ОБЗОР ЛИТЕРАТУРЫ **REVIEW**

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Minimally invasive treatment of pilonidal sinus disease (a systematic review and meta-analysis)

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ABSTRACT AIM: to estimate the effectiveness of minimally invasive methods for treatment of chronic inflammation in pilonidal sinus disease by systematic review.

> PATIENTS AND METHODS: fifty-two clinical trials were selected from 2,576 papers in databases for systematic review. It included the following methods: the fibrin glue, the sinusectomy, the video-assisted pilonidal sinus treatment, the laser coaquiation and the chemical destruction using crystallized phenol or its solution. Regarding the last two methods, a meta-analysis was carried out.

> RESULTS: the meta-analysis demonstrated the high effectiveness of phenol and laser coagulation for pilonidal sinus disease. When comparing the results of phenol use and excisional techniques, there was a significant difference in higher frequency complications rate after excisional techniques (HR 0.42; 95% CI: 0.05–3.71), while the recurrence rate was the same (HR 0.98; 95% CI: 0.45-2.16). The probability of recurrence was significantly higher than after excision techniques in compare with SiLaC (HR 4.02; 95% CI: 1.13 14.3, p = 0.03). However, there was no significant differences in complication rate after SiLaC and excisional techniques (HR 0.63; 95% CI: 0.29-1.34).

> CONCLUSION: the chemical destruction and laser coaqulation are the most effective methods for pilonidal sinus treatment.

KEYWORDS: Pilonidal sinus disease, PD, pilonidal cist, minimally invasive treatment, laser coagulation, EPSiT, VAAFT, SiLaC, phenol, fibrin glue

CONFLICT OF INTEREST: The authors declare no conflict of interest

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INTRODUCTION

Pilonidalsinus (PS) is a narrow channel under the skin, lined with epithelium from the inside, containing hair follicles and sebaceous glands, reaching 10 cm long and blindly ending in soft tissues in the coccyx area. PS communicates with the skin surface by several (from 1 to 6) point primary fistula openings located in the inter-gluteal fold along the midline. As a result of chronic inflammation of the PS, 1 or more secondary fistula openings may appear, located on the skin of the sacrococcygeal or adjacent areas [1].

The estimated incidence of PSD is 26 per 100,000 people. In male patients, the disease occurs 4 times more often than in women, while PS inflammation rarely occurs before puberty or in old age, mainly developing in young persons [2]. There is no consensus in the literature regarding the etiology of PSD. Currently, there are several theories of the development of chronic inflammation of the pilonidalsinus: neurogenic, ectodermal invagination, invert hair growth, etc. In Russia, the innate theory of the origin of this disease has become the most widespread [3]. According to foreign literature, it is believed that this disease is associated with the proliferation and hyperfunction of

hair follicles in the sacrococcygeal area, followed by blockage of the sebaceous glands and the development of the inflammatory process. Features of the anatomy and biomechanics of the gluteal area can cause a vector violation of hair growth, which in turn also contributes to the blockage of hair follicles. As a result, a pathological sinus is formed under the skin of the inter-gluteal fold, followed by the addition of inflammatory reactions [4].

To date, the choice of the method of surgical treatment of chronic inflammation of the pilonidal sinus remains controversial. Over the past 30 years, a fairly large number of techniques have appeared, which had the peak of their popularity at the moment when they were proposed, and their effectiveness was studied. Most of the methods aimed to reduce or completely close the wound lesion with a relatively low risk of the disease recurrence. So, recently, there are a number of very popular techniques for reducing a postoperative wound such as: by stitching its edges to the bottom [5,6], the layer-by-layer suturing of the wound tightly [7], options for plastic closure of the wound using a laterally displaced skin-fat flap according to Karidakis [8] or Bascom 2 [9], excision of PS with plastic surgery of a wound lesion with a displaced rhomboid skin-fat flap (Limberg's procedure), and variants of Z, Y plasty [10-12]. Nevertheless, gradually the methods accompanied by radical excision of PS began to yield the palm to more gentle approaches. The surgery which can be conditionally called a "bridge" between radical excision and minimally invasive techniques was sinusectomy or subcutaneous excision of the pilonidalsinus [13,36]. Already, experience has accumulated in world practice, demonstrating that in the case of uncomplicated PSD, its treatment options associated with tissue excision are significantly inferior to minimally invasive ones. The optimal method of PSD treatment should meet the following criteria: be simple, cost-effective, with the possibility of outpatient treatment, including under local anesthesia, cause minimal discomfort and do not affect performance, as well as have a low recurrence rate. All surgical methods are far from ideal, as they are usually performed under general or spinal anesthesia, require hospital stay and cause temporary loss of patients' working capacity [8]. In this regard,

the application of minimally invasive techniques in clinical practice is relevant. However, the data of the world literature on the effectiveness and indications for the use of a minimally invasive method vary significantly. As part of the evaluation of the effectiveness of minimally invasive techniques, a literature review was performed, including an analysis of the results of such methods as: EPSiT (endoscopic pilonidal sinus treatment), VAAPS (video-assisted ablation of pilonidal sinus) [13-15], the use of fibrin glue [16,17], laser thermocoagulation of the fistula (SiLaC — Sinus Laser Coagulation) [18–20], sinusectomy [5,6], the use of phenol [21-25]. In addition, taking into account the absence of meta-analyses evaluating the effectiveness of PSD treatment methods associated with the use of phenol and laser coagulation (SiLaC), the availability of publications characterizing the experience of their application accumulated in the world practice, a meta-analysis of data on their effectiveness was done.

MATERIALS AND METHODS

A literature search was performed in the Medline, Cochrane library, Google Scholar, and E-library databases. A total of 2,576 articles were found for a query containing the following terms: "pilonidal sinus", "sacrococcygeal sinus", "sacrococcygeal", "pilonidal". Restrictions on the date of publication of articles and language restrictions were not applied. Statistical data processing when comparing binary indicators was carried out in the Review Manager 5.3 program. For dichotomous data, the odds ratio (OR) with 95% CI was calculated. After screening, 52 articles were selected on evaluating the effectiveness of minimally invasive techniques in the treatment of PSD. Of these, fibrin glue was used in 5 studies for the treatment of PSD [17], EPSiT/ VAAPS technique was used in 14 studies [26], phenol applications were used in 13 [26-28,31], sinusectomy was used in 9 [28], SiLaC was used in 11 [18,19,29-31] articles (Fig. 1).

EPSiT (endoscopic pilonidal sinus treatment) is a minimally invasive method of PSD treatment, first described in 2013 by Mainero, P. et al. The technique of this surgery consists in

removing the contents of the fistula passage under the control of vision through a special rigid fistuloscope followed by ablation of the sinus walls with a monopolar electrode [17,36]. This technique is based on a technology similar to the technique of treating anal fistula VAAFT (video-assisted anal fistula treatment).

Milone M., et al. in 2016 in their randomized study compared the effectiveness of EPSiT with radical excision of PS. The primary point in the study was the duration of disability, which was 1.6 ± 1.7 days in the EPSiT group, which was significantly less than with PS excision — 8.2 ± 3.9 days (p = 0.001) [14]. There was also a marked decrease in pain syndrome when using EPSiT (p = 0.001). However, the complication rate was comparable in both groups (p = 0.1). These studies indicate the obvious advantage of minimally invasive technique over radical excision of PS in such important aspects of treatment as the duration of the period of disability and the intensity of pain syndrome in the postoperative period with comparability of the frequency of complications. A comparative analysis of the recurrence rate after surgery was not performed in the study, which significantly complicates the final assessment of all the advantages and disadvantages of the EPSiT method [14].

In another later publication in 2019, Milone, M. and co-authors compared the results of EPSiT with sinusectomy. With comparability of the complication rate, the intensity of pain syndrome and the duration of the period of disability, a significantly lower recurrence rate was observed after the use of EPSiT (7.5% vs. 25%; p = 0.035) [33]. In the work by Foti, N. et al. (2021), which included 42 patients, the results of video-assisted technologies for PSwere demonstrated.

In the first week of the postoperative period, the level of pain syndrome on a visual-analog scale was 2.1 ± 1.3 points. Complications occurred in 8.7% of cases, the period of disability was 3.8 ± 1.4 days. The most often complication was prolonged non-healing of the wound. The recurrence rate was 10.9%. When analyzing all 14 studies included in the review, the complication rate ranged from 0% to 11.5%, with the most frequent complication being bleeding from a postoperative wound. The recurrence rate of the disease was shown in 5 out of 14 studies and ranged from 0% to 26.9%.

A small number of papers devoted to the evaluation of the results of the use of video-assisted PSD treatment and the fragmentation of the data presented do not allow for its full

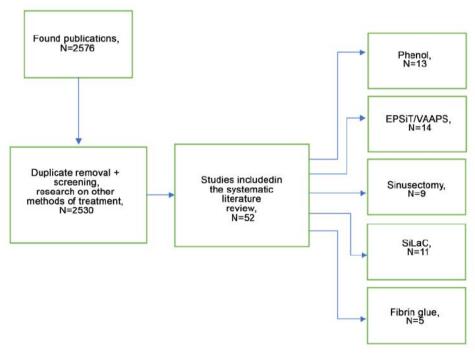


Figure 1. Literature search diagram

assessment and aggregation of data in the form of meta-analysis.

Sinusectomy is a minimally invasive technique, which consists in subcutaneous excision of the pilonidalsinus with preservation of the skin bridge between the fistula openings [6]. The method was first described by Soll, Ch. et al. in 2011 [15,37]. Enriquez-Navascues, J.M. et al. (2014) in their meta-analysis, which included 25 studies, compared the effectiveness of sinusectomy and PS excision [28]. Such indicators as the period of wound healing, the recurrence rate, and the time to return to work did not differ significantly between the groups (HR 0.6; 95% CI 0.17-2.38; p = 0.856). Thus, the authors revealed that the effectiveness of sinusectomy was completely comparable with radical excision of the PS; however, the analysis of the data obtained did not reveal advantages in the form of accelerated wound healing and faster return to working capacity [28]. In total, when evaluating the results of 9 studies, it was found that the complication rate after the use of the technique ranged from 3.6% to 18.7%, and the recurrence rate-from 4.1% to 14.7%. The most often complications were bleeding from the wound and destruction of the skin bridge. It should be noted that according to some authors, sinusectomy has a number of technical limitations. Thus, according to a study conducted at the RNMRC of Coloproctology, it was found that subcutaneous excision of the PS is most convenient to perform with its length not exceeding 5 cm and when there is no history of surgeries for PSD, which makes it applicable only in some patients [35].

Fibrin glue (a mixture of fibrinogen and thrombin) is used to fill the fistula passage, which promotes its healing without the need for excision of the fistula canal [36]. In analyzing the effectiveness of the technique, the metanalysis data by Lund, J. et al. are of interest. (2017), which included 253 patients [17]. In this paper, the effectiveness of the use of fibrin glue in the treatment of PSD is compared, both in the form of monotherapy and as an adjunct to the plastic closure of a wound lesion according to the methods by Limberg and Karidakis. So, in the case of using fibrin glue during PS excision

surgery with plastic closure of the wound lesion with a displaced diamond-shaped flap along as per Limberg, the glue was applied to the wound surface, after which the wound lesion was covered with a displaced skin-fat flap. This combination allowed the authors to reduce the healing time by an average of 13.9 (95% CI -16.7-11.1) days compared to the classical Limberg surgery. The intensity of the pain syndrome, on average, decreased from 4 to 2 points according to VAS (p < 0.001), and the time of return to working capacity from 17 to 8 days (p < 0.001). It was also demonstrated that filling the wound with fibrin glue as an addition to the plastic of the wound lesion after excision of the PS by lateral displacement of the skin-fat flap according to the Karidakis method reduces the duration of hospital stay to an average of 2 days compared to 3.7 days in the classic version of the Karidakissurgery (p < 0.001). The effectiveness of using fibrin glue in mono mode was compared with the results by Bascom 1 surgery. With isolated use of fibrin glue, the pain syndrome estimated by VAS was, on average, 2.5 points lower (95% CI-4.03 - -0.97), and the time to return to normal life, on average, was 34.8 days less compared with the Bascom 1 surgery (95% CI -66.8 — -2.78). The recurrence rate in the groups did not differ significantly. Nevertheless, the technique of filling the PS channel with fibrin glue has not found wide popularity, the range of its use is limited only to the addition to plastic methods of closing a wound lesion as a cementing agent that improves the fusion between the wound surface and the flap [17].

Phenol is a single-substituted aromatic hydrocarbon with antiseptic, analgesic and sclerosing properties. For the first time, the use of phenol in the treatment of PSD was described by Maurice, A. and co-authors back in 1964 [24]. But the technique has gained the greatest popularity since the 2000s. The analysis of the literature data revealed technical differences in the use of phenol in the treatment of PSD. Thus, applications of crystalline phenol were used in 9 studies [19,26,31,40–45], and in 4 studies a phenol solution was used [27,28,46,47]. In addition, some authors have used a combination of phenol applications

with other minimally invasive methods of PSD treatment. So, Gecim, I. et al. (2017) in their study applied crystalline phenol after fistuloscopy and removal of detritus and hair from the fistula passage through the fistuloscope channel [15].

As part of the evaluation of the effectiveness of phenol in the treatment of chronic inflammation of the pilonidalsinus, a systematic review of the literature was performed, which included 13 studies.

In total, the results were evaluated in 682 patients with PSD, in the treatment of which phenol was used. The overall recurrence rate when using phenol in the treatment of chronic PS inflammation, taking into account all the studies, was 8.7% (60/682) (Table 1).

During the meta-analysis, which included 4 studies, the recurrence rate after the use of phenol and radical excision of PS was compared. So, Ates, A. et al. (2017) in their work compared the results of the technique with the use of phenol withthe PSexcision, accompanied by suturing the wound tightly.

Calikoglur, I. et al. (2017) and Pronk, A. et al. (2019) compared the use of phenol with the PS excision and open wound management. Bayhan, Z. et al. (2015) compared the technique of the PS excision with plastic closure of a wound lesion

with a displaced diamond-shaped flap along as per the Limberg method.

When evaluating the results of these studies, it was found that the probability of recurrence did not significantly differ statistically between the methods accompanied by excision of the pilonidal cyst and methods with phenol application (OR 0.98; 95% CI: 0.45–2.16) (Fig. 2).

The complication rate with the use of phenol was described in 8 studies. The overall rate of complications after its use in the treatment of PSD was 9.7% — 53 cases among 546 patients. The main complications arising after the use of phenol were chemical burns and abscessing.

Chemical burns in most cases did not affect the results of the treatment, while abscessing was associated with a high risk of ineffective therapy and the likelihood of the disease recurrence. After the PS excision, complications were bleeding from wounds and divergence of sutures. (Table 3).

When performing the meta-analysis of the data, it was revealed that the overall probability of complications with the use of phenol did not differ statistically significantly from the methods in which radical PS excision was performed. However, there was a tendency towards the possibility of a statistically significant difference in the direction of a higher incidence of

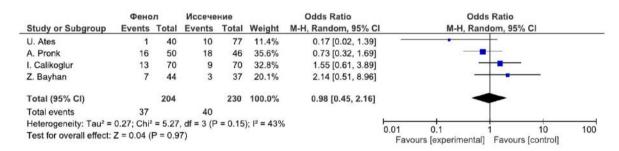


Figure 2. Forrest plot of the analysis of the reccurence rate when using phenol and pilonidal sinus exision

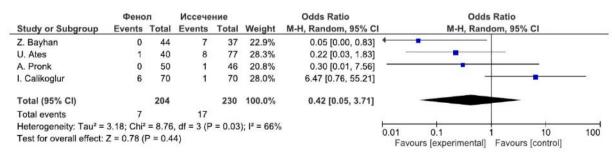


Figure 3. Forrest plot of the analysis of the complication rate in groups where phenol and pilonidal sinus excision were used

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complications after PS excision, provided that the sample of patients increased (OR 0.42; 95% CI: 0.05–3.71) (Fig. 3).

SiLaC (Sinus Laser Coagulation) — is one of the most popular methods of treatment of chronic PS inflammation today, consisting in coagulation of the walls of the fistula passage with a diode laser [45-49]. The technique has proven itself well due to its low traumatism, the possibility of coaqulation of the walls of the sinus with a small laser light quide in diameter, regardless of the PS length, low pain syndrome after the surgery, as well as rapid recovery of working capacity. Dessily, M. et al. were among the first to start using this technology in 2014 [22,33,34]. When analyzing the results of recent studies, it was found that the rate of healing after the application of the technique is in the range of 87-95%. So, Dessily, M. et al. (2017)

gave data on the treatment of 200 patients by SiLaC according to which the authors achieved PSD healing in 94% of cases [30]. Similar results were demonstrated in the work by Pappas, I. et al. in 2021, which included an analysis of the results of treatment of 237 patients. The healing rate after the SiLaC application in this study was 90.3% [47]. Nevertheless, a small number of publications devoted to the results of the application of the SiLaC technique does not allow us to develop clear indications and contraindications for its use [23,35,53]. To date, there are no data summarizing the world experience in the treatment of chronic PS inflammation using laser coaquilation in the literature.

In this regard, a meta-analysis of the literature data was carried out, in which SiLaC was compared with radical excision of PS by several indicators [35,50].

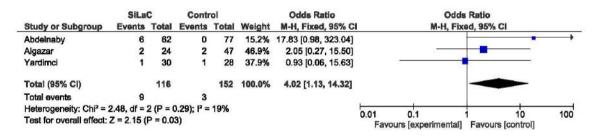


Figure 4. Forrest plot, showing a comparative analysis of the recurrence rate in groups where the SiLaC technique and pilonidal sinus excision were used

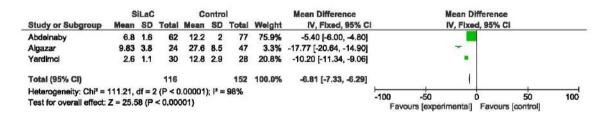


Figure 5. Forrest plot, showing a comparative analysis of the duration of the period of disability in groups where the SiLaC technique and pilonidal sinus excision were used

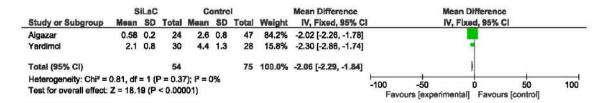


Figure 6. Forrest plot, showing a comparative analysis of the intensity of pain on the day of discharge (VAS) in groups where the SiLaC technique and pilonidal sinus excision were used

In total, 3 studies were found in which laser coagulation of PS (SiLaC) was compared with surgical excision of PS. In the studies by Algazar, M. et al. (2021) and Yardimci, V. et al. (2020) in the control group, PS excision was performed with plastic replacement of the wound lesion according to Karidakis and Limberg, respectively. And in the work by Abdelnaby, M. et al. (2021) in the control group, PS excision was performed without suturing the wound [21,31,33]. The methodology of laser coaqulation according to all the authors coincided with the technique proposed by Dessily M. et al. (2017), who first described this technology in the treatment of PSD [18]. In the original, a diode laser with a wavelength of 1,470 nm was used for this technique, a light quide with radial energy radiation was used.

It should be noted that Dessily, M. et al. (2017) used a 10 W diode laser in their study, while Yardimci, V. et al. (2020) — 12-14 W, Algazar, M. and co-authors (2021) — 13.5 W, and Abdelnaby, M. and co-authors (2021) in their article do not indicate the exact power of the laser used. In all the studies, the expansion of primary and secondary holes was performed by a sharp way and with the help of a clamp; Yardimci, V. et al. (2020) supplemented the procedure with circular excision of the skin around the holes using a biopsy needle (derma-punch). The results of the analysis comparing the effectiveness of SiLaC with techniques accompanied by excision of PS are presented below (Tabl. 6,7). In the metaanalysis of comparative studies included in the systematic review, we found that the probability of the disease recurrence was statistically significantly higher after the use of SiLaC than after PS excision techniques [OR 4.02 (95% CI: 1.13 14.3, p = 0.03] (Fig. 4).

However, the comparative analysis of the duration of the period of disability revealed that after using the SiLaC technique, the return to work occurs, on average, 6.8 days earlier than after radical excision of the PS (95% CI: -7.33 — -6.29, p = 0.000001) (Fig. 5).

In the comparative analysis of the intensity of pain syndrome using a visual-analog pain scale (VAS) in 2 papers (Yardimci, V. et al., 2020; Algazar, M. et al., 2021), it was demonstrated that the level of pain after SiLaC, on average, was 2.06 points lower than after excision of PS (95% CI: -2.29 - -1.84, p = 0.00001) (Fig. 6).According to the analyzed publications, it was found that the complications that developed after the use of SiLaC were not of a specific nature and were mainly represented by purulentinflammatory processes in the surgery site and bleeding. The meta-analysis included 2 comparative studies, with no statistically significant differences in the incidence of complications between SiLaC and radical excision of PS (OR 0.63 (95% CI: 0.29-1.34)) (Fig. 7). As in the case of evaluating the results of phenol use, after SiLaC there was a tendency towards a decrease in the complication rate. However, the probability of achieving statistical significance could be realized with a larger sample of patients.

DISCUSSION

Inflammation of the pilonidal sinus, despite its benign course and favorable prognosis, is a socially significant disease, which is due to the predominant morbidity among the young able-bodied population [2]. The main method of PSD treatment currently continues to be radical surgical excision of the PS. Surgery for a long time can reduce the

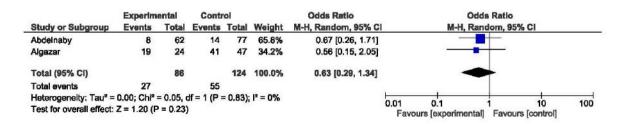


Figure 7. Forrest plot, showing a comparative analysis of the rate of complications in groups where the SiLaC technique and pilonidal sinus excision were used

quality of life of the patient, as well as affect his ability to work. Plastic closure of a wound lesion does not always lead to a faster recovery of the patient and is associated with the risk of purulent-inflammatory complications. The emergence of new minimally invasive techniques in the treatment of PSD is aimed at preserving the effectiveness of surgical treatment — minimizing the recurrence and complication rate [8].

Despite the variety of methods of minimally invasive treatment of chronic inflammation of the pilonidal sinus, there is currently no universal method that could become the "gold standard".

Each of the techniques, along with the presence of significant advantages due to less injury, also carries limitations and disadvantages. For example, the use of EPSiT technology is associated with pronounced technical difficulties and the need to use expensive video endoscopic equipment. In addition, despite the comparable effectiveness of the EPSiT method with PS excision, the complication rate was also identical. The use of fibrin glue is practically not considered as an independent technique and is currently regarded by most authors as a satellite of other surgical techniques (Bascom 2, Limberg, Karidakis surgeries). Sinusectomy, despite the satisfactory immediate results of the treatment and a good cosmetic effect, does not have significant advantages over PS excision in terms of wound healing. Also, a significant limitation of the technique is the complexity of its application when the length of the fistula is over 5 cm.

The use of phenol is one of the least traumatic minimally invasive techniques in the treatment of PSD.

During the analysis of the literature data, we found that the use of phenol in the treatment of PSD is an effective technique with a recurrence rate of 8.7%. There was no statistically significant difference in the risk of disease recurrence when using phenol compared with radical surgical excision of PS (OR 0.98 [95% CI: 0.45–2.16]).

Moreover, the incidence of complications (9.7%) not only did not differ statistically significantly between the methods, but also tended to decrease with the use of phenol (OR 0.42 [95% CI: 0.05–3.71]) (Fig. 2). Thus, the use of phenol is a reliable minimally invasive method of PSD

treatment, not accompanied by a high risk of complications.

The use of SiLaC in the treatment of chronic inflammation of PS, despite the greater risk of recurrence compared with excision of the PS (OR 4.02 [95% CI: 1.13 14.3, p = 0.03]), carries a number of advantages in the form of a pronounced reduction in pain syndrome and accelerated recovery of the patient's ability to work. The low traumatization of tissues during the surgery, as well as the possibility of its use for various PS lengths, makes SiLaC the method of choice in the treatment of the disease. An important advantage when using SiLaC is the preservation of the possibility of using any more radical surgical techniques in the event of a return of the disease.

CONCLUSION

The data analysis has demonstrated that the use of minimally invasive methods has a number of advantages, such as: low tissue injury, less impact on the quality of life and ability to work of the patient, low intensity of pain syndrome, which makes the techniques promising for wide application. Taking into account the literature data, 2 methods have proven themselves most well: chemical coagulation of PS using phenol and laser coagulation of PS. However, a small number of comparative studies, especially randomized ones, makes it difficult to fully evaluate the effectiveness of these techniques, as well as to develop clear indications and contraindications for their use. To identify the advantages and disadvantages of using phenol and SiLaC in the treatment of PSD, further randomized studies are necessary.

AUTHORS CONTRIBUTION

Concept and design of the study: Sabina B. Kozyreva, Ivan V. Kostarev, Leonid A.

Collection and processing of the material: Sabina B. Kozyreva, Ivan V. Kostarev, Leonid A. Blagodarny, Vadim V. Polovinkin

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