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A new device for removing foreign bodies from soft tissues (experimental study)

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Abstract

Aim: to perform a comparative evaluation of a newly developed device for removing foreign bodies from soft tissues.

Material and methods. A minimally invasive endoscopic system has been developed to facilitate the removal of foreign bodies from soft tissues while decreasing the procedure duration and intervention-related injury. An experimental study was performed using a comparative group design. Blind gunshot wounds were simulated in porcine thigh specimens (pistol shots from a distance of 25 meters). In the main study group (20 wounds) extraction was performed using the developed device, in the comparison group (20 wounds), using a standard Grasper's clamp under ultrasound guidance. The bullet extraction time was measured with a stopwatch, and the extent of soft tissue damage was quantified by the volume of soft tissue excised.

Results. The duration of bullet extraction in the study group MED [Q1;Q3] 178,5 [148,5; 223,7] s was shorter than in the control group: MED [Q1;Q3] 322,0 [248,5; 350,0] s (p=0.001). The number of muscle fragments extracted along with bullets was higher in the control group (31 fragments) than in the study group (9 fragments). The novel device reduced intervention-related trauma in the study group compared to the control group.

Conclusion. The novel device for extraction of foreign bodies from soft tissues demonstrated a significant reduction in tissue trauma and a shorter procedure time in an experimental model. The combined use of endoscopic and ultrasound guidance enhances targeting precision, facilitates secure grasping and stable retention of the foreign body, and enables its minimally traumatic extraction.

Keywords: foreign bodies, wound debridement, endoscopic surgery.
Conflict of interest: nothing to disclose.

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Новое устройство для удаления инородных тел из мягких тканей (экспериментальное исследование)

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Аннотация

Цель: провести сравнительную оценку эффективности разработанного устройства для удаления инородных тел из мягких тканей.

Материал и методы. Для упрощения удаления инородных тел из мягких тканей, сокращения продолжительности и травматичности вмешательства была разработана малоинвазивная эндоскопическая система. Выполнено экспериментальное исследование в группах сравнения. Проводили моделирование огнестрельных пулевых слепых ранений на фрагменте свиного бедра (выстрелы из пистолета с дистанции 25 метров). В основной группе (20 шт.) удаление пуль осуществляли с применением разработанного устройства, в группе сравнения (20 шт.) – с применением зажима Граспера под ультразвуковым контролем. Оценивали продолжительность удаления пули с применением секундомера и травматичность манипуляции по количеству дополнительно удаленных мягких тканей.

Результаты. Продолжительность удаления пули в основной группе МЕД [Q1;Q3] 178,5 [148,5; 223,7] с была меньше, чем в группе сравнения – МЕД [Q1;Q3] 322,0 [248,5; 350,0] с (p=0,001). В основной группе вместе с пулями дополнительно было извлечено 9 фрагментов мышц, окружающих пули, в группе сравнения – 31 фрагмент. Травматичность вмешательства с использованием разработанного устройства в основной группе была ниже, чем в группе сравнения.

Заключение. Разработанное устройство для удаления инородных тел из мягких тканей позволяет снизить травматичность и сократить продолжительность экстракции предметов (в эксперименте). Применение в его составе эндоскопической визуализации совместно с ультразвуковой обеспечивает повышение точности позиционирования инородного тела в мягких тканях, а также способствует его захвату, надежному удержанию и малотравматичному удалению.

Ключевые слова: инородные тела, хирургическая обработка ран, эндоскопическая хирургия.
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INTRODUCTION

Traumatic injuries involving foreign bodies penetrating the tissue are quite complicated for diagnostics and treatment. Among the peacetime injuries, they account for approx. 50% of traumas and usually are household injuries [1]. The foreign bodies are, as a rule, fragments of wood, glass, metal cuttings, plastic, parts of components of high-speed household appliances.

Most frequently, foreign objects penetrate the patients' bodies during warfare. In the course of the Second World War, shrapnel (56.8%) and bullet (43.2%) gunshot wounds prevailed. In the warfare of the last decades, the most common gunshot wounds are mine-blast and explosion wounds [2, 3]. According to V.V. Solosin *et al.*, in the period of the special military operation (SMO) the incidence of shrapnel wounds was 79%, and bullet wounds, 10% [4]. In terms of localization of most injuries, wounds of the extremities account for 81.4% of all admitted wounded patients [5]. Such injuries are accompanied with damage of various anatomic areas with foreign bodies deeply penetrating the soft tissues and causing various complications. An unremoved foreign object is a source of infectious complications, it can cause pain, and, in case of its migration, cause damage of various structures, arrosion of vascular walls with formation of hematomas and development of bleeding. In the event of their migration in the vascular structure, urgent conditions may develop [6]. In the event of penetration of chemically active objects, intoxication of the surrounding soft tissues occurs [7, 8]. Another thing to be considered is the certain psychological discomfort that the patients feel when having unremoved foreign objects.

The analysis of literature shows that currently there are no clear indications for the removal of foreign bodies. The problem is approached on a case-by-case basis and depends on a variety of factors, such as position of the wound tract and the foreign body, its size and shape, presence of nervous and vascular branches in its vicinity. The surgeon always faces the question of what would cause the greater harm, the removal of the object or leaving it in the body. Standard operations to remove foreign objects are quite complicated and involve a great number of unsuccessful interventions, from 50 to 80% [9].

According to the Guidelines for Military Field Surgery, removal of foreign bodies (projectiles, their elements, secondary shrapnel, pieces of clothing) is one of the stages of primary surgical treatment of gunshot wounds. In the course of provision of qualified surgical treatment, only those foreign objects are removed that are located along the path of the wound tract. At this stage of medical evacuation, the foreign objects that are located near large vessels, deep inside vital organs, and the foreign objects requiring complex additional access are not subject to removal [10].

Different methods of identification of location of foreign bodies have been developed. Usually, these methods involve X-ray irradiation of the patient, e.g. with the use of an electronic-optical image converter. It is to be noted that this method enables identification of the location of the foreign object and the surgical tool bit involves considerable radiation exposure of the patient and the medical staff. The use of an electronic-optical image converter enables visualization of the object to be removed only in one plane, which does not give the surgeon any information about the location of the object in three dimensions during the operation. Moreover, this method cannot be used in extraction of X-ray negative objects [11].

Ultrasonic-controlled removal of foreign objects via wound tract facilitates the work of the surgeons. At the same time, such manipulations necessitate respective highly precise manual skills on part of ultrasonic diagnosticians [12].

Currently, there are numerous surgical tools and operations for the extraction of different objects, yet they all come with certain shortcomings, restrictions in use, and are not universal. Traditional surgical access may not always be used to remove foreign objects, especially if they are positioned deeply, close to the passage of nervous and vascular bundles. In the event of a large number of foreign objects, e.g., in mine-blast injuries, their extraction with the use of traditional surgical intervention also does not look possible.

Thus, at the moment, it is necessary to develop low-invasive surgical tools incorporating components for navigation ensuring low-trauma removal of foreign objects from the soft tissues.

AIM

To perform a comparative evaluation of a newly developed device for removing foreign bodies from soft tissues.

MATERIAL AND METHODS

In order to simplify the removal of foreign objects from soft tissues, to reduce duration and trauma of the intervention, a special device was developed: "Device for foreign object removal from soft tissues" (patent of the Russian Federation for the invention No.2844631 dated 17.12.2024). The appearance of the working specimen in its carrying case is shown in **Fig. 1**.

The device is an endoscopic system that is inserted into the wound tract until contact with the foreign object. The process is controlled visually (on a monitor screen) and ultrasonically. In the wall of the casing there are channels for the water pump tubes, a tube for the removal of washing fluid, and clamps

Figure 1. *Functional prototype of the device: 1 – Wi-Fi transmitter, 2 – irrigation pump, 3 – main body of the device, 4 – flexible endoscope, 5 – fixation mechanism controls, 6 – storage case.*

Рисунок 1. *Действующий образец устройства: 1 – wi-fi передатчик, 2 – водяная помпа, 3 – корпус устройства, 4 – гибкий эндоскоп, 5 – органы управления внутренними фиксаторами, 6 – кейс.*

to hold the foreign object. Wound washing is performed by a water pump, through which antiseptic solution or normal saline is fed. The removal of the foreign object is controlled endoscopically, once it is held in clamps (**Fig. 2**).

The L-shaped clamps are concealed in the channels of the casing and the grooves of its frontal surface. This ensures atraumatic insertion of the surgical tool in the wound tract until contact with the foreign body. Next, under visual control, the clamps are extended along and beyond the foreign body. The clamps are then rotated 90 degrees and closed beyond the object (Fig. 2). Once the foreign object is held with all clamps, the tool with the foreign object is retracted through the wound tract. Throughout the procedure of object extraction, the wound is washed with normal saline or antiseptic solution. The washing fluid is removed through the channel in the wall of the tool.

Once the foreign object is removed, the wound may be drained using the same tool. For that purpose, it is inserted in the wound tract under endoscopic control to reach the position of the removed object. The endoscope is then retrieved, and a perforated polyvinyl chloride tube is inserted in the channel of the tool to the entire length of the wound tract. After that, the surgical tool is removed from the wound tract.

In order to test the proposed tool, experiments were performed on a fragment of a porcine ham on the base of the Department of Traumatology and Orthopedics of the Voronezh State Medical University named after N.N. Burdenko. At the outset, bullet gunshot wounds were modeled in the “Bunker-M” shooting gallery (Voronezh). The fragment of the porcine ham was shot at from a distance of 25 meters from a rifled-bore firearm: Chiappa 1911 pistol with .22LR (5.6 mm) cartridges, and Makarov pistol with 9×19 Luger cartridges. The result was the fragment of the ham with 20 blind-ended bullet wounds containing foreign objects, i.e. bullets (**Fig. 3**).

Two comparison groups were formed (20 manipulations in each). In the main group, the removal of the foreign objects from the fragment of the porcine ham was performed with the proposed tool. In the comparison group, the removal was performed with a Grasper clamp under ultrasonic control (Mindray DC-4, China). The comparison groups were comparable, for the bullets were removed from one fragment of the porcine ham. Since the majority of wounds were perforating, the bullets were implanted in the wound tracts to model the blind-ended wounds.

The study involved assessment of duration of foreign object removal. To that end, a SOPpr-2a-3-000 stopwatch was used. Another object of assessment was the trauma intensity of intervention judging by the presence of additionally removed fragments of soft tissue that were extracted together with the foreign object or apart from it.

Statistical analysis was performed using SPSS Statistics software suite, version 26. The distribution in both groups deviated from normality. The Shapiro–Wilk test was used to assess the normality of the distribution. Intergroup comparisons were made using the nonparametric Mann–Whitney U test.

RESULTS

The duration of the foreign object (bullet) removal in the main group was lower than in the comparison group (p=0.001). The data follows in **Table 1**.

In the comparison group, the duration of the foreign body extraction was greater: the removal process was complicated

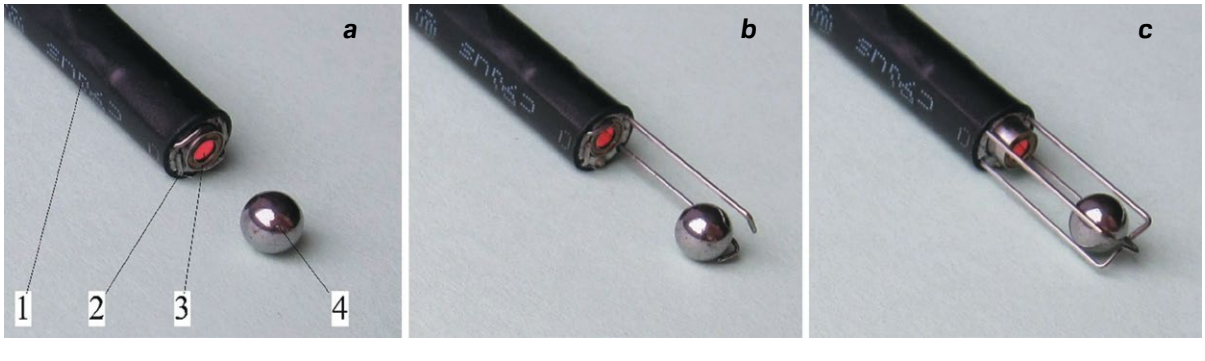

Figure 2. *Foreign body grasping sequence: a – initial position, b – extension of clamps, c – rotation and grasping; 1 – mane body of the device, 2 – clamps, 3 – endoscope, 4 – foreign body (pellet).*

Рисунок 2. *Схема захвата инородного тела: a – начальное положение, b – выдвижение фиксаторов, c – поворот фиксаторов и захват инородного тела; 1 – корпус устройства, 2 – фиксаторы, 3 – эндоскоп, 4 – инородное тело (дробь).*

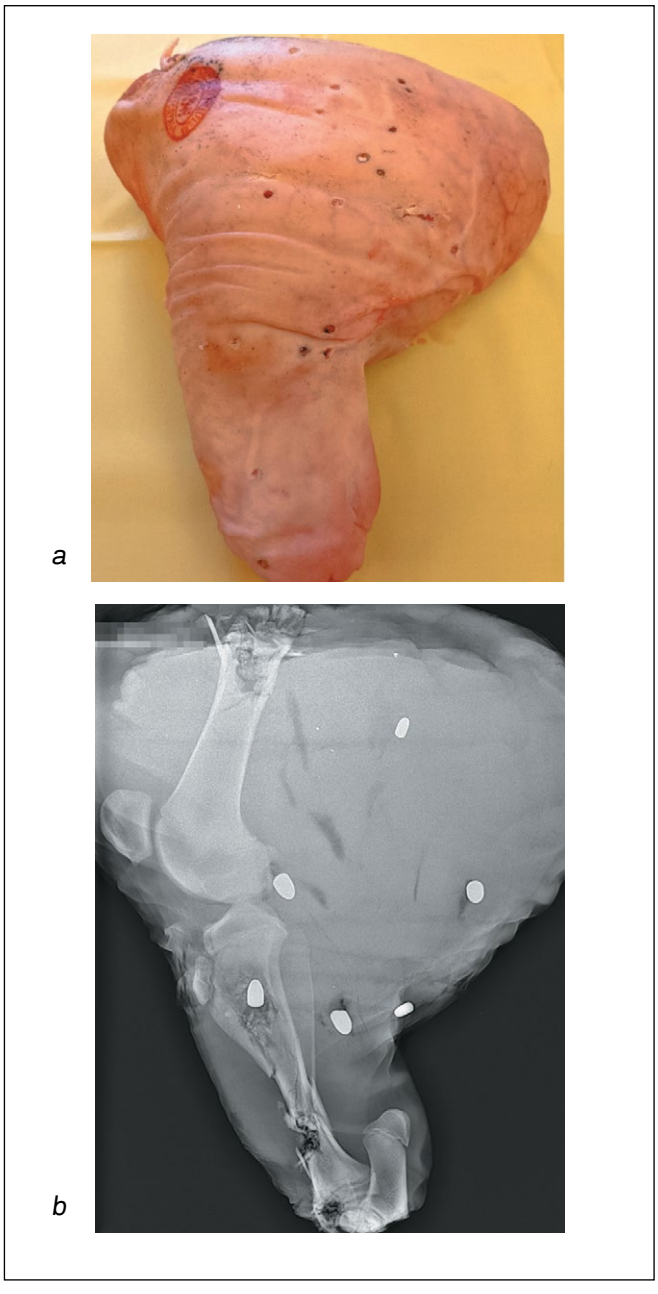

Figure 3. *The appearance of the porcine thigh specimen (a) and its corresponding radiograph (b) during the experimental procedure.*
Рисунок 3. *Внешний вид фрагмента свиного бедра (a) и соответствующая ему рентгенограмма (b) во время эксперимента.*

with technical difficulties on the stage of bullet grasping and with bullet slipping out in the course of movement in the wound tract. This necessitated repeated grasping of the foreign body extending the time of the manipulation. In the main group, in all cases the bullets were removed after the initial grasping with clamps of the proposed tool (**Fig. 4**).

One of the reasons of increased duration of bullet removal in the comparison group was the necessity of ultrasonic visualization of the foreign object and the Grasper clamp. In some cases, it was further complicated by the presence of air in the wound tract which rendered the process of foreign object removal more difficult. In the main group, the ultrasonic visualization of the bullet and the wound tract had a secondary role to identify the course of the wound tract and

Criteria	Main group	Comparison group
MED [Q1;Q3], s	178.5 [148.5; 223.7],	322.0 [248.5; 350.0]
Min; Max, s	92; 280	125; 403
MED±SD, s	183.7 ± 55.7	294.3 ± 88.1

Table 1. *Results of foreign body removal in the comparison groups*
Таблица 1. *Результаты удаления инородных тел в группах сравнения*

the position of the foreign object. All major manipulations to grasp the object were done under endoscopic control.

In the main group, 9 fragments of muscles surrounding the bullets were extracted together with the bullets, whereas in the comparison group the number of fragments was 31. Thus, the trauma intensity of the developed tool in the main group was lower than that in the comparison group.

In our study, when the foreign object was grasped with the jaws of the Grasper clamp, the tissues of muscles surrounding the foreign object would get between the jaws resulting in their further trauma. In the comparison group, when the bullet slipped out of the clamp in the course of its transportation in the wound tract, it had to be grasped again. Soft tissues would regularly get between the jaws of the Grasper clamp, and they were extracted with the bullet.

DISCUSSION

Foreign objects may penetrate the patients' body due to occupational or household trauma, blasts of mines or other ammunition and due to iatrogenic injury. Such objects are removed in two major stages: exact identification of the foreign body and its extraction.

Currently, there are different methods and tools for the extraction of objects from the patients' bodies. Traditional technologies (surgeries) are relatively traumatic, involve loss of blood and, in some cases, involve large incisions.

One of the methods of extraction of foreign bodies is their removal under ultrasonic control using various clamps: Mosquito, Crocodile, Grasper clamps. Ultrasonic navigation ensures precise visualization of foreign objects and their extraction. At the same time, this method requires good manual skills of the ultrasonic diagnostician. When using the above mentioned clamps, additional trauma of the soft tissues around the foreign object is possible since they may get between the jaws of the clamp. In the event the foreign object is located inside a bone or in the marrowy canal, this method may not be used due to limitations of the ultrasound. Another shortcoming of these clamps is the insufficient fixation of the foreign object between the jaws of the tool. In the process of extraction of foreign bodies, they might slip out necessitating repeated grasping [13, 14].

N.V. Momot et al. Suggest using angiographic tools in the course of the operation to speed up the procedure and to improve their efficacy and safety [15]. Without doubt, such intraoperative radiographic navigation ensures simplification and optimization of shrapnel removal technique from soft tissue; however, it requires costly radiographic equipment.

There are methods of removal of foreign object with the aid of magnets inserted in the wound tract. While the magnets are effective in the removal of ferromagnetic foreign objects [16], they cannot be used to remove paramagnetic objects.

One of the methods of extraction of foreign bodies is the use of endoscopic technologies. U. Haramoto et al. suggest

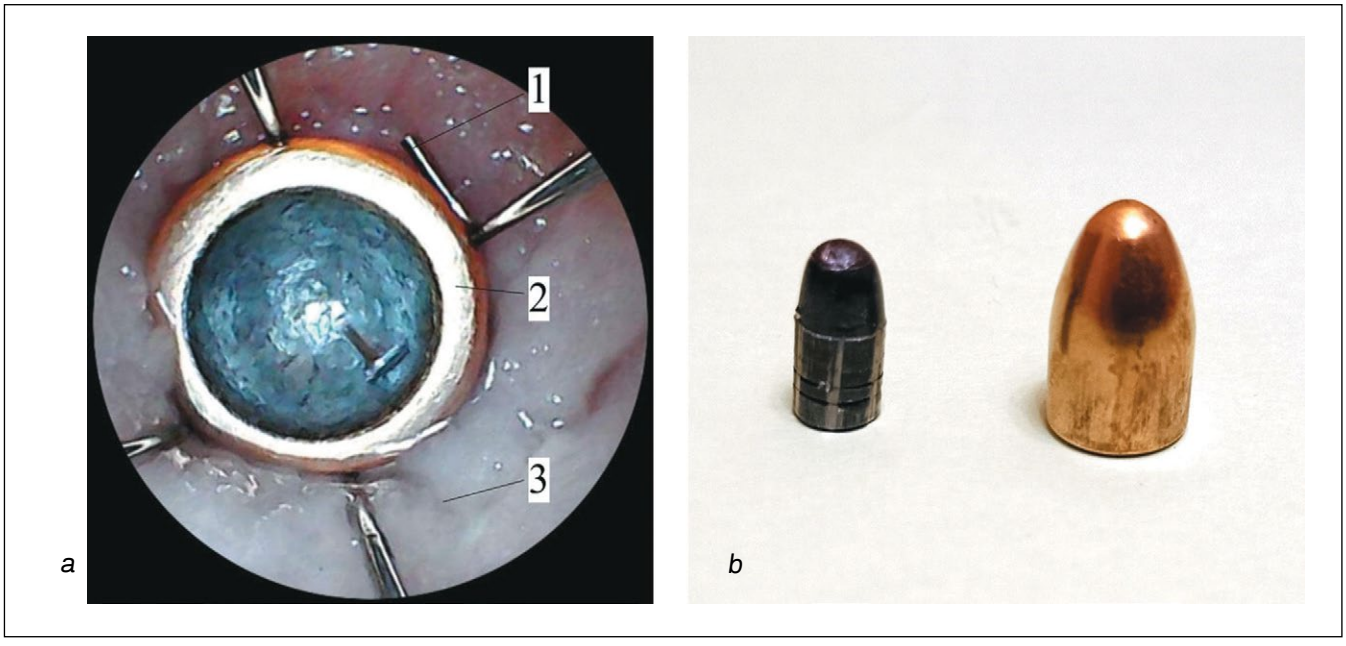

Figure 4. *Endoscopic view of bullet extraction from the wound channel (a) and extracted bullets (b): 1 – retainer, 2 – bullet, 3 – muscle tissue.*
Рисунок 4. *Эндоскопическая картина удаления пули из раневого канала (a) и удаленные пули (b): 1 – фиксатор, 2 – пуля, 3 – мышечная ткань.*

using the endoscope to wash the wound tract and remove foreign objects from it [17]. V.I. Egorov et al. recommend usinf videoendoscopic equipment combined with navigational systems [18].

The tool for the removal of foreign objects developed by us combines two types of navigation: ultrasonic and visual. The proposed tool has a system for grasping the foreign object that ensures secure fixation of the object and prevents its migration in the course of extraction. When removing sharp-edged fragments of ammunition via the wound tract, this system ensures protection of soft tissues. It is to be noted that the designed tool ensures fixation of foreign objects of any geometry. The availability of the endoscopic system ensures all manipulations are visually controlled, which contributes to decreased trauma during the procedure.

The tool is transported in a small-sized carrying case, which ensures easy transportation and use in any operating or dressing room. The ultrasonic tools used can be portable ultrasonic devices. Their use assists identification of the position of the foreign object, vascular and nervous bundles nearby, and allows for control of the tool insertion in the wound tract.

CONCLUSION

The designed tool allows for reduced trauma and decreased duration of foreign object removal (experimentally). The use of endoscopic and ultrasonic visualization ensures increased precision in the positioning of the foreign objects in the soft tissue, and assists grasping, holding and low-trauma removal of foreign objects. The proposed tool may be used for removal of all types of objects that penetrated organs and tissues, magnetic and non-magnetic, radiographically positive and negative. The tool may become an auxiliary tool for orthopedic traumatologists in the treatment of patients with foreign objects in the soft tissues.

ADDITIONAL INFORMATION	ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ
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