Objective(s): Various biomechanical, anatomic and hemodynamic forces have presented their unique challenges in the endovascular management of SFA disease and associated stent complications. Currently there are several FDA-approved, on-label stents for the treatment of SFA lesions. However, certain off-label stents have had varying popularity in the past. The MAUDE database was established by the FDA to allow for voluntary reporting of adverse outcomes with medical devices. We sought to investigate at three commonly placed SFA stents, Cordis Flexstent (off-label), Abbott Supera (on-label), Covidien/Medtronic Everflex (on-label) and their reported adverse events and failure mechanisms in the MAUDE database. Methods: This is an IRB exempt, retrospective, observational study using a publicly accessible database. The MAUDE database was searched from January 1, 2012 to December 31, 2017, at a single time point for entries related to Cordis Flexstent, Abbott Supera and Covidien Everflex (off-label) deployed in the SFA. This study identified the total number of reported adverse events and subdivided them into the categories of incidence of death, injury, and malfunction by stent fracture, failure in deployment, stent migration and miscellaneous. The adverse events for all three stents were compared using the chi-squared test. Results: Over the past 5 years, 497 total entries of reportable adverse events (AEs) were identified for Abbott Supera, 136 for Covidien Everflex, and 79 for Cordis Flexstent. Everflex was found to have the highest percentage of injury among reportable events (51%) compared to Supera (41%) and Flexstent (42%), as well as the highest mortality rate (4%) vs Supera (0.02%) and Flexstent (0%). Paradoxically, Everflex also demonstrated the lowest malfunction rate (22.79%) compared to Supera (29.18%) and Flexstent (29.11%). The adverse event rates for all three stents were statistically significantly different by Chi-squared test (Chi2 18.2, df=4, P=0.001). For all 3 stents, the highest reported malfunction was associated with delivery. There was no death reported with off-label use. Conclusions: Through examination of the MAUDE database, the study found higher percentage of reportable injury and death associated with Everflex compared to Supera and off-label Flexstent use. While off-label usage has become a recent of topic of interest with respect to both insurance reimbursement and litigation, this investigation found no evidence that reportable adverse events bear a direct relationship with FDA-approved indications.

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