Review Article

Brief Report: Mitochondrial Donation in a Reproductive Care Pathway for mt DNA Disease

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Abstract: Mitochondrial DNA (mt DNA) diseases are a group of severe maternally inherited disorders characterized by debilitating and unpredictable clinical manifestations. Conventional reproductive approaches, including preimplantation genetic testing, are often limited in efficacy due to the stochastic nature of mt DNA transmission driven by the mitochondrial bottleneck effect. Mitochondrial donation (MD), an advanced in vitro fertilization technique, has emerged as a promising strategy to reduce the risk of disease transmission. This review synthesizes current clinical outcomes, scientific debates, and the ethical and legal challenges surrounding MD. Data from a landmark United Kingdom trial demonstrate short-term success, with eight healthy infants born carrying significantly reduced pathogenic mt DNA loads. Nonetheless, unresolved concerns—including the potential for mt DNA "reversal" and the theoretical risk of Mito nuclear incompatibility—highlight important safety considerations. While MD represents a transformative reproductive option that can substantially lower transmission risk, it is not curative, and its long-term safety profile remains uncertain. Ongoing scientific investigation, coupled with robust regulatory frameworks in countries such as the UK and Australia, will be essential to guide its responsible implementation.

Keywords: mitochondrial, donation, reproductive, care pathway, mt DNA disease

1. INTRODUCTION

Mitochondrial diseases represent a class of severe and often fatal genetic disorders that arise from dysfunctional mitochondria, the cellular organelles responsible for generating energy [1]. These conditions are characterized by a wide spectrum of debilitating symptoms, frequently affecting organs and tissues with high energy demands, such as the brain, heart, and muscles. Clinical phenotypes can include chronic fatigue, muscle weakness, seizures, metabolic strokes, cardiomyopathy, and developmental disabilities [2]. In many cases, these disorders lead to premature death in infancy or childhood [6]. The prevalence of mitochondrial diseases is estimated to be approximately one in 4,300 individuals in the United States, with severe forms affecting roughly one in 5,000 babies, or more than one per week in a country like Australia. Given the varied and complex potential presentations, these diseases can be difficult to diagnose and are often misdiagnosed [2]. The lack of a cure means that current treatments are limited to managing symptoms and do not alter the disease course [10]. A distinctive feature of mitochondrial diseases is their non-Mendelian inheritance pattern. Unlike nuclear DNA (n DNA) which is inherited from both parents, mitochondrial DNA is passed down almost exclusively from the mother to her children [12]. This maternal-only inheritance pattern is a key factor in the transmission of these diseases. The complexity is further compounded by a phenomenon known as heteroplasmy, which is the presence of a mixture of both normal and mutated mitochondrial DNA within a single cell or individual. The severity of the disease is directly correlated with the proportion of mutated mt DNA; symptoms typically manifest when the mutant load exceeds a certain threshold, often

cited as being between 60% and 80% [5]. The transmission of heteroplasmy is governed by a process known as the mitochondrial bottleneck effect [14]. During the development of a female embryo, the precursor cells of oocytes experience a reduction in their mt DNA copy number. This small pool of mt DNA is then randomly amplified in mature oocytes. As a result, oocytes from the same woman can have widely varying levels of pathogenic mt DNA, making the risk of disease transmission and the severity of the clinical phenotype highly unpredictable even among siblings.14 This biological unpredictability poses a significant challenge for traditional reproductive options. For example, preimplantation genetic testing (PGT), which screens embryos for genetic abnormalities, is often an unsuitable method for mt DNA diseases because a single biopsy of an embryo cannot reliably predict the pathogenic heteroplasmy level in all the future tissues of the child [4].The inherent randomness of mt DNA segregation means that an embryo with a low mutation percentage at the time of biopsy could still give rise to a child with a high-level, disease-causing mutation later in development, a risk that conventional PGT cannot mitigate.5 This fundamental biological challenge of random segregation is the core problem that mitochondrial donation aims to address. Given the limitations of existing reproductive strategies, mitochondrial donation (MD) has emerged as a groundbreaking and highly innovative in vitro fertilization (IVF) technique. MD offers a potential solution for women who carry pathogenic mt DNA mutations and wish to have healthy, genetically related children without transmitting the disease [10]. This report aims to provide a comprehensive and critical review of MD, exploring its underlying scientific mechanisms, the clinical outcomes from recent trials, the unresolved long-term safety questions, and the complex ethical, social, and legal debates that surround this nascent technology. The goal is to synthesize the current state of knowledge for a specialized audience, providing a nuanced perspective on MD's potential and its remaining challenges.

2. MECHANISMS AND TECHNIQUES OF MITOCHONDRIAL DONATION

Mitochondrial donation is an umbrella term for a group of IVF-based techniques designed to prevent the maternal transmission of mt DNA diseases by replacing the mother's faulty mitochondria with healthy ones from a donor egg [7]. The foundational principle is nuclear transfer, a process that combines the nuclear DNA (n DNA) from the intended parents with the healthy mitochondrial DNA (mt DNA) from a donated egg. The resulting embryo contains the full genetic blueprint from the mother and father, while the mitochondria, which constitute approximately 0.1% of a cell’s genome, are provided by the donor [10]. This novel genetic combination allows the intended parents to have a biological child who is free from the risk of inheriting the mother's pathogenic mt DNA mutations. The two primary techniques that have been developed and approved for clinical use are Maternal Spindle Transfer (MST) and Pronuclear Transfer (PNT) [26]. Maternal Spindle Transfer (MST) is a technique performed before fertilization [28]. The procedure begins with two unfertilized eggs: one from the intended mother, which contains the mutated mitochondria, and one from a healthy donor with healthy mitochondria.5 The nuclear spindle, which contains the mother's chromosomes and her unique nuclear genetic material, is carefully removed from her egg [5].The mother's egg is then discarded, while the spindle is inserted into the donor egg, which has had its own nuclear material removed. This reconstructed egg, now containing the mother's n DNA and the donor's healthy cytoplasm and mt DNA, is then fertilized in vitro with the father’s sperm [22]. The resulting embryo is then cultured and tested before being transferred to the uterus. Pronuclear Transfer (PNT) is performed after fertilization has occurred [22]. In this process, both the mother's egg and the donor's egg are fertilized simultaneously with the father's sperm, creating two zygotes [26]. At this early stage of development, the genetic material from the parents exists in two distinct structures called pronuclei [30]. The pronuclei are carefully removed from the mother's zygote and transferred into the enucleated donor zygote [26]. The donor's pronuclei are discarded, leaving a reconstructed zygote with the intended parents' nuclear DNA and the donor's healthy mitochondria [29]. This embryo is then cultured and can be transferred

to the uterus. A third, less-developed technique is Polar Body Transfer (PBT) [27]. This method utilizes a polar body—a small cell with very little cytoplasm and few mitochondria that is a byproduct of oocyte formation. PBT is considered promising because the transfer of the polar body, which contains the mother's n DNA, would carry a greatly reduced risk of transferring any mutated mitochondria, thereby minimizing the issue of carry-over [27]. However, this technique has not yet resulted in any recorded live births and is not as extensively studied as MST and PNT [5]. The choice between these techniques has profound ethical and social implications. PNT involves the creation and subsequent destruction of a fertilized embryo, which is a significant ethical obstacle for many individuals and religious groups who believe that life begins at conception [30]. In contrast, MST is performed on an unfertilized egg, which some consider to be more ethically acceptable [32]. This distinction is not merely theoretical; the first reported live birth using MST in Mexico was performed for a family who chose this method for religious reasons, demonstrating the direct clinical relevance of these ethical considerations [28].

Table 01: The key distinctions between the primary mitochondrial donation techniques.

Technique	Stage of Transfer	Key Procedural Steps	Ethical Issues
Maternal Spindle Transfer (MST)	Pre-fertilization (unfertilized oocyte)	The mother's nuclear spindle is removed and placed into an enucleated donor egg. The reconstructed egg is then fertilized with the father's sperm.	Avoids embryo destruction, which is more ethically acceptable to some groups.
Pronuclear Transfer (PNT)	Post-fertilization (zygote)	The mother's and donor's eggs are fertilized. The pronuclei from the mother's zygote are transferred into the enucleated donor zygote. The donor zygote is destroyed.	Involves the destruction of a fertilized embryo, which is a major ethical concern for many religious and philosophical perspectives.
Polar Body Transfer (PBT)	Pre- or post-fertilization (polar body)	The polar body from the mother, which contains her nuclear DNA but very few mitochondria, is transferred into an enucleated donor oocyte or zygote.	Theoretically minimizes mt DNA carry-over but is less studied and has not yet resulted in live births.

3. CLINICAL OUTCOMES AND SHORT-TERM EFFICACY

The clinical viability of mitochondrial donation has been a subject of intense research and debate for years. The first robust, peer-reviewed clinical data on the procedure emerged from a landmark trial conducted in the United Kingdom, with results published in the New England Journal of Medicine in 2025 [15]. The trial was a crucial step in moving the technology from a theoretical possibility to a practical medical option under strict regulatory oversight. The study involved a cohort of 22 women who carried pathogenic mt DNA mutations, putting them at a high risk of transmitting severe, incurable diseases to their offspring [25]. The results from the UK trial were highly encouraging, demonstrating

the procedure's efficacy and viability. Out of the 22 women who underwent pronuclear transfer (PNT), eight gave birth, with one additional pregnancy still ongoing at the time of publication, representing a clinical pregnancy rate of 36% [18]. This result was contextualized by a comparison with a parallel preimplantation genetic testing (PGT) arm of the study, which involved 39 women and resulted in 16 pregnancies, leading to 18 babies, for a clinical pregnancy rate of 41%.36 The fact that roughly three-quarters of the couples in the PNT arm were able to generate at least one suitable embryo further highlights the clinical feasibility of the method [36]. The most significant finding of the trial was the health status of the children. All eight babies born—four girls and four boys, including one set of identical twins—were reported to be healthy at birth and developing normally [11]. The study's primary objective was to reduce the transmission of the mother's pathogenic mt DNA, and the results showed remarkable success. Pathogenic mt DNA levels were either undetectable or well below the disease-causing threshold in all children [15]. For six of the babies, the amount of mutated mt DNA was reduced by 95% to 100%, and for the other two, the reduction was 77% to 88%, with all levels falling significantly below the approximately 80% threshold needed for clinical disease [12].While a couple of the children developed minor clinical issues, these were deemed unrelated to the procedure and resolved either with treatment or spontaneously, with one child having a successfully treated abnormal heart rhythm [15].

Table 02: The key outcomes reported in the UK trial.

Outcome	Result
Total Women Treated with PNT	22
Clinical Pregnancies Confirmed	8 (36% of patients)
Live Births	8 (4 boys, 4 girls, including a set of twins)
Pathogenic mt DNA Reduction	95-100% in 6 babies; 77-88% in 2 babies
Health Status of Offspring	All healthy at birth and developing normally
Reported Early Health Issues	Minor, seemingly unrelated issues in a few babies, including one case of cardiac arrhythmia 15

It is important to acknowledge that the UK trial was not the first time a baby was born using mitochondrial donation. The first live birth from an MST procedure was reported in 2016 from a US team working in Mexico, where there are no specific regulations on the practice. Since then, births have also been reported in clinics in Greece and Ukraine, often performed for infertility rather than for mitochondrial disease [5]. These cases, however, lack the rigorous, transparent, and long-term follow-up that is mandated by the UK's regulated framework, making their scientific value and safety assessments difficult to validate [5]. The transparent and publicly reported results from the UK trial are therefore of paramount importance, providing the first reliable dataset for the international scientific community. The success of the UK trial provides a strong signal of MD's potential. However, the data represents a small cohort with a short follow-up period of only a few years [8]. The reported health issues in a few children, even if deemed unrelated, underscore the need for cautious interpretation and highlight the inherent tension between the promise of a new technology and the unknown long-term risks. This is a critical point that must be thoroughly explored to provide a comprehensive analysis of the subject.

4. LONG-TERM SAFETY AND RESEARCH IMPERATIVES

Despite the encouraging initial clinical outcomes, significant questions remain regarding the long-term safety and efficacy of mitochondrial donation. A primary concern is the phenomenon of mt DNA

"reversal," which is a sudden and significant increase in the proportion of pathogenic maternal mt DNA that was initially present at very low levels in the embryo [35]. This reversal phenomenon challenges the assumption that MD can permanently eliminate the risk of disease. Evidence of reversal has been observed in some of the babies from the UK trial 35 and in a separate study on meiotic spindle transfer (MST), where the proportion of maternal mt DNA increased dramatically in samples taken after the blastocyst stage [42]. In the latter study, the proportion of maternal mt DNA averaged 44.4% in one child and 30.0% in another, suggesting that the initial efficacy of the procedure could be compromised [42]. This phenomenon is attributed to the inevitable mt DNA carry-over that occurs during the nuclear transfer process, where a small amount of the mother's cytoplasm—and thus her mutated mitochondria—is transferred along with the nuclear DNA [5]. The reversal is thought to be caused by the selective amplification of these carried-over maternal mt DNA variants, possibly due to a competitive advantage they hold over the donor mt DNA, a mechanism that is still not fully understood [35]. This evidence demonstrates that MD should be regarded as a risk-reduction strategy, not a definitive cure that completely eliminates all pathogenic mt DNA from the offspring. Another major long-term safety concern is the theoretical risk of mito-nuclear mismatch. The nuclear and mitochondrial genomes have co-evolved over millennia, developing a complex and coordinated functional relationship that is essential for cellular health. By combining the nuclear DNA of the intended parents with the mitochondrial DNA of a third, unrelated donor, MD creates a novel genetic combination that has never existed before [18]. Preclinical studies in animal models have shown that different combinations of mitochondrial and nuclear DNA can plausibly have differential effects on gene expression, cellular bioenergetics, and disease susceptibility. For example, studies in mice have shown that certain mismatches can alter oxygen utilization and responses to cardiac tissue injury, as well as affect the levels of oxidative stress and resistance to heart failure [18]. These models also suggest that a mismatch could elicit an allo antigenic response, where the body's immune system rejects the "foreign" mitochondria, a process analogous to immune rejection in organ transplantation.18 The introduction of a new mt DNA haplogroup that is not harmonized with the nuclear genome bypasses aspects of "mito-Mendelian" evolution, raising questions about potential long-term health consequences such as developmental disorders, expedited aging, or an increased risk of cancer [44]. These risks are theoretical but biologically plausible and cannot be dismissed without long-term data. The existence of carry-over, the reversal phenomenon, and the theoretical risks of mito-nuclear mismatch underscore the absolute necessity of long-term follow-up. The current follow-up period from the UK trial, which is only a few years, is simply insufficient to rule out these potential delayed health effects [8]. The scientific community and regulatory bodies are in broad consensus that rigorous, long-term monitoring of children born from MD is essential to fully understand the safety and efficacy of the procedure [7]. This is not a matter of a single clinical trial, but an ongoing scientific experiment that will require decades of data to provide definitive answers.

5. ETHICAL, SOCIAL, AND LEGAL LANDSCAPE

Mitochondrial donation has been a subject of intense ethical and social debate, frequently summarized by the controversial and widely used term "three-parent baby" [25]. This label, however, is considered a misnomer by many experts and is misleading to the public, as the donor contributes a minuscule amount of genetic material—approximately 0.1% of the child's total DNA [10].Proponents of the technology argue that the mitochondrial DNA from the donor does not influence personal characteristics such as height, eye color, or intelligence, which are determined by the nuclear DNA inherited from the mother and father [10].Therefore, the genetic makeup of the mitochondria is considered irrelevant to a person's core identity or "ipseity" unless it is causing a debilitating disease [47]. The debate is not about the amount of DNA but rather about its heritable nature and the ethical implications of modifying the human germline, a concern that has driven regulatory decisions in many

countries [20]. The global regulatory landscape for mitochondrial donation is highly varied and highlights different approaches to balancing medical innovation with ethical concerns. The United Kingdom stands as a global leader, having become the first country in the world to legalize MD in 2015 following years of careful review and public consultation [20]. The UK's approach is characterized by a strict, highly regulated framework overseen by the Human Fertilization and Embryology Authority (HFEA), which requires that each case be individually approved. This regulatory model mandates long-term follow-up of children to ensure a robust body of safety data is collected [26]. Australia has followed a similar, staged, and regulated approach. The Mitochondrial Donation Law Reform (Maeve's Law) Act of 2022 legalized the procedure for clinical trial purposes, with the government investing up to $15 million to fund a pilot program at a single clinic.7 This framework also includes the creation of a donor registry, which allows children born from the procedure to access non-identifying information about their donor once they turn 18 [7]. In stark contrast to these models, the technology is effectively banned in the United States [21]. This ban is not the result of a single prohibitive law but rather a combination of congressional budget riders and a lack of action by the Food and Drug Administration (FDA) to approve any clinical trials. The US's inaction is rooted in a cautious approach to the unresolved safety and ethical questions. However, this policy has an unintended and negative consequence. Because patients in the US cannot access MD legally, they may seek the procedure in unregulated clinics in other countries, such as Mexico and Ukraine [5]. This creates a situation where there is no scientific transparency, no regulatory oversight, and no mandatory long-term follow-up, which ultimately makes the procedure less safe for patients and hinders the collection of crucial safety data that the UK and Australia are actively generating. The bioethical debate surrounding MD is multi-faceted. One prominent line of critique comes from religious groups who oppose the destruction of fertilized embryos inherent in the PNT technique and view the child as a "manufactured item" rather than a gift with intrinsic value [30]. Another significant critique comes from the disability rights movement, which argues that genetic selection technologies like MD could be a form of modern-day eugenics [52]. This perspective expresses concern that by portraying genetic disorders as inherently tragic, these technologies risk devaluing the lives of people with disabilities and may lead to increased societal stigmatization and discrimination [47]. The argument is that the societal push to "cure" or "eliminate" genetic differences can obscure the vibrant lives and contributions of individuals with disabilities, and that ethical debates should include the voices and perspectives of these communities, not just scientific experts [52].

6. CONCLUSION

Mitochondrial donation is a landmark innovation in reproductive medicine, offering the first real hope for women with severe mt DNA diseases to have healthy, genetically related children. The recent publication of clinical outcomes from the UK’s pronuclear transfer trial provides the first robust evidence of the procedure's short-term efficacy, with eight healthy babies born showing a significant reduction of pathogenic mt DNA variants. However, the analysis of the available data reveals that MD is not a simple cure but rather a complex risk-reduction strategy. The existence of the "reversal" phenomenon, where pathogenic mt DNA can selectively amplify over time, and the theoretical risks of "mito-nuclear mismatch" demand a sober assessment of the technology's long-term safety. The current scientific understanding and follow-up data are insufficient to dismiss these concerns. Future research must focus on answering several critical questions to fully validate the safety of MD. Continued, long-term follow-up of children born from the procedure is essential to monitor for any delayed health effects and to track the stability of the mt DNA heteroplasmy over a lifetime.8 Research is also needed to elucidate the precise biological mechanisms that drive the reversal phenomenon and to understand the clinical implications of a mito-nuclear mismatch.18

7. RECOMMENDATIONS

The contrasting regulatory approaches of the UK and Australia versus the US illustrates a critical dilemma. The US's de facto ban, while intended to be cautious, has inadvertently pushed patients to seek the procedure in unregulated jurisdictions where there is no oversight, no transparency, and no long-term data collection. A more responsible and ethical path forward is a regulatory model that embraces a pragmatic, evidence-based approach, as demonstrated by the UK and Australia. This model, which allows for cautious clinical application under strict regulatory oversight and mandates long-term follow-up, is the only way to build a robust body of scientific evidence. It is the most effective way to ensure patient safety, mitigate risks, and ultimately realize the full potential of this groundbreaking technology for the families it aims to help.

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