1. Participant flow

The PEEK-OA study originally intended to enroll ten (10) subjects however, the Sponsor concluded enrolment at nine (9) subjects. Data was available for all nine at the 6-month primary endpoint visit. Four (4, 44.4%) subjects completed follow-up out to 5 years (60 months). Four subjects withdrew consent and one's participation was terminated by the investigator (after 2-year visit) due to subject relocation and inability to continue in follow-up.

2. Baseline characteristics

A table of baseline demographic and clinical characteristics is provided below.

Table 1. Baseline demographic and clinical characteristics

	Intervention (N=9)
Age (years; mean (SD))	55.1 (5.5)
Sex (female; n (%))	3 (33.3%)
Smoker (n (%))	6 (66.7%)
BMI (mean (range))	29.4 (23.6-34.7)
Symptom duration (years; mean (SD))	10.4 (11.7)

3. Outcome measures

The PEEK-OA clinical study primary effectiveness and safety endpoints were met.

The primary effectiveness endpoint of decrease in clinically relevant pain and function were measured by 20% relative and 10-point absolute reduction in WOMAC pain and function, respectively at 6 months compared to baseline. Seven (7/9, 77.8%) and eight subjects (8/9, 88.9%), respectively, experienced at least 20% relative and 10-point absolute reduction in WOMAC pain and function scores, meeting the primary effectiveness endpoint. Subjects experienced significant reduction in pain and function, with a mean reduction of 44.7% and 54.8%, respectively, at 6 months.

The primary safety endpoint was determined by evaluating the incidence of treatment-emergent adverse events (AEs), and physical examination findings assessed at 6 months post procedure. In the first 6 months, there were no device-related adverse events. Therefore, the primary safety endpoint was met.

4. Adverse events (AEs)/harms

Safety in the study was supervised by a Medical Monitor. As noted above, in the PEEK-OA clinical study, the primary safety endpoint was determined by evaluating the incidence of treatment-emergent AEs at 6 months. Eight AEs in five subjects were reported at 6-months, none of which were device-related, and the endpoint was met. Two procedure-related events of deep vein thrombus and cellulitis were assessed as serious, which are typical peri-procedural events for orthopaedic knee procedures.