

# Inguinal Hernia Repair with ProGrip™ Mesh Under Local Anesthesia in High-Risk Elderly Patients

## Yüksek Riskli Yaşlı Hastalarda Lokal Anestezi Altında ProGrip™ Yama ile Kasık Fıtığı Onarımı

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### Abstract

**Background:** Inguinal hernia operation is one of the most common operations in the world and in our country. A wide variety of operation types are available. In elderly patients with high risk and / or comorbid comorbidity, inguinal hernia repair is a good option under local anesthesia. The aim of this study is to demonstrate the reliability and effectiveness of open inguinal hernia surgery using ProGrip (Parietex) patch in high-risk elderly patients under local anesthesia.

**Materials and Methods:** The results of 160 patients who underwent inguinal hernia surgery using Parietex ProGrip mesh between January 2014 and March 2018 were retrospectively reviewed. Local anesthesia was administered by anesthesiology expert with using a mixture of 20 mg/ml lidocaine + 0.0125 mg / mL epinephrine, 2% prilocaine, 0.5% bupivacaine and saline. Preoperative ultrasonography was performed to assess the type of inguinal hernia, and Gilbert was the preferred classification method. The operative and mesh application times, postoperative recurrence of hernia and health status, along with follow-ups were statistically evaluated.

**Results:** In the present study, 160 patients had a mean  $\pm$  standard deviation (SD) age of  $73.6 \pm 3.4$  y. Most were diagnosed with Gilbert type 2 (n = 42; 26.3%) and type 3 (n = 49; 30.6%) inguinal hernias; all were ASA Grade 3 (n = 83; 51.9%) or Grade 4 (n = 77; 48.1%). The mean  $\pm$  SD operative and mesh application times were  $30.0 \pm 3.8$  min and  $1.18 \pm 0.6$  min, respectively. No anesthesia-related side effects or treatment-related mortalities were observed. No readmission, systemic complication, postoperative recurrence or death occurred during the 6-month follow-up period. Postoperative seroma was observed in 6 patients and confirmed by a radiologist via ultrasonography. The pain visual analog scale (VAS) score decreased significantly and the health VAS score increased significantly over time (p=0.0001 for both).

**Conclusions:** Open inguinal hernia surgery performed using a self-adhesive Parietex ProGrip mesh under local anesthesia is a safe and effective treatment option for high-risk elderly patients.

**Key Words:** Inguinal hernia, Local anesthesia, Comorbidities

Öz.

**Amaç:** Kasık fıtığı operasyonu dünyada ve ülkemizde en sık görülen operasyonlardan biridir. Çok çeşitli operasyon tipleri mevcuttur. Yüksek riskli ve/veya eşlik eden komorbite taşıyan yaşlı hastalarda, lokal anestezi altında inguinal herni onarımı iyi bir seçenektir. Bu çalışmanın amacı, lokal anestezi altında yüksek riskli yaşlı hastalarda ProGrip (Parietex) yama kullanarak açık inguinal herni ameliyatının güvenilirliğini ve etkinliğini göstermektir.

**Materyal ve Metod:** Ocak 2014 - Mart 2018 tarihleri arasında ProGrip (Parietex) yama ile inguinal herni ameliyatı olan 160 hastanın sonuçları retrospektif olarak incelendi. Anestezi tipi, anestezi uzmanı tarafından yapılan lokal anestezidir. Lokal anestezi, 20 mg / ml lidokain + 0.0125 mg / ml epinefrin, % 2 prilokain, % 0.5 bupivakain ve serum fizyolojisi karışımı kullanılarak yapıldı. Preoperatif ultrasonografi tüm hastalara radyolog tarafından inguinal herni tipini korele etmek için yapıldı ve fıtığı sınıflandırmak için Gilbert'in sınıflandırması seçildi. Operasyon zamanı , yama uygulama zamanı , ameliyat sonrası fıtık nüksü ve takip ile birlikte sağlık durumu istatistiksel olarak değerlendirildi.

**Bulgular:** Bu çalışmada 160 hasta, ortalama - standart sapma (SD) yaşı  $73.6 \pm 3.4$  (65-82) idi. Kasık fıtığı hastalarının çoğuna Gilbert tip 2 (n = 42;%26,3) ve tip 3 (n = 49;% 30,6) tanısı kondu. Bu gruptaki katılımcıların tamamı ASA Grade 3 (n = 83; 51,9) veya Grade 4 (n = 77;%48,1) idi. Ortalama  $\pm$  SD cerrahi süresi  $30.0 \pm 3.8$  dk (20-45 dk) ve kendinden yapışkanlı yama uygulaması için gereken süre 0.5 dk ila 4 dk (ortalama  $1.18 \pm 0.6$  dk) idi. Anestezi ile ilişkili yan etkiler veya tedavi ile ilişkili mortalite tespit edilmedi. Altı aylık takipte geri kabul, sistemik komplikasyon, ameliyat sonrası nüks veya ölüm görülmedi. Postoperatif seroma 6 hastada gözlemlendi ve radyolog tarafından ultrasonografi ile doğrulandı. Yaş, cinsiyet, VKİ (vücut kitle indeksi), fıtık yeri, Gilbert Sınıflaması, Mesh Yerleştirme Süresi, ameliyat süresi, ASA ve postop VAS skorları arasında istatistiksel olarak anlamlı bir ilişki bulunmadı.

Yaş, cinsiyet, VKİ, fıtık yeri, Gilbert Sınıflaması, yama yerleştirme süresi, ameliyat süresi, ASA ve postop sağlık VAS skorları arasında istatistiksel olarak anlamlı bir ilişki bulunmadı.

Sağlık VAS skorunun zamanla belirgin olarak arttığı ve VAS skorunun zamanla önemli ölçüde azaldığı bulundu (p = 0,0001).

**Sonuç:** Bu çalışmanın sonuçları, kendinden yapışkanlı yama (ProGrip) kullanılarak yapılan açık kasık fıtığı ameliyatının, lokal anestezi altında yüksek riskli yaşlı hastalar için güvenilir ve etkili bir yöntem olduğunu göstermektedir.

**Anahtar kelimeler:** Kasık fıtığı, Lokal anestezi, Komorbidite

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## Introduction

Inguinal hernia repair surgery is one of the most commonly performed surgical procedures worldwide, treating over twenty million people annually (1). There exist many variations of this surgery, owing to a surgeon's specific training (2), and as such, the best method remains controversial.

A dramatic improvement in the outcome of inguinal hernia repair surgery has been observed with the Lichtenstein open herniorrhaphy procedure (3), as well as the use of local anesthesia. Many surgeons have since proceeded to use this technique, making it the gold standard (4,5); however, it is not without complications, which include longer postoperative recovery time and chronic inguinal pain (6). With regard to local anesthesia, it has been shown to have many benefits over regional and general anesthesia. Increasing experience in the administration of local anesthesia appears to be important for reducing the risk of reoperation (2).

Roughly 1-3% of patients suffer from chronic pain after inguinal hernia repair surgery (3). Although the cause of this pain after hernioplasty has not been fully elucidated, it is believed to be attributed to the type of repair technique (such as mesh fixation) and skin agitation from different mesh types (7). In particular, heavyweight polypropylene mesh causes inflammation leading to scar tissue and mesh shrinkage (8). Therefore, using a lighter weight mesh and decreasing the degree of fixation may help prevent these unwanted side effects (9-11). To this point, self-adhesive mesh, such as Parietex ProGrip, has been used with great success in repairing incisional and inguinal hernias.

The purpose of the present study was to investigate the reliability and efficacy of open inguinal hernia surgery utilizing Parietex ProGrip mesh in high-risk elderly patients under local anesthesia. Postoperative complications, hernia recurrence and chronic pain were evaluated at a 6-month follow-up.

## Materials and Methods

This was a retrospective study (n=160) that assessed outcomes from open inguinal hernia repair surgery using Parietex ProGrip self-adhesive mesh between January 2014 and March 2018. Individuals with a unilateral or bilateral inguinal hernia and over 65 years of age were eligible for the study. If an individual had an incarcerated femoral hernia, a scrotal hernia, or had undergone a laparoscopic inguinal hernia operation or emergency surgery, they were excluded from the study. The clinical ethics board with the Faculty of Medicine at Cukurova University (reference no:94 6 December 2019) approved the study.

Parietex ProGrip is a self-adhesive mesh, made of polylactic acid (PLA) microgrips and monofilament polyester, that enables instant fixation for safer surgeries. PLA microgrips allow surgeons to deploy the mesh in <1 min and without the need for extra fixation (12). In this study, surgeries were

carried out using the 12 x 8 cm Parietex ProGrip meshes (PP1208DL/DR), placing them over the transversalis fascia and behind the spermatic cord surrounding the myopectineal orifice (Figure 1).

Local anesthesia was administered as described by Wantz, using a mixture of 20 mg/mL lidocaine + 0.0125 mg/mL epinephrine, 2% prilocaine, 0.5% bupivacaine, and serum physiology (13). Open inguinal hernia repair surgery was carried out by an experienced surgeon following the Lichtenstein method, as described by Amid (14,15). Preoperative ultrasonography was performed by a radiologist to assess the type of inguinal hernia. Cases were classified according to the Gilbert system (16,17), and categorized by the American Society of Anesthesiologists' (ASA) method to assess comorbidities existing before operation (18). Follow-up was carried out by the surgeon at day one and seven, and month one and six month after the operation. Outcome criteria involved operative and mesh application times, hernia recurrence after surgery, and health status. Preoperative and postoperative pain and health were evaluated utilizing a pain visual analog scale (VAS) and a health VAS, respectively, with endpoints ranging for the former from 0 to 10 (0 being pain-free, 10 being the most intense pain) and endpoints ranging for the latter from 0 to 100 (0 being worst conceivable condition, 10 being best conceivable condition) (19,20).

## Results

Table 1 shows there were 160 patients with a mean  $\pm$  standard deviation (SD) age of  $73.6 \pm 3.4$  (65-82) y, 44 (27.5%) being female and 116 (72.5%) being male. Most were diagnosed with Gilbert type 2 (n=42; 26.3%) and type 3 (n=49; 30.6%). All the participants were ASA Grade 3 (n=83; 51.9%) or Grade 4 (n=77; 48.1%).

Table 2 shows the mean  $\pm$  SD surgical time was  $30.0 \pm 3.8$  (20-45) min, and the time required for the self-adhesive mesh application was  $1.18 \pm 0.6$  (0.5-4) min. Anesthesia-associated side effects or treatment-associated mortalities were not detected. Follow-up at 6 months revealed no re-admission, systemic complications, postoperative recurrence or death. Postoperative seroma was observed in six patients and confirmed by the radiologist via ultrasonography; three patients had seromas evacuated under ultrasound guidance, and three had seromas spontaneously resorb. A postoperative wound infection developed in one patient and urinary tract infections developed in five patients, though these subsided after treatment.

Tables 3-4 and Figures 2-3 detail the postoperative health status, pain at day one and seven, and month one and sixth during the follow-up period. The mean  $\pm$  SD pain VAS score decreased from  $3.5 \pm 0.8$  on day one to  $0.07 \pm 0.2$  at month 6. The mean  $\pm$  SD health VAS score increased from  $53.9 \pm 3.9$  on day one to  $96.1 \pm 2.1$  at month 6. All 160 participants attained good health and reported

mild/painless quality of life at one-month follow-up. The pain VAS score decreased significantly and the health VAS score increased significantly over time ( $p = 0.0001$  for both). There was no significant association between preoperative VAS scores and postoperative day one VAS scores ( $p = 0.066$ ), nor were there any associations between age, gender, body mass index, hernia location, Gilbert classification, mesh placement time, operation time, ASA and postoperation pain and health VAS scores.

**Table 1.** Patients Demographics and Operational Details

	n	%
<b>Sex</b>		
Female	44	27,5
Male	116	72,5
<b>Age(y)*</b>	73.6± 3.4	(65-82)
<b>BMI(kg/m2)*</b>	30.7± 2.0	(23-35)
<b>Gilbert Classification</b>		
1	21	13.1
2	42	26.3
3	49	30.6
4	23	14.4
5	18	11.3
6	7	4.4
<b>ASA</b>		
3	83	51.9
4	77	48.1
<b>Operation Time(min)*</b>	30.0± 3.8	(20-45)
<b>Mesh Placement Time(min)*</b>	1.18± 0.6	(0.5-4.0)
<b>Duration of Hospital Stay(hour)*</b>	22.07± 4.5	(12-48)

\* mean±SD(range);

ASA=American Society of Anesthesiologists; BMI=body mass index; SD=standard deviation

**Table 2.** Postoperative Complications

	n	%
<b>Hematoma</b>		
No	159	99.4
Yes	1	0.6
<b>Urinary Tract Infection</b>		
No	155	96.9
Yes	5	3.1
<b>Wound Infection</b>		
No	159	99.4
Yes	1	0.6
<b>Seroma</b>		
No	154	96.3
Yes	6	3.8
<b>Recurrence</b>		
No	160	100.0

**Table 3.** Postoperative Health VAS Score

	Health VAS A day 1	Health VAS A day 7	Health VAS A month 1	Health VAS A month 6	p
<b>Mean±SD</b>	53.9±3.9	66.8±3.9	80.1±4.0	96.1±2.1	$p=0.0001$
<b>Median (Min-Max)</b>	54 (40-65)	68 (55-75)	79 (72-89)	96 (90-100)	

### Discussion

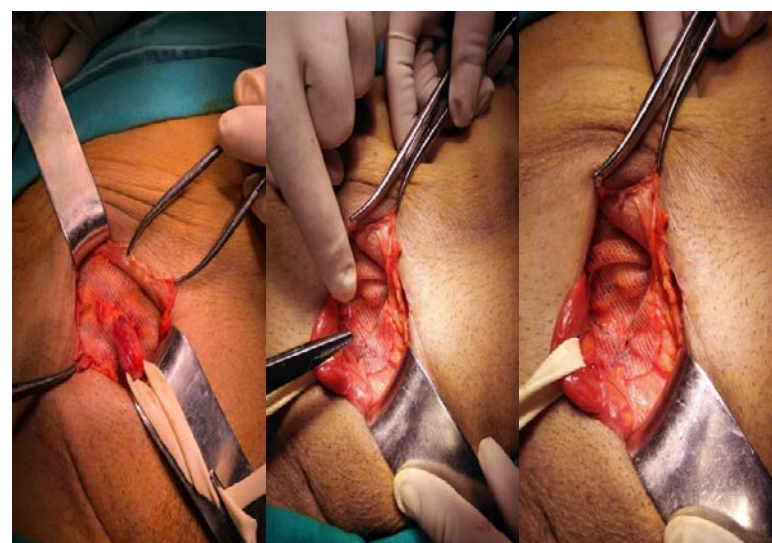
An increase in information, better education, national supervision and expertise in the management of inguinal hernias will enhance consistency and ensure more successful

and efficacious outcomes. All of these factors are modifiable in surgical practices, and allocation branches in subsequent outcome researches could be balanced against these acquired and demographic risk determinants (2). Inguinal hernia repair surgeries can be performed easily with local anesthesia; however few surgeons choose this method. Administering local anesthesia confers many advantages in open repair, but the surgeon must be experienced with this method. For such operations in high-risk patients, this is a superior option because findings show that it results in a quicker recovery time than general anesthesia (2,21). In the present study, postoperative hospital stay was  $22.07 \pm 4.5$  h.

**Table 4.** Preoperative and Postoperative VAS Score

	Preoperative VAS	Postoperative VAS day 1	Postoperative VAS day 7	Postoperative VAS month 1	Postoperative VAS month 6	p
<b>Mean±SD</b>	3.3±1.4	3.5±0.8	1.7±0.7	0.44±0.6	0.07±0.2	$p=0.0001$
<b>Median (Min-Max)</b>	3 (0-8)	3 (2-5)	2 (0-4)	0 (0-2)	0 (0-1)	

Side effects of spinal anesthesia such as urinary tract retention, hypotension and bradycardia are well known. In high-risk patients treated under general anesthesia, complications often include urinary retention, arrhythmia, respiratory depression, bronchoconstriction and the need for postoperative mechanical ventilation. Notably, the incidence of urinary retention after inguinal hernia repair surgery can range from 1-20%, and the reason for this condition is generally due to the usage of general and spinal anesthesia (2). In our study, urinary tract retention was not observed in any patients.



**Figure 1.** Appearance of Mesh Placement

The mesh settle down to the tissue with the micro-grips promptly and not requesting any additional fixation.

Parietex ProGrip mesh is promising adhesive because it is attached suture-free, minimizing the risk of nerve injury and protecting anatomical frameworks. Furthermore, the resorbable PLA micro holdings of the mesh are largely blind which impeding injury to enclosing tissues (22). Repeatedly shifting the mesh placement can decrease adhesion to tissues and raise the risk of mesh displacement or emigration, yes with using Parietex ProGrip – whose mesh is doubled over the long axle – the mesh field is reduced, facilitating a better positioning of the mesh. Furthermore, this technique can prevent mesh dislocation or emigration, which may be rooted in postoperative chronic pain and hernia recurrence.

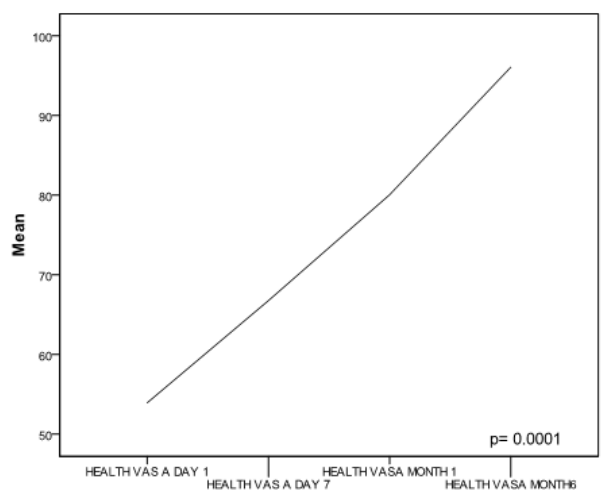


Figure 2. Postoperative Health VAS Score

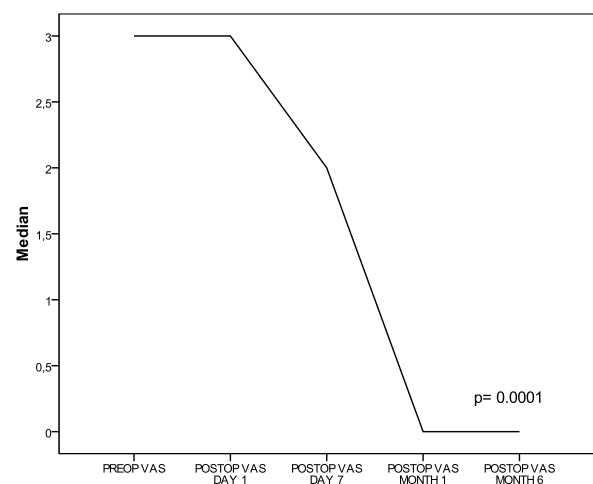


Figure 3. Preoperative and Postoperative VAS Score

Pioneering research on the usage of a self-adhesive Parietex ProGrip mesh (polypropylene with wide pores and absorbable PLA microgrids) has reported less pain on the postoperative day one in contrast to the usage of other wide porous non-gripping polypropylene mesh (23). Addi-

tionally, in an investigation consisting of 557 males receiving open hernia repair surgery followed by suture fixing or self-adhesive ProGrip mesh, findings showed that initial postoperative pain scales were lower in patients who had received the self-adhesive mesh over the sutures: mean pain VAS (0–150) score at baseline was +1.3 and +8.6, respectively, at discharge (p=0.033), and mean operative pain VAS score at baseline was +4.2 and +9.7 respectively, on day seven (p=0.027) (24). In our study, pain was minimal on the first postoperative day. The pain VAS score was found to decrease significantly over time, whereas the health VAS score was found to increase significantly over time.

A few studies have reported shorter surgical times without suture mesh fixing. Two in particular evaluated self-gripping meshes with suture fixing and revealed 9 min (p=0.01) and 12 min (p=0.008) reductions in mean surgical times (23,25). In our study, the operation time and mesh placement time were 30.0 ± 3.8 and 1.18 ± 0.6 min, respectively. Indeed, the self-adhesive mesh ensures the benefit of achieving repair without the use of any sutures, and as such, all patients declared no or minimal pain and good health at the one-month follow-up.

**Conclusion**

The outcomes from this study show that inguinal hernia repair surgery using the Lichtenstein method with self-adhesive mesh is a reliable and effective method for high-risk elderly patients under local anesthesia.

**Ethical Approval:** This study was approved by the Institutional Review Ethics Committee at Cukurova University. (Ethics Committee reference number: 94 and date 6 December, 2019).

**Conflict of Interest**

The authors declare that there is no financial support and there is no conflict of interest

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**Abbreviations**

- PLA: Polylactic acid
- ASA: American Society of Anesthesiologists
- VAS: Visual analog score
- BMI: Body mass index

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