

# Microincision Vitrectomy Procedure Using Intrector Technology

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**Objective:** To describe the procedure of pars plana vitrectomy (PPV) using an instrument designed for microincision vitrectomy.

**Methods:** In this retrospective, noncomparative, interventional case series, 6 different surgeons performed 4509 PPV procedures from August 1, 2005, through May 31, 2010, with 1-port vitrectomy using a miniaturized multifunction probe (the Intrector).

**Results:** Complications were reported in 20 eyes (0.44%). Culture-positive endophthalmitis occurred in 2 eyes

(0.04%), sterile endophthalmitis occurred in 6 eyes (0.13%), intraoperative or postoperative retinal detachment occurred in 4 eyes (0.09%), and vitreous hemorrhage occurred in 8 eyes (0.18%). None of the 20 eyes with complications of 4509 total eyes had worse visual outcomes than preoperative visual acuity.

**Conclusion:** One-port vitrectomy using the Intrector is a procedure that can be used efficiently for selected cases that do not require membrane peeling.

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**T**HE IDEAL VITREORETINAL surgical procedure is one in which the surgeon can pass an instrument through the eye wall without opening the conjunctiva and close the scleral wound without hypotony, bleeding, or risk of infection. Iatrogenic factors in surgery are dependent on incision size, number of incisions, wound architecture, and postoperative treatment of the wound(s). A sharper instrument for creating the entry wound would likely improve surgical outcomes in respect to these factors.

With this in mind, a miniaturized multifunction probe requiring a single incision was developed. The Intrector (Insight Instruments, Stuart, Florida) is sharp at its tip and allows transconjunctival, sutureless access into the vitreous cavity. Once introduced, the Intrector facilitates a partial or subtotal removal of vitreous and infuses balanced salt solution, pharmaceuticals, air, or intraocular gases before the probe is removed from the eye, leaving a self-sealing wound.

The formerly developed Vitrector (Mid-Labs, San Leandro, California)<sup>1,2</sup> was analyzed, and the sharp hypodermic needle tip of the device was redesigned to incorporate an independent infusion channel exiting at the distal end of the 23-gauge

probe. The infusion channel exits at an approximately 45° to 90° angle to the aspiration port.

The Intrector, introduced in 2007, allows subtotal removal of vitreous in the anterior, middle, and posterior segments of the vitreous cavity, infusing and aspirating through independent channels (**Figure 1**).

The intraocular tip measures 23 gauges (0.64 mm) to the first 12 mm with a safety stop of 0.9 mm at the extraocular shaft to prevent the sharp tip from being inserted past the midvitreous (**Figure 2**). The Intrector has a battery-driven power unit (**Figure 3**) that can be used as a microincision vitrectomy device for a 23-gauge, single-port, sutureless PPV. A head-mounted indirect ophthalmoscope preferably guides surgery with the Intrector, and the surgery can be displayed on an accompanying video monitor (**Figure 4**). Alternatively, the action of the device can be controlled through a plano-concave contact lens under the microscope (using microscopic illumination or chandelier, eg, Tornambe Torpedo illumination [Insight Instruments], and a second 26-gauge sclerotomy). Other external illumination techniques, such as diaphanoscopy transillumination, are currently under investigation.<sup>3</sup>

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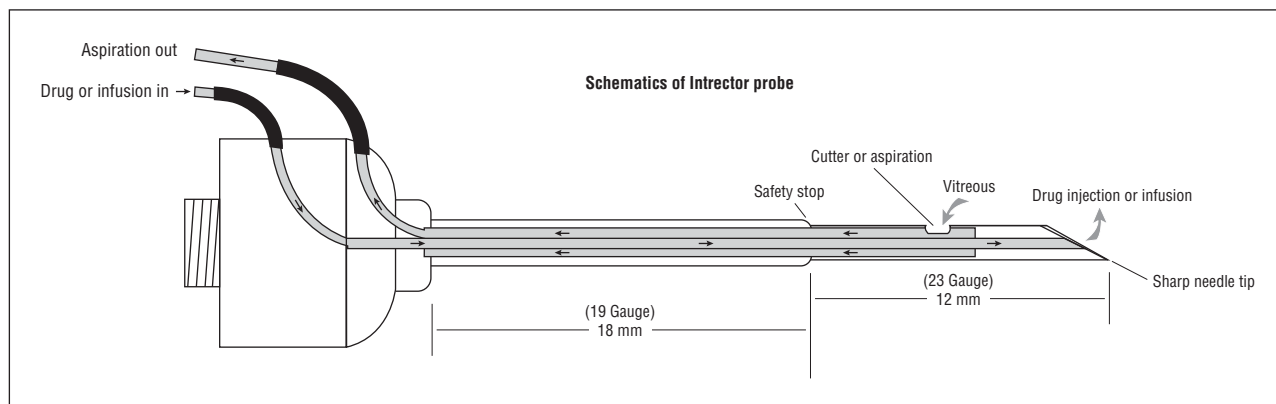


Figure 1. The design of the Intrector, showing the separate infusion and aspiration lines.

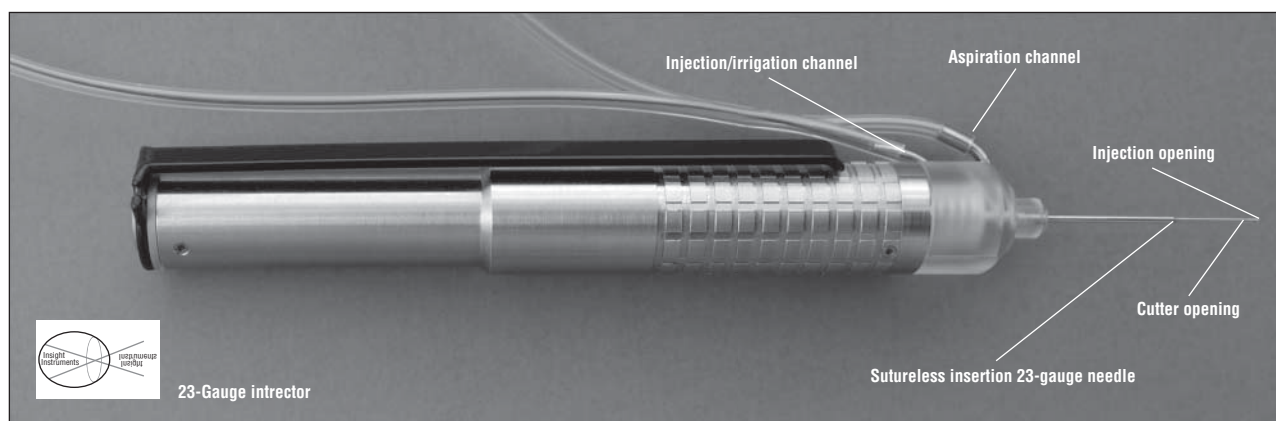


Figure 2. Outer design of the Intrector.

## METHODS

This was a retrospective, noncomparative, interventional case series of microincision vitrectomy procedures performed by 6 surgeons with varying experience using the 23-gauge Intrector. Patient consent was collected from all patients with regard to pseudonymous data analysis.

Indications for surgery are listed in **Table 1**. Most of the procedures (n=2098) were performed for choroidal neovascularization in age-related macular degeneration with visual acuity decrease and leakage on optical coherence tomography (OCT). All of the procedures were performed with the patients under local anesthesia, requiring topical gel anesthesia in 91.7% of the cases and a peribulbar anesthesia in 8.3%. A total of 62.9% of the cases were performed in an office setting, and 37.1% were performed in an outpatient surgery center. Intravitreal triamcinolone acetonide was administered primarily for the indications of diabetic macular edema (4 mg) and macular edema secondary to retinal vein occlusion (8 mg).

A total of 4509 cases from August 1, 2005, through May 31, 2010, were analyzed with our in-hospital computer software that allows for perioperative complication management (ORBIS Care; Agfa Healthcare, Bonn, Germany). The analyses yielded 3279 patients who underwent unilateral vitrectomy and 615 patients who underwent bilateral vitrectomy for a total of 3894 patients. Of these, 2134 were female (54.8%). Search criteria were surgery-related complications per patient, which were entered in an electronic file that could later be rechecked with different keywords (eg, *Intrector*, *hemorrhage*, and *retinal detachment*).

After the Intrector is inserted through a 2-mm to 5-mm oblique tunnel, the vitreous is removed and fluid, air, or gas is

injected. The device is then pulled out and the oblique tunnel is inserted using no manipulation (cotton-tip pressure and massage). A scleral smiley face-shaped closed wound results.

## RESULTS

Instrument- and procedure-related complications (eg, bleeding, retinal detachments, or sterile endophthalmitis due to triamcinolone acetonide slippage in the anterior chamber in pseudophakic eyes and presumed weakened zonule) were reported in 0.44% of cases and were not clustered around a single surgeon. Complication rates were as follows: 0.60% (7/1174) for surgeon 1, 0.40% (3/743) for surgeon 2, 0.31% (2/653) for surgeon 3, 0.31% (2/649) for surgeon 4, 0.50% (3/598) for surgeon 5, and 0.43% (3/692) for surgeon 6. In accordance with standards set forth by German law, the procedures were performed in a sterile operating room environment.

Culture-positive endophthalmitis was diagnosed after Intrector procedures in 2 eyes (0.04%) of 2 patients with a long history of diabetes mellitus and insufficient blood glucose control. After a full PPV with systemic antibiotic treatment, visual acuity was +0.08 Snellen lines. In 6 eyes (0.13%), sterile endophthalmitis occurred after microincision vitrectomy using the Intrector with injection of 4 to 8 mg triamcinolone acetonide (Kenalog; Bristol-Myers Squibb, New York, New York). Resolution was spontaneous in all 6 eyes, and visual acuity was



**Figure 3.** The battery-powered unit. Infusion and aspiration lines are seen as they are connected and enter the Intrector.

+2.4 Snellen lines. Intraoperative or postoperative retinal detachment was reported in 4 eyes (0.09%). In 1 of these 4 eyes, the detachment occurred 6 months after vitrectomy and a subsequent cataract surgery, and the retina was reattached using a full PPV with gas injection (no macular involvement). In 2 of the detachment eyes, the stream of infusion was examined using the indirect ophthalmoscope; after the immediate injection of 1.0 mL of 100% sulfur hexafluoride gas in 1 of the eyes, the retina was attached on the next day (no macular involvement). In 1 eye (uveitis) a 3-port PPV was performed to reattach the retina (no macular involvement). One patient was lost to follow-up for 6 months. On the next postoperative visit, the patient presented with 360° retinal detachment, and the retina was reattached using silicone oil. Eight eyes (0.18%) showed different degrees of vitreous hemorrhage immediately after the microincision vitrectomies using the Intrector. The hemorrhages spontaneously cleared after a single-site procedure with the Intrector. Most of the eyes had previous retinal breaks or proliferative diabetic vitreoretinopathy. None of the 20 eyes that experienced complications of the 4509 eyes that underwent microincision vitrectomy with the Intrector had an outcome worse than the initial preoperative visual acuity. A full summary of complications data is given in **Table 2**.

The Intrector is introduced in a similar manner as injection needles and cannulae. After displacement of the conjunctiva, the 23-gauge shaft should be guided through a 2-mm to 5-mm scleral tunnel incision (approximately



**Figure 4.** Surgical procedure with the Intrector. Surgery is guided by an indirect ophthalmoscope displayed on a video monitor.

45° angle). The difference between a bevel-up or bevel-down position did not appear to be measurable. The Intrector does not interact with peripheral vitreous to the extent to which the cannula systems that we evaluated with the gradient index endoscope.<sup>4</sup> Much like the 27-gauge Tornambe Torpedo, the Intrector can be removed without drawing significant amounts of vitreous into the sclerotomy. To illustrate the efficacy of a limited core PPV using the Intrector, we present a selection of cases.

A 28-year-old woman came to us with a history of chronic uveitis that was fully controlled with cyclospor-

ine and corticosteroids. She reported that vision in her left eye had decreased from 20/20 to 20/30, and on examination, we observed opacifications in front of the center of the macula. The opacifications moved up and down, depending on her head and eye movements. Because these opacifications were clear on initial examination, we did not perform OCT or fluorescein angiography (FA). We removed the opacities in the network with a single-incision approach using the Intrector. We completed the procedure in 2 minutes, leaving most of the vitreous behind to protect the lens from oxygen increase.

Postoperatively, the patient reported clear vision, and we did not detect any opacities on examination. Furthermore, she did not experience further lens transparency loss (follow-up time, 1 year). As noted in Table 1, 47 of the operations in this series were performed for floaters.

Indications	No. (%) of Patients	Age of Patients, Mean (SD), y
CNV		
CNV in AMD with visual acuity decrease and leakage on OCT	2098 (100.0)	78.2 (11.4)
Occult CNV	1695/2098 (80.8)	
Predominantly classic CNV	403/2098 (19.2)	
Macular edema in diabetic retinopathy	714/4509 (15.8)	59.3 (8.4)
Macular edema secondary to retinal vein occlusion	872/4509 (19.3)	62.9 (6.3)
Hemorrhage (eg, in proliferative diabetic retinopathy)	157/4509 (3.5)	63.7 (18.4)
Vitreous opacity (eg, in uveitis or endophthalmitis)	271/4509 (6.0)	58.7 (14.9)
Pneumatic retinopexy	289/4509 (6.4)	51.8 (14.3)
Floaters	47/4509 (1.0)	43 (15.1)
Regenerative after cataract surgery	11/4509 (0.2)	73.2 (4.9)
Complications in cataract surgery	39/4509 (0.9)	69.7 (6.7)
Malignant glaucoma	3/4509 (0.07)	73.4 (8.6)
Tumor biopsy	4/4509 (0.08)	74.1 (8.3)
Combined enzymatic-mechanical pars plana vitrectomy	5/4509 (0.1)	47.4 (11.4)

Abbreviations: AMD, age-related macular degeneration; CNV, choroidal neovascularization; OCT, optical coherence tomography.

For a patient 36 years of age with diabetes mellitus, we were able to take FA and OCT images at the beginning of the proliferative activity in both eyes. This patient was a physician who was remarkably adherent to his care regimen, so we had been treating him for some time. Thus, we had rare access to his FAs before and immediately after the proliferation began. At the beginning of the proliferative activities, FA revealed retinal neovascularization and disc neovascularization in both eyes that could not be seen on FA 8 months earlier. The OCTs showed corresponding cystic changes in both eyes.

After consultation, the patient agreed to undergo core PPV in his right eye and peripheral laser in his left eye. For the reasons of enhanced intraocular oxygen distribution after vitrectomy, the Intrectomy procedure was performed because oxygen is the main vascular endothelial growth factor inhibitor.<sup>5-10</sup> At 15-month follow-up, the right eye is more stable than the left eye with better visual acuity (20/25 OD vs 20/40 OS), adding to the evidence that enhanced intraocular oxygen distribution after core PPV with an Intrector may be a viable alternative to the peripheral laser.

Patients 1 and 2 demonstrate that limited core PPVs with monoincision access can offer good surgical and visual outcomes. In the diabetic eye, core PPV with the Intrector can increase the flow of oxygen to the retina. The role of partial vitreous removal combined with modified laser application warrants further research.

#### COMMENT

A complete or subtotal 3- or 4-port PPV and a limited 1-, 2-, or 3-port PPV have been used to achieve different surgical goals. Modern vitrectomy procedures have expanded indications and must therefore be considered differentially. In a complete or subtotal PPV scenario, the subtotal removal of vitreous, even in the outermost periphery, is considered essential. In a limited PPV scenario, the surgical access to the posterior pole and/or the pooling of oxygen is intended.<sup>5,6</sup>

Even when performing a limited PPV, the amount of vitreous that is eliminated is proved to have an effect on several parameters, such as the induction of vitreous liquefaction, oxygen redistribution in favor of the central retina, and elimination of growth factors. Our experimental work in rabbits clearly demonstrates the impressive and volume-related oxygen response to core PPV with the removal of different (small) volumes of

Variable	Culture-Positive Endophthalmitis	Sterile Endophthalmitis	Retinal Detachment	Vitreous Hemorrhage
No. (%) of patients	2 (0.04)	6 (0.13)	4 (0.09)	8 (0.18)
Eye complications	DR in all	DR in 4, CRVO in 2	AMD in 3, DR in 1	DR in 5, CRVO in 2, and AMD in 1
Mean No. of patients with complications at follow-up	14 at 2-mo follow-up	19 at 6-mo follow-up	24 at 12-mo follow-up	21 at 11-mo follow-up
Visual acuity before and after complications	+0.08 Snellen lines	+2.4 Snellen lines	+3.1 Snellen lines	+2.6 Snellen lines

Abbreviations: AMD, age-related macular degeneration; CRVO, central retinal vein occlusion; DR, diabetic retinopathy.

formed vitreous. Measurements with Oxymicro MicroTips (World Precision Instruments, Sarasota, Florida) were successfully used with cooperation of the developers of this technique.<sup>7,11,12</sup>

The level of vitrectomy that is enabled with the Intrektor procedure depends on the aspirated (vitrectomized) fluid, which has physiologic and clinical consequences. Adhering to the classic laws of physiology (laws of Fick, Stokes-Einstein, and Hagne-Poiseuille), the molecular transport by diffusion or convection is inversely related to the viscosity of the medium.<sup>13</sup> After an Intrektor procedure, the clearance of vascular endothelial growth factor and other cytokines, and presumably the clearance of intraocular drugs, are increased because the intraocular oxygen transport toward ischemic areas is improved.<sup>14</sup>

Monoincision vitrectomy procedures using the Intrektor are not intended to replace vitrectomy procedures with multifunction vitrectomy systems. The Intrektor does not have membrane-peeling capabilities, so, in procedures that require membrane peeling at the interface, a vitrectomy system is required. There are a variety of surgical procedures, however, that do not necessitate membrane peeling, and the use of the Intrektor for these indications would allow for a procedure that could be performed using a portable small-gauge vitrectomy system that does not require cannulae. Possible indications for the Intrektor include vitreous hemorrhages, macular edema, core PPV for diabetic retinopathy with drug injection through the integrated infusion channel, enhanced pneumatic retinopexy, simple posterior vitrectomy for complications of anterior surgery (ie, shallow chamber or vitreous loss), malignant glaucoma, floater or vitreous opacity removal, and vitreous biopsy for endophthalmitis or uveitis. The ability to perform a fast and safe core vitrectomy to gain a significant vitreous biopsy sample in patients with early endophthalmitis and/or uveitis, in whom a complete 3-port vitrectomy may not be indicated or cannot be performed because of various reasons, is clinically one of the strengths of using the Intrektor. Furthermore, if the clinical course leads to a progressing inflammation and a complete 3-port PPV with oil is indicated, a previous antibiogram will lead to a more purposeful antibiotic drug application in the advent of varying antibiotic susceptibilities.<sup>15</sup>

In comparison to the existing standard line of management (23-gauge and 25-gauge 3-port vitrectomies), it must be emphasized that the Intrektor procedure holds the advantage of a single site vs a 3-port access, with wound closure based on conjunctival displacement and oblique tunnel only. No suturing is required in any cases; in addition to a reduced surgical time, the use of the Intrektor may provide better wound structure based on the solid, sharp, 23-gauge, hypodermic, needle-type architecture.

The risk-benefit profile with the Intrektor appears to be favorable. As noted previously, we have found the procedure- and technology-associated rate of complications to be 0.44% in 4509 cases. A common feature of transconjunctival 3-port PPV procedures is postoperative hypotony in the immediate phase after surgery. Using the 1-port approach allows the Intrektor to be removed from the single self-sealing tunnel incision. Intraocular fluid leakage and hemorrhage are infrequent in mono-

incision PPV, as has been demonstrated with gradient index high-resolution endoscopy.<sup>16,17</sup>

Questions have arisen regarding the safety of the aspiration and infusion lines exiting from a single tip. The flow from each line runs in different directions, at approximately 45° to 90° angles. The Intrektor is designed to be placed in the midvitreous, allowing forward advancement. Kept at that plane, the Intrektor poses no clinically significant risk of damage. After staining the posterior vitreous base with triamcinolone crystals, assessment and even induction of a posterior vitreous detachment can be achieved, whereas the mild flow will help to identify the potential position of the vitreous base. Thus, the posterior vitreous cortex could be detached in some cases directly. We speculate that in other cases, posterior vitreous detachment is not induced intraoperatively but postoperatively via liquefaction of vitreous.

A patient consent form will help to impress on patients that a monoincision PPV procedure is considered as seriously as any intraocular intervention, from intravitreal injections to lengthy 3-port PPV procedures. The information provided on the consent form, however, should also clearly explain the procedure and illustrate the simplicity and efficiency of the intervention, thus calming potential preoperative anxiety on the part of the patient.

We followed up patients with choroidal neovascularization related to macular degeneration in 2 case series for changes in visual acuity after a combined PPV with an Intrektor with bevacizumab (Avastin; Genentech, South San Francisco, California) and dexamethasone. During 6 months, visual acuity remained stable in 38 of 96 patients (39.6%) and improved in 31 patients (32.3%) by 1 to 3 lines and in 7 patients (7.3%) by greater than 3 lines in 106 eyes with occult choroidal neovascularization.<sup>18</sup> In 52 patients with predominantly classic choroidal neovascularization, a low-fluence photodynamic therapy was accompanied with the same Intrektor regimen with bevacizumab and dexamethasone. At the end of the follow-up period of 9 months, visual acuity had improved by greater than 1 line in most patients (72.9%) with a re-treatment rate of 25%.<sup>19</sup>

We conclude that the Intrektor allows for single-port vitrectomy for many indications and has a favorable risk-benefit profile in the 4509 cases that were reviewed. The efficiency of a single incision and the miniature multifunction probe, when indicated, provides an acceptable alternative to the 3-port PPV.

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