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"CLINICAL EVALUATION AND DESIGN INSIGHTS OF THE PROMESA™ JOY SELF-EXPANDING BRAIDED NITINOL PERIPHERAL STENT SYSTEM IN PERIPHERAL ARTERIAL AND VENOUS DISEASES"

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Abstract- Peripheral arterial and venous diseases, such as Peripheral Arterial Disease (PAD), Popliteal Artery Aneurysm, Popliteal Artery Entrapment Syndrome (PAES), Intrapopliteal Posterior Tibial Artery Occlusion, and May-Thurner Syndrome, are not only difficult to handle but also require special management in the case of chronic smokers and patients suffering from hypertension and hyperlipidemia. On the other hand, self-expanding braided stents have turned out to be a good and minimally invasive alternative for restoring the blood vessels and giving the blood supply to the limb back.

The objective is to assess the technical performance, safety, and mid-term clinical effect of the Meril Medical Innovations Promesa™ JOY Self-Expanding Braided Peripheral Stent in patients suffering from extensive peripheral vascular lesions.

In the study, five patients with an age range of 49-63 years (mean 54 ± 5.4 years) who had peripheral arterial or venous disease and were symptomatic, underwent endovascular stenting using the Promesa™ JOY system. Deployment of stents was carried out with the use of sheaths ranging from 6F to 7F and guidewires of 0.014 to 0.018 inch under fluoroscopy. The diameters of the stents were from 5 to 7 mm and their lengths from 100 to 150 mm. The patients were put on dual antiplatelet therapy as well as receiving other supportive medications. The patients were followed up at 1 week, 1 month, and 6 months, where they were subjected to clinical assessment and imaging (Doppler ultrasound and MRA) to check for stent patency and symptom relief.

There was a technical success in all the patients with correct stent placement and instantaneous restoration of blood flow. Also, no complications occurred during the procedure. There was a large improvement in the patient's condition which was already reflected in the follow-up, the improvement of the claudication, pain, numbness, and the increase in mobility. The images of the stent location showed no change to the stent at all, and there was no case of the stenosis or thrombosis occurring either. The braided Nitinol stent demonstrate.

Keyword- Peripheral Artery Disease (PAD), complex vascular regions, Promesa™ JOY Self-Expanding Braided Peripheral Stent System, braided Nitinol, superior flexibility, radial strength, and biocompatibility, PAD lesions

I. INTRODUCTION

Peripheral Artery Disease (PAD) refers to a pathological condition where the arteries that carry blood to the legs get constricted or obstructed due to a process known as atherosclerosis, where fatty deposits are the main culprits. As a result of the lack of blood supply, patients may experience pain, cramps, and in very advanced stages, even tissue death (gangrene) or amputation. Treatment, especially if it is effective, has become a major challenge in the medical field considering the worldwide rise of PAD, especially in the elderly population.

One of the treatment methods to be considered is the use of peripheral stent systems which have been of great assistance to restore blood flow in the arteries that were previously blocked. Stents are tiny tubular devices that are introduced into the artery, usually after balloon angioplasty, to ensure that the blood vessel remains open and to prevent it from getting narrow again (restenosis) either due to recoil of the artery or formation of scar tissue.

Over time, the development of stent technology has turned PAD treatment into something completely different. The first stents were manufactured using stainless steel; however, the modern designs frequently utilize the alloy of nickel and titanium, called nitinol, which is toughened with superelasticity. Nitinol stents are characterized by their flexibility, strength, and their ability to take on the natural contour of the arteries, thereby making them extremely effective in intricate vessels like the femoral and popliteal ones (Lejay et al., 2012). Moreover, nitinol has excellent compatibility with living tissue, thereby minimizing immune reactions, thrombosis, and other complications (Bertrand et al., 1998).

Furthermore, peripheral stents have been developed with specific clinical requirements in mind. There are stents that are able to expand on their own, which means they can adapt to the movements of the artery without losing the stability that is necessary during the daily activities like walking that involve the patient. This property is extremely desirable when dealing with difficult lesions located in arteries such as the superficial femoral artery (Wang et al., 2025).

The advantages of peripheral stents are supported by clinical data. The patients' ability to endure pain is markedly reduced.

Despite these advancements, current stent platforms face several limitations:

1. Fracture risk: The risk of stent fracture is higher with repetitive bending, compression, or torsion, particularly in mobile arteries such as the popliteal artery.

2.Restenosis: The occurrences of in-stent restenosis and neointimal hyperplasia are still prevalent, especially in small or diffuse vessels.

3.Design trade-offs: One of the benefits of using denser stents is the increased support, however, it may come at the cost of less flexibility of the vessel and difficulty in accessing side branches.

4.Delivery challenges: It is very challenging to navigate through long, tortuous or calcified lesions; large delivery systems can result in an increase in access-site complications.

5.Limited long-term data: There are very few studies that demonstrate reliable outcomes after 3-5 years.

6.Patient variability: Certain conditions such as diabetes, kidney disease, and diffuse atherosclerosis can have a detrimental effect on the stent performance.

These limitations underscore the ongoing need for next-generation stents, such as the Promesa™ JOY Self-Expanding Braided Peripheral Stent, designed to provide higher radial force, improved fatigue resistance, and long-term biocompatibility, aiming to achieve durable vessel patency and better patient outcomes.

II. MANUFACTURING OF PERIPHERAL VASCULAR STENTS

The production of peripheral vascular stents is a very complicated and controlled process that allows the combining of modern engineering with tight quality assurance to attain safety, dependability, and clinical effectiveness. The process can basically be classified into a number of main steps.

2.1 Material Selection

The process starts off by choosing the biocompatible metals which are usually Nitinol or stainless steel because of their high strength, excellent corrosion resistance, and the capability to get along with the changing environment of blood vessels. These raw materials are then put through a series of tests to ensure they meet not only the mechanical property requirements but also the ISO 10993-1 biocompatibility standards (Cambiaghi & Alice, 2018; Lincoln & John, 2012).

2.2 Tube Preparation and Laser Cutting

After the approval, the unrefined metal pipes are subjected to cleaning and then subsequently sliced into the right lengths. The main process in manufacturing is laser cutting, which results in the tube getting accurate geometric patterns. This procedure is very important as the patterns give the stent the required flexibility, strength, and growth capacity, thus allowing it to hold the walls of the blood vessel during and after the deployment (Feldman et al., 2025).

2.3 Surface Finishing and Cleaning

Stents after going through laser cutting receive electropolishing and ultrasonic cleaning in order to get rid of the microscopic burrs and particles that otherwise might lead to the formation of blood clots. These methods not only make the stent more compatible with the biological environment but also contribute to reducing the chances of thrombosis and inflammation (Siewert et al., 2022).

2.4 Heat Setting for Nitinol Stents

Nitinol stents need further heat-setting to be completed. During this stage, the stents which have been laser-cut are placed on the mandrels that are specialized for this purpose and are heated to the controlled temperatures of 450°C-550°C. The alloy is thus treated and it acquires its unique characteristic along with the properties of shape memory and superelasticity, so that the stent can again expand by itself after it is released in the artery. This characteristic of being able to expand by itself is of great use especially in the treatment of lesions in peripheral vessels (Stoeckel & Dieter, 2000).

2.5 Surface Treatment and Passivation

Stents are subjected to surface passivation as an important process to improve their corrosion resistance and long-term compatibility further. By following this step, ASTM F86 regulations (ASTM F86-21:2021) will be met regarding reliable performance and safety of patients**.**

2.6 Dimensional Verification and Quality Assurance

Each stent undergoes a dimensional verification process to ascertain the structural integrity and that the critical parameters of length, diameter, and strut geometry fall into the tolerances of acceptance. This process secures the predictable deployment and is done according to the ISO 25539-2 requirements (ISO 25539-2:2020).

2.7 Delivery System Assembly

After verification, the stents are attached to their respective delivery systems. The balloon-expandable stents are crimped onto the balloon catheters, while the self-expanding stents are put into the sheaths. These assemblies are made in cleanroom conditions to avoid contamination.

2.8 Sterilization

The assembled stent systems are subjected to sterilization procedures like gamma irradiation or ethylene oxide gas. The techniques are validated according to international standards to ensure that no microbes are alive and the materials' properties are intact (ISO 11135:2020; ISO 11137).

2.9 Final Quality Control and Packaging

Prior to sale, every product goes through a series of rigorous visual inspections, mechanical tests, and sterility assurance evaluations based on AAMI TIR33 (AAMI TIR33:2015) guidelines. Only when the stents have successfully cleared all the hurdles are they put in boxes, labeled, and authorized for use in patients.

III. UNDERSTANDING THE MECHANISM, ENGINEERING, AND MANUFACTURING OF PERIPHERAL STENT SYSTEMS

The over 200 million patients suffering from peripheral artery disease are not being treated properly as a cause of ischaemia, pain, and disability, particularly when the lower limb artery stenosis is due to atherosclerosis (Lyden et al., 2009). The use of periphery stent system technology has revolutionized the treatment of PAD by providing a new way of keeping the blood vessels open and improving the delivery of blood through a small surgical procedure. The stents that look very simple on the outside are, in fact, an application of precision engineering, biomechanics, and materials science that is very advanced (Lau et al., 2004).

3.1 Mechanism of Action

Peripheral stents are intraluminal scaffolding stents, which push the plaque up against the arterial wall with the intent of stabilizing and remodelling the vessel lumen (Patel et al., 2015). Employed for fluoroscopically guided intervention with catheter-delivery systems, stents may be categorized into:

- Self-expanding stents, based on the superelasticity of nitinol, and
- Balloon-expandable stents, which expand due to controlled inflation of a balloon (Mewissen & Mark, 2004).

They are also resistant to elastic recoil after implantation and support vessel diameter, thus providing blood supply and oxygen to the tissues (Grenon et al., 2013). Sophisticated models also reduce vascular trauma, endothelialization, and inducing optimal long-term vessel healing (Jahnke et al., 2002).

3.2 Material Science and Design Engineering

- Material choice for stents is the core of the capability to compromise durability, performance, and safety.
- Most commonly utilized is Nitinol (Nickel–Titanium alloy) with shape-memory and superelastic which offers self-expansion support and tortuous anatomy conformability (Pelton, 2011).
- Stainless Steel and Cobalt–Chromium are utilized in balloon-expandable configurations for tensile strength and radiopacity (Schillinger et al., 2006).
- Bioresorbable material such as poly-L-lactic acid is a next-generation scaffold which offers temporary support and later biologically degrades to preserve the integrity of the native vessel (Forrestal et al., 2020).
- Designurally, stents must strike an optimal balance between radial stiffness, compliance, and endurance strength if they are to perform maximally in the highly dynamic peripheral arteries (Jahnke et al., 2002).

The above-mentioned open-cell, closed-cell, hybrid, and braided architectures have all enjoyed mixed trade-offs in fracture resistance, conformability, and flexibility (Zhao et al., 2009). Braided nitinol devices have even been found to be superior to repetitive mechanical loading and motion of femoropopliteal arteries (Schillinger et al., 2006).

3.3 Surface Modification and Coating Technologies

- Surface treatment has been found to prevent effective thrombosis, inflammatory reaction, and restenosis.
- Electropolishing decreases surface finish to lowest possible level, thus reducing platelet adhesion and microdefects (Grenon et al., 2013).
- Paclitaxel or sirolimus drug-eluting coats inhibit neointimal hyperplasia (Rosenfield et al., 2015).
- Polymer or biocompatible coating improves hemocompatibility with improved endothelial healing (Forrestal et al., 2020)

3.4 Technical Deployment and Mechanical Demands

Peripheral stents are delivered with low-profile catheter systems through radial or femoral access (Lai et al., 2020). It has a radiopaque marker delivery catheter and a preconstrained stent, which is expanded by sheath withdrawal or balloon.

Under implantation, stents need to be torque-resistant, compressive, extension-resistant, and bending-resistant because of the motion of the limbs (Zhao et al., 2009). Unrelenting testing radial force, durability life, and fracture is not to be shied away from. Type tests in accordance with ISO 25539-2 necessitate in-vitro mechanical strength performance testing (Rosenfield et al., 2015).

IV. TUBE TO IMPLANT MANUFACTURING AND QUALITY CONTROL

The production of peripheral stents integrates different types of control of precision, and they all play a role in their performance and safety.

- Tube Preparation: Precision-tested cobalt-chromium or nitinol tubes tested in a uniform manner and microdefect-tested are used.
- Laser Cutting: CAD-guided femtosecond lasers with micron precision and no heat injury cut complex scaffolding shapes (Raval et al., 2017; Lally et al., 2005).
- Deburring & Electropolishing: Electropolished stent surface is used for deburr, improve fatigue strength, and decrease thrombogenicity (Garg et al., 2010).
- Shape Setting: Nitinol stent shape memory is established by thermal cycling 500–550 °C on mandrels (Pelton et al., 2011) between 10 to 60 minutes.
- Surface Coating: Antiproliferative drug like Paclitaxel or sirolimus or biocompatible polymers are dip-coated or spray (Kolandaivelu et al., 2011).
- Sterilization & Packaging: Materials are sterilized by ethylene oxide (ISO 11135:2020) or gamma radiation (ISO 11137:2020) and packaged in an aseptic cleanroom environment.

4.1 Assurance of Quality and Conformity to Standards

All stents are thoroughly tested for dimensional conformance, radial rigidity, endurance life, corrosion resistance, and sterility. ISO 25539-2:2020 attests to mechanical as well as biological safety compliance and requirements for surface finish specifications are supplied by ASTM F86-21. A stent should not be used in a clinic if it did not pass all the above tests. This guarantees repeatable delivery and repeatable long-term performance.

4.2 Post-Deployment Engineering Considerations

In-stent peripheral stents for delivery are to be subjected to dynamic mechanical loads of unrelenting limb movement. Engineer validation includes physiologic simulation with axial compression, bending, twisting, and cyclic fatigue decreasing fracture, risk of migration, and restenosis (Zhao et al., 2009). Electropolishing, drug-eluting drug coating, and surface treatment were found to promote endothelial regeneration and preservation of vessel patency (Grenon et al., 2013; Rosenfield et al., 2015).

4.3 New Horizons and Emerging Technology

The future of the stent is characterized by the blending of new materials, computer simulation, and accurate manufacturing:

- Engineering geometry and rapid prototype development by additive manufacturing (3D printing).
- Nano-textured surface for platelet evasion and inflammation (Forrestal et al., 2020).
- Bioresorbable scaffolds for intermediate mechanical support prior to resorption (Forrestal et al., 2020).
- Computer-aided design simulation with artificial intelligence and finite element modeling (FEM) provides patient-specific mechanical performance prediction.

All of these technologies are propelling peripheral stent technology towards increasingly long-duration, biocompatible, and patient-specific therapy a marriage of biomedical engineering, material science, and clinical science.

V. PROMESA™ JOY – SELF-EXPANDING BRAIDED PERIPHERAL STENT SYSTEM: MERIL'S ADVANCED SOLUTION FOR PERIPHERAL ARTERY DISEASE

The Promesa™ JOY Self-Expanding Braided Peripheral Stent System, represents an advanced vascular device engineered to address the unmet challenges in peripheral artery disease (PAD) management. PAD, a chronic and debilitating condition caused by stenotic or occlusive atherosclerosis of peripheral arteries, manifests as impaired limb perfusion, claudication, non-healing ulcers, and critical limb ischemia. Promesa™ JOY integrates biomaterial innovation, precision manufacturing, and physician-driven design to ensure reliable vessel support in complex and dynamic vascular anatomies.

5.1 Design and Engineering Principles

The stent is made of ASTM F2063-grade nitinol wires which are braided into a mesh scaffold. The configuration gives converging properties such as radial strength and coverage coupled with the flexibility of nitinol, and the superelasticity and shape-memory effect of the alloy allow uniform expansion, conformability to tortuous arterial paths, and resistance to kinking or fracture under repeated biomechanical loading.

Through intricate optimization of the braid angle, the device gets the permissible range between the radial rigidity and the longitudinal flexibility hence with the ability to withstand vessel motion via bending, torsion, and compression. The implant, therefore, is highly suitable for the application in dynamic vascular areas like the femoropopliteal artery which is most prone to stent fracturing due to fatigue.

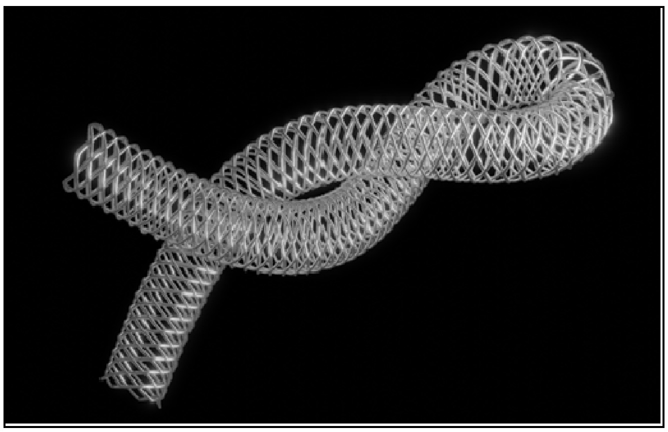

Fig:1 Self-Expanding Braided Peripheral Stent

5.2 Manufacturing Precision and Durability

Promesa™ JOY is produced by means of computer-aided braiders, which guarantees the product family to have reproducible pore geometry and consistent mechanical performance. The stent is first vacuum heat-set to fix the shape memory and then it is subjected to electropolishing and chemical passivation to improve hemocompatibility and corrosion resistance. Furthermore, the stent goes through a series of processes which include edge strengthening, trimming, and precision laser welding to increase the structural durability of the product.

To test the long-term performance of the device, it undergoes step-up fatigue testing of more than 400 million cycles, which represents more than fifty years of arterial pulsation. The production takes place in ISO-classified cleanroom facilities, along with stringent in-process quality control (IPQC), sterilization with ethylene oxide, and sterile barrier packaging to make sure that the patients are safe and the devices are reliable.

5.3 Bench-Top and Mechanical Testing

Comprehensive bench-top evaluations confirm the device's mechanical reliability and deployment accuracy:

- Deployment testing in anatomical models demonstrated uniform expansion and apposition.
- Cyclic fatigue testing confirmed resistance to fracture during long-term use.
- Radial strength and recoil testing validated resistance to vessel recoil.
- Compression testing established stability against axial and circumferential forces.

These tests, conducted in alignment with international vascular device standards, affirm Promesa™ JOY's durability and ability to withstand the mechanical forces encountered during implantation and long-term function.

5.4 Clinical Features and Device Benefits

Promesa™ JOY comes in diameters between 4 and 8 mm and a maximum length of 150 mm, which allows for the treatment of all the femoral, popliteal, iliac, and tibial arteries. The system for delivery over-the-wire assures a highly controlled navigation and, thus, reducing the chances of wrong positioning and complications during the procedure.

Compared to earlier-generation self-expanding devices, laser-cut stents, and balloon angioplasty, Promesa™ JOY provides:

- Greater conformability and scaffolding coverage,
- Superior fatigue strength**,**
- Resistance to recoil, restenosis, and mechanical fracture.

These properties make it particularly suitable for long, calcified, or angulated lesions, where traditional stents frequently fail.

5.5 Comparative Advantage and Expanded Indications

Balloon angioplasty always faces the problems of elastic recoil and restenosis, while laser-cut stents have limitations in fatigue resistance and flexibility. Promesa™ JOY is a solution that solves these drawbacks by bringing radial strength and longitudinal flexibility together, thus removing the compromise between endurance and flexibility that is usually associated with many self-expanding stents.

Moreover, the system not only has peripheral vascular applications but also has received regulatory approval for repeated or unsuccessful percutaneous transluminal angioplasty (PTA) and some non-vascular indications like the palliative treatment of malignant biliary strictures, thus increasing its therapeutic area.

5.6 Meril's Innovation Commitment

The Promesa™ JOY development is indicative of Meril's dedication to the manufacture of vascular innovations through engineering accuracy and the usability directed towards the medical practitioners. By integrating all three properties - durability, flexibility, and precision manufacturing, the system guarantees in the long run the patenting of vessels, the decrease in complications, and the provision of better outcomes for patients. Since the demand for the least invasive endovascular therapies is rapidly increasing, Promesa™ JOY is very likely to be an innovative solution in PAD management and even in other areas of usage.

VI. CLINICAL DATA

TABLE: 1 CLINICAL DATA

Cases	Age	Gender	Disease	Location
Case-1	52 yrs	Male	Superficial Femoral Artery(SFA), Peripheral Arterial Disease (PAD)	Hyderabad
Case-2	49 yrs	Female	Popliteal Artery Aneurysm	Hyderabad
Case-3	63 yrs	Male	Popliteal Artery Entrapment Syndrome (PAES) of the Popliteal Fossa and Tibial Artery	Nagpur
Case-4	56 yrs	Male	Intrapopliteal Posterior Tibial Artery occlusive disease, Peripheral Arterial Disease (PAD)	Vishakhapatnam
Case-5	50 yrs	Female	May-Thurner Syndrome	Kolkata

Case-1

A 52-year-old man from Hyderabad who smoked for a long time was diagnosed with total occlusion of the Superficial Femoral Artery (SFA) which is the cause of his Peripheral Arterial Disease (PAD). He experienced persistent and cramping pain in his legs, intermittent claudication, and numbness in the right leg, which had been getting worse for several months. Clinical evaluation was performed and the

diagnosis was confirmed by Doppler vascular ultrasound.In order to restore blood supply to the limb, an endovascular intervention was carried out. A small incision was made beneath the knee to facilitate the introduction of a 6F sheath and a 0.018-inch guidewire that would cross the occluded segment. A Promesa™ JOY Self-Expanding Braided Peripheral Stent (7 mm × 100 mm) was then deployed at the lesion site using fluoroscopic guidance and this was done successfully.

The patient was then placed on dual antiplatelet therapy and the follow-ups were scheduled for 1 week, 1 month, and 6 months. The patient showed remarkable improvement in clinical symptoms, with complete disappearance of the symptoms, and reestablished blood flow. No complications were reported, thus showing the effectiveness of peripheral stenting for PAD even in patients with high co-morbidities.

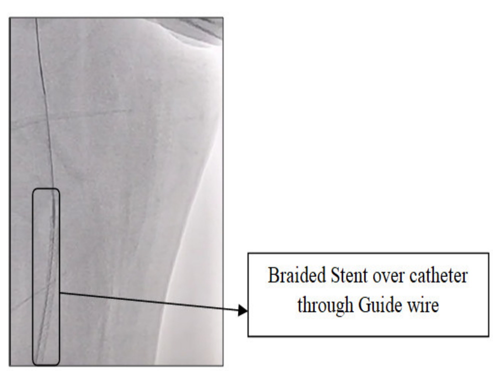

Fig:2 Promesa JOY™ stent inserted in Superficial Femoral Artery (SFA)

Case-2

A 49-year-old woman from Hyderabad who had a history of hypertension came to the doctor suffering from severe cramping, persistent inflammation, numbness, pallor, and inability to walk in her left leg, all of which had been getting worse over a few months. The physician suggested an MRA which showed a popliteal artery aneurysm with critical stenosis.

In order to treat this vascular problem a procedure was performed endovascular. An access point was made below the ankle and through this a 6F sheath inserted and a 0.014-inch guidewire was pushed through the diseased area successfully. As per imaging guidance a Promesa™ JOY Self-Expanding Braided Peripheral Stent (5 mm × 150 mm) was placed at the aneurysmal and stenotic site to restore blood vessel strength and flow.

After the procedure the patient was put on antiplatelet therapy and underwent follow-ups at 1 week, 1 month, and 6 months intervals. The evaluations showed remarkable clinical improvement including disappearance of symptoms, recovery of limb function, and keeping stent patentacy with no complications related to the procedure. This case highlights the success of peripheral stenting as a treatment option for complex popliteal artery lesions.

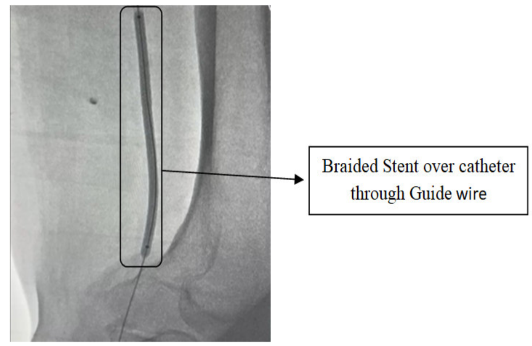

Fig:3 Promesa JOY™ stent inserted in Popliteal Artery

Case-3

A 63-year-old man from Nagpur, with a history of chronic smoking and hypercholesterolemia, presented with severe cramping, persistent lower leg pain, calf claudication, and numbness in the left leg, progressively worsening over several months. Clinical evaluation, along with Magnetic Resonance Angiography (MRA) and vascular ultrasound, confirmed a diagnosis of Popliteal Artery Entrapment Syndrome (PAES) affecting the popliteal fossa and tibial artery.

To restore adequate blood flow and relieve symptoms, an endovascular intervention was performed. A small puncture was created just above the ankle, allowing insertion of a 6F sheath, and a 0.014-inch guidewire was carefully advanced through the compressed arterial segments. Under fluoroscopic guidance, a

Promesa™ JOY Self-Expanding Braided Peripheral Stent **(**6 mm × 100 mm**)** was successfully deployed at the site of vascular compression and stenosis.

Post-procedure, the patient was prescribed antiplatelet therapy and cholesterol-lowering medications. Follow-up assessments at 1 week, 1 month, and 6 months demonstrated significant clinical improvement, including relief from claudication, restoration of limb function, and patent stented arteries**,** with no reported complications. This case highlights the effectiveness of peripheral stenting in treating PAES and restoring functional blood flow in high-risk vascular patients.

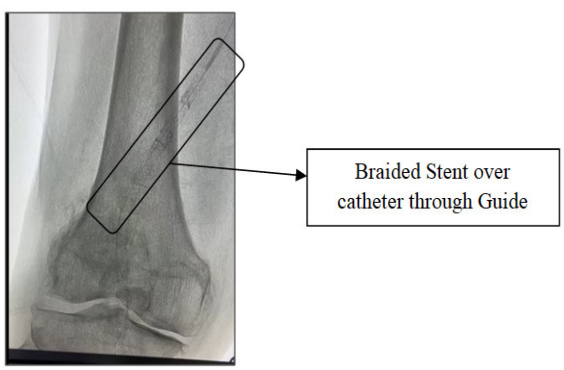

Fig:4 Promesa JOY™ stent inserted in Popliteal Fossa and Tibial Artery

Case-4

A 56-year-old male patient from Visakhapatnam visited the hospital with a history of hyperlipidemia and symptoms that had been getting worse for several months. These included severe cramps, persistent pain in the lower leg, claudication in the calf, and numbness in the right leg. Clinical examination and Magnetic Resonance Angiography (MRA) followed by vascular ultrasound confirmed the diagnosis of intrapopliteal occlusive disease of the posterior tibial artery, a condition usually related to peripheral artery disease (PAD).

To re-establish blood flow to the area and to relieve the symptoms, an endovascular intervention was carried out. The first step was to make the puncture above the ankle and to insert a 7F sheath. After that, a 0.018-inch guidewire was carefully passed through the occluded section of the posterior tibial artery. A Promesa™ JOY Self-Expanding Braided Peripheral Stent (6 mm × 120 mm) was then implanted at the location of the occlusion under fluoroscopy with the aim of restoring the vessel and enhancing blood flow.Shortly after the emboli had been cleared, the patient was prescribed dual antiplatelet therapy along with lipid-lowering medications and then sent home.

The patient's progress was monitored with follow-up visits at 1 week, 1 month, and 6 months, which all showed marked clinical improvement, including the disappearance of claudication and numbness, and the imaging confirmed the sustained stent patency. The surgery was without complications, and the patient gradually returned to all normal activities with the improved vascular function.

This particular case showcases the effectiveness of stenting in the peripheral arteries for the treatment of patients with PAD and intrapopliteal tibial artery occlusions, such as those who are also suffering from hyperlipidemia.

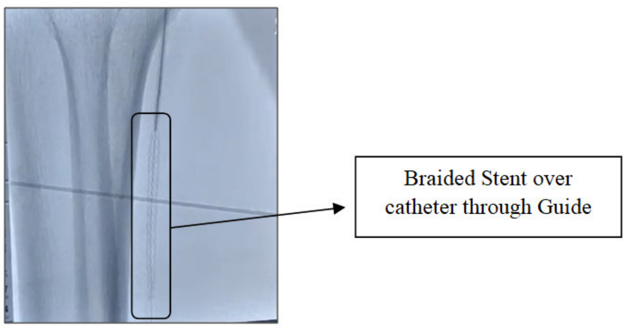

Fig:5 Promesa JOY™ stent inserted in Intrapopliteal Posterior Tibial Artery

Case-5

A 50-year-old lady from Kolkata was the one to complain about her left leg with very painful cramps, swelling, numbness, skin discoloration, and difficulty in walking. These symptoms had lasted for months. Her doctor suggested that she should have an imaging study and thus it was done, Magnetic Resonance Angiography (MRA) and showed that the major iliac vein was very much compressed leading to the diagnosis of May-Thurner Syndrome, venous insufficiency, and the patient's symptoms.

The physician has decided to perform an endovascular procedure to open the venous flow and consequently reduce the symptoms. Above the knee a small incision was made to reach the iliac vein and the introduction of a 7F sheath followed. A guidewire of 0.018-inch was then pushed very carefully across the stenosis. Through fluoroscopy, a Promesa™ JOY Self-Expanding Braided Peripheral Stent (6 mm × 100 mm) was placed at the compression site to restore normal venous flow.

After the stent placement, the patient was put on antiplatelet drugs and also on venous compression therapy. During the follow-up visits at 1 week, 1 month, and 6 months the patient showed quite an improvement in her condition: swelling was less, skin tone was better, and mobility was back to normal. Besides, no complications had occurred during the procedure. The imaging showed that the stented iliac vein kept its long-term patency and the patient also returned to her normal leg function.

This case is evidence of the high efficacy of peripheral stenting in the treatment of May-Thurner syndrome and the resolving of symptoms due to compression of the iliac vein.

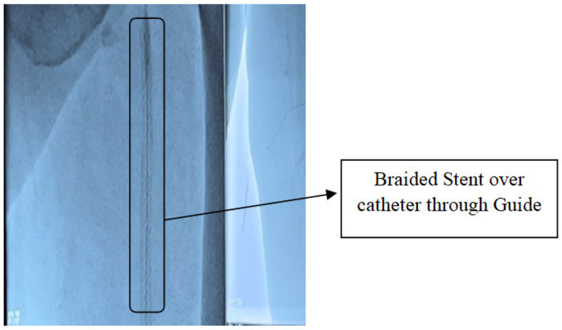

Fig:6 Promesa JOY™ stent inserted in Left Iliac Vein

VII. RESULT

A total of five patients, aged 49–63 years (mean age 54 ± 5.4 years), with complex peripheral vascular pathologies were treated using the Promesa™ JOY Self-Expanding Braided Peripheral Stent. The cohort included patients diagnosed with Peripheral Arterial Disease (PAD), Popliteal Artery Aneurysm, Popliteal Artery Entrapment Syndrome (PAES), Intrapopliteal Posterior Tibial Artery Occlusion, and May-Thurner Syndrome. All patients shared common cardiovascular risk factors, including chronic smoking, hypertension, and hyperlipidemia, representing a clinically challenging population.

1). Technical Success

The process of deploying endovascular stents resulted in a 100% technical success rate, which was the case for every single patient. The entry points were determined as per the location of the lesion, which could be below the knee, above the ankle, or above the knee. The size of the sheath used was either 6F or 7F while the guidewire was either 0.014-inch or 0.018-inch according to the size of the vessel and the nature of the lesion. Stents with various diameters from 5 mm to 7 mm and lengths from 100 mm to 150 mm were implanted with the help of high-precision fluoroscopic guidance. There were no intra-procedural complications like vessel rupture, stent malposition, or device malfunction, were reported during the procedure.

2). Immediate Post-Procedure Outcomes

Every single patient experienced an instant blood flow restoration right after the deployment of the device. There was not a single case of acute thrombosis, stent displacement, or any other complication due to the procedure. The use of dual antiplatelet therapy (DAPT) and complementary therapies, like lipid-lowering drugs or venous compression therapy, were given according to the medical situation.

3). Follow-Up and Clinical Improvement

Follow-ups were conducted at 1 week, 1 month, and 6 months post-procedure. Across all patients, there was substantial clinical improvement, including:

- Resolution of claudication and limb pain
- Reduction in numbness and swelling

- Improved gait and functional mobility

Imaging assessments, including Doppler ultrasound and Magnetic Resonance Angiography (MRA), confirmed patent stented vessels with no evidence of restenosis, thrombosis, or stent deformation at the 6-month follow-up.

4). Device Performance

The Promesa™ JOY stent's braided Nitinol design showed remarkable flexibility, radial strength, and conformability, which make it possible to open up and fit even the most twisted parts of the blood vessels, especially in the areas of the femoral and popliteal arteries. The stents kept their mechanical integrity and opened up the blood vessels for a long time without showing any signs of fracture or migration throughout the follow-up period.

In conclusion, the investigation proves that the Promesa™ JOY Self-Expanding Braided Peripheral Stent not only acquires technical success but also does so reliably, guarantees vessel patency, and brings about significant clinical improvement in patients with complicated peripheral vascular lesions.

VIII. DISCUSSION

Peripheral artery disease (PAD) is a health issue that keeps hitting hard worldwide, especially in the elderly who are at risk due to factors like smoking, high blood pressure, and diabetes among others. The management of PAD is predominantly complicated by the continuous reduction and blocking of the peripheral vessels, mainly in the feet, which eventually lead to different levels of blood deprivation giving rise to the patient experiencing intermittent claudication or critical limb ischemia and tissue death (Lejay et al., 2012).

The last few decades have seen the therapeutic approaches for PAD gradually shifting from major surgical operations to minimally invasive endovascular interventions, which are claimed to take less time, offer reduced procedural risk, and faster recovery. The self-expanding Nitinol stent is one among these and has become the most popular option in anatomically complicated and moving vessels such as the femoral and popliteal arteries due to its gentle nature and elastic and shape-memory properties (Bertrand et al., 1998; Lejay et al., 2012). These properties make the stent to expand in a natural way when being deployed, shape itself to the curves of the vessel, and give support with its consistent radial force thus preventing problems like recoil or kinking which could shorten the period of being patent for the long term.

The Promesa™ JOY Self-Expanding Braided Peripheral Stent shows the effectiveness of these concepts through its braided Nitinol design, which provides greater flexibility, radial strength, and mechanical stress resistance. The stent was used successfully during the five clinical cases studied—those involved were aged 49 to 63 years and had different diseases: PAD, Popliteal Artery Aneurysm, Popliteal Artery Entrapment Syndrome (PAES), Intrapopliteal Posterior Tibial Artery Occlusion, and May-Thurner Syndrome. Besides, the stent received through various vascular anatomies successfully. There were different access sites (below-knee, above-ankle, and above-knee) and the stent diameters were ranging from 5 mm to 7 mm with a length of 100–150 mm. Technical success was observed in all cases, with precise stent placement and immediate restoration of blood flow, and no intra-procedural complications such as vessel rupture or device malfunction were reported.

Post-procedural follow-ups at 1 week, 1 month, and 6 months demonstrated substantial clinical improvement. Patients experienced relief of claudication, numbness, swelling, and gait impairment, while imaging via Doppler ultrasound and Magnetic Resonance Angiography (MRA) confirmed stent patency throughout the follow-up period. These findings underscore the stent's biomechanical stability, conformability, and biocompatibility, which collectively minimize complications such as restenosis, thrombosis, or stent migration (Wang et al., 2025; Zemaitis et al., 2023).

The manufacturing precision of the Promesa™ JOY stent also contributes to its clinical performance. High-quality Nitinol is carefully selected, laser-cut or braided to specific geometries, heat-set to retain shape-memory, and surface-treated via electropolishing and passivation to enhance hemocompatibility (Duerig et al., 1999; Kolandaivelu et al., 2011). Rigorous mechanical, dimensional, fatigue, and sterility testing ensures consistency, safety, and durability, which are critical for high-risk patient populations.

Despite these positive outcomes, limitations exist. The small sample size and relatively short follow-up period limit the generalizability of these findings. Furthermore, long-term performance in highly calcified or extremely tortuous vessels requires further investigation. Comparative studies with other self-expanding or drug-eluting stent platforms would provide more robust evidence on relative efficacy and safety.

In conclusion, the Promesa™ JOY Self-Expanding Braided Peripheral Stent demonstrates technical reliability, mechanical resilience, and favorable short-term outcomes in the treatment of complex peripheral vascular pathologies. Its design and manufacturing precision, combined with endovascular deployment, make it a valuable tool in modern PAD management. Further long-term and comparative studies are warranted to confirm sustained efficacy and to establish broader clinical guidelines for its use in diverse patient populations.

IX. LIMITATIONS AND FUTURE DIRECTIONS

While Promesa™ JOY Self-Expanding Braided Peripheral Stent System has yielded hopeful outcomes, some limitations need to be considered. Clinical data available so far are largely derived from single-case experience and short-term follow-up. Despite positive findings, they are lacking in the scenario of the device's long-term efficacy and safety, especially among multi-comorbid and multi-level complex arterial disease patients. Large prospective, randomized trials will thus be needed to confirm initial results and guide further in larger and more representative groups of patients.

Another drawback is the absence of comparison trials against other emerging technologies like drug-eluting stents, stents with a covering material, or bioresorbable scaffolds. A head-to-head comparison would more accurately determine the relative advantages of the braided design in terms of patency rate, prevention of restenosis, fatigue strength, and cost. Although the Nitinol braided stent is said to be more flexible and fracture-resistant, long-term chronic biomechanical stress performance in dynamically stressed areas of the vascular system like the femoropopliteal artery has to be proven.

The future is promising in a number of areas of research. Elution of drugs into the braided matrix may have the added effect of suppressing restenosis and neointimal hyperplasia, as would further advanced surface processing to ensure greater hemocompatibility and endothelialization. New generation imaging and intravascular guidance systems will continue to improve deployment accuracy and reduce procedural complications. Long-term mechanical survival, such as fatigue and physiologic crush resistance levels, will be useful to extend long-term survival in difficult anatomies. Additional clinical trials to non-first target anatomic locations. e.g., below-knee arteries and venous disease will establish new device indications. Long-term registries and post-market surveillance will be required to identify unusual complications, follow real-world performance, and guide iterative design refinement and delivery technique development.

Against the backdrop of such transgressions in the context of mass-scale clinical trials, strict comparative trials, and sustained innovation, the Promesa™ JOY self expanding peripheral stent system can further enhance its standing as a tried, trusted, and versatile product for peripheral vascular interventions, delivering better outcomes for patients globally.

X. CONCLUSION

The Promesa™ JOY Self-Expanding Braided Peripheral Stent is a considerable improvement in the treatment of complex peripheral vascular diseases. Its patented Nitinol braid allows for a combination of superelasticity, shape-memory, and mechanical strength, thus enabling the perfect and precise placement, the best conformity to the vessel, and the provision of radial support in the challenging and moving arterial areas.

Clinical cases show that it can perform technically well, cause the blood flow to be restored instantaneously, and give considerable relief from the symptoms experienced by patients with different pathologies, such as Peripheral Arterial Disease, Popliteal Artery Aneurysm, Popliteal Artery Entrapment Syndrome, Intrapopliteal Posterior Tibial Artery Occlusion, and May-Thurner Syndrome. The rigorous manufacturing processes that the company employs, which include laser cutting, braiding, heat-setting, and surface treatments like electropolishing and passivation, guarantee the device's consistent performance, biocompatibility, and long-term patency.

In general, the device- Promesa™ JOY is a safe, effective, and lasting option for patients with complex peripheral vascular lesions when the surgical route is not taken, especially for those who are at high risk due to other health conditions. Without a doubt, the long-term follow-up studies and the comparative trials will all gear towards the establishment of its clinical advantages and its role in the modern-day endovascular therapy.

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