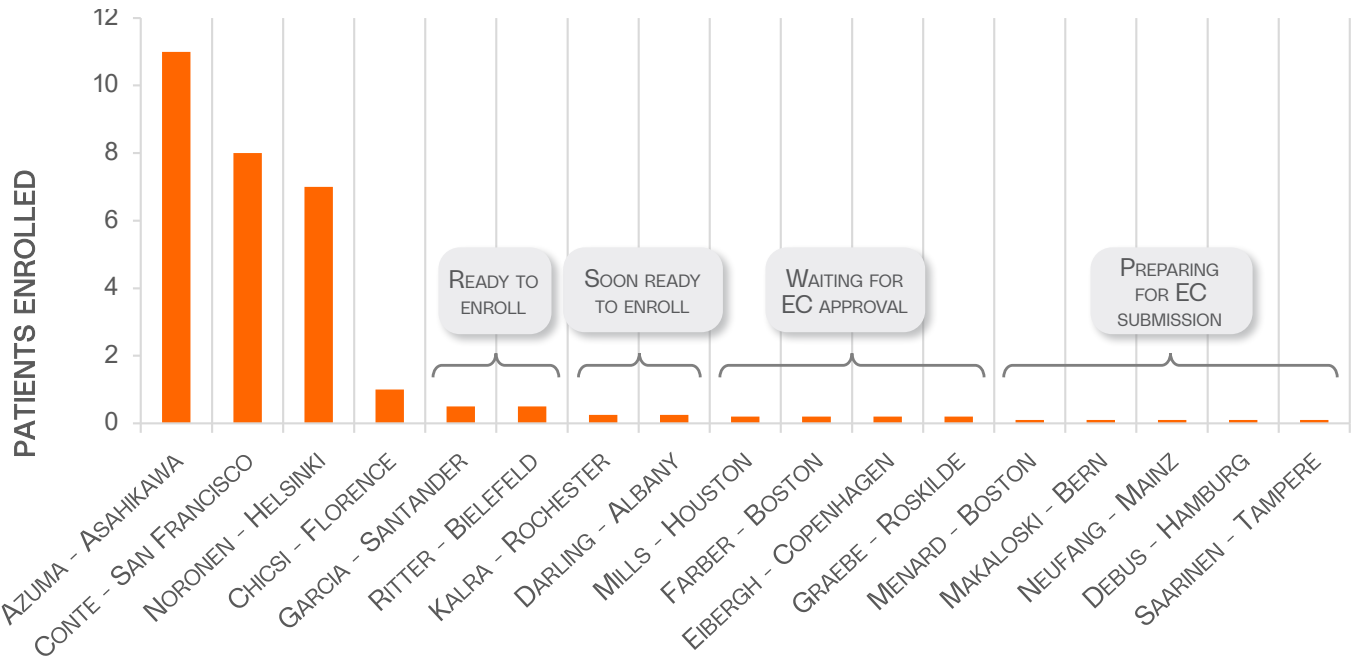


PATENTstudy NEWSLETTER

Total # patients enrolled: **27/450**


Dear investigators and participants in the PATENT study!

This is the second Newsletter meant to keep you updated and engaged in the study. Many centers are still waiting for approval by Ethical Committee (EC) but we are very happy to see that the sites with this in place have been quick to start enrolling patients. Find your site and place in the race in the chart below:




Top enrollers

11




Azumas' team in Asahikawa, Japan, started with a very high enrolment pace and is still in the lead.

8



Conte's team in San Francisco enrolled three patients in April.

7



The team in Helsinki, led by Noronen is the only team with an enrolment in May.

1




NEW ENROLLING SITE!
Chisci's team in Florence has started up and enrolled their first patient. We're looking forward to following their progress.

CRF clarifications

PAPAVERINE DOSE
Start with 30 mg. If no increase in flow within 2 min., inject a 2nd dose of 30 mg.

REVASCULARIZATION AFTER INDEX SURGERY
Replacing up to 2/3 of vein graft with artificial graft is acceptable for keeping the patient in the study.

GRAFT PATENCY FOLLOW UP WITH DUPLEX ULTRASOUND
Measurement of the inner diameter of graft require a circular shape. If a circular shape cannot be achieved, no data should be entered.

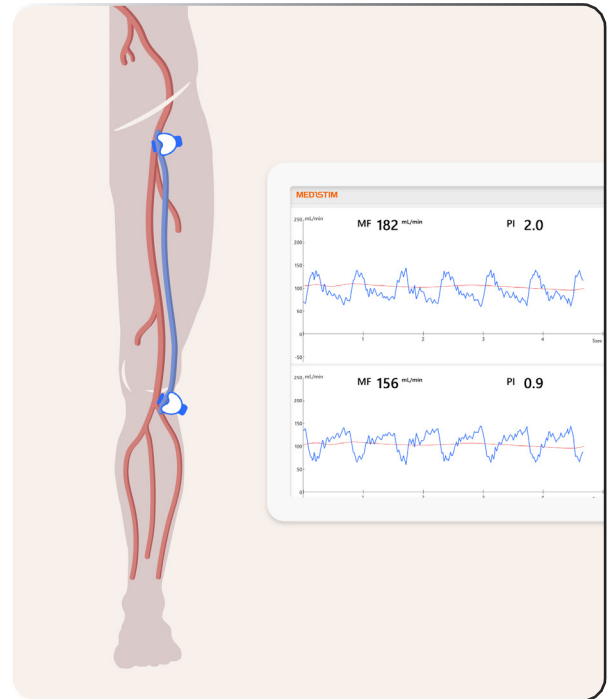
IMPORTANT!

How to get correct TTFM measurements

TTFM measurements from the initial patients frequently show large variations in flow between the measurements close to the proximal versus the distal anastomoses. To avoid that this is due to using the wrong probe sizes, we have decided that the measurements proximally and distally should be performed **simultaneously**, using two probes.

If the flow differs by more than approximately 10% between the two measurements, check if there is a reason for this, eg. open vein branch or incorrect probe size. If the probe size is too small, the flow measured will always be too low. If the probe is too large, measurements could be inaccurate unless the vein is perfectly aligned perpendicularly between the TTFM reflectors

E.G. if the minimum caliber of the vein graft is in the range 4.0 – 4.5 mm, the probe size should be 5 mm at the distal end of a non-reversed graft, and larger at the proximal part dependent on graft length (5, 6, 7, or 8 mm).



Sponsor's Corner

When monitoring the enrolled patients' data and measurements, it's important that the measurements and imaging videos are correctly labeled. We found an easy solution to this:

There are 9 files that must be stored in the system and the necessary labeling. We only need **3 different labels**:

1. TTFM of Proximal anastomosis before vasodilatation
2. TTFM of Distal anastomosis before vasodilatation
3. TTFM of Proximal or distal anastomosis after vasodilatation
4. Transversal HFUS of proximal anastomosis in 2D
5. Longitudinal HFUS of proximal anastomosis in 2D
6. Longitudinal HFUS of proximal anastomosis in Colour
7. Transversal HFUS of distal anastomosis in 2D
8. Longitudinal HFUS of distal anastomosis in 2D
9. Longitudinal HFUS of distal anastomosis in Colour

Labeling:

1. Proximal
2. Distal
3. Post vasodilator
4. Proximal
5. Proximal
6. Proximal
7. Distal
8. Distal
9. Distal



We invite all investigators and coordinators attending ESVS to a **PATENT investigator meeting in Istanbul: 24 September, 19:00-20:30**, followed by dinner. Venue and restaurant to be decided.

FUN FACT: The PATENT study is included in the preliminary program for the meeting. A video update will be presented on Thursday 25th of September