



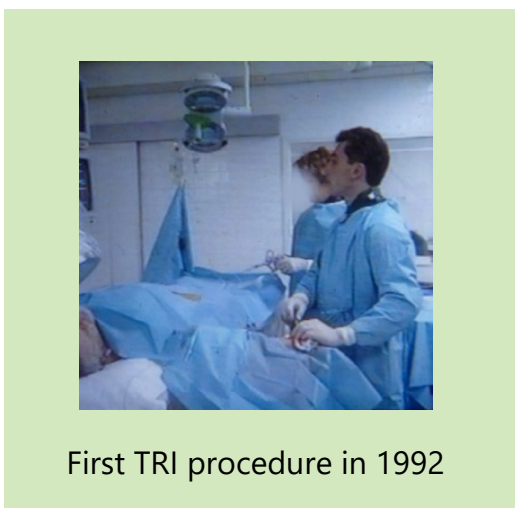
TRI 30th Anniversary Newsletter Vol.1

Looking back at 30 years of TRI

The year 2022 marks the 30th anniversary of transradial coronary intervention - TRI. The first TRI procedure was performed on August 14, 1992, by Dutch physician Dr. Ferdinand Kiemeneij. It was inspired by Dr. Lucien Campeau's paper on transradial coronary angiography, published in 1989. At that time, the more traditional transfemoral intervention (TFI) sometimes resulted in bleeding complications, which could be life-threatening. The idea behind using a TRI approach was that the issues with the groin could be resolved if the wrist was used as an alternate insertion site in PCI, in other words, using the radial artery to access the coronary artery.



Dr. Ferdinand Kiemeneij



First TRI procedure in 1992

Access via the radial artery had several advantages over the femoral. It is a relatively superficial artery, with no major nerves or veins in the nearby vicinity. A radial approach could also reduce the risk of retroperitoneal hemorrhaging, a complication associated with femoral artery access, making it a relatively safer technique. In addition, it offered a simplified hemostasis. Patients treated with TRI could leave immediately after the treatment, unlike those treated with TFI who needed bed recovery time. The contrast was striking.

PUSHING BOUNDARIES





Radial 30th TRANSFORM LIVES WITH TRANSRADIAL

The advantages of TRI as a way to improve patient wellbeing were clear. The next step was finding a way to share the value of the procedure to a bigger audience. In 1994, Dr. Kiemeneij gave the first presentation on TRI at a meeting of the American Heart Association (AHA). Physicians gradually became interested in this new procedure, including Dr. Jean Fajadet and Dr. Yves Louvard and other subsequent TRI key opinion leaders. In fact, Dr. Fajadet was the first to disseminate TRI globally, performing a live demonstration of TRI from Toulouse for TCT held in Washington, garnering attention for TRI. As interest among physicians grew, the first Kiemeneij TRI course was held in 1995. Physicians who learned the procedure in turn brought TRI to different regions, accelerating the recognition and dissemination of the technique.

As TRI gradually became more widespread, there was also a need to find a way to reduce the risk of radial artery spasms, an issue associated with the procedure. TRI needed dedicated needles and sheaths designed specifically for the procedure, and while the Cook hydrophilic-coated sheath was sufficient, it came with the risk of sterile inflammation in the wrist.*1

With the expectation that the Radifocus™ Introducer II M coat™ sheath from Terumo (brand name in North America: Glidesheath) could resolve this issue, the TRACTORS study, the first joint study by Dr. Kiemeneij and



Dr. Jean Fajadet



Dr. Yves Louvard

TRACTORS Study

(TransRadial Angioplasty and Coated Terumo Radifocus Sheaths)

Study

Comparison of force required for sheath retrieval in coated and uncoated sheaths.

Evaluator

Dr. Ferdinand Kiemeneij, [ADIC-OLVG, The Netherlands]

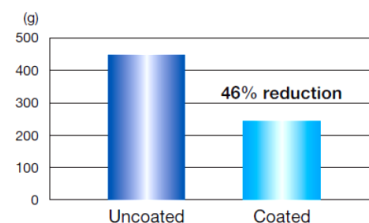
Method

- N=90 patients (45 each) treated via transradial angioplasty by double blinded randomization.
- Sheath: 6Fr., 25cm of M Coat sheath and uncoated Terumo sheath.
- Measurement of force: By automatic pullback device.

Conclusion

- The M Coat sheaths require less force to retrieve from the radial artery.
- Use of a coated sheath is associated with less discomfort for the patient.
- No adverse events associated with this coating have been recorded.

Result ■ Maximum Pullback Force



■ Pain during sheath removal

	Uncoated sheath N=45	M Coat sheath N=45	P
Pain Out	1.42	1.09	0.009
Pain >1	12 (27%)	3 (7%)	0.02

1 = nothing felt, 2 = noticeable sensation but no pain, 3 = mild pain, 4 = significant pain, 5 = unbearable pain

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Terumo, was conducted to demonstrate its efficacy. This study was the first to numerically demonstrate the effect of a hydrophilic coating on sheath removal force. The study demonstrated that the hydrophilic-coated sheath was more easily retrieved and was associated with less discomfort for patients.

With its early focus on TRI, Terumo proactively developed and supported the use of devices for transradial procedures, including hydrophilic-coated sheaths and the hemostatic TR Band. The advent of appropriate devices was a key factor in accelerating the widespread use of TRI procedures and Terumo has continuously provided devices and tools, alongside opportunities for the training of healthcare providers. Terumo has also developed educational tools including a radial procedure simulator and a vessel puncture training model, in addition to creating educational programs with Dr. Shigeru Saito and other pioneers of the radial approach, serving as lecturers around the world. In Japan, Terumo's home, the Terumo Medical Pranex, a comprehensive training facility, to provide training to healthcare providers was established.

Thanks in part to steady and consistent promotional activities, the transradial approach gradually gained popularity worldwide and is now used for the vast majority of coronary procedures. In the United States, which lagged behind in the shift to radial access, a recent report indicates that more than 50% of procedures are now performed with TRI. The European Society of Cardiology (ESC) guidelines and the ACC/AHA/SCAI guidelines in the US now recommend TRI as the standard procedure, based on the demonstrated safety of radial procedures in clinical studies. In the coronary area, TRI is now firmly established as a standard procedure.



PUSHING BOUNDARIES



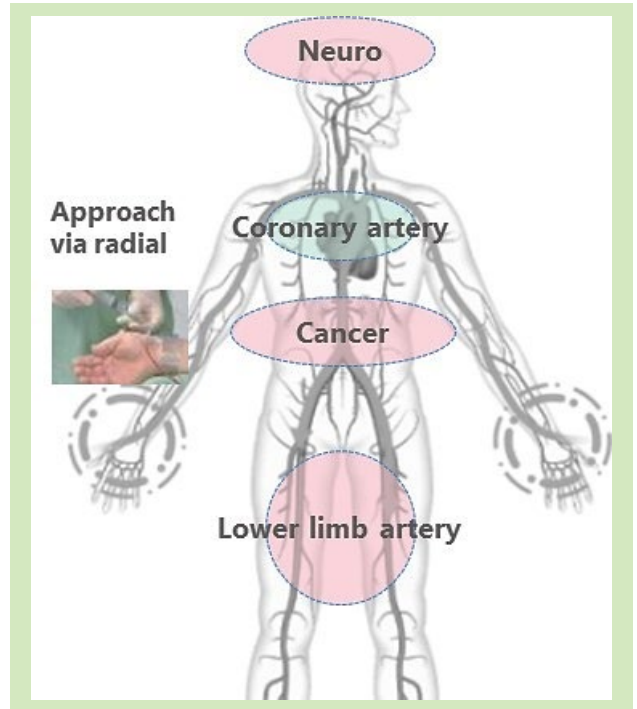


Radial 30th

TRANSFORM LIVES WITH TRANSRADIAL

In recent years, the new distal radial approach has become more common and is expected to provide more patient-friendly treatment options. At EuroPCR 2022, the results of the DISCO RADIAL trial were reported, the first randomized, international, multicenter trial to compare conventional and distal radial access which was conducted in a large population of 1,300 subjects. The use of radial procedures has now expanded into other areas including the visceral, peripheral, and head and neck.

The more progress made in radial procedures, the more advantages can be expected for patients, and medical device manufacturers will be expected to produce dedicated devices tailored to these new procedures. At Terumo, we hope to continue using our expertise and knowledge in TRI to support the needs of healthcare providers and improve the quality of life for more patients.



*1. Rajesh V. Swaminathan , et al, Radial Access Site Inflammatory Reaction to Recently Available Hydrophilic Coated Sheath Catheterization and Cardiovascular Interventions 77:1050–1053 (2011)



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