VCD - Vein Closure Device

Selective closure of superficial veins through percutaneous access under UltraSound guidance

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Professor University of Brescia

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MY DISCLOSURES

I herewith declare that with respects to the topics of this presentation:

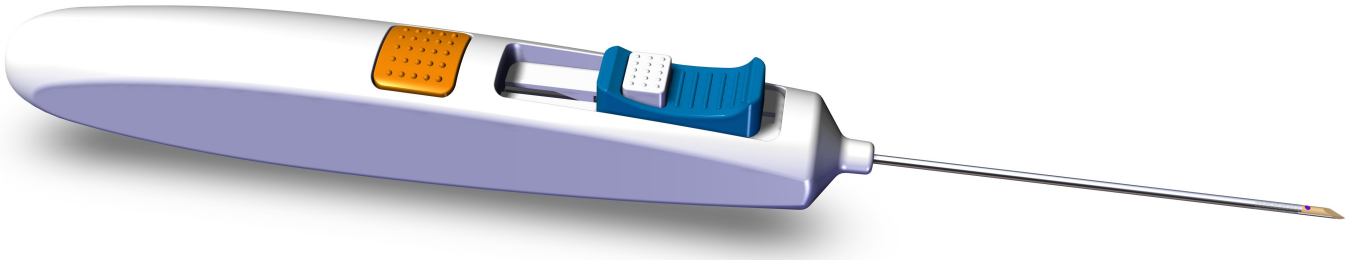
- I am a consultant for VCD Medical
- VCD device is under development and not approved for clinical use

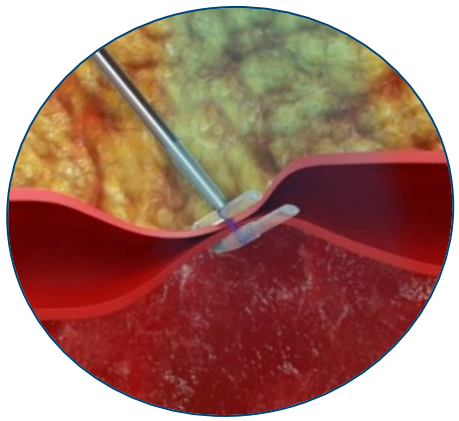
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THE TECHNOLOGY

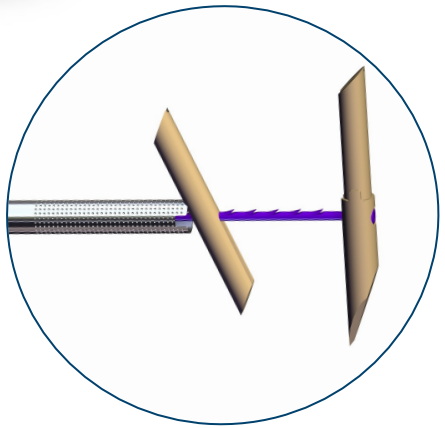
VCD device is intended for **selective closure of superficial veins** through **percutaneous access** under **Ultrasound guidance**.

VCD delivers two **bioabsorbable clips** preloaded in a metallic cannula.





Selective vessel closure through VCD clips.



Bioabsorbable clips and suture

Device Feature	Specification
Clip length	13 mm (0.5”)
Clip material	PLGA
Stainless steel cannula	17 G
PDO suture	2-0 (barbed)
Implant degradation time	6-12 months
Target vein diamter	Up to 11 mm

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HOW IT WORKS



- Percutaneous
- Minimally invasive
- Resorbable
- **Office-based** procedure
- Cost-effective
- **Simple** and **fast** procedure

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STATE OF THE ART

Superficial vein ligation alone or combined with non-thermal treatments

Outcomes of Fluoroscopy-Guided Percutaneous High Ligation of the Great Saphenous Vein Combined With Foam Sclerotherapy for Symptomatic Great Saphenous Veins

Jie Kong, PhD, Zher *J Vasc Interv Radiol 2022; 33:445–450* BS, Guoping Chen, MD, Wensheng Lou, MD, Boxiang Zhao, PhD, Maofeng Gong, MD, Zhaoxuan Lu, MD, Yangyi Zhou, MD, Liang Chen, MD, Haobo Su, PhD, Jianping Gu, MD, and Xu He, MD

Conclusions: Fluoroscopy-guided high-ligation combined with foam sclerotherapy in the GSVs achieved an occlusion rate of 92% and improved the clinical symptoms at 1 yr.

Mini-invasive high-tie by clip apposition versus crossectomy by ligature: Long-term outcomes and review of the available therapeutic options

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Sergio Gianesini, Erica Menegatti, Anna Maria Malagoni, Savino Occhionorelli and Paolo Zamboni

Conclusions: "…proper high-ligation technique provides satisfying outcomes both in terms of recurrence rate and patient aesthetic satisfaction."

Selective crossectomy combined with mechanochemical ablation in the treatment of great saphenous vein insufficiency: Early results of a single center experience

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Anna Petrone[1], Antonio Peluso[1], Raffaele P Ammollo[1], Davide Turchino[1], Luca del Guercio[1], Michele Andreucci[2], Raffaele Serra[3,4] and Umberto M Bracale[1]

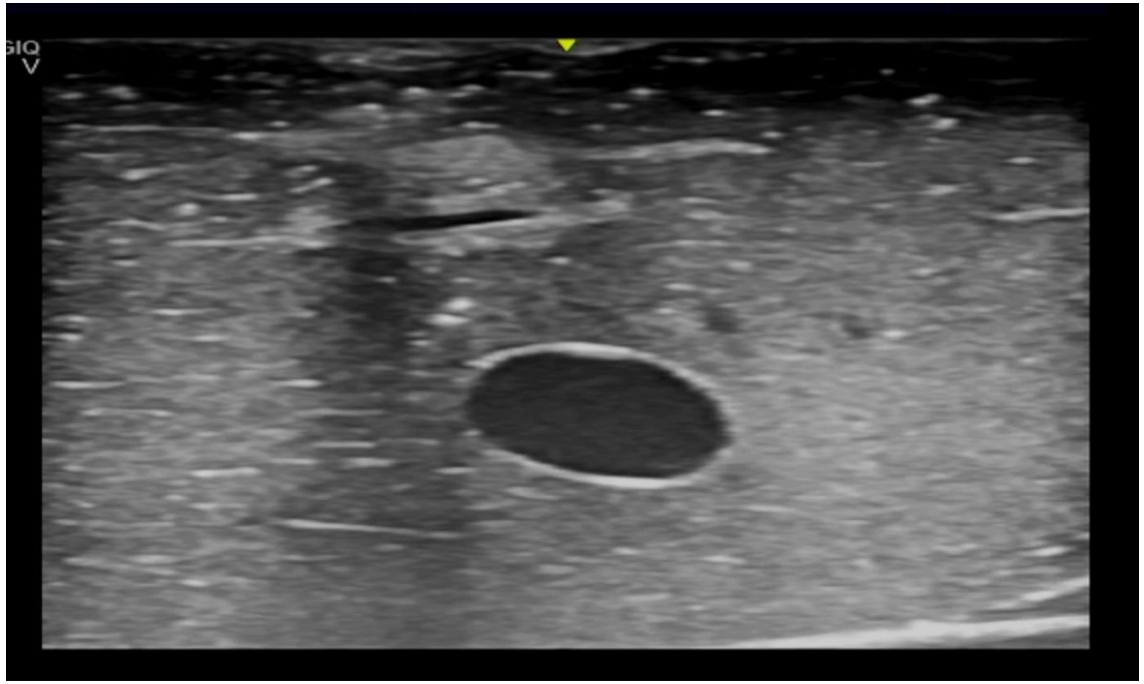
Conclusions: "…the association of crossectomy with MOCA significantly reduces the recanalization rate of GSV, and it is also characterized by a higher free survival from recurrence (SS) than with MOCA alone

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PRE-CLINICAL TEST (ex-vivo)

Ex-vivo bench testing on explanted liver flushed with saline at 37°C

- Clips deployment closing vessels up to **11 mm**
- **Vessel closures** using **VCD clips standalone,** or combined with **foam sclerosant** or **cyanoacrylate glue** injection



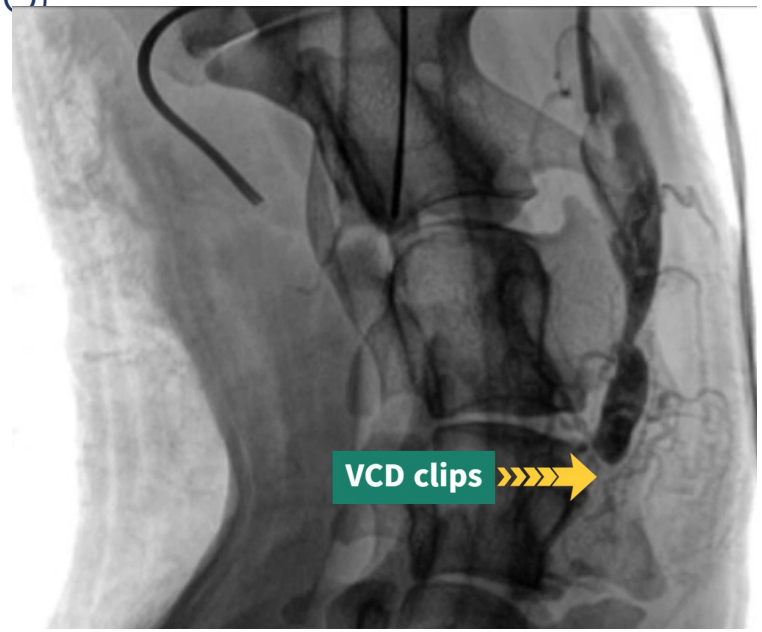
PRE-CLINICAL TEST (in-vivo)

CRABCC, Italy

In-vivo sheep study (1 month f/u) - angiographic results

Left jugular vein

- Percutaneous clipping of left vein (13 mm, 20 mmHg)
- Foam injection via 5F sheath (3% Polidocanol, VARIXIO)



Left jugular vein treated with clips + foam at *1 month f/u*

Right jugular vein (control)

- 3 min manual compression of right vein (12 mm, 18 mmHg)
- Foam injection via 5F sheath (3% Polidocanol, VARIXIO)



Right jugular vein treated 3' manual compression + foam at *1 month f/u*

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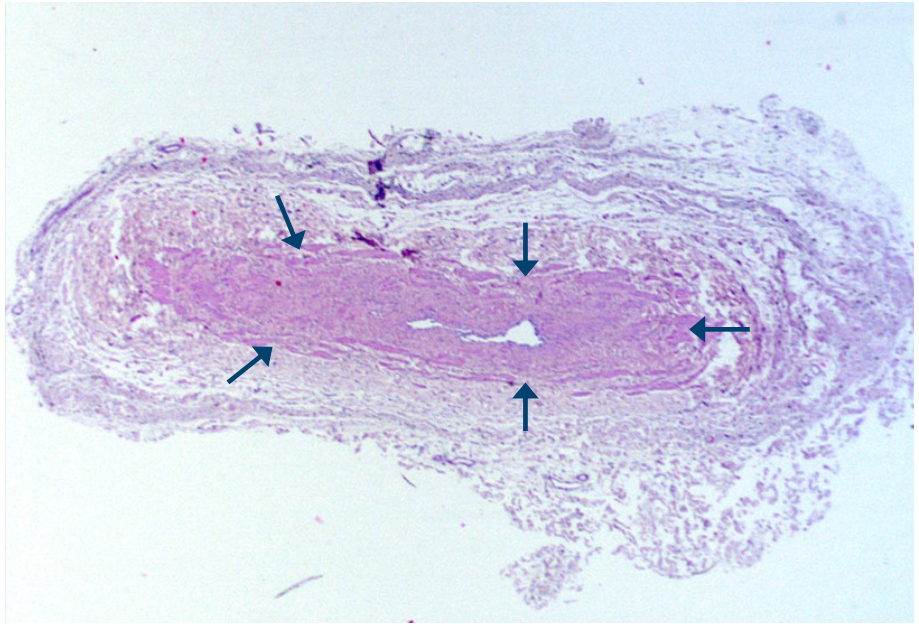
PRE-CLINICAL TEST (in-vivo)

MapLab, University of Milan, Italy

In-vivo sheep study (1 month f/u) - histology

Left jugular vein

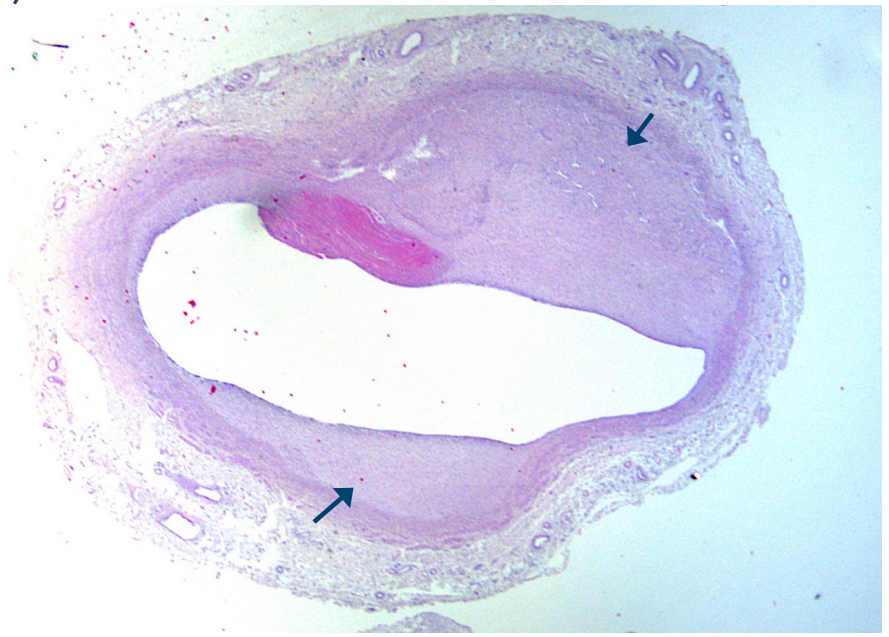
Complete stenosis and fibrosis all around the circumferential section (blue arrows)



Left jugular vein treated with clips + foam at *1 month f/u*

Right jugular vein (control) at the explant

Normal lumen, **mild** fibrosis in limited areas (blue arrows)



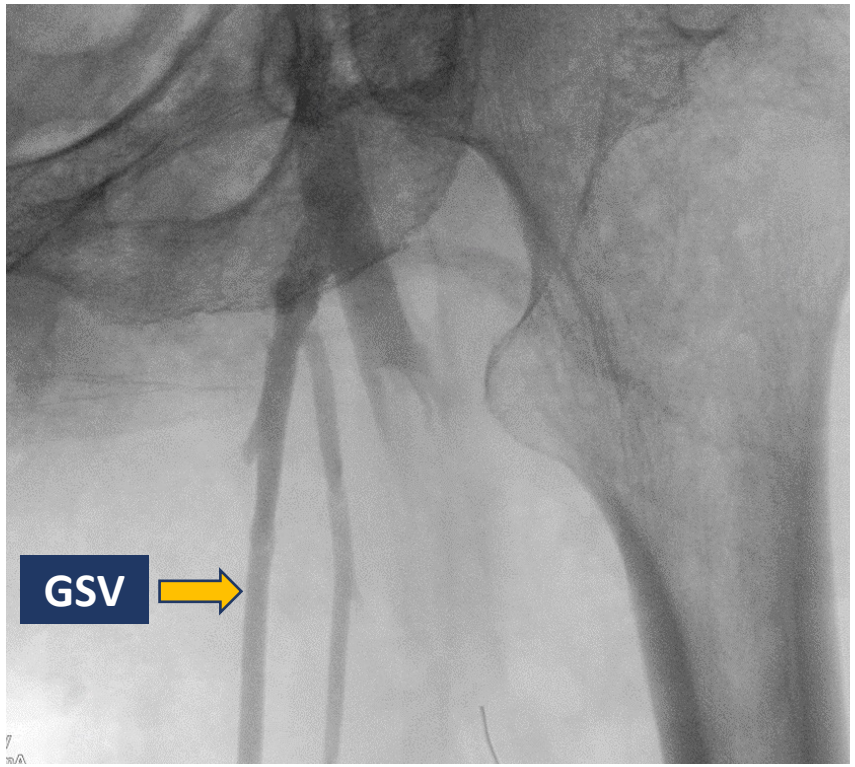
Right jugular vein treated with manual compression + foam at *1 month f/u*

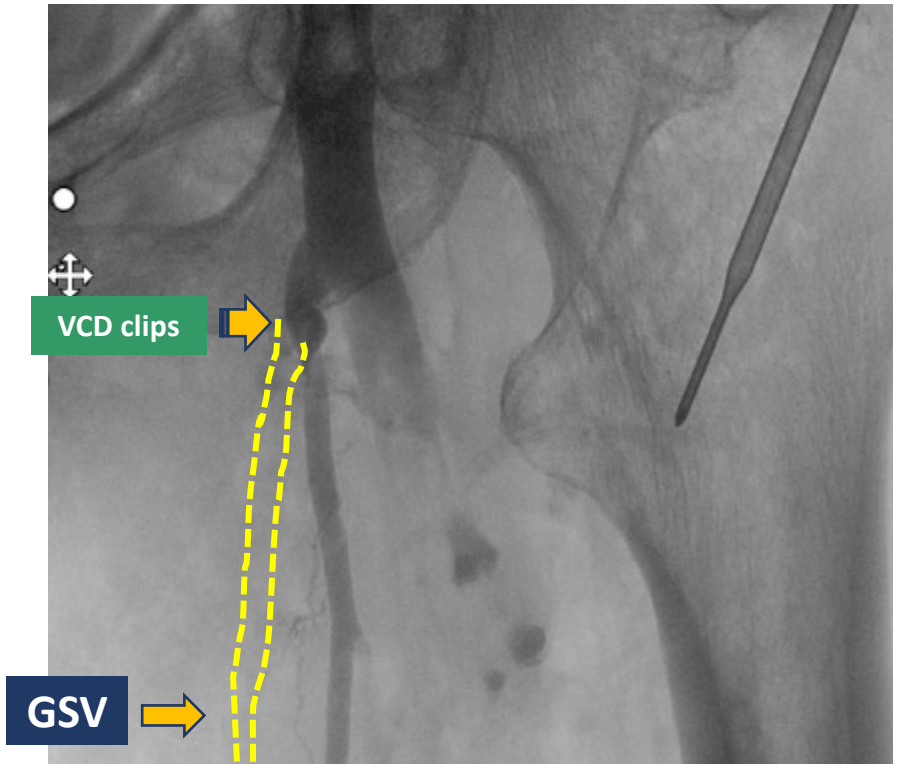
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PRE-CLINICAL TEST (cadaver)

Test in cadaver flushed with saline at 37°C

- **Vessel closures** using **VCD clips standalone,** or combined with **cyanoacrylate glue** (VenaSeal, Medtronic)





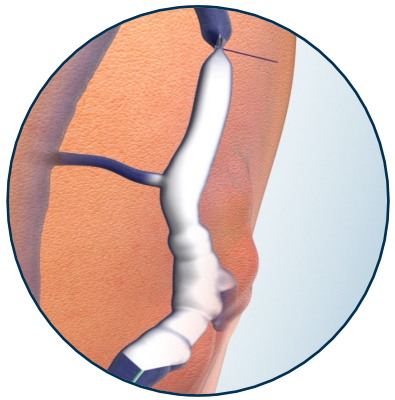
Courtesy of Dr. Steven Kum, Changi Hospital, Singapore

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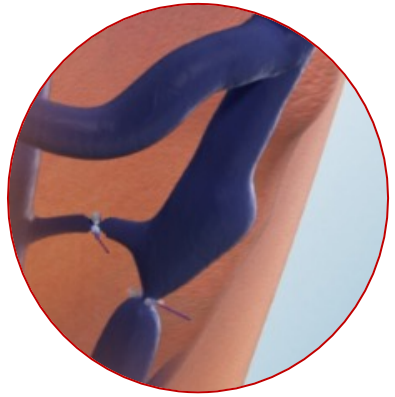
TARGET APPLICATIONS IN SUPERFICIAL VENOUS DISEASE

How I would use the device in my daily practice





In combination with **non-thermal techniques** to **maximize effectiveness** and **minimize thromboembolic risk** in treating **GSV, SSV, recurrent reflux, tortuosity, neovascularization**



Stand-alone treatment for **extra-saphenic** and **perforator veins, above** and **below the knee**

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FUTURE DEVELOPMENTS

Work in progress…

- FIH safety and feasibility trial by end ‘23
- First regulatory approval expected 2024
- Expand target indications
- Any suggestions?

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THANK YOU