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Materials used for knee ligament grafting

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Abstract

The authors have presented the review of scientific literature on producing grafts intended for surgical reconstruction of ligament ruptures. The treatment of ligament ruptures in reconstructive plastic surgery could be performed by using synthetic grafts, autologous and allogenic grafts from tissue donors. Advantages of synthetic grafts include the possibility of their regular manufacturing under sterile conditions, and providing mechanical properties, high biocompatibility. However, synthetic implants significantly increase the risk of synovitis and other complications, they can not be replaced by the native tissue, and have no ability to regeneration. Autologous grafts have ideal tissue compatibility and quick biointegration, could be harvested from different anatomical sites, but commonly the graft harvesting is followed by donor site morbidity and potential risk of injury nerves, elongates operation time, bad cosmetic results. The use of autografts may be also limited by

anatomical features of the patient. Allogenic ligament biomaterial could provide wide range of grafts, but in our days there is no standardized methods for ligament graft sterilization and long storage. Well-known sterilization methods, such as ionized radiation and chemical treatment, gave controversial results. One could conclude that estimation of ligament graft viability must include a complex study of biomechanical properties, cell and fibers integrity.

Keywords: synthetic implants, allograft, autologous grafts, ligament reconstruction

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ABC, Active Biosynthetic Composite

ACL, anterior cruciate ligament

BPTB, Bone – Patellar Tendon – Bone

QFM, quadriceps femoral muscle

SCF, supercritical fluid

Introduction

Physical activity plays an important role in the life of any person, regardless of the age and gender. As part of physical activity, extreme and contact sports are becoming increasingly popular, and are always associated with a high risk of injuries to the musculoskeletal system. Most ruptures of the anterior cruciate ligament (ACL) of the knee joint occur as a result of contact sports. The share of such injuries, according to different sources, makes from 7% to 62% of all injuries of the capsular ligamentous apparatus of the knee joint [1]. According to world literature, over the past 15 years, the number of operations for ligament ruptures in the working population has increased by 416% [2]. Meantime, the rate of such injuries in women recently exceeds similar parameter in men, which requires higher cosmetic results [3]. To date, the most effective way to treat ruptured ligaments and tendons is the surgical reconstruction using minimally invasive techniques that ensure a less traumatic intervention and an adequate restoration of damaged structures. The treatment of ligament rupture in reconstructive plastic surgery can be performed using autologous, allogeneic materials or synthetic implants with a high level of biocompatibility. Meanwhile, the problem of choosing the optimal graft for performing these operations is still relevant.

The purpose of this review was to analyze the homeland and foreign experience in the use of synthetic implants, autologous and allogeneic tendon grafts, as well as the methods of their modification and preservation.

To achieve this goal, we analyzed the results of Russian and foreign scientific studies on the manufacture, preservation, and sterilization of grafts for plastic surgery of the cruciate ligaments of the knee joint.

Literature search was performed in the electronic search systems Scopus, PubMed, eLibrary, CyberLeninka using the keywords: allogeneic cruciate ligament grafts, autologous cruciate ligament grafts, synthetic knee ligament implants, allogeneic graft sterilization, tendon cryopreservation. For the analysis, we selected scientific articles published in the period from 1980 to 2021. More than 50% of the reviewed studies are no older than 10 years.

Synthetic implants

The first experiments on replacing ligaments with artificial materials were conducted in the early twentieth century. At that time, silver and silk were used as plastic materials, and later on the polymer materials based on polyamides were used, but the clinical results were unsatisfactory [4]. The first successful plastic surgery of the ligamentous apparatus was performed in the late 50s-early 60s of the twentieth century, using teflon (polytetrafluoroethylene) and dacron (polyethylene terephthalate) [5]. In our country, dacron tape has been used in orthopedics to restore the ligamentous apparatus of the knee joint since 1961.

According to Z.S. Mironova et al., the proportion of good and satisfactory results of treatment using synthetic implants was 91%. However, later it was shown that the grafts based on simple polymer filaments have insufficient physical and mechanical characteristics, cause synovitis and secondary instability of the knee joint [6]. In this regard, new structures based on polyesters with increased mechanical strength, stability, and biocompatibility have been developed in Europe and the United States since the 1980s. Thus, once, the Active Biosynthetic Composite (ABC) (Surgicraft Ltd), being a combination of dacron and carbon filaments, became widely known [7]. The construction of this

material included a polyester base with a partial polyester braid. The ABC core fibers were arranged in a flat zigzag configuration, which formed a dynamic frame and protected the implant from plastic deformation. To facilitate fixation, the ABC ligament had a radial braid at both ends in the form of loops. The tensile strength was 3130 N, which was a high value. However, recently the ABC ligament has not practically been used due to a high incidence of graft failure and emerging complications [8, 9].

Also, there is known the artificial ligament of the frame type LARS (Ligament Augmentation and Reconstruction System) made of polyethylene terephthalate fibers, which was developed by J.P. Laboureau in 1992 [10]. Unlike earlier synthetic implants, LARS consists of 2 separate segments: intraosseous and intra-articular. The intraosseous segment is composed of longitudinal fibers bound together by a transverse knitted structure, and the intra-articular segment consists of multiple parallel longitudinal fibers twisted at 90° angles to each other. Cutting forces are reduced by orienting the free fibers of the intra-articular part of the graft clockwise or counterclockwise for use in the right and left knees, respectively. Additionally, the intra-articular segment of the graft acts as a scaffold, causing fibroblasts to in-grow between the ligament fibers due to the porosity of the material. The soft tissue that in-grows between the ligament fibers acts as a viscoelastic element that protects the ligament from friction in the bony tunnel, as well as between the artificial fibers themselves [11, 12]. The LARS ligament is available in various sizes: 60, 80, 100 and 120 fibers in diameter. The ultimate tensile strength of the ligament depends on its size, starting from 2500 N for 60 fibers and up to 3600, 4600 and 5600 N for 80, 100 and 120 fibers, respectively [12].

In the Russian Federation, the Don-M cruciate ligament endoprosthesis was developed (RF Patent for Invention No. 2289361)

[13], similar to LARS in all physical, mechanical, and biological parameters. Increased strength and wear resistance of the endoprosthesis is achieved due to its special design: the prosthesis is made in the form of a seamless tube of fibers intertwined in a staggered pattern, filled with longitudinal bundles of fibers from the same material. The ends of the tube are solidly cylindrically fused, at the distal end there is a thread for tension and fixation. This design provides good compressibility and low elasticity of the artificial ligament, and also has high mechanical strength [14].

Synthetic implants have the following advantages:

- injury rate is minimized (due to the absence of trauma to the donor area) and the time of performing the operation is reduced;
- significantly shortened recovery time for patients;
– in the vast majority of cases in the immediate postoperative period, the pain and swelling of the knee joint being quite moderate [15].

The disadvantages of synthetic implants include:

– high incidence of implant destruction in the long-term period;
– high incidence of synovitis and resorption of bone channels around the implant [15].

It should be recognized that all synthetic implants do not have the ability to self-repair and regeneration inherent in normal biological tissue, for example, autologous or allogeneic tendons. The reparative potential of tendons is ensured by the presence of viable cells, tendinocytes, which provide not only the synthesis of collagen and elastin fibers, but also the production of chemoattractants (attraction of progenitor cells to the tissues). In this regard, the use of grafts based on natural tendons is still relevant.

Autotransplants

Many autologous materials can be used for ligamentous repair. Initially, reconstruction of the ligamentous apparatus of the knee joint was performed using the broad fascia of the thigh. However, due to subsequent problems in the donor area and insufficiently good strength characteristics of the graft, this method has not been widely used for the treatment of adult patients [15]. For a long time, an autograft taken from the middle third of the patellar ligament with two bone blocks was considered the "gold standard" in the reconstruction of the anterior cruciate ligament (ACL). In the literature, the term "Bone–Patellar Tendon–Bone" (BPTB) is widely used to refer to autografts of this type. The tensile strength of this graft is 2300-2900 N, the shear strength is 620 N/mm, while the tensile strength of the native ACL is about 2100 N, and the shear strength is 240 N/mm, respectively [16]. When using this type of graft, many patients are concerned about prolonged pain in the donor site, patellar tendinitis, patellofemoral osteoarthritis, and arthrofibrosis [17]. Cases of calcification of the patellar ligament [18] and patellar fractures [19] have also been described.

An autograft made of the tendon of a semi–tendon muscle in combination with or without a tender muscle tendon has high biomechanical properties (tensile strength up to 4000 N, sheer strength 770-800 N/mm). In a number of studies, this type of autograft is considered optimal [20]. When using it, pain in the area of the donor site rarely develops, but the rate of tendon fusion with the walls of bone channels and the fixation strength are lower compared to BPTB autograft. The disadvantages of using this graft described in the literature are residual medial instability that develops in the postoperative period, impaired rotational movements, and a decrease in flexion strength in the knee joint [21].

The quadriceps femoral muscle (QFM) tendon is most often used in revision surgery and the need for plastic surgery of several ligaments. Modern medical technologies make it possible to perform explantation of the QFM tendon using minimally invasive techniques, but, nevertheless, the use of this graft is limited due to long-term rehabilitation after surgical treatment and problems with denervation.

It is also possible to use the tendon of the long fibula muscle for grafting the cruciate ligaments. Explantation of the graft in this case is simpler compared to other autoplasty options. The tendon of the long fibula muscle is long enough to make a graft of the desired size. The disadvantages include insufficient knowledge of this tendon explantation effect on the foot function.

In general, the clear advantages of autologous tendons include the lack of immunogenicity, as well as relatively fast integration, especially when using grafts with bone blocks. Disadvantages are primarily associated with injury to the donor area. In addition, when autologous tendons are explanted, there is a risk of damage to sensitive nerve branches, and the operation time increases. It is not always possible to obtain a graft of the required length [22]. A short graft severely restricts the choice of fixators, reserving possible to use hybrid methods and cortical fixation only. In some patients, explantation of autologous tissues may be very difficult or even impossible. In such cases, the use of allogeneic tendons is currently most justified.

Prospects for using allografts

Initially, allogeneic tendons were considered only as a reserve material intended for revision operations, and were considered unsuitable for transplantation in patients with high physical activity. Subsequently, it was shown that with proper screening and processing, tendon allografts

can provide an effect comparable to autografts [23]. This has been shown in both prospective and retrospective studies involving patients of different ages and activity levels [24]. The sources of allografts are the same anatomical areas as in the preparation of autografts, as well as the tendon of the anterior tibial muscle and the Achilles tendon [25].

When using allografts, there is no need to explant native tissues. This approach eliminates the problem of injury to the donor site, and also reduces the likelihood of postoperative pain. In addition, the use of allografts reduces the time of surgical intervention and reduces the length of the incision. The disadvantages of using allogeneic tendons include the higher cost of an allograft, a higher rate of graft ruptures in the postoperative period, and the risk of transmission of vector-borne diseases. If the first two causes are very controversial, then the possibility of infection transmission via the graft is certainly a serious problem. There is evidence that allogeneic grafts have a very low risk of infection if strict rules for graft preparation and patient care are followed. The paper by Greenberg et al. presents the results of treatment of 640 patients with allogeneic tendon transplantation made in tissue institutions certified by the special certificate of the American Association of Tissue Banks AATB-certi. Two hundred twenty one patients operated on using autologous tendons were selected as the comparison group. The results of treatment of patients in both groups were comparable, and the postoperative period was free of infectious complications.

In order to reduce the risk of infection, procedures for sterilizing tendon grafts, such as gamma radiation and chemical treatment methods, have been described [26]. However, many researchers note the damaging effect of these techniques on the final quality of the graft: it has been shown that after sterilization, the use of tendon grafts gives lower clinical results compared to the grafts without sterilization [27]. Using an

inefficient allograft sterilization technique can significantly reduce its structural integrity. On the other hand, with an adequate method of harvesting and storing allogeneic tendons, this problem can be avoided.

The objective disadvantages of the known allografts of tendons include significantly increased ligamentation time (the process of intra-articular transformation of the tendon, in which the graft acquires the properties and structure characteristic of native ACL) of the tendon after surgery. According to A.A. Akhpashev et al., when performing magnetic resonance imaging studies of the knee joint, an inhomogeneous diffuse increase in the MR signal from the tendon allograft and surrounding tissues can be observed for 2 years after surgery, which indicates the absence of complete acceptance during this period. The process of complete ligamentation after ACL repair takes about two years when using an allograft and about one year when using autografts [28]. In addition, the revision arthroscopy after a hamstring autograft repair showed a significantly better synovial coverage of soft tissues compared to allografts [29]. The intensity of ligamentation directly affects the long-term clinical outcome in ligamentous apparatus plastic surgery, so the issue of increasing the acceptance of allogeneic tendons is very relevant.

Methods of preservation and storage of tendon allografts

Tissue preservation is an important and necessary step in the production of tissue transplants, without which neither long-term nor short-term storage of these products is possible. Among the known methods of preserving tissue grafts, the lyophilization methods (a method of gentle drying of material) are the most common. Lyophilization is effective for storing grafts based on bone, dura mater, and collagen matrices, but all these grafts do not contain biologically complete cells, so lyophilization cannot disrupt their cellular component [30]. In case of

tendion lyophilization, a mass destruction of tendinocytes occurs. Moreover, it has been shown that after lyophilization there is a breakdown and fragmentation of collagen fibers in tendons, the initial topography of collagen is disrupted, collagen homogenization occurs in large areas of the graft and numerous areas of destroyed tissue are formed [31]. According to L.A. Bulgakova, lyophilized tendons lose about 40%-50% of their initial strength. In this case, the average diameter of the fibers changes by 3-4 times compared to the initial one. Lyophilization and rehydration cause both thinning of the fibers and their acute swelling. All this leads to a significant disruption of the original fiber architectonics and negatively affects the final clinical effect of allografts. There is evidence that in some cases lyophilized tendons retain biomechanical properties close to the initial ones, but this effect should still be considered an exception, since in all cases a uniform lyophilization technique was used. Apparently, drying is ineffective for long-term storage of tendon allograft. There are methods of preserving tendons in solutions with a low concentration of formalin and glutaraldehyde (S. I. Boltrukevich et al.), of glycerol, which, according to the authors, allow the preservation of the collagen native structure for several months. However, these factors are used in biology to fix tissues, i.e. to kill them while preserving their overall structure. These preservatives are highly toxic and have a high penetrating power, so their use for preserving cell viability is highly questionable [32]. Apparently, the preservation and storage of tendons require the use of cryobiology techniques. There is a technique for using fresh frozen tendons, thanks to which the native tendon is frozen in an antibiotic solution after quarantine at ultra-low temperatures. Meanwhile, the allogeneic tissue absorbs liquid during quarantine and damages the structure of the collagen fiber during defrosting. It has also been described that all viable cells die during

defrosting [33]. From our point of view, the most promising method for preserving the native structure of tendons is the preservation at ultra-low temperatures using cryoprotectants. Meantime, the tendon cryopreservation techniques have been described superficially lacking an evidence base, which requires a comprehensive, detailed study of the issue and revision of the available data from the current scientific literature.

Thus, the success of clinical use of allografts in ACL plastic surgery is largely predetermined by the choice of the tendon preservation method. Collagen has a high ability to self-organization, while at the same time, for long-term preservation of collagen fibers in tendons, a properly selected preservative is needed, which will allow one to keep all the structures of the tendon intact: fibers, cells, and the intercellular matrix. In this regard, the final stage of preparing tendon allografts for clinical use is a thorough study of their structural integrity, using modern methods of cell biology.

Ensuring the biological safety of tendon allografts

One of the most important aspects of preparing tendon allografts for clinical use is to ensure the infection safety. Common methods of the sterilization of medical devices, as a rule, irreversibly disrupt the ability of DNA to replicate and transcribe, and the sterilization target includes viruses and pathogenic flora. But one should take into account: the exposure to sterilizing factors equally affects the graft's native cells. Therefore, it is most important to maintain the viability of tendon cells during the sterilization process to ensure normal acceptance and functioning of the graft.

Currently, the sterilization with ionizing radiation at a dose of 25 kGy or higher is considered the "gold standard" for ensuring the biosafety

of tissue grafts. The American Association of Tissue Banks estimates that the risk of pathogen contamination of allografts during this treatment is only 1 in 450,000. In the course of irradiation, pathogens die both by the direct energy effect on DNA and by the effect of various molecular biological reactions (crosslinking, branching, chain breaking, nucleotide elimination, etc.) caused by free radicals formed during irradiation [34]. The effect of sterilization with ionizing radiation depends on many factors, such as the sensitivity of pathogens to direct radiation, the absorption capacity of the tissue, the total number of pathogens in the tissue, the irradiation temperature, the presence of oxygen in the medium, and the presence of natural radioprotectors. It is noteworthy that dimethyl sulfoxide used in cryobiology also has radioprotective properties that help preserve the overall structure of tendons during sterilization. It was established that for effective destruction of pathogens in tendons, the dose of gamma radiation should be at least 20-25 kGy. Meanwhile, the data on the structural safety of tendons are very contradictory. The main disadvantage of using gamma radiation is that tendon grafts are usually in a solution. Exposure to gamma rays causes ionization of the water, which creates additional gamma radiation. As a result, it is much more difficult to determine the working dose. Compared to gamma radiation, an electron beam sterilization can provide a more accurate range of radiation doses and significantly reduce the time of radiation treatment [35]. If gamma radiation takes several hours, the electron beam radiation lasts only a few seconds and potentially causes less damage to tissues. There have been only a few studies that confirm the effect of electron beam sterilization of tendons [36]. Using the example of goat ACL, the authors showed that a radiation dose of 15-25 kGy did not cause changes in the biomechanical properties of tendons, whereas higher doses (35 kGy) led to changes in their strength characteristics. Hoburg et al. suggest using the

electron beam sterilization method as the safest and most effective one that does not lead to serious biomechanical damage to the tendons [37]. At the same time, ionizing radiation somehow has a pathological effect on the cells in the tendons and causes a change in the structure of collagen fibers, the formation of interprotein crosslinking. All this may ultimately prove critical when the allografts sterilized with ionizing radiation are used in the clinic. Therefore, many authors suggest to abandon ionizing radiation when working with tendon allografts.

An alternative to ionizing radiation is chemical sterilization. Chemical sterilization can combine disinfecting and preserving effects. Solutions of antibiotics and antiseptics (furacilin, gentamicin, rifamycins, sodium bromide, ethanol, peracetic acid), various gases (ethylene, carbon dioxide) were used as disinfectants at different times. In this case, it is very difficult to ensure the permeability of the tendons to sterilizing agents. Passive soaking of tendons in alcohol solutions or antibiotics has been shown to allow only the surface layers of the graft to be sterilized. To intensify the process, the treatment with chemical agents is carried out under high pressure. In particular, an automated BioCleanse technology was developed (Regeneration Technologies, Alachua, Florida), where soft tissues were alternately treated in high and low pressure modes. Alternating vacuum and pressure cycles allow removing endogenous donor material (blood components, lipids) and perfusing the tissue with chemicals: antibiotics and antiseptics. When comparing the biomechanical parameters of tendons sterilized by the BioCleanse system and ionizing radiation, no significant differences were found. It is shown that with the BioCleanse technology, the tendons retain their native stiffness and flexibility, but the strength decreases noticeably, as with the action of ionizing radiation.

Supercritical carbon dioxide treatment is a promising method for allograft sterilization [38]. A supercritical fluid (SCF) is a special aggregate form of a substance that is achieved by the substance at a pressure and temperature above its critical point. SCL simultaneously exhibits the properties of a liquid and a gas, so in the SCL state, a substance is able to penetrate through solids like a gas, and dissolve materials like a liquid. SCC penetrates deeply into tissues and can be considered as organic solvents [39]. In recent years, there have been publications about the use of supercritical carbon dioxide for the sterilization of menisci and bone grafts [40]. Sterilization with supercritical carbon dioxide makes it possible to achieve the same effect of inactivation of viruses, bacteria, microscopic fungi, and spores as with ionizing radiation [41]. In this case, the packaged allografts are placed in a carbon dioxide chamber, where a pressure of 74 bar is created at a temperature of 31°C. However, as in the case of the BioCleanse system, there is still no accurate data on changes in the morphological structure and viability of tendon cells at different stages of processing. Of course, the decision related to the choice of sterilization method is an important task of tissue transplantation for the near future.

Conclusion

It so happened historically that allogeneic tendons have caused a lot of questions for both arthroscopic surgeons and patients during operations for ruptures of the anterior cruciate ligament. Objectively, lower rates of the ligamentation of allografts require a slower rehabilitation program and increase the requirements for patient self-organization. Of particular concern is the use of allografts in the treatment of patients in the younger age group. However, when working with allografts, the most fundamental limitation is not the individual

characteristics of the patient, but the adequacy of the selected methods for obtaining, storing, processing, and distributing human allograft tissue. A bio-safe allogeneic graft, which has structural and mechanical properties similar to an autologous one, will certainly be of high value for clinical practice. The ability to work with donor material significantly increases the variety of grafts, allows the development of effective methods for their storage and sterilization.

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