Is Shouldice the best NON-MESH inguinal hernia repair technique? A systematic review and network metanalysis of randomized controlled trials comparing Shouldice and Desarda

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IS SHOULDICE THE BEST NON-MESH INGUINAL HERNIA REPAIR TECHNIQUE? A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS COMPARING SHOULDICE AND DESARDA.

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Abstract

**Background**: Current guidelines state that the Shouldice technique has lower recurrence rates than other suture repairs and therefore is strongly recommended in non-mesh inguinal hernia repair. Recently a new tissue repair technique has been proposed by Desarda and studied in trials against Lichtenstein technique.

**Methods**: The present study was performed according to the PRISMA Statement for Network Meta-analysis and the AMSTAR 2 checklist. The method of network meta-analysis was chosen to evaluate randomized controlled trial published on tissue repair and comparing Lichtenstein respectively with Desarda and Shouldice techniques. The following parameters: operative time, recurrence, complications (general, intraoperative, Surgical Surgical Site Occurrences), VAS score on postoperative day 1, numbness, chronic pain and return to daily activities.

**Results**: Fourteen RCTs, involving 2791 patients, fulfilled the inclusion criteria and were selected for final analysis. The anchored indirect treatment comparison showed that Desarda’s technique requires a significantly shorter operative time (MD: -12.9 min; 95% CI: -20.6 to -5.2) and has a quicker recovery (MD: -6.6 days; 95% CI: -11.7 to -1.4). Outcomes concerning intraoperative complications, early postoperative pain, seroma/hematoma, hydrocele and infection rates, recurrence, numbness and chronic pain were similar among the two techniques.

**Conclusions**: Desarda’s hernia repair can be a valuable alternative to Shouldice technique for the treatment of primary inguinal hernia repair if a non-mesh technique is chosen, because of its reproducibility and quicker postoperative recovery. We recommend performing well designed prospective studies comparing both techniques directly.
Introduction

Inguinal Hernia Repair (IHR) represents one of the most commonly performed surgical procedures worldwide. Nearly 800,000 patients undergo surgery for groin hernia in the United States each year\(^1\). Recently, the HerniaSurge Group recommended, in the International Hernia Guidelines, mesh repair as the treatment choice, either by an anterior open procedure or a laparoscopic technique\(^2\). In the context of non-mesh techniques, Shouldice technique has lower recurrence rates than other suture repairs and therefore is strongly recommended as non-mesh inguinal hernia repair by International and 2009 European Hernia Guidelines\(^3\). However, after these recommendations, additional studies have reported novel evidences concerning the comparison between different non-mesh repairs. Moreover, in 2001 a new surgical option for non-mesh IHR, Desarda technique, was introduced in the daily clinical practice of some centers, especially in eastern countries and low resource settings. A recent study would suggest that Desarda Technique seems to satisfy, more than Shouldice, recurrence rate, rate of complications and reproducibility\(^4\). In light of this, our study aims to compare the efficacy of Shouldice and Desarda for primary inguinal hernia repair based on data reported by randomized controlled trials (RCTs). Because of the lack of RCTs directly comparing Shouldice and Desarda, we performed an indirect comparison through a network meta-analysis\(^5\).
Methods

Search Strategy and Selection Criteria

We conducted a Network Meta-analysis to compare Shouldice and Desarda Techniques. The present study was performed according to the PRISMA Statement for Network Meta-analysis and the AMSTAR 2 checklist. It was registered on Research Registry.com with the following ID: XXXXXXX.

We judged eligible all trials with the following characteristics: treatment of primary inguinal repair irrespective whether unilateral or bilateral in adult patients in the context of a randomized controlled trial comparing Shouldice or Desarda versus Lichtenstein. It was decided to limit our research only to English language reports. Exclusion criteria were recurrent inguinal hernias.

PubMed, Ovid and Web of Science databases were used to identify previous meta-analyses and RCTs comparing Shouldice or Desarda versus Lichtenstein for groin hernia repair starting from 01/01/2008 up to 01/09/2018.

The search terms and strategies were constructed as follows: "inguinal hernia"; "groin hernia"; "Desarda"; “Shouldice”; "Lichtenstein”; "Tissue-based”; "mesh repair"; "hernioplasty”; "tension-free repair”; "randomized”; "controlled trials" and "clinical trials" in combination with the Boolean operators and/or.

Search strategies for each electronic database are described in AppendixS1 (supporting information).

Data extraction and quality assessment

Two authors (UB and GM), independently, screened all titles and abstracts for eligibility. The same authors independently analyzed the full texts of each screened paper to evaluate the coherence with the aim of the study. A third Author (CS) independently checked the results of the screening search. Discrepancies were resolved by discussion with the senior author (CS).

Data were extracted and entered in a preformed Excel sheet by two authors independently: data included study and patient characteristics, intervention details, and outcome measures. Study authors were contacted to request missing data necessary for the indirect comparison. The following outcomes were considered: recurrence, operative time, overall postoperative complication rates, intraoperative complications, postoperative chronic pain or numbness, incidence of seroma/hematoma, wound infection, and time to return to normal activities. Number of recurrences
were extracted as reported in the manuscripts of the included studies and both clinically or radiologically confirmed recurrences were included. Operative time was defined as skin to skin closure as described in papers. Overall morbidity was considered as all adverse event reported within 30 days postoperatively, it was not possible to differentiate the gravity of each complication as proposed by Clavien-Dindo classification. Among secondary outcomes, intraoperative complications were considered as all adverse event, irrespective of type, registered during the course of the procedure. Postoperative surgical site occurrence was recorded separately as hematoma, seroma, wound infection, hydrocele. Regarding pain, we recorded mean postoperative VAS at 1 day, chronic postoperative pain, and postoperative numbness.

Statistical Analysis

In both meta-analyses, continuous outcomes, such as operative time, duration of hospital stay, time to return to work, and postoperative VAS, were expressed by weighted mean differences (WMD), with the relative 95% confidence interval (CI). Binary outcomes, such as complications and recurrences, were expressed as rate ratios (RR), with the relative 95% CI. We assessed the heterogeneity by using the $I^2$ test. Because the heterogeneity was statistically significant, we used the random-effect model. P<0.05 was considered statistically significant (P value was reported in each Forest Plot Figures). We represented the obtained results by forest plots, and we looked at the funnel plots to assess the potential for publication bias. Finally, the effect size of Desarda versus Shouldice was assessed by using network meta-analysis methodology. We adopted a geometry of network called “anchored indirect treatment comparison” in order to perform the indirect comparison, since RCTs directly comparing Shouldice and Desarda were not available. In this geometry of network, no direct evidence in treatment network was computed, and consequently, no inconsistency could arise. We assessed the risk of bias within studies and across studies for each important outcome as described in the Cochrane handbook. We considered randomized controlled trials as being at low risk of bias if all the domains except blinding of participants or personnel were adequately assured. As the outcome measures were almost always assessed by objective means, we did not consider blinding to be crucial.

Continuous outcomes were expressed by standardized mean differences, with the relative 95% CI, while binary outcomes were expressed as RR with the relative 95% CI. Because the heterogeneity was statistically significant, we used the random-effect model. We used the software MetaXL to perform both conventional and network meta-analysis.
Results

Search results and study characteristics

The electronic database search and study selection process is summarized in Figure 1. Fourteen RCTs\textsuperscript{11-24}, involving 2791 patients, fulfilled the inclusion criteria and were selected for final analysis. Figure 2 summarizes the network of direct evidence available for outcomes. Characteristics of included studies (PICOS) are summarized in Table 1 and Appendix 2. All the RCTs generally referred to the surgical technique described by Desarda or Shouldice in their original article\textsuperscript{25-27}. The risk-of-bias assessment of the included trials is summarized in Table 2 (supporting information, which shows the domain assessment for individual trials). Only four trials\textsuperscript{14, 15, 22-24} were judged as at low risk of bias.

Two systematic reviews comparing Shouldice and Desarda techniques versus Lichtenstein respectively\textsuperscript{28, 29} were found. We didn’t find any others comparing Shouldice and Desarda directly.

Operative time

Seven studies\textsuperscript{17-24} comparing Shouldice versus Lichtenstein reported operative time. The latter was significantly longer for Shouldice (MD: 7.1min; 95% CI: 0.9 to 13.4 - Fig. 3a). Five studies comparing Desarda versus Lichtenstein\textsuperscript{11-14, 16} reported a significantly shorter operative time for Desarda (MD: -5.8 min; 95% CI: -10.3 to -1.3 - Fig. 3b). The indirect comparison showed that Desarda requires a significantly shorter operative time in comparison to Shouldice to be performed (MD: -12.9 min; 95% CI: -20.6 to -5.2).

Recurrence

Seven studies comparing Shouldice versus Lichtenstein\textsuperscript{18-24} reported a significantly higher recurrence rate associated with Shouldice (RR: 3.3; 95% CI: 1.5 to 7.6 - Fig. 4a). Three studies\textsuperscript{12, 15, 16} comparing Desarda versus Lichtenstein reported a higher recurrence rate for Desarda (RR: 1.4; 95% CI: 0.3 to 7.2 - Fig. 4b). Overall, the indirect comparison showed that Desarda and Shouldice have a similar rate of relapse (RR: 0.4; 95% CI: 0.1 to 2.6).

Overall Postoperative complications

Eight studies compared Shouldice and Lichtenstein\textsuperscript{17-24} in terms of overall postoperative complications, and a higher number was associated with Shouldice (RR: 1.1; 95% CI: 0.9 to 1.3 – Fig. 5a). Four studies\textsuperscript{12, 14-16} comparing Desarda versus Lichtenstein techniques reported
postoperative complications, which were significantly lower in the group submitted to Desarda (RR: 0.8; 95% CI: 0.6 to 1.1 – Fig 5b). Overall, the indirect comparison did not show a statistically significant difference among the two techniques (RR: 0.7; 95% CI: 0.5 to 1.1).

**Intraoperative complications**

Eight studies\textsuperscript{17-24} comparing Shouldice versus Lichtenstein reported intraoperative complications and a higher number of complications was associated with Shouldice (RR: 1.1; 95% CI: 0.3 to 4). Two studies\textsuperscript{14, 16} comparing Desarda versus Lichtenstein reported intraoperative complications and a higher number of complications was associated with Desarda (RR: 2.9; 95% CI: 0.4 to 19). Overall, the indirect comparison did not show a statistically significant difference among the two techniques (RR: 2.7; 95% CI: 0.3 to 26.4).

**Seroma/Hematoma**

Eight studies\textsuperscript{17-24} compared Shouldice versus Lichtenstein and reported seroma and hematoma incidence in the results: a similar incidence was encountered in both groups (RR: 1; 95% CI: 0.6 to 1.5 - Fig. 6a) as shown in. Six studies\textsuperscript{11-16} compared Desarda versus Lichtenstein reported seroma and hematoma incidence and Desarda had a lower incidence (RR: 0.7; 95% CI: 0.4 to 1.1- Fig. 6b). Overall, the indirect comparison did not show a statistically significant difference among the two techniques (RR: 0.7; 95% CI: 0.4 to 1.4).

**Hydrocele**

Five studies\textsuperscript{18, 21-24} comparing Shouldice versus Lichtenstein reported the incidence of hydrocele and a similar incidence was associated with Shouldice (RR: 1; 95% CI: 0.6 to 1.8). Two studies\textsuperscript{14, 16} comparing Desarda versus Lichtenstein reported the incidence of hydrocele and a lower incidence was associated with Desarda (RR: 0.6; 95% CI: 0.1 to 2.7). Overall, the indirect comparison did not show any statistically significant difference among the two techniques (RR: 0.6; 95% CI: 0.1 to 3).

**Wound infection**

Eight studies\textsuperscript{17-24} comparing Shouldice versus Lichtenstein reported the incidence of wound infections and a lower rate was associated with Shouldice (RR: 0.8; 95% CI: 0.4 to 1.6). Four studies\textsuperscript{11, 14-16} comparing Desarda versus Lichtenstein reported the incidence of wound infection and a lower rate was associated with Desarda (RR: 0.6; 95% CI: 0.1 to 2.6). Overall, the indirect comparison was not able to show a statistically significant difference among the techniques in terms of wound infection (RR: 0.8; 95% CI: 0.2 to 3.9).
VAS Day 1

Three studies\(^1\)\(^8\), \(^1\)\(^9\), \(^2\)\(^3\) comparing Shouldice versus Lichtenstein reported the VAS after one day and Shouldice has a higher VAS (MD: 1.3; 95% CI: -1.6 to 4.1). Three studies\(^1\)\(^1\)\(^1\), \(^1\)\(^4\), \(^1\)\(^6\) comparing Desarda versus Lichtenstein reported the VAS after one day and Desarda has a lower value (MD: -2.9; 95% CI: -8.2 to 2.4). Overall, the indirect comparison did not show a statistically significant difference among the two techniques (MD: -4.2; 95% CI: -10.2 to 1.9).

Numbness

Five studies\(^1\)\(^8\), \(^1\)\(^1\)\(^4\)-\(^1\)\(^8\) compared Shouldice versus Lichtenstein reported the incidence of numbness and a higher incidence of it was associated with Shouldice (RR: 1.3; 95% CI: 0.9 to 1.9). Two studies\(^1\)\(^4\), \(^1\)\(^6\) comparing Desarda versus Lichtenstein reported the incidence of numbness and a higher incidence was associated with Desarda (RR: 2.4; 95% CI: 0.4 to 16.1). Overall, the indirect comparison did not show a statistically significant difference among the two techniques (RR: 1.8; 95% CI: 0.3 to 12.9).

Chronic pain

Five studies\(^1\)\(^8\), \(^1\)\(^1\)\(^4\)-\(^1\)\(^8\) comparing Shouldice versus Lichtenstein reported the incidence of chronic pain and a lower rate was associated with Shouldice (RR: 0.6; 95% CI: 0.3 to 1.2) as shown in Fig. 7a. Two studies\(^1\)\(^5\), \(^1\)\(^6\) comparing Desarda versus Lichtenstein reported the incidence of chronic pain and a higher rate was associated with Desarda (RR: 1.5; 95% CI: 0.5 to 4.2) as shown in Fig. 7b. Overall, the indirect comparison was not able to identify a statistically significant difference among the techniques (RR: 2.4; 95% CI: 0.7 to 8.4).

Return to daily activities

Five studies\(^1\)\(^9\), \(^1\)\(^2\)-\(^1\)\(^4\)\(^2\) comparing Shouldice versus Lichtenstein reported the mean day of return to daily activities and a significantly longer time was observed with Shouldice (MD: 5.2 days; 95% CI: 0.3 to 10) as shown in Fig. 8a. Also for the Desarda versus Lichtenstein comparison, five studies\(^1\)\(^1\)\(^1\), \(^1\)\(^2\)-\(^1\)\(^4\)\(^6\) reported the mean day of return to daily activities and a lower time was observed for Desarda (MD: -1.4 days; 95% CI: -3.2 to 0.3) as shown in Fig. 8b. Overall, the indirect comparison showed that Desarda technique allows a significantly faster return to daily activities (MD: -6.6 days; 95% CI: -11.7 to -1.4).
Discussion

The present network meta-analysis of trials comparing Shouldice and Desarda techniques shows that Desarda takes approximately 13 minutes less than Shouldice to be performed and offers the patients an earlier return to normal activities, on average 6.6 days less than Shouldice technique. No other statistically significant differences could be detected in terms of intraoperative and postoperative complications, recurrence, postoperative pain and discomfort among the two non-mesh techniques.

The latest guidelines published on the topic\(^2\) state that possible indications to a tissue-based hernia repair are the following: lower cost or non-availability of meshes in low-resource settings, contaminated cases, and patient refusal of a mesh repair. Some questions are also raised on its adoption in case of young males with indirect hernias (L1-L2 according to EHS).

Furthermore, in the recent past, a significant concern among patients and patients' associations has been raised on the safety profile of synthetic implants. This was mainly driven by a high number of complications observed in female patients treated for pelvic prolapse with intraperitoneal implants of polypropylene meshes\(^30\).

Robert Bendavid has raised a similar debate among hernia specialists on the long-term effects of meshes, their chemical stability\(^31\), and their effect on male fertility because of possible erosion in vas deferens\(^32\).

Accordingly, it is quite reasonable the interest raised by articles publishing good results with pure tissue repairs performed in large cohort of selected patients\(^33\).

Haastrup et al. in 2017\(^34\) showed a low reoperation rate after the analysis of 2330 patients submitted to simple annulorrhaphy (removal and ligation or invagination of the hernia sac and then narrowing of the hernia ring by suture) in the age group of 18-29 from the Danish Hernia Database. Taking in consideration also the increased incidence of chronic postoperative pain in the same age population reported in a previous analysis of the same database\(^35\), the authors claim that tissue-based repair could have a role in a tailored approach to young male patient treatment.

Kockerling et al.\(^36\) in a recent paper, analyzed 2608 patients from HerniaMed database submitted to tissue repair, open and laparo-endoscopic mesh repairs. They outlined that, in the subset of young patients with small defects, Shouldice technique was comparable in terms of recurrence and better in terms of chronic postoperative pain in comparison to Lichtenstein.

Accordingly, the debate over the best non-mesh repair is far from being over and needs further investigations. Before the present study, the best available evidence comparing non-mesh techniques came from a Cochrane review published in its final revision in 2012\(^28\). Amato et al. showed that while mesh repair has the lowest recurrence rate in comparison to Shouldice (OR 3.80,
95% CI 1.99 to 7.26), this latter is the most effective in treating hernia among tissue repairs (OR 0.62, 95% CI 0.45 to 0.85).

It should be mentioned that the trials included in the review were heterogeneous and flawed by issues of randomization, follow-up rate and blinding. Nevertheless, Hernia Surge guidelines issued an upgraded strong recommendation in favor of the adoption of Shouldice technique over other tissue repair techniques. Moreover, despite the available evidence coming from RCT studies included in the present network meta-analysis, Desarda was judged still under evaluation at the time of guidelines publication.

In the first publication of Desarda original technique, a 1.5 strip of external oblique aponeurosis (EOA) is detached from the medial leaf of the opened EOA, sutured without tension inferiorly to inguinal ligament and superiorly to the internal oblique muscle to reinforce the posterior inguinal wall. The postulated physiological advantages behind this repair are several. First, in the authors' interpretation, the repair performed with EOA should be durable and effective since age-related degeneration of the transversalis fascia does not affect tendons and aponeuroses. Second, the strip, in continuity with the main EOA, would act with a dynamic mechanism as a barrier in all the phases of intrabdominal pressure variation protecting from recurrence. Third, the technique is easily mastered and reproducible, being different from complex Bassini and Shouldice dissections which require high experience to be performed correctly. Fourth, the technique avoids implantation of foreign material with its related long-term complications.

The first long-term results published in 2006 by Desarda contained a series of 860 patients followed for a median of 7.8 years (range 1-12 years) reporting a 0% recurrence and 0% postoperative pain rates. These results were criticized for inconsistency showed by a follow-up rate lower than 75% and the suboptimal follow-up strategy adopted (phone questionnaire). Moreover, the fact that Desarda was an author of simultaneous publications on the same technique in 2001 and that the series overlap with that of 2006 raised several skepticisms in the surgical community over the technique itself and the author.

Moreover, despite Desarda claiming the novelty of his technique this was not new in the scientific community: other surgeons have reported on the use of autologous tissue to reinforce the posterior hernia repair.

One of the main advantages of Desarda technique, which can be derived from our present analysis, is the quickness of performance. The included trials come mainly from general surgery units located in developing countries with results and efficiency comparable to Lichtenstein repair. A twelve-minutes reduction in operative time not necessarily has a clinical or economic impact on the results but could suppose the ease of the procedure and the possibility of a quick learning curve.
This is very important in particular when considering, according to literature that the estimated learning curve and surgeon’s yearly volume for Lichtenstein is hernia repair has been recently reported as being respectively 60 cases\textsuperscript{41, 42} and 150 cases\textsuperscript{41, 42}, while for Shouldice it has been postulated a volume of 500 cases per year\textsuperscript{41, 42} to reach true proficiency. Moreover the results (current and historical) from the Shouldice Clinic are representative of excellence\textsuperscript{42} as proved by their traditional recurrence rate of around 1\%\textsuperscript{27}, rising, in less experienced hands, to 15\%\textsuperscript{43}. In this light, Desarda could be a solution for those cases unsuitable for mesh repair in centers where experience in tissue repairs is low.

The second advantage of Desarda technique highlighted in our network meta-analysis is a quicker return to normal activity. Even if some of the physiological effects attributed to this repair are largely unproven and only hypothesized by the author\textsuperscript{25}, the technique itself could be considered “more tension-free” than Shouldice explaining the effect on postoperative recovery. Our results and those of a recently published metaanalysis\textsuperscript{29} seem to indirectly confirm the reduced tension of Desarda’s as highlighted by a shape of postoperative pain occurrence similar to that of tension-free mesh repair, even if not confirmed in our indirect comparison among the two tissue repair.

Our network meta-analysis has some limitations. First, it regards the type of study analyzed, those comparing Desarda to Lichtenstein are more recently published. Moreover, the included studies showed a high heterogeneity (e.g., due to the patient population, follow-up length,) and only a few of them were judged at low risk of bias. Finally, the lack of direct evidence in the comparison between the two techniques did not allow to assess inconsistency.

Conclusion
The present network meta-analysis shows that Desarda technique can be considered at least as a safe and effective alternative to Shouldice technique, that is still considered the gold standard in non-mesh approaches to groin hernia repair. However, Desarda has showed potential advantages such as reduced operative time and quicker return to life activities.

Further studies are needed in the future focusing on the short and long-term results specifically in the group of currently accepted indications for tissue repair (i.e., contaminated cases, young adults and in cases of patients refusal to mesh implants).

Conflict of Interests
The present network meta-analysis was not founded by third parties; the authors declare no conflict of interest in conception and drafting of the manuscript.
Provenance and peer review

Not commissioned, externally peer-reviewed

References


Figures Legend

**Fig 1** PRISMA flow chart for the study

**Fig 2** Network map of evidence. The size of each circle (node) is proportional to the number of patients who received the treatment. The width of the lines represents the number of RCTs that directly compared the connected pair of treatments. The values in parentheses denote the number of RCTs that investigated the associated comparison, followed by the combined number of patients in those RCTs

**Fig. 3** Forest plots of the operative time: Shouldice vs Lichtenstein (a). Forest plots of the operative time: Desarda vs Lichtenstein (b).

**Fig. 4** Forest plots of the recurrence: Shouldice vs Lichtenstein (a). Forest plots of the recurrence: Desarda vs Lichtenstein (b).

**Fig. 5** Forest plots of the postoperative complications: Shouldice vs Lichtenstein (a). Forest plots of the postoperative complications: Desarda vs Lichtenstein (b).

**Fig. 6** Forest plots of the seroma/hematoma: Shouldice vs Lichtenstein (a). Forest plots of the seroma/hematoma: Desarda vs Lichtenstein (b).

**Fig. 7** Forest plots of the chronic pain: Shouldice vs Lichtenstein (a). Forest plots of the chronic pain: Desarda vs Lichtenstein (b).

**Fig. 8** Forest plots of the return to daily activities: Shouldice vs Lichtenstein (a). Forest plots of the return to daily activities: Desarda vs Lichtenstein (b).
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Table 1 Details of included studies (PICOS).
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Tab.2 Risk-of-bias table, showing the domain assessment for individual trials
Fig. 1 PRISMA flow chart for the study
Fig. 2: Network map of evidence. The size of each circle (node) is proportional to the number of patients who received the treatment. The width of the lines represents the number of RCTs that directly compared the connected pair of treatments. The values in parentheses denote the number of RCTs that investigated the associated comparison, followed by the combined number of patients in those RCTs.
Fig. 3a-b: Forest plot of operative time, figure A Shouldice vs Lichtenstein; figure B Desarda vs Lichtenstein
Figure 4a-b: Forest plot of recurrence, figure A Shouldice vs Lichtenstein; figure B Desarda vs Lichtenstein
Figure 5a-b: Forest plot of post-operative complications, figure A Shouldice vs Lichtenstein; figure B Desarda vs Lichtenstein
Figure 6a-b: Forest plot of seroma/hematoma, figure A Shouldice vs Lichtenstein; figure B Desarda vs Lichtenstein
Figure 7a-b: Forest plot of chronic pain, figure A Shouldice vs Lichtenstein; figure B Desarda vs Lichtenstein
Figure 8a-b: Forest plot of return to daily activities, figure A Shouldice vs Lichtenstein; figure B Desarda vs Lichtenstein
1- Analysis of results of the new tissue repair technique for groin hernia surgery: the Desarda technique
2- Comparison by network (indirect) meta-analysis of tissue repair techniques Desarda and Shouldice
3- Evidence of the effectiveness of tissue repair techniques for groin hernia surgery