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# First Results of Lichtenstein Hernia Repair with Ultrapro®-mesh as Cost Saving Procedure

## Quality Control Combined with a Modified Quality of Life Questionnaire (SF-36) in a Series of Ambulatory Operated Patients

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Abstract: There are about 200,000 hernia repairs per year in Germany and about 770,000 in the U.S.. In the United States most hernia repairs (80-90%) are performed as day surgery procedure; 90% of operations are open herniorrhaphies with mesh. Quality control includes the registration of complications, recurrence, and quality of life.

In a prospective study 50 consecutive patients with inguinal hernia eligible for open mesh repair (modified Lichtenstein hernia repair), mostly Nyhus III and IV classification, were operated using light-weight Ultrapro®-mesh (monocryl-prolene-composite, Ethicon Products), and interviewed 10 days after the operation according to a modified SF-36 questionnaire. Patients were examined three months later.

There were 29 direct hernias, 21 combined (direct and indirect) hernias, 8 indirect hernias; 8 patients had hernias on both sides. 8 patients (16%) presented with recurrent hernias, mostly suture or laparoscopic repairs before. There were no intra-operative complications. 2 patients suffered from a moderate haematoma, which did not necessitate a surgical repair, after accidental intake of aspirin preoperatively in one case and after preoperative low-molecular-weight heparin prophylaxis. There were no other complications. All 50 patients (100%) had returned the questionnaire. 38 patients (78%) reported no or mild pain; only one patient (2%) suffered from severe pain, none had very severe pain. 32 patients (64%) applied no pain medication or only for 48 hours; only one patient (2%) used pain medication for more than 14 days. 34 patients (68%) admitted that their health status improved after the operation; 11 patients (22%) with good or very good health status indicated no change in health. Follow-up examination of the patients three months after the operation did not detect any recurrence. 49 patients (98%) were free of pain or restriction; one patient (2%) continued to have chronic pain which developed after two laparoscopic herniotomies performed at a different clinic before. There was no sign of mesh-related complication. The Ultrapro®-mesh has been well accepted by the patients.

In conclusion, open mesh repair according to Lichtenstein is safely done in specialised ambulatory day surgery clinics. Most patients benefit from this form of treatment according to a quality of life audit. The new light-weight mesh Ultrapro® contributes to the improvement of hernia repair. There is evidence that ambulatory open mesh repair should be the method of choice for primary inguinal hernia. If in Germany an equal proportion of hernia repair as in the United States would be done as ambulatory procecure (80-90%), there would be an annual cost saving of several hundert million Euro.

### Introduction:

In Germany each year about 220,000 hernia repairs are performed (Horeyseek 1997). 15-20% of hernia repairs in Germany and approximately 80% in the U.S. are done as outpatient procedure, 90% as open mesh repair (Rutkow 2003). According to guidelines the open mesh repair should be the preferred procedure for primary inguinal hernia repair (Simons et al. 2003). In a recent large randomised study comparing open mesh with laparoscopic hernia repair, the recurrence rate after open mesh was half that of laparoscopic repair (Neumayer et al. 2004). Next to recurrence the quality of life after hernia repair is important to the patient. This prospective study was performed to investigate the quality of life after open mesh hernia repair according to a modified Lichtenstein procedure using Ultrapro® mesh. With regard to the Medline survey, this is the first time results of ambulatory hernia repair with Ultrapro® are presented.

### Methods

End of 2003 and beginning of 2004, 50 patients with inguinal hernia eligible for a modified Lichtenstein (Lichtenstein 1966) hernia repair – mostly type III and IV according to the Nyhus hernia classification (Nyhus 1993); American Society of Anaesthesiologists (ASA) class I, II and under certain circumstances III – were included in this prospective ongoing study using Ultrapro®-mesh (Ethicon Products), a monocryl-prolene-composite. All patients received one-shot antibiotic prophylaxis ampicillin-sulbactam (Unacid®, Pfizer), and thromboprophylaxis with dalteparin (Fragmin®, Pfizer) together with combined pain prophylaxis di-

clofenac (Diclofenac-ratiopharm 100 suppositories), mepivacain 1% (Scandicain®, Astra-Zeneca) and bupivacain 0.25% (Carbostesin®, Astra-Zeneca). All patients had general anaesthesia. We used a mesh of 15x15 cm for sufficient medial overlap to avoid recurrences (Amid 2002). The same surgeon operated all patients. Postoperatively the patients were mobilized after a recovery period of 30-60 minutes and were allowed to take pain medication diclofenac (Diclo dispers®, betapharm). Day one, three and 10 after the operation all patients were examined. At day 10 all patients were interviewed using a quality of life questionnaire modified according to the SF-36 questionnaire (Jenkinson et al. 1996). All patients were re-examined three months after the operation.

## Results

50 patients (43 males and 7 females; mean age 48.4 years; range 15-75 years) presented with a symptomatic inguinal hernia, mostly type III and IV according to the Nyhus classification, with a defect of the posterior wall and/or enlarged interior ring. The hernia repair, a modified Lichtenstein procedure, lasting 45 in primary to 90 minutes in case of recurrent hernias, was done in 36 cases at the left side, in 22 cases at the right side, and in 8 patients (16%) at both sides. In most instances there was a direct hernia (n = 29) or a combined direct and indirect hernia (n = 21); in 8 cases the hernia was indirect. 8 patients (16%) presented with a recurrent inguinal hernia; one had a recurrent hernia after two laparoscopic hernia repairs at the same side (Table 1).

There were no intra-operative complications. In two patients (4%) a superficial, self-resolving haematoma occurred, which was attributable in one case to an accidental intake of aspirin preoperatively and in the second patient to the preoperative thromboprophylaxis with low-molecular-weight heparin. There were no other complications.

50 patients (100%) returned the questionnaire. 64% (n = 32) considered their health good, very good or excellent. 10 patients (20%) rated their health poor, but 9 of them reported an improvement in health after the hernia repair. One patient (2%) did not feel to have an improvement in health suffering from chronic inguinal pain after two laparoscopic hernia repairs two years before and a recurrent hernia. 34 patients (68%) felt that their health improved after the hernia repair. 11 of 13 patients (26%) who indicated no change in health had rated their health as good or very good (Table 3).

40 patients (80%) had only minor restrictions in their daily activities, 8 patients (16%) none. 10 patients (20%) had attributed their problems with work or other regular daily activities to emotional problems. 12 patients (24%) thought that they were restricted in the social contacts moderately, quite a bit or extremely. 4 patients (8%) were nervous, felt down in the dumps that nothing could cheer them up, or felt downhearted and low, tired or worn out most the time (n = 2) or a good bit of time (n = 2).

*Table 1.* Classification of inguinal hernias.

| Side | Direct | Indirect | Combined direct and indirect | Recurrent hernia among these | total |
|---|---|---|---|---|---|
| Left | 21 | 2 | 13 | 6 | 36 |
| Right | 8 | 6 | 8 | 4 | 22 |
| Total | 29 | 8 | 21 | 10 | 58 |

*Table 2.* Pain, restriction of activities by pain and pain medication in patients younger or older than 40 years.

| N | Pain None – mild | Pain Moderate – severe | Restriction by pain not at all – moderately | Restriction by pain quite a bit – extremely | Pain medication none – 48 hours | Pain medication 1 week – 2 weeks |
|---|---|---|---|---|---|---|
| **Male > 40 years n = 28** | 23 (82.1%) | 5 (17.9%) | 26 (92.9%) | 2 (7.1%) | 20 (71.4%) | 8 (28.6%) |
| **Female > 40 years n = 4** | 2 (50%) | 2 (50%) | 3 (75%) | 1 (25%) | 2 (50%) | 2 (50%) |
| **Male ≤ 40 years n = 15** | 12 (80%) | 3 (20%) | 12 (80%) | 3 (20%) | 8 (53.3%) | 7 (46.7%) |
| **Female ≤ 40 years n = 3** | 1 (33.3%) | 2 (66.7%) | 2 (66.7%) | 1 (33.3%) | 2 (66.7%) | 1 (33.3%) |
| **Total n = 50** | **38 (76%)** | **12 (24%)** | **43 (86%)** | **7 (14%)** | **32 (64%)** | **18 (36%)** |

*Table 3.* General health and change in health after hernia repair.

| General Health | Much better now | Somewhat better | About the same | Somewhat worse | Much worse | total |
|---|---|---|---|---|---|---|
| Excellent | 3 (75%) | 1 (25%) | - | - | - | 4 |
| Very good | 5 (41.7%) | 2 (16.7%) | 4 (33.3%) | 1 (8.3%) | - | 12 |
| Good | 4 (25%) | 4 (25%) | 7 (43.8%) | - | 1 (6.2%) | 16 |
| Fair | 5 (62.5%) | 1 (12.5%) | 1 (12.5%) | 1 (12.5%) | - | 8 |
| Poor | 8 (80%) | 1 (10%) | 1 (10%) | - | - | 10 |
| | **25 (50%)** | **9 (18%)** | **13 (26%)** | **2 (4%)** | **1 (2%)** | **50** |

Most patients (n = 38; 76%) had no or only mild pain after hernia repair; only 2 patients (4%) reported to have severe pain. 10 patients (20%) had moderate pain. 12 patients (24%) felt they were restricted in their daily activities by pain moderately or more. 19 patients (38%) used pain medication never or only during the first 24 hours. After 48 hours 32 patients (64%) did not need pain medication, after one week 45 patients (90%) (Table 2).

The decision and planning of an operation is influenced in 34 cases (68%) by inguinal pain, in 18 cases (36%) by family, in 15 cases (30%) by conditions at work, and in 16 cases (32%) by the family practitioner. Less important were seasons, lunar phase, and natural healing.

Three months after the hernia repair all patients but one (98%) are free of pain and complaints. The mesh has been well accepted and there was no recurrence due to technical defects.

## Discussion

In general, hernia repair can be safely and successfully done as outpatient ambulatory procedure according to Lichtenstein (Lafferty et al. 1998). The results of hernia repair are presented with the rate of recurrence, intra- and post-operative complications, pain and quality of life (Cheek et al. 1998).

In a randomised, controlled study of 2184 patients with open mesh or laparoscopic inguinal hernia repair the recurrence rate of open mesh repair was half that of the laparoscopic repair (4.9% versus 10.1%) (Neumayer et al. 2004). Technical defects during the operation or constitutional factors may be responsible for the recurrence of the hernia. Patients with abnormal collagen distribution, emphysema, chronic bronchitis or smokers may have an increased risk for a recurrent hernia, especially during the first three months after the operation (Schumpelick 2000; Sorensen et al. 2002). It is well known that the wound healing allows in the first month 30% and in the second month 40% of mechanical strength of normal tissue (Douglas 1952/53). Nonresorbable sutures allow for about 70% of mechanical strength (Lichtenstein et al. 1970). We did not observe any recurrence during the first three months, which would be attributable most likely to technical defects. 16% of patients who presented with a recurrent inguinal hernia had an increased risk for re-recurrence. 13-15% of hernia repairs in specialised institutions are due to recurrences (Nilsson et al. 1998). The rate of recurrence after primary inguinal hernia repair is between 0.2 and 15%; however, in case of a recurrent hernia the risk of re-recurrence is between 8 and 33% (Weber 2001).

Intra-operative complications occur seldom or never – as in this study - during open mesh hernia repairs. However, there is growing evidence that intra-operative complications may be more life threatening in laparoscopic hernia repairs (Hair et al. 2000).

The rate of post-operative complications (bleeding, infection, thromboembolic event, damage to bowel, bladder, blood vessels, nerves) after inguinal hernia repair is low (4%); wound complications may, however, be observed in 10% of cases (Lau and Lee 2000; Hair et al. 2000). We observed in two patients (4%) superficial haematoma, which occurred after accidental intake of aspirin or preoperative thromboprophylaxis. This may occur more often when the injection is not applied to the contra lateral thigh (Wright et al. 1998). Although the risk for an infection or thromboembolic event is low after hernia repair (Bitzer et al. 2000; Hair et al. 2000; Riber et al. 1996; Anwar and Scott 2003) we offer all our patients protection by antibiotic and thromboprophylaxis. There is evidence that the risk for a thromboembolic event during and after laparoscopic repair is higher due to pneumoperitoneum, longer operation time and reverse Trendelenburg position (Catheline et al. 1999) compared to open hernia repair; guidelines recommend therefore open mesh repair for the primary inguinal hernia (Simons et al. 2003). Up to 20% of patients in Southern Germany consider lunar phase an important factor contributing to postoperative complications. In a recent study we demonstrated that surgical quality is not influenced by lunar phase or the personal perception of the postoperative follow-up (Holzheimer et al. 2003). With regard to the five to six times higher costs of in-patient hernia repair in Germany (430 Euro out-patient versus 2300-2600 Euro in hospital), the costs for ambulatory antibiotic and thrombo-prophylaxis may be irrelevant.

Meshes have been accused to cause complications (shrinkage, damage to the spermatic cord, migration, mesh infection, nerve damage) (Hofbauer et al. 1998; Schumpelick and Klinge 2000; Sakorafas et al. 2001).

It is known that mesh can cause an inflammatory response (Di Vita et al. 2000). Patients with postoperative complaints after mesh implantation may not suffer from a mesh-related complication, but may have other coincident disease, e.g., varicocele (Holzheimer and Schreiber 2003). There is reason to believe that light-weight meshes are less antigenic and therefore are more comfortable for patients (Post et al. 2004). All our patients had received Ultrapro®-mesh and at the follow-up examination none had complaints about foreign body or pain. 9 of 10 patients who felt their health was poor indicated improvement in their health after the hernia repair. 68% of patients reported that their health has improved after the hernia repair.

There is an increasing number of reports on chronic pain (30%) after hernia repair (Poobalan et al. 2001; Kumar et al. 2002). The occurrence of chronic pain may be due to neuroma formation (Ducic and Dellon 2004), heavy-weight mesh (Post et al. 2004) or asymptomatic inguinal hernias (Page et al. 2002). Risk factors for the development of chronic pain were recognized to be age below 40 years, recurrent hernia and operation at the same side, pain before the operation (Poobalan et al. 2001). Most of our patients rate their pain as nonexistent, very mild or mild (n = 38; 76%) compared to 50% in other studies (Barth et al. 1998). We observed only one patient (2%) with chronic pain who in fact developed this chronic pain after two laparoscopic hernia repairs at a different clinic. 3 patients in our study complained of temporary moderate (n = 2) to severe (n = 1) pain, but none of them had pain at three months after the hernia repair. 18 patients (36%) were younger than 40 years. There was a tendency to more pain and prolonged pain medication in younger patients. Others reported that post-operative pain was not affected by surgical technique, sex, hernia anatomy and post-operative morbidity but only by the age of the patient (Lau and Lee 2001). Patients also considered active demanding sport, sexual activity or farming work as usual daily activities or social contact, which may explain why some of them felt restrictions after hernia repair during the first ten days. Although most patients had no or minimal pain and only minimal restriction of daily activities, the return to work may be influenced by other factors, e.g., insurance status (Lawrence et al. 1996). The implantation of heavy-weight mesh may lead to more pain and restriction in daily activities (Langenbach et al. 2003). Most of our patients were not or only slightly restricted in their daily activities which may also be attributed to the light-weight mesh. It has been demonstrated that patients with a disposition to pessimism may report a delay in their return to work and normal daily activities (Bowley et al. 2003).

In summary, ambulatory open mesh repair with Ultrapro® is well tolerated and successful. There is evidence that the ambulatory open mesh repair should be the method of choice for primary inguinal hernia repair.

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