НАЦИОНАЛЬНЫЙ ЦЕНТР ЭКСПЕРТИЗЫ
лекарственных средств и медицинских изделий

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Адрес редакции:
050004, РК, г. Алматы,
пр. Абылай хана, 63, оф. 215,
тел.: +7 (727) 273 03 73,
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E.A. ALIMBEKOV, F.E. KAYUPOVA, B.M. MUKANOV, D. BAGDAT,
Department of organization, management and economy of pharmacy and clinical pharmacy, \Kazakh S. D. Asfendiyarov National Medical University Almaty, Kazakhstan

OVERVIEW OF SURGICAL SUTURE MATERIALS

Resume: *The article provides an overview of the main works that investigate the history, classification, use of surgical suture materials, and their research in the market of Kazakhstan.*
Key words: *medical devices, suture materials, surgical, absorbable sutures.*
Keywords: Covid-19, cardiac involvement, antiviral therapy, Kazakhstan

INTRODUCTION

Surgical sutures are sutures designed to connect tissue cut during surgery or when injured. In the modern world, suture materials play an important role in medicine, as they are a necessary attribute and tool of any surgical intervention. The development of medical technologies now allows the creation of perfect samples for more effective healing of surgical wounds. To choose the right suture material, one should take into account the patient's history and current condition, anatomical features in the surgical area, the course of the healing process, as well as the expected cosmetic effect.
For most operations, suture material is the only foreign body that remains in the tissues after the end of operations. And therefore, the outcome of operations depends on the quality, chemical composition, structure of the suture material and the reaction of the surrounding tissues to it. The use of adequate, non-reactive suture material is one of the ingredients for a successful operation.

AIM OF RESEARCH

Overview of the state of suture materials in the Kazakhstan market.

MATERIALS AND METHODS

Electronic resources, review, analysis of the received data.

RESULTS OF RESEARCH

As early as 2000 BC, in a Chinese treatise on medicine, intestinal and skin sutures were described using vegetable threads. In ancient times, various materials were used for seams: horse hair, cotton, skin flaps, tree fibers and animal tendons. The Edwin Smith Papyrus, which is estimated at 4,000 years old, describes the use of linen surgical sutures by the ancient Egyptians. Despite this, until the 19th century there has been very little progress in mastering new materials [1-2]. Catgut sutures, still widely used in surgery, were created by Galen in 175 BC, popularized in 1840 by Luigi Porta, a professor of surgery from Pavia, and in 1868 in England, improved by chromium plating by Joseph Lister. Catgut was the first known absorbable suture material. The second most common suture material is natural silk, the use of which was first described in surgery in 1050 AD. From surgeons it was applied and described by E.T.

Kocher in 1887. Later, in 1913, the technique of using silk was improved by W. Halsted.
In 1924 in Germany, Hermann and Hohl first obtained polyvinyl alcohol, which is considered the first synthetic suture material. In 1927, in America, Korotes repeated the discovery and called the resulting material nylon. In the 1930s, two more synthetic suture materials were created in Western laboratories: nylon (polyamide) and lavsan (polyester). Already in the late 30s and 40s, these materials began to be widely used in surgery [2].
In the XX century a detailed study of the properties of catgut and silk revealed a number of disadvantages of these materials: high reactogenicity, allergenic effect, difficult to predict timing of absorption. The need to replace catgut and silk with suture materials, devoid of these shortcomings, became obvious.
In the 40-60s of the XX century a large number of works appeared devoted to the problem of finding new suture materials. Many threads were proposed, among which there were many exotic ones: horsehair, tendon threads of rats, cats, reindeer, kangaroo, threads from the aorta and dura mater of cattle, from dog nerves, from the human umbilical cord. It was also used as a suture material and fishing line. However, the shortcomings of these materials (the difficulty of obtaining, the reaction of tissues, the possibility of infection of the thread, mechanical qualities) prevented their widespread introduction into surgical practice.
In 1956, a fundamentally new material appeared: polypropylene. In 1968, the first synthetic absorbable suture material, Dexon, appeared on the world market, created by Davis & Geck on the basis of polyglycolide, a polymer of glycolic acid [3]. Further research led to the creation by Ethicon in 1972 of a new suture material based on a copolymer of glycolic and lactic acids in a ratio of 9:1 (polyglactin-910). The new suture material was named vicryl. After some time, its qualities were significantly improved with the help of a special polymer coating, which facilitates the passage of the thread through the fabric.
In subsequent years, several more synthetic absorbable suture materials were developed, such as PDS and PDS 2, monocryl, polysorb, maxon. These materials have a number of advantages, which makes them widely used in surgery.
The search for new materials led to the creation of a number of promising areas, work on which continues to this day.

Modern surgical suture material
In modern surgery, more and more attention is paid to the search for the ideal suture material, to the necessary qualities of which the Russian scientist, the founder of military field surgery N.I. Pirogov, in the "Principles of Military Field Surgery" ranked the following:
a) suture material should cause minimal damage and inflammation in the tissues;
b) suture material should have a smooth, even surface;
c) suture material should not absorb the contents of the wound, swell, cause fermentation and become a source of infection;
d) the thread, with sufficient strength and elasticity, should not be bulky and stick to the surrounding tissues [2-3].
In 1965 A. Shchupinsky formulated the requirements for modern surgical suture material:
• Easy sterilization
• Inertia
• The strength of the thread should exceed the strength of the wound at all stages of its healing
• Reliability of the node
• Resistance to infection
• Absorbability
• Comfort in hand, softness, plasticity, good handling properties, lack of thread memory
• Applicability for any operation
• Lack of electronic activity
• Lack of allergenic properties
• The tensile strength in the knot is not lower than the strength of the thread itself
• Low cost [4].

Suture requirements
Biocompatibility
The concept of biocompatibility includes the absence of toxic, allergenic, teratogenic effects of the suture thread on the tissues of the body. Ideally, there should be no reaction to the suture material.
Biodegradation
This is the ability of a material to disintegrate and be excreted from the body. The suture material must hold the tissue until a scar is formed (the exception is the seam of the prosthesis, since a scar is never formed between the prosthesis and its own tissue). After that, it becomes unnecessary. The rate of biodegradation should not exceed the rate of scar formation.
Atraumatic suture material
- the surface properties of the thread.
All twisted and braided threads have an uneven, rough surface. When the thread passes through

the fabric, a "sawing effect" occurs, which leads to tissue injury. Only monofilaments are deprived of this property. Slip in the knot is also associated with the surface properties of the thread. Most modern threads are produced with a polymer coating, which reduces sawing effect, improves thread slip, however, these coatings, as a rule, reduce the reliability of the knot;
- method of connecting the thread with the needle. At present, atraumatic needles are considered the best, when the thread is soldered into the needle and is, as it were, its continuation. In microsurgery, where threads of especially small sizes are required, needles are sometimes made by spraying metal onto the thread;
- the manipulative properties of the thread, which include the elasticity and flexibility of the thread. Elasticity is one of the important properties of the suture material. It is more difficult for a surgeon to manipulate rigid threads [5]. This leads to more tissue damage. In addition, scar formation always goes through the stage of inflammation. At the same time, the volume of tissues connected by a thread increases. Inelastic thread in this case can lead to tissue eruption. Excessive elasticity of the thread is also undesirable, since the edges of the wound may diverge. The flexibility of the thread is mainly associated with manipulative convenience for the surgeon. It is believed that silk has the best manipulative properties (according to its manipulative properties, silk is called the "gold standard" in surgery). It should be noted that it is difficult to hold, stretch and tie small-diameter threads, this requires certain skills of the surgeon.

Thread strength and preservation until scar formation

The thinner the thread, the less by weight of the insulating suture material remains in the tissues. Studies have shown that the use of suture № 4/0 instead of suture № 2/0 decreases tissue reaction by 2-3 times, therefore, in many areas of surgery, it is preferable to use sutures of small diameters. The main obstacle in this case is a decrease in the strength of the thread, and not only and not so much the strength of the thread itself, but the strength of the thread in the knot should be taken into account, since for most threads the loss of strength in the knot is from 20 to 50% [5-6]. Absorbable sutures require that they retain sufficient strength before scarring. Scar formation occurs at different rates in different tissues. Sometimes up to 10-20 days after the operation, tissue matching is mainly carried out using the thread. If the thread quickly loses its strength, then it may break with a divergence of the edges of the wound. The decrease in thread strength should not outpace the process of strengthening the scar. According to V.V. Yurlov et al. the atraumatic properties of the suture are important, since by switching from a non-atraumatic needle and twisted nylon to atraumatic needles and monofilament suture material during the imposition of colonic anastomoses, they reduced the incidence of anastomoses failure from 16.6 to 1.1%, and lethality from 26 to 3% [6].

Suture classification

There are several signs by which suture materials are divided.

Historically and temporally: traditional and modern suture materials.

By material

A. Natural threads made from natural materials.

1. Organic. Made from animal fabrics.

Organic suture materials include:

• catgut obtained from the serous tissue of cattle; often causes inflammation;
• silk obtained from the cocoon of the silkworm; a high probability of inflammation, but less than in the case of catgut;
• horse hair;
• threads from fascia, tendons, arteries of animals;
• threads from the umbilical cord of a person;
• cellulose derivatives – rimin, katselon, occelon.

2. Inorganic. Made from inorganic natural materials. Inorganic suture materials include platinum, steel, nichrome wire [6-7].

B. Synthetic threads made from artificial materials obtained in production.

1. Derivatives of polydioxanone. Polydioxanone is devoid of antigenic or pyrogenic properties and, in the process of resorption, causes only a slight tissue reaction. These are the PDO threads. Polydioxanone thread retains its strength for a long time. By 6 weeks PDO retains up to 40-60% of its original strength. Full loss of strength occurs at 180-210 days.

2. Derivatives of polyglycolic acid. Strong absorbable suture for medium-term wound support with good knot holding. They are non-collagen, non-antigenic, non-allergic, and non-toxic [8].

3. Polyolefins: polypropylene, prolene, polyethylene, sirgipro and surgilene. Non-absorbable material that does not lose its properties even after many years in the body. Reliable, tear-resistant and elastic.

4. Polyesters: lavsan, mersilene, ethiflex, polyester, surgidac, dagrofil, ethibond, astralene,

ticron, dacron and terylene. Non-absorbable suture material. Flexible and durable, holds the knot well. Possesses high handling properties.
5. Polybutesters. Non-absorbable material with excellent knot strength, minimal trauma, fiber-resistant, non-inflammatory. It is used to make novafil threads.
6. Fluoropolymer materials: ftorest, fluoroline, fluorex, fluorlon and gore-tex. Non-absorbable suture material with high strength, biological inertness and good handling properties.
By thread structure
A. Monofilament (monofilament) in cross section represents a single structure with an absolutely smooth surface.
B. Polyline (multifilament) in cross-section consists of many threads:
1. A twisted yarn is made by twisting several filaments along an axis;
2. A braided thread is obtained by weaving many filaments like a rope;
3. A complex thread is a braided thread impregnated and (or) covered with polymeric materials. By the ability to resorb (biodegradation) in body tissues
A. Absorbable – threads capable of being completely absorbed in human tissues within a certain time.
1. Natural threads obtained from the serous tissue of cattle. These include catgut. The biological durability of an ordinary thread is 7-10 days, and of chrome-plated – 15-20 days The period of complete resorption of a regular thread is 50-70 days, and a chrome-plated one is 90-100 days. The rate of resorption of catgut depends on the health of the person, as well as on the health of the animal from which the thread was made. The splitting of this thread in the body occurs by cellular proteolytic enzymes.
2. Synthetic a thread of artificial origin from polylecaprone, polyglycolic acid and polydiaxonone.
2.1. Short absorption time. Polyglycolic acid derivatives. The biological strength is 7-10 days, and the period of complete resorption is 40-45 days. Well suited for all operations in which 7 days are enough for the formation of a scar, a good option, for example, for intradermal cosmetic sutures.
2.2. Medium resorption period. The biological strength of woven threads is 21-28 days, and the period of complete resorption is 60-90 days. In monofilaments, the biological strength is 18-21 days, and the period of complete resorption is 90-120 days. Surgical threads of average resorption are most often used in surgery [7-8].
2.3. Long-term absorption. Made from polyglyconate or polydioxanone. These are monofilament threads from the 1st fiber. The biological strength of woven threads is 40-50 days, and the period of complete resorption is 180-210 days. They are used for sewing tendons, cartilage and fascia. They are more often used in traumatology, maxillofacial surgery and thoracic surgery.
B. Conditionally absorbable
• Silk is a natural suture material with high strength, softness and plasticity. But due to its natural origin, it often leads to inflammatory reactions, suppuration and the formation of microbes in the wound. It is absorbed in the body from six months to a year.
• Nylon or polyamides – one of the first synthetic materials. It is not very suitable for surgical operations, as it causes sluggish inflammation all the time the thread is in the human body. Less reactions are caused by polyamide monofilaments, more braided and the highest reaction of the body occurs to twisted threads. They are more often used for suturing vessels, tendons, bronchi and organs of vision. They are absorbed in the body within 2-5 years.
• Polyurethanes are monofilaments with high handling properties – flexible, ductile and soft. Does not cause tissue inflammation. Does not cut the wound, is capable of stretching with edema and returning to its original state when edema subsides. It is used in plastic, vascular, general surgery, gynecology and traumatology. Absorbs in tissues after 5-8 years.
C. Non-absorbable – threads that do not absorb at all in the tissues of the body.
• Polypropylene – monofilament that does not cause a reaction of the body. They can be used in infected tissues, do not lead to the formation of a keloid scar and ligature fistulas. But they have poor handling properties and require a large number of nodes. They are used in almost all areas of surgery where a non-absorbable thread that does not cause inflammation is required [9].
• Polyester – braided threads that cause a weak reaction in the body. They have a very high strength. They are used only in cases where strength and good thread tension are needed for a long time after the operation. In other cases, polyester is inferior to polypropylene. Fluoropolymer materials - threads that have all the properties of polypropylene threads, only more flexible, softer and more plastic. Requires fewer nodes.

• Steel, titanium – metal threads. They can be either braided or monofilament. They are used in traumatology, orthopedics and general surgery.
By thickness
To indicate the size of the threads in surgery, the metric size for each thread diameter, increased 10 times, is used.
• 3-0 – for skin sutures, subcutaneous sutures.
• 5-0 – for stitches on the skin, fingers, as well as in pediatric surgery.
• 2-0 – for vascular ligatures.
• 0 to 2 – for muscle sutures.
• 1-3 – for fascial sutures.
• From 5-0 to 7-0 – for seams on vessels.
• From 8-0 to 10-0 – for stitches on nerve tissues [7].
Application of suture materials
The most common uses for suture material by medical field are:
1. Gastrointestinal tract. Preference should be given to absorbable materials such as Polysorb, Vicryl, Dexon, Maxon, PDS. The use of non-absorbable suture material (polypropylene, monofilament polyamide) is also possible. For operations on the colon and esophagus, it is better to use polysorb. Good results have been observed when using a staple suture.
2. Bile ducts. The best material is Polysorb, PDS. Polyolefins can be used from non-absorbable materials. All other materials (especially silk, nylon, etibond) can cause the formation of ligature stones.
3. Pancreas. The use of polyolefins is possible. All polyfilament materials give a pronounced reaction of the gland tissue.
4. Cardiovascular system. For seam and prosthetics - polyolefins, prolene, polypropylene, gortex.
5. Urinary system. It is better to use absorbable materials (on non-absorbable, the formation of urinary stones is possible), such as polysorb, PDS, vicryl, dexon, maxon.
6. Aponeurosis. When suturing a laparotomic wound, it is possible to use a continuous suture with a polysorb, PDS. Polypropylene, polyesters, polyamide are used more often. When suturing a hernial orifice, polypropylene is preferable.
7. Skin. The best results are observed when using a removable seam with polypropylene, possibly polyamide.
8. Nerve. It is also advisable to use absorbable materials [10-11].
So, the main suture materials and their areas of application are considered, which should help to understand the importance of choosing a good suture material in the course of any surgical intervention. The frequency of complications after surgery, and sometimes the life of the patient, depends on what material is used. The current trend is the use of synthetic absorbable and non-absorbable sutures that do not have the negative effects of natural and braided threads. In this case, the emphasis is on the use of monofilament yarns and multifilament filaments.
In the production of modern synthetic surgical suture material, only high quality raw materials should be used - that is, high-quality chemical fibers and needles from high-quality alloys and steels. All stages of the technological process must be implemented at a high level. A documentary display of this and a guarantee of safety and consistently high quality can be international quality certificates that confirm compliance with modern standards of raw materials (chemical composition and physical characteristics of threads, alloy composition and physical characteristics of needles), production conditions and technological process, quality standards for finished products specified in national and international regulations (European Directive 93/42/CEE).

CONCLUSION

Suture materials are mainly supplied to Kazakhstan through distributors such as Medilyux LLP, Format NS LLP from various countries such as Russia, the USA, Turkey, EU countries etc. At the moment, the domestic manufacturer is a joint venture (Kazakhstan, Uzbekistan and Russia) KAZ AMT LLP, founded in 2018. Located at the address Shymkent, 36/1 Karatyubinskoe highway. The total area of the production site is 400 sq.m. The company employs 11 people. The main activities are the production of medical devices. At the moment, the production of sterile suture surgical material of various modifications (with and without needles), ready for use, according to the standard of the European Pharmacopoeia 7.0, has been organized.
The main production cycles consist of:
1. Attaching the needle to the thread
2. Packing
3. Packaging
4. Sterilization.
In April 2019, the company received a state license. Also in that year, its own laboratory

was created and certified to determine the quality control of manufactured products. All production cycles are validated.

In 2020, the company received an international certificate in accordance with quality management ISO 13485-2016.

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Е.А. Алимбеков, Ф.Е. Каюпова,
Б.М. Муканов, Д. Бағдат
Фармацияның ұйымдастырылуы, басқарылуы және экономикасы және клиникалық фармация кафедрасы, С.Д. Асфендияров атындағы Қазақ ұлттық медицина университеты, Алматы қ., Қазақстан

ХИРУРГИЯЛЫҚ ТІГІС МАТЕРИАЛДАРҒА ШОЛУ

Түйін: Мақалада хирургиялық тігіс материалдарының тарихын, жіктелуін, қолданылуын зерттейтін негізгі жұмыстарға және олардың қазақстандық нарықтағы зерттеулеріне шолу жасалған.
Түйінді сөздер: медициналық бұйымдар, тігіс материалдары, хирургиялық, сіңірілетін тігістер.

Е.А. Алимбеков, Ф.Е. Каюпова,
Б.М. Муканов, Д. Багдат
Кафедра организации, управления и экономики фармации и клинической фармации, Казахский национальный медицинский университет имени С.Д.Асфендиярова, г. Алматы, Казахстан

ОБЗОР ХИРУРГИЧЕСКИХ ШОВНЫХ МАТЕРИАЛОВ

Резюме: В статье представлен обзор основных работ, в которых исследуются история, классификация, применение хирургических шовных материалов, и их исследование на рынке Казахстана.
Ключевые слова: медицинские изделия, шовные материалы, хирургические, рассасывающиеся нити.