Docket #: S20-453

Magnetic medical device for efficient removal of kidney stones during ureteroscopy

Researchers at Stanford University have developed a new medical device, MagSToNE (Magnetic System for Total Nephrolith Extraction), which utilizes magnetization to remove kidney stones during ureteroscopy to maximize the stone-free rate and minimize operating time. Surgical management of kidney stone disease includes ureteroscopy, in which a ureteroscope is passed endoscopically up to the stone and a laser fiber is used to fragment/and or dust the stone. While fragmentation and active retrieval of stone fragments achieves higher stone-free rates, it is often associated with a significantly longer operating time as fragments are extracted one by one with a basket. Dusting creates smaller fragments which are left in the kidney and are assumed to pass spontaneously in the urine, however this assumption is not true in all patients.

Complete stone clearance is desirable, as residual stone fragments can re-obstruct the ureter and are associated with complications such as emergency room visits and repeat surgery. Only 60-75% of ureteroscopic treatments achieve complete stone-free status, and around 30% of patients with even small (2 mm) residual fragments experience stone-related complications.

The MagSToNE technology provides a solution to improve surgical efficiency and efficacy by quickly removing stone fragments and achieving more complete stone clearance. The invention consists of two components, a small-diameter flexible magnetic wire (MagWIRE) and superparamagnetic particles with surface chemistries that bind to kidney stones. After a kidney stone is fragmented, a superparamagnetic particle solution is instilled through the ureteral access sheath and coats the fragments, rendering them magnetizable. The MagWIRE is able to enter through the ureteroscope or the access sheath and uses a unique magnetic configuration to generate a strong magnetic field to optimize the capture of stone fragment along

the entire length of the wire (Figure 1).

The MagWIRE can quickly pass in and out multiple times to retrieve multiple fragments with each pass, resulting in the efficient and effective removal of all fragments. This device is designed to work with existing ureteroscopy setups, making it a convenient tool to incorporate into urology practices and presents a great opportunity for companies involved in kidney stone management devices.

Stage of Research

In vitro studies were performed with iron oxide particles of a range of sizes (7 nm to 4.5 µm) and kidney stones of a variety of compositions (calcium phosphate (CaPO4), calcium oxalate monohydrate (CaOxM), uric acid, and struvite). Particles ranging from 50 nm to 3 µm in diameter facilitate the magnetic capture of > 90% of calcium phosphate stone fragments 1 mm in diameter (Figure 2). Ferumoxytol, an FDA-approved nanoparticle used intravenously for the treatment of iron deficiency anemia, also performs satisfactorily. Larger 1 µm particles perform more consistently across a range of stone compositions, also achieving > 90% capture of stone fragments 1 mm in size (Figure 3). For stones 1mm, when compared to conventional basket retrieval, the MagSToNE system retrieved > 10-fold more stone and performed 20 times faster (Table 1).

Research is ongoing to further optimize the particle surface chemistry, particle delivery, and wire design to facilitate capture of larger stone fragments. Particle biocompatibility and proof of concept studies are planned for porcine models.

Figure 1:

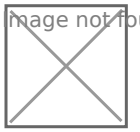

Figure Description: Stone fragments (20% calcium oxalate dihydrate, 80% calcium phosphate) 1 mm in diameter were coated with 1 µm iron oxide particles, rendering them magnetizable. The MagWIRE attracts the coated fragments along the entire length of the wire.

Figure 2:

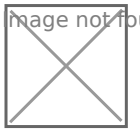

Figure Description: Comparison of MagSToNE capture efficiencies for calcium

phosphate stones of different sizes using different particles. For stones 1 mm in diameter, superparamagnetic particles ranging in diameter from 7 nm to 3 µm facilitate capture efficiencies up to 100%. Capture efficiencies decrease with increasing stone fragment diameter. The 7 nm nanoparticle is ferumoxytol, an FDA-approved nanoparticle.

Figure 3:

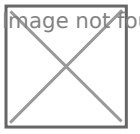

Figure Description: In vitro comparison of MagSToNE capture efficiencies for stones 1 mm of different compositions, using 7 nm particles (ferumoxytol) or 1 µm particles. Ferumoxytol facilitates capture efficiencies of 75%, but 1 µm particles perform superiorly and more consistently across different stone compositions.

Table:

Table Description: In vitro retrieval rate of 100% calcium phosphate stone fragments 1 mm in size, coated with 1 um particles. The conventional NCircle basket had difficulty capturing smaller fragments, and could only capture 2.4 mg of stone (8.6% of total stone burden) in a total time of 150 s, with the attempt being aborted after 150s due to inability to extract further stone. The MagSToNE was able to capture 100% of the stone burden in 76 seconds, representing a > 10-fold increase in efficacy and 20-fold increase in efficiency.

Applications

- Efficiently removes kidney stone fragments using magnetization in stone procedures. Designed for use in ureteroscopy but can also be applied to percutaneous nephrolithomy (PCNL) and cystoscopy for bladder stones.

Advantages

- Maximizes stone free rate while minimizing operative time

- Able to remove small fragments that are difficult to retrieve with conventional baskets
- MagWIRE has slim profile similar to existing guide wires used for ureteroscopy
- MagWIRE has been well-characterized, studied and prototyped in a previous application (see publication)
- Designed to work with existing ureteroscopy setups
- Currently no magnetic stone extraction technologies in commercial use
- Can potentially utilize an existing FDA-approved nanoparticle to facilitate clinical translation

Publications

- Vermesh et. al An intravascular magnetic wire for the high-throughput retrieval of circulating tumour cells in vivo Nature Biomedical Engineering (2018)

Patents

- Published Application: WO2023220755
- Issued: 11,903,666 (USA)

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