HEALAFlow

Slow resorption drainage implant for glaucoma surgery

HEALAELOW





What is HealaFlow?





HealaFlow is a slowly resorbable gel indicated for penetrating and non penetrating glaucoma surgery.

Injected under the scleral flap and the conjunctiva, it acts as a space-filler and limits the postoperative fibrosis thus improving the surgical success rate.





Made of highly concentrated CROSSLINKED non-animal origin NaHA



CROSSLINKING

Slow resorbable, biodegradable implant

Keep the excellent biocompatibility profile of native NaHA

Enhancement of the in-vivo residence of the product (up to several months, longer than the regular healing process duration)

NOT a cataract visco-surgical device (Healon, Viscoat...)





A space-filling product

- Long-lasting effect (slow resorption)
- Prevent adhesions between flap and sclera and between conjunctiva & episcleral tissue

An anti-inflammatory effect

Reduces inflammation and fibrosis

Non-animal origin / better "safety"

Less risk of allergy caused by animal proteins. Non-toxic.

Easy-to-use, an injectable implant

- Gel texture Sterile Colorless -Totally transparent.
- HealaFlow is presented in a disposable glass syringe





HealaFlow use





INDICATION

HealaFlow indicated in many types of glaucoma surgeries:

- Trabeculectomy
- Deep Sclerectomy
- Shunts / stents / tubes / Valves
- MIGS (depending on the approach)
- Alternative to MMC / 5FU
- Needling & bleb reopening





HealaFlow can be injected :

- Into the scleral cavity
- Under the scleral flap
- Under the conjunctiva

• HealaFlow fills up the subconjunctival space preventing scarring and fibrosis thus helping in achieving a functionally filtering bleb

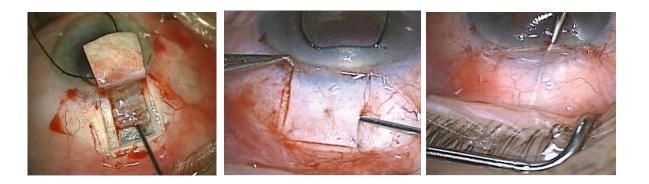
• In deep sclerectomy, HealaFlow is also inserted under the conjunctiva to facilitate the formation of a visible subconjunctival filtration bleb and improve the surgical results



HealaFlow is easy to use

- Easy to handle, injectable
- No suture of the implant
- Compatible with antimetabolites (Mitomycin C, 5 FU...)







Added value of Healaflow

AFTER THE SURGERY: 3 means time points

Immediately post-op

HealaFlow shows anti-inflammatory properties, less post-op complications, post-op hypotonies...Nice diffuse bleb.

Mid term (4-12 months)

HealaFlow reduces the aftercare needs (bleb revisions, antimetabolites, ...)

Long term (several years)

Less medication (-80%) HealaFlow retrospective studies (18 months follow-up)





Positioning



Healaflow positioning

- Positioned as a slow resorbable drainage implant
- To be used in all surgeries technics and implants
- Compatible or as substitutes with antifibrotic
- □ A space-filling product
- Long-lasting effect (slow resorption)
- Prevent adhesions between flap and sclera and between conjunctiva & episcleral tissue





Penetrating and non-penetrating glaucoma surgeries:

- Healaflow can be used in combination with penetrating and non penetrating surgeries
- As 35% of Trabeculectomy surgeries failed and need a re-visit. Healaflow can be positioned as **an alternative to needling and bleb reopening**
- Healaflow can be positioned as alternative to MMC/5FU by highlighting the non-toxic aspect
- Healaflow can also be positioned in combination with drainage valves to create bigger spaces for more outflow in case of very high pre-op IOP (>35mmHg)





Clinical



Healaflow has been utilised in more than **9 clinical studies**, involving **up to 547 eyes**, in various countries with various surgical techniques. The results all speak in the direction of an improvement of the success rate as compared to common techniques, whether with or without control products.

		Number of studies	
Develoption	Trabeculectomy	Retrospective with MMC (140 eyes)	
Penetrating	Phacotrabeculectomy	Healaflow + MMC (20) vs MMC (18)	
Non penetrating	Deep sclerectomy	Retrospective with MMC (137 eyes) Retrospective with MMC (60 eyes) Healaflow with MMC (17) vs Aquaflow + MMC(13) Healaflow (36) vs 5 FU (36) Healaflow (32) vs no treatment (30)	
	Visco-canalostomy	Retrospective (51 eyes) Healaflow (16) vs Healon GV (14)	

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NON CONTROLLED STUDY RESULTS

	Penetrating surgery	Non penetrating surgery			
	Trabeculectomy Healaflow + MMC 12 months FU	Deep sclerectomy Healaflow + MMC 18 months FU	Deep sclerectomy Healaflow + MMC 24 months FU	Visco canalostomy Healaflow 18 months FU	
Qualified success (IOP <= 18)	97%	95%	92%	94%	
Complete success (IOP <= 18)	90%	81%	91%	86%	
Failure (IOP > 18 mmHg) / Surgery	3%	5%	8%	6%	



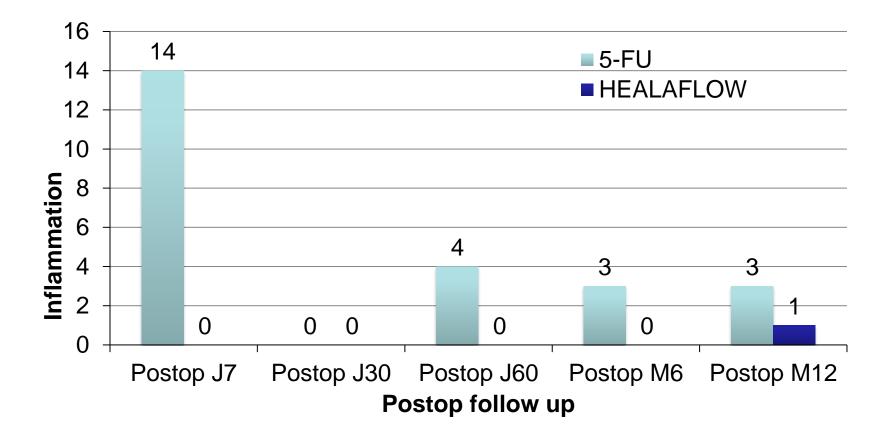
CONTROLLED STUDY RESULTS

Study	Succes rate	Time point	Healaflow	Control
Deep Sclerectomy - Healaflow + MMC	Complete	10	92%	85%
vs Aquaflow + M	Qualified 18 months	88%	71%	
Deep Sclerectomy - Healaflow vs 5FU	Complete	12 months	47%	28%
– severe cases	Qualified		N/A	N/A
Visco-canalostomy - Healaflow vs	Complete		81%	57%
Healon GV	Qualified	18 months	100%	79%

Conclusions: in each controlled trials, Healaflow showed a statistically significant superiority vs control



Healaflow influences the post-op inflammation



Result from El-Afrit study, Healaflow vs 5FU, 2 groups of 36 eyes each

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Healaflow reduces the number of side effects and adjunctive treatments

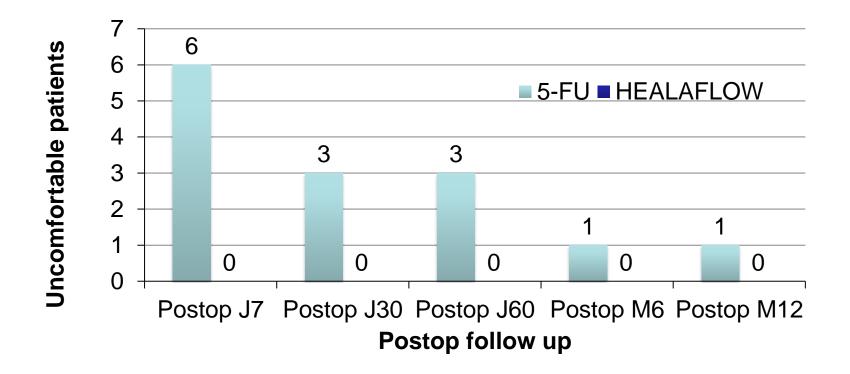
Side effects	Cataract	НТО	Hypotension	Necrotic bleb	Ν
5-FU	4	8	1	1	14
HEALAFLOW	4	5	0	0	9

Adjunctive treatments	Needling	Goniopuncture	Ν
5-FU	41	16	57
HEALAFLOW	25	16	41

Result from El-Afrit study, Healaflow vs 5FU, 2 groups of 36 eyes each



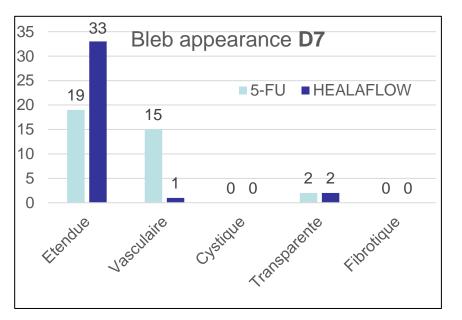
Healaflow improves patient comfort



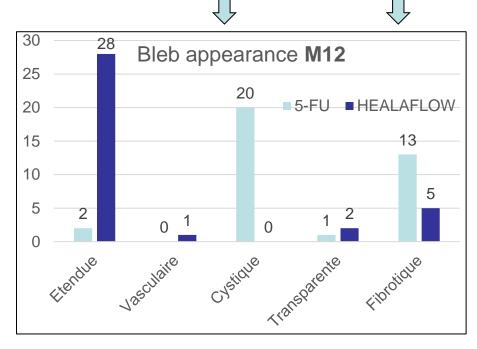
Result from El-Afrit study, Healaflow vs 5FU, 2 groups of 36 eyes each

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Healaflow preserves tissues



At 12 months, blebs from 5FU group are qualified as fibrotic and cystic, while large and satisfying in Healaflow group



Result from EI-Afrit study, Healaflow vs 5FU, 2 groups of 36 eyes each





Take home message

- □ Healaflow is easy to use (no learning curve)
- Acts as a long-term space maintainer
- In modulating the inflammatory response, it influences the scarring response and tissue remodelling
- Adapts to most type of surgery
- May replace or complement other implants
- Could be a substitute for antimetabolites such as MMC or 5-FU
- Compatible with some MIGS devices
- Needling
- Healaflow improves the results of glaucoma surgery



"With HealaFlow, don't change your practice, improve your results."