D as a measure of a person's overall HRQOL.[20] The EQ-5D comprises five generic questions regarding pain & discomfort, mobility, self care, usual activities, and anxiety and depression.

Comparative EQ-5D data are available for typical population samples including that of the UK.[21] In addition, the EQ-5D has been applied to a range of conditions, allowing comparison of the effect various diseases have on quality of life. For procedures in which PROMs data collection is mandated, the EQ-5D data are collected and analysed centrally.

Alongside the EQ-5D, the DoH recommends using either a disease-specific or region-specific outcome measure. Within podiatric surgery, a region-specific measure would seem to be the most sensible choice. The FHSQ is an example of a region or anatomical outcome measure that has been in existence now for over 10 years.[15] It has previously been successfully applied to outcome measurement in podiatric surgery within Australia.[22] Indeed, the scale was developed and validated for the Australian healthcare system.

That aside, the FHSQ has been utilised more recently in the UK in a paper reviewing the outcomes of day care foot surgery, and found a significant improvement in quality of life for a cohort of 917 patients.[23] In addition to podiatric surgery, the FHSQ has been increasingly utilised to measure the outcomes of conservative intervention.

A recent addition to the list of PROMs instruments is the MOXFQ.[16] This is a significant development in the measurement of foot surgery outcomes and is, in part, a response to the criticisms of the Cochrane review of hallux valgus interventions. The MOXFQ evaluates the impact of foot pathology in three quality-of-life domains: pain and anxiety; walking and standing; and social interaction.

The questionnaire was developed specifically for use in foot surgery, and has been validated in the context of hallux valgus surgery on the premise that this is a commonly operated foot complaint. To confirm construct validity, the new questionnaire was tested against the SF 36 and AOFAS scores. The authors concluded that the MOXFQ was a reliable and valid measure of outcomes in hallux valgus surgery.[16]

Subsequently, the MOXFQ has been applied to the outcomes of orthopaedic hallux rigidus surgery, demonstrating a significant improvement in HRQOL.[24] It has also been repeatedly applied to hallux valgus surgery, demonstrating the positive impact of surgery on HRQOL.[25,26]

The latest incarnation of PASCOM was released in May 2010. The most significant of the new developments in this online audit tool is the inclusion of the MOXFQ outcome measure. For the first time in the UK, it offers podiatric surgeons and podiatrists the opportunity to efficiently collect PROMS data and subsequently analyse the results for all their surgical interventions.

We now have, as a profession, the opportunity to collect wide-ranging PROMs data for our interventions ahead of any governmental demands. Not only that, with strength in numbers we have the ability to demonstrate the value of our profession in a language managers and commissioners understand.

In keeping with the ever-increasing demand for quality, podiatric surgeons have the opportunity to market themselves as the provider of choice for day care foot surgery.

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Further reading on this subject is available on the members website.