American Vein and Lymphatic Society
formerly the American College of Phlebology

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Position Statement
Healthcare Policy Committee
Mechanochemical Venous Ablation

Revised: January 7, 2019

Introduction

Historically, treatment options for patients with venous insufficiency and varicose veins primarily consisted of high ligation and stripping of the great saphenous vein (GSV) in association with phlebectomy of individual varicosities. During the past 18 years, such painful interventions, which required general anesthesia along with several days in the hospital and weeks of recuperation, have been supplanted by outpatient office-based endovascular ablation techniques with conscious sedation and/or local anesthesia and an almost immediate return to normal activities of daily living. Such endovascular treatment of venous disease has been primarily performed with thermally-based radiofrequency or laser ablation that require percutaneous, perivenous tumescent anesthesia. They are superior to high ligation and stripping and are recommended by published multi-society guidelines for the treatment of the incompetent superficial axial incompetent veins (GSV, SS, AASV etc.) [Gloviczki P et al. ***The care of patients with varicose veins and associated chronic venous diseases: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum***. *J Vasc Surg.* 2011;53(5 suppl):2S-48S] With these approaches, patients achieve excellent vein occlusion rates and more importantly improved quality of life for years after intervention. Newer approaches seek to improve upon these currently available methods by achieving similar clinical outcomes without thermal energy and thus obviate the need for tumescent anesthesia. Elimination of tumescent anesthesia results in less intraoperative pain, no risk of nerve injury and minimal skin damage. The opportunity for physicians to have a choice of treatment options in order to choose the one that is optimal for an individual patient will result in the best outcomes in the treatment of venous insufficiency and varicose veins.

Mechanochemical ablation (MOCA; ClariVein)

Mechanochemical ablation (MOCA) is an endovenous technique that treats superficial axial vein reflux (GSV, SSV, AASV etc.) The mechanism of action is two-fold: A rotating wire breaks down the surface tension between blood and vein wall and the instillation of a liquid sclerosant allows better penetration into the vein wall to cause damage to the media of the vein wall. This medial damage has been shown to lead to effective vein closure in thermal endovenous techniques. Since this ablation method does not use thermal energy, the potential for nerve and skin damage is minimized.

After percutaneous ultrasound-guided access into the target vein, a disposable catheter connected to a disposable motor drive is inserted and advanced to 2 centimeters from the junction of the target vein and the deep vein (SFJ or SPJ). As the catheter is slowly pulled back, a wire rotates at 3500 rpm within the lumen of the vein. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It has been demonstrated that the combination of the mechanical and chemical effect results in vein closure better than either method alone and equal to occlusion rates of standard thermal techniques. The closure occurs without the need for the tumescent anesthesia used with thermal endovenous ablation techniques (radiofrequency ablation [RFA] and endovenous laser treatment [EVLT]).

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MOCA (Clarivein) is an FDA-approved nonthermal, nontumescent ablation system used in GSV, SSV (small saphenous vein) and below-the- knee in smaller vein segments where risk of nerve injury is higher using thermal techniques. Clinical data for ablation procedures with MOCA include prospective and retrospective studies – some RCTs and some observational – that demonstrated the clinical equivalence in occlusion rates (short- and long-term) to radiofrequency and laser ablation occlusion rates, as well as reduction in validated scores of pain (Visual Analog Scale), symptomology (Venous Clinical Severity Score), and days until return to normal function and most importantly, return to work. In January 2017 CPT codes were added to specifically describe MOCA: 36473, 36474.

- **Date for First in Human Use**

  February 2009
  Steve Elias, MD
  Englewood Hospital and Medical Center
  Englewood, NJ

- **Number of peer-reviewed articles on the technique**

  15 Total Peer Reviewed Publications
  - 2- 1 year follow-up
  - 2- 2 year follow-up
  - 1- 3 year follow-up

- **Summary of pivotal study**

  - In 2008, the ClariVein® Infusion Catheter (Vascular Insights) was cleared by FDA through the 510(k) process (K071468) for mechanochemical ablation. FDA determined that this device was substantially equivalent to the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796).

  - The ClariVein® IC is an infusion catheter system designed to introduce physician specified medicants into the peripheral vasculature. Infusion is through an opening at the distal end of the catheter and fluid delivery is enhanced by the use of a rotating dispersion wire to mix and disperse the infused fluid in the blood stream and on the vessel wall.

  - The study used to demonstrate equivalency in the 510(k) process is:

    - Elias, S, and J K Raines. "*Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial*." Phlebology: The Journal of Venous Disease, vol. 27, no. 2, 2011, pp. 67–72., doi:10.1258/phleb.2011.010100. PMID: 21803800.

  - Objective: The purpose of this study was to assess the safety and efficacy of the ClariVein system that employs mechanochemical ablation of the great saphenous vein (GSV). Method: Patients eligible for ablation of the GSV underwent micropuncture access with only local anesthesia to insert a 4 or 5 Fr sheath. The

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ClariVein catheter was placed through the sheath, the wire was extruded, and the distal tip of the wire positioned 2 cm from the saphenofemoral junction under ultrasound guidance. Catheter wire rotation was then activated for 2–3 seconds at approximately 3500 rpm. With the wire rotating, infusion of the sclerosant was started simultaneously with catheter pullback. The sclerosant used was 1.5% liquid sodium tetradecyl sulphate (Sotradecol#, Bioniche Pharma Group, Geneva, Switzerland).

- Results: Thirty GSVs in 29 patients were treated. All patients have reached six-month follow-up; the average number of postoperative days is 260. No adverse events have been reported. The Primary Closure Rate is 96.7%.

- Conclusion: Mechanochemical ablation appears to be safe and efficacious. The ClariVein technique eliminates the need for tumescent anesthesia. The great majority of incompetent GSVs can be treated with this technique.

Other supporting publications include a randomized controlled trial for treatment of the refluxing great saphenous vein (GSV), comparing MOCA with radiofrequency ablation procedure that has been approved by the FDA since 2000 (Bootun et al). Several additional publications also support the safety and high rate of success of MOCA, similar to that following thermal ablation. Below are summaries of some of the highlights of this literature.

a. *Bootun et al.* conducted a randomized, controlled trial to assess intra-operative pain between MOCA and RFA in 117 patients/119 limbs (MOCA: 59; RFA: 60). Pain scores were measured using a validated 100 mm visual analogue scale (VAS) with mean maximum results being 19.3 mm for MOCA and 34.5 mm for RFA. The study demonstrated less intra-procedural pain for MOCA with equivalent improvement in clinical and patient-reported quality of life measures at one month with similar occlusion rates as documented by Duplex US. MOCA showed a faster return-to work and normal activities. MOCA was associated with no adverse events, while RFA patients had a 3.4 percent incidence of thrombophlebitis and 1.7 percent incidence of non-occlusive popliteal vein deep vein thrombosis.

b. A number of comparative trials and prospective cohort studies have drawn similar conclusions. Among these studies was one by *Ozen* which looked at the 2-year results for MOCA treatment of the refluxing great saphenous vein. At that time interval, the saphenous occlusion rate was 95 percent, which was seen along with a significant decrease in a physician derived score of the severity of venous disease in the treated limb (Venous clinical severity score or VCSS).

c. *Boeersma* demonstrated the safety and efficacy of MOCA in the small saphenous vein as well, with a 94 percent 1-year occlusion of the treated vein with no major complications and decrease in the VCSS and patient reported pain score.

d. *Vun et al.* assessed procedural pain for MOCA, RFA and endovenous laser ablation (EVLA) in 127 patients/147 veins (MOCA: 57; RFA: 50; EVLA: 40). Pain scores were collected by a nurse, blinded to the procedure, using VAS. Median pain scores were as follows: MOCA-1, RFA-5, EVLA-6. Technical success as evidenced by occlusion was similar for all three modalities with no major complications reported.

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e. *Van Eekeren et al.* studied postoperative pain and early quality of life after RFA and MOCA in 68 patients (34 to each group). Occlusion rates were over 90 percent in each group. Pain was assessed with a 100 mm VAS and found mean procedural pain to be 22 mm for MOCA and 27 mm for RFA. Post-operative pain was measured at days 3 and 14 with MOCA mean pain to be 6.2 mm and 4.8 mm, while RFA mean pain was 20.5 mm and 18.6 mm. This demonstrated a 74 percent comparative reduction in post-operative pain at day 14. RFA patients were shown to use post-operative analgesics for 2.8 days on average compared to 0.5 days for MOCA patients. The median Venous Clinical Severity Score (VCSS) at week six showed a decrease from 3.0 to 1.0 for MOCA, while the RFA group decreased from 4.0 to 3.0. Quality of life outcomes were measured using the Aberdeen Varicose Vein Questionnaire (AVVQ) at 6 weeks and showed a change for the MOCA group from 7.1 to 5.0, and 9.5 to 4.5 in the RFA group. The authors stated that this was not clinically significant. MOCA and RFA patients returned to normal activities in one day, but the RFA group tended to take an extra day before returning to work. There were no major complications in either group.

- **Year of FDA Approval**
  - 2008
- **Number of Units/Patients treated with technology**
  - Over 100,000 in the US
- **Single most important benefit of the technology**
  - As with all NTNT modalities, there is no need for tumescent anesthesia with ClariVein, due to the lack of heat, which also allows safe use below the knee without concern of nerve or tissue damage. In fact, with the 85cm catheter, patients can be treated to the lowest level of reflux with a single access point. Additionally, ClariVein can be used in a retrograde approach to treat below venous ulcer beds, where tumescent anesthesia, heat, and compression are not possible.

Conclusion

Based on current evidence, ClariVein should be allowed and covered in the armamentarium of interventions that venous clinicians can offer to our patients suffering from venous disease. We request carriers provide reimbursement for this procedure when physicians choose to use it to treat their patients. Attached are the clinical data and references to substantiate these recommendations.

- **Bibliography**
  - Bootun R, Lane T, Dharmarajah B, Lim C, Najem M, Renton S, et al. *Intra-procedural pain score in a randomized controlled trial comparing mechanochemical ablation to radiofrequency ablation: The Multicentre Venefit™ versus ClariVein® for varicose veins trial*. Phlebology: The Journal of Venous Disease. 2014May;31(1):61–5. DOI: 10.1177/0268355514551085. Epub 2014 Sep 5. PMID: 25193822.
  - Vun S, Rashid S, Blest N, Spark J. *Lower pain and faster treatment with mechanico-chemical endovenous ablation using ClariVein®.* Phlebology: The Journal of Venous Disease. 2014Aug;30(10):688–92. DOI: 10.1177/0268355514553693. Epub 2014 Oct 8. PMID: 25300311.
  - Bishawi, M, et al. "Mechanochemical abl*ation in patients with chronic venous disease: A prospective multicenter report.*" Phlebology: The Journal of Venous

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Disease, vol. 29, no. 6, Feb. 2013, pp. 397–400., doi:10.1177/0268355513495830. PMID: 23820117.

- Boersma, D., et al. "*Mechanochemical Endovenous Ablation of Small Saphenous Vein Insufficiency Using the ClariVein® Device: One-Year Results of a Prospective Series.*" *European Journal of Vascular and Endovascular Surgery*, vol. 45, no. 3, 2013, pp. 299–303., doi:10.1016/j.ejvs.2012.12.004. PMID: 23312507.
- Deijen CL, Schreve MA, Bosma J, Nie AJD, Leijdekkers VJ, Akker PJVD, et al. *ClariVein mechanochemical ablation of the great and small saphenous vein: Early treatment outcomes of two hospitals.* Phlebology: The Journal of Venous Disease. 2015;31(3):192–7. DOI: 10.1177/0268355515600573. Epub 2015 Aug 24. PMID: 26307590.
- Eekeren RRV, Boersma D, Holewijn S, Werson DA, Vries JPPD, Reijnen MM. *Mechanochemical endovenous ablation for the treatment of great saphenous vein insufficiency*. Journal of Vascular Surgery: Venous and Lymphatic Disorders. 2014;2(3):282–8. DOI: 10.1583/11-3394.1 PMID: 21679070.
- Eekeren RRV, Boersma D, Konijn V, Vries JPPD, Reijnen MM. *Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins*. Journal of Vascular Surgery. 2013;57(2):445–50. DOI: 10.1016/j.jvs.2012.07.049. Epub 2012 Nov 8. PMID: 23141679.
- Elias, S, and J K Raines. "*Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial.*" *Phlebology: The Journal of Venous Disease*, vol. 27, no. 2, 2011, pp. 67–72., doi:10.1258/phleb.2011.010100. PMID: 21803800.
- Kim PS, Bishawi M, Draughn D, Boter M, Gould C, Koziarski J, et al. *Mechanochemical ablation for symptomatic great saphenous vein reflux: A two-year follow-up.* Phlebology: The Journal of Venous Disease. 2016Sep; 32(1):43–8. DOI: 10.1177/0268355515627260. Epub 2016 Jul 9. PMID: 26811425.
- Lane, Tristan, et al. "*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.*" *Phlebology: The Journal of Venous Disease*, vol. 32, no. 2, Sept. 2016, pp. 89–98., doi:10.1177/0268355516651026. PMID: 27221810.
- Özen YCBC, Çekmecelioğlu D, Sarikaya S, Rabuş MB, Aydin E, Dedemoğlu M, et al. *Mechano-Chemical Endovenous Ablation of Great Saphenous Vein Insufficiency: Two-Year Results.* Damar Cerrahi Dergisi. 2014;23(3):176–9. DOI: 10.9739/uvcd.2014-41766.
- Ramon R. J. P. Van Eekeren, Boersma D, Elias S, Holewijn S, Werson DAB, Vries J-PPMD, et al. *Endovenous Mechanochemical Ablation of Great Saphenous Vein Incompetence Using the ClariVein Device: A Safety Study. Journal of Endovascular Therapy.* 2011;18(3):328–34. DOI: 10.1583/11-3394.1. PMID: 21679070.
- Stanisić M-G, Węgrzynowski A, Pawlaczyk-Gabriel K. *One-year results of fifty consecutive patients treated with mechanochemical ablation of great and small saphenous vein.* Phlebological Review. 2015;4:102–5. DOI: 10.5114/pr.2015.59018.
- Tang T, Kam J, Gaunt M. *ClariVein® – Early results from a large single-centre series of mechanochemical endovenous ablation for varicose veins*. Phlebology: The

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Journal of Venous Disease. 2016Sep; 32(1):6–12. DOI: 10.1177/0268355516630154. Epub 2016 Jul 9. PMID: 26908638.

- Van Eekeren Ramon R.J.P. , Boersma Doeke, Elias Steven, Holewijn Suzanne, Werson Debbie A.B., de Vries Jean-Paul P.M., Reijnen Michel M.J.P. *Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins.* J Vasc Surg 2013; 57: 445-50.
- Witte ME, Holewijn S, Eekeren RRV, Vries J-PD, Zeebregts CJ, Reijnen MMPJ. *Midterm Outcome of Mechanochemical Endovenous Ablation for the Treatment of Great Saphenous Vein Insufficiency.* Journal of Endovascular Therapy. 2016; 24(1):149–55. doi: 10.1177/1526602816674455. Epub 2016 Oct 15. PMID: 27742900.