

Rethinking Balloon Angioplasty: Why Vessel Remodeling Matters

Incorporating Serration Remodeling Therapy to help achieve more predictable luminal gain and minimize vessel trauma to create the best possible foundation for durable outcomes.

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Balloon angioplasty remains one of the most commonly performed procedures in vascular intervention. It is simple, familiar, and serves as the foundation for treating peripheral artery disease, dialysis access stenosis, and plays a role in most vascular reconstructions. Yet, despite decades of innovation surrounding adjunctive technologies, the balloon itself has changed very little.

Conventional angioplasty relies on force rather than precision. The vessel stretches until plaque fractures unpredictably or the artery dissects. Operators have come to expect elastic recoil, uncontrolled dissections, inconsistent luminal gain, and the possibility that additional devices—or permanent implants—will be needed simply to achieve an acceptable result. Negative outcomes have become routine and are viewed as an unavoidable consequence of angioplasty.

But they shouldn't be.

As our understanding of vascular biology has advanced, it has become increasingly clear that *how* we modify plaque is just as important as *how much* we expand the vessel. The goal should simply be a larger lumen and a controlled remodeling process that minimizes vessel injury while creating a durable foundation for long-term success.

Serration Remodeling Therapy (SRT) approaches angioplasty differently. Rather than relying solely on circumferential stretching, the serrated balloon creates controlled linear micro-fissures along the plaque surface, directing the energy in a manner that helps determine how the vessel expands during inflation (Figure 1). This allows plaque to yield more predictably, improving luminal expansion while reducing the uncontrolled vessel trauma.

The impact extends beyond the angiographic result. More predictable arterial expansion influences subsequent

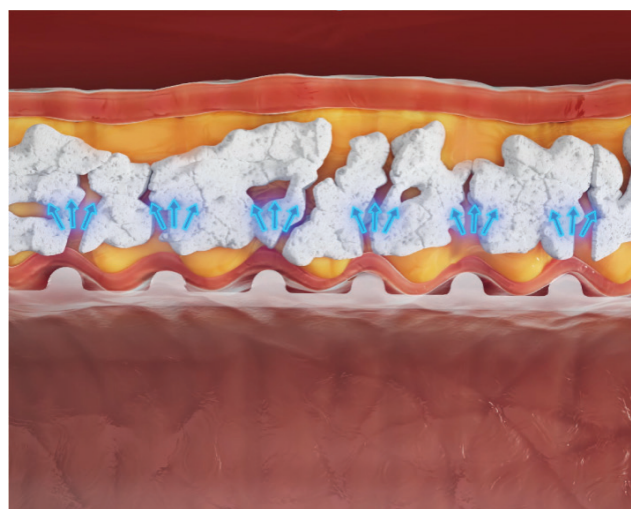


Figure 1. Serrator mechanism of action.

treatment decisions, whether the physician intends to use drug-coated balloons, avoid bailout stenting, preserve future treatment options, or simply achieve the best possible outcome with balloon angioplasty alone.

Importantly, the concept of SRT is supported by a growing body of core lab–adjudicated clinical evidence (Figure 2). In the PRELUDE-BTK study, treatment with the Serrator® PTA Serration Balloon (Cagent Vascular) demonstrated a 97.7% freedom from clinically driven target lesion revascularization at 6 months, with a low bailout stent rate of 1.9%. In a subset of lesions, intravascular imaging also demonstrated the intended mechanism of action, with serrations identified by optical coherence tomography or intravascular ultrasound in all target lesions evaluated.¹

Perhaps even more compelling is what we have learned when SRT has been directly compared with conventional

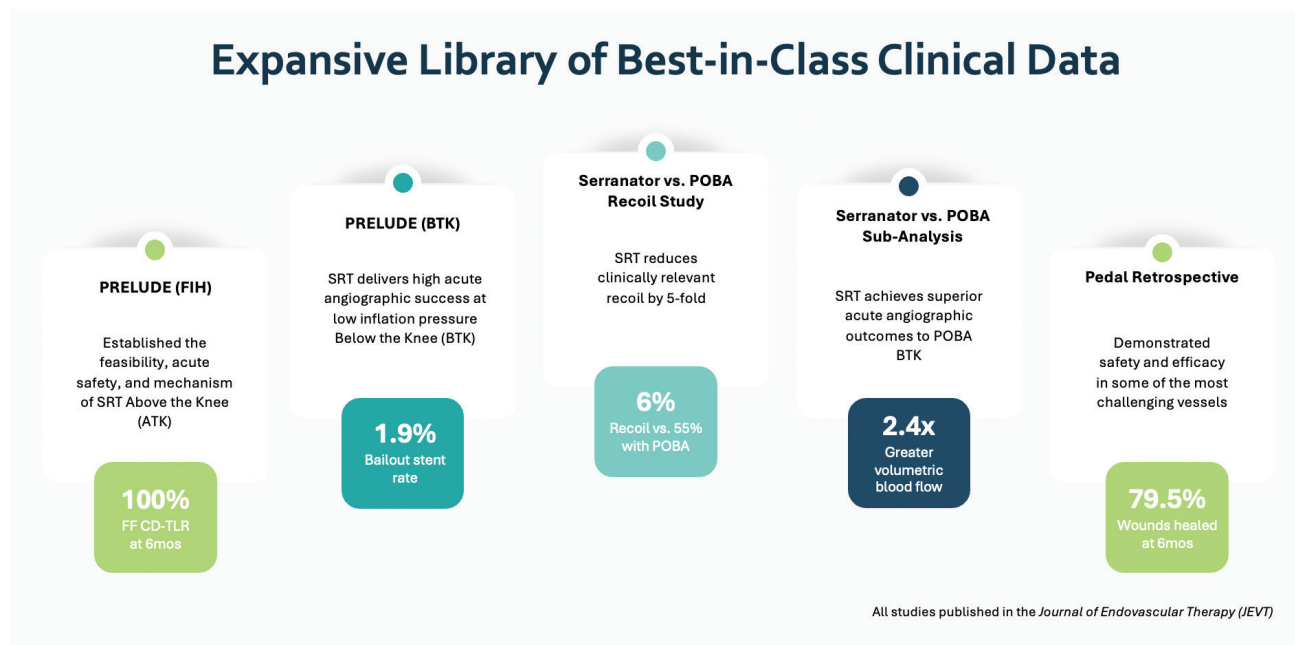


Figure 2. Growing body of clinical evidence supporting SRT.

balloon angioplasty. In a single-center analysis of PRELUDE-BTK, Serranator achieved significantly lower final residual stenosis than plain old balloon angioplasty (POBA), resulting in a 49% improvement in luminal gain and 2.4 times greater volumetric blood flow.² The RECOIL study further highlighted an important distinction between remodeling and conventional angioplasty, demonstrating mean recoil of just 6% following SRT compared with 55% following POBA, as assessed by angiography at 15 minutes after revascularization.³ More recently, the Pedal Study demonstrated the use of SRT in the challenging inframalleolar vasculature, with 79.5% of wounds healed or improving at follow-up and no vessel perforations or distal embolization reported in the study, further supporting the safety profile of controlled vessel remodeling observed with SRT in small, complex vessels.⁴ These findings begin to define what I believe differentiates vessel remodeling from conventional angioplasty: achieving lumen gain is important, but maintaining that gain while minimizing vessel injury and recoil may be equally important.

SRT is not limited to one lesion type or one vascular territory. As physicians have incorporated this technology into their practices, its role has expanded naturally—from femoropopliteal disease to below-the-knee interventions, dialysis access, pedal arteries, and large-bore access for structural and aortic procedures. The common thread is not anatomy. It is the need for controlled vessel remodeling wherever balloon angioplasty remains the cornerstone of treatment.

The cases presented throughout this supplement reflect that evolution and demonstrate how experienced physicians are integrating SRT into their treatment algorithms across diverse clinical scenarios. Although each anatomy presents unique challenges, the objective remains the same: achieve more predictable luminal gain, minimize vessel trauma, and create the best possible foundation for durable outcomes. ■

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Disclosures: Consultant to Medtronic, Boston Scientific Corporation, Cagent Vascular, Acotec, Abbott, Endologix, Shockwave Medical, Healthcare Inroads, BD Interventional, Stryker, and Cordis.