

Medical audit

# A prospective study of 1000 hernias: results of the Plymouth Hernia Service

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*Background:* A hernia service within a general hospital was prospectively evaluated to establish whether evidence-based protocols could deliver results comparable to those reported from specialist hernia clinics.

Methods: Protocols were devised according to established models. With the support of a nurse specialist, 1015 patients with inguinal hernia were treated. Quality-of-life analysis was undertaken using the Short Form 36.

Results: Patients ranged in age from 16–98 years (median, 56 years). Ambulatory day-case surgery was achieved in 820 patients (81%), with local anaesthesia in 891 (88%). Wound infection occurred in 10 patients (0.98%). Wound haematoma requiring surgical intervention occurred in three patients. Two patients formed wound seromas that settled spontaneously. One patient developed ischaemic orchitis resulting in testicular atrophy. At 5 days after operation, 91% of patients had returned to normal activity. At 1 year, 7 patients (0.7%) had pain sufficient to limit normal activity or employment. There were 8 recurrences (0.78%) at a median follow-up of 2.5 years. Quality-of-life was enhanced at 1 year postoperatively.

Conclusion: A protocol-driven hernia service within a general hospital can provide patient outcomes comparable to specialist hernia clinics.

Key words: Inguinal hernia - Protocol - Outcome - Specialist nurse

Inguinal hernia is a common condition with approximately 113,000 new cases per annum in England.¹ Specialist hernia centres such as the Shouldice Clinic, the Lichtenstein Hernia Institute, The Hernia Institute of Florida and the British Hernia Centre have achieved recurrence rates of less than 1% with low morbidity and fast return to activity resulting in highly cost-effective treatment of inguinal hernias.³-6

However, a recent leading article suggested that there is relatively little evidence of best practice in inguinal hernia repair being implemented across Britain's NHS.<sup>2</sup> The results of the Plymouth Hernia Service, during its first 3

years of activity indicated that improved patient outcome could be achieved with substantial cost savings.<sup>7</sup>

Devlin and Barwell in the UK, have previously demonstrated that an individual with a specialist interest in inguinal hernia surgery can personally deliver excellent results within existing surgical centres.<sup>8,9</sup> In the US, Deysine and co-workers took this process one step further and organised a clinic for abdominal wall hernias staffed by a number of general surgeons with a special interest in hernia and delivered improved outcome.<sup>10</sup> The Plymouth Hernia Service was based on the Deysine model.

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Ambulatory surgery has been shown to be safe, efficient, convenient, economical and able to soften the emotional impact of operation.<sup>11</sup> Compared to general anaesthesia, local anaesthesia and i.v. sedation have fewer adverse effects on respiratory function, shorter time to home-readiness, lower immediate postoperative pain and higher patient satisfaction.<sup>12,13</sup> Balanced analgesia provided by preoperative non-steroidal anti-inflammatory drugs and postoperative, simple oral analgesics are considered by some authors to be a prerequisite for optimal recovery.<sup>14,15</sup> The Lichtenstein technique with anterior on-lay of a prosthetic mesh has been shown to reduce recurrence rates, compared to other techniques in the hands of general surgeons.<sup>16,17</sup>

## **Patients and Methods**

Since its inception in 1996, the Plymouth Hernia Service has been refined and enhanced. With the assistance of the National Booked Admission Project, the Plymouth Hernia Service now provides a dedicated, nurse-led hernia clinic. This is run in parallel with the senior author's out-patient clinic. General practitioners (GPs) are able to refer directly to the nurse specialist using a dedicated hernia referral form that details inclusion and exclusion criteria.

All patients are provided with an information booklet before consultation in the out-patient clinic. Patients are then assessed pre-operatively by the Hernia Nurse Specialist and provided with verbal information about the clinical care pathway. The latest development by the hernia service is production of a patient information video. The video outlines the hernia care pathway and provides a further opportunity for patients to assimilate information in their own time.

Patients are generally advised to have local anaesthesia depending on the presence or absence of the relative contraindications, including obesity (BMI > 30) or psychiatric disorders. If a patient's home circumstances are suitable they are listed for day-case surgery. A date for surgery is offered to the patient at the initial consultation and may be selected for the convenience of the patient. Elderly men with asymptomatic direct hernias are counselled not to undergo repair in selected cases.

On the day of admission, a brief history and physical examination is undertaken by the admitting surgeon to confirm the diagnosis, and fitness for operation. Antibiotic prophylaxis is not given, nor prophylaxis for thromboembolism in day-cases. 18,19 Intravenous access is established for the administration of sedation or other medication in all instances. A 100 mg Diclofenac suppository is given prior to the insertion of a field block of local anaesthetic (by the surgeon) or induction of general anaesthesia. Intraoperative monitoring of pulse, blood pressure and pulse oximetry is by a nurse assistant or anaesthetist, if available.

Operation in the reported cases was undertaken by the open, tension-free, mesh technique except in cases entered into clinical trials in which other methods of mesh repair were being examined.<sup>20,21</sup>

The hernias were classified according to the Aachen classification as direct, indirect or combined and the size of the defect estimated in centimetres (the tip of a surgeon's index finger is approximately 1.5 cm in diameter.<sup>22</sup>

With the intention to prevent ischaemic orchitis, indirect inguinal sacs were left *in situ* if they extended beyond the pubic tubercle; these sacs were not excised, but transected at the neck and the proximal end transfixed at the internal ring. and distal to the pubic tubercle no dissection was performed in order to preserve the vasculature of the spermatic cord.<sup>23</sup>

Both intra-operative protection of the nerves<sup>24</sup> and prophylactic neurectomy<sup>25</sup> have been advocated to reduce the incidence of inguinodynia. Policy at Plymouth is to preserve the nerves whenever possible, but if the surgeon thinks the nerve has been damaged, then to divide the nerve well laterally and bury the cut end in muscle.

If the operation was performed under general anaesthesia, the wound was infiltrated with 20 ml of 0.5% bupivacaine prior to closure. The wounds were closed with an absorbable subcuticular suture and occlusive dressings applied.

After operation, the patients are reviewed by the Hernia Nurse Specialist and given written postoperative instructions and an information sheet for their GPs. A 3-day prescription for Diclofenac and Cocodamol analgesia is dispensed.

Follow-up is by telephone with the Hernia Nurse Specialist within 24 h. Patients were encouraged to return to activity and work within a few days of operation. Frequent patient contact has been shown to reduce time off work and time to resumption of normal activities for both the patient and their carer. In the reported cases, time taken to return to normal activity and to paid employment was determined by telephone questioning.

Quality-of-life was assessed by the Short Form 36 (SF-36). This is a 36-item questionnaire that measures eight dimensions: physical functioning, role limitations due to physical and emotional problems, social functioning, mental health, energy, vitality and pain and general health perception. The lower the SF-36 score, the greater the adverse impact of the measure being assessed. SF-36 has been shown to be an accurate measure of quality-of-life and has been validated in assessing outcomes after hernia surgery. Quality-of-life data were analysed using analysis of variance with the SPSS (v. 9.0) statistical package under the Windows 95 operating system.

The Plymouth Hernia Service was initially provided by a single consultant surgeon (ANK) and his junior surgical staff, but by the fifth year, the Hernia Nurse

Table 1 Prospective data for the first 1015 patients treated by the Plymouth Hernia Service

Age range	16–98 years
In-patients	195
Day-case	820 (81%)
General anaesthetic	124
Local anaesthetic	891 (88%)

Specialist was supporting 8 general surgeons in the hospital and the modified care pathway as outlined in Figure 1 had been instituted.

#### Results

Between 1 April 1996 and 1 April 2001, 1015 patients underwent inguinal herniorrhaphy within the Plymouth Hernia Service under the care of the senior author (ANK; Table 1).

Pre-operative sedation was used routinely; the most commonly used dose was 2 mg of midazolam (64% of patients). Surgeons of all grades undertook the operations, many for training purposes. Consultants undertook 71% of the operations, registrars 5% and supervised senior house officers did 24% of the surgery.

Of the hernia defects, 38% were direct, 58% were indirect and 4% were combined. The majority of defects were in the range 1.5–3.0 cm, which represents a normal profile of patients similar to other large series that have been published and there was no selection on basis of size of hernial defect; irreducibility being a criterion of exclusion for local anaesthetic day-case operation. The hernial sac was excised in less than 3% of cases; these sacs were dissected free from the spermatic cord and reduced into the preperitoneal space. All hernias were repaired with mesh, the majority using the Lichtenstein technique in a context of 3 clinical trials undertaken during the study period in which a number of patients were randomised to receive mesh configured as a plug or a bilayer. The mean operating time was 38.3 min and the mean size of the skin incision was 7.8 cm.

Complications occurred in a minority of patients (Table 2). The peri-operative complication rate was 2.16% (22/1015) and the recurrence rate (median follow-up 2.5 years) was 0.78% (8/1015). At 1 year, 7 patients (0.7%) had pain sufficient to limit normal activity or employment. This gives an overall complication rate of 2.95%.

Of the patients, 45% were retired and 45% in full or part-time salaried employment. Only 5% of patients were unemployed, while 5% were self-employed. At 5 days after operation, 91% of patients declared that they had returned to normal activities of daily living. Of the patients in employment, the mean delay to return to work was 20.5 days. The proportion of patients returning to work within 10 working days was 39%.

Table 2 Morbidity in the first 1015 patients treated by the Plymouth Hernia Service

Wound infection	10 (0.98%)
Recurrence	8 (0.78%)
Haematoma	3
Urinary retention	3
Conversion to GA	3
Seroma	2
Ischaemic orchitis	1
Overall	30 (2.95%)

All SF-36 dimensions, with the exception of mental and general health, fell after surgery to a minimum within the first 14 days. At 12 months after surgery, SF-36 scores had increased where there had been a fall. By 12 months, all dimensions were similar to or higher than those at baseline, except in the 7 patients with persistent pain who had a decreased global SF-36 score.

Repeated measures analysis (ANOVA) highlighted that there was a real effect in relation to SF-36 scores (except mental health and general health) after mesh hernia repair. In other words, there was an adverse impact of hernia surgery on quality-of-life, especially within the first 2 weeks after surgery, but recovery to or above baseline by 12 months, indicating that hernia repair improves quality-of-life, an observation that has not been proven before by scientific quantification.

## Discussion

The incidence of chronic pain in this prospective study was low and quality-of-life was enhanced at 1-year review. Pain is a complex sensory and emotional experience, closely associated with factors such as stress and anxiety.<sup>28</sup> It has been shown that the incidence of chronic pain is independent of the different types of hernia, the different types of surgical repairs, or the different types of anaesthesia employed.<sup>29</sup> It is our belief that enhanced patient information attenuates the impact of surgery and provides for realistic patient expectations after inguinal hernia surgery. This may explain the low reported incidence of chronic pain.

The outcomes provided by the Plymouth Hernia Service, which is currently offered with a Hernia Nurse Specialist by 8 general surgeons in Derriford Hospital, provides results comparable with those published from the best hernia units internationally. Inguinal hernia surgery in England, Wales and Scotland is currently performed far below this standard. 30-33

The most obvious deficiency is the UK-wide day-case rate of 20%, where huge cost-savings could be made by the utilisation of ambulatory surgery. We previously analysed the potential number of days in hospital saved by the application of ambulatory surgery in 81% of the patients and local anaesthesia in 89% of the cases as we are able to achieve

in the Plymouth Hernia Service.<sup>7</sup> This saving in costs in our hospital amounted to more than 800 hospital days when one surgeon was operating on approximately 200 patients per annum and the general surgical service was treating 500 patients per annum. In two consecutive years, the number of hospital days saved was 800 per annum the cost of which would more than cover the funding of the Hernia Nurse Specialist. In Denmark, a hernia service operating in a public hospital in Copenhagen treated 98% of its inguinal hernia patients with ambulatory surgery.<sup>34</sup>

The hernia service enables patients to effectively enter a pool to wait for their surgery. Not being 'tied' to a named

consultant allows for extremely effective use of theatre time and may be a mechanism whereby long waits for routine surgery are reduced. A consultant was either operating or scrubbed supervising in 95% of hernia repairs reported in this series; this may also be a factor leading to the excellent results of the service.

Surgical practice and surgical techniques evolve rapidly. To adapt to this rapidly changing environment during the 5 years of this review, there has been refinement of the care pathway. This rapid change is a major factor in the paucity of randomised controlled trials (RCTs) in surgical practice and why the EU Hernia Trialists' search of the literature for RCTs

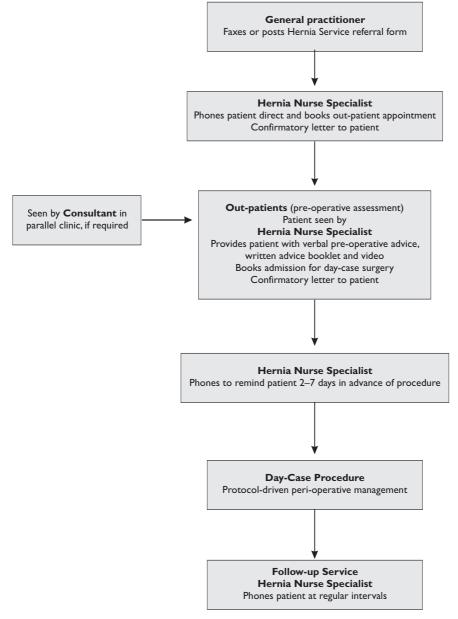


Figure 1 Plymouth Hernia Service care pathway.

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produced few good quality trials with large enough numbers to draw definitive conclusions. 17,35

#### Conclusions

Since the first reports more than 50 years ago, the Shouldice Clinic followed by the Lichtenstein Hernia Institute have set the standard for the surgery of groin hernias. In spite of the lack of data from randomised trials produced by these units, the methods utilised by them remain the gold standard. Where RCTs have been performed in other institutions, generally they confirm that the methods of surgery used in specialised units reflect best practice. Therefore, we feel confident that the accumulated experience now applied in the Plymouth Hernia Service, which is based on practice in specialist hernia units, and data from RCTs, provides an optimal care pathway (Figure 1)

The Plymouth Hernia Service aims to optimise the use of ambulatory surgery, local anaesthesia, balanced analgesia and patient information and also to constrain the costs of antibiotics and thrombo-embolic prophylaxis using protocol-driven care pathways. We have shown that, in over 1000 patients treated by general surgeons and supported by a Hernia Nurse Specialist, this approach results in a low perioperative complication rate and a recurrence rate of 0.78% at median follow-up of 2.5 years.

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