Medical hypothesis discovery and innovation in ophthalmology

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Hypothesis

Stapler for corneal transplantation: a hypothesis

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ABSTRACT

Background: Corneal transplantation requires exquisite microsurgical precision, particularly during the suturing of donor and recipient tissues. In corneal transplantation procedures such as penetrating keratoplasty, the donor cornea is traditionally secured using ultrafine 10-0 nylon sutures, meticulously placed under an operating microscope to achieve precise tension and promote optimal wound healing. Although this technique remains the reference standard, it is inherently time-intensive and requires advanced microsurgical expertise. To enhance surgical efficiency and maintain clinical outcomes, recent innovations have proposed the use of a modified stapling device equipped with ultrafine nylon staples as an alternative to conventional suturing. Although experimental stapling systems have been engineered to facilitate graft fixation, widespread clinical adoption or regulatory approval has not yet been achieved, largely because of unresolved concerns regarding precision, stability, and long-term safety.

Hypothesis: To address these challenges, we propose an adaptation of the skin stapler mechanism, employing nylon-based staples specifically engineered for corneal application. This study hypothesizes that the development of a specialized corneal stapler as a viable, time-efficient alternative to manual suturing in keratoplasty is feasible, contingent upon addressing critical challenges. These include replicating the biomechanical finesse and tension control of sutures, ensuring the biocompatibility of staple materials with ocular tissues, and minimizing the risk of postoperative complications such as astigmatism, wound dehiscence, and infection. The specialized corneal stapler utilizing ultrafine, biocompatible nylon staples can replicate the precision, tension control, and wound stability achieved by traditional 10-0 nylon suturing in penetrating keratoplasty, while significantly reducing operative time and technical demands. Rigorous preclinical testing and clinical validation are essential to evaluate whether stapling technology can match or exceed the standards established by traditional suturing techniques in corneal transplantation.

Conclusions: The conceptual model for a specialized corneal stapler presents a promising alternative to traditional suturing techniques. However, substantial technological innovation is necessary to meet the intricate anatomical and surgical requirements of the cornea. Further research, including iterative prototyping and preclinical validation, is essential before clinical applications can be realized. Moreover, further research and clinical validation are necessary to determine whether staplers can safely and effectively replace traditional sutures during corneal transplantation.

KEYWORDS

cornea transplantation, keratoplasty, surgical stapler, nylon, skin surgery

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How to cite this article: Ramirez-Miranda A, Haber-Olguin A, Moya-Villamar JA, Pedro-Aguilar L, Vera-Duarte GR, Ortiz-Morales G, Navas A, Loya-Garcia D, Graue-Hernandez EO. Stapler for corneal transplantation: a hypothesis. Med Hypothesis Discov Innov Ophthalmol. 2025 Spring; 14(1): 239-246. https://doi.org/10.51329/mehdiophthal1515

Received: 9 October 2024; Accepted: 22 April 2025

INTRODUCTION

Surgical stapling has several advantages for efficiency and improving surgical outcomes. Skin stapling significantly reduces surgical time compared to conventional suturing methods [1, 2]. The faster closure speed of staples benefits patients at risk of complications of prolonged anesthesia or intraoperative contamination [2]. This time-saving technique can be crucial in emergency settings and for patients with comorbidities. Regarding surgical complications, the evidence is conflicting. Some studies report lower rates of superficial surgical site infections with staples compared to sutures, especially in minimally invasive colorectal surgery [3, 4]. However, other studies have reported higher rates of wound dehiscence with staples, particularly in emergency cases [5].

The efficacy of staples appears to depend on specific procedures and patient factors [6, 7]. Interestingly, while staples do not necessarily improve wound strength, they have yielded better cosmetic results in some studies, particularly in the long term [1, 5]. Initially, sutures may provide a better appearance; however, after 6 months, stapled incisions tend to have more favorable scarring [1]. Skin stapling offers clear advantages in terms of surgical efficiency and potentially improved cosmetic outcomes [8, 9]. However, its impact on complication rates varies depending on the specific surgical context [10]. Surgeons should consider factors such as the type of procedure, patient risk factors, and potential for wound dehiscence when choosing between staples and sutures for wound closure [2].

Corneal transplantation, one of the most frequently performed transplantation procedures globally, is highly dependent on meticulous microsurgical techniques [11]. Despite advancements in surgical methods, the manual placement of sutures remains the standard method for attaching donor tissue to a recipient's corneal bed. This process requires precision, is time-consuming, and presents a steep learning curve for ophthalmic surgeons [11]. Recent technological advances in microdevices have raised the question of whether a stapling mechanism, such as that used in skin closure [1, 4], could be adapted for corneal transplants. This study proposes and evaluates the feasibility of a novel corneal stapling device as an alternative to conventional suturing techniques for corneal transplantation. The key objectives include addressing critical challenges related to device miniaturization, staple material biocompatibility, tension precision, and mitigation of postoperative complications, with the ultimate goal of improving surgical efficiency without compromising clinical outcomes.

HYPOTHESIS

In corneal transplantation procedures such as penetrating keratoplasty, the donor cornea is traditionally secured with ultrafine 10-0 nylon sutures [12] (Figure 1), manually placed under a microscope to ensure precise tension control and optimal healing. Although this technique is well established, it is time-consuming and technically demanding. Recent proposals have explored the use of a modified stapler equipped with ultrafine nylon staples as a potential alternative to enhance surgical precision and reduce operative time without compromising outcomes. Although experimental stapling devices have been developed to facilitate graft anchoring, none have yet gained widespread acceptance or regulatory approval [13, 14]. The feasibility of such devices remains under investigation, with key challenges including the need to replicate the delicate precision and stability of manual suturing while minimizing the risk of postoperative complications. Further research and clinical validation are necessary to determine whether staplers can safely and effectively replace traditional sutures during corneal transplantation.

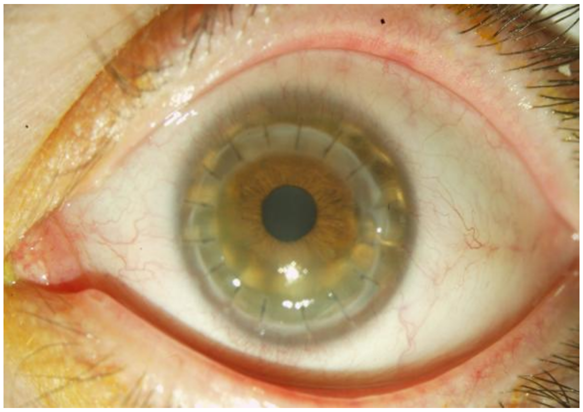

Figure 1. Standard penetrating keratoplasty (corneal transplant) showing 16 uninterrupted 10-0 nylon sutures. The sutures are evenly spaced, maintaining corneal clarity and structural integrity. The transplant area is well-defined, with no signs of vascularization or inflammation, indicating a successful surgical outcome. The manual placement of sutures remains the standard method for attaching donor tissue to a recipient's corneal bed.

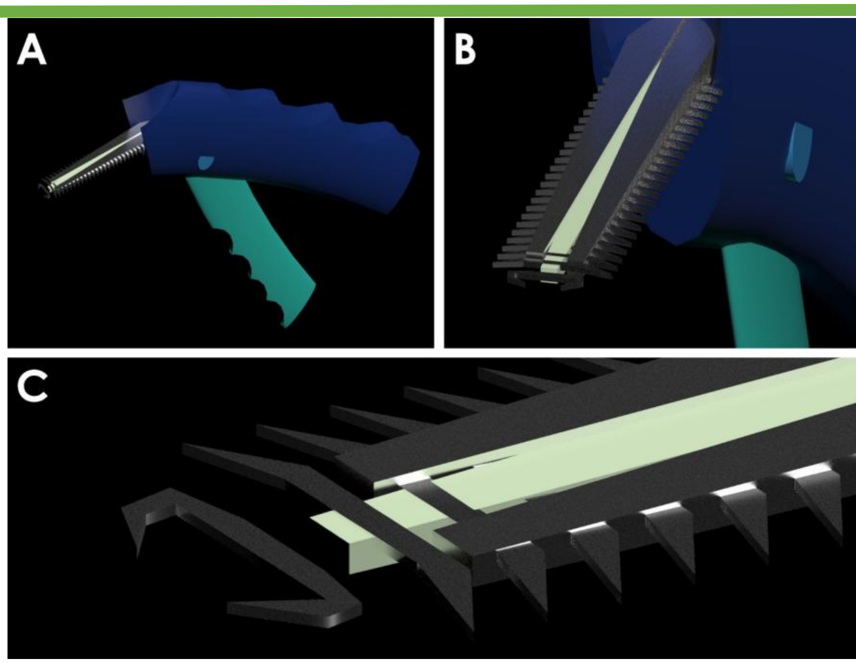

Figure 2. Hypothetical specialized skin stapler designed for corneal transplantation with rigid nylon staples (rendered by A.H.O.). (A) The stapler's ergonomic design features a curved handle for precision control and a trigger mechanism for ease of use during microsurgical procedures. (B) Close-up view of the stapler head, showing the alignment and feeding mechanism of the rigid nylon staples specifically designed to accommodate the delicate curvature and thickness of the corneal tissue. (C) Detailed view of the staple configuration, highlighting the sharp, angled prongs for secure tissue penetration and fixation, ensuring minimal damage and optimal wound closure in corneal transplant procedures.

Registered inventions related to corneal staplers are in existence. A Chinese patent [13] describes a corneal suture staple made from a shape-memory alloy (titanium-nickel). This design leverages the shape-memory effect to adjust the legs of the staple, facilitating wound closure and promoting healing [13]. A European patent [14] outlines an ophthalmic staple intended for implantation in the eye. This staple has adjustable tension and is designed to minimize tissue trauma during ophthalmic surgeries [14]. Although these patents indicate an interest in stapling devices for ocular procedures, a corneal stapler specifically designed for corneal transplantation does not appear to be commercially available or widely adopted in clinical practice.

We hypothesize that a specialized corneal stapler utilizing ultrafine, biocompatible nylon staples can replicate the precision, tension control, and wound stability achieved by traditional 10-0 nylon suturing in penetrating keratoplasty, while significantly reducing operative time and technical demands.

EVALUATION OF HYPOTHESIS

To test this hypothesis, a conceptual stapler model was designed to address the unique challenges posed by corneal tissue (Figure 2). The key considerations are as follows:

Miniaturization: Creating a device small enough to operate within the confines of the anterior segment of the eye, particularly the corneal plane, requires highly specialized miniaturization strategies. The design must account for the limited working space, typically no more than 10–12 mm in diameter at the graft-host interface during penetrating keratoplasty. To avoid obstructing the surgical field and allow for high-precision maneuvering under an operating microscope, the device must be compact, preferably with a diameter of less than 5 mm, and have a low-profile distal end to accommodate the corneal curvature. Mechanically, the stapler must incorporate micromechanical actuators capable of delivering staples no thicker than 10-0 nylon equivalents (approximately 30–40 microns in diameter) with exacting control over insertion depth and spacing parameters currently applied manually by experienced surgeons. Material selection is critical; high-strength [15], biocompatible polymers or lightweight alloys such as titanium [16, 17], can be used to maintain structural integrity while minimizing bulk. The device can be actuated pneumatically or electronically [18, 19] with a single-handed trigger or foot pedal control [20], allowing the surgeon to operate it without disrupting the sterile field or requiring additional personnel.

Miniaturization could be achieved using microfabrication techniques such as laser micromachining, micro-injection molding, or MEMS-based (micro-electromechanical systems) components [21]. A disposable cartridge system may also be incorporated to preload multiple ultrafine staples in a linear or radial configuration, allowing rapid sequential deployment along the graft-host junction. Optical guidance or integration with optical coherence tomography (OCT)-based feedback can further enhance precision [22]. Ultimately, the challenge lies not only in reducing the size of the device, but also in preserving the tactile sensitivity, adjustability, and safety currently afforded by manual suturing—all within the unique anatomical and optical constraints of the ocular surface.

Material selection: Nylon was selected for corneal staplers because of its proven use in ophthalmic surgery, particularly in corneal transplantation, in which 10-0 nylon sutures are the reference standard [23]. Its key advantages include high tensile strength, flexibility to minimize astigmatism, excellent biocompatibility, and low inflammatory response. Unlike absorbable materials such as polyglycolic acid and polydioxanone sutures (or simply polydioxanone), nylon resists biodegradation, providing the prolonged support essential for corneal healing [24]. Compared to alternatives such as polypropylene or metallic staples, nylon [25, 26] offers superior comfort and reduced risk of neovascularization, and it is available in ultrafine diameters (approximately 30–40 microns), making it ideal for precise ocular applications. Its compatibility with sterilization methods further supports its clinical utility.

Tissue compatibility: The corneal stapler was conceptualized to deliver ultrafine nylon staples in a controlled, atraumatic manner that distributes tension evenly across the graft-host interface. This uniform tension aims to minimize localized mechanical stress and postoperative irregularities, such as suture-induced astigmatism [27]. The interaction between nylon staples and the corneal tissue is central to the device's design. Nylon, a non-absorbable monofilament material, is widely used in ophthalmology because of its excellent biocompatibility, minimal tissue reactivity, and low risk of corneal neovascularization [23, 25]. Its smooth surface and low friction coefficient reduce mechanical irritation to the surrounding tissues, supporting faster epithelialization and minimizing chronic inflammation. Staples are intended to penetrate only the superficial third of the corneal stroma, avoiding deeper layers such as Descemet's membrane or the endothelium, which are more susceptible to damage. This shallow implantation mimics the placement depth of conventional interrupted sutures and supports proper wound apposition, while limiting exposure to foreign bodies.

In terms of healing dynamics, the resistance of nylon to biodegradation ensures prolonged structural support during the critical healing phase, which often spans several months for corneal grafts [24]. The staples would remain in place until removal, similar to traditional sutures, with the expectation of maintaining graft alignment and wound integrity without eliciting fibrotic encapsulation or chronic inflammatory responses. Long-term biocompatibility is supported by a wealth of clinical experience with 10-0 nylon in penetrating keratoplasty, for which the material has shown excellent tolerability and low complication rates [28]. Based on this evidence, use of the same material in staples is unlikely to introduce new biocompatibility concerns, provided that the insertion techniques and staple geometry are optimized for corneal tissue.

We also evaluated the potential for robotic assistance to enhance the precision of staple application, using visual guidance systems similar to those employed in advanced ophthalmic surgeries [29-31].

DISCUSSION

The use of nylon staples for corneal transplantation has several potential advantages, including shorter operative time, reduced technical complexity, and reduction of induced corneal astigmatism. However, multiple obstacles must be addressed before its clinical implementation. The curvature and delicacy of the corneal tissue, the need for high precision in placement, and the risk of inducing astigmatism or other refractive errors are major challenges [32]. Moreover, the material properties, biodegradability, and ease of removal of nylon staples must be explored *in vivo*.

Corneal transplantation techniques have evolved significantly over the past few decades, leading to improved patient outcomes and reduced complication rates [33]. Advances in corneal procurement have allowed for better preservation of donor tissue and improved graft survival and availability [34]. Moreover, the development of lamellar keratoplasty, such as Descemet's membrane endothelial keratoplasty and deep anterior lamellar keratoplasty, has enabled more selective tissue replacement, reduced risk of rejection, and enhanced visual recovery [35, 36]. Postoperative care has also advanced with the use of anti-rejection medications, refined follow-up protocols, and better understanding of graft-host interface healing [37]. Despite these improvements, techniques for wound closure—particularly the use of sutures—remain largely unchanged, representing a potential area for further technological innovations [38, 39].

The suture technique for corneal transplantation has not evolved substantially compared to other aspects of the procedure [40]. Although effective, sutures are associated with complications such as suture-related infections, astigmatism, and prolonged healing times [38, 41]. Moreover, the variability in tension and the need for postoperative adjustments can lead to inconsistent visual outcomes [42]. This stagnation in wound closure technology calls for the reconsideration of alternatives that can streamline the process and reduce complications [39]. A specialized corneal stapler inspired by the design and function of conventional skin staplers could offer a novel solution to the limitations of corneal transplantation [41, 43].

Comparing this proposed system with existing suturing techniques, staples may offer uniform closure and reduced risk of wound dehiscence. However, the current suturing method allows for fine-tuned tension adjustments, which staples might not provide [44]. Advances in robotic control and 3D imaging may mitigate this problem by allowing precise adjustments or controlled tension during surgery [45].

While clinical trials are necessary to establish its safety and efficacy, the adaptation of stapling technology for corneal transplantation holds significant potential to enhance surgical outcomes, reduce operative time, and potentially decrease infection rates through the followings:

1. Reduced surgical time: Stapling could significantly decrease the time required for graft attachment compared with traditional suturing methods. Faster procedure completion may lead to reduced exposure to anesthesia and its associated risks [46].

2. Simplified technique: A specialized stapler could standardize the attachment process, potentially reducing variability between surgeons. This standardization may lead to more consistent outcomes across different surgical centers [47].

3. Improved graft stability: Ultrafine nylon staples could provide more uniform tension around the graft circumference. Enhanced stability may reduce the risk of graft dislocation or detachment during the early postoperative period [23].

4. Minimized tissue manipulation: Stapling may require less handling of delicate corneal tissue than suturing [48]. Reduced manipulation could potentially decrease the risk of tissue damage and inflammation.

5. Decreased suture-related complications: Eliminating the need for traditional sutures may reduce the incidence of suture-related infections, irritation, and neovascularization. This could potentially lead to faster healing and improved visual outcomes [49, 50].

6. Enhanced wound closure: Staples may provide a more secure and uniform wound closure than individual sutures. Improved wound closure could reduce the risk of wound dehiscence and associated complications [5, 7].

7. Potential for reduced inflammation: If staples are truly biocompatible, they may elicit a weaker inflammatory response than traditional suture materials. Decreased inflammation could contribute to faster healing and reduced risk of graft rejection [1, 50].

8. Improved surgical ergonomics: A stapler device could potentially improve the ergonomics of the procedure for surgeons [51]. This may lead to reduced surgeon fatigue during long procedures or multiple transplants.

9. Potential for outpatient procedures: If the procedure becomes significantly faster and less complex, the feasibility of performing corneal transplantation in an outpatient setting may increase. This could reduce healthcare costs and improve patient convenience [52].

10. Accelerated visual recovery: If the stapling technique results in a more stable graft with less induced astigmatism, patients may experience faster visual recovery [27].

The proposed use of a corneal stapler for transplantation may present promising advantages, including enhanced surgical efficiency, reduced complexity, and improved patient convenience. These benefits could lead to more accessible corneal transplantation procedures, particularly in outpatient settings, with a possible reduction in costs. However, it is important to acknowledge the limitations. This concept remains theoretical, and no practical prototypes have yet been developed or tested using human tissues. Therefore, extensive preclinical and clinical studies are required to evaluate the safety, efficacy, and long-term outcomes of stapler-based corneal closure. A key limitation of this approach is its untested nature in real-world surgical environments, particularly regarding its impact on corneal healing and visual acuity outcomes. The effects of stapler-based closures on corneal endothelial cell density and graft survival over time should be investigated in greater detail. Moreover, scalability and technical challenges, such as miniaturization and material compatibility, must be addressed before clinical application. Further research should focus on prototype development, followed by rigorous in vitro and in vivo testing to explore the practicality of stapler-based corneal closure. Comparative studies between traditional suturing methods and the stapler technique are essential to assess not only the technical feasibility but also the potential advantages in terms of surgical time, postoperative recovery, and graft longevity. Additionally, exploring the incorporation of biocompatible materials or growth factors could further enhance the healing process and reduce the risk of complications and graft rejection. By overcoming these challenges, the corneal stapler has the potential to revolutionize corneal transplantation, leading to more efficient and effective surgical outcomes.

CONCLUSIONS

The proposed corneal stapler design introduces a novel approach to corneal transplantation with the potential to significantly enhance surgical efficiency and precision. However, several technical challenges remain, particularly in terms of device miniaturization, material selection, and tissue compatibility. Further research should prioritize the development and refinement of prototype models, along with rigorous preclinical testing, to evaluate the viability of this technique in real-world surgical settings. Critical to the success of this approach is understanding the impact of stapler-based closure on corneal endothelial cell density, as these are essential factors for long-term graft survival. In addition, comparative studies between traditional suturing techniques and the proposed stapler method are necessary to fully assess the relative advantages and limitations of each approach. The incorporation of biocompatible materials or growth factors into the stapler design could further enhance corneal wound healing and minimize the risk of rejection. Although the concept is still in the theoretical stages, this study lays a foundation for further research on stapler-assisted corneal closure techniques. Future studies should explore potential design modifications such as biodegradable materials or coatings that promote tissue integration, as well as the comparative benefits of stapler closure in terms of surgical time, postoperative complications, and long-term graft survival.

ETHICAL DECLARATIONS

Ethical approval: This study did not involve human or animal subjects; therefore, ethics approval was not required.
Conflict of interest: None.

FUNDING

None.

ACKNOWLEDGMENTS

None.

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