Randomized clinical trial

Randomized clinical trial of open suture repair *versus* totally extraperitoneal repair for treatment of sportsman's hernia

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Background: **Sportsman's hernia/athletic pubalgia is a recognized cause of chronic groin pain in athletes. Both open and laparoscopic surgical repairs have been described for treatment, but there are no comparative studies. The hypothesis here was that relief of pain would be achieved earlier in patients treated with open minimal suture repair than totally extraperitoneal repair.**

Methods: **A randomized multicentre trial in four European countries was conducted to compare open minimal suture repair with totally extraperitoneal repair. The primary endpoint was complete relief of pain (visual analogue scale (VAS) score 20 or less on a scale from 0 to 100 mm) at 1 month. Secondary endpoints included complications, time to return to sporting activity, and number of patients returning to sport within 1 year.**

Results: **A total of 65 athletes (92 per cent men) with a median age of 29 years were enrolled (31 open repair, 34 totally extraperitoneal repair). By 4 weeks after surgery, median preoperative VAS scores had dropped from 70–80 to 10–20 in both groups ($P < 0{\cdot}001$). Relief of pain (VAS score 20 or less) during sports activity 4 weeks after surgery was achieved in 14 of 31 patients after open repair and 24 of 34 after totally extraperitoneal repair ($P = 0{\cdot}047$). Return to full sporting activity was achieved by 16 and 18 patients respectively after 1 month ($P = 0{\cdot}992$), and by 25 *versus* 31 after 3 months ($P = 0{\cdot}408$).**

Conclusion: **Totally extraperitoneal repair was less painful than open repair in the first month, but otherwise both procedures were similarly effective in treating chronic pain due to sportsman's hernia. Registration number: NCT02297711 (http://www.clinical.trials.gov).**

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Introduction

The prevalence of chronic groin pain in athletes, as well as adults participating in regular physical activity, ranges between 5 and 10 per cent[1–3]. Most chronic groin injuries are treated conservatively but sometimes groin surgery may be beneficial. Contact sports involving sudden muscle contraction with side-to-side motion, seen particularly in football, ice hockey and rugby, are most commonly associated with groin injuries[1,2]. Chronic groin pain has various aetiologies, such as adductor tendonitis, rectus abdominis tendinopathy, osteitis pubis or disruption of the posterior wall of the inguinal canal[1–3]. The latter may be confirmed by dynamic ultrasonography, and is analogous to an early direct inguinal hernia. It is often called sportsman's hernia or athletic pubalgia[4–7]; the terms are interchangeable.

First-line management for long-standing groin pain includes rest, physiotherapy, anti-inflammatory analgesics and local anaesthetic/corticosteroid injections. Surgeons have tested various surgical procedures to solve the problem, especially when conservative treatment has failed[4–6,8–11]. For example, a tenotomy can be considered for painful tendinopathy[12,13]; a release procedure for muscle tension or neurectomies of inguinal nerves have been tried[9,11,14]. Open minimal suture repair (OMR) or totally endoscopic extraperitoneal (TEP) repair are among the most successful surgical approaches for the treatment of sportsman's hernia[4,8,10], but comparative studies are

lacking. The OMR technique was developed to strengthen the posterior inguinal wall using non-absorbable sutures. The TEP technique may heal a wider area of the groin than OMR, because a large mesh is placed in the preperitoneal space[15–18].

The aim of this study was to compare the effectiveness of OMR and TEP repair for the treatment of sportsman's hernia; the primary endpoint was pain relief at 1 month after surgery. Secondary endpoints were operative complications, time to full return to the athlete's chosen sporting activity and groin pain during the first postoperative year.

Methods

A randomized multicentre trial comparing OMR with TEP repair was conducted. The allocation ratio of the participants was 1 : 1. The enrolled subjects were consecutive athletes suffering from sportsman's hernia recruited by the surgeons undertaking this study. No interim analysis was performed. The CONSORT statement was followed[19]. Patients fulfilling the diagnostic criteria for sportsman's hernia received written and oral information on the aims and methods of the study, in accordance with the Helsinki Declaration. Informed consent was signed by each participant. The study was approved by the national ethics committee of Finland (Kuopio University Hospital) and registered in ClinicalTrials.gov (NCT02297711). The participating hospitals in Europe reapproved the study protocol in their local ethics committees (REC ref number: 14/NW/1046; IRAS number: 140413 (UK)).

Participants were recruited from surgical units in Europe with experience in treating sportsman's groin. The operating surgeons had a proven track record of performing both operative techniques (OMR and TEP repair). Four surgeons participated in this study (1 in each centre). All surgeons had undertaken over 100 TEP repairs and more than ten OMR operations before the trial. Before surgery, all patients were assessed by a multidisciplinary team including a physiotherapist, sports medicine physician (usually club physician), orthopaedic surgeon, musculoskeletal radiologist and the general surgeon performing the surgery. Professional and non-professional athletes of both sexes over 18 years old with chronic groin pain were evaluated for possible enrolment. Pelvic MRI was undertaken to exclude other causes of groin pain.

Sportsman's hernia was defined by a history of chronic dull, diffuse groin pain lasting over 6 weeks. The pain occurred above the inguinal ligament in the deep inguinal ring, and could radiate to the inner thigh, scrotum or pubic bone. Minor pain was allowed that could radiate to the adductor origin or symphysis pubis on finger palpation or muscle stretching tests. Grade I–II oedema at the pubic symphysis shown by MRI as a secondary effect of groin disruption was also acceptable for recruitment. Athletes with either unilateral or bilateral pain were included; the more painful groin was included in the analysis for those with bilateral symptoms. Patients were excluded if they were not willing to participate, or had an inguinal or femoral hernia, other treatable pathologies revealed by MRI (such as bursitis, hip injury or stress fracture), isolated adductor tendonitis with groin pain below the inguinal ligament, femoroacetabular impingement, isolated severe osteitis pubis (marked X-ray changes; grade III oedema on MRI), previous groin surgery to the actual groin, or allergy to polyester or other contraindications to surgery.

Randomization

Athletes were randomized to OMR or the TEP procedure. Randomization was stratified in groups for each centre (block randomization of 20). Numbered and sealed opaque envelopes were opened on the day of operation, after which both the patient and surgeon were informed of the surgical technique. Study nurses opened the sealed envelopes to avoid selection bias. All excluded patients were recorded. All centres that recruited more than five patients were included in the final report. The staff conducting the postoperative assessment and the patients were all aware of the treatment allocation.

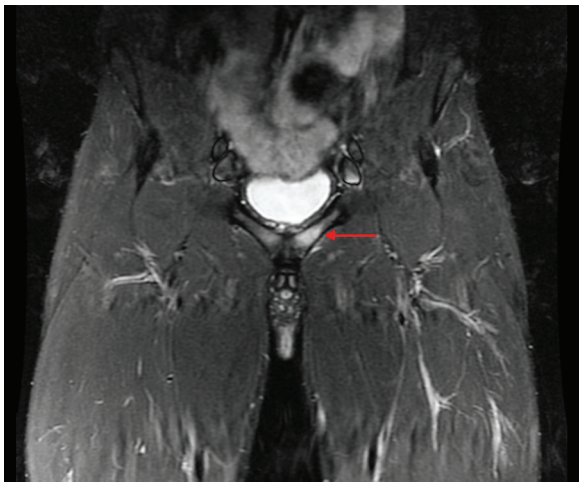
Imaging

Pelvic MRI of the groin region was always done to exclude other musculoskeletal injuries[20,21]. MRI was undertaken using routine T1- and T2-weighted and short-T1 inversion recovery (STIR) sequences. The findings were grouped as normal, mild tendinopathy at the pubic origin or oedema at the pubic joint (grade I–III) (*Fig. 1*). If necessary, pelvic X-ray or groin ultrasound examination was used to confirm the diagnosis. Patients were not excluded if they had negative imaging, as long as they had persistent groin pain typical of sportsman's hernia.

Operative techniques

OMR was performed using local or spinal anaesthesia (general anaesthetic was used only at the patient's request), as described originally by Muschaweck and colleagues[4,9]. The external oblique aponeurosis was split through a small inguinal skin incision. Care was taken not to damage the ilioinguinal nerve, or the genital branch of the genitofemoral nerve. The fascia transversalis was split towards

Fig. 1 Magnetic resonance image (STIR sequence) of the groin in a soccer player



Grade II bone marrow oedema (arrow) is demonstrated in the left pubic symphysis with an adductor longus injury (bright signal below pubic bone).

the deep internal ring, enclosing only the area of fascial weakness. The femoral canal was inspected. A continuous non-absorbable 2/0 polypropylene suture was inserted from the medial towards the deep inguinal ring, creating a free fascial lip. The suture was reversed at the pubic bone including the free lip brought to the inguinal ligament. The posterior defect was not enlarged and all suturing was as tension-free as possible. The rectus abdominis muscle was lateralized with sutures to counteract the increased tension at the pubic bone, caused by retraction of the rectus muscle in the upward and medial direction. The cremaster muscle was preserved when possible. The external fascia was closed using a 3/0 absorbable continuous suture and subcuticular closure was achieved using a rapidly absorbable suture. A video of the operative technique was distributed to all surgeons at the start of the trial to ensure consistency.

The endoscopic (TEP) technique was performed under general anaesthesia. The camera port was placed adjacent to the umbilicus and the anterior rectus fascia was incised on the affected side. The rectus abdominis muscle was split to enter the retromuscular/preperitoneal space either by balloon dilatation or using a blunt port. Two 5-mm trocars were introduced in the midline above the pubic symphysis. Blunt dissection was undertaken from the symphysis, exposing the obturator fascia moving laterally under the inferior epigastric vessels passing the internal ring to the anterior superior iliac spine. The peritoneum was retracted, exposing the triangle of doom by at least 5–10 cm to allow flat mesh placement. The dissection allowed a wide view of the pubic tubercle, and the insertions of the conjoined tendon and rectus muscles. A true inguinal hernia was excluded. The dissected area was covered by a 10×15-cm partly absorbable lightweight polyester mesh (Parietex™; Medtronic, Minneapolis, Minnesota, USA) without using any fixation. In bilateral repairs, one large or two smaller meshes were used as described previously[17]. The skin was closed using rapidly absorbable sutures.

Unless otherwise indicated clinically, patients were discharged on the day of operation or occasionally the next day (after general anaesthesia). Conventional non-steroid anti-inflammatory drugs and/or paracetamol were prescribed for postoperative pain relief. Patients were allowed to walk and lift up to 20 kg immediately after surgery. Running and cycling were allowed on the second postoperative day, with a specific training schedule allowed on days 5–7 and free training encouraged after the first week[7].

Primary and secondary outcomes

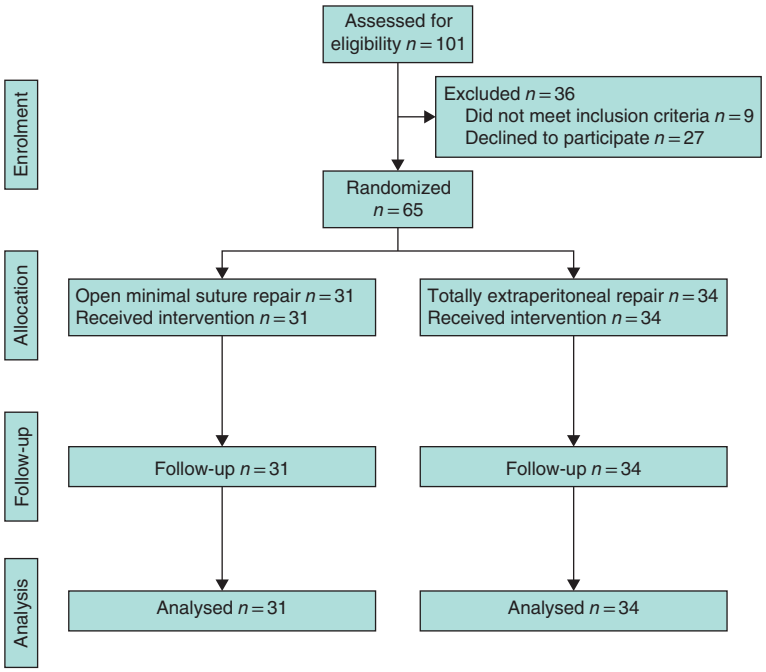
The primary endpoint was relief of pain during sports activity (score 20 or less on a visual analogue scale (VAS) ranging from 0 to 100 mm) at 4 weeks after surgery. Secondary endpoints included time to resume low-level training, time to resume full-level training/competition, and complications. For bilateral repairs, only the worse side was included in the analysis.

Patient data and outcomes

Age, sex, weight, height, type of sport, previous injuries to the groin, previous treatments and ability to participate in any sports activity before surgery (no, partially, full) were recorded. Time unable to play sports before operation, duration of groin symptoms, treatment (painkillers, corticosteroids, physiotherapy and reoperations) were recorded. Operative data included: type of anaesthesia and operation, duration of surgery, postoperative complications, and equipment used in the operation.

Clinical examination was carried out before operation and at 4 weeks. Additional clinical evaluations (other than at time points below) were performed only in patients with prolonged groin pain. Pain scores were assessed using the 0–100-mm VAS at rest and during physical activity before surgery, and 1, 2 and 4 weeks, 3 months, 6 months and 1 year after operation. Physical activity meant normal sporting activity. The need for postoperative pain medication was reported on days 7, 14 and 30. Short- and long-term recovery was reported at 2 weeks, and 1, 3 and 12 months as being full, partial or no recovery. Partial

Fig. 2 CONSORT diagram for the trial



recovery meant that the athlete could do some physical activity/sports but not at the same level as before the groin injury. Follow-up and rehabilitation were matched across the centres, as reported previously[7].

Statistical analysis

The study hypothesis was that the OMR technique would cause less postoperative pain and thereby possibly allow a quicker resumption of sports than the TEP operation. In previous studies[4,9], complete relief of pain was achieved in 79 per cent and resumption of sport in 99 per cent 1 month after OMR. Respective rates after laparoscopic techniques were 47–60 and 60–70 per cent[8,10,17]. It was hypothesized that the proportion of patients with complete relief of pain after 4 weeks would be 85 per cent after OMR and 50 per cent after TEP repair. To show this difference, 27 patients in each treatment group would be needed to achieve a statistical power of 0·80 with an α of 0·05 (2-tailed). The expected 10 per cent drop-out meant that 30 patients were required in each study group.

Fisher's exact test was used for analysis of categorical variables and Student's *t* test for numerical variables. Multiple dependent variables (VAS scores) measured at multiple time points were modelled using the generalized linear model repeated-measures procedure. $P < 0{\cdot}050$ was considered statistically significant. All data were analysed according to the intention-to-treat approach. Statistical analysis was done using SPSS® version 22.0 for Windows® (IBM, Armonk, New York, USA).

Results

Between January 2013 and December 2017, a total of 101 athletes were eligible for recruitment (*Fig. 2*). Thirty-six were excluded as they either preferred the TEP procedure or had hip and/or isolated adductor injury. The remaining 65 patients were randomized. All patients recruited reached 1-year follow-up.

Patient characteristics and MRI findings

In all, 92 per cent of the participants were men (*Table 1*). The median age at operation was 29 years and median BMI was 24·0 kg/m^2. Most were soccer players. Some 60 per cent were unable to play sports before operation, 34 per cent could partially undertake sport and 6 per cent could participate without restriction. No significant differences were noted between the two groups. Grade I bone marrow oedema at the pubic symphysis was observed in 29 per cent of patients and grade II in 12 per cent; there was

Table 1 Characteristics of athletes in the study

	All ($n = 65$)	Open ($n = 31$)	Totally extraperitoneal ($n = 34$)
Age (years)*	29 (18–57)	29 (18–57)	29 (18–49)
Sex ratio (M : F)	60 : 5	29 : 2	31 : 3
BMI (kg/m^2)*	24·0 (19·7–31·1)	23·7 (19·7–31·1)	24·4 (21·6–30·1)
Duration of symptoms (months)*	4 (1–36)	4 (1–24)	4·5 (1–36)
Previous groin injuries	4	1	3
Able to play sport without restriction			
No	39	21	18
Partially	22	10	12
Yes	4	0	4
Bone marrow oedema on MRI			
No	38	18	20
Grade I	19	11	8
Grade II	8	2	6
Location of pain in groin			
Right	24	13	11
Left	20	11	9
Bilateral	21	7	14
Type of sport			
Soccer	34	16	18
Ice hockey	11	5	6
Gymnastics	5	3	2
Floor ball	3	1	2
Running	4	4	0
Other	8	2	6

*Values are median (range).

no correlation with ability to play sport. For example, of eight athletes with grade II oedema (*Fig. 1*), three were not able to train, three could train partially and two had full ability to play sport. Pelvic MRI was normal in 58 per cent of athletes. Bilateral repair was needed in seven and 14 patients in the OMR and TEP groups respectively.

At open surgery, 25 of 31 patients had a clear weakness or bulge in the posterior wall of the inguinal canal, five had a small lipoma adjacent to the spermatic cord, and one had a small indirect hernia and posterior weakness of the inguinal canal. In the TEP group, 20 of 34 athletes had some posterior weakness, five a tear at the rectus abdominis insertion at the pubic bone, and four had small lipomas. Five patients had minimal peroperative findings, including irritation of pubic symphysis.

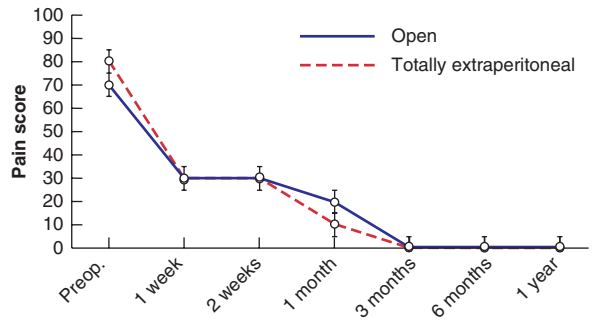
Primary endpoint

Preoperative median VAS scores were 70 and 80 in the OMR and TEP groups respectively ($P = 0{\cdot}913$). There was a decrease between preoperative scores and those measured at 4 weeks in both groups ($P < 0{\cdot}001$) (*Fig. 3*). There was no difference in median postoperative VAS scores between groups at any time point. The primary endpoint, relief of pain (VAS score no more than 20) during sporting activity 4 weeks after surgery was achieved in 14 of 31 patients in the OMR group and 24 of 34 in the TEP group ($P = 0{\cdot}047$). Six patients in the OMR group and 12 in the TEP group were totally pain-free (VAS score 0) after 1 month ($P = 0{\cdot}176$). In addition, eight and 12 patients respectively had a VAS score of 10–20 mm at 4 weeks ($P = 0{\cdot}435$).

Secondary endpoints

The duration of surgery was similar for both procedures: median 31 (range 20–70) min for OMR and 40 (20–60) min for TEP repair ($P = 0{\cdot}913$). No adductor tenotomies were undertaken. No early postoperative complications were reported. There were no differences in short-term recovery after surgery (2 weeks, 1 month and 3 months) between the groups; one patient in each group had not recovered after 3 months. A total of 61 patients (94 per cent) were either fully or partially recovered at 1 month, with no difference between groups (*Table 2*). There were no differences in the recovery of professional

Fig. 3 Pain scores before and after open minimal suture repair and totally extraperitoneal repair



Values are median pain scores measured on a visual analogue scale ranging from 0 to 100 mm, with 95 per cent confidence intervals. All patients reached the 1-year follow-up (open 31, endoscopic 34).

Table 2 Analgesics used and recovery after surgery for sportsman's hernia

	Open ($n = 31$)	Totally extraperitoneal ($n = 34$)	P*
Analgesia used			0·597
Day 7	18	13	
Day 14	5	2	
Day 30	6	2	
Recovery			
2 weeks			0·279
Full	1	4	
Partial	5	8	
No	25	22	
1 month			0·992
Full	16	18	
Partial	13	14	
No	2	2	
3 months			0·408
Full	25	31	
Partial	5	2	
No	1	1	
12 months			0·238
Full	28	32	
Partial	2	2	
No	1	0	

*Fisher's exact test.

or amateur/recreational athletes. Analgesia requirements, in terms of number of painkillers required, were similar in the two groups at 7, 14 and 30 days ($P = 0·597$). After 30 days, six patients who had OMR and two who had TEP repair required some form of analgesia ($P = 0·138$). The analgesia required was commonly 600 mg ibuprofen or 500–1000 mg paracetamol per day. Three months after surgery, one athlete in each study group occasionally needed painkillers. Almost all athletes were pain-free at 1 year; one woman in the OMR group reported poor recovery. No recurrence of groin pain was reported up to 1 year after surgery.

Discussion

This RCT comparing OMR with TEP repair for the treatment of chronic pain due to sportsman's hernia showed that both procedures improved pain and allowed return to sporting activities. TEP repair had a slight advantage over OMR for the primary outcome, complete relief of pain at 1 month, but there were no differences in secondary outcomes such as analgesic consumption, complications, time to resumption of low-level and full training, and pain up to 1 year.

The OMR technique was developed with the aim of strengthening the weakness of the posterior wall of the inguinal canal[4,9]. The TEP procedure repairs multiple potential deficiencies around the pubic tubercle, such as the insertion site of inguinal ligament, tears of rectus abdominis origin, pubic periosteal irritation/bone marrow oedema and weakness of the floor of the inguinal canal[17]. Chronic groin pain in athletes can have different aetiologies, like inflammation at the site of insertion of the adductors, inguinal ligament, conjoint tendon and rectus abdominis muscles. Athletes with chronic groin pain with or without grade I–II bone marrow oedema were included in this study. MRI was used to ensure that patients with problems causing similar clinical symptoms, such as inguinal hernia and femoroacetabular impingement, were excluded[15,22,23]. In fact, the MRI was normal in many athletes in the study (58 per cent). MRI is highly sensitive in diagnosing pathology in athletes with groin pain and a higher percentage of abnormalities has been published in other MRI studies[21–23]. One reason for the large number with normal MRI in this study might be the strict exclusion criteria; for example, painful adductor tendonitis or hip impingements were excluded.

Non-operative treatment strategies are an alternative to surgery for chronic groin pain. Two RCTs[24,25] comparing different non-surgical strategies had conflicting results. In a study[24] of 68 athletes, active physical training was more effective than conventional physiotherapy in returning athletes to playing sports without groin pain ($P = 0·006$). In the other study[25], multimodal physical treatment was more effective than standard exercise therapy, but only half the athletes returned to full activity. This could be why many patients seek a surgical option.

Most non-randomized studies have indicated that laparoscopic treatment of sportsman's hernia is effective in 80–90 per cent of patients[8,10,11,18,26,27]. Two previous RCTs[17,28] included surgical treatment, but neither compared different surgical techniques. In the RCT[17] from Finland that enrolled 60 patients and compared TEP repair with non-operative treatment, a retropubic mesh was more effective than conservative therapy. The other RCT[28] from Sweden included 66 soccer players randomized into four groups: open operative repair including inguinal nerve neurectomy, individual training, use of anti-inflammatory analgesics and physical therapy. Operative repair significantly reduced groin symptoms.

This study showed some minor differences between the two techniques, mainly that there was less early postoperative pain after TEP repair than OMR. The hypothesis of this study for the primary outcome might not have been the most important for the athlete. Athletes need fast recovery and return to sporting activities, but long-term treatment success may be more important. The number of patients in both groups was quite small, which is another weakness of the study. Recruitment difficulty was compounded not only by the limited numbers of patients who present with this diagnosis, but also by the small number of centres that have competence in both operative techniques. Furthermore, many athletes requested endoscopic surgery. Another limitation of the study was that patient-reported outcome questionnaires were not used to analyse pain[29]. At the beginning of the study, a VAS was thought to be easier for patients than more extensive questionnaires. The advantage of this RCT is that it uses a multicentre European approach. All surgeons were known internationally for their experience and expertise in both the open and laparoscopic techniques and, importantly, in the care of patients presenting with sportsman's hernia.

These results will perhaps allay fears with regard to which operation should be recommended for sportsman's groin because the two approaches provided similar outcomes. The endoscopic technique offered a slightly less painful recovery, with fewer patients requiring analgesia at 30 days, although overall differences in the use of analgesia did not reach statistical significance. Only half were fully recovered at 1 month after either operative technique; all but one in each group was fully or partially recovered after 3 months. The advantages of the open technique are that it can be undertaken under local anaesthesia, and without using a mesh. The advantage of TEP repair is that it can be used with similar outcomes for bilateral repair. The present results are similar to those reported recently from the Netherlands, indicating that 60 per cent of athletes were fully recovered by 3 months after TEP repair[30]. The TEP technique is more expensive due to the cost of mesh, and more expensive surgical instruments. The present result means that treatment of sportsman's hernia may be individualized and patients have options after deciding on surgery.

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