Five-year results of inguinal hernia treatment with the Prolene Hernia System in a regional training hospital

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Abstract
Purpose Long-term results of inguinal hernia repair with the Prolene Hernia System (PHS) in our regional training hospital were retrospectively analysed. Research was conducted in an identical cohort of patients previously investigated for short-term results.

Methods One-hundred and fifty-eight patients (217 inguinal hernias) treated with the PHS were traced and included. Patients were invited to visit the outpatient clinic for a brief history, physical examination and ultrasound. A quality of life questionnaire was completed by all patients. The primary endpoint was recurrence rate. Testis atrophy, chronic pain and hypaesthesia were secondary endpoints.

Results The mean age of the population (n = 187) was 62.2 years (range 28–92), with a male:female ratio of 15:1 (175:12). The median follow-up was 5.5 years (range 3.9–6.8). One-hundred and forty-five patients visited the outpatient clinic, while 13 patients were included by telephone interview. Twenty-one patients died during follow-up and eight others were lost to follow-up. The resulting follow-up rate was 85% (158/187). In our initial study, we found four recurrences (1.8%) and seven patients with persisting pain (3.2%) after 32 months. During current follow-up, five patients were diagnosed with recurrent herniation (2.3%, 5/217) and only four patients (1.8%) suffered from persisting pain. Three patients (1.4%) were diagnosed with testicular atrophy, while ten patients (4.4%) experienced hypaesthesia.

Conclusion In a regional training hospital, the recurrence rate and long-term complications of patients treated for inguinal hernia with the PHS are acceptable after a follow-up of 5.5 years. The number of patients experiencing persistent pain seems to decrease over time.

Keywords Inguinal hernia · PHS · Recurrence · Long-term complications · Pain

Introduction

Inguinal hernia repair is the most frequently performed procedure in general surgery [1]. The introduction of anterior tension-free techniques, in combination with a patch and/or plug, has led to acceptable results of recurrence and morbidity compared with tension-producing approaches [1–5].

In 2003, an evidence-based guideline for the treatment of inguinal hernia was introduced in the Netherlands [6]. The most important recommendation was the use of a mesh-based technique in adults when performing an anterior approach. The Lichtenstein technique was recommended for primary unilateral inguinal hernia based on available studies up to 6 years ago. Despite different modifications in order to improve the results, this technique is still known to have recurrence rates of over 5% after 12 months and chronic pain in more than 20% of all patients [7–12].

The use of the bilayer Prolene Hernia System (PHS), which combines the anterior approach and posterior mesh augmentation with minimal fixation, is becoming an accepted technique. Many reports have already shown a low recurrence rate and morbidity [13, 14] and several randomised clinical trials (RCTs) were conducted comparing the PHS with Lichtenstein, a technique widely implemented.
in Dutch hospitals [6]. Despite a significantly shorter operation time in favour of the PHS approach, these studies reported almost comparable results regarding the recurrence rate and recovery after operation [1, 15]. However, long-term follow-up is lacking so far.

In a previous study 3 years ago, we reported on the short-term results of our patients treated with the PHS in a Dutch regional training hospital [5]. The aim of the current study is to analyse the long-term results in the same cohort of patients.

**Patients and methods**

All patients (187 patients with 217 inguinal hernias) who were treated with the PHS during the period 2002–2004 were included. The group consisted of 178 primary hernias and 39 recurrent hernias (after non-mesh repair). All patients were over the age of 18 years. Patients diagnosed with American Society of Anesthesiologists (ASA) class IV or V [16], strangulated hernias and/or with previous mesh repair were excluded. No other selection was performed.

All patients were operated on using the bilayer PHS (Ethicon, Norderstedt, Germany). Informed consent was obtained by letter and all patients were asked to visit the outpatient clinic for history, physical examination and ultrasound. Patients who refused to come to the outpatient clinic were visited at their home address.

The primary endpoint of this study was the recurrence of inguinal hernia. Secondary endpoints were long-term complications, such as chronic pain, hypaesthesia and testicular atrophy.

In case of clinical suspicion of a recurrence and/or pain during physical examination, an ultrasound was performed. Hypaesthesia was defined as sensory change, sensory loss or numbness in the innervation areas of the ilioinguinal, genitofemoral and iliohypogastric nerve. Sensory changes in these areas were compared with contralateral skin and testicular atrophy was assessed by the Prader orchidometer by also comparing to the contralateral testis. Chronic pain was notified through history and was classified as mild, moderate or serious.

Quality of life was analysed through a short form (SF) 36-item questionnaire. The results were transformed for various aspects of well being and compared with the findings of typical Dutch inhabitants [17, 18].

**Surgeon and surgical technique**

All operations were performed by general surgeons with varying subspecialties or surgical residents (postgraduates 1–6 years) supervised by a surgeon. In all procedures, the inguinal canal was opened through an oblique incision followed by incision of the external oblique aponeurosis. In case of indirect hernias, blunt dissection was used to separate the hernia sac from the cord followed by ligation and resection of the sac. For direct hernias, the preperitoneal space was entered by dividing the transversalis fascia at the level of the hernia and exposing the preperitoneal space by using a finger or sponge dissection in a blunt manner. Epigastric vessels were not routinely ligated. After insertion, the entire myopectineal orifice (MPO) can be covered by the underlay of the PHS device. The onlay part was cut and both slips of the mesh were slid around the spermatic cord and fixed to each other. Additionally, the onlay part was fixed with one single stitch near the pubic bone.

**Results**

Thirty patients had bilateral hernias (21 primary hernias and nine recurrent hernias). The mean age was 62.2 years (range 28–92) with a male:female ratio of 15:1.

From the group of 187 patients, 21 patients died during follow-up without signs of recurrence. Eight other patients were lost to follow-up. All of the remaining 158 patients were included to take a brief history and were asked to fill out a questionnaire; 145 patients were clinically examined. Thirteen patients refused to be examined due to various reasons. This resulted in a follow-up rate of 85% (158/187).

After a median follow-up of 5.5 years (range 3.9–6.8), just one additional patient was diagnosed with a recurrent inguinal hernia after treatment with PHS. This results in a total recurrence rate of 2.3% (five patients). Two additional patients were diagnosed with testicular atrophy (three in total), while the occurrence of hypaesthesia decreased to ten patients (4.4%) compared to 19 patients in the former study (8.8%; Table 1). Four patients experienced pain 66 months after surgery and all patients described their pain as being mild.

The SF 36-item scores (Table 2) were comparable to those of typical Dutch inhabitants scores [18].

<table>
<thead>
<tr>
<th>Table 1 Results of the previous [5] and current study</th>
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<tbody>
<tr>
<td>Number of analysed patients</td>
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<tr>
<td>-------------------------------</td>
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<tr>
<td>Follow-up rate (%)</td>
</tr>
<tr>
<td>Median follow-up (years)</td>
</tr>
<tr>
<td>Chronic pain (%)</td>
</tr>
<tr>
<td>Testicular atrophy (%)</td>
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<tr>
<td>Hypaesthesia (%)</td>
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<td>Recurrence (%)</td>
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</table>
Table 2 Quality of life assessed by the short form (SF) 36-item questionnaire

<table>
<thead>
<tr>
<th>SF-36</th>
<th>Current study</th>
<th>Previous study</th>
<th>Typical Dutch inhabitants</th>
</tr>
</thead>
<tbody>
<tr>
<td>General health</td>
<td>66</td>
<td>68</td>
<td>67</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>76</td>
<td>64</td>
<td>78</td>
</tr>
<tr>
<td>Vitality</td>
<td>70</td>
<td>57</td>
<td>62</td>
</tr>
<tr>
<td>Mental health</td>
<td>79</td>
<td>63</td>
<td>71</td>
</tr>
<tr>
<td>Role emotional</td>
<td>85</td>
<td>64</td>
<td>70</td>
</tr>
<tr>
<td>Role physical</td>
<td>76</td>
<td>76</td>
<td>78</td>
</tr>
<tr>
<td>Social functioning</td>
<td>76</td>
<td>80</td>
<td>83</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>81</td>
<td>72</td>
<td>75</td>
</tr>
</tbody>
</table>

Discussion

This is the first study reporting the long-term follow-up (5.5 years) of patients treated with the PHS for inguinal hernia. The results were analysed in a cohort of previously investigated patients. Efforts were made to include 158 patients from the initial group of 187 patients. This was achieved in 85% of all patients.

Several RCTs have been conducted comparing the PHS with other techniques. Kingsnorth et al. [15] investigated short- and medium-term outcomes of patients treated with the PHS compared to those who were treated with the Lichtenstein technique. This study showed a 10% decrease in operating time when the PHS was used. Furthermore, no recurrences were reported in the PHS group, while two recurrences were reported after Lichtenstein hernioplasty. The follow-up was restricted to 1 year. Vironen et al. [1] revealed no statistically significant difference in postoperative pain between patients treated by the Lichtenstein technique or the PHS. However, the operation time was shorter with the PHS and patients regained sporting activities earlier. Follow-up was also restricted to 1 year postoperatively.

The recurrence rate in our current study was 2.3% after more than 5 years. The reported recurrence rate in specialised clinics varies from 0.1 to 0.6% [13, 19]. Our results are comparable with the published data for general surgeons, varying from 1.0 to 4.9% [5, 20–24]. It is worth mentioning that all five patients with recurrences in our study were operated by first- and second-year residents, supervised by a surgeon. Also, remarkably, all five patients were treated with a medium-size PHS, used during the first months after introduction, which has an underlay patch diameter of just 7 cm. This will not cover the entire MPO (6–8 cm) and may, therefore, have influenced our recurrence rate [25]. The study reported by Hasegawa et al. [21] shares the point of view that fully deploying the underlay patch is essential in regard to preventing recurrences of the direct type. Nowadays, only large-size PHS meshes are used for the treatment of inguinal hernia in our hospital.

The current study also shows a decrease in the amount of patients affected by chronic pain from seven patients after 32 months (3.2%) to four patients after 5.5 years (1.8%). All patients described the pain as mild and said that they had learned to live with it. Possibly, fixation of the mesh with Prolene during the first months after the introduction of this technique contributes to the occurrence and maintenance of chronic pain, as all patients with chronic pain had medial fixation with Prolene. This was only used during the first 12 months, after which Vicryl was used. The fact that the PHS requires only minimal fixation could be an explanation for this significantly lower rate of chronic pain in relation to the Lichtenstein technique, even after its modifications with lightweight material [12].

The SF 36-item questionnaire also shows also a decreasing trend regarding the bodily pain dimension of these patients 5.5 years after the procedure, as well as lower scores for general health and social functioning dimensions. A possible explanation is the ageing process and the occurrence of co-morbidity.

This study also shows a slight increase in the amount of an atrophic testis. We do not know whether this can be related to the procedure 5 years earlier or not. Possibly the contact between the mesh and inguinal cord is resulting in an ongoing effect on the cord.

Hypaesthesia occurred in 10 patients (4.4%) versus 19 patients (8.8%) in the previous study, which is a remarkable decrease. The number of patients suffering from chronic pain and/or hypaesthesia decreases over time. It is unclear whether these patients actually experience less pain or are getting more used to the pain.

The PHS technique has previously shown acceptable short-term results. This procedure is characterised by a short learning curve, short duration of the procedure, low complication rate and is applicable for all types of inguinal hernias. The PHS is, therefore, an exceptionally fit procedure 5 years after the introduction of this technique contributes to the occurrence and maintenance of chronic pain, as all patients with chronic pain had medial fixation with Prolene. This was only used during the first 12 months, after which Vicryl was used. The fact that the PHS requires only minimal fixation could be an explanation for this significantly lower rate of chronic pain in relation to the Lichtenstein technique, even after its modifications with lightweight material [12].

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Conflicts of interest statement The authors declare that they have no conflict of interest.

References