

The Meiotic Spindle Transfer Technique from the Legal Perspective in the Republic Argentina

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Abstract

Spindle transfer makes it possible to avoid diseases of mitochondrial inheritance. The art. 57 of the Civil and Commercial Code, which uses a broad wording so as not to become obsolete, would point the prohibition to the manipulation of embryos in search of certain improvements, but not to those practices that have a therapeutic purpose. However, it is necessary to rethink the limits of the prohibition and the reasonableness of this treatment.

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Introduction

On September 23, 2021, a 31-year-old woman gave birth to the first living of Argentina- and South America- which was conceived through a fertility method that requires the genetic material of three people and is called transfer of meiotic spindle.

This birth was the product of an assisted human reproduction treatment carried out by a medical team of the Procrete Clinic, of the Autonomous City of Buenos Aires and occurred in the Otamendi Sanatorium.

This is the procedure of greater technical complexity that can be done in a fertility clinic and very few laboratories in the world have achieved it.

The transfer of spindle is to extract the meiotic spindle or core of the oocyte of a patient carrying mutations in the mitochondrial DNA and transfer it to the cytoplasm of a donated oocyte, previously enucleated, with healthy mitochondria. This reconstituted oocyte, when fertilized, produces pregnancy.

This allows to avoid mitochondrial inheritance diseases caused by alterations in the DNA located in the mitochondria. This DNA is transmitted only by maternal way, from mother to children.

According to scientific studies we are conditioned by the non-genetic composition derived from the cytoplasm of the ovule that produces us for what the individual born through this new technique will receive the influence of three people in their development as a human being.

Because this method consists of a manipulation of human cells, but not of embryos, it can be less problematic. But you also have to be cautious in case unforeseen consequences will appear since these

changes will be transmitted to future generations and the technique is very new.

Some voices against alarm arguing that a class of human beings would be discarded that would be born with a problem and the door would open to the production of a higher offspring.

This practice has been carried out for the first time in Mexico in 2017 by Dr. John Zhang and a team of American scientists. Since in the US it is not allowed to do it, the lack of regulation in Mexico about assisted reproduction techniques made birth possible. Instead, the United Kingdom pioneered to authorize it in its legislation.

While the transfer of meiotic spindle was developed to avoid mitochondrial disorder its indications have been extended to healthy patients but with repeated implementation failures offering, although not in all cases, an alternative to those patients who must resort to an oocyte bank, renouncing your genetic identity.

In the case of the first baby who was born in Greece from the application of the transfer technique of the spindle in 2019, through a procedure carried out by the Spanish Embryotools center and the Institute of Life of Athens, the mother presented a Low ovarian response.

Here the progress of this technique is evidenced since with the first baby in the world born in Mexico it was sought to avoid the transmission of mitochondrial diseases and not a solution to the infertility of women.

In the first part of this work, I will address the legal framework that governs in the Argentine Republic and then expand me about international legislation and the main problems presented by the regulation of these issues.



Genetic alterations on a germinal line - which are those that are transmitted to the descendants - are prohibited by art. 57 of the Civil and Commercial Code.

The medical procedure that was carried out in Argentina leads to rethinking the limits of this prohibition and the reasonableness of these treatments.

Interventions applied in in vitro embryos presuppose ethical and legal dilemmas in relation to human dignity and are of public interest, guidelines for taking responsible attitudes regarding their manipulation must be established.

National Legislation

The art. 57 of the Civil and Commercial Code uses a wide writing so as not to become obsolete. The basis of prohibition is the protection of the genetic pattern of humanity and the precautionary principle with respect to little safe technical interventions.

The doctrine also mentions that it seeks to protect the right of descendants to a non-manipulated genome and information about their genetic identity [2].

Therefore, being this new technique, the Civil and Commercial Code is silent about it. But, analyzing all the normative plexus it is possible to make certain deductions.

The tendency that prevails in the drafting of our code regarding reproductive rights seems to be individualistic. An important protection of the desire of the parents is observed, even, according to some authors [3], at the expense of the common good.

The art. 57 It is limited to prohibiting practices that modify the genetic constitution of offspring [4], and doctrine has interpreted that those techniques are exempted to prevent genetic diseases or the predisposition to them, provided that they do not cause alterations in said offspring [5].

Following this reasoning, the preimplantation diagnostic tests can be interpreted as possessors of a therapeutic purpose and the selection of embryos that leads to discarding those who have alterations before their implementation in the uterus could be allowed, selecting a healthy embryo.

From the same point of view, spindle transfer also has a therapeutic purpose and could be allowed since the prohibition of art. 57 would point to embryo manipulation practices in search of certain improvements, but not those that have a therapeutic purpose.

Although it can also be argued that this healthy child who gives birth to avoiding the transmission of a certain anomaly to future offspring could be seen as a healing baby of his descendants and feeling instrumentalized. Those who maintain these ideas remember the deontological position of Kant, who proclaims that people cannot be used as an instrument for the benefit of others.

Also, given the fact that when transmitted to the offspring, the genetic pattern of humanity is acting at the cellular level, which means doing it on the genetic pattern of humanity, the debate includes issues such as the integrity of the person and the identity of the identity of the Human race in general.

But when the parents decide on the realization of the treatment, the right to decide from the newborn is hindered as some authors maintain? Is someone likely to be born with a serious hereditary disease?

Would the transfer of meiotic spindle really negative for humanity at a relevant level? Or would it be a positive practice because it avoids the transmission of a serious illness?

Our norm is confusing and does not allow a unified criterion to be set.

International regulations - which under the National Constitution integrate our positive law - relative to human rights was interpreted by the Inter-American Court of Human Rights in the ruling "Murillo Artavia and others C/ Costa Rica", in the sense that the Existence of the human person begins with the implementation of the embryo, therefore, the undefeated embryo is not a person.

Following this criterion, the norm does not prohibit the selection of sex of the embryos for implementing in an assisted reproduction treatment.

Since the mitochondrial DNA is inherited by maternal way of the mitochondria present the ovule, the girls born by means of a transfer of spindle would pass the mitochondria donated to their own children, which would make the genetic change be hereditary. However, men would not.

Therefore, if only male embryos were used in mitochondrial donation, changes in the human germinal line would be transmitted to future generations. It is a delicate issue from the ethical point of view that the countries that have discussed the use of this technique in their laws failed to resolve.

Our legislation (6), so far, does not explicitly say that the embryo is not a person, however, it is what supports an important part of the doctrine and is overturned in the interpretation of assisted human fertility legislation and voluntary interruption of pregnancy.

For our part, we maintain that the Argentine Republic needs a modification in the assisted fertilization law to regulate on the transfer of meiotic spindle. It would be beneficial, for example, to submit to an ethics committee each particular case where this technique is needed and, in turn, that an approval of the medical institutes enabled to carry it to an authority of an authority of an authority of app.

These are substantive issues that cannot be released to the procedural or the decision of a judge in each specific case. Human rights are compromised, such as those linked to reproductive genetics and assisted reproduction and a regulation is needed to save interpretive lagoons.

Critics warn that the scientific evidence available to support this procedure is limited. In the midst of these legislative gaps and the legal confrontation of norms, the aforementioned fertility clinic carried out the procedure and this can be repeated and even replicated in other laboratories, in the same way that the assisted reproduction centers carry out the adoption of embryos, even if legislated and replacement gestation. In Argentina, the discussion about the right to life and fertilized embryo is not resolved, but nevertheless the decision is at the discretion of each medical center. These insufficiencies lead to each issue should be prosecuted for interpretive resolutions and in turn launch the problem to judges without solving the matter of the whole.

There are still lagoons even with respect to the right to identity of children born by gametes. The closing principle embodied in art. 19 of the National Constitution, which expresses that everything that is not prohibited is allowed, fails to save them and most issues must be resolved through a resource for health protection.



The panorama continues to be complex, it is undeniable that at the present time individual rights have acquired utmost importance and we must decide, while we build our society, what place we give to the desire for procreation.

International Legislation

Recommendation 934/82 of the Council of Europe of January 26, 1982 was already talking about the intangibility of humanity's genetic inheritance and requested to include it in the list of human rights to protect it from any artificial intervention from science or technique.

The resolution on the ethical and legal problems of the genetic manipulation of the European Parliament also referred to this issue. In his arts, 27 and 28 asks to prohibit attempts to reprogram genetically to humans and the penalty of any transfer of genes to human germ cells.

The Human Rights and Biomedicine Agreement, in its art. 13, prohibits "any genetic intervention that is not preventive, diagnostic or therapeutic on condition that it is not intended to modify the genome of the offspring" and the UNESCO declaration on the responsibilities of current generations for the future generations of the year 1997, in its arts. 7 and 8 expresses the need to protect human genome by virtue of human dignity, human rights and the need to preserve biological diversity.

In Australia, there is currently an intense debate about the approval of a bill that would allow mitochondrial donation [7].

Citing ethical and religious issues and questioning the effectiveness of the technique, one of the proposals against its approval has been based on the fact that there are already safer ways to prevent the transfer of this mother's disease to children through ovidonation. This solution, however, implies for the mother to resign to not be able to transfer her genes.

The Australian bill was submitted to a series of public consultations and the vote of conscience in Parliament, resulting in this attempt to modify the law in a long debate of several years.

The Australian model resembles the United Kingdom double license system, the first country that legalized the mitochondrial donation [8].

In Australia, only one clinic would have the license to offer the donation of mitochondria during the first phase of the model, which is expected to last 10 to 12 years. Each patient who wishes to use the procedure will also need a separate approval, with similar eligibility requirements, although not in everything, to those of the United Kingdom.

One of the differences between the two texts is given in terms of the right to information on the identifying data of donors, where in the Australian model this right would be expanded to children born by mitochondrial donation, being that in the United Kingdom donors Mitochondria can remain anonymous.

The United Kingdom allowed its anonymity since it was considered to contribute only a small genetic contribution to the resulting child, so the identity of mitochondria donors should import children less than the identity of standard ovules donors.

Recall that, unlike Argentina, both in Australia and in the United Kingdom, children born after an *in vitro* fertilization with gamete donation have the legal right to obtain identifier information from their donors when reaching the age of majority.

Some of the problems that arise

Although the presence of DNA of third parties in heterologous assisted fertility is already common where the donation of male, female or both gametes is used, the worrying thing in the transfer of meiotic spindle is that it is a modification of the germinal line In humans, and the ghost that is about that, in some way, human evolution is changed.

What consequences can be derived from legislating prioritizing the procreational will of those who want to generate healthy children?

For some scientists, the enormous advance of the last years of genetics and biotechnology presumes that the genetic modification of the germ line is inevitable. If the benefits exceed risks, medicine and patients will want to use it.

In Australia they argued that the bill would open the door to ethically debatable practices. In principle, it would be the first law to allow researchers to change the human genome, causing this change to be inherited throughout generations. It would also allow to produce and destroy embryos until a viable one is for the implementation in the woman's uterus with the mitochondrial ailment, which by law is prohibited in that country.

Questions arise around equality and how the state must distribute the money from the health budget and perhaps we have to weigh, following the style of John Rawls [9], the bioethical principles at stake to generate equal opportunities from of a substantive equality to access to them.

If they only had access to this new technique who have a social work or a prepaid medicine coverage, the principle of equality would be broken causing even more inequality by guaranteeing access to genomic techniques to individuals of medium or high purchasing power that have had opportunities educational and labor.

On the other hand, if we require from the State the use of mitochondrial replace strong social injustice.

Although prepaid medicine and social works companies can also argue an unplanned budget imbalance. It is important to determine whether the cost of implementing this technique is equal, greater or lesser to the option of resorting to the donation of gametes and the number of patients who would effectively resort to the transfer of meiotic spindle according to statistics that determine the number of people Affected with this disease.

Individual freedom being a central value of constitutional democracy, the state obligation to establish limits to its exercise must be analyzed with respect to the enjoyment of new rights and its reasonable regulation.

A great question is if the selection of the sex of the embryo intervened should be allowed so that, if male, it does not transmit the mitochondria donated to their own children preventing genetic change from transmitting to future generations.

In contrast to the rejection of this option by the United Kingdom in Australia, a third alternative has been proposed: letting parents decide whether to transfer a male embryo or proceed without sex selection.

This intermediate proposal does not resolve ethical issues on sex selection or hereditary changes in the germ line if daughters are born women. In addition, although parents receive advice prior to treatment, they may not be well positioned to elucidate between the scientific and ethical complexities of this decision.



Another issue is how donor's ovids should be obtained. They could be extracted from the existing reserve of donated ovids for assisted fertility. However, the ethical difficulty that is presented is that current ovids donors would not have anticipated that their ovids would be used for mitochondrial donation. They have not given their consent specifically for that use. If the ovids were obtained from donors who have given their consent specifically, perhaps this could limit the availability of ovids for mitochondrial donation, but would ensure that the ovids are not used without a consent informed so that an ethical donation system should be established Mitochondrial in a law.

The modification of the assisted fertilization law to allow mitochondrial donation in the United Kingdom generated important criticisms of both the Catholic Church and the Protestant who argued that this technique is not yet safe, taking into account the principle of prevention that is applied in potential risk situations.

If our art. 57 of the Civil and Commercial Code prohibits producing a genetic alteration but not selecting embryos for therapeutic purposes or avoiding diseases, then the transfer of meiotic spindle would not be prohibited. The key would be to ask about the convenience of a prohibition to intervene in the genome online germinal when the only objective is to avoid the transmission of a genetic disease to the offspring and to what extent this can be considered promoter of the development of social eugenics. The dilemma then moves from the individual sphere to the World Cup. To modify an entire offspring forever, which country can be enabled?

Conclusion

From the panorama of the current international regulation regarding the transfer of meiotic spindle it is inferred that it is not totally prohibited, since there are spaces for the realization of the practice in the countries cataloged as ambiguous in its regulation and even some have allowed it.

The Argentine Assisted Fertilization Law does not specify anything about this technique, which is very novel, although it does refer to the fact that new procedures could be included provided that they are approved by the application authority that is the Ministry of Health of the Nation.

The biologists, doctors and laboratories of our country are trained to carry it out, but we estimate that a specific regulation would be necessary and, if society and Congress approve it, a code of ethics and an application entity.

Just as the current regulation is raised, a judge has authority alone to resolve this issue by not being expressly legislated, but it is not

what corresponds since, as with subrogated pregnancy, beyond the ethical approach and of Not knowing exactly how the technique will influence the created individual, it would be in the hands of the judges to elucidate any situation that arises. The path of judicialization is not adequate. The Argentine Judiciary must focus on other issues since the analysis of social problems and the dictation of legislation corresponds to the legislative power. It is not correct what has been happening in matters of assisted reproduction such as the status of the undefeated embryo that, when a law is not discussed and sanctioned, the judiciary has to solve the problem.

Argentina must resolve if it opts clinically the mitochondrial donation and, if so, elucidate its edges such as the anonymity of donors, the granting of licenses to the clinics to carry out the procedure and the prior authorization before Each treatment emanated by an application authority, among others.

Declarations

The authors declare that they have no conflicts of interest, that the work has been approved by the ethics committee responsible in the workplace, and do not declare means of financing of the work carried out.

References

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2. Declaration on Law No. 26,862 of medically assisted reproduction of the National Academy of Moral and Political Sciences on the reform of civil and commercial codes.
3. Unlike modifications in somatic cells, that is, body tissues or non -reproductive organs, which produce genetic alterations and whose effects are limited to the recipient human person, germ, bone modifications, in reproductive cells -óvulos or sperm - or embryos modify the genome of these cells, either enhancing, silencing or decreasing the defective genes, so they will have consequences and impact on both the individual and their offspring.
4. University of Buenos Aires (2019) Genetic manipulation. Argentina.
5. Recall that in transitory provisions art. 9, establishes: "Dispose as transitory norms for the application of the Civil and Commercial Code of the Nation, the following: (...) Second." The protection of the undefeated embryo will be subject to a special law. " In turn, article 19 of the CCIVCOM does not grant legal status to the embryo or regulates on the matter.
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