Randomized trial

# Randomized clinical trial of Lichtenstein's operation *versus* mesh plug for inguinal hernia repair

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**Background:** **Two of the most commonly used open prosthetic tension-free techniques for inguinal hernia repair are Lichtenstein's operation and the mesh plug repair. The technique of choice remains a subject of ongoing debate. The objective of the present investigation was to compare the two surgical procedures with respect to associated morbidity and recurrence rates.**

**Methods:** **Five hundred and ninety-five patients with 700 primary or recurrent inguinal hernias were randomized to undergo either Lichtenstein's operation or mesh plug repair. The primary endpoint of the investigation was the recurrence rate 1 year after surgery. Secondary endpoints were perioperative complications and reoperation rates.**

**Results:** **At 12-month follow-up, 597 hernia repairs (85·3 per cent) were evaluated. There were no significant differences regarding recurrence rates and perioperative complications. However, there was a significant difference in the overall reoperation rate between the two treatment groups, with 13 reoperations (4·2 per cent) in the Lichtenstein group and four (1·4 per cent) in the mesh plug group ($P = 0·047$).**

**Conclusion:** **Lichtenstein's operation and the mesh plug repair are comparable with respect to perioperative complications and recurrence rates.**

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## Introduction

There are a considerable number of techniques for inguinal hernia repair. Until the last decade, the technique introduced by Shouldice in 1945 was regarded as the standard for open hernia repair in Europe[1]. Very low recurrence rates of 0·8–2·5 per cent more than 5 years after Shouldice repair were reported by the pioneers of this method and others[2–4]. However, these recurrence rates could not be reproduced by surgeons in non-specialized centres[5,6]. In an important randomized controlled trial comparing three conventional hernia repairs, the long-term recurrence rate (12–15 years) after Shouldice repair for primary inguinal hernia was 15 per cent[7]. Owing to this unacceptably high recurrence rate following pure tissue repair, the concept of prosthetic tension-free hernioplasty emerged. Numerous randomized comparative trials have demonstrated the superiority of tension-free mesh repair over the traditional tissue-sutured procedures[8]. Even in the hands of non-specialized surgeons, recurrence rates for this technique are reported to be less than 2 per cent[9,10]. Two of the most commonly used procedures for open tension-free groin hernia repair with prosthetic mesh are Lichtenstein's operation and mesh plug hernia repair[11,12]. Some authors advocate Lichtenstein's operation[13], whereas others favour the mesh plug repair[14]. The technique of choice remains a subject of ongoing debate. The aim of the present prospective randomized multicentre trial was to compare these two surgical procedures with respect to postoperative morbidity and recurrence rates.

## Patients and methods

The study was designed as a prospective randomized multicentre trial, conducted at three teaching hospitals in Switzerland (University Hospital Basle, Kantonsspital Olten and Kantonsspital Luzern). Patients were eligible if they were older than 40 years, provided written informed consent, and presented with symptomatic unilateral or

bilateral inguinal hernia. The lower age limit was set because of the potential complications of mesh implantation and the relatively low recurrence rate after sutured hernia repair in younger patients[15]. Sutured hernia repair in younger patients with a primary hernia was established before designing the present study. Exclusion criteria were presence of a femoral hernia, history of hernia repair with mesh, type I diabetes, presence of local or diffuse infection (urine, skin, lung, sepsis), immune deficiency, severe medical problems contraindicating safe induction of general anaesthesia or elective surgery, pregnancy, malignant tumours and life expectancy of less than 2 years. Patients were enrolled consecutively between September 1999 and December 2001. The study was approved by the local research ethics committees.

## Randomization

Patients were randomly allocated at each hospital to undergo either Lichtenstein's operation or mesh plug repair. Randomization was computer generated, using sealed numbered envelopes that were opened at the induction of anaesthesia. In patients with bilateral hernias, both sides were repaired simultaneously using the same technique. The study was not blinded and information about the type of procedure was given to patients and their family doctors.

## Outcomes

The primary outcome was the recurrence rate 12 months after surgery. Secondary outcomes included perioperative complications, seroma formation, early and late infection, sensory loss in the groin region, postoperative pain and reoperation rate. Sensory loss was defined as the presence of numbness or complete loss of touch sensation in the groin region. Moderate pain was defined as an occasional irritation in the groin region that did not limit daily activities or work. Severe pain was defined as a persistent or almost persistent pain that interfered with normal daily activities and required analgesic medication or surgical intervention. Chronic pain was defined as persistent groin pain or any groin discomfort affecting daily activities that did not disappear by 1 year after surgery. Reoperation was defined as any surgical treatment or intervention performed after operation in the groin region.

## Surgical technique

The operations were performed under general, spinal, epidural or local anaesthesia according to patient and anaesthetist choice. All patients underwent standard repairs performed by residents, staff surgeons or attending surgeons, following a detailed protocol. All surgeons participating in the study were taught personally by the principal investigators and trained adequately in both surgical techniques. The surgeons' experience was noted at the beginning of each operation. A senior surgeon experienced in hernia repair was present during every operation, either performing or supervising the procedure. A single dose (1·5 g) of intravenous cefuroxime was given to all patients at the induction of anaesthesia.

Lichtenstein's operation was performed as described by Amid *et al.*[16,17] using 3/0 polypropylene (Prolene®; Ethicon, Johnson & Johnson Medical AG, Spreitenbach, Switzerland) to secure the mesh. An 8 × 16-cm polypropylene mesh (Bard Medica, Croix-de-Rozon, Switzerland) was trimmed to match the size of the inguinal floor, with a 2-cm overlap medial to the pubic tubercle.

The mesh plug repair was performed as described by Robbins and Rutkow[18] using a preformed Marlex mesh hernia plug (PerFix; Bard Medica). The plug is available in four sizes (small, medium, large and extra large), although a large plug was used routinely. To keep the plug in position, two interrupted sutures were placed through the mesh and the internal ring. For a direct hernias the fusiform or saccular direct defect was elevated with an Allis clamp, and the base of the sac was circumscribed with electrocautery to reveal preperitoneal fat and areolar tissue. The freed sac and overlying attenuated fascia transversalis layer were invaginated. The plug was inserted through the defect, and interrupted sutures were used to secure the device. All indirect and direct herniorrhaphies were then reinforced with a preformed flat Marlex onlay patch (Bard Medica), which was placed on the anterior surface of the posterior wall of the inguinal canal from the pubic tubercle to above the internal ring and secured with 3/0 polypropylene. As in Lichtenstein's operation, the tails of the mesh were crossed behind the spermatic cord and sutured with 3/0 polypropylene.

Whenever possible, the ilioinguinal, iliohypogastric and genital nerves were visualized and protected throughout the operation. As the ilioinguinal nerve passes over the spermatic cord sometimes hampering correct placement of the tails of the mesh behind the spermatic cord, a neurectomy was performed rather than manipulating or dissecting the nerve from its natural bed.

After hernioplasty and closure of the external oblique fascia, the skin incision was closed with a non-absorbable suture.

## Data collection

Perioperative complications were collated during the hospital stay. Patients were reviewed in outpatients

4 weeks after surgery, when a physical examination was performed to assess early complications or hernia recurrence. Postoperative pain was assessed using a verbal scale (none, moderate or severe). Sensory testing was done in inguinal, femoral and genital areas, and compared with the contralateral side. Recurrences were confirmed through clinical examination by a senior surgeon. At the follow-up visit 1 year after surgery, all patients were again evaluated clinically according to the standard protocol.

### Statistical analysis

Continuous data with a normal distribution were expressed as mean(s.d.) and compared using a paired *t* test. If the distribution was not normal, results were expressed as median (range) and compared using the Mann–Whitney *U* test. Comparisons of dichotomous outcomes were performed by $\chi^2$ or Fisher's exact test. $P < 0{\cdot}050$ was considered statistically significant. All tests were two sided.

## Results

The patients involved were 573 men and 22 women, with a median age of 59 (range 40–92) years. A total of 700 inguinal hernia operations (355 Lichtenstein, 345 mesh plug) were performed. One hundred and fifty-three hernia repairs (21·9 per cent) were performed under local anaesthetic with or without sedation. Spinal, epidural and general anaesthesia were used in 281 (40·1 per cent), 117 (16·7 per cent) and 149 (21·3 per cent) operations respectively. Some 93·3 per cent of the patients had a primary hernia, whereas 6·7 per cent had a recurrent hernia. Six hundred and forty-eight hernia repairs (92·6 per cent) were evaluated at the first postoperative visit 4 weeks after surgery. At 1-year follow-up, 597 repairs (85·3 per cent) were evaluated (*Fig. 1*).

The baseline characteristics of the patients according to treatment group are shown in *Table 1*. Demographic characteristics, anaesthetic fitness, employment status and type of hernia were similar in both groups.

### Perioperative data

The mean duration of operation was significantly shorter in the mesh plug group than in the Lichtenstein group (mean(s.d.) 59·0 (18·0) (range 20–130) *versus* 65·0 (22·6) (range 15–170) min; $P = 0{\cdot}002$). There were

**Table 1** Patient characteristics

| | Lichtenstein | Mesh plug | Total | *P* |
|---|---|---|---|---|
| No. of patients | 297 | 298 | 595 | |
| No. of operations | 355 | 345 | 700 | |
| Age (years)* | 59 (40–92) | 58 (40–91) | | 0·690† |
| Body mass index (kg/m$^2$)* | 25·3 (16·6–37·2) | 24·9 (16·4–36·8) | | 0·150† |
| ASA | | | | 0·626‡ |
| I | 153 (51·5) | 164 (55·0) | 317 (55·3) | |
| II | 117 (39·4) | 111 (37·2) | 228 (38·3) | |
| III | 27 (9·1) | 23 (7·7) | 50 (8·4) | |
| Sex ratio (M : F) | 288 : 9 | 285 : 13 | 573 : 22 | |
| Employment status | | | | 0·395‡ |
| Self-employed | 30 (10·1) | 26 (8·7) | 56 (9·4) | |
| Employed | 137 (46·1) | 154 (51·7) | 291 (48·9) | |
| Retired | 130 (43·8) | 118 (39·6) | 248 (41·7) | |
| Type of hernia | | | | |
| Direct | 134 (37·7) | 121 (35·1) | 255 (36·4) | |
| Indirect | 150 (42·3) | 182 (52·8) | 332 (47·4) | |
| Combined | 71 (20·0) | 42 (12·2) | 113 (16·1) | |
| Primary | 331 (93·2) | 322 (93·3) | 653 (93·3) | 1·000§ |
| Recurrent | 24 (6·8) | 23 (6·7) | 47 (6·7) | |
| Anaesthesia | | | | 0·322‡ |
| Local, with or without sedation | 76 (21·4) | 77 (22·3) | 153 (21·9) | |
| Spinal | 150 (42·3) | 131 (38·0) | 281 (40·1) | |
| Epidural | 64 (18·0) | 53 (15·4) | 117 (16·7) | |
| General | 65 (18·3) | 84 (24·3) | 149 (21·3) | |
| Surgeon | | | | 0·674‡ |
| Resident | 252 (71·0) | 250 (72·5) | 502 (71·7) | |
| Staff surgeon | 41 (11·5) | 43 (12·5) | 84 (12·0) | |
| Attending surgeon | 62 (17·5) | 52 (15·1) | 114 (16·3) | |

Values in parentheses are percentages unless indicated otherwise; *values are median (range). ASA, American Society of Anesthesiologists fitness score. †Student's *t*-test; ‡$\chi^2$ test; §Fisher's exact test.

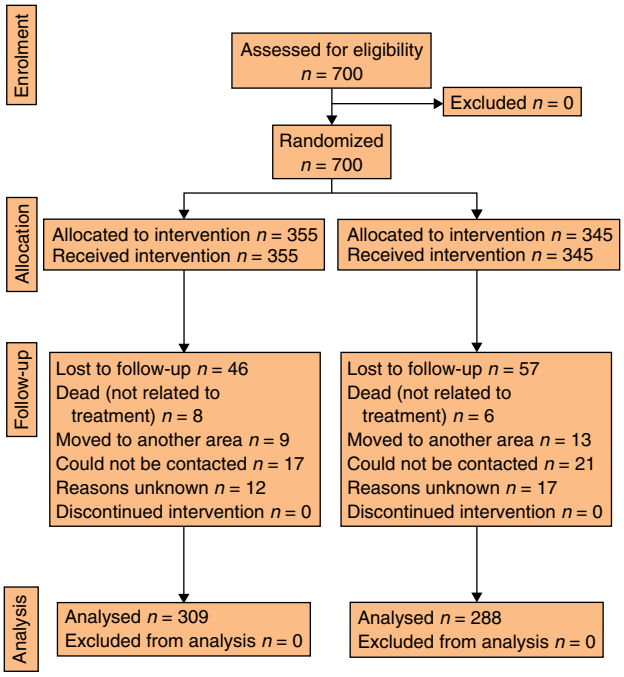


**Fig. 1** Randomized trial of Lichtenstein's operation *versus* mesh plug for inguinal hernia repair

**Table 2** Perioperative complications in 595 patients with 700 inguinal hernia repairs

| | Lichtenstein | Mesh plug | *P* |
|---|---|---|---|
| No. of hernia operations | 355 | 345 | |
| Intraoperative complications | | | |
| None | 352 (99·2) | 341 (98·8) | 0·721† |
| Injury to vessel | 3 (0·8) | 2 (0·6) | 1·000† |
| Injury to spermatic cord structure | 0 (0) | 2 (0·6) | 0·212† |
| Postoperative complications | | | 0·985† |
| None | 330 (93·0) | 320 (92·8) | |
| Reoperation for haematoma | 3 (0·8) | 3 (0·9) | |
| Haematoma | 17 (4·8) | 18 (5·2) | |
| Urinary retention | 5 (1·4) | 4 (1·2) | |
| Hospital stay | | | 0·154‡ |
| < 24 h | 15 (4·2) | 15 (4·3) | |
| 1 day | 61 (17·2) | 81 (23·5) | |
| 2 days | 148 (41·7) | 122 (35·4) | |
| 3 days | 131 (37·0) | 125 (36·2) | |
| 4 days | 0 (0) | 2 (0·6) | |

Values in parentheses are percentages. †Fisher's exact test; ‡$\chi^2$ test.

no conversions to a different method in either group. Intraoperative and postoperative complications are shown in *Table 2*. There were no statistically significant differences between the two groups. There was no significant difference in length of inpatient stay.

**Table 3** Four-week results

| | Lichtenstein | Mesh plug | *P** |
|---|---|---|---|
| No. of hernia operations | 355 | 345 | |
| No. of hernias at follow-up | 332 (93·5) | 316 (91·6) | |
| Seroma | 5 (1·5) | 15 (4·7) | 0·022 |
| Infection | 1 (0·3) | 0 (0) | 1·000 |
| Sensory loss | 97 (29·2) | 94 (29·7) | 0·931 |
| Pain | 14 (4·2) | 7 (2·2) | 0·189 |
| Recurrence | 0 (0) | 1 (0·3) | 0·488 |
| Reoperation | 5 (1·5) | 4 (1·3) | 1·000 |

Values in parentheses are percentages. *Fisher's exact test.

## Early complications

Complications reported at the first follow-up visit 4 weeks after surgery are shown in *Table 3*. Seroma formation occurred significantly more often in the mesh plug group ($P = 0·022$). One superficial infection was diagnosed in the Lichtenstein group, whereas no infection was reported in the mesh plug group. Moderate or severe pain was reported by a similar number in each group. One patient in the mesh plug group was diagnosed with an early failure of repair and revision was required. Another eight patients had reoperation within 4 weeks of hernia repair, four because of seroma formation, two with nerve entrapment causing severe pain, and two with a symptomatic femoral hernia. The latter patients were both in the Lichtenstein group, and the hernia was missed during the first operation.

## Intermediate term results

One late infection was noted in the mesh plug group 4 months after surgery. This was superficial and healed without reoperation. Sensory loss in the groin region was found in a fifth of patients in both groups. The frequency of chronic pain 12 months after surgery was similar in the two treatment groups (4·2 per cent in the Lichtenstein group *versus* 3·1 per cent in the mesh plug group; $P = 0·522$). There was no correlation between chronic pain and sensory loss. Five patients (1·6 per cent) in the Lichtenstein group and three (1·0 per cent) in the mesh plug group had a recurrent hernia ($P = 0·425$). There

**Table 4** Reasons for reoperation within 12 months

| | Lichtenstein | Mesh plug |
|---|---|---|
| Haematoma or seroma | 4 | 3 |
| Infection | 1 | 0 |
| Chronic pain | 3 | 0 |
| Femoral hernia | 2 | 0 |
| Recurrence | 4 | 1 |

were 13 reoperations (4·2 per cent) in the Lichtenstein group and four (1·4 per cent) in the mesh plug group in the first 12 months ($P = 0·047$), but there was no statistically significant difference in overall complication rates. The most common reason for reoperation was seroma formation, followed by recurrence and chronic pain (*Table 4*). One patient in the Lichtenstein group requiring revision for chronic pain was additionally diagnosed intraoperatively with a recurrence.

## Discussion

The present study provided evidence that Lichtenstein's operation and the mesh plug technique are comparable with respect to recurrence rates at 1-year follow-up. Although there were significantly more reoperations after Lichtenstein's operation, the overall complication rates were similar after both procedures.

The recurrence rate after mesh plug repair was slightly higher in this study (1·0 per cent) than in the largest published, non-randomized collective study[14]. Rutkow and Robbins[14] reported a recurrence rate of less than 0·2 per cent after 2060 primary mesh plug repairs and 2·3 per cent after 343 mesh plug repairs for recurrent hernia after a follow-up of almost 6 years. This result can be explained by the fact that all of these patients had surgery in a highly specialized centre for inguinal hernia repair by high-volume surgeons. The long-term follow-up of almost 6 years was adequate, as most hernia recurrences appear within 5 years of surgery. However, many patients were lost to follow-up during this time. The recurrence rate in the Lichtenstein group in the present study (1·6 per cent) compared favourably with that in a recent multicentre study. Neumayer *et al.*[19] reported a recurrence rate at 2-year follow-up of 4·9 per cent in 994 patients undergoing Lichtenstein's operation. This relatively high recurrence rate may be explained partly by the fairly high percentage of recurrent hernia repairs (8·9 per cent compared with 6·8 per cent in the present study).

In the present study there was a marginally significant difference in overall reoperation rates between the Lichtenstein and mesh plug groups, despite the fact that the overall complication rates were similar. The increased rate of reoperation after Lichtenstein's operation should therefore be interpreted cautiously in light of the relatively short follow-up.

The most common reasons for reoperation were seroma formation, followed by recurrence and chronic pain. Recurrence and chronic pain were more frequent reasons for reoperation in the Lichtenstein group. Chronic pain is a common and problematic late complication of inguinal hernia repair[20]. In a double-blinded randomized controlled trial evaluating short-term outcomes, Kingsnorth *et al.*[13] reported that patients who had plug-and-patch repair had significantly less pain than those who had Lichtenstein's operation. Conversely, Huang *et al.*[21], who compared the Prolene® Hernia System (PHS, Ethicon Inc., Sommerville, NJ, USA) with mesh plug, reported chronic non-disabling pain more frequently when the mesh plug technique was chosen. There were no differences in chronic pain between the two groups in the present study. Neumayer *et al.*[19] reported a rate of neuralgia or other pain of 14·3 per cent, considerably higher than in the present investigation. Moreover, in a randomized clinical trial comparing the Prolene® Hernia System, mesh plug repair and the Lichtenstein method for open inguinal hernia repair, Nienhuijs *et al.*[22] reported that 138 (43·3 per cent) of 319 patients had chronic pain 15 months after surgery. This difference may be only partly explained by the fact that a genitofemoral or ilioinguinal neurectomy was performed systematically in the present trial if postoperative nerve entrapment appeared to be likely. In a randomized controlled trial, Picchio *et al.*[23] showed that pain after open hernia repair was unaffected by elective dissection of the ilioinguinal nerve. In their study resection of the ilioinguinal nerve was significantly related to sensory disturbances in the area of distribution of the nerve. Another explanation for the low rate of chronic pain 1 year after hernia repair in the present study may be the fairly high percentage of patients of retirement age. Of the 22 patients with chronic pain at 1-year follow-up, only three were retired. These findings correlate with the observation of Nienhuijs *et al.*[22] that younger age is an independent factor related to chronic pain.

The present investigation has certain limitations. For example, to come to a definite conclusion regarding recurrence rates, follow-up should be longer. All patients will be reviewed 5 years after surgery. In addition, the average age of the study population was higher than in other investigations[13,22], because the lower age limit was set at 40 years. Hence, the results may not be generalized to younger patients.

However, the study was one of the largest randomized trials to compare Lichtenstein and mesh plug techniques, with a good rate of follow-up at 1 year and all patients evaluated clinically at the follow-up visits. It provided no evidence that either technique is superior.

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The authors declare that they have no financial competing interests.

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