Ultrasound Detection of a Biodegradable Embolic Microsphere after Prostatic Artery Embolization

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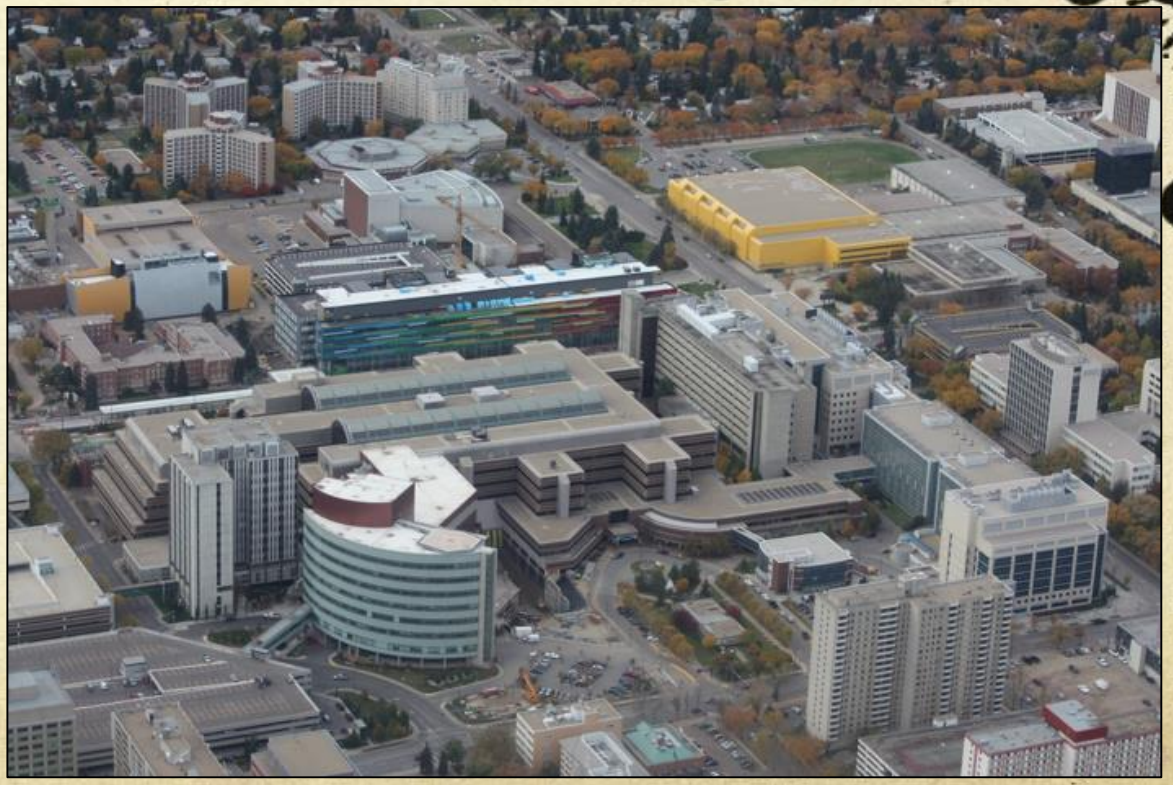
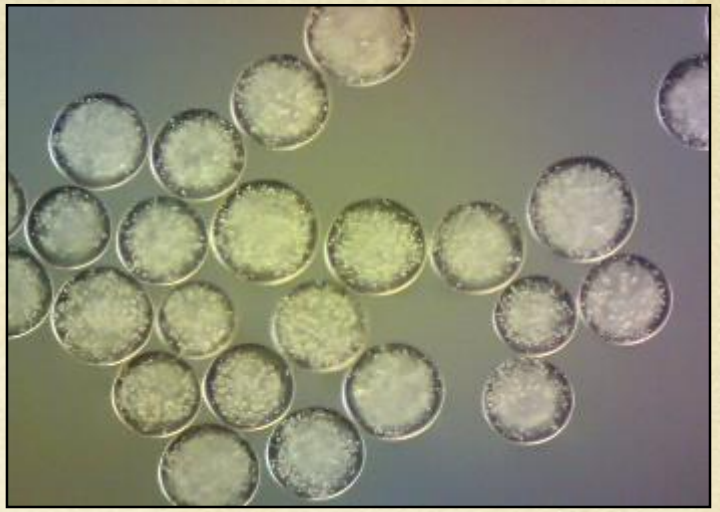


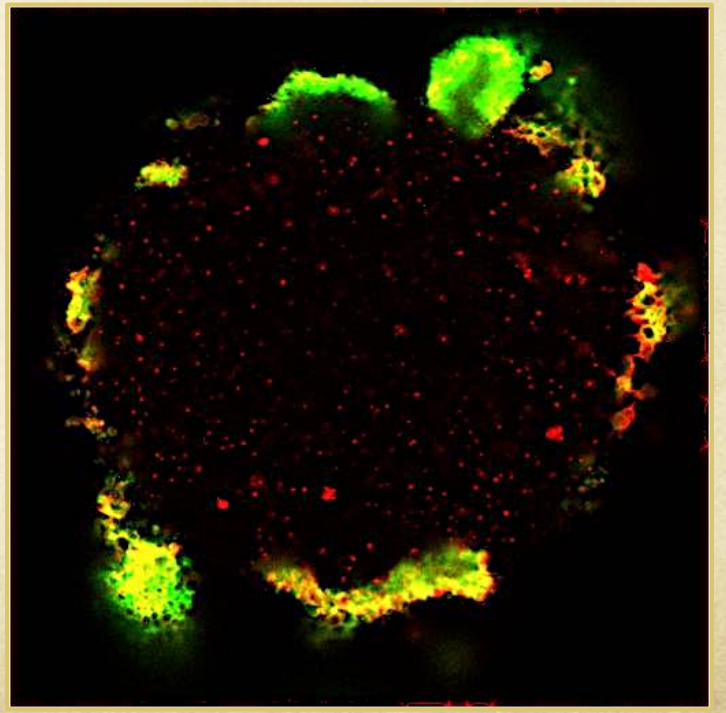
Disclosures

- Trials of OCL 500 series in PAE and UAE (Biocompatables/IMBiotechnologies)
- Recipient of Alberta Innovative Grant funding trials of OCL500 in PAE and UAE
- Consultant for Cook Inc

Introduction

- OCL 503 is a biodegradable microsphere, composed of PLGA
  - Class II medical device
  - FDA approved for hypervascular tumors, Canada and CE mark approval pending
  - Comes as a dry powder reconstituted with contrast (Isobuoyant with Omnipaque 240)
  - Eliminated in the body in 3-6 months*
  - Degrades to $C0_2$ and H_20
  - Density is 1.1 gm/ml (Liver 1.05, water 1)





Cardiovasc Intervent Radiol. 2012 Jun;35(3):636-44.
A preclinical study of the safety and efficacy of Occlusin™ 500 Artificial Embolization Device in sheep. * Owen RJ et al

Materials and Methods

- Open Label, Single Center, Pilot Study to Evaluate the Safety and Effectiveness of OCL 503 in Prostate Artery Embolization for Treatment of Men with Benign Prostatic Hypertrophy
- Patients with moderate to severe lower urinary tract symptoms secondary to BPH
- 15 patients for embolization with OCL 503 (150 – 212 µm)
- Standard technique for embolization in PAE with bilateral embolization using 2.8F microcatheter.
- Catheter position confirmed with cone beam CT
- Safety evaluation Lab studies and adverse events
- Outcome measures - IPSS, Uroflometry, MRI pre/post

Materials and Methods

- Patients imaged with ultrasound (Phillips IU22) using trans abdominal approach
- Trans abdominal ultrasound prior to, within 24 hours of PAE and at 3/12 follow up

Results

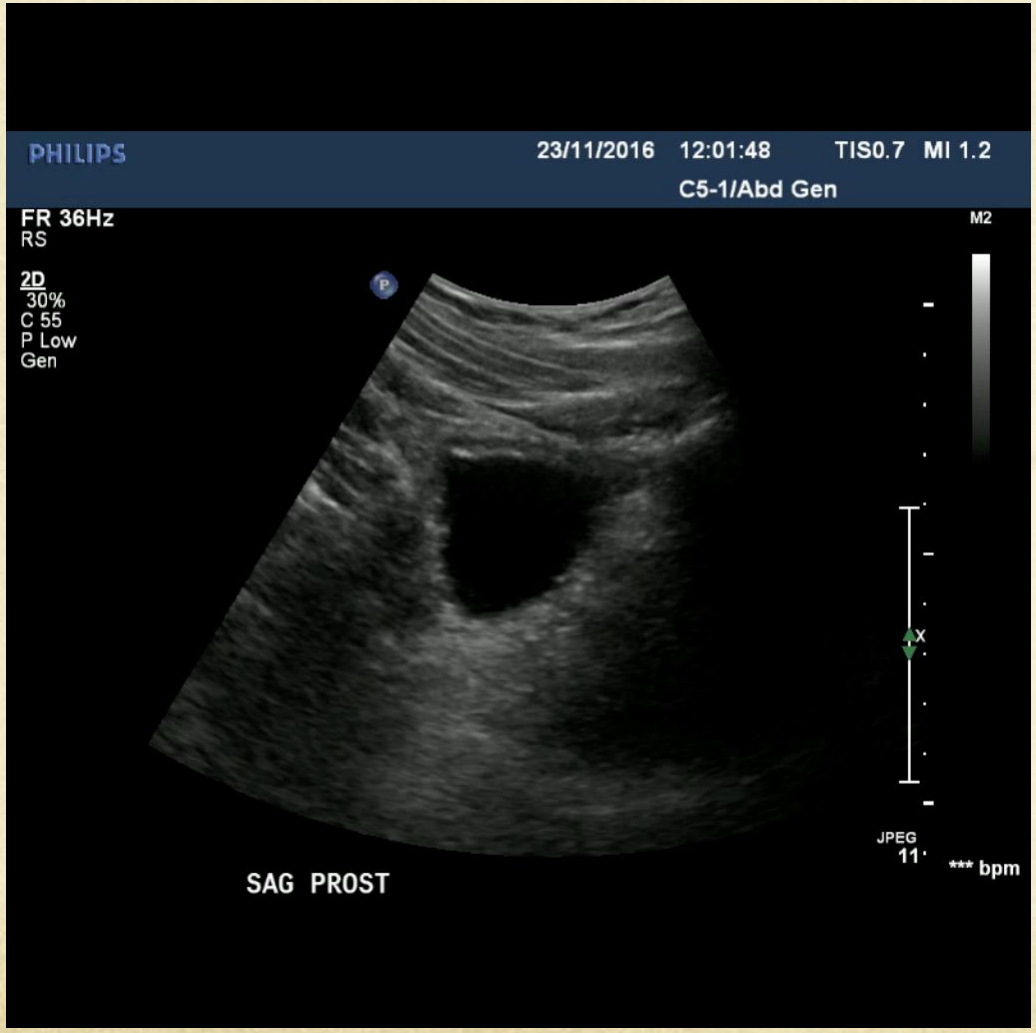
- 15 patients screened, 5 failed screening, 10 patients treated with OCL 503
- Ten subjects followed for 12 months, 8/10 demonstrated decreased IPSS
- 8 underwent ultrasound, 4 patients with bilateral PAE and 4 patients with unilateral PAE

Results

- Hyper-echoic areas were observed in the prostatic tissue of all patients within 24 hours of PAE
- Blinded observation of ultrasound images identified patients that received unilateral vs bilateral embolization
- Qualitative assessment of the signal intensity within 24 hours of PAE correlated with the number of microspheres delivered to the prostatic tissue
- Hyper-echogenicity of the prostatic tissue was not observed at the 3 month follow up ultrasound

Pre and Post unilateral PAE

Pre and Post unilateral PAE



Pre and Post bilateral PAE

Pre and Post bilateral PAE

Unilateral PAE

Conclusions

- OCL 503 is clearly visible in the embolized prostate (relates to differential density)
- The echogenicity relates to the amount of embolic delivered
- Particles are also visible in other embolized tissues
- Provide a useful tool at the time of embolization to confirm the entirety of embolization

Thank you