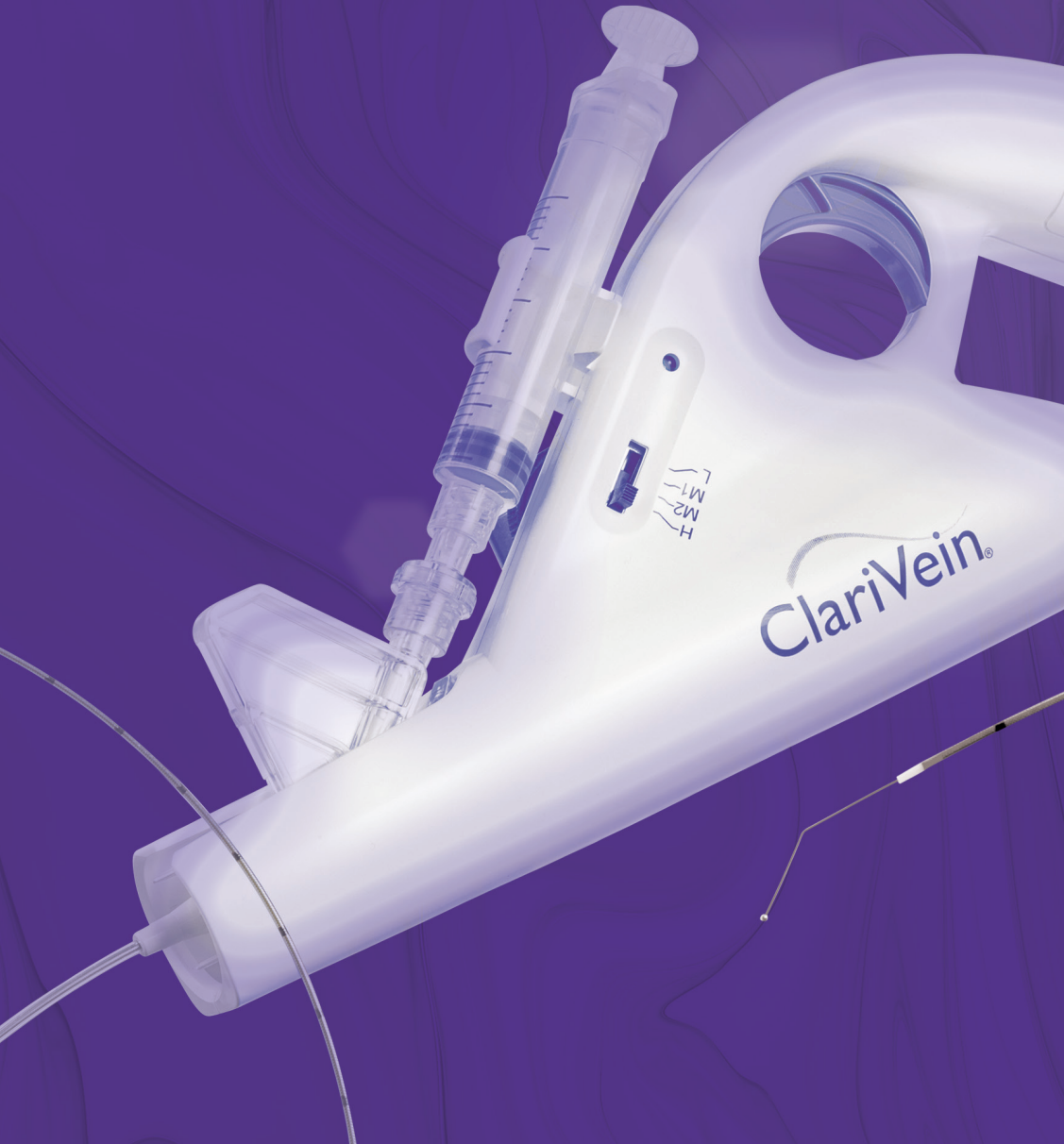


# ClariVein<sup>®</sup> OC Literature Table



# ClariVein® OC – Literature

## Author / Journal / Title

Mirandola, M, Griso, A, Migliara, B, Cappellari, T, F, Giovannini, F and Lino, M

## Journal of Vascular Surgery

*“An Italian experience with mechanochemical ablation of the saphenous vein since 2012”*

## Conclusion

“MOCA in our experience is safe and effective. Nonthermal options promise comparable treatment efficacy without the added morbidity associated with high thermal energies. The potential of treating venous reflux in a faster way without tumescent anesthesia may change the approach to superficial venous disease in the near future, which could truly be an office treatment.”

## Country

Italy

## Design

retrospective single-centre study of data collected prospectively

## Sclerosant

polidocanol 2%

## Patients (Limbs)

329 patients

## GSV/SSV

GSV and SSV

## Follow up

1 week, 1 month, 6 months, and 1 year and then once every year

## Occlusion rates

94% at 1 year, 91% at 2 years, 88% at 3 years, 88% at 4 years, and 84% at 5 years

# ClariVein® OC – Literature

## Author / Journal / Title

Epstein D, Onida S, Bootun R, Ortega M, and Davies AH. (2018)

## Value in Health

*“Cost-Effectiveness of Current and Emerging Treatments of Varicose Veins”*

## Conclusion

“At a threshold of £20,000/QALY, RFA was the treatment with highest median rank for net benefit, **with MOCA second**, EVLA third, HL/S fourth, CAE fifth, and CONS and UGFS sixth. Further evidence on effectiveness and health-related quality of life for MOCA and CAE is needed. At current prices, CAE is not a cost-effective option because it is costlier but has not been shown to be more effective than other options.”

## Country

Spain and UK

## Design

Systemic Review

## Sclerosant

-

## Patients (Limbs)

-

## GSV/SSV

-

## Follow up

-

## Occlusion rates

-

# ClariVein® OC – Literature

## Author / Journal / Title

Ramon R, van Eekeren RR, Boersma D, Holewijn S, Werson D, de Vries JP, and Reijnen MM. (2014)

## Journal of Vascular Surgery

*“Mechanochemical endovenous ablation for the treatment of great saphenous vein insufficiency”*

## Conclusion

“MOCA is a safe and effective technique in the treatment of GSV insufficiency with good **clinical and anatomic success at 1-year follow-up. The technique is related to low postprocedural pain scores, low complication rate, improved quality of life, and rapid resumption of normal activities and work.**”

## Country

The Netherlands

## Design

Multicenter,  
prospective,  
observational

## Scerosant

2% POL  
(proximal 10 cm)

1.5% POL  
(remainder of vein)

## Patients (Limbs)

92 (106)

## GSV/SSV

GSV

## Follow up

1 year

## Occlusion rates

92% at 1 year

# ClariVein® OC – Literature

## Author / Journal / Title

Witte ME, De Vries JP, Reijnen MM, Zeebregts CJ. (2017)

### Journal of Endovascular Therapy

*“Midterm Outcome of Mechanochemical Endovenous Ablation for the Treatment of Great Saphenous Vein Insufficiency”*

## Conclusion

“This study shows **MOCA to be an effective treatment modality for GSV insufficiency at midterm follow-up**, but clinical results seem to drop over time.”

## Country

-

## Design

-

## Sclerosant

-

## Patients (Limbs)

-

## GSV/SSV

-

## Follow up

3 years

## Occlusion rates

90% at 2 years

87% at 3 years

# ClariVein® OC – Literature

## Author / Journal / Title

Kim SY, Safir S, Maximilian Png, BS, Faries PL, Ting W, Vouyouka AG, Marin ML, and Tadros RO. (2019)

## Journal of Vascular Surgery

*“Mechanochemical ablation as an alternative to venous ulcer healing compared with thermal ablation”*

## Conclusion

**“MOCA is safe and effective in treating chronic venous ulcers and appears to provide comparable results to methods that rely on thermal ablation.** Younger age and use of MOCA favored wound healing. **MOCA was an independent predictor of ulcer healing.** Randomized studies are necessary to further support our findings.”

## Country

USA

## Design

Monocenter, retrospective, matched cohort

## Sclerosant

1.5% POL or 1.5% STS

## Patients (Limbs)

66 (82)  
53 MOCA  
29 Thermal

## GSV/SSV

GSV  
SSV  
Perforators

## Follow up

1 year

## Occlusion rates

Ulceration healing post  
MOCA: 2.3 months

Ulceration healing post  
thermal: 4.4 months

# ClariVein® OC – Literature

## Author / Journal / Title

Khor SN, Lei J, Kam JW, Kum S, Tan YK, Tang TY. (2018)

## Phlebology

*“ClariVein - One year results of mechano-chemical ablation for varicose veins in a multi-ethnic Asian population from Singapore”*

## Conclusion

**“Early results are similar to what is described so far in the mechano-chemical ablation literature** but recurrences are more than expected at one year. This is disappointing but is tempered by the fact **that the majority of patients were asymptomatic and required no reintervention”**

## Country

Singapore

## Design

Monocenter, prospective, observational

## Sclerosant

2% STS

## Patients (Limbs)

121

## GSV/SSV

GSV  
SSV

## Follow up

1 year  
(duplex)

## Occlusion rates

90%-96% at 3 months  
87%-91% at 6 months  
84%-94% at 1 year

# ClariVein® OC – Literature

## Author / Journal / Title

Kugler NW and Brown KR. (2017)

### Journal of Vascular Surgery

*"An update on the currently available nonthermal ablative options in the management of superficial venous disease"*

## Conclusion

**"Advances in nonthermal ablative techniques have led to a developing role and acceptance in the primary management of varicose veins and venous insufficiency, even in the setting of challenging cases"**

## Country

USA

## Design

Systematic Literature Review

## Sclerosant

21

## Patients (Limbs)

## GSV/SSV

## Follow up

## Occlusion rates

1 year:

RFA 85%-98%

EVLA 89%-100%

Endovenous Foam 67%-93%

ClariVein 88%-97%

Venaseal 92%-93%

2 years:

RFA 85%-96%

EVLA 74%-97%

Endovenous Foam 53%-97%

ClariVein 96%-97%

Venaseal 92%

The logo for ClariVein.OC features a stylized red and purple wave above the text "ClariVein.OC" in a purple serif font.



# ClariVein® OC – Literature

## Author / Journal / Title

Bishawi M, Bernstein R, Boter M, Draughn D, Gould CF, Hamilton C and Koziarski L. (2014)

### Phlebology

*“Mechanochemical ablation for symptomatic great saphenous vein reflux: A two-year follow-up”*

## Conclusion

**“MOCA of the saphenous veins has the advantage of endovenous ablation without tumescent anesthesia, making it an almost pain-free procedure. High occlusion rates with significant clinical improvement can be achieved with this method at short term.”**

## Country

UK

## Design

Multicenter, prospective, observational

## Sclerosant

1.5% POL or 1.5% STS

## Patients (Limbs)

126

## GSV/SSV

GSV

## Follow up

6 months

## Occlusion rates

100% at 1 week

98% at 3 months

94% at 6 months

# ClariVein® OC – Literature

## Author / Journal / Title

Kim SY, Marin M, Ting W, Faries P, Vouyouka A, Yi Png C, Tadros R. (2016)

## Phlebology

*“Mechanochemical ablation for symptomatic great saphenous vein reflux: A two-year follow-up”*

## Conclusion

**“Early high occlusion rate with mechanochemical ablation is associated with significant clinical improvement which is maintained at 24 months, making it a very good option for the treatment of great saphenous vein incompetence.”**

## Country

-

## Design

-

## Sclerosant

-

## Patients (Limbs)

-

## GSV/SSV

-

## Follow up

2 years

## Occlusion rates

95% at 1 year

92% at 2 years

# ClariVein® OC – Literature

## Author / Journal / Title

Bootun R, Lane TR, Dharmarajah B, Lim CS, Najem M, Renton S, Sritharan K, Davies AH. (2016)

## Phlebology

*“Intra-procedural pain score in a randomised controlled trial comparing mechanochemical ablation to radiofrequency ablation: The Multi-centre Venefit™ versus ClariVein® for varicose veins trial”*

## Conclusion

“Early results show that the **mechanochemical ablation is less painful than the radiofrequency ablation procedure**. Clinical and quality of life scores were similarly improved at one month.”

## Country

UK

## Design

Multicenter, randomized, controlled trial, MOCA vs RFA

## Sclerosant

2% STS

## Patients (Limbs)

165

83 MOCA

82 RFA

## GSV/SSV

GSV

## Follow up

1 month

## Occlusion rates

MOCA 92% at 1 month

RFA 92% at 1 month

# ClariVein® OC – Literature

## Author / Journal / Title

Lane TR, Bootun R, Dharmarajah B, Lim SC, Najem M, Renton S, Sritharan K, and Davies AH. (2016)

## Phlebology

*"A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins - Final results of the Venefit versus ClariVein for varicose veins trial"*

## Conclusion

**"Pain secondary to truncal ablation is less painful with MOCA than RFA with similar short-term technical, quality of life and safety outcomes."**

## Country

UK

## Design

Multicenter, randomized, controlled trial, MOCA vs RFA

## Sclerosant

2% STS

## Patients (Limbs)

165

83 MOCA

82 RFA

## GSV/SSV

GSV

## Follow up

6 months

## Occlusion rates

There was no significant difference in occlusion rates at one month or six months.

# ClariVein® OC – Literature

## Author / Journal / Title

Tang TY, Kam JW, and Gaunt ME. (2016)

### Phlebology

*“ClariVein - Early results from a large single-centre series of mechanochemical endovenous ablation for varicose veins”*

## Conclusion

**“ClariVein can be used to ablate long and short saphenous varicose veins** on a walk-in–walk-out basis. **Bilateral procedures can be successfully performed, and these are well tolerated as can multiple veins in the same leg.** Early results are promising but further evaluation and longer term follow-up are required.”

## Country

UK

## Design

Monocenter,  
prospective,  
observational

## Sclerosant

2% STS

## Patients (Limbs)

300 (371)

## GSV/SSV

GSV

SSV

## Follow up

8 weeks

(duplex)

## Occlusion rates

97% GSV at 8 weeks

100% SSV at 8 weeks

The logo for ClariVein.OC features a stylized red and purple wave above the text "ClariVein.OC" in a purple sans-serif font.

# ClariVein® OC – Literature

## Author / Journal / Title

Witte ME, Reijnen MM, de Vries JP, Zeebregts CJ. (2015)

## Surgical Technology International

*“Mechanochemical Endovenous Occlusion of Varicose Veins Using the ClariVein Device”*

## Conclusion

**“Mechanochemical occlusion using Clari-Vein® has proven to be safe and effective and has several advantages compared to endothermal techniques. The possibility of retrograde ablation of distal SSV insufficiency in C6 ulceration is considered a significant advantage.**

Randomized comparative studies with long-term follow up will continue to define the definite place of mechanochemical occlusion.”

**“Sustained quality of life improvement. Significantly less postoperative pain and earlier return to normal activities with ClariVein”**

## Country

The Netherlands

## Design

Systematic Literature Review

## Sclerosant

## Patients (Limbs)

## GSV/SSV

-

## Follow up

-

## Occlusion rates

MOCA is comparable to endothermal techniques

# ClariVein® OC – Literature

## Author / Journal / Title

Deijen CL, Schreve MA, Bosma J, de Nie AJ, Leijdekkers VJ, van den Akker PJ, Vahl A. (2015)

## Phlebology

*“Clarivein mechanochemical ablation of the great and small saphenous vein: Early treatment outcomes of two hospitals”*

## Conclusion

**“The Clarivein device proves to be safe and had a high short-term technical effectiveness”**

## Country

The Netherlands

## Design

Multicenter, prospective, observational

## Sclerosant

2% or 1.5% POL

## Patients (Limbs)

449 (570)

## GSV/SSV

GSV

SSV

## Follow up

3 months

## Occlusion rates

90%

# ClariVein® OC – Literature

## Author / Journal / Title

Stanisić MG, Węgrzynowski A,  
Pawlaczyk-Gabriel K. (2015)

## Phlebological Review

*“One-year results of fifty consecutive patients treated with mechanochemical ablation of great and small saphenous vein”*

## Conclusion

**“MOCA using the ClariVein device is a safe method for ablation of incompetent truncal veins in patients who prefer to be managed quickly, without pain and with satisfactory results after 1 year.”**

## Country

Poland

## Design

Multicenter,  
prospective,  
observational

## Sclerosant

2% POL or 2% STS

## Patients (Limbs)

50 (60)

## GSV/SSV

GSV  
SSV

## Follow up

1 year

## Occlusion rates

93%



# ClariVein® OC – Literature

## Author / Journal / Title

Vun SV, Rashid ST, Blest NC and Spark JI.(2014)

## Phlebology

*“Lower pain and faster treatment with mechanico-chemical endovenous ablation using ClariVein”*

## Conclusion

**“Mechanochemical ablation with the Clari-Vein system is safe and effective.**

After some initial failures, >90% which accords with the limited published literature.

**Pro-cedure times and pain scores are significantly better than for RFA and EVLT.**

We await the longterm clinical outcomes.”

## Country

Australia

## Design

Monocenter,  
prospective,  
observational

## Sclerosant

1.5% STS

## Patients (Limbs)

55

## GSV/SSV

GSV

SSV

## Follow up

6-weeks

(duplex)

## Occlusion rates

91%

# ClariVein® OC – Literature

## Author / Journal / Title

Özen Y, Çekmecelioglu D, Sarikaya S, Rabus MB, Aydın E, Dedemoglua M, Kirali K. (2014)

### Damar Cer Derg

*“Mechano-Chemical Endovenous Ablation of Great Saphenous Vein Insufficiency: Two-Year Results”*

## Conclusion

**“ClariVein is a simple, reliable, and efficient treatment method for GSV insufficiency. In 2-year follow-up, the anatomical success rate was found as 95%, and no major complications were observed.”**

## Country

Turkey

## Design

Monocenter,  
prospective,  
observational

## Sclerosant

2% POL

## Patients (Limbs)

63 (73)

## GSV/SSV

GSV

## Follow up

6 months

1 year

2 years

## Occlusion rates

94% at 6 months

95% at 1 year

95% at 2 years

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# ClariVein® OC – Literature

## Author / Journal / Title

van Eekeren RR, Boersma D, Konijn V, de Vries JP, Reijnen MM. (2013)

## Journal of Vascular Surgery

*“Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins”*

## Conclusion

**“MOCA is associated with significantly less postoperative pain, faster recovery, and earlier work resumption compared with RFA in the treatment of GSV incompetence. MOCA and RFA are both related to a rapid improvement in quality of life.”**

## Country

The Netherlands

## Design

Multicenter, prospective, observational, MOCA vs RFA (non-randomized)

## Sclerosant

2% or 1.5% POL

## Patients (Limbs)

68

34 MOCA

34 RFA

(non-randomized)

## GSV/SSV

GSV

## Follow up

6 weeks

## Occlusion rates

-

# ClariVein® OC – Literature

## Author / Journal / Title

Sullivan LP, Quach G and Chapman T.  
(2013)

### Phlebology

*“Retrograde mechanico-chemical endovenous ab-lation of nfrageniculate great saphenous vein for persistent venous stasis ulcers”*

## Conclusion

**“Mechanico-chemical endovenous ablation can be safe and effective in the treatment of patients with below the knee great saphe-nous vein insufficiency with venous ulcers.”**

MOCA can be delivered directly to the veins feeding the ulcer.

## Country

USA

## Design

Multicenter, prospective, observational

## Sclerosant

Sclerosant

## Patients (Limbs)

6 (patients with persistent venous ulcers following above the knee GSV ablation)

## GSV/SSV

Below the knee-GSV

## Follow up

3 months  
After Ulcer healed

## Occlusion rates

Average ulcer healing time was  $28 \pm 11$  days, compared with a mean of 5 months under traditional methods.

# ClariVein® OC – Literature

## Author / Journal / Title

Moore HM, Lane TRA, Franklin IJ and Davies AH. (2013)

### Vascular

*“Retrograde mechanochemical ablation of the small saphenous vein for the treatment of a venous ulcer”*

## Conclusion

“This report highlights that **patients with small saphenous vein incompetence and active ulceration can be treated suc-cessfully with retrograde mechanochemical ablation.**”

## Country

UK

## Design

Case Report

## Sclerosant

2% STS

## Patients (Limbs)

1 (previously non healing ulcer, 4cm diameter)

## GSV/SSV

SSV

## Follow up

3 months

## Occlusion rates

Following MOCA ulcer size decreased to 3mm with evidence of granulating tissue at the base. VCSS score decreased from 16 to 12. Occluded SSV and competent deep system.

# ClariVein® OC – Literature

## Author / Journal / Title

Boersma D, van Eekeren RR, Werson DA, van der Waal RI, Reijnen MM, de Vries JP. (2012)

### European Journal of Vasc and Endovasc Surgery

*“Mechanochemical Endovenous Ablation of Small Saphenous Vein Insufficiency Using*

## Conclusion

**“MOCA is a safe, feasible and efficacious technique for treatment of SSV insufficiency. One-year follow-up** shows a 94% anatomic success rate and no major complications.”

## Country

The Netherlands

## Design

Multicenter, prospective, observational

## Scerosant

2% or 1.5% POL

## Patients (Limbs)

50

## GSV/SSV

SSV

## Follow up

1 year

## Occlusion rates

94%

# ClariVein® OC – Literature

## Author / Journal / Title

Elias and Raines (2012)

### Phlebology

*"Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial"*

## Conclusion

"Mechanochemical ablation appears to be safe and efficacious. **The ClariVein technique eliminates the need for tumes-cent anaesthesia. The great majority of incompetent GSVs can be treated with this technique.**"

## Country

USA

## Design

Monocenter,  
prospective,  
observational

## Sclerosant

1.5% STS

## Patients (Limbs)

29 (30)

## GSV/SSV

GSV

## Follow up

6 months

## Occlusion rates

96%

# ClariVein® OC – Literature

## Author / Journal / Title

Boersma D, van Eekeren RR, Kelder HJ, Werson DA, Holewijn S, Schreve MA, Reijnen MM, de Vries JP. (2014)

## Trials

*“Mechanochemical endovenous ablation ver-sus radiofrequency ablation in the treatment of primary small saphenous vein insufficiency (MESSI trial): study protocol for a randomized controlled trial”*

## Conclusion

“The hypothesis of the **MESSI trial** is that the anatomic success rate of MOCA™ is not inferior to RFA. The second hypothesis is that **post-procedural pain is significantly less after MOCA compared to RFA.**”

## Country

The Netherlands

## Design

Multicenter, randomized, controlled trial

## Scerosant

3% POL  
(proximal 10-15cm)

1.5% POL  
(remainder of vein)

## Patients (Limbs)

160  
MOCA vs RFA (1:1)

## GSV/SSV

SSV

## Follow up

1 month  
1, 2, 3, 4, 5 years

## Occlusion rates

-



# ClariVein® OC – Literature

## Author / Journal / Title

Leung CCM, Carradice D, Wallace T and Chetter IC. (2016)

## Trials

*“Endovenous laser ablation versus mechanochemical ablation with ClariVein® in the management of superficial venous insufficiency (LAMA trial): study protocol for a randomised controlled trial”*

## Conclusion

**“The aim of the LAMA trial is to establish whether MOCA is superior to the current first-line treatment, EVLA. The two main hypotheses are that MOCA may cause less initial pain and disability** allowing a more acceptable treatment with an enhanced reco-very. The second hypothesis is that this may come at a cost of decreased efficacy, which may lead to increased recurrence and affect longer term quality of life, increasing the requirement for secondary procedures.”

## Country

UK

## Design

Multicenter,  
randomized,  
controlled trial

## Sclerosant

1.5% STS

## Patients (Limbs)

140

MOCA vs EVLA (1:1)

## GSV/SSV

GSV

## Follow up

1,6 weeks

6 months

1 year

## Occlusion rates

-