Table 1: Ongoing Trials of Novel Scaffolds in BTK PAD

Study Name	Study Design	Comparator Groups	Cohort Size	Aims	Results
STAND trial (NCT03477604)	Prospective, multi-center, two-arm, randomised trial	MicroStent versus standard PTA	Estimated 177 participants with RC 4–5 BTK PAD	- Primary outcomes were 6-month patency of the target lesion, 30-day freedom from perioperative death, and 6-month freedom from major adverse limb. - Secondary outcomes were 6-month freedom from major amputation, 6-month freedom from major amputation, 6-month reduction in size of ischaemic leg/foot ulcers, 36-month freedom from major adverse limb event, and 36-month frequency and severity of serious adverse events and device and	- Ongoing

					procedure related adverse events.	
DEEPER LIMUS trial (*NCT0416241)*	Prospective, single-center, non-randomised pilot study	Temporary Spur Stent System and a commercially available, limus-base, drug coated balloon	Estimated 30 participants with RC 3–5 BTK PAD	-	The primary endpoint was a 6-month composite endpoint of all-cause mortality, freedom from CD-TLR, and major amputation. - Secondary efficacy endpoints included 6-month late lm loss, primary patency, change in RC, and wound healing.	- Ongoing
PROMISE trial	Prospective, single-center, randomised controlled trial	LimFlow stent graft system	32 patients with RC 5–6 BTK PAD	-	Primary and secondary safety endpoints were AFS at 30 days and 6 months respectively. - Secondary efficacy endpoints included primary patency, wound healing, and technical success.	- Mustapha JA, et al. report 100% amputation-free survival at 30 days and 6 months with 100% technical success rate and no reported procedural complications. 1- and 6-month primary

			patency rates were 90 and 40% respectively with 30% of patients requiring reintervention. At 6 months, 80% of patients had greater than 60% wound healing. - Clair DG, et al. report 97% technical success rate, 30-day, 6-month, and 12-month AFS rates of 91, 74, and 70%. seventy-five% of wounds were healed of healing at 12 months. fifty-two% of patients required reintervention, predominantly driven by inflow disease proximal to the DVA circuit. At 24 months, AFS rate was 59% driven by overall

							increase in all-cause mortality with stable rate of freedom from major amputation. eighty-five% of patients had fully healed wounds.
PROMISE II trial (*NCT03970538*)	Prospective, multi-center, single-arm, randomised pivotal study	LimFlow stent graft system	Estimated 120 patients with RC 5–6 BTK PAD	-	Primary and secondary safety endpoints were AFS at 30 days and 6 months respectively. - Secondary efficacy endpoints included primary patency, wound healing, and technical success.	-	Ongoing
SAVAL trial (*NCT03551496*)	Prospective, multi-center, two-arm, randomised study (Phase A) and non-randomised study (Phase B)	SAVAL BTK drug-eluting stent system versus standard PTA	Estimated 301 subjects total with RC 4–5 BTK PAD	-	Primary effectiveness endpoint was primary patency at 12 months and primary safety endpoint is major adverse events (i.e. above ankle amputation in index	-	Ongoing

					limb, major re-intervention, and 30-day perioperative mortality at 12 months). - Secondary outcomes included patency, major amputation, and CD-TLR.	
LIFE-BTK trial (NCT04227899)	Prospective, multi-center, two-arm, randomised controlled study	Espirit BTK device versus standard PTA	Estimated 225 participants with RC 4–5 BTK PAD	-	Primary outcome measures were the composite of limb salvage and primary patency at 6 months and freedom from major adverse limb event and perioperative death at 30 days and 6 months. - Secondary efficacy endpoints included patency, technical success, and wound healing.	- Ongoing

Glossary: DVA=deep vein arterialisation.