Prospective, Multi-center, Randomized, Crossover Clinical Trial Comparing the Safety and Effectiveness of Cooled Radiofrequency Ablation to Corticosteroid Injection in the Management of Osteoarthritic Knee Pain

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Introduction
Chronic knee pain from conditions such as osteoarthritis (OA) is a significant cause of disability in the aging patient population. While total joint replacement is a well-established surgical treatment for late stage OA, not all patients are well-suited for this procedure due to issues of age, health, or other factors. Cooled radiofrequency ablation (CRFA) has emerged as a minimally invasive option for pain control for patients with knee OA. This study sought to evaluate the safety and effectiveness of cooled RFA (CRFA) when compared to intraarticular steroid injection (IAS) in an OA knee population.

Materials and methods (NA for case report)
After IRB approval was obtained, 151 knee OA patients were properly consented and underwent diagnostic block injection to the superomedial and inferomedial branches of the saphenous nerve and the superolateral branch of the femoral nerve. Patients who had a minimum of 50% pain relief from the diagnostic blocks were randomized to receive either CRFA at the same 3 anatomic sites or a single IAS injection. One hundred and thirty-eight (138) patients proceeded to treatment (n=67 CRFA and 71 IAS). Patients were evaluated at 1, 3, and 6 months following the study intervention. Patients who did not respond to IAS were given the option to cross over to CRFA after the 6-month visit. Pain, function, and safety outcome measures were recorded at all time points.

Results/Case report
The two treatment groups were homogenous for demographic, pain and functional parameters at baseline. Mean NRS (Numeric Rating Scale) at Baseline was 7.3 ± 1.2 (Mean ± SD) for the CRFA group and 7.2 ± 1.0 for the IAS group. One hundred and twenty-six (126) patients remained in the study and were evaluated at 6-months post treatment (n = 58 CRFA and 68 IAS). In the CRFA group, 74.1% of patients had ≥ 50% reduction in NRS pain score compared to 16.2% in the IAS group at the 6 month follow up evaluation (p < 0.0001, primary endpoint). At 6 months, the mean NRS was 2.5 ± 2.3 for the CRFA group and 5.9 ± 2.2 for the IAS group (p < 0.0001), representing a 4.9 point drop in NRS for the CRFA group. The mean Oxford Knee Score was 35.7 ± 8.8 in the CRFA group at 6 months compared to 22.4 ± 8.5 in the IAS group (p < 0.0001). At 6 months, 91.4% of subjects in the CRFA group reported improvement in Global Perceived Effect compared to 23.9% in the IAS group (p < 0.0001). No serious adverse events related to either procedure were noted, and overall adverse event profiles were similar.

Discussion
These results demonstrate that cooled RFA is a safe and effective non-narcotic option for managing pain and improving physical function and quality of life for patients suffering from OA knee pain. CRFA treated patients demonstrated a significant improvement in both pain relief and overall function when compared to patients treated with IAS. Further follow up from this study will evaluate the long-term durability of cooled RFA in this patient population.

Disclosures
I declare that there are no conflicts of interest or support that may cause bias in my presentation.