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PROLENE MESH CORSET FUNCTIONAL REPAIR OF SAPHENO-FEMORAL JUNCTION: AN EVOLUTION OF THE EXTERNAL BANDING VALVULOPLASTY.

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ABSTRACT

Chronic venous insufficiency is a fairly common and debilitating problem, affecting over half of the adult population in the western world. Besides being unsightly, patients complain of significant pain, heaviness, tightness, itchiness of the affected leg with prolonged standing. If left untreated, the condition can progress to skin discolouration, ulceration and sclerosing scar formation. Current treatment is mostly aimed at cosmesis and symptoms relief with compression stocking, varicose vein stripping and endovascular ablation, which mainly deals with the dilated varicose veins but not the primary pathology of vavular incompetence. There are several surgeries designed to repair and correct the valvular incompetence but the uptake of these surgeries is poor, partly due to their procedural complexity or availability of specialised exo-stents. We have developed a single innovative technique which we called Prolene mesh corset repair for correcting saphenofemoral junction incompetence and the early results have been promising.

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ABSTRACT
Chronic venous insufficiency is a fairly common and debilitating problem, affecting over half of the adult population in the western world. Besides being unsightly, patients complain of significant pain, heaviness, tightness, itchiness of the affected leg with prolonged standing. If left untreated, the condition can progress to skin discolouration, ulceration and sclerosing scar formation. Current treatment is mostly aimed at cosmesis and symptoms relief with compression stocking, varicose vein stripping and endovascular ablation, which mainly deals with the dilated varicose veins but not the primary pathology of vavular incompetence. There are several surgeries designed to repair and correct the valvular incompetence but the uptake of these surgeries is poor, partly due to their procedural complexity or availability of specialised exo-stents. We have developed a single innovative technique which we called Prolene mesh corset repair for correcting saphenofemoral junction incompetence and the early results have been promising.

Keywords: External valvular banding, Prolene mesh corset repair, Surgical treatment, Venous insufficiency, Varicose veins, Valvuloplasty.

INTRODUCTION
Chronic venous insufficiency (CVI) typically characterised by dilated tortuous superficial veins or varicose veins (VVs) in the lower limb is a common venous disease. It is estimated that over half of the adult population in the western nations are affected by CVI with reported prevalence ranging from 5-40%.[1-4] This prevalence increases to about 80% of men and 85% of women if early CVI such as spider telangiectasia and reticular veins are also included.[5]

Besides being unsightly, if varicose veins are left untreated, they will lead to a progressive syndrome of lifelong complaints of aches or throbbing discomfort, burning sensation, pruritus, dry irritated skin, and in the chronic severe stage causes heaviness and fatique, cramping, hyperpigmentation, oedema, lipodermatosclerosis, ulceration, chronic infection and disability.[6,7] All these changes of CVI are secondary to prolonged raised venous pressures and have a significant impact on patients' health-related quality of life (HRQOL) and is associated with considerable healthcare cost in treating these patients especially those

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with chronic venous ulcers.[8]

Compression therapy using graduated compression stockings (GCS) is commonly prescribed as first line therapy, although it is associated with high non-compliance rate of over 60% which may account for the high failure rate.[7,9,10] The current main stay of surgical treatment of VVs is greater saphenous vein (GSV) stripping, stab phlebectomy, sclerotherapy injection, endovenous mechanochemical ablation, thermal ablation, injection of cyanoacrylate adhesive and transilluminated powered phlebectomy.[7-8] High recurrence rate of 50% has been reported for some of these procedures such as stripping while others such as the Endovenous laser ablation (EVLA) is associated with lesser degree of recurrence.[8] All these techniques sacrifice the GSV to achieve success but they do not correct the primary problem of saphenofemoral, saphenopopliteal and perforator valvular incompetence and hence are non- functional or physiological.

Surgical repair of incompetent venous valves have been previously described such as external venous valve banding valvuloplasty (EBV), external valvular stenting (EVS) and venous valve cusps plication and repair. [6,7,11,12] These techniques preserve the GSV and are functional as well as physiological. Although most of these procedures have good initial success, recurrence rate as high as 15-19% has been reported.[13,14] We describe here a novel evolution of EBV technique for saphe-no-femoral junction and perforator incompetence, which we have named as the 'Prolene mesh corset functional repair (PMCFR)' of venous valve insufficiency. This new technique is both simple to do and is extremely successful in abolishing the valvular incompetence while maintaining patency and function. We describe here our first case of PMCFR of SFJ.

CASE REPORT

A 30 years old Venezulan man presented to the surgical outpatient clinic with left leg lower limb CVI for several years. His main complaints were itchiness and burning pain on prolonged standing. His father also suffered from CVI (CEAP-C_{2-5}). He was also under regular follow up with the Gastroenterologist for gastroesophageal reflux symptoms and was on mesoprazole for his symptoms. He admitted to taking horse chestnut tablets to ease the itchiness in his leg. Clinical Trendeleburgs's examination suggested left saphenofemoral junction (SFJ) incompetence with dilated VVs. A duplex Doppler ultrasound was performed which confirmed the left SFJ incompetence with no thigh or calf perforators incompetence. A diagnosis of CVI (CEAP-$C_2E_pA_sP_r$) was made. Patient was not keen on VVs stripping, for which his father had undergone several times with recurrence of symptoms and VVs after several years. He was advised for PMCFR instead and consented for the procedure.

He underwent PMCFR of his left SFJ incompetence under spinal anaesthesia. Intraoperatively, the SFJ was noted to be dilated to 12mm in diameter (Figure 1). Intraoperative milking of the dilated left SFJ confirmed clinical significant incompetence of the SFJ with back refilling of the SV (Video 1). A 15mm x 30mm prolene mesh was used to create an overlapping corset sutured with 5/0 prolene sutures in 2 layers, around the SFJ and the saphenous vein (Figure 2). The PMCFR reduced the initial dilated diameter of the SFJ from 12mm down to 4mm, which is a 66% reduction in the diameter of the SFJ. Intraoperative assessment of the SFJ post PMCFR by milking the distal SV between two forceps confirmed successful repair of the SFJ without any incompetence and back filling of the SV which remains collapsed (Video 2). He was discharged the next day without any complaint of pain. Post-operative dupler Doppler ultrasound confirmed competency of the left SFJ without any reflux or obstruction.

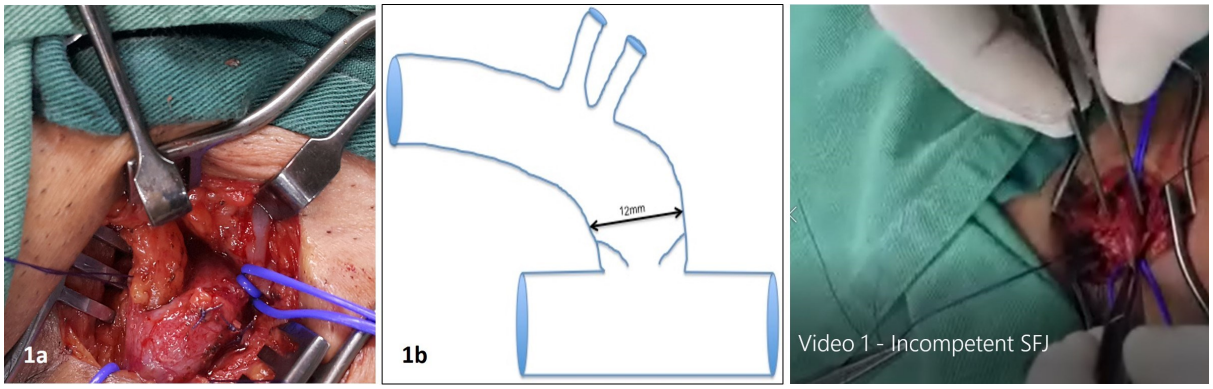

Figure 1: (a) Dilated left SFJ with a diameter of about 12mm, (b): Schematic representation of the dilatation of SFJ causing separation of venous valve leaflets, leading to incompetence.

Video 1: Intra-operative testing of incompetent left SFJ by milking the vein between two forceps and clearly showing back refilling of the SV indicating incompetence of the left SFJ. (Click on the video to start the video.)

Clinically at one month follow up, patient was free of any symptoms including his constant leg itchiness. After 2 months of follow up, patient requested to be discharged from the clinic.

SURGICAL PROCEDURE – PMCFR OF INCOMPETENT SFJ

Under spinal anaesthesia, the patient's groin is cleaned and prepped. A 5cm skin crease incision is made in the groin crease, medial to the femoral pulse and dissected down to expose the great saphenous vein (GSV). Dissection is then carried proximally to expose the draining branches of the GSV (3-5 branches). These branches are looped with silastic loops for control. Smaller branches which may interfer with repair are ligated and divided, but maintaining larger branches. Dissection of the GSV is continued proximally to expose the SFJ right up to the common femoral vein (CFV). The GSV is dissected free for 20-30mm distally from the SFJ. The dimension of the SFJ is then measured and recorded. The average diameter of a normal competent SFJ is about 5 ± 2.4mm.[15] Thus it is recommended to reduce the diameter during PMCFR down to less than 5mm or 50-60% reduction, depending on the initial diameter of the incompetent valve. The prolene mesh dimension is calculated based on the diameter of the final post repair SFJ dimension. In the case above, for a final diameter of 4mm, using the formula for

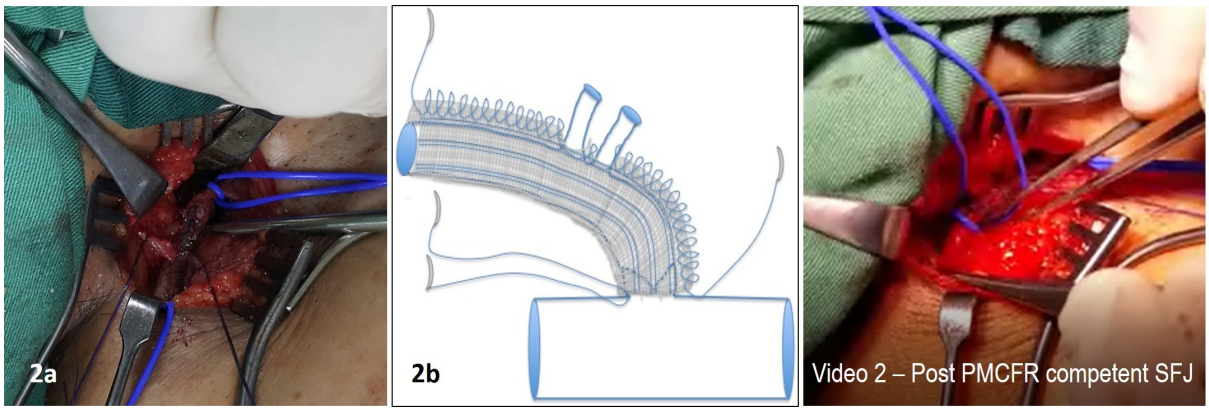

Figure 2: (a) Post PMCFR of left SFJ from a diameter of 12mm, reduced to 4mm, (b): Diagram representing PMCFR forming a mesh corset around the dilated SFJ and reducing it down to 4mm allowing for the venous valve leaflets to co-ap.

Video 2: Intra-operative testing of left SFJ post PMCFR by milking the vein between two forceps and clearly showing absence of back filling of SV which remains collapsed, indicating competence of the left SFJ. (Click on the video to start the video.)

circumference, 2πr, the dimension of the mesh should be a width of 15mm to allow for a 2mm overlap of the mesh during suturing. This will give a prolene mesh dimension of 15mm x 30mm patch. The prolene mesh is wrapped around the posterior part of the SFJ and the two anterior flaps of the mesh are overlapped to form a corset around the SFJ and sutured together using 5/0 prolene sutures to achieve the desire diameter. This end is further sutured onto the CFV to anchore the mesh. The free anterior edge is cut by 1-2mm at intervals to fit the branches draining into the GSV. The corset is sutured together and around the branches with the 5/0 prolene sutures in 2 layers and secured at the distal end of the 30mm prolene mesh corset. The competency of the repair can now be tested by using a tissue forceps to occlude the distal free end of the GSV and milking the GSV proximally using another tissue forcep to empty the GSV proximal to the occluding forceps to empty the vein, ensuring that all draining branches are also occluded by tightening the vicryl loops. If the vein remains empty when the proximal forceps is removed, then the PMCFR is successful and the SFJ is competent.

DISCUSSION

The current main stay of treatment of CVI is GSV stripping, VVs avulsion and SFJ truncal ligation.[6-8] The less invasive alternative is sclerotherapy (liquid or foam) or endovascular surgery (foam sclerotherapy, laser or radiofrequency ablation).[6-8] Despite high initial success rate associated with these methods, such procedure only deal with the physical varicose vein and not the primary cause which, 80% of the time is due to SFJ or SPJ incompetence either due to dilatation of the junction or less commonly (4%) valvular leaflets abnormality.[16,17] Thus recurrence rate after 5 years has been reported to be as high as 50-60% and may be due to neovascularisation, duplex saphenous vein system, recannulisation or unresolved primary pathology leading to formation of other new VVs.[8]

Various repair methods have been introduced and reported to alleviate the primary problems of venous valvular incompetence starting with the SFJ banding reported by Jessup et al in 1988.[18] The PMCFR is a novel technique which is conceptualized based on the principle mitral valve annuloplasty for mitral regurgitation due to a dilated annulus. As majority of SFJ incompetence is due to junctional dilatation leading to failure of coaptation of the venous valve leaflet, by wrapping a prolene mesh corset around the dilated SFJ and reducing the diameter of the SFJ to normal dimension will ensure functional coaptation of the venous valve leaflets and abolishing the regurgitation or incompetence, which can be tested and confirmed perioperatively by milking the GSV. Post-operative duplex Doppler ultrasound also confirmed this to be true with complete disappearance of the incompetence seen preoperatively.

The theoretical advantage of the PMCFR over the other banding or SFJ incompetence repair techniques is that the use of prolene mesh corset will allow fibrosis to form a semi-rigid frame or corset around the SFJ and the GSV, thus preventing future recurrent dilatation of the junction and GSV. Thus in theory, the PMCFR will provide a more permanent solution to repairing SFJ incompetence. The use of prolene mesh for inguinal hernia repair have been shown to be very successful and studies have already shown this to be due to the formation of a fibrous layer which prevents future recurrence of the inguinal hernia.[19] The same principal may also apply for PMCFR for SFJ incompetence.

Clinical success is evident perioperatively when the repair is tested by milking the SV and competency can be shown almost immediately with the SV remaining collapse when the inflow is occluded by a pair of

forceps (Video 2). Unlike, SV stripping or chemical or energy SV ablation which can be extremely painful from thrombophlebitis, with reduced mobility, patients following PMCFR have reported minimal pain and are usually walking within 6 hours with full symptomatic relief from pain or itchiness within a few days.[7,20]

Long-term follow up is required to assess the long-term benefit of PMCFR which theoretically by abolishing the reflux or incompetence will result in normalizing the venous pressures in the GSVs, which has already been proven to be true for procedures such as high ligation and stripping, varicosectomy and EBV.[21,22] This will of course need to be measured objectively for PMCFR. With the normalization of venous pressure, the enlarged varicose veins may undergo remodeling and reduce in size which is a possible long-term outcome. If proven true, the unsightly varicose veins may not need to be stripped for cosmetic outcome. A significant benefit is the reversal of chronic venous insufficiency changes such as lipodermatosclerosis and venous ulcers healing by reducing the venous pressure in the lower limb in the long-term but long-term follow up is require to confirm this. A limitation of this technique is that it is not applicable to patients with CVI without junctional incompetence.

CONCLUSION

PMCFR is a novel surgical technique aim at correcting the primary pathology leading to CVI, which is the valvular incompetence at the SFJ or even the SPJ. Currently we are also using this technique for repairing SPJ and perforator incompetence. Immediate results are very promising in terms of relieving symptoms with majority reporting resolution of pain, itchiness or swelling in the lower limb. However, long-term follow up of these patients is required to see if any of the CVI changes can be reverse with repairing of the reflux and also to monitor for recurrence.

Financial disclosure or conflict of interest

The authors of this manuscript certify that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

Consent

We have acquired consent from patient for all photographs of patients' body parts and images used in publication purpose.

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