

through the VWNG using a standard blunt dialysis needle. This included one patient who achieved self-cannulation of a deep cannulation site. There have been 261 successful cannulations in 270 attempts (97% success rate). There have been no device related AVF stenosis, thrombosis or infection. There has been no AVF loss or intervention due to the device. Palpability, insertion attempts, ease of insertion, insertion pain and time to hemostasis are clinically comparable to non-VWNG cannulation site.

Discussion: First In Human clinical experience demonstrates good functionality and safety of VWNG as an implanted needle guide to provide buttonhole access to a previously difficult to cannulate, deep AVF. Access to AVF through the VWNG is comparable to an accessible AVF site. There have been no serious complications resulting from use of the device including stenosis, thrombosis or infection.

Randomized Trial Utilizing Elastase for AVF Surgery

Eric Peden

Methodist DeBakey Heart & Vascular Center, Houston, TX - USA

Background: AVF utilization has improved dramatically in response to the Fistula First Initiative. AVF maturation however has continued to be quite variable and generally falls below hoped for levels. Elastase utilization at the time of AVF creation has been proposed to potentially improve AVF outcomes with increased vein diameters and improved fistula maturation.

Methods: A trial sponsored by Proteon Therapeutics randomized patients to placebo vs. escalating doses of PRT201, a recombinant human elastase, as a Phase 1/2 study in patients undergoing creation of a radiocephalic or brachiocephalic fistula. Investigational drug was dripped onto the anastomotic area for 10 minutes after fistula creation and then irrigated with saline for 1 minute. Patients were followed for up to 12 months with duplex evaluations at 6 weeks, 3 months, and 6 months. Outcomes measured included immediate vasodilation, changes in blood flow, patency, maturation, and adverse events. The treatment groups were lumped into placebo, low, medium, and high doses for analysis purposes.

Results: Analysis of results continues at the time of writing this abstract. No safety concerns were identified. No significant immediate change in vessel diameter occurred. Vessel diameter and blood flow increased in all patient groups with no significant difference in maturation at 6 weeks or primary patency at 6 months. There were 3 early failures in the low dose group (within 14 days) that were not thought to be due to the study drug. If these 3 failures are excluded from analysis, primary patency, maturation, and reduction in hemodynamically significant stenoses are all improved in the low dose group compared to the placebo group.

Conclusion: Elastase treatment of the anastomotic area of AVF's appears to be safe and maybe efficacious in improving AVF outcomes. Further data collection and analysis of the current trial is required to better evaluate these results. Another study is currently underway with more adequately powered subject numbers to further explore the outcomes of PRT201.

Tissue Engineered Blood Vessels for A-V Access: Transitioning toward Widespread Clinical Use

Todd N. McAllister^{1,2}, Wojciech Wystrychowski³, Lech Cierpka³, Krzysztof Zagalski³, Sergio Garrido⁴, Jaime Velez⁵, Samuel Radochonski¹, Nathalie Dusserre¹, Nicolas L'Heureux^{1,2}

¹Cytograft Tissue Engineering, Inc. Novato, CA - USA

²Saint Joseph's Translational Research Institute, Atlanta, GA - USA

³Department of General, Vascular, and Transplant Surgery, Medical University of Silesia, Katowice - Poland

⁴Fleni Hospital, Buenos Aires - Argentina

⁵Farallones Hospital, Cali - Colombia

End Stage Renal Disease (ESRD) is one of the most costly and debilitating chronic diseases in the industrialized world, with nearly 400,000 patients on hemodialysis in the U.S. alone (1). Creation and maintenance of access shunts continues to be a principal challenge associated with dialysis, and accounts for nearly 20% of all ESRD-related expenses (2,3). While recent initiatives to decrease graft usage have been successful in shifting clinical