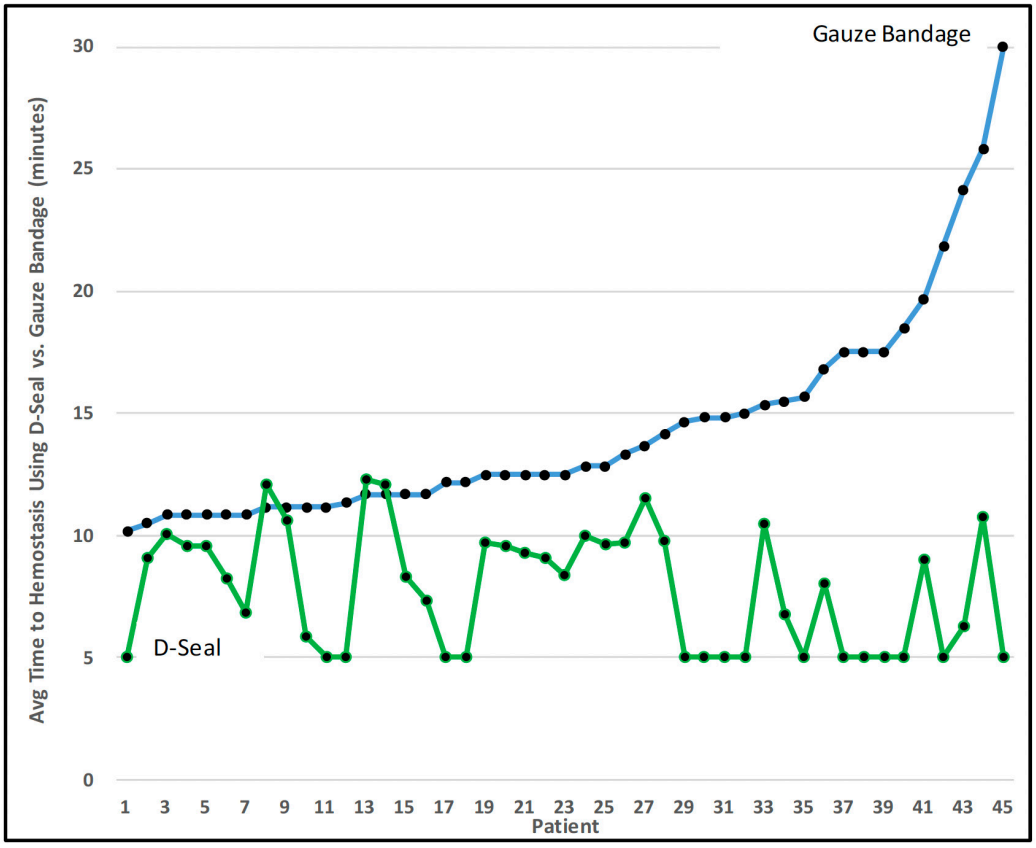
Excerpts from Chitogen's 2023 Vendor Request for Information Survey regarding the efficacy, patient satisfaction, staff satisfaction and overall performance of the D-Seal® pads vs previous methods used to achieve hemostasis.

Clinical Outcomes

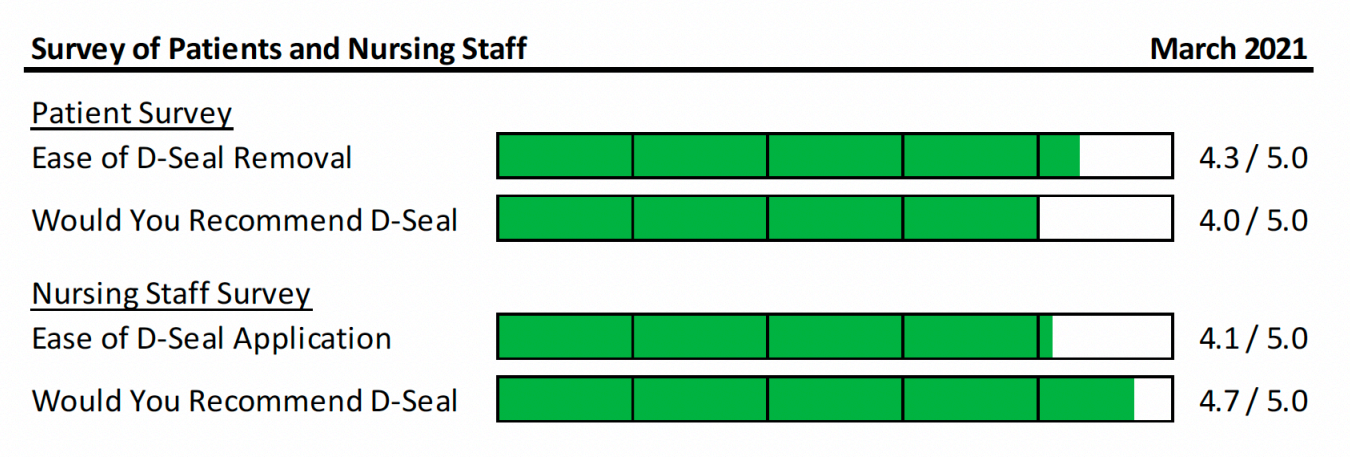
Since its introduction into the Marketplace in Q4 2021, Chitogen has grown its deployment of D-Seal to 18 dialysis centers, and, as of March 31, 2023, has seen D-Seal used in more than 40,000 dialysis treatments with no adverse occurrences reported.

Prior to its introduction in Q4 2021, D-Seal was used in 3 trials consisting of 45 patients who developed a baseline performance (gauze bandage) greater than 10 minutes for 2 weeks and a D-Seal trial performance for 2 weeks. In these trials, the average baseline time to hemostasis (with gauze bandage) was 14.4 minutes, compared to D-Seal, with which the average time to hemostasis was 8.6 minutes – an average of 5.8-minute savings per treatment. When isolating the baseline performance to those patients whose baseline was greater than 15 minutes, the average savings per treatment was 13.1 minutes. A chart of the 45 patients follows.



Patient and Staff Satisfaction

In addition to its above-described clinical results, the D-Seal trials were met with excellent feedback from patients and caregivers. The following chart summarizes the feedback.



In addition to the D-Seal studies, several clinical studies report on the SoftSeal-STF Hemostatic Pad performance that demonstrates reduced hold time to achieve control of bleeding. These studies are described below:

Nolan Machernis, MD, at the Aurora St. Luke's Medical Center: a study of 1,348 patients in propensity match analysis. The patients were entered into the study from April 2015 to June 2016. The hold time to achieve hemostasis after transfemoral catheterization was 7.79 minutes for the SoftSeal group compared with the traditional manual compression group reported as 20 minutes. These data were statistically significant at $P<0.001$. Complications for each group were statistically equal. The study citation is: Machernis, N., Mengesha, T., Shearer, R., Kostopoulos, L., Shalev, Y., Nfor, T., & Allaqaband, S. (2017). Clinical efficacy of SoftSeal®-STF Hemostatic pad with short hold time compared to traditional manual compression after transfemoral catheterization. Journal of the American College of Cardiology, 11(69), 1165.

Yoseph Shalev, MD, at the Wheaton Franciscan St. Joseph Campus: completed an open-label, nonrandomized, prospective study to assess the usefulness of SoftSeal to achieve hemostasis from a percutaneous, femoral, access. The patients were entered into the study from October 2014 to December 2014. The SoftSeal group, 30 patients, was pre-determined to be a six-minute hold, compared to the retrospective group which averaged 19 minutes. Complications were reduced in the SoftSeal group with hematoma incidence was statistically reduced at the $p<0.05$ level. The study citation is: Shalev, Y. and Mahn, M. (2016). SoftSeal Hemostatic Pad clinical utility in the control of bleeding after Trans Femoral Access (TFA) intervention using a 6 French Sheath. AVA Annual Meeting, September 2016.

David Lasorda, DO, at the Allegheny General Hospital: the average hold time for 30 patients was 13.3 minutes, and was reduced such that the post procedure pad use was moved from the catheter lab to the recovery room. The patients were entered from April 2015 to August 2015. This was a trans radial access and the post procedure ACT was 223 with a range of 173 to 306. No late bleeding or hematoma was observed in the SoftSeal group. The comparison or institute standard of care specified the TR Band. The study citation is: Smith, T., Lasorda, D., Rhalil, R., Chakravarthy, M. & Rayl, K. (2016, February). A pilot study of post procedure care using a SoftSeal®-STF Hemostatic Pad to control Survey of Patients and Nursing StaffMarch 2021Patient SurveyEase of D-Seal Removal4.3 / 5.0Would You Recommend D-Seal4.0 / 5.0Nursing Staff SurveyEase of D-Seal Application4.1 / 5.0Would You Recommend D-Seal4.7 / 5.0 bleeding following trans radial coronary angiography. Presented at the annual meeting Cardiovascular Research Technologies.

Carmelo Panetta, MD, at HealthEast Heart Care, St. Joseph Hospital: SoftSeal was used in a novel method to achieve hemostasis after radial sheath removal; 59 patients were enrolled in the study. The patients were entered into the study from November 2014 to February 2015. The conclusion was that SoftSeal applied with manual pressure when combined with ulnar compression could be an alternative to using an inflatable compression band. The ACT average was 261 and hemostasis was achieved in 15 minutes. Some minor (6%) re-bleeding was reported. The study citation is: Panetta, C. and Rao, S. (2018). Novel method for radial sheath removal using manual pressure over hemostatic pad combined with ulnar compression. Catheter Cardiovasc Inter:92: 322-3324. (DOI:10.1002/ccd27579).