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## Total Human Eye Allograft Transplantation: Developing Surgical Protocols for Donor and Recipient Procedures

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### Abstract

**Background**—Vascularized composite allograft transplantation of the eye is an appealing, novel method for reconstruction of the nonfunctioning eye. The authors' group has established the first orthotopic model for eye transplantation in the rat. With advancements in immunomodulation strategies together with new therapies in neuroregeneration, parallel development of human surgical protocols is vital for ensuring momentum toward eye transplantation in actual patients.

**Methods**—Cadaveric donor tissue harvest ( $n = 8$ ) was performed with orbital exenteration, combined open craniotomy, and endonasal approach to ligate the ophthalmic artery with a cuff of paraclival internal carotid artery, for transection of the optic nerve at the optic chiasm and transection of cranial nerves III to VI and the superior ophthalmic vein at the cavernous sinus. Candidate recipient vessels (superficial temporal/internal maxillary/facial artery and superficial temporal/facial vein) were exposed. Vein grafts were required for all anastomoses. Donor tissue was secured in recipient orbits followed by sequential venous and arterial anastomoses and nerve coaptation. Pedicle lengths and calibers were measured. All steps were timed, photographed, video recorded, and critically analyzed after each operative session.

**Results**—The technical feasibility of cadaveric donor procurement and transplantation to cadaveric recipient was established. Mean measurements included optic nerve length (39 mm) and caliber (5 mm), donor artery length (33 mm) and caliber (3 mm), and superior ophthalmic vein length (15 mm) and caliber (0.5 mm). Recipient superficial temporal, internal maxillary artery, and facial artery calibers were 0.8, 2, and 2 mm, respectively; and superior temporal and facial vein calibers were 0.8 and 2.5 mm, respectively.

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**CLINICAL QUESTION/LEVEL OF EVIDENCE:** Therapeutic, V.

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**Conclusion**—This surgical protocol serves as a benchmark for optimization of technique, large-animal model development, and ultimately potentiating the possibility of vision restoration transplantation surgery.

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Restoration and even preservation of a functional eye for treatment of congenital differences, following injury, degenerative disease, or other acquired abnormality has long been a clinical challenge. Vascularized composite allotransplantation represents the latest paradigm shift in approaches to reconstruction of complex defects resulting from trauma and congenital abnormality. Face, abdominal wall, lower extremity, hand, and upper extremity transplants have now successfully been performed in a combined total of over 100 known patients in five countries.<sup>1</sup> As this treatment continues to grow in application, so does the scope to which it might be applied.<sup>2,3</sup>

Given the highly specialized function of the eye and its unique anatomical components, vascularized composite allotransplantation of the eye is appealing for restoration, replacement, and reconstruction of the nonfunctioning eye. With the global prevalence of blindness estimated to be nearly 40 million, the potential for such treatment is vast.<sup>4</sup> Furthermore, given that at least three patients known to have received face transplants to date have had loss of at least one functioning eye, concomitant eye transplantation is an obvious reconstructive adjunct for similar clinical scenarios in the future.<sup>5</sup>

With the advances in microsurgery and immunomodulation that have heralded successful vascularized composite allotransplantation, together with new therapies in neuroregeneration, strategies for overcoming the challenges previously thought to undermine the possibility of eye transplantation are now emerging. For vascularized composite allotransplantation of the human eye to become a clinical reality, it is necessary to develop a reliable animal model for testing of immunomodulation and neuroregeneration therapies and to perform cadaveric studies for optimization of surgical technique ahead of advancing to large-animal primate testing and ultimately eye transplantation in actual patients. Our group has established the first viable orthotopic model for vascularized eye transplantation in the rat. Maintenance of structural integrity and viability have been confirmed by slit-lamp examination, optical coherence tomography, and histology.<sup>6</sup> Others have described the hurdles to optic nerve regeneration following injury or neurodegeneration; increasing retinal ganglion cell survival, overcoming the inhibitory environment of the optic nerve, enhancing retinal ganglion cell intrinsic axon growth potential, and optimizing the mapping of retinal ganglion cell connections back into their targets in the brain.<sup>7</sup> Furthermore, investigation of neurotrophin mediation of retinal ganglion cell survival and optic nerve function, genetic intervention for optic nerve regeneration and protection, and prospects of optic nerve regeneration and protection by stem cells are ongoing.<sup>8</sup> Full-length axon regeneration and partial recovery of simple visual behaviors have been demonstrated in an adult mouse optic nerve injury model.<sup>9</sup>

The present study attempts for the first time to develop surgical protocols for procurement and implantation of a transplanted eye, in a human cadaveric model, as a vital step to achieving eye transplantation in actual patients. This will improve scientific knowledge of ocular and periorbital anatomy as applied to vascularized composite allotransplantation, and

introduces technical capability in approaches to ocular tissue harvest and implantation. This surgical protocol parallels our institution's animal model investigations of eye vascularized composite allotransplantation. This will serve as a benchmark for further optimization and refinement of technique, and as a springboard for development of a large-animal primate model for study. Ultimately, the long-term objective is to potentiate the scope of face transplants to include eye tissue and revolutionize the clinical practice of management of visual impairment and blindness by introducing the possibility of vision restoration transplantation surgery.

## MATERIALS AND METHODS

Preserved injected human cadaveric heads ( $n = 8$ ) underwent donor and recipient procedures. Bilateral transplants were performed between two cadavers in each surgical session (a total of four transplants). A globe and periorbital model was adopted, consisting of the entire orbital contents including the globe; periorbital; optic nerve; cranial nerves III, IV, and VI; ophthalmic artery with a portion of the adjacent carotid artery; and the superior ophthalmic vein. Neurovascular pedicle lengths and calibers were measured using calipers. All measurements were verified by two investigators. All steps were timed, photographed, video recorded, and critically analyzed after each operative session. All activities were compliant with regulations of the University of Pittsburgh Committee for Oversight of Research and Clinical Training Involving Decedents and the Office for Oversight of Anatomic Specimens.

### Donor Procedure

Donor procurement requires combined transorbital, endonasal, and transcranial approaches to allow for 360-degree decompression of the bony structure of the orbit and orbital apex (Fig. 1). First, endonasal resection of middle turbinate, maxillary enterostomy, total ethmoidectomy, and bilateral sphenoidotomy are performed to gain access to the medial and inferior orbit, orbital apex, and canalicular segment of the optic nerve (Fig. 2, *above*). Then, a small posterior septectomy is created to allow for binocular access. The lamina papyracea and medial orbital floor, orbital apex, and bony optic canal are decompressed, keeping the periorbital intact (Fig. 2, *below*). An endoscopic endonasal transplanum approach is performed to gain access to the optic chiasm, ophthalmic artery, and carotid artery.<sup>10</sup> Initially, the dura is preserved to minimize the duration of the associated cerebrospinal fluid leak during the procedure. (See Video, Supplemental Digital Content 1, which shows the endonasal approach to decompress the orbital apex, <http://links.lww.com/PRS/B935>.) Subsequently, with a coronal incision, the temporalis is reflected and an extended pterional craniotomy is made (Fig. 3). Extradural dissection of the anterior and middle cranial fossae provides access for removal of the orbital roof and lateral orbital wall. After transection of the meningo-orbital band, the superior orbital fissure and lateral wall of the cavernous sinus are exposed. The roof of the optic canal is drilled out all the way to the medial wall where the dura had been previously exposed from the endonasal approach. The anterior clinoid process is removed to provide access to the lateral optic canal. At this point, the frontotemporal dura is opened in a curvilinear fashion. The optic nerve and internal carotid artery are identified after opening the opticocarotid cistern (Fig. 4). Transorbital exenteration

is then performed to include globe, muscles, fat, suspensory ligaments, and trochlea within the periosteum of the orbit. The lateral orbital apex is decompressed, the superior orbital vein is identified and preserved, and the canthal tendons are disarticulated on each side. Next, again through an endonasal approach, the dura of the planum sphenoidale is opened to the suprasellar cistern. The optic chiasm, medial optic nerve, ophthalmic artery, and carotid artery are identified. The medial dural ring of the medial clinoid is incised to allow separation of the optic nerve from the internal carotid artery (Fig. 5). Returning transcranially, the optic nerve is followed posteriorly and transected before it reaches the optic chiasm. The oculomotor nerve is identified at its entrance into the oculomotor triangle of the cavernous sinus; the oculomotor triangle dura is opened to expose the oculomotor nerve traveling at the roof of the cavernous sinus; the transection of the nerve is completed before entering the triangle to maximize its length. Similarly, the trochlear nerve is sectioned at its cisternal segment before entering the cavernous sinus, the ophthalmic nerve is transected right after the trigeminal ganglion as it enters the cavernous sinus, and the abducens nerve is sectioned at the distal Dorello canal. The ophthalmic artery is not transected, but the internal carotid artery is ligated proximally at the paraclival-petrous segment and distally at the supraclinoid segment just before the origin of the posterior communicating artery. Finally, en bloc mobilization of the cavernous sinus and superior orbital fissure along with the orbital apex and full globe-periorbita-orbital contents are obtained to deliver the donor specimen (Fig. 6).

### Recipient Procedure

A recipient defect model was recreated by the same methods described for donor harvest, with combined transorbital, endonasal, and transcranial orbital apex decompression and exenteration, such that cranial nerves III, IV, V<sub>1</sub>, and VI are isolated at the entrance into the cavernous sinus, and the optic nerve is isolated at the cisternal space before joining the chiasm. Similarly, the ophthalmic artery is not directly ligated, but the carotid artery is isolated proximal and distal to the ophthalmic artery origin. The recipient procedure thereafter requires harvesting of vein grafts for both arterial and venous anastomoses, recipient vessel exposure, inset of donor tissue, arterial and venous anastomoses, and sequential coaptation of cranial nerves (Fig. 7). Choice of recipient vessels would in clinical reality be determined based on recipient anatomy. Candidate recipient vessels exposed include the superficial temporal artery and vein if available, although these could be damaged in any potential injury. Another option for the recipient artery is the internal maxillary artery; exposed by the coronal incision and turndown of the temporalis muscle with an extended lateral orbitotomy approach as in middle cerebral artery bypass.<sup>11</sup> However, the accompanying venous plexus here is not amenable to venous anastomosis. Alternatively, the facial artery and vein are exposed through a Risdon incision and are a good size match, but require long vein grafts. Vein grafts from recipient facial vessels are tunneled through the temporalis. All candidate recipient vessels would require vein grafting to provide sufficient length for anastomosis to the donor pedicle. Vein graft anastomoses to recipient artery and vein are performed (Fig. 8) before inset of donor tissue, which is secured with 3-0 permanent Prolene sutures (Ethicon, Inc., Somerville, N.J.) parachuted into drill holes in four orbital quadrants. Arterial anastomosis is then performed from vein grafted recipient vessel to donor carotid artery transcranially using standard microsurgical

techniques with 9-0 Ethilon sutures (Ethicon) (Fig. 9). Similarly, venous anastomosis to the donor superior ophthalmic vein is performed transcranially using standard microsurgical techniques with 9-0 Ethilon sutures (Fig. 10). Then, sequential coaptation of cranial nerves from deep to superficial (cranial nerves VI, V<sub>1</sub>, IV, III, and II) is performed (Fig. 11). (See Video, Supplemental Digital Content 2, which shows the transcranial optic nerve coaptation, <http://links.lww.com/PRS/B936>.) Finally, the bone graft is replaced, the temporalis resuspended, and the coronal incision closed. Endoscopic endonasal nasoseptal flap repair of the skull base can then aid in cerebrospinal fluid leak prevention.

## RESULTS

The technical feasibility of cadaveric donor procurement and transplantation to cadaveric recipient was established with donor and recipient procedures as described. Mean measurements of donor neurovascular pedicle length and caliber are listed in Table 1. Similarly, recipient vessel calibers and lengths of vein graft required are listed in Table 2. Donor and recipient procurement timings are listed in Table 3 and Table 4 respectively.

Notably, mean donor ophthalmic artery pedicle length and caliber were  $13.5 \pm 0.5$  and  $1 \pm 0.04$  mm, respectively; however, with a stem of paraclival internal carotid artery, these values can be increased to  $33 \pm 1.6$  and  $3 \pm 0.2$  mm. Mean optic nerve was  $25 \pm 1.5$  mm from the orbital apex to the annulus of Zinn and  $14 \pm 0.4$  mm from the annulus of Zinn to the optic chiasm, essentially 14 mm of mobile pedicle. Similarly, cranial nerves III to VI had mobile pedicle lengths of 10 to 14 mm. Recipient internal maxillary and facial artery were the closest size match to donor ophthalmic artery with supraclinoidal carotid artery origin. The internal maxillary artery required the shortest vein graft but had no accompanying usable vein for venous anastomosis. Facial vessels required the longest vein grafts. Superficial temporal vessels were the smallest in caliber.

## DISCUSSION

Surgical solutions to blindness are lacking; treatments for globe avulsion, anophthalmia, composite traumatic defects of the eye, and neurodegenerative disease are limited and compromise the fundamental reconstructive principle of “replacing like with like,” which vascularized composite allotransplantation could potentially afford.<sup>12–16</sup> Previously, the concept of eye transplantation had been thought of as unfeasible because of the inability of retinal ganglion cells to recover from injury, inadequate restoration of circulation, and immune rejection.<sup>17</sup> Now, with success in other modalities of vascularized composite allotransplantation, together with animal models of eye transplantation,<sup>6,18</sup> and emerging nerve regeneration strategies,<sup>7–9</sup> the need to elucidate the technical details of the surgical procedures for eye transplantation is also an important forerunner to a clinical eye transplant program.

The cadaveric studies presented in this article are a further springboard toward a clinical reality for vascularized composite allotransplantation of the eye. Use of cadavers to model actual clinical scenarios carries the limitation that cadaveric tissues are not the equivalent of living tissue but rather have the artifact of processing that to some extent undermines any



Moreover, the accompanying venous plexus is not amenable to anastomosis and thus would require exposure of a vein at another site. The facial vessels, although requiring lengthy vein grafts, present a good size match and are easily exposed through a Risdon incision. Ultimately, the propensity for these different candidate vessels to support patent anastomoses requires testing in actual physiologic circulation such as in nonhuman primate studies. The extended pterional craniotomy allows for considerable access to coapt the cranial nerves; given its deeper anatomical location, the abducens nerve must first be coapted, followed sequentially by cranial nerves V<sub>1</sub>, IV, III, and II working deep to superficial. Importantly, this recipient protocol we believe to be safe, as each step replicates tested techniques, albeit in a novel context.

Ultimately, the success of any transplantation protocol depends on expeditious harvest and transfer to reduce ischemia time. This remains true in this transplant modality as with others. Retinal function of an enucleated eye is greatly decreased or absent within 5 minutes. Maintenance and restoration of retinal function as measured by electroretinography has been demonstrated *ex vivo* in isolated perfused eyes for up to 10 hours. In these studies, eyes were enucleated, and perfusion was initiated shortly thereafter. The eyes were perfused under positive pressure with various buffered perfusates.<sup>24–28</sup> The sequencing of our proposed protocol is such that the recipient can be prepared before any ischemia time such that, on availability of the donor tissue, inset, vessel anastomosis, and nerve coaptation can begin immediately. The timings outlined in Tables 3 and 4 would obviously be longer in actual clinical scenarios (e.g., with physiologic bleeding) but nonetheless demonstrate the spectra of this surgery to be within the realm of the achievable.

## CONCLUSION

This surgical protocol serves as a benchmark for optimization of technique, potentiating the scope of face transplants to include eye tissue and revolutionizing the clinical management of visual impairment and blindness by introducing the possibility of vision restoration transplantation surgery.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

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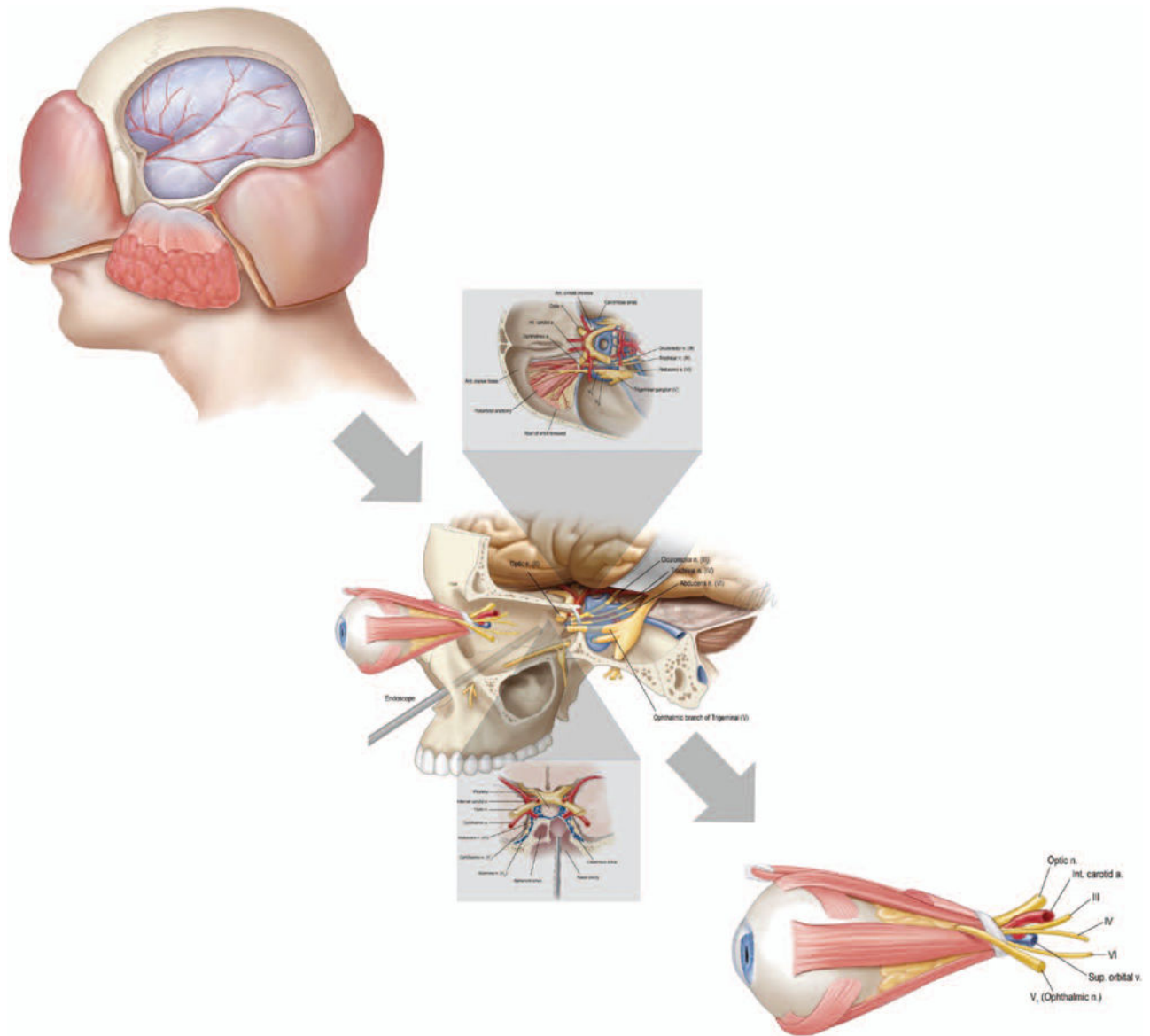
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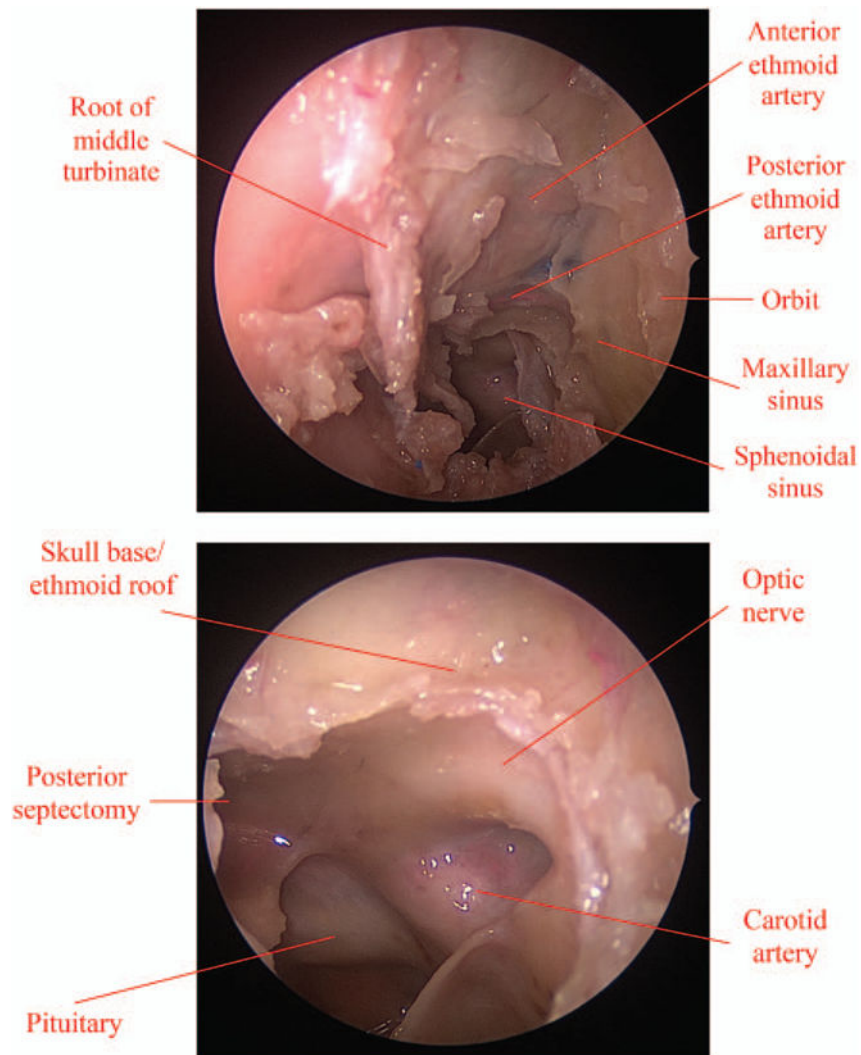
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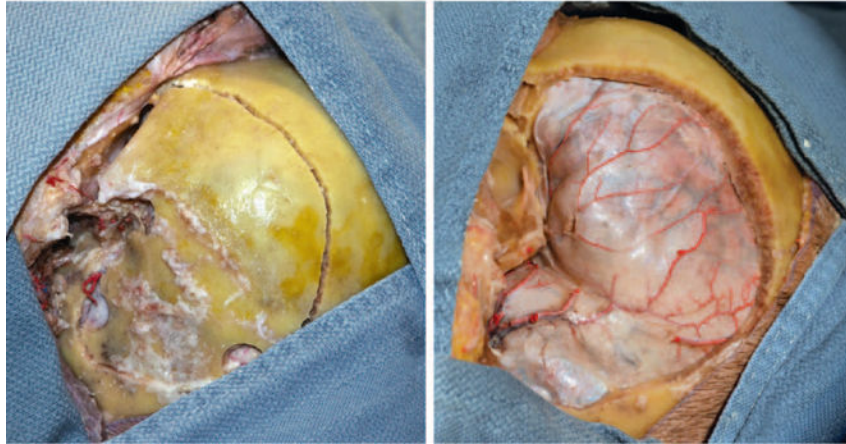
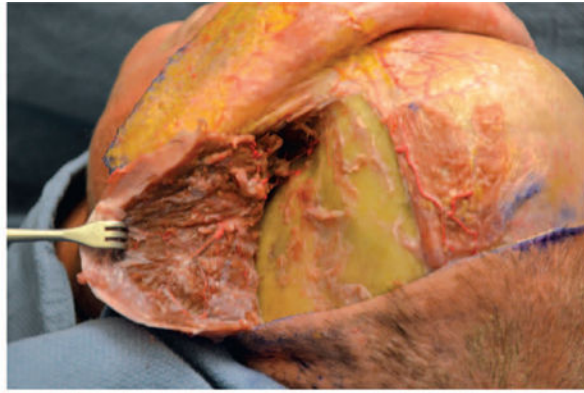
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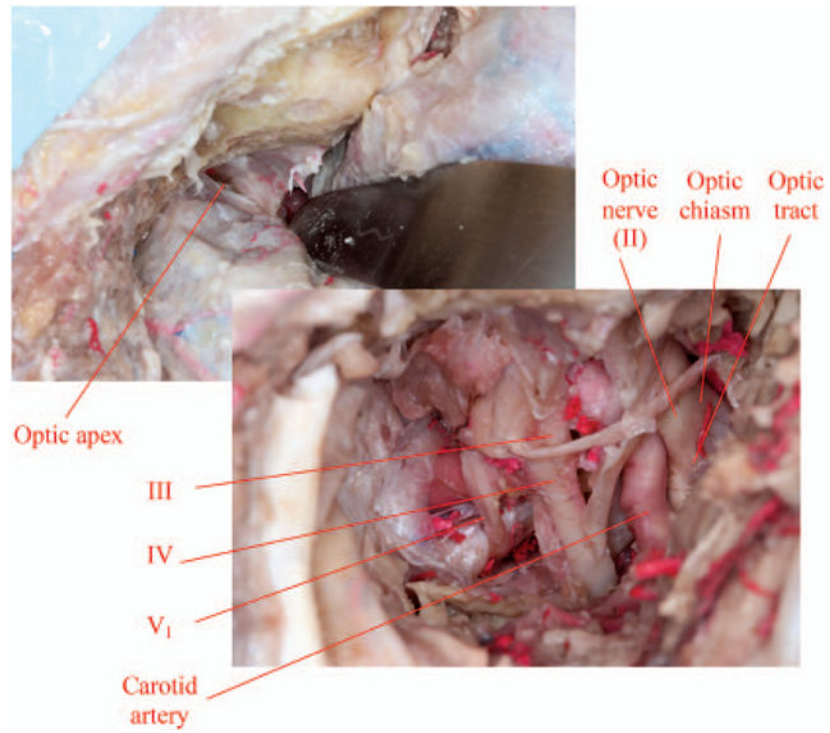
**Fig. 1.** Schematic representation of donor procurement requiring combined transorbital, endonasal, and transcranial approaches to allow for 360-degree decompression of the bony structure of the orbit and orbital apex.



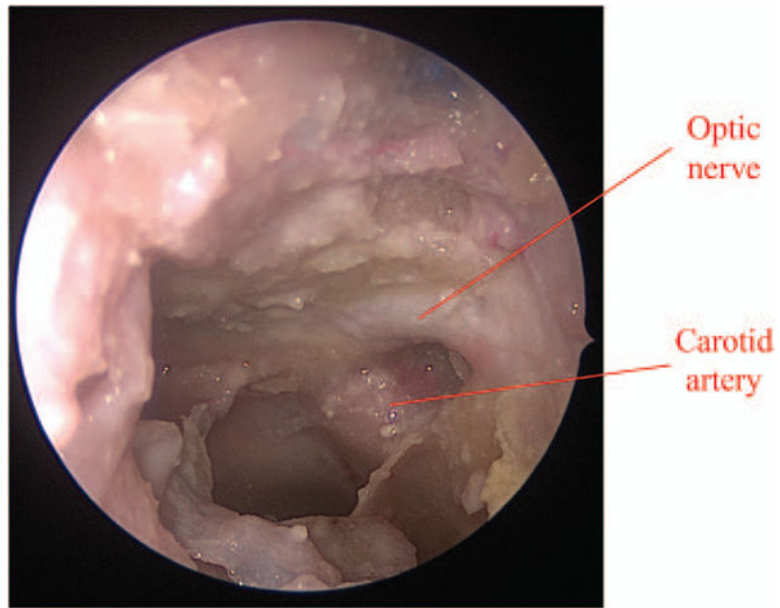
**Fig. 2.** Donor procurement requires a combined endonasal and transcranial approach to decompress the orbital apex. (*Above*) First, endonasal resection of middle turbinate, maxillary enterostomy, total ethmoidectomy, and bilateral sphenoidotomy are performed. (*Below*) A small posterior septectomy, the lamina ptecia, medial orbital floor, orbital apex, and bony optic canal are decompressed.



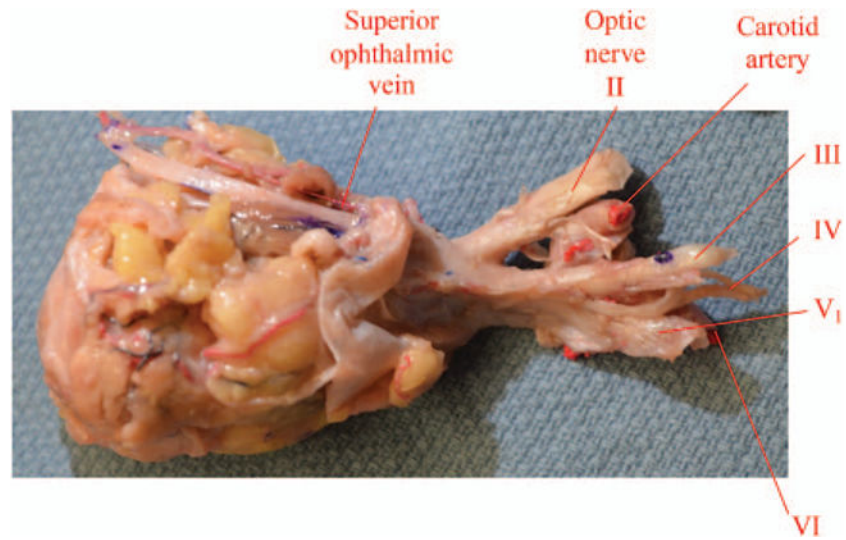
**Fig. 3.** With a coronal incision, the temporalis is reflected and an extended pterional craniotomy is made.



**Fig. 4.** Anterior clinoidectomy with removal of the orbital roof exposes the cavernous sinus, superior orbital fissure, optic nerve, and internal carotid artery (note that cranial nerve VI lies deepest and is not visualized in this image).



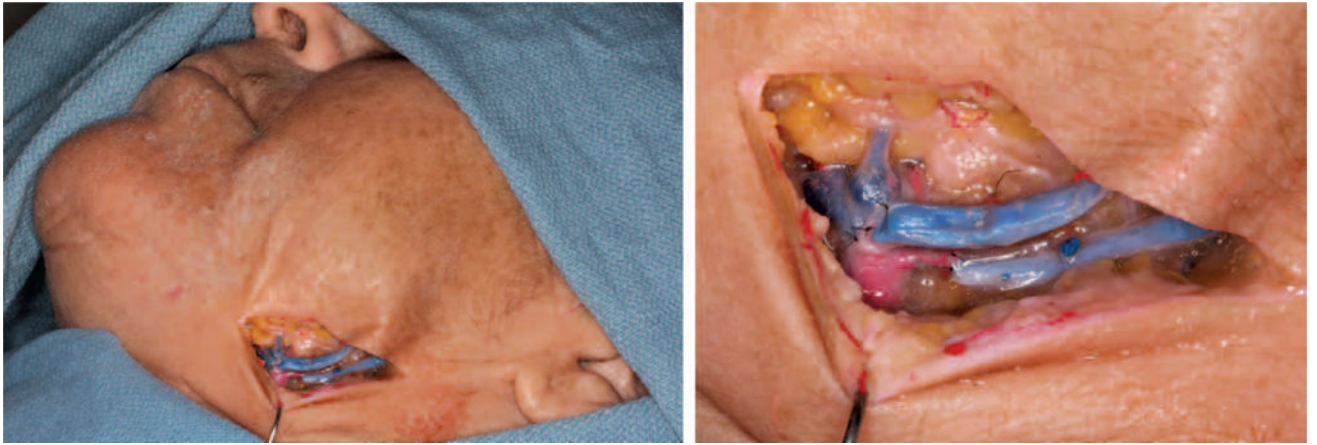
**Fig. 5.**  
The medial dural ring around the optic nerve is cut to separate it from the internal carotid artery.



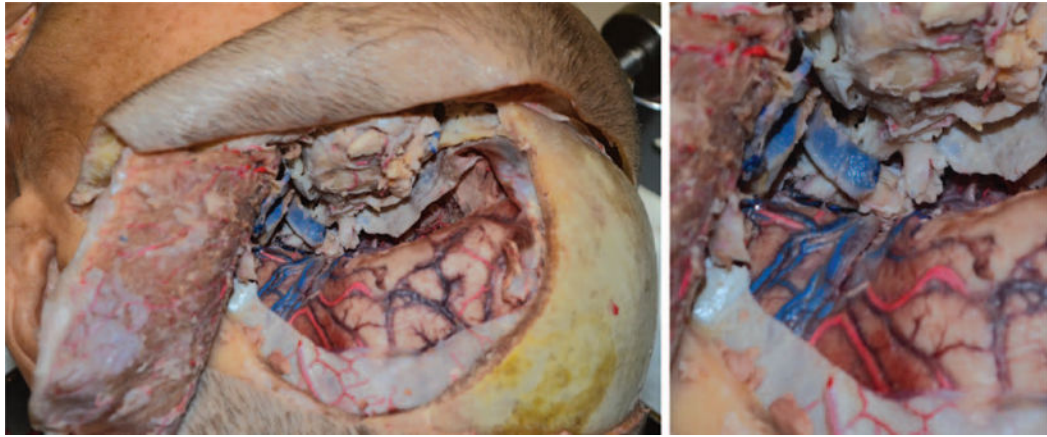
**Fig. 6.** Transection of the optic nerve, oculomotor nerve, trochlear nerve, ophthalmic nerve, and abducens nerve is performed at the cavernous sinus transcranially and the carotid artery is ligated in the paraclival space to deliver the donor specimen.



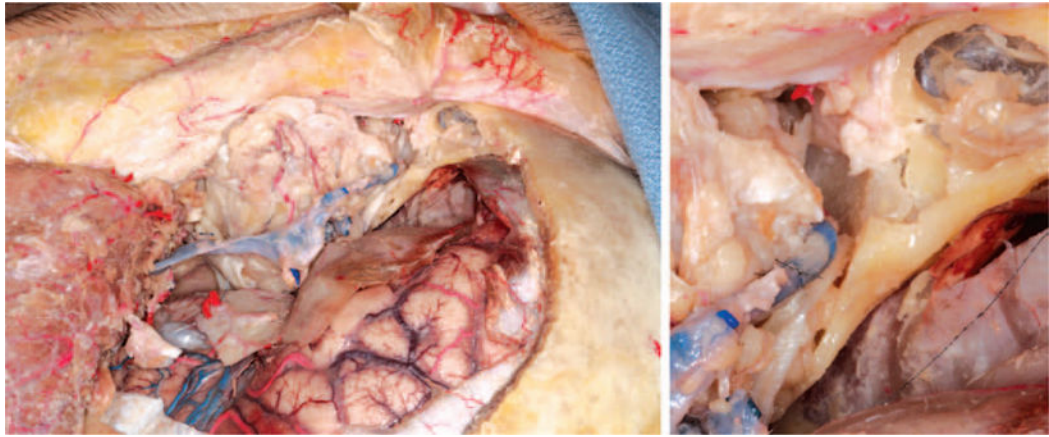




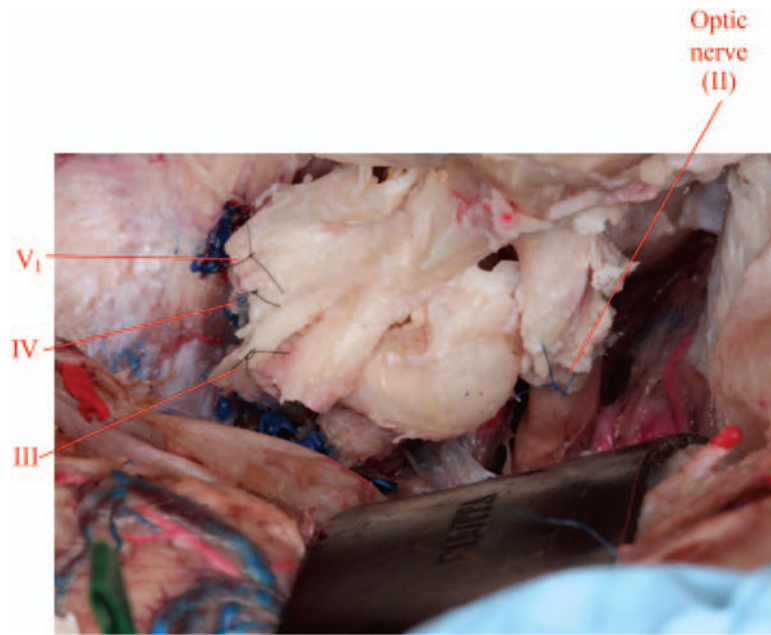
**Fig. 8.** Recipient procedure, which requires harvesting of vein grafts for both arterial and venous anastomoses, recipient vessel exposure, inset of donor tissue, arterial and venous anastomoses, and sequential coaptation of cranial nerves. Vein graft anastomoses to the recipient facial artery and vein.



**Fig. 9.**  
Arterial anastomosis from vein grafted recipient vessel to donor carotid artery.



**Fig. 10.**  
Venous anastomosis to donor superior ophthalmic vein.



**Fig. 11.** Coaptation of cranial nerves from deep to superficial (VI, V<sub>1</sub>, IV, III, and II) is performed (note that cranial nerve VI lies deepest and is not visualized in this image).



**Video 1.** Supplemental Digital Content 1 shows the endonasal approach to decompress the orbital apex, <http://links.lww.com/PRS/B935>.



**Video 2.**  
Supplemental Digital Content 2 shows the transcranial optic nerve coaptation, <http://links.lww.com/PRS/B936>.

**Table 1**

## Donor Measurements

	Mean Pedicle Length (mm)	Mean Caliber (mm)
Ophthalmic artery	13.5 ± 0.5	1 ± 0.04
Ophthalmic artery with cuff of internal carotid	33 ± 1.6	3 ± 0.2
Superior ophthalmic vein	15 ± 2.6	0.5 ± 0.2
Optic nerve (II)	14 ± 1.5	5 ± 0.4
Occulomotor nerve (III)	10 ± 1.8	3 ± 0.7
Trochlear nerve (IV)	12 ± 1.0	0.8 ± 0.2
Ophthalmic nerve (V <sub>1</sub> )	14 ± 1.0	2 ± 0.03
Abducens nerve (VI)	10 ± 0.7	4 ± 0.5

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**Table 2**

## Recipient Measurements

	Mean Caliber (mm)	Mean Vein Graft Length Required (mm)
Superficial temporal artery	$0.8 \pm 0.03$	$50 \pm 10$
Superficial temporal vein	$0.8 \pm 0.05$	$70 \pm 10$
Internal maxillary artery	$2 \pm 0.0$	$30 \pm 0$
Facial artery	$2 \pm 0.1$	$120 \pm 5$
Facial vein	$2.5 \pm 0.5$	$150 \pm 5$

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**Table 3**

## Donor Procedure Timings

	<b>Mean Time (min)</b>
Endonasal approach and decompression	57 ± 11
Transcranial approach and decompression	63 ± 16
Exenteration	27 ± 3
Dissection and transection of nerves and vessels	30 ± 7
Back-table preparation	13 ± 3

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**Table 4**

## Recipient Procedure Timings

	<b>Mean Time (min)</b>
Harvest of vein grafts	12 ± 2
Superficial temporal artery and vein exposure	7 ± 2
Internal maxillary artery exposure	29 ± 7
Facial artery and vein exposure	16 ± 4
Inset of donor tissue	22 ± 5
Arterial anastomosis	11 ± 3
Venous anastomosis	13 ± 3
Cranial nerve coaptation (VI, V <sub>1</sub> , IV, III, and II)	61 ± 12

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