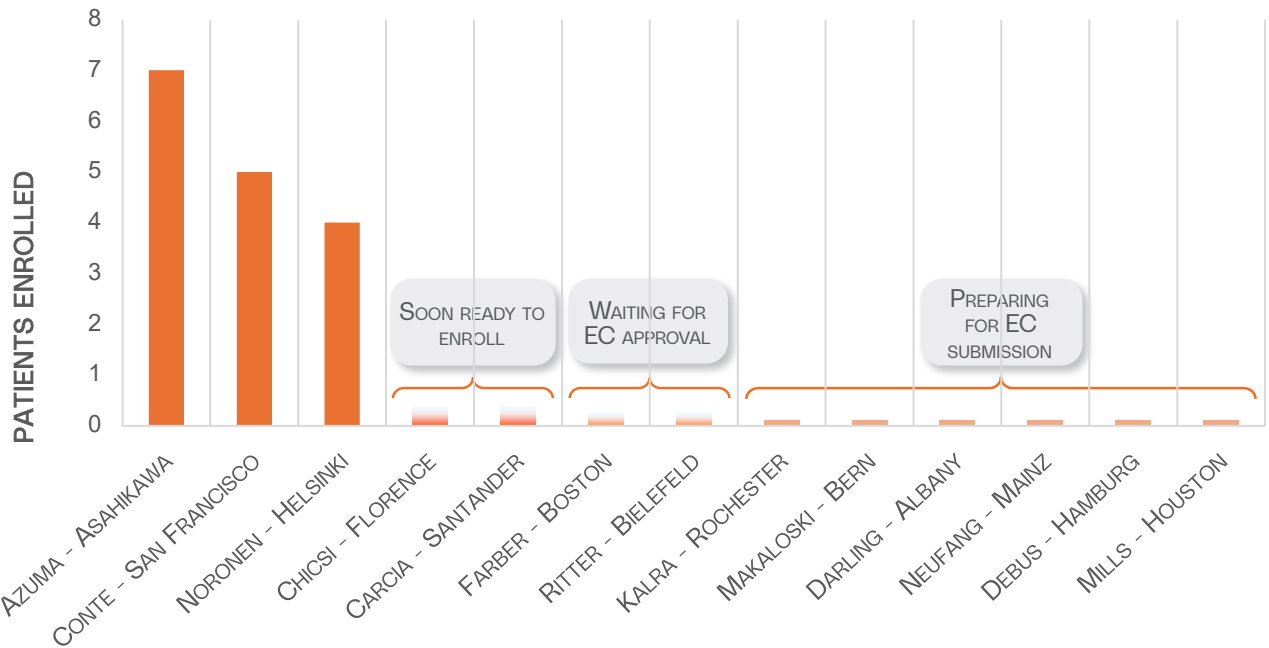


PATENTstudy NEWSLETTER

Total # patients enrolled: **16/450**

Dear investigators and participants in the PATENT study!

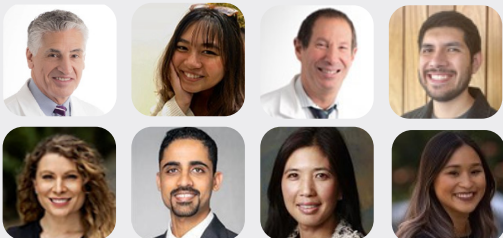
This is the first Newsletter meant to keep you updated and engaged in the study. We're still in the phase where many centers are waiting for approval by Ethical Committee (EC) but are very happy to see that the sites with this in place have been quick to start enrolling patients. Find your site and place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



Top enrollers



Azumas' team in Asahikawa, Japan, is currently in the lead with 7 patients enrolled. Interestingly, more than half of the patients have in-situ grafts. With this speed, this site might finish enrollment first.



UCSF with Michael Conte and Alexis Callanta have been busy in San Francisco, staking out the path for others by testing out the protocol and the upload procedure. This team enrolled the first patient already in December and have enrolled 5 patients so far.



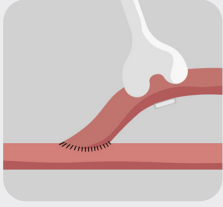
The team in Helsinki, led by Katariina Noronen, have unfortunately had some challenges with the hospital's firewall, a crashing Flash drive and even a crashing MiraQ. After we sorted this out, they have enrolled 4 patients in less than one month.

Sponsor's Corner

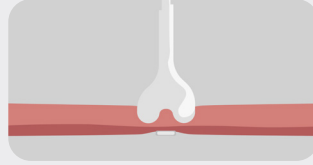


After reviewing the test cases and the first enrolled patients, we have a few things we would like to remind all sites of. Most important: write the **PATENT patient number** in the Comments field on the MiraQ.

TTFM measurements are to be performed **on the SVG graft** and not the native artery.



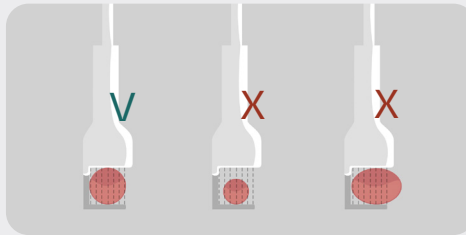
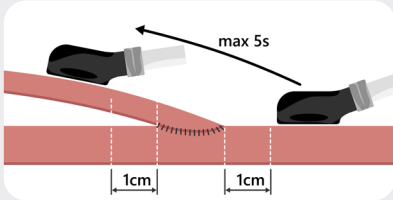
For TTFM on the SVG, you will probably need **two probes** - one for the proximal and one for the distal measurement. Using a too small or too large probe will lead to less accurate measurements.



A too small probe narrows the graft, hence the flow will be underestimated and PI will be elevated.

It is very important that all measurements include the **anatomic location labeling** for us to be able to understand what we are looking at. This means to choose SVG proximal or distal for TTFM and proximal or distal anastomosis for HFUS. If you need to add more labels, this can be added. Contact us if you need help with this.

For both HFUS and TTFM, **pressing save** will store the data leading up to the time you tap "Save" - 60 seconds for TTFM and 5 seconds for HFUS.



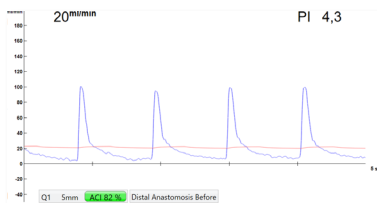
A too large probe allows for angle errors so that the measurements will be less accurate. The vessel should fit snugly in the probe.

For in-situ grafts, remember to perform TTFM and HFUS **assessments with MiraQ** before you start looking for open vein side-branches with additional Duplex ultrasound or angiography.

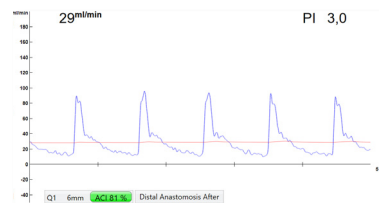
Cases Corner

This first case is from UCSF. Dr. Ahmed Naiem performed a diagnostic angiogram for severe CLTI which showed heavily calcified infrapopliteal vessels with disease not amenable to endovascular treatment. After bypass, there was minimal increase in flow after Papaverine due to the stiff arteries in the distal bypass target and below the ankle. Note the jagged downsloping curve in the diastolic phase that shows the high resistance in the vascular bed.

A similar lack of flow increase after papaverine can be seen if there are spasms in the target arteries.



Distal before papaverine

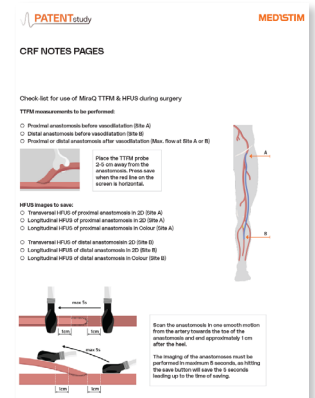


Distal after papaverine

Clinical Coordinator's Corner

We received valuable input from Alexis at UCSF regarding the CRF Notes pages for OR. She suggested that we extended this file to cover the entire eCRF.

We did so, and this PDF can be downloaded from the eTMF (Folder 02.01.07) as well as the shorter version (CRF notes pages for OR).



Upcoming events



Investigator meeting at SVS in New Orleans the 4th of June at 6:00 to 8:00 pm, followed by dinner. Invitation has been sent.



Investigators meeting at ESVS in Istanbul one of the days 23-26th of September. A separate invitation will be sent out.

Sponsored by:

