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**THE INCIDENCE OF INGUINAL HERNIA RECURRENCE AFTER LAPAROSCOPIC  
HERNIORRHAPHY – A RETROSPECTIVE MULTICENTRE COHORT STUDY OF PATIENTS  
OPERATED ON AT A PRIVATE PRACTICE IN CAPE TOWN**

by

**Dr. Colin Iain McGuire**  
**Student number: MCGCOL005**

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Supervisors:  
Professor D. Kahn (Head of the Department of Surgery – University of Cape Town)  
Professor R.J. Baigrie (Department of Surgery – University of Cape Town)

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# **Part A - Protocol**

University of Cape Town

## RESEARCH PROPOSAL – July 2010

# **THE INCIDENCE OF INGUINAL HERNIA RECURRENCE AFTER LAPAROSCOPIC HERNIORRHAPHY – A RETROSPECTIVE MULTICENTRE COHORT STUDY OF PATIENTS OPERATED ON AT A PRIVATE PRACTICE IN CAPE TOWN.**

C.I. McGuire, R.J. Baigrie, D. Theunissen, D. Kahn

Department of General Surgery, Groote Schuur Hospital, University of Cape Town

## **INTRODUCTION**

Inguinal hernias have plagued mankind for thousands of years. The complexity of this problem has resulted in numerous methods of repair being developed over the past centuries. It was not until 1884 that a safe and effective operation was discovered by Professor Bassini of Italy.<sup>1</sup> His recurrence rate was unheard of at the time and marked a distinct turning point in the evolution of herniorrhaphy.<sup>2</sup> The operation was considered the gold standard for inguinal hernia repair for most of the twentieth century.<sup>3</sup> Lotheissen, McVay, Halsted, Shouldice, and others described modifications of Bassini's repair in attempts to further reduce the recurrence rate and to avoid complications.

The problem with these tissue repair methods is the tension placed upon the tissues which can lead to recurrence. This led to the introduction of mesh repairs in an attempt to reduce wound tension. Lichtenstein popularised this technique and his repair was the first pure prosthetic, tension-free repair to achieve consistently low recurrence rates in long-term

outcomes analysis.<sup>4</sup> A Lichtenstein type operation has now become the method of choice in many centres around the world. The superiority of mesh repair was confirmed in a 2001 review of open mesh versus non-mesh techniques, conducted by the Cochrane group in conjunction with the European Hernia Trialists Collaboration.<sup>5</sup>

### **Laparoscopic Inguinal Herniorrhaphy**

Laparoscopic inguinal herniorrhaphy was introduced in the late 1980s. It was first described by Ger in 1982,<sup>6</sup> and pointed out its potential advantages such as:

- less postoperative discomfort or pain
- reduced recovery time allowing earlier return to full activity
- easier repair of a recurrent hernia because the repair is performed in tissue that has not been previously dissected
- the ability to treat bilateral hernias

It is not universally accepted that these advantages have been achieved, and the operation remains controversial. Detractors point to the possibility of a laparoscopic accident resulting in a major complications and the need for a general anaesthetic. In addition, many surgeons are concerned about the expensive equipment needed. They argue that the open operation can be performed under local anaesthesia on an outpatient basis, with minimal risk of intra-abdominal injury, and at less cost.<sup>3</sup>

Today, most laparoscopic inguinal hernia repairs are performed with placement of a synthetic mesh into the preperitoneal space, which can be accomplished in one of two ways: the transabdominal preperitoneal (TAPP) approach or the totally extraperitoneal (TEP) approach.

## **Laparoscopic or open tension-free mesh repair?**

A Cochrane review in 2003 showed recurrence rates for laparoscopic and open repair to be equivalent.<sup>7</sup> Besides recurrence rates, other important factors to consider are the duration of the operation, complication rates, length of hospital stay, time to return to usual activities, persisting pain and numbness and port site hernias. The same Cochrane review found that laparoscopic techniques had:

- Longer operating times of about 15 minutes
- Lower incidence of haematomas, wound infection, and persisting pain and numbness
- Higher incidence of seromas
- Higher incidence of vascular injuries and visceral injuries (predominantly bladder but also stomach, small bowel and post-operative bowel obstruction)
- Faster return to usual activities by about seven days

There were 6 cases of port site hernias of the 3138 patients that underwent laparoscopic repair (0.2%).

## **Aims**

The primary outcome will be the incidence of hernia recurrence. Secondary outcomes will be the incidence of post-operative and long-term pain and complications.

## **Methods and analysis**

At the institution where this study will occur, all patients' records are recorded on an electronic database. This institution uses the laparoscopic TEP method to repair inguinal hernias. Contactable patients who underwent laparoscopic inguinal herniorrhaphy before 2006 will be interviewed telephonically, providing at least a 5 year follow up. The following information will be recorded on a data sheet:

### **DEMOGRAPHICS**

- Hospital number, age, sex, and date of surgery

### **CLINICAL NOTES**

- If the patient had a previous appendicectomy
- If the patient had a previous ipsilateral or contralateral hernia repair
- Whether the hernia was irreducible
- The side of the hernia according to the patient
- If the hernia was unilateral or bilateral according to the assessment by the surgeon

### **OPERATION NOTE**

- If a bilateral hernia was found at surgery
- If a unilateral or bilateral repair was performed
- The type of hernia (direct or indirect)
- If there was a large lipoma of the spermatic cord
- If the operation had to be converted to an open repair

- Any other significant problems encountered during surgery
- Which surgeon performed the operation

#### FOLLOW UP VISIT

- Any complication (e.g. urinary retention, testicular swelling, pain)

#### TELEPHONIC INTERVIEW

- If the patient had a recurrence of their hernia, and if so had this been confirmed by a surgeon
- If the patient still suffers from chronic groin pain
- If the patient had a previous open repair of their hernia, which technique was more painful

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## **Part B – Literature Review**

University of Cape Town

## The history of inguinal hernias

Hernia derives from the Greek word *hernios*, which means offshoot or bud and dates back 3000 years. There is even evidence that the Pharaohs of ancient Egypt suffered this affliction.<sup>1</sup>

Before the advent of modern techniques, numerous methods of hernia repair (many of them barbaric) have been tried but all have failed, either through death of the patient or recurrence of the hernia.<sup>1</sup> The first evidence of operative repair of a groin hernia dates to the first century AD. The original hernia repairs involved wide operative exposures through scrotal incisions requiring orchidectomy. Centuries later, around 700 AD, principles of operative hernia repair evolved to emphasise mass ligation and en bloc excision of the hernia sac, cord, and testis distal to the external ring.<sup>2</sup> Due to the unappealing nature and high recurrence rates of these techniques, the use of a supporting truss became the mainstay of treatment. This was the standard treatment for inguinal hernias up until the late 1800's. The truss consisted chiefly of flexible steel bands, and was placed around the hips and groin. At the site of the hernia was a leather cushion which kept the hernia site permanently under pressure, thus replacing the lost counter-pressure of the abdominal wall and preventing the re-emergence of the hernia.<sup>1</sup>

It was not until 1884 that a safe and effective operation was finally discovered by Edoardo Bassini of Padua, Italy.<sup>1</sup> By 1890 Bassini had operated on 262 patients and reported 100% follow-up of patients over a 5year period, with just 5 recurrences. This rate of recurrence was unheard of at the time and marked a distinct turning point in the evolution of herniorrhaphy. Bassini's repair emphasises both the high ligation of the hernia sac in the internal ring, as well as suture reinforcement of the posterior inguinal canal.<sup>2</sup> This was the first time this method had come to the attention of the world, and thereafter Padua became

the Mecca for numerous surgeons eager to learn the Bassini method of repair.<sup>1</sup> Edoardo Bassini is considered the father of modern inguinal hernia surgery. It is universally agreed that this concept was responsible for the advent of the modern surgical era of inguinal herniorrhaphy and is still valid today. The operation was considered the gold standard for inguinal hernia repair for most of the twentieth century.<sup>3</sup>

The advances in groin hernia repair have shared the primary goal of reducing long-term recurrence rates. To this end, efforts have been directed at developing a repair that imparts the least tension on the tissues.<sup>2</sup> Lotheissen, McVay, Halsted, Shouldice, and others described modifications of Bassini's repair in attempts to further reduce recurrence rates and avoid complications. Low recurrence rates have been achieved with these variations in the hands of expert surgeons. However, population-based studies have shown an unacceptably high recurrence rate of approximately 15% in general surgery. In addition, these operations have been considered relatively painful because of the tension created by approximating tissues that are not naturally in apposition.<sup>3</sup>

The most popular was the Shouldice technique, initially introduced in 1958, and is in essence a modification of the Bassini operation. This technique involves meticulous dissection of the entire inguinal floor and closure of the inguinal canal in four layers. The Shouldice Hospital reports excellent long-term outcomes from their operation with recurrence rates consistently less than 1%.<sup>4</sup> These results have not been achieved with any other pure tissue technique. The dissection is complicated, however, and requires excellent surgical technique and anatomic awareness. Moreover, other surgeons utilising the Shouldice method have not achieved recurrence rates this low. Thus, the low rate of recurrence associated with the Shouldice technique likely depends on the level of surgical expertise and the patient selection.<sup>4</sup> In one report of 183 inguinal hernia repairs using the

Shouldice technique under local anaesthesia, the recurrence rates for beginners versus more experienced surgeons were 9.4% versus 2.5%, respectively.<sup>5</sup> The Shouldice technique is now often regarded as the gold standard non-mesh or tissue repair method.

The problem with the tissue repair methods is the tension placed upon the tissues which can lead to hernia recurrence. Darn repairs were first introduced in the early 20th century to reduce wound tension by using either autologous tissue or synthetic suture to bridge the gap between fascial tissues. Muscle and fascial flaps were attempted without consistent success. In 1918, Handley introduced the first use of silk as a prosthetic darn and nylon followed several years later. However, it was found that heavy prosthetic material increased the risk of wound infection, and the silk suture ultimately lost its strength over time. The use of autologous or synthetic patches was also attempted in order to reduce wound tension and improve rates of recurrence. The first patches, beginning in the early 20th century, consisted of silver wire filigree sheets that were placed along the inguinal canal. Over time, the sheets suffered from metal fatigue leading to hernia recurrence. Reports of the wire patches eroding into adjacent inguinal structures and even the peritoneal cavity itself caused even more concern with this technique. The modern synthetic patch, made of a plastic monofilament polymer (polyethylene), was introduced by Usher in 1958.<sup>2</sup> Stoppa introduced the posterior approach to the inguinal hernia in 1975. The hallmarks of this approach included complete dissection of the preperitoneal space, identification of all myopectineal orifices, and placement of mesh over the entire inguinal-femoral region.<sup>6</sup>

Lichtenstein popularised this technique by developing a hernia repair using an onlay mesh patch placed across the inguinal floor.<sup>7</sup> The Lichtenstein repair was the first pure prosthetic, tension-free repair to achieve consistently low recurrence rates in long-term outcomes

analysis; even when performed by general surgeons with no specific interest in inguinal hernias.<sup>8</sup> A Lichtenstein type operation has now become the method of choice in many centres around the world.

Some less popular tension free repairs include the plug-and-patch technique; the Kugel patch and other preperitoneal techniques; and the Prolene hernia system. In 1993 Rutkow and Robbins described the plug-and-patch technique which consists of plugging the hernia defect with a mesh-plug and an on-lay patch over Hesselbach's triangle.<sup>9</sup> The main concern with this technique has been the incidence of chronic pain, which was shown to be significantly greater than the Lichtenstein technique in a randomised controlled trial.<sup>10</sup> Kugel described his minimally invasive preperitoneal patch in 1999.<sup>11</sup> Placing mesh behind the transversalis fascia, requires dissection in the complex preperitoneal space and can lead to injury of the pelvic structures or haematoma formation.<sup>12</sup> A randomised controlled trial showed no significant difference in recurrence rates between the Lichtenstein repair and a preperitoneal repair.<sup>13</sup> The Prolene hernia system is a bilayer mesh that combines the Lichtenstein repair and the preperitoneal repair. Blind dissection of the preperitoneal space to create the pocket for the deep layer is required which may cause bleeding. Furthermore, the deep layer is not fixed in place and may fold or wrinkle.<sup>12</sup>

### **Open mesh repair versus open non-mesh repair for groin hernia repair**

The literature is largely in favour of mesh repair methods in terms of recurrence rates. A 2002 review of twenty trials comparing open mesh techniques with open non-mesh techniques was conducted by the Cochrane group in conjunction with the European Hernia Trialists Collaboration.<sup>14</sup> There were no clear differences between mesh and non-mesh

groups for haematomas, seromas or wound/superficial infections. Overall, those in the mesh groups had a shorter length of hospital stay and quicker return to usual activities, but this pattern was not observed for all trials. There was a suggestion that persisting pain was less frequent after mesh repair than after non-mesh repair. There was no evidence of a difference between the groups with respect to persisting numbness. Recurrence rate after mesh repair was consistently lower and overall was reduced by between 50% and 75%. This was seen regardless of whether Shouldice or another non-mesh method was used.

### **Laparoscopic Inguinal Herniorrhaphy**

Laparoscopic inguinal herniorrhaphy was introduced in the late 1980s and early 1990s. The first laparoscopic inguinal hernia repair was performed by Ger in 1990 on a dog by stapling the abdominal opening of the patent processus vaginalis.<sup>15</sup> He first described the procedure in 1982,<sup>16</sup> and pointed out its potential advantages such as:

- less postoperative discomfort or pain
- reduced recovery time allowing earlier return to full activity
- easier repair of a recurrent hernia because the repair is performed in tissue that has not been previously dissected
- the ability to treat bilateral hernias
- the performance of a simultaneous diagnostic laparoscopy
- the highest possible ligation of the hernia sac
- improved cosmesis

It is not universally accepted that these advantages have been achieved, and the operation remains controversial. Detractors point to the possibility of a laparoscopic accident resulting

in a major complication such as bowel perforation or vascular injury, potential adhesive complications at sites where the peritoneum has been breached or prosthetic material has been placed, port site hernias and the need for a general anaesthetic. In addition, many surgeons are concerned about the expensive equipment needed, especially when dealing with an uncomplicated unilateral inguinal hernia. They argue that the open operation can be performed under local anaesthesia on an outpatient basis, with minimal risk of intra-abdominal injury, at less cost.<sup>3</sup>

Since the introduction of laparoscopic herniorrhaphy, there has been a steady increase in the number of cases performed. A study in Olmsted county in the United States of America, showed that open mesh repairs predominated in 2001 with 72% of all repairs performed. In 2008 open mesh repair had decreased to 55%, while laparoscopic repair had increased steadily from 6% in 1992 to 41% in 2008.<sup>17</sup>

Today, most laparoscopic inguinal hernia repairs are performed with placement of a synthetic mesh into the preperitoneal space, which can be accomplished in one of two ways: the transabdominal preperitoneal (TAPP) approach or the totally extraperitoneal (TEP) approach. The TAPP approach, first described by Arregui and colleagues in 1992, requires laparoscopic access into the peritoneal cavity and placement of mesh in the preperitoneal space after reducing the hernia sac. The first TEP inguinal hernia repair was described by McKernan and Laws in 1993. This approach involves preperitoneal dissection and mesh placement without entering into the abdominal cavity.<sup>15</sup> The laparoscopic intraperitoneal onlay mesh technique involves placing mesh over the hernia site in the

peritoneal cavity. Although a more simple operation, it is now rarely performed due to the risk of mesh erosion into bowel.<sup>15</sup>

### Laparoscopic or open mesh repair?

The introduction of tension-free mesh repairs and laparoscopic techniques in the 1990's created a great deal of interest in the outcomes of the various surgical options. Many study groups and societies were completely devoted to researching this topic. By the end of the decade it had been conclusively shown that both open and laparoscopic mesh techniques were superior to conventional tissue repairs.<sup>14,18,19</sup> It was shown that recurrence rates were less and the incidence of chronic pain was decreased. This resulted in the focus being shifted toward comparing laparoscopic and open tension-free mesh repairs.

A number of multicentre prospective randomized trials have been conducted to compare the two techniques. Some of the larger studies are listed in the table below.

Investigator	Year	Follow up	No. of patients	Recurrence rate		Statistically significant?
				Laparoscopic	Open	
MRC <sup>20</sup>	1999	1 year	928	1.9%	0	Yes
SCUR <sup>21</sup>	1999	1 year	613	2%	5.5%	No
VA <sup>22</sup>	2004	2 years	1696	10.1%	4.9%	Yes
Eklund, et al <sup>23</sup>	2009	5 years	1512	3.5%	1.2%	Yes

### VA Trial

The recurrence rates at 2-year follow-up were 10.1% and 4.9% after laparoscopic and open mesh repair, respectively. This rate is significantly higher than that quoted in other articles and information is not given linking the specific operation with the recurrence. However, when surgeon experience was taken into consideration, the recurrence rate for surgeons who had performed more than 250 laparoscopic repairs was equivalent to open repairs (5.1% versus 4.1%). Although 250 repairs are many more than most experienced laparoscopic hernia surgeons consider necessary to become proficient, this may be testimony to differences in reported recurrence rates.<sup>22</sup>

### Eklund, et al

Eklund, et al used 26 surgeons in the laparoscopic group, but found that one surgeon was responsible for a third of the recurrences. The exclusion of this surgeon from the results lowered the cumulative recurrence rate to 2.4% in this group, which resulted in no statistically significant difference in the recurrence rates. They concluded that the significantly higher recurrence rate in the laparoscopic group could be attributable to surgical technique.<sup>23</sup>

A Cochrane review in 2003<sup>24</sup> identified 41 randomised controlled trials involving 7161 patients, which compared laparoscopic and open techniques. The recurrence rate for laparoscopic repair was 2.7% and for open repair 3.1%,  $p=0.16$  (not statistically significant). This was found regardless of whether the laparoscopic technique was TAPP or TEP.

The Cochrane review also found that laparoscopic techniques had:

- Longer operating times of about 15 minutes

- Lower incidence of haematomas, wound infection, and persisting pain and numbness
- Higher incidence of seromas
- Higher incidence of vascular injuries and visceral injuries (predominantly bladder but also stomach, small bowel and post-operative bowel obstruction).
- Faster return to usual activities by about seven days

There were 6 cases of port site hernias of the 3138 patients that underwent laparoscopic repair (0.2%).

The possibility of a major complication such as a vascular or visceral injury, which may be associated with significant morbidity, is considered by many to be a major drawback to laparoscopic repair. In the Cochrane review these complications were very rare. In the laparoscopic group there were three intra-operative vascular injuries and six visceral injuries (four bladder, one small bowel and one stomach). In the open group there was one small bowel injury. There were no deaths in either group that were related to the hernia repair.<sup>24</sup>

One of the major criticisms of laparoscopy is the higher cost. Cost is difficult to evaluate as it includes many hidden costs such as depreciation of equipment. Nevertheless, studies have consistently demonstrated a significantly higher cost for laparoscopic repair.<sup>20,21,25,26</sup> A 2005 review<sup>27</sup> showed laparoscopic repair to be more costly to the United Kingdom by 300-350 GBP per patient. A large randomised multicentre study conducted in Sweden in 2010 showed the total hospital cost of laparoscopic repair to be 710 Euros higher per patient than Lichtenstein repair.<sup>28</sup>

## **TAPP or TEP?**

TEP is considered more difficult than TAPP but may result in fewer complications by not exposing the intra-abdominal organs to injury.<sup>29</sup> TAPP has been advocated for complicated hernias (sliding or incarcerated) and hernias with previous pelvic surgery (radical prostatectomy).<sup>29</sup> Wake and colleagues in a 2005 Cochrane review<sup>30</sup> comparing TAPP and TEP identified only one randomised control trial which found no statistical difference in length of operation, length of stay, time to return to normal activity, or recurrence rates between the two techniques. This trial involved only 52 patients with a mean follow up of only three months. They identified eight non-randomised studies, including retrospective case series involving a total of more than 15000 TAPP or TEPP repairs, which suggest that TAPP is associated with higher rates of visceral injuries and port site hernias, whilst there appear to be more conversions with TEP. They concluded that there is insufficient evidence to allow conclusions to be drawn between the two methods, and that more trials are needed.

## **Indications and contraindications**

In certain situations, most surgeons would agree that laparoscopic repair is better than open repair. Such as:

- A recurrence from a prior open repair – dissection through scar tissue is avoided. A 2009 meta-analysis<sup>31</sup> comparing laparoscopic and open repair of recurrent hernias showed there was no difference in future recurrence or chronic pain. However, laparoscopic surgery was associated with significantly less postoperative pain, a quicker return to normal activities and fewer wound infections, at the cost of a

longer operating time. There was no difference in haematoma formation or the need for additional operations.

A recent nationwide Danish analysis of 2117 re-operations for inguinal hernia recurrence concluded that laparoscopic repair is the operation of choice for recurrence after a primary open Lichtenstein repair.<sup>32</sup>

- Bilateral inguinal hernias – studies significantly favour laparoscopic repair in terms of less post-operative pain and an earlier return to work, without finding any difference in recurrence rates or complications.<sup>33,34</sup>

Other possible indications include:

- If the diagnosis of an inguinal hernia is not certain, diagnostic laparoscopy provides a definitive diagnosis and the opportunity to repair the hernia at the same time.
- Morbidly obese patients – diagnosis is sometimes difficult and it avoids the large incision required in patients who are susceptible to wound complications.
- Patients who are eager to return to normal activity. Due to the posterior repair used in laparoscopy, any increase in intra-abdominal pressure will push the mesh into position; therefore physical activity is not limited after laparoscopic repair.<sup>15</sup>

However, there is no evidence that physical activity is detrimental after an open repair.

Possible contraindications:

- Previous lower abdominal surgery
- Pelvic radiation
- Previous extraperitoneal surgery (e.g. radical retropubic prostatectomy)

- Patients not suitable for a general anaesthetic <sup>35</sup>
- Strangulated inguinal hernia
- Recurrence of a previous laparoscopic repair <sup>15</sup>

In patients with clinically unilateral hernias, laparoscopic repair has the advantage of exploring the contralateral side for an occult hernia. A high incidence of occult contralateral hernia has been reported in the literature. One study involving 100 consecutive patients with clinically unilateral hernias showed an occult contralateral hernia rate of 22% when the contralateral side was routinely explored.<sup>36</sup> Consequently many surgeons routinely explore the contralateral side and perform a prophylactic repair. One study retrospectively reviewed 976 patients who underwent laparoscopic TEP repair over a period of 14 years. 95% of these patients underwent bilateral exploration regardless of whether a bilateral hernia was clinically evident. 55% were found to have bilateral hernias of which one third were occult. 409 patients had a bilateral exploration with a unilateral repair. There was a yearly risk of developing a contralateral hernia in this group of 1.2% per year.<sup>37</sup> The benefit of performing a prophylactic repair needs to be balanced against the risks which appear to be low. One study of 150 patients showed no difference in complication rates or pain when performing a bilateral or unilateral repair.<sup>38</sup>

## **SUMMARY**

Techniques have been evolving for over a century, shifting from tissue repairs to mesh repairs and now to laparoscopic repair. This new technique is slowly gaining worldwide acceptance and is now the first choice for inguinal hernia repair in many centres around the world. Laparoscopic herniorrhaphy can be performed safely with a low recurrence rate

comparable to that of open repair. It has distinct advantages such as less post-operative pain and an earlier return to work. However, it takes longer to perform, is more difficult to learn, is more expensive and requires a general anaesthetic, all reasons why it is not more commonly performed. Nevertheless, with efforts to cut the cost of equipment and the continuous honing of laparoscopic skills by surgeons these disadvantages can be offset.

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# **Part C – Manuscript**

University of Cape Town

**THE INCIDENCE OF INGUINAL HERNIA RECURRENCE AFTER**  
**LAPAROSCOPIC HERNIORRHAPHY – A RETROSPECTIVE**  
**MULTICENTRE COHORT STUDY OF PATIENTS OPERATED ON AT A**  
**PRIVATE PRACTICE IN CAPE TOWN.**

C.I. McGuire, R.J. Baigrie, D. Theunissen, D. Kahn

**Abstract**

*Aim:* The primary outcome parameter was recurrence. The secondary outcome parameters were post-operative and long term complications.

*Methods:* At this institution, 507 patients underwent laparoscopic totally extraperitoneal (TEP) inguinal hernia repair prior to September 2005. An attempt was made to contact all of these patients to perform a telephonic interview. Only the patients who underwent a telephonic interview were included in this study. Patients operated on after September 2005 were not considered, thus ensuring a minimum 5 year follow up. Patient demographic data, clinical notes, operation notes and outpatient follow up notes were studied. Patients were interviewed telephonically regarding hernia recurrence, chronic pain and if they had previously undergone an open repair, which technique had been more painful. All data collected was recorded on an electronic database.

*Results:* Of the 507 patients, 267 patients were contactable telephonically. There were 395 hernia repairs with a mean follow up of 8.8 years. There were 9 recurrences (2.3%). The overall complication rate was 7.9%. Two percent of patients suffered from chronic groin pain with gradual improvement since surgery. Sixteen percent of patients had a previous

open repair of an inguinal hernia, either on the ipsilateral or contralateral side, and all judged the open repair to have been more painful.

*Conclusions:* The recurrence and complication rates for laparoscopic TEP inguinal hernia repair in this study are low and comparable to other series. There is a low incidence of persistent post-operative pain with the laparoscopic technique, and this technique was found to be less painful by patients who had previously undergone an open repair.

## **Introduction**

Inguinal hernias have plagued mankind for thousands of years.<sup>1</sup> The complexity of this problem has resulted in numerous methods of repair being developed and it is now the most commonly performed operation in general surgery. It was not until 1884 that a safe and effective operation was finally discovered by Edoardo Bassini in Italy.<sup>1</sup> The Bassini repair was considered the gold standard for inguinal hernia repair for most of the twentieth century.<sup>2</sup> The problem with tissue repair methods is the tension placed upon the tissues which can lead to hernia recurrence. This led to the introduction of mesh repairs in an attempt to reduce wound tension and lower recurrence rates. Lichtenstein popularised this mesh technique and the Lichtenstein repair was the first pure prosthetic, tension-free repair to achieve consistently low recurrence rates in long-term outcomes analysis.<sup>3</sup> A Lichtenstein type operation has now become the method of choice in many centres around the world. The superiority of the mesh repair over tissue repairs was confirmed by a 2001 review which was conducted by the Cochrane group in conjunction with the European Hernia Trialists Collaboration.<sup>4</sup>

Laparoscopic inguinal herniorrhaphy was first described by Ger in 1982.<sup>5</sup> Proponents of this technique have claimed several advantages over open repair: less postoperative discomfort or pain; reduced recovery time and earlier return to full activity; easier repair of a recurrent and bilateral hernia, less wound complications and improved cosmesis.

It is not universally accepted that these advantages have been achieved, and the operation remains controversial. Detractors point to the possibility of a laparoscopic accident resulting in a major complication such as bowel perforation or vascular injury, potential adhesive complications at sites where the peritoneum has been breached or prosthetic material has been placed, port site hernias and the need for a general anaesthetic. In addition, many surgeons are concerned about the expensive equipment needed, especially when dealing with an uncomplicated unilateral inguinal hernia. They argue that the open operation can be performed under local anaesthesia on an outpatient basis, with minimal risk of intra-abdominal injury, at less cost.<sup>2</sup>

A Cochrane review in 2003 showed recurrence rates for laparoscopic and open repair to be equivalent.<sup>6</sup> It also concluded that laparoscopic techniques were found to have:

- Longer operating times of about 15 minutes
- Lower incidence of haematomas, wound infection, and persisting pain and numbness
- Higher incidence of seromas
- Higher incidence of vascular injuries and visceral injuries (predominantly bladder but also stomach, small bowel and post-operative bowel obstruction)
- Faster return to usual activities by about seven days

## Aims

The primary outcome parameter was recurrence. The secondary outcome parameters were post-operative and long term complications.

## Methods

In this practice, all patients' records are stored on an electronic database. This specifically designed, non-commercial practice management system contains a complete clinical and management record for over 200 000 general surgical patients over more than 20 years. All patient details (demographic, clinical, operative details, ICD-10 codes, procedural codes and billing records) are entered contemporaneously into the database ensuring complete retention of all consultation notes and operative records. Patients for the study were identified using ICD-10, procedural and billing codes, providing a high level of accuracy of data retrieval in this retrospective study. The details of 850 consecutive patients undergoing laparoscopic TEP inguinal herniorrhaphy between July 1997 and July 2010 were identified. In order to obtain a follow up of at least 5 years, 507 patients who underwent repair before September 2005 were selected for a telephonic interview. Patients who were not contactable or who declined an interview were not included in this study. The following information was obtained during the telephonic interviews which were undertaken by 2 medical students with no affiliation to the practice, who were supervised by the first author:

- If the patient had a recurrence of their hernia, and if so had this been confirmed by a surgeon
- If the patient suffers from chronic groin pain since the surgery. The pain was not graded.

- If the patient had a previous open repair of their hernia, which technique was more painful

The following information was obtained from the patient's electronic record:

#### CLINICAL NOTES

- Previous appendicectomy
- Previous ipsilateral or contralateral hernia repair
- Whether the hernia was irreducible
- If the hernia was unilateral or bilateral according to the assessment by the surgeon
- The side of unilateral hernias

#### OPERATION NOTE

- If a bilateral hernia was found at surgery
- If a unilateral or bilateral repair was performed
- The type of hernia (direct or indirect)
- If there was a large lipoma of the cord
- If the operation had to be converted to an open repair
- Any other significant problems encountered during surgery
- Which surgeon performed the operation

#### FOLLOW UP VISITS

- Any complication (e.g. urinary retention, testicular swelling, seroma)

Ethical approval for the study was obtained from the ethics committee of the University of Cape Town.

## Results

All surgeons in this practice use the TEP technique for laparoscopic hernia repairs. The repairs were performed by six surgeons working in three centres. These patients include the learning curve of five surgeons, the group's initial proctor being surgeon 04. This resulted in a high level of homogeneity amongst the surgeons in operative TEP technique, for example, a spiral tacker was routinely used by all surgeons, but mesh selection was not standardised for type and size.

Patient demographics and hernia characteristics are shown in Table 1. A telephonic interview was conducted on 267 of the 507 patients in the original cohort. The remaining 240 patients were not contactable or declined to be interviewed. The age ranged from 22-92 years with a mean of 63 years old, and 98% were males. The mean follow-up was 8.8 years, ranging from 5.3 to 14 years.

A total of 395 hernias were repaired. There were 128 bilateral hernias (48%) of which 34 had been occult contralateral hernias found during bilateral exploration of a clinically apparent unilateral hernia. There were more right sided hernias than left. Twenty six of the hernias operated upon were recurrences from previous conventional open repairs. Indirect hernias were found to be more common than direct hernias. Two hernias were irreducible at the time of surgery, 1 of which required conversion to open repair.

Sixteen percent of patients had a previous open repair of an inguinal hernia, either on the ipsilateral or contralateral side. These patients were asked which procedure had been more painful and all of them reported more pain after the open repair.

Five percent of patients had a previous appendicectomy. None of these patients required conversion to open repair or had a recurrence of their hernia.

Of the 395 hernias repaired, there were 9 recurrences (2.3%) (Table 2). Six recurred within the first year, and there were three late recurrences which occurred after 8, 10 and 13 years respectively.

There were 27 complications (7.9%) (Table 2). The most common complications were chronic groin pain and post-operative seromas. All 8 patients with chronic groin pain reported gradual improvement since surgery and in none was it considered restrictive at the time of interview. Post-operative seromas in 9 patients resolved with conservative management. All patients with post-operative umbilical port site cellulitis were managed satisfactorily with antibiotics with no reintervention. There were 3 umbilical port site hernias. Two operations were converted to standard open mesh repairs. A left sided irreducible sliding hernia, involving the sigmoid colon was unable to be reduced laparoscopically. Bleeding, sufficient to obscure the anatomy was responsible for the second conversion. Fifty four (14%) hernias were associated with a large lipoma of the cord, of which 2 (3.7%) developed a recurrent hernia. There were no deaths, vascular, visceral or testicular complications.

Each surgeon has a practice code number and the number of repairs by each was

03 - 2 repairs, 04 – 124, 06 - 55, 08 – 57, 09 - 10, 10 -19. The recurrence were spread evenly amongst surgeons 04, 06 and 08.

## Discussion

Although the techniques of modern tension free hernia repairs have been developing for more than a century, it was only about 20 years ago that minimally invasive laparoscopic hernia repairs were introduced. In the early 1990's, laparoscopic hernia repair was controversial. Some early studies showed complication rates as high as 17%, and recurrence rates as high as 10%.<sup>7,8</sup> Since then, laparoscopic techniques have become more standardised, equipment and meshes have improved and surgeons have become more experienced. This has resulted in lower laparoscopic recurrence and complication rates so that a 2003 Cochrane review reported equivalent recurrence rates for laparoscopic and conventional open repairs.<sup>6</sup>

The 2003 Cochrane review of 41 randomised controlled trials involving 7161 patients found the recurrence rate for laparoscopic repair to be 2.7% and 3.1% for open repair,  $p=0.16$ .<sup>6</sup> Some of these trials had follow ups of only 6 weeks. In our study the recurrence rate of 2.3% with a follow up of more than five years is similar. It is possible that there may be asymptomatic recurrences in some of our patients. Due to the difficulty in recalling all patients for confirmation, we elected to rely on patient opinion only. There is a paucity of data comparing the two techniques for repair of recurrent hernias. A 2009 meta-analysis identified four suitable randomised controlled trials involving a total of 404 patients and found equivalent recurrence rates for repair of recurrent hernias. The mean length of follow up in these trials ranged from three to five years.<sup>9</sup> Several studies use complication rates as

the primary or secondary focus of their analyses.<sup>8,10-15</sup> Complication rates vary from 4%-39%. A lack of standardisation plays a major role in the variability. Some combine perioperative with long-term complications and include everything from constipation to urinary retention. Others list only perioperative events and are less liberal with the labelling of a complication. In this study the complication rate was comparatively low (7.9%) and no serious complications were recorded. Compared to some of the larger series<sup>7,13,14,16,17</sup> our incidence of seromas, infections, testicular complications, bowel and vascular injuries is equivalent or better. The incidence of port site hernias is infrequently reported in the literature. The incidence in some of the larger series ranges from 0.1-0.5%<sup>6,13,16</sup> which is lower than our rate of 1.1%.

The reasons for recurrence are technical, the two most common causes being incomplete dissection of the myopectineal orifice and inadequate mesh size.<sup>18</sup> Incomplete dissection leads to inadequate reduction of the hernia sac and missed hernias and lipomas of the cord (herniated preperitoneal fat). It also results in too small a space being created to accommodate the mesh causing it to roll or buckle at the edges. The average mesh size in patients who had a recurrence in the trial by Fitzgibbons and colleagues was 6.0 x 9.2 cm.<sup>7</sup> It is now generally accepted that mesh size should be at least 10 cm x 14 cm to ensure coverage of all potential hernia sites and provide at least 4 cm overlap of the hernia, in order to minimise recurrences associated with mesh migration, shrinkage, and rolling.<sup>19</sup> Mesh size was not recorded in our study database. Mesh fixation with staples or tackers is widely practised to prevent migration, but it has also been associated with persistent pain and increasing cost. Two randomised trials showed no difference in recurrence rates or

persistent pain after repairs using fixation or no fixation.<sup>20,21</sup> In this study, all surgeons routinely fixed meshes with spiral tacks.

The learning curve for laparoscopic repair is long. A 2005 Cochrane review identified seven learning curve studies which indicate that it takes between 30 and 100 procedures to become experienced in performing laparoscopic hernia repairs, although in the majority of the studies the figure was closer to 50.<sup>22</sup> This study included the learning curve for five of the six surgeons yet the results were still good. The reasons for this may be the consistent proctorship in this group, as well as a highly standardised technique shared by all surgeons. TEP is considered more difficult than TAPP but may result in fewer complications by not exposing the intra-abdominal organs to injury.<sup>16</sup> TAPP has been advocated for complicated hernias (sliding or incarcerated) and hernias with previous pelvic surgery (radical prostatectomy).<sup>16</sup> A 2005 Cochrane review comparing TAPP and TEP identified only one suitable randomised control trial, which found no statistical difference in length of operation, length of stay, time to return to normal activity, or recurrence rates between the two techniques.<sup>22</sup> This trial involved only 52 patients with a mean follow up of only three months. They identified eight non-randomised studies, including retrospective case series involving a total of more than 15000 TAPP or TEPP repairs, which suggest that TAPP is associated with higher rates of visceral injuries and port site hernias, whilst there appear to be more conversions with TEP. They concluded that there is insufficient evidence to allow conclusions to be drawn between the two methods, and that more trials are needed.

Laparoscopic repair has several advantages over open repair, the most obvious being reduced pain, fewer wound complications and earlier return to normal activities. There is

wide variability in the reporting of post-operative pain, making it difficult to compare between studies, but most report less pain after laparoscopy.<sup>10-12,14,15,23,24</sup> Chronic persisting pain is more debilitating. This may be due to nerve entrapment during the fixation of the mesh in open and laparoscopic techniques. The 2003 Cochrane meta-analysis<sup>6</sup> and a recent randomised controlled trial looking at chronic pain as a primary outcome<sup>25</sup> found less chronic pain after laparoscopic repair. The reporting of chronic pain in our study was subjective but our rate of 2.1% parallels those in the current literature. Quicker recovery times and return to normal activities is consistently reported in favour of the laparoscopic repair.<sup>8,13,14</sup>

In this study there were 128 bilateral hernias (48%). The incidence of bilateral hernia in the literature ranges from 25-55%.<sup>26-30</sup> The reason for such a high reported incidence in laparoscopic series is likely due to the presence of occult contralateral hernias in patients thought to have a unilateral hernia. During an open repair only clinically apparent hernias are explored. However, during a laparoscopic hernia repair the surgeon has the advantage of the option to explore both sides. This is frequently performed and the rate of occult contralateral hernias in the literature ranges from 11-30%.<sup>26-29,31</sup> In this study 94 (73%) of the bilateral hernias were clinically apparent pre-operatively, and 34 (27%) were occult contralateral hernias. In this practice, bilateral exploration is commonly performed for clinically apparent unilateral hernias, in which case mesh is placed on both sides whether or not a contralateral occult hernia is found.

One of the criticisms of laparoscopy is the higher cost. Cost is also difficult to evaluate but the laparoscopic repair is consistently more expensive.<sup>12-14,23</sup> It is also reported to be

associated with longer operating times. The 2003 Cochrane review found laparoscopic repair to be longer by about 15 minutes, however it does not state the duration of surgery for each technique.<sup>6</sup> A meta-analysis published in 2000 of 34 trials involving 6804 patients from the 1990s, showed laparoscopic operating times ranging from 31 minutes to 128 minutes.<sup>32</sup> The Medical Research Council Laparoscopic Groin Hernia Trial Group performed a cost-utility analysis on a prospective randomized trial conducted in the United Kingdom comparing laparoscopic to open inguinal hernia repair.<sup>33</sup> The higher costs for laparoscopic repair have been shown to be mostly due to increased operating room time and the costs of disposable equipment. The operating time and hence the cost may be less in the hands of experienced surgeons. In a case series of 3100 hernias repaired laparoscopically by experienced surgeons, the mean operative time for unilateral hernias was 17 minutes and for bilateral hernias 24 minutes.<sup>16</sup> Costs could be further reduced with re-usable instruments.

Strengths of this study include the quality and completeness of the record keeping in the practice computerised management system, resulting in a high level of accuracy in the data points recorded; an adequate follow up of at least 5 years; and the study being multicentre with multiple surgeons using a homogenous technique. Weaknesses include the study being retrospective; the follow up being telephonic; a significant number of patients originally included were not contactable; and the absence of recording of operation times, mesh details, and duration of hospital stay.

## **Conclusion**

The recurrence and complication rates for laparoscopic TEP inguinal hernia repair in this private practice are low, despite the inclusion of surgeons' learning curves. There is a low incidence of persistent post-operative pain with the laparoscopic technique, and this technique was found to be less painful by patients who had previously undergone an open repair.

**APPENDICES****Table 1** Patient demographics and hernia characteristics

Number of patients	267
Mean age (range)	63 (22-92)
Sex	
Male	263 (98%)
Female	4 (2%)
Mean follow up (range)	8.8 years (5.3-14)
Number of hernias	395
Side of hernia	
Left	60 (22%)
Right	79 (30%)
Bilateral	128 (48%)
Clinically apparent pre-operatively	94 (73%)
Occult contralateral hernia	34 (27%)
Type of hernia	
Indirect	238 (60%)
Direct	131 (33%)
Recurrent	26 (7%)
Irreducible hernias	2 (0.5%)
Previous open repair (ipsilateral or contralateral)	43 (16%)
Previous appendicectomy	12 (5%)

**Table 2** Recurrences and complications

Recurrence	
Immediate	0
Within 1 year	6 (1.6%)
After 1 year	3 (0.8%)
Total	9 (2.3%)
Mortality	0
Complications	
Conversion to open repair	2 (0.5%)
Seroma	9 (2.3%)
Umbilical port site infection	5 (1.9%)
Umbilical port site hernia	3 (1.1%)
Chronic groin pain	8 (2.1%)
Testicular complications	0
Vascular complications	0
Visceral injuries	0
Total	27 (7.9%)

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