



Introducing a Better Treatment Paradigm
for Patients and Physicians

16

% Injection-free
after loading phase

Ranibizumab
Monotherapy

65

% Injection-free
after loading phase

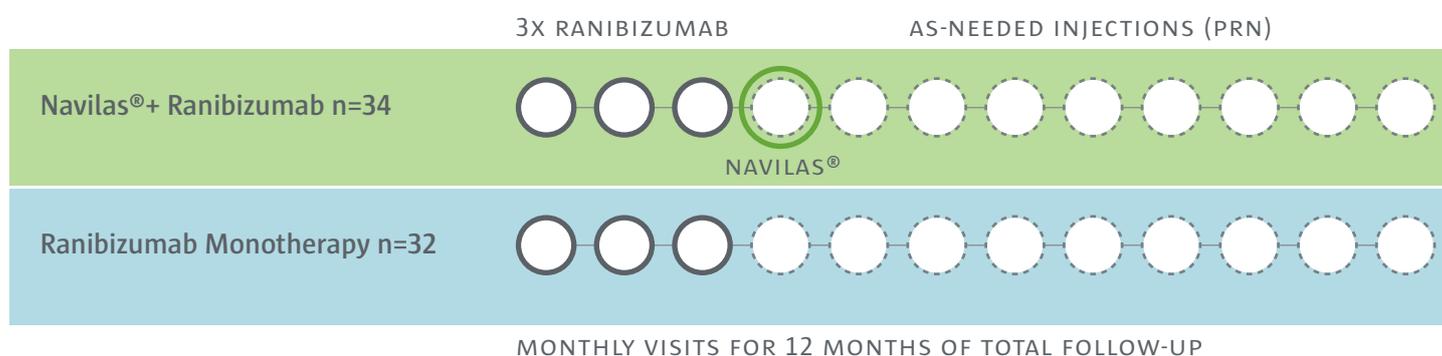
Navilas®+
Ranibizumab

CAVNAV – Combination Anti-VEGF and Navigated Laser in Diabetic Macular Edema

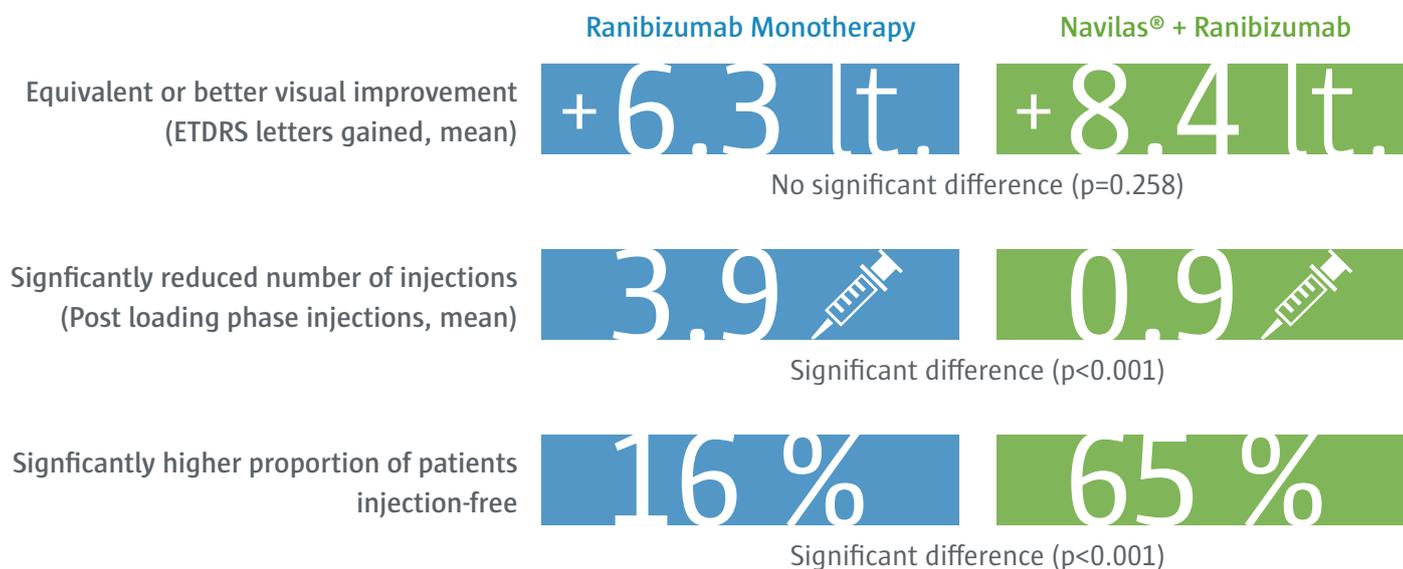
A 12-month, prospective, comparative cohort study of 66 patients with DME.

Marcus Kernt, MD and colleagues, LMU Munich, Germany*

Standardized combination regimen and control



Results overview

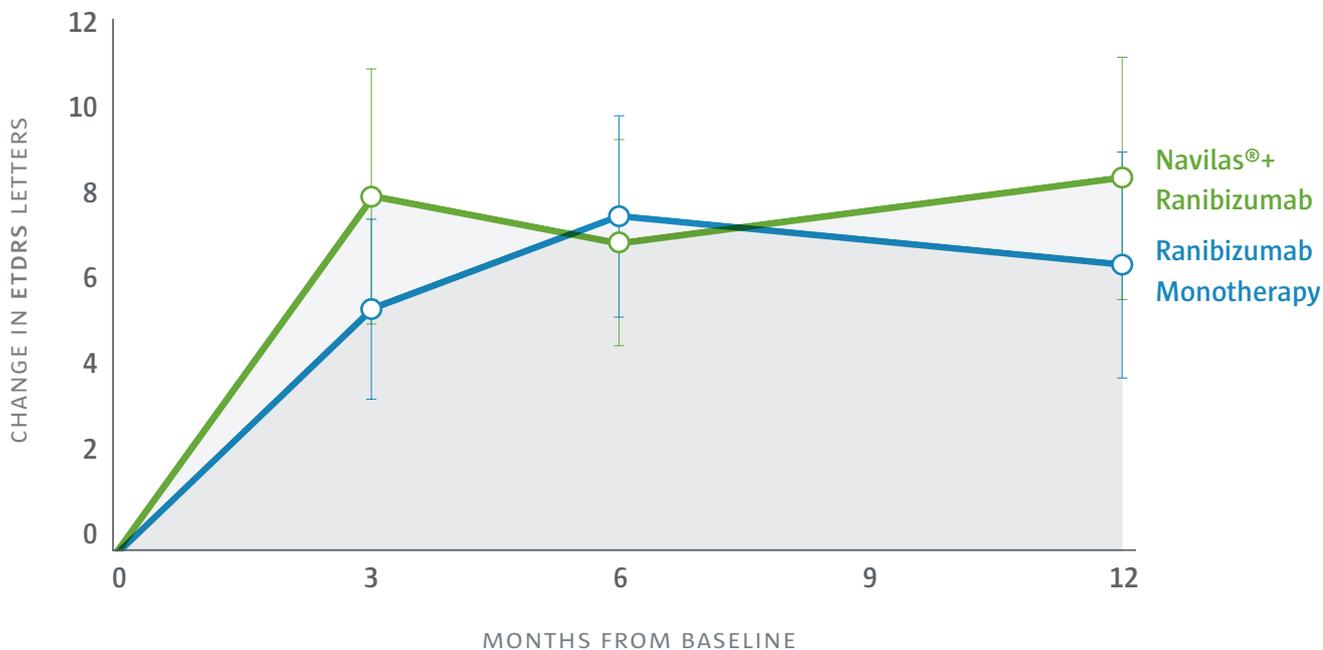


“The results of our study, as well as those of Prof. Freeman’s study, demonstrate clearly that the combination of navigated laser and anti-VEGF is an important option for patients with DME, as this novel treatment paradigm allows to reduce the number of injections needed with comparable good visual outcome as anti-VEGF monotherapy.”

Marcus Kernt, MD, LMU Munich, Germany

CAVNAV combination therapy patients demonstrated stable visual gains achieved with significantly less injections after Navilas.

Gains from baseline were significant in both cohorts ($p < 0.001$), cohort differences n.s.

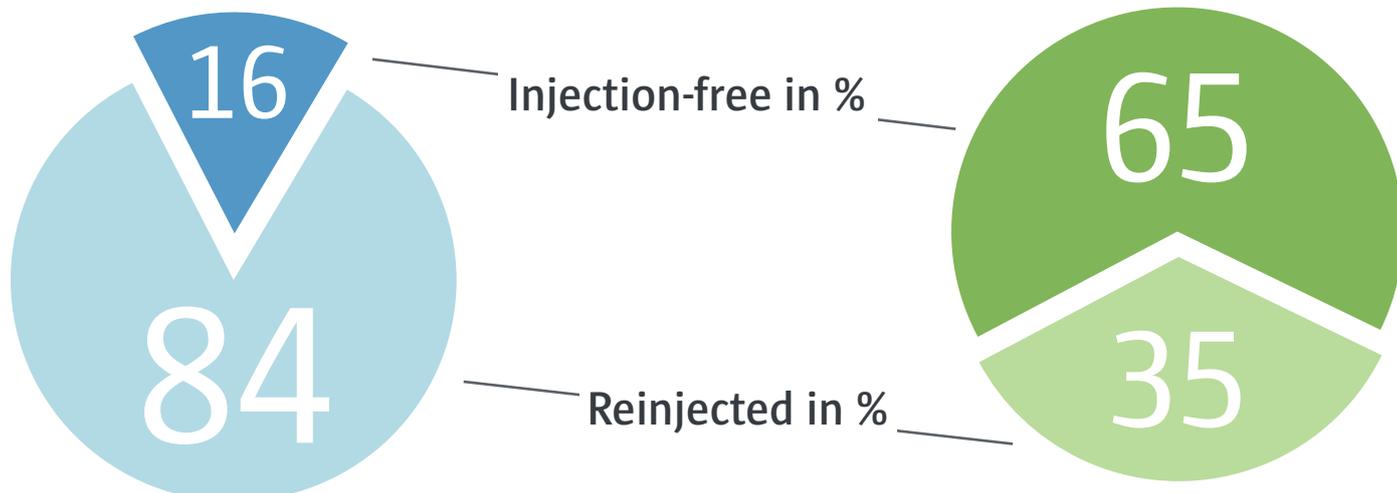


65% of combination therapy patients remained injection-free after ranibizumab loading and Navigated Laser.

84% of monotherapy patients required retreatment.

Ranibizumab Monotherapy

Navilas®+ Ranibizumab



US-based CAVNAV study supports similar results for Navilas + Bevacizumab combination.

	CAVNAV Germany*		CAVNAV US**
	Ranibizumab Monotherapy n = 32	Navilas + Ranibizumab n = 34	Navilas + Bevacizumab n = 23
Change in ETDRS letters	6.3 ± 6.5	8.4 ± 8.3	10.6 ± 18
Total injections in 12 months	6.9 ± 2.3	3.9 ± 1.3	4.0 ± 1.2
Post loading phase injections	3.9 ± 2.3	0.9 ± 1.2	0.8 ± 1.2
% patients injection-free after loading phase	16%	65%	57%

“Navilas® allows for a highly standardized and reproducible treatment. With image-based planning and accurate navigated execution, our diabetic patients appear to have a reduced need for re-injections in the year after Navigated laser therapy. This type of combination therapy may very well be the preferred solution for most DME patients in the future.”

William R. Freeman, MD, Jacobs Retina Center, UCSD, La Jolla, CA, USA

References

* Liegl R, Langer J, Seidensticker F, Reznicek L, Haritoglou C, Ulbig MW, Neubauer AS, Kampik A, Kernt M. Comparative evaluation of combined navigated laser photocoagulation and intravitreal ranibizumab in the treatment of diabetic macular edema. PLoS One. 2014 Dec 26;9(12):e113981. Full Text: <https://doi.org/10.1371/journal.pone.0113981>

OBJECTIVE: To evaluate if a standardized combination therapy regimen, utilizing 3 monthly ranibizumab injections followed by navigated laser photocoagulation, reduces the number of total ranibizumab injections required for treatment of diabetic macular edema (DME).

RESEARCH DESIGN AND METHODS: A 12-month, prospective comparison of 66 patients with center-involving DME: 34 patients with combination therapy were compared to 32 patients treated with ranibizumab monotherapy. All patients initially received 3 monthly ranibizumab injections (loading phase) and additional injections pro re nata (PRN). Combination therapy patients additionally received navigated laser photocoagulation after the loading phase. Main outcome measures were mean number of injections after the loading phase and change in BCVA from baseline to month 12.

RESULTS: Navigated laser combination therapy and ranibizumab monotherapy similarly improved mean BCVA letter score (+8.41 vs. +6.31 letters, $p=0.258$). In the combination group significantly less injections were required after the 3 injection loading phase (0.88 ± 1.23 vs. 3.88 ± 2.32 , $p<0.001$). By month 12, 84% of patients in the monotherapy group had required additional ranibizumab injections as compared to 35% in the combination group ($p<0.001$).

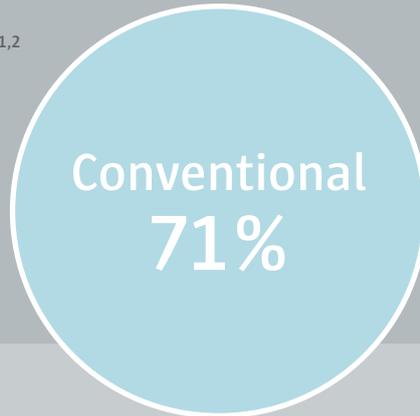
CONCLUSIONS: Navigated laser combination therapy demonstrated significant visual gains in most patients. Retreatment rate and number of injections were significantly lower compared to ranibizumab monotherapy and compared to the results of conventional laser combination therapy previously reported in pivotal anti-VEGF studies.

** Barteselli G, Kozak I, El-Emam S, Chhablani J, Cortes MA, Freeman WR. 12-month results of the standardised combination therapy for diabetic macular oedema: intravitreal bevacizumab and navigated retinal photocoagulation. Br J Ophthalmol. 2014 Aug;98(8):1036-41.

Navilas® Benefits over Conventional Laser

Higher Accuracy +28% ↑

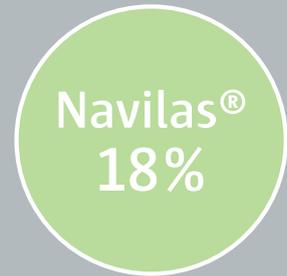
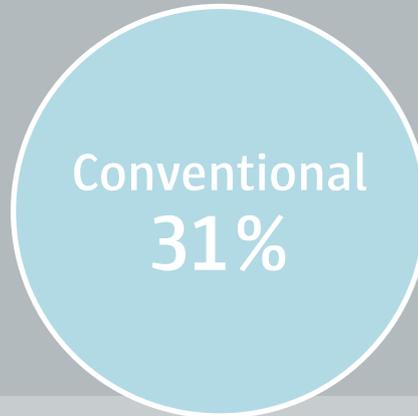
- ⊕ Accuracy and precision through image-guided laser pre-positioning^{1,2}



MICROANEURYSM/PLAN SPOT HIT RATE

Less Retreatments -42% ↓

- ⊕ Completeness through standardized digital planning and documentation
- ⊕ Durability, lower retreatment rate in laser monotherapy³



RETREATMENTS DURING 8 MO. FOLLOW-UP

"No longer is retinal laser treatment a leap of faith. The Navilas system enables me to see on the screen where the navigated laser will hit based on the treatment plan designed from the fluorescein or OCT. This guidance system is amazing and the infrared light makes for a much easier patient experience. The Navilas focal laser treatment is better than me at the slit-lamp, and that's saying a lot from a confident surgeon!"

David M. Brown MD, Retina Consultants of Houston, Houston, TX, USA

References:

1. Kozak I, Oster SF, Cortes MA, Dowell D, Hartmann K, Kim JS, Freeman WR. Clinical Evaluation and Treatment Accuracy in Diabetic Macular Edema Using Navigated Laser Photocoagulator NAVILAS. Ophthalmology. 2011 Jan 24
2. Pain and accuracy of focal laser treatment for diabetic macular edema using a retinal navigated laser (Navilas). Kernt M, Cheuteu RE, Cserhati S, Seidensticker F, Liegl RG, Lang J, Haritoglou C, Kampik A, Ulbig MW, Neubauer AS. Clin Ophthalmol. 2012;6:289-96
3. Navigated macular laser decreases retreatment rate for diabetic macular edema: a comparison with conventional macular laser. Neubauer AS, Langer J, Wolf J, Kozak I, Seidensticker F, Ulbig M, Freeman WR, Kampik A, Kernt M. Clin Ophthalmol. 2013;7 121-128

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Eyetube series on
Navilas Navigated
Laser Therapy:

[http://eyetube.net/
search.asp?q=navilas](http://eyetube.net/search.asp?q=navilas)



The Navilas® Navigated Laser System, a clinically significant advance in the management of retinal disease, reduces treatment burden on patients and staff and is also a sound investment for the practice.

- Navilas® distinguishes the practice as a technology center of excellence
- Enables you to efficiently meet the needs of a growing referral base while optimizing patient flow
- Improves patient compliance by reducing the number of repeat injections
- Integrates comprehensive technology designed to effectively manage a wide range of clinical indications in a busy retinal practice

Financial modeling tools are now available to help you discover how the Navilas® Navigated Laser System can make a difference in your practice. Contact OD-OS today for a consultation and to learn how this unique platform technology can help your practice provide better medicine with reduced burden.

OD-OS GmbH

Warthestr. 21
D-14513 Teltow
GERMANY
phone: +49 (3328) 31 282-100
e-mail: info@od-os.com

OD-OS Inc.

6201 Oak Canyon Drive, Suite 200
Irvine, CA 92618
USA
phone: +1 (949) 415 7258
e-mail: info@od-os.com



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Indications for use

The Navilas® Laser System is indicated for use:

- In Retinal Photocoagulation for the treatment of Clinically Significant Diabetic Macular Edema (Focal or Grid Laser), Proliferative Diabetic Retinopathy (Panretinal Photocoagulation), Sub-retinal (Choroidal) Neovascularization (Focal Laser), Central and Branch Retinal Vein Occlusion (Scatter Laser Photocoagulation, Focal or Grid Laser), Lattice Degeneration, Retinal Tears and Detachments (Laser Retinopexy).
- For the imaging (capture, display, storage and manipulation) of the retina of the eye, including via color, fluorescein angiography and infrared imaging; and for aiding in the diagnosis and treatment of ocular pathology in the posterior segment of the eye.