

## **TRACS: TransRadial Access bleeding Control using SoftSeal**

A pilot study of post procedure care using a SoftSeal®-STF Hemostatic Pad to control bleeding following transradial coronary angiography

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### Introduction

Transradial access (TRA) for coronary angiography and intervention has increased in popularity due to reported lower rates of vascular complications, earlier patient mobility and improved patient comfort compared to the transfemoral route. To attain hemostasis after radial sheath removal, standard practice employs use of a compression band for a period of two to four hours. The band compression is monitored by the nursing staff and gradually reduced over the application time.

The purpose of this investigation was to evaluate an FDA cleared topical hemostat, SoftSeal®-STF Hemostatic Pad (Chitogen, Inc.) as a substitute for the TR Band™ (Terumo Corp.) The SoftSeal topical pad is composed of the biopolymer, chitosan.

### Methods

After providing informed consent the patients underwent the angiography procedure as per routine protocol. Unfractionated heparin 4,000 or 5,000 units were used in the standard radial cocktail depending on the patient's weight and history. 4 Fr to 6 Fr introducer sheaths were used. Immediately post procedure an ACT was performed, the introducer sheath removed and the pad applied with mild compression with a target of 2 minutes per Fr size or until complete hemostasis was attained. A small thin gauze covered with transparent bio occlusive dressing was then applied to be able to visualize any recurrence of bleeding.

### Results

Thirty (30) patients were entered into the study. The average age was 64 years, 21 were male, and 10 had diabetes mellitus. A 6 Fr introducer sheath was used in 23 patients, 5 Fr in 3, and 4 Fr in 4 patients. The average hold time to achieve hemostasis was 13.3 minutes (range 8-22 min), with an average ACT of 223 (range 173-306). No late bleeding events occurred and no hematoma was reported in this series of patients.

Initially the application of the pad was done in the cath lab but with experience we were able to move the patient to the recovery room for the hold time and thereby begin preparing the lab for the next procedure.

### Conclusions

The SoftSeal hemostatic pad can be used to effectively control bleeding following a TRA procedure without vascular complications. This small patient study could be expanded to elaborate upon its findings of clinical effectiveness, impact on radial artery occlusion rates and convenience of use.

Presented at Cardiovascular Research Technologies,  
Annual Meeting, CRT 16, February 20<sup>th</sup> to 23<sup>rd</sup> in Washington D.C.