Int Surg 2014;**99**:391–397
DOI: 10.9738/INTSURG-D-14-00064.1

ULTRAPRO Hernia System Versus Lichtenstein Repair in Treatment of Primary Inguinal Hernias: A Prospective Randomized Controlled Study

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The Lichtenstein repair has been recommended as the gold standard for inguinal hernia repair. However, postoperative discomfort still constitutes a concern and an area for improvement. New mesh materials have been continuously introduced to achieve this goal. The goal of the present study was to investigate the outcomes of ULTRAPRO Hernia System (UHS) compared with Lichtenstein mesh repair. A total of 99 male patients with primary unilateral inguinal hernia were included in the study during the period of September 2010–January 2012. Patients with body mass index >30, comorbid diseases, and anesthetic risk of ASA-III and ASA-IV were excluded. The patients were randomly allocated to operation with the Lichtenstein technique (group L) or UHS. Demographics, operative and postoperative/recovery data, and short- and medium-term outcomes of the patients were recorded. A total of 50 patients in group L and 49 patients in group UHS were analyzed. The median follow-up time for the study was 33 months. There were no significant differences regarding demographics, complications, and rehabilitation between the groups. Overall, there was a prolonged operation time in the UHS group compared with the L group (UHS: 53.7 ± 5.7 minutes; L: 44.5 ± 5.5 minutes; $P < 0.001$). UHS may provide results similar to those for the Lichtenstein technique in open repair of inguinal hernias regarding perioperative course, complications, recovery, and

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recurrence rates. However, because of reduced costs and the lack of need for the exploration of the preperitoneal space, we conclude that the Lichtenstein technique should be recommended as the first choice.

Key words: Inguinal hernia – Repair – Lichtenstein – Mesh – Operation time – Chronic pain

Inguinal hernias occur in about 15% of adult men, and hernia repair is the most common surgical procedure performed by general surgeons.[1] Previously, recurrence was a major problem after inguinal hernia repair, but because tension-free prosthetic repairs have been introduced, recurrence rates have decreased to a range of 1% to 2%. However, chronic groin pain, foreign body sensation, and impaired quality of life still constitute an important issue that must be improved. Suggested possible mechanisms for such side effects include excessive remaining fixation or mesh material causing nerve injury and/or scar tissue.[2,3] Therefore, new mesh materials and mesh designs have been continuously introduced with the aim of reducing postoperative discomfort.

The Prolene Hernia System (PHS; Ethicon, Norderstedt, Germany), with a bilayer polypropylene mesh design and a connector between the layers, has become a technique that is relatively commonly used in the United States as well as in Europe.[4] The bilayer mesh covers the inguinal floor and the preperitoneal space, whereas the connector levels up the abdominal wall defect. It has been hypostasized that the use of a bilayer device could reduce postoperative pain and/or discomfort because of the lessened need for fixation by sutures, and therefore might reduce the risk of nerve entrapment.

Although associated with a possible increased risk of recurrence, lightweight meshes, consisting partially of resorbable materials, have been reported to cause less postoperative pain and groin discomfort in Lichtenstein repair.[5,6] With a similar aim, a second generation of PHS, UltraPro Hernia System (UHS; Ethicon, Johnson & Johnson Company, Somerville, NJ) has been designed. The onlay patch, connector, and underlay patch of UHS are manufactured from approximately equal parts of absorbable poliglecaprone 25 monofilament fiber and nonabsorbable polypropylene monofilament fiber.

However, whether the results with either or both of these two meshes are superior to those for the traditional Lichtenstein technique with polypropylene mesh has not yet been clearly demonstrated. The aim of the present study was to compare the outcomes of open inguinal hernia repair using the Lichtenstein repair, and UHS techniques with respect to perioperative and postoperative course, complications, and postoperative rehabilitation in a single-center, prospective, and randomized setting.

Patients and Methods

This study was carried out in the Department of General Surgery, Adana Numune Training and Research Hospital, Adana, Turkey. The study was approved by the institutional ethics committee, and all patients gave their written informed consent after being informed about the nature and the purpose of the treatment and the study (clinical trial number A.N.E.A.H.*EK.2010/43*).

Study design

Male patients older than 30 years with an uncomplicated and primary unilateral inguinal hernia were selected as being eligible for the study during the period of September 2010–January 2012. Exclusion criteria included irreducible inguinoscrotal hernia, recurrent hernia, and failure to consent to randomization. In addition, men with body mass index >30, anesthetic risk according to American Society of Anesthesiologists (ASA) physical status classification system (ASA-III and ASA-IV scores), diabetes mellitus, chronic obstructive pulmonary disease, benign prostatic hypertrophy, and cancer were excluded from the study.

The patients eligible for the study were randomly assigned into two groups: Lichtenstein group (L group) with a polypropylene mesh, and a second group with a composite mesh (UHS group). Randomization was performed by opening sequentially numbered envelopes containing the name of the operative procedure to be performed. Random allocation sequence was generated by the authors H.B. and S.O. The participants were enrolled by F.K., E.M., and M.O.

Surgical procedures

All operations were performed by F.K. and S.O., who were experienced in performing both techniques following the same technical principles.

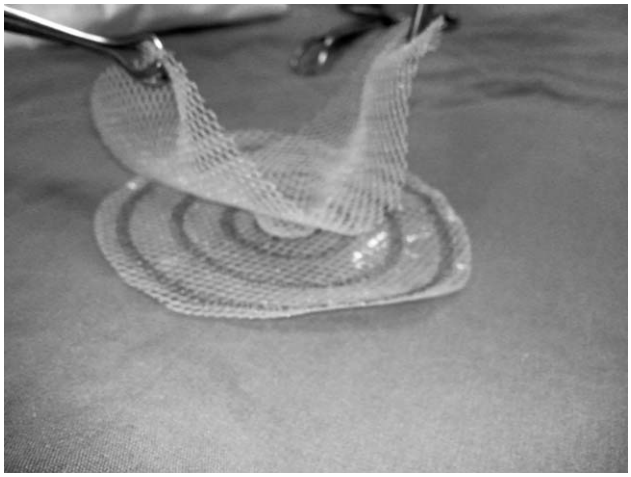

Fig. 1 UHS. The circular part of the mesh is placed under the transversalis fascia after enough blunt dissection is done in the preperitoneal space. The anterior component is positioned on the transversalis fascia in an onlay manner and fixed with a few single sutures.

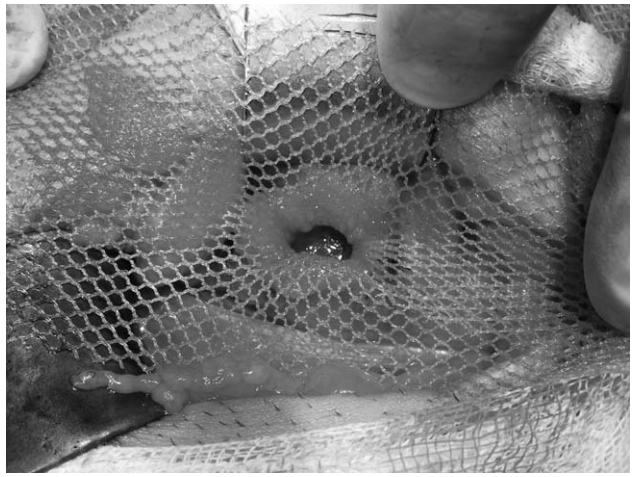

Fig. 2 The operative photograph of UHS. The circular part has been placed under the transversalis fascia in the preperitoneal space, and the anterior component has been prepared to be placed onlay.

Spinal anesthesia was used in all cases. Preoperative intravenous antibiotic prophylaxis with 1 g of a first-generation cephalosporin was given routinely.

Lichtenstein technique

The Lichtenstein procedure was performed as described by Amid.[7] After an oblique incision was made, the inguinal canal was exposed through an open anterior approach and the spermatic cord was dissected free. Inguinal nerves were not sacrificed in any of the patients. Direct hernias were inverted, and high dissection was performed for indirect hernia sacs. A standard polypropylene mesh was secured to the lateral border of the rectus sheath, the aponeurotic tissue over the pubic tubercle, and the inguinal ligament, using 2/0 polypropylene sutures. The mesh was split to re-create the internal ring. The external oblique, Scarpa fascia, and skin were then closed.

UltraPro Hernia System

The UHS procedure was performed as described by Gilbert *et al*.[8] After exposure of the inguinal canal, the preperitoneal space was dissected by dividing the transversalis fascia. The circular component of the mesh was placed preperitoneally after enough space was created by blunt dissection. The anterior component was positioned on the transversalis fascia and fixed with a few single sutures with absorbable material (Figs. 1 and 2). As with the Lichtenstein procedure, the mesh was split to re-create the internal ring.

Data collection and follow-up

Data were collected on standardized case forms. Patients' demographics, classification of hernia type according to Nyhus, operating time, procedure performed, and postoperative follow-up data were recorded. All patients were physically examined by one of the senior surgeons during follow-up.

All patients received a single dose of nonsteroidal anti-inflammatory analgesic at the fourth postoperative hour. Extra doses were given on demand. No per-oral analgesics were prescribed after discharge. From day 1, week 1, and 3 months after surgery, patients were asked to estimate postoperative pain by the use of a 0 to 10 graded visual analog scale (VAS). A point of 0 meant that the patient had no pain, and a point of 10 stated that the patient suffered from most severe pain. The patients were asked for the time of return to normal activity. Early and late postoperative complications (scrotal hematoma, wound hematoma or surgical site infection, urinary retention) were recorded. The patients were asked about hernia recurrence, groin discomfort, numbness, and testicular atrophy during the study period.

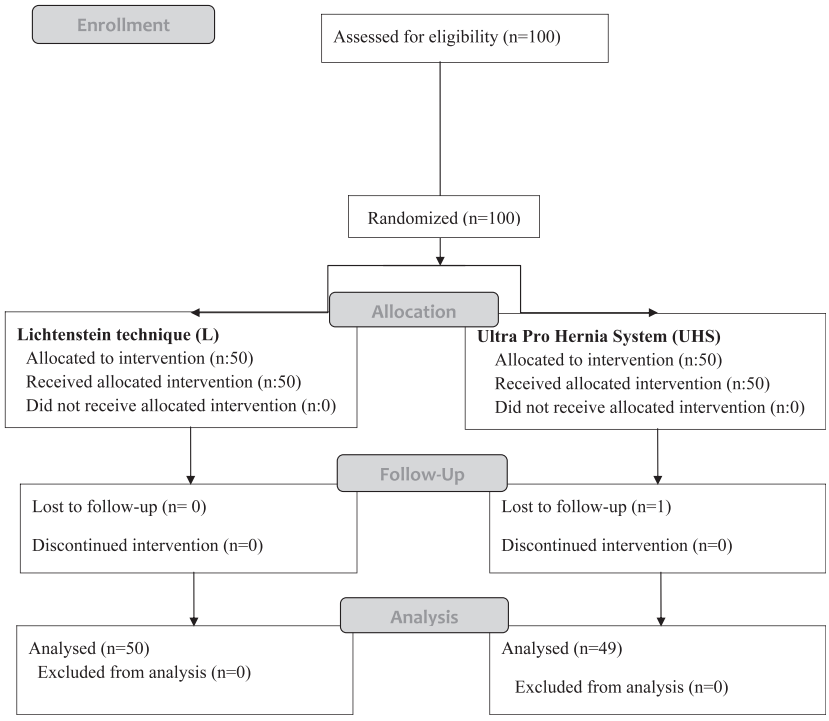

Fig. 3 Flow diagram of the study.

Statistical analysis

Data are presented in numbers and percentages or as mean ± SD or SEM, when appropriate. For comparisons within and between groups, χ^2 test, and Student *t* test were used when appropriate. Analysis was performed with the aid of the SPSS 18.0 statistics program for windows (SPSS, Chicago, Illinois). $P < 0.05$ was considered statistically significant.

Results

One patient was lost during follow-up; therefore, a total of 99 male patients were included in the study for statistical analyses. Of these, 50 patients were randomly divided to Lichtenstein technique and 49 to UHS (Fig. 3). The mean age was 45.43 years (range, 30–65 years), and the mean body mass index was 24.4 (SD, 2.6). The characteristics at randomization were similar between the two groups (Table 1).

Operative and early postoperative/recovery data

The hernia types according to Nyhus classification were similar between the groups. Intraoperative and immediate postoperative complications were observed in 4 patients. Two patients in group UHS had bleeding intraoperatively during the exposure of preperitoneal space due to injury of epigastric vessels that required hemostasis with ligation. One patient in group L developed inguinal hematoma after 3 to 4 hours, which required drainage, and one patient was readmitted to the hospital on the postoperative third day because of superficial surgical site infection that was treated with wound care and the first generation of cephalosporin. There was no difference between the groups in hospital stay. The operation time was significantly longer in the UHS group. The self-reported time needed until return to normal daily activity was similar between groups. Operative and early postoperative/recovery data of all patients are presented in Table 2.

Table 1 Characteristics of patients undergoing primary inguinal hernia repair

Variables	L group	UHS group	*P* value
Age, y, mean ± SD	46.48 ± 10.74	44.37 ± 9.29	ns
BMI, kg/m^2, mean ± SD	24 ± 3.2	25 ± 3.0	ns
Laterality, n (%)			ns
Right	34 (68)	34 (69)	
Left	16 (32)	15 (31)	
ASA class, n (%)			ns
I	18 (36)	19 (39)	
II	32 (64)	30 (61)	

BMI, body mass index; ns, not significant.

Table 2 Operative and early postoperative/recovery data for all patients

	L group	UHS group	*P* value
Nyhus class, n (%)			ns
Type 2	19 (38)	17 (34.6)	
Type 3a	23 (46)	22 (44.8)	
Type 3b	8 (16)	10 (20.4)	
Operation time, min, mean ± SD	44.5 ± 5.5	53.7 ± 5.7	<0.001
Hospital stay, d	1.0	1.0	ns
Return to normal activity, d	7.7 ± 1.28	7.43 ± 1.21	ns
Complications (operative or immediate)	Hematoma (n = 1); wound infection (n = 1); urinary retention (n = 3)	İntraoperative bleeding (n = 2); urinary retention (n = 4)	ns

VAS pain scores and complaints of patients

The mean follow-up time was nonsignificant between groups. There were no significant differences in pain scores on the VAS scale between groups (Table 3). There were also no differences in early and late postoperative analgesic needs between groups ($P > 0.05$). Objective findings in patients complaining about symptoms within 30 days and between 30 days and 6 months after primary inguinal hernia repair were nonsignificant during the follow-up time. Intermediate-term outcomes of the patients are presented in Table 4. There were no cases of early recurrence at the end of the study period.

Discussion

The ideal inguinal hernia repair with a prosthetic material should provide effective coverage of the myopectineal orifice and have the lowest possible recurrence rate, minimal operative and postoperative discomfort, and allow a rapid return to normal activities. Furthermore, it should be cost-effective and ideally should be applicable to most types of hernias encountered.[9] In general, the results of inguinal hernia repair are presented with the rate of recurrence, intraoperative and postoperative complications, recovery, and rehabilitation.[1] For these purposes, surgeons continue to search for the repair with the best outcome.

The placement of the mesh still constitutes the most important area to be improved. In open repair techniques, the mesh is placed anteriorly in most cases. However, it can be secured in the preperitoneal space. These two approaches differ not only in anatomic view but also in mechanism, because the preperitoneal mesh placement closes the Fruchaud myopectineal orifice completely, whereas the Lichtenstein operation reinforces the superficial muscle shutter mechanism. The previous studies support that the placement of the mesh in the preperitoneal or superficial position is similar with regard to recurrence rates, postoperative complications, and long-term results in the treatment of primary hernias.[10,11]

Gilbert *et al*[8] have developed an approach, known as PHS, to the preperitoneal space for inguinal hernia repair in attempt to improve Lichtenstein repair. The PHS mesh is consisted of an underlay patch (provides complete coverage of the entire myopectineal orifice), an overlay patch, and a joining connector, and has potential benefits, and thus would be expected to have lower recurrence rates. Some previous reports of the PHS use have shown a 10% reduction in operating time, extremely low recurrence rates, and also less postoperative pain and discomfort in comparison with the Lichtenstein repair.[12–15]

However, a recent meta-analysis revealed that the use of PHS mesh is associated with an increased risk of perioperative complications compared with Lich-

Table 3 VAS scores of the patients

	L group		UHS		
VAS scores ± SEM	Rest	Motion	Rest	Motion	*P* value
VAS first day	0.52 ± 0.01	1.88 ± 0.17	0.34 ± 0.08	1.4 ± 0.16	ns
VAS first week	0.1 ± 0.04	0.34 ± 0.07	0.08 ± 0.04	0.38 ± 0.09	ns
VAS third month	0.04 ± 0.02	0.08 ± 0.04	0.06 ± 0.03	0.06 ± 0.03	ns

Table 4 Medium-term outcomes of the patients undergoing primary inguinal hernia repair

	L group	UHS group	*P* value
Follow-up time, mo, mean ± SD	33.34 ± 3.10	33 ± 2.98	ns
0–30 d, n			
Scrotal hematoma	3	2	ns
Seroma	2	3	
Ischemic orchitis	1	0	
Total, n (%)	6 (12)	5 (10.2)	ns
30 d–6 mo, n			ns
Sensory disturbance	1	1	
Testicular atrophy	1	0	
Groin discomfort	1	2	
Foreign body sensation	2	1	
Neuralgia	2	2	
Total, n (%)	7 (14)	6 (12.2)	ns

tenstein repair, whereas both techniques have comparable short- and long-term outcomes.[16]

Another aspect of prosthetic inguinal hernia repairs is mesh material. Several recent controlled studies have suggested that lightweight meshes may improve patient comfort; however, standard heavyweight polypropylene mesh is still the type most frequently used.[17] UHS is a lightweight counterpart of PHS that provides less chronic discomfort and foreign body feeling. To date, the only study comparing Lichtenstein repair, PHS, and UHS has been carried out in the Karolinska Institutet in Sweden. They concluded that the Lichtenstein technique, PHS, and UHS provided similar outcomes regarding perioperative course, complications, recurrence rates, development of chronic groin pain, and improvement in quality of life after 12 months. However, because of reduced costs and the lack of need for the exploration of the preperitoneal space, the authors stated that the Lichtenstein technique should be recommended as first choice.[18]

There are a very limited number of studies in the literature about the outcomes after UHS use and its long-term results. The present study gives the outcomes with a mean follow-up of 33 ± 3.03 months. This study may also be of importance because it compares two edges of the spectrum in open prosthetic repair of primary inguinal hernias: one edge is lightweight bilayer mesh, and the other edge is heavyweight anterior mesh. Theoretically, UHS may have advantages of lower recurrence, being bilayer mesh, and being lightweight, making it more comfortable. However, the present study revealed that none of these theoretical advantages were proven true clinically.

In the present study we confirmed no differences between groups regarding perioperative course, intraoperative complications, postoperative rehabilitation, or recurrence. The lack of differences seen in our study may be due to the selection of a population that was relatively healthy and had a good healing potential. In contrast to some previous studies, we found a significantly longer operation time in the UHS group. Although the surgeons had experience with UHS before becoming involved in the study, a longer experience with the Lichtenstein technique and the need to explore preperitoneal space might have contributed to this finding.

This study was a small, single-center, 2 surgeon–based prospective randomized trial. It has several limitations. For example, only healthy male patients with primary inguinal hernia were included in the study. This is why our conclusions should be validated for larger patient populations. At the time of study design power analysis showed ($P < 0.05$, power 0.80) that sample size for each group should be 55 based on the studies, which has been done prior to the study date. However, new tendencies during the study period have shown that power should be elevated to 0.90 (N = 141; 70 for each group). Because there was not any statistical trend toward a significant difference except prolonged operation time in the UHS group during the first 100 patients, a decision was made to stop the enrollment of patients in the study.

Conclusions

Our study demonstrates that in treatment of primary inguinal hernias, bilayer mesh systems in their best and most expensive form cannot provide better short-term outcomes in comparison with the Lichtenstein repair with standard single-layer polypropylene mesh. We think that the Lichtenstein repair should be recommended as the first choice for this group of patients.

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