Abstract

**Purpose.** The efficacy of ULTRAPRO™ HERNIA SYSTEM (UHS) technique was evaluated by comparison with standard Prolene hernia system (PHS) technique and the direct Kugel patch (DKP) technique.

**Methods.** Forty-one patients with inguinal hernias treated by using UHS technique. They were compared with 84 patients treated with PHS technique and 116 patients treated by the DKP technique. These 3 groups were compared with respect to postoperative wound pain, wound swelling, and seroma formation.

**Results.** The incidence of wound pain at the first outpatient visit after discharge was 7.3%, 17.9%, and 13.8%, in the UHS, PHS, and DKP groups, respectively. It was lower in the UHS group. The incidence of wound swelling was 4.9%, 11.9%, and 15.5%, respectively. The incidence of seroma was 2.4%, 9.5%, and 9.5% respectively. Both of these postoperative complications showed also lower incidence in the UHS group.

**Conclusion.** Although we found that postoperative pain, wound swelling, and seroma tended to be less frequent in the UHS group than in the PHS and DKP groups, it did not show significant superiority in this study.

**Key words:** inguinal hernia, ULTRAPRO™ HERNIA SYSTEM, comparative study

Introduction

Tension-free repair using mesh is a common surgical technique for inguinal hernia in adults. Prolene hernia system (PHS) technique and the direct Kugel patch (DKP) technique are widely used in Japan, but sometimes cause postoperative wound pain, wound swelling, and seroma formation due to a foreign body reaction. Kingsnorth et al. reported that 16.4% of patients experienced pain which affected their social activities for 1 year or more after surgery. For the purpose of decreasing such postoperative complications, use of Ultrapro hernia system (UHS) technique (Fig. 1; a light-weight semiabsorbable mesh with large pores) has also become popular recently in Japan. The guidelines of the European Hernia Society recommend light-weight mesh and large pore mesh as grade A materials for biocompatibility and prevention of chronic pain when treating inguinal hernia in adults. It was also reported that the recurrence rate was similar, but the
incidence of pain and an abnormal sensation at 3 years after surgery, was lower with light-weight mesh than heavy mesh in patients having primary repair of a unilateral inguinal hernia by the Lichtenstein technique. In the present study, the surgical outcome was compared among patients treated at our hospital using UHS technique, PHS technique, and the DKP technique. The efficacy and weaknesses of UHS technique are reported together with discussion of the relevant literature.

**Patients and Methods**

Among inguinal hernia patients operated on between January 2007 and March 2011, 41 patients treated with UHS technique were compared with 84 and 116 patients treated with PHS technique and the DKP technique, respectively.

**Demographic characteristics**

The 41 patients in the UHS group included 39 men and 2 women with a mean age of 68.9 years (range: 32-90 years). The hernia was located on the right, left, and bilaterally in 22, 14, and 5 patients, respectively. According to the Japanese Hernia Society classification, the hernia was stage I, II, III, and IV in 34, 6, 1, and 1 of the patients, respectively. An incarcerated hernia (without intestinal necrosis) was noted in 3 patients. The PHS group consisted of 84 patients (80 men and 4 women) with a mean age of 65.7 years (range: 24-92 years). The hernia was located on the right, left, and bilaterally in 36, 35, and 13 patients, respectively. The Japanese Hernia Society stage was I, II, III, and IV in 55, 22, 1, and 4 patients, respectively. Incarceration of the hernia (without intestinal necrosis) was found in 6 patients. The DKP group comprised 116 patients (106 men and 10 women) with a mean age of 67.4 years (range: 27-86 years). The hernia was on the right side, left side, and bilateral in 61, 49, 6 patients, respectively. The Japanese Hernia Society stage was I, II, III, and IV in 67, 40, 2, and 7 patients, respectively. Incarceration (without intestinal necrosis) was seen in 8 patients (Table 1). These background factors showed no significant differences among the 3 groups.

**Surgical procedure**

A skin incision approximately 5 cm long was made at the midpoint of a line connecting the anterior superior iliac spine to the pubic tubercle in order to expose the aponeurosis of external oblique muscle. Then an incision was made from the external inguinal ring as far as the aponeurosis of external oblique to open the inguinal canal. After the vas deferens was taped at the upper margin of the pubic tubercle, a search was made for the hernial sac. If the sac was identified, parietalization was performed, and the hernial opening and the inferior epigastric artery and vein were confirmed. If the sac was large, high ligation was added, the preperitoneal cavity was reached via the preperitoneal fascia, and the space was expanded manually. In the UHS and

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Table 1  Profile of the 3 groups

<table>
<thead>
<tr>
<th></th>
<th>UHS (41 patients)</th>
<th>PHS (84 patients)</th>
<th>DKP (116 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (M : F)</td>
<td>39 : 2</td>
<td>90 : 4</td>
<td>106 : 10</td>
</tr>
<tr>
<td>Mean age</td>
<td>68.9 years (32-90 years)</td>
<td>65.7 years (24-92 years)</td>
<td>67.4 years (27-86 years)</td>
</tr>
<tr>
<td>Site of hernia (right : left : both)</td>
<td>22 : 14 : 5</td>
<td>36 : 35 : 13</td>
<td>61 : 49 : 6</td>
</tr>
<tr>
<td>Incarcerated : nonincarcerated</td>
<td>3 : 38</td>
<td>6 : 78</td>
<td>8 : 108</td>
</tr>
</tbody>
</table>

These background factors showed no significant differences among the groups.
PHS groups, an underlay patch was inserted into the preperitoneal cavity. After cutting a slit in the onlay patch, it was fixed to the pubic symphysis by 3 sutures and also to the aponeurosis of external oblique and the inguinal ligament by approximately 3 sutures each of 3-0 absorbable treated. In the DKP group, after mesh was inserted into the preperitoneal cavity, the strap was fixed, and an onlay patch was inserted as required (Fig. 2). The wound was closed after hemostasis was confirmed.

Items investigated the Mann-whitney U test or the χ²-test was used to assess intergroup differences of the following factors: 1) operating time, 2) use of analgesics on discharge, 3) pain at the first visit to the outpatient clinic after discharge, 4) use of analgesics at the first visit to the outpatient clinic after discharge, 5) use of analgesics from 1 month after surgery, 6) wound swelling at the first visit to the outpatient clinic after discharge, 7) seroma formation, 8) wound infection, and 9) recurrence. Differences of p<0.05 were considered to be statistically significant. The first visit to the outpatient clinic after discharge was defined as the first attendance at clinic within 4-14 days of discharge. Wound swelling was considered to exist if the patient complained of it and palpation disclosed marked induration of the wound. Seroma was diagnosed it was confirmed by palpation and ultrasonography.

Results
The result of postoperative factors show Table 2. The mean operating time was 82.75, 76.85, and 65.34 min in the UHS, PHS, and DKP groups, showing significant differences. There were no significant differences between the UHS group and the PHS group. But the UHS group was significantly long compared to the DKP group (p=0.2159, p=0.002).

Incidence of wound pain
Analgesics on discharge were used by 13 patients (31.71%), 35 patients (41.67%), and 46 patients (39.66%) from the UHS, PHS, and DKP groups, respectively, with no significant intergroup differences (p=0.552). Pain at the first outpatient visit was noted in 3 patients (7.32%), 15 patients (17.86%), and 16 patients (13.79%) from the UHS, PHS, and DKP groups, respectively, showing no significant differences (p=0.280). Analgesics at the first outpatient visit after discharge were used by 3 patients (7.32%), 8 patients (9.52%), and 11 patients (9.48%) from the UHS, PHS, and DKP groups, respectively, showing no significant differences (p=0.440). Analgesics use from 1 month after surgery were noted in 1 patient (2.44%), 4 patients (4.76%), and 5 patients (4.31%) from the UHS, PHS, and DKP groups, respectively, showing no significant differences (p=0.824).

Incidence of wound swelling and seroma
The wound swelling at the first outpatient visit after surgery were noted in 2 patients (4.88%), 10 patients (11.9%), and 18 patients (15.52%) from the UHS, PHS, and DKP groups, respectively, showing no significant differences (p=0.204). Seromas were found in 2 patients (4.88%), 8 patients (9.52%), and 11 patients (9.48%) from the UHS, PHS, and DKP groups, respectively, showing no significant differences (p=0.633).

Wound infection and recurrence
The wound infection only occurred in 1 patient (0.89%) from the DKP group, but there were no significant intergroup differences (p=0.582). The Recurrences were noted in 1 patient (1.19%) and 2 patients (1.79%) from the PHS and DKP groups.
respectively, showing no significant intergroup differences (p=0.692).

**Discussion**

Tension-free repair using mesh is a common surgical procedure for adult inguinal hernia that is performed by the mesh plug, Kugel, and PHS techniques. However, because heavy mesh is usually employed for these techniques, problems such as pain, wound swelling, and seroma may occur after surgery due to a foreign body reaction. In recent years, with the objective of decreasing such complications, tension-free repair using light-weight mesh has also been performed increasingly in Japan. Klosterhalfen et al.\(^5\) classified mesh with a pore size of 1 mm or more as light-weight mesh and mesh with a smaller pore size as heavy mesh. Based on the polypropylene content, Cobb et al.\(^6\) classified mesh as light-weight (35 g/m\(^2\) or less), heavy (90 g/ m\(^2\) or more), or medium (more than 35 g/m\(^2\) to less than 90 g/m\(^2\)). Because light-weight mesh is light and has large pores, excessive scar formation may be inhibited and more physiological tissue integration may be achieved. Based on the results of studies in rats, Klinge et al.\(^7\) reported that dense scarring was noted and chronic inflammation occurred when heavy mesh with small pores was used, while the inflammatory reaction was inhibited and more physiological tissue integration was achieved when light-weight mesh with large pores was used. UHS is characterized by large pores and a light weight (28 g/m\(^2\)) and is a semiabsorbable mesh composed of nonabsorbable Prolene and absorbable Monocryl. Monocryl accounts for 70% of the mesh and it is absorbed within approximately 120 days, thus decreasing the amount of foreign material. Bellon et al.\(^8\) reported that the content of type I collagen in repair tissue tended to be higher when semiabsorbable mesh was used. Thus, it is suggested that use of light-weight mesh can inhibit foreign body reactions and decrease complications. However, to prevent recurrence of the hernia, the most important consideration when selecting mesh for repair is sufficient resistance to pressure. The intra-abdominal pressure is usually 4 and 13 mmHg in the supine and standing positions, respectively, but increases to a maximum of 252 mmHg when a person jumps. However, the Ultrapro mesh (comparable to the overlay UHS) can withstand 650 mmHg, which is at least twice the maximum intra-abdominal pressure, so it seems unlikely that problems regarding strength will arise. Current mesh products show 20% contraction over time after insertion\(^9\), and loss of adequate fixation due to such contraction is also considered to be a factor in recurrence. In contrast, Ultrapro mesh has been reported to show only 1.9% contraction\(^10\), and this may also be an advantage for preventing recurrence.

Although the incidence of postoperative wound pain, wound swelling, and seroma was lower in the UHS group than in the PHS and DKP groups, it did not show significant superiority in this study. Thus, our results did not contradict the concept that light-weight mesh causes a less severe foreign body reaction and decreases postoperative complications. Watanabe et al.\(^11\) applied the Lichtenstein technique with light-weight mesh in 20 men with unilateral inguinal hernia, and they found that the patients were pain-free at 1 month after surgery and were satisfied with the outcome. Shimada et al.\(^12\) investigated a total of 143 patients, and reported that the incidence of wound swelling was significantly lower, while postoperative pain and seroma tended to be less frequent, in the group treated by the mesh plug technique using light-weight mesh compared with groups treated by the Kugel technique or the mesh plug technique using heavy mesh.

As a weakness of UHS technique, the operating time was significantly longer in this series, presumably because more sutures were used for fixing the onlay patch in the UHS and PHS groups than were used to fix the strap in the DKP group. At present, we fix the onlay patch with a total of 9 sutures when using UHS technique. However, the operating time could be shortened if our skill in performing this technique improved and the number of suture was reduced. There has been no recurrence so far (a maximum of 20 months after surgery) in patients treated with UHS technique at our hospital, but it is necessary to continue follow up for a longer period.

In conclusion, although we found that postoperative pain, wound swelling, and seroma tended to be less frequent in the UHS group than in the PHS and DKP groups, it did not show significant superiority in this study. Using of UHS may have the possibility to tend to improve the quality of life after inguinal hernia repair. Because light-weight mesh should be used more widely in the future, it is expected
that more reports will be published concerning long-term results and comparison with endoscopic surgery.

References


