RENAL ON FLEXIBLE ULTRASOUND - IMAGING TECHNOLOGIES

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Our project addresses the medical condition *Nephrolithiasis* (kidney stones), specifically ExMC Gap 4.13: Limited capability to diagnose and treat a renal stone. Astronauts are at an increased risk of renal stone development because of microgravity, dehydration, and altered bone metabolism associated with space flight. The risk is that a stone, while innocuous when still in the kidney, will cause debilitating pain as it passes or worse, become obstructing, which can lead to urinary tract infection, sepsis, renal failure, and death. Short of surgery there is currently no available technology to affect when the stone moves from the kidney or manipulate the stone once it has begun to move. We report on progress to develop and validate three new technologies to provide options to manage stones in space. These technologies have been developed on a Flexible Ultrasound System (FUS).

The first technology is to improve imaging of stones, called ‘Stone mode’ or ‘S-mode’, and has two parts: detection and sizing. Size resolution has been improved using the image of the stone itself as well as the shadow behind the stone. With the imaging modifications, the estimated stone size error between S-mode™ ultrasound and computed tomography (CT) in human subjects is <1 mm (95% confidence). Signal to noise ratio of S-mode was 17 times greater on average than that of B-mode.

The second technology is repositioning stones, called ‘ultrasonic propulsion’ or UP. Using a Verasonics FUS (VFUS), commercial handheld probe, and real-time imaging, the stone and kidney are visualized and, with a touch of the screen, a short burst of ultrasound waves is focused on the stone to reposition (push) the stone to a new location. This technology could provide flight surgeons and astronauts the option to expel a small stone when it is likely to pass safely or to push an obstructing stone back into the kidney to relieve symptoms and avoid urgent surgery. With NSBRI funding we have completed the first clinical feasibility test of repositioning stones. No adverse events were associated with the treatment and stones were moved in 14 of 15 subjects. Pain was eliminated for one subject with a 12-mm potentially obstructing stone. Four of 6 post-lithotripsy subjects cumulatively passed over 30 fragments. In 4 subjects what appeared as single unpassable stones on clinical imaging proved to be collections of small passable stones. Pushing capability has been added to NASA’s FUS.

The third technology is the capability to use ultrasound pulses and not shock waves to fragment stones. We call the technology ‘burst wave lithotripsy’ (BWL) and operate it with real-time ultrasound image guidance and feedback on fragmentation. Human stones were fragmented within a ureter phantom, and the addition of UP to BWL accelerated comminution in vitro. Human stones implanted in three porcine bladders were fragmented in <10 min. Stones were similarly fragmented in three pigs breathing elevated carbon dioxide at levels possible in NASA vehicles. Treatment appears safe and effective in preliminary results on 6 pigs. BWL does not appear to be inhibited by the change of respiratory gases and any subsequent effect on cavitation in the body.

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