

HISTORICAL NOTE

Cardiovascular tissue transplant in Mexico. “The history to know and a story to tell”

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The history of transplantation of cardiovascular tissues began in the late 19th century. In the world, the first vascular homograft was implanted in humans in the 40's, and the first valvular homograft was performed in the 60's. In México, this story occurred in the beginning of the 21st century with 10 homografts in six patients in the General Hospital of Mexico. Since then, this experience has not been reproduced anymore. We discuss here the new horizons of a new type of homografts for the modern cardiovascular surgery.

Key words: History; cryopreserved allograft; valvular, vascular allograft.

La historia del trasplante de tejidos cardiovasculares comenzó a finales del siglo XIX. En el mundo, el primer homoinjerto vascular se implantó en humanos en los años 40's, y el primer homoinjerto valvular en los años 60's. En México, esto ocurrió al principio del siglo XXI, con 10 homoinjertos en 6 pacientes en el Hospital General de México, Desde entonces, esta experiencia ya no se ha vuelto a realizar. Discutimos aquí los nuevos horizontes de un nuevo tipo de homoinjertos en la cirugía cardiovascular moderna.

Palabras clave: Historia; Aloinjertos criopreservados; aloinjertos vasculares, valvulares.

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The history of cardiovascular tissue transplants in Mexico is anecdotal but deserves some comments. These tissues composed mainly of connective tissue, also called "cardiovascular tissues" are the aortic, pulmonary and mitral valves, as well as any useful segment of the arterial vascular conduits such as the ascending aorta, aortic arch, descending aorta, bifurcated aorta, iliofemoral arterial segments, venous segments such as saphenous vein and the pericardium. The tissues can be sterilized with antibiotics and preserved in refrigeration and cryopreserved in liquid nitrogen and / or decellularized. They have been called homografts for a long time, and recently they have called allografts.

In general the idea of transplant is not new, the first ideas about it were fantasies and mythological literary stories. The developmental concepts and history of tissue transplants were linked to the advances in skin grafting techniques of Gaspar Tagliacozzi in the 16th century and John Hunter in the 18th century who was the first physician to establish the term tra-

splant. By the 19th century, the skin transplants consisted of allografts, xenografts and isografts . Unfortunately many of these practices were not published [1].

THE HISTORY OF CARDIOVASCULAR TISSUES

a) Arterial allografts

In practice, the global context of transplantation of cardiovascular tissues was basically limited to the late 19th and 20th centuries. There were a few ideas and experiences and only a few surgeons dared to use these tissues . Sometimes the tissue were just extracted from the corpses without preserving them and in other cases they used with poorly preservation techniques. Facing a failure of complex operations some surgeons were forced to use these tissues as their last resort. Trial and error was the norm for many of the advances in cardiovascular surgery. The vascular lesions generated by trauma during wartime and the need to repair the arterial injuries, led some surgeons to look for an arterial substitute. In the beginning arterial ligation was the procedure of choice in order to prevent hemorrhage and death. Subsequently lateral repair of arterial injuries was adopted, and finally with the advent of the “end to end anastomosis technique” arterial

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injuries were repaired.

The first surgeons to published this technique and describe the arterial grafts were Mathieu Jabouley and Eugene Briau from France in 1896, describing the eversion technique of the edges and end to end anastomoses [2]. Later, Alexis Carrel perfected the technique of anastomosis with continuous suture, ushering a new paradigm in vascular, cardiac and trasplant operations. He was also a pioneer in the preservation of tissues and organs [3].

In the first haft of the 20th century these vascular techniques were mastered and during this time surgeons around the world raised the possibility of using human arteries, for the correction of traumatic injuries and aneurysms. There were advances in the preservation tissue process by cooling them with nutrient media, others procedures used rapid freezing in the storage of arteries and veins. Other surgeons such Robert Gross en 1949, used preservation with alcohol and carbon dioxide, he was the first to report the use of arterial allografts in human surgeries. He transplanted nine preserved arterial allografts to resolve congenital heart diseases such as aortic coarctations and the surgery of Blalock-Taussig shunts [4].

In the fifties, Michael De Bakey and Denton Cooley in the United States and Charles Dubost in France showed the treatment of thoracic and abdominal aneurysms with aortic allografts [5-7]. However, not all were successes, there were failures and deaths due to the ruptures of infrarenal allografts that were used [8].

The first "blood vessel bank" was promoted by the New York Times in 1950 as "an option to make possible the replacement of segments of diseased or abnormal arteries" [9]. During that time Arthur B Voorhees, in 1949, first described the experimental use of a synthetic woven material as a substitute for the abdominal aorta in dogs and thereafter began the search for the best material as a substitute for the arteries. Materials such as dacron and polytetrafluoroethylene have been developed since that time. Right now they are the most popular materials for arterial reconstruction [10].

In this international race, and according to Fernando Quijano Pittman, from Mexico, arteriorrhaphy was performed in 1911 in San Luis Potosí. In 1922 Jose Castro Villagran talked about the first arterial homografts in humans in Mexico. In 1950 and 1951 Raúl Baz, Topete and Larrañaga performed experimental work on aortic grafts and Patricio Benavides found a simple method of preserving arterial grafts with refrigeration and antibiotics [11-13].

It is noteworthy that the reports of vascular surgical practice in Mexico between 1955 and 1956, arterial allografts were already prepared and used as a possible solution for thoracic aortic aneurysms and in other arterial territories. A bank of arterial grafts was also established in the General Hospital of Mexico under the care of Dr. Manuel Castañeda Uribe in 1955, he treated some patients, with these homografts. In one case he described the repair of a femoral artery aneurysm with homograft. He did this only a few years after the establishment of the first blood vessel banks in the United States [14-15].

With the advent of new synthetic materials in arterial reconstructions in the seventies, eighties and nineties arte-

rial allografts were no longer used as much. However, they were used in complex scenarios of arterial reconstruction such as aortoesophageal, aortobronchial or aortoenteric fistulas. Some groups reported using homografts in arterial beds without infection, in replacement of large caliber arteries and in limb salvage. Another advantage of arterial allografts is that they can be tailored to any size using several allografts [16-19]. Actually, arterial allografts remain valid in their indications of complex reconstructions, in clean or infected territories in large and small-sized territories and now with the possibility of the use of grafts manufactured with tissue engineering

b) Valvular allografts

With the advent of extracorporeal circulation (John Gibbon 1953) and the possibility of repairing and replacing diseased heart valves, the search for the best valve substitute initiated. To this end, Conrad Lam in 1952 experimentally placed a dog aortic valve allograft in the descending aorta with adequate function. Gordon Murray in Toronto in 1956 placed fresh human aortic valves in the descending aorta. Carlos Duran and Alfred Gunning in Oxford in 1962 established the experimental possibility of using an aortic valve allograft in a subcoronary position to replace the aortic valve [20]. Sir Donald Ross, surgeon at Guy's Hospital London, described the implantation of an aortic valvular homograft in a subcoronary position in a 43-year-old man in that same year [21]. Years later, Ross would describe details of this procedure "in one of my aortic valve decalcification surgeries, the surgery became a disaster and the entire valve disappeared under the aspirator. We rush to reconstitute a frozen valve and place it with a single suture line. We took this aortic valvular homograft from a small bank of valves preserved with dry cold and ready for use and we placed it." ...it is important to emphasize that we had little confidence in the first homograft that we considered it a temporary resource until we could import a Starr valve and buy time," Ross said this in a note to the editor in 1991 [22-23].

In 1964 Sir Brain Gerard Barrat Boyes in Auckland New Zealand described a series of 44 patients where aortic homografts were used in a subcoronary position. This series was started simultaneously but independent of the publication by Donald Ross. Barrat-Boyes commented in this article that "the results suggest that the replacement of the aortic valve with a homograft is the method of choice for the treatment of aortic valve incompleteness and of most calcified aortic stenoses [24]. In 1966 a pulmonary atresia was corrected by Ross with an aortic homograft, in that same year Giancarlo Rastelli and Dwight C. McGoon corrected a truncus arteriosus using a homograft at the Mayo Clinic. In 1967, Donald Ross reported the use of a pulmonary autograft in the aortic or mitral valve position, procedure that now bears his name. This procedure tried to eliminate the structural failures and ruptures of the aortic homografts due to the different forms of preservation at that time. The Ross procedure offered a unique solution, an autologous valve in the aortic position, especially in children and young adults, and finally the reconstruction of the right ventricle outflow with a pulmonar allograft. [25].

From the beginning and progressively the cardiovascular tissues were first used in vascular surgery and later on in cardiac surgery. The vascular allografts were used in the replacement of the thoracic and abdominal aorta as well as in arterial substitutions in the extremities. The valvular allografts were

used in the replacements of the aortic valve or in the Ross procedure, and in the repair of congenital heart diseases . Initially they were used in any surgical field but later they have been used only in infected fields or complex surgical fields such as valvular endocarditis or in synthetic vascular graft infections.

c) *The preservation process*

The process of preservation of allografts has evolved; between 1960 and 1970 they were preserved in simple refrigeration at 4 degrees. Later preserved by irradiation, in formaldehyde, with chlorhexidine or beta propiolactone. Others used ethylene oxide or sterilization in low concentrations with antibiotics. Based on Angell 's studies in 1970 Mark O'Brain described the protocol of sterilization and cryopreservation of valvular and vascular allografts at The Prince Charles Hospital in Brisbane, Australia in 1974 [26]. This standardized procedure was the technique used for four decades worldwide for the preservation and sterilization of valvular and vascular homografts . Many tissue banks around the world adopted this technique, experiences have been reported of cardiovascular tissue banks in England, Belgium, Spain, Germany, United States, Brazil, Argentina, Uruguay, Slovakia, Poland, Australia, Italy, Singapore and Japan [27-34].

However, the immunological response of rejection with this type of preservation has been subject of multiple studies. The evidence has shown that this type of preservation favors long-term valve dysfunction, due to the presence of donor endothelial cells in the graft. This phenomenon occurs earlier in children and young people, requiring the use of immunomodulators. *Even so 30 to 40% of valvular allografts placed 20 years ago are still functioning.*

This has allowed the search for new forms of preservation of valvular or vascular allografts. The most important at this time is the de-cellularization without cryopreservation and

re-cellularization "in vivo" (post-implantation) or "in vitro". Thereby diminishing the immunological rejection reported by recent studies [35-37].

THE STORY TO TELL OF THE CARDIOVASCULAR TISSUE TRANSPLANTATION IN MEXICO

In Mexico, the experience in the use of cardiovascular allografts is scarce. The use of arterial allografts in femoral reconstructions took place in the fifties and the efforts of the Children's Hospital of Mexico in corrections of congenital heart disease with valvular allografts occurred in 2003 .

Our history started at the beginning of the 21st century in the General Hospital of Mexico " Dr. Eduardo Liceaga" from January 2000 to December 2002. We performed the transplant of 10 cryopreserved cardiovascular allografts from 9 donors and placed in 6 patients, four men and 2 women. The cryopreserved allografts were donated to the General Hospital of Mexico by two institutions: The Cardiovascular Tissue Bank of the Hospital Clinic Provincial of Barcelona Spain and the Homograft Bank of the Juan Garrahan Hospital of Buenos Aires Argentina. They were implanted as soon as they arrived to Mexico City . All the legal requirements from each country and the National Center of Transplants of Mexico for their import, transfer and implantation were cover .

Our first case was a woman 30 years old O+ with an aortic valve endocarditis and severe aortic insufficiency we made an aortic valve replacement with an O+ 20mm cryopreserved aortic valve allograft in subcoronary position with good follow up to 4 weeks (**Fig. 1**).

In the case of a woman 76-year-old, A +, with right hemicolectomy for colonic diverticulitis. After this first surgery ,she

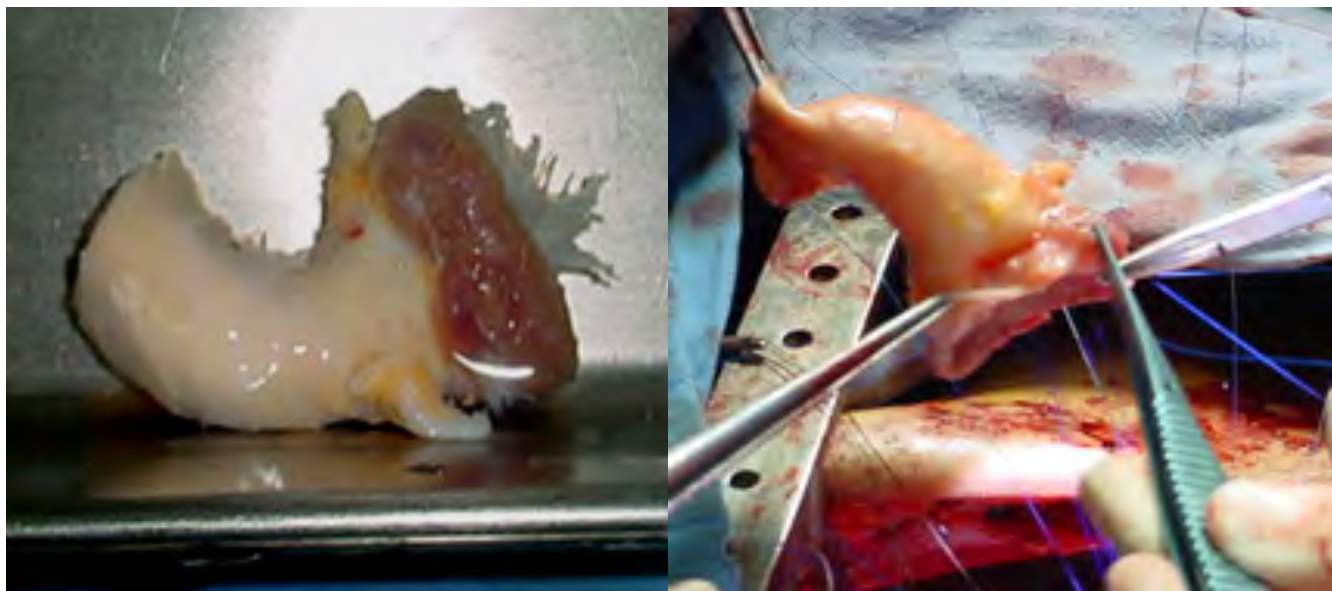


Figure 1. Cryopreserved aortic valvular allograft for subcoronary position in a patient with aortic valve endocarditis.



Figure 2. Cryopreserved aortobifurcated artery allograft used for aorto bifemoral reconstruction in occlusive aortoiliac disease

presented a contained rupture of an infrarenal aortic aneurysm that measured 10x9 cm with no involvement of the iliac arteries. She was taken to the operating room and a cryopreserved A + thoracic aortic allograft of 20mm proximal diameter (PD), 18mm of distal diameter (DD) and 100 mm of length (L) was placed in infrarenal position. His abdominal and vascular evolution was good with follow-up 4 weeks after discharge.

A third case was a 72 years old man A+, with left iliac occlusive disease treated 8 years earlier with a femoro-femoral bypass with 7mm dacron, with an abscess and exposure of the left sided anastomosis dacron graft. Surgery was performed to remove the prosthetic material and and reconstruction of the femoral-femoral bypass with a cryopreserved arterial femoral allograft, A +. The right femoral artery was also repaired with a patch of the same allograft and covered with sartorius muscle. The patient was discharged without complications two weeks later.

A fourth case was that of a 74 years old man O+ with aorto-occlusive atheromatous disease with collateral reconstruction at the femoral level. We decided to use as a first option a aorto bifurcated graft with two femoral cryopreserved arterial allografts of a different donor , achieving a length of 13mm x 5mm x 300mm (PDxDDxL), both of O + donors (Fig. 2). His evolution showed abdominal sepsis due to ischemic colitis of the sigmoid so it was necessary to perform left hemicolectomy and resection of the sigmoid segment with colostomy. The allograft remained permeable and in adequate conditions at three weeks.

Another case was a 57 year old man O+, previously operated for correction of an arteriovenous fistula in the left thigh two years before. He presented with an aneurysm of the left femoral artery that measured 17 x 10 cm. The resection was performed using an arterial allograft consisting of 11mmx-8mm x210mm (PDxDDxL) made of three cryopreserved arterial allografts of thoracic aortas from three pediatric donors that were type O + as the first reconstruction option (Fig. 3).

The patient did well and was discharged 4 weeks after the operation.

Finally, a 63 years old man O+, presented with an ischemic ulcer and pain of three weeks. Arteriography showed occlusion of 80% of the femoral artery at the level of the Hunter channel. An infragenicular femoropopliteal bypass was made with two ileofemoral allografts from the same donor O + to



Figure 3. Composed allograft with three different cryopreserved pediatric thoracic aortic allografts for femoro-femoral reconstruction in femoral aneurysm.



Figure 4. Cryopreserved ileofemoral allograft for infragenicular femoropopliteal bypass.

build a 6mm x 4mm x 350mm (PDxDDxL) graft (Fig 4). With adequate healing of the ulcer and good postoperative evolution after discharge.

FINAL COMMENT

The present work corresponds to the first group of patients treated in the field of cardiovascular surgery with cryopreserved cardiovascular tissue transplants in Mexico. Ten allografts in 6 patients, one aortic valve allograft and 9 vascular allografts were placed as the first option for surgical management in infected or clean cases, with adequate function once transplanted. The average age was 62 years, 4 men and two women, with group compatibility in both the donors and the recipients. The rest of the postoperative management was the routine for patients with this type of surgery.

This experience of the use of cardiovascular tissues in Mexico is unique, both in the cardiac and vascular territory and despite having happened a few years ago, it has not been possible to reproduce them until now. The need for alternative conduits other than synthetic materials is paramount in our country, the implementation of one or several tissue banks of cardiovascular conduits is important especially in the current era of novel tissue preservation techniques.

The use of aortic valve allografts has been limited considerably in one hand by the difficulties in obtaining them and by the other hand by the efficiency of biological valves or xenografts. Among the actual indications for allografts are the Ross procedure, women who want to get pregnant, patients with contraindications for anticoagulation, aortic, mitral or tricuspid valve endocarditis and in congenital heart diseases of right or left ventricular reconstruction. The use of vascular allografts on the other hand has remained until now even as a

first option for vascular reconstruction, for infected fields or infections of synthetic grafts previously placed in any arterial territory.

There are new and more frequent alternatives of tissue engineering that allow the construction of valves or vascular grafts from allografts, xenografts or from polymers manipulated "in vivo or" in vitro ". Reviews about the future of valve replacements in the heart show a different reality to what we know as daily practice in our environment. The replacement of heart valves in a conventional manner that has been carried out for decades has experienced a sharp in recent years. Valvular replacements with "non-regenerative" valves (mechanical valves, bioprostheses or polymer valves) will give way to valve replacements with "regenerative valves" that are allografts or decellularized xenografts or polymer valves that allow recellularization "in situ with autologous cells. All this with different implantation procedures every day less invasive (transcatheter implantation techniques or minimally invasive cardiac surgery).

This model has already been tested with clinical work by Francisco Da Costa and Igor Tudorache with allografts de-cellularized for aortic and pulmonary valve replacements with good results.

It is also important to control the processes of valve integration and regeneration by controlling the interface of implanted materials, platelet antiaggregation and complement modulation and coagulation system, as well as modulation of inflammatory processes and cell growth factors [38].

Seventy years after its first use in humans by Robert Gross in 1949, arterial vascular allografts still have an important role in the field of vascular surgery. The abdominal aorta can

be reconstructed "in situ" as a first option, in reoperations, in septic fields or with infected grafts. From the reports and anecdotes of the fifties to the current reports from all over the world, repairs with arterial allografts can be carried out in any arterial and even venous territory. In the entire extension of the aorta, in the limb salvage and for vascular accesses for hemodialysis. In the same way, tissue engineering has already been able to construct ducts from treated allografts or xenografts based on the human extracellular matrix and fibroblasts with good results [39-42].

"God knows that we have been waiting for an ideal valved conduit, that lasts forever and that any progress in that direction is welcome," Yves D'Udekem would say in 2016 in paper called "de-cellularized homografts: fashion or superior reality", "the saint valve grail" would say others in relation to the ideal valve. We would add the same words for arterial allografts.

It was believed that allografts had no immunogenicity and that tissue compatibility did not affect their longevity. Over the years it would be known that allografts even cryopreserved maintain their immunogenicity and that this fact is responsible for the degeneration of allografts. The de-cellularization of the allografts showed to clean its immunogenicity and many groups in the world began to test favorably this new form of preparation. It is still early to say that the ideal vascular or valve allograft was found but it is a breakthrough [43]. Companies in the United States (Cryolife), in Germany (Corlife) and in England (dCell) already have available aortic and pulmonary de-cellularized valvular allografts available with their technical differences in preservation but following the principle of decellularization. Now we can see recent results in Collaborative trial in Europe showing good results in pulmonar de-cellularized allografts in the ESPOIR trial and ESPOR Registry and ARISE EU Trial with Aortic Valve Replacement using Individualised Regenerative Allografts in 2019 [44-45].

In conclusion we could say that valvular and vascular allografts are a good option for the management of aortic endocarditis, and arterial reconstruction of the aortoiliac and femoropopliteal infected vascular beds. The segments of arterial allografts of the donor can be used in almost any site of the recipient, respecting the diameters and lengths necessary for its implantation.

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