Funded Project Summaries
Description, Unmet Need, and Innovation Status
September 20, 2016

38 unique technologies have been funded by CMI, including two licensed and two optioned. Five projects received external research grants. Five won university innovation competitions. Five became Coulter TPII projects.

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<tr>
<td><strong>DESCRIPTION</strong> An acoustic measurement device attached to a surgical drill can provide information on bone thickness remaining under the drill, press force, and the tool’s condition for display to the operator.</td>
<td><strong>DESCRIPTION</strong> This device would provide fine computerized control of the direction, shape, and intensity of endoscopic lasers with less scope movement. It would greatly enhance surgical visibility, accuracy, and speed.</td>
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<td><strong>UNMET NEED</strong> Drilling through skull requires tremendous precision, limited by the lack of visibility of underlying structures before the drill penetrates. Furthermore, drills are prone to intraoperative malfunction with frequent use, resulting in direct patient injury, delays and increased costs. Powered surgical tools are a $11bil market with 4% growth.</td>
<td><strong>UNMET NEED</strong> Endoscopic laser surgery has several applications, particularly in the kidney, where it is used to ablate kidney stones. Safe and efficient surgery relies on surgeon skill and the ability to maintain visibility, which is gradually eroded by tool movement. These procedures could thus be shorter and less risky.</td>
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<tr>
<td>Jeffrey Vipperman, PhD, Mechanical Engineering. Paul Snyderman, MD, Otolaryngology.</td>
<td>Kevin Chen, PhD, Electrical Engineering. Tatum Tarin, MD, Urology.</td>
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<tr>
<th>Respiratory Dialysis: CO₂ Removal for Patients with Respiratory Failure – 2012-2013</th>
<th>Thermal Gel-controlled Release for Intraocular Therapeutic Delivery – 2012-2013</th>
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<td><strong>DESCRIPTION</strong> By removing bicarbonate (the predominant form of CO₂) from blood instead of CO₂, this process can provide continuous venovenous hemodialysis in a less invasive manner.</td>
<td><strong>DESCRIPTION</strong> This specific reverse thermal gel can provide a controlled drug release platform for use in the eye. The drug is dripped onto the eye as a liquid. Upon reaching the vitreous cavity, the higher temperature causes the solution to gel, slowing the release rate of the drug.</td>
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<td><strong>UNMET NEED</strong> Critically ill patients are at increased risk for acute respiratory distress syndrome (ARDS), which affects more than 140,000 adults/yr with a mortality rate of ~40-45%, and costs over $57K per admission.</td>
<td><strong>UNMET NEED</strong> Age-related macular degeneration (AMD) is major cause of blindness in the Western world. For the current treatment, blood vessel growth-blocking drugs must be injected frequently, an invasive process that carries a risk of infection.</td>
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<td>William Federspiel, PhD, Bioengineering. John Kellum, MD, Critical Care Medicine.</td>
<td>Yadong Wang, PhD, Bioengineering. Thomas Friberg, MS, MD, FARVO, Ophthalmology.</td>
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<td><strong>DESCRIPTION</strong> Using its onboard computer, this automated device can deliver optimal chest compressions by adjusting depth and rate in response to patient physiological data. Metrics include arterial pressure, tissue oxygen saturation, CO₂, and ECG waveform analysis.</td>
<td><strong>DESCRIPTION</strong> By combining a wearable device with an online toolbox, inter-ACTION can support patients in reaching their rehab goals. Data it captures can also be used by clinicians to track compliance and effectiveness.</td>
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<td><strong>UNMET NEED</strong> Out-of-Hospital cardiac arrest (OHCA) is a leading cause of mortality in the US, with 166,000 occurrences annually and a survival rate of only 6.4%. The standard treatment, manual CPR with chest compressions, is particularly limited by the negative pressure vacuum in the chest cavity during recoil.</td>
<td><strong>UNMET NEED</strong> Compliance is critical to good rehabilitation outcomes, but adherence to prescribed exercise therapy is ~35%. 2-3 months after knee replacement, most patients still have not reached maximum function. Also, the current therapy solution, a bundled package of 6-10 PT visits, comes at a high cost.</td>
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### Degradable Metallic Plates and Screws for Bone Fixation – 2012

**DESCRIPTION** Made of magnesium alloy with controllable degradation, these bone fracture fixation implants would have multiple advantages over present technology: enhanced regrowth and no removal surgery while remaining sufficiently strong to resist re-injury.

**UNMET NEED** When surgery is required to induce correct healing of fractured bones, surgeons often use implanted plates, screws, and wires to keep pieces in place. Neither long-standing Ti alloy nor new resorbable polymer products achieve an ideal balance of strength and biocompatibility.

**Prashant Kumta, PhD,** Bioengineering. **Charles Sfeir, DMD,** PhD, Periodontics. 

Now a Coulter project.

### Novel Guidewires for Smooth Navigation in Interventional Radiology – 2012

**DESCRIPTION** A new guidewire is being designed that would hold center in cerebral vessels, avoiding branches. The two designs considered involve preimposing an angle at the tip of the wire and including a segment of temperature-modulated stiffness proximal to the tip.

**UNMET NEED** Acute ischemic stroke, along with other cerebrovascular diseases, causes 134,000 deaths and hospitalizes 892,000 patients each year in the US. 5-10% would be candidates for acute stroke intervention, but current methods have difficulty in maneuvering thrombectomy devices through tortuous vascular anatomy.

**Youngjae Chun, PhD,** Industrial Engineering. **Brian Jankowitz, MD,** Neurological Surgery.

### Point of Care Molecular Diagnostic Instrument with Data Tracking – 2012-2013

**DESCRIPTION** Palmtop computer-based POC testing via an isothermal DNA amplification protocol would provide rapid, inexpensive detection of infectious agents. Bluetooth wireless would transmit data to a mobile phone or computer.

**UNMET NEED** Molecular diagnostics (MDx), the detection of pathogen RNA or DNA in specimen samples, is the fastest growing segment of in vitro diagnostics, currently a $7.5 bil market. Infectious disease testing is a growing sub-segment because of it can reduce overall health care costs.

**Alex Jones, PhD,** Electrical Engineering. **Abhay Vats, MD,** Pediatrics.

### Thyroplasty Implant – 2013

**DESCRIPTION** This novel, universal implant would improve patient voice and breathing outcomes and reduce the rate of second procedures addressing posterior glottic gaps. Adjustable features would allow paraglottic placement, limiting soft tissue trauma and decreasing OR time.

**UNMET NEED** The paralysis or impairment of any one vocal cord can negatively affect a person's ability to breathe and speak. One common cause of such paralysis is iatrogenic nerve impairment from intubation or surgery. Annual incidence varies from 17k to 30k patients.

**April Chambers, PhD,** Bioengineering. **James Jaber, MD,** PhD, Otolaryngology.

### iPad App for ACL Injury Diagnosis – 2013

**DESCRIPTION** iPad technology tracking knee motion on video would provide value in two ways: first by quantifying the normally subjective pivot shift test performed immediately after injury, and second by closely tracking range of motion progress during and after surgery.

**UNMET NEED** The ACL is the most commonly injured ligament in the knee, with a rate of 0.35 per 1000 per year, especially impacting athletes. ACL injury results in pain and instability of the knee. Currently, ACL injury is assessed with the pivot shift test, graded subjectively by a practitioner.

**Richard Debski, PhD,** Bioengineering. **Volker Musahl, MD,** Orthopedic Surgery.

Now licensed.

### Nitinol Prosthetic Tongue – 2013

**DESCRIPTION** A novel non-invasive dental device would replace movement of the native tongue, lost due to glossectomy or tongue paralysis. The braided nitinol lattice structure would bulge upward and backward with jaw closure to induce swallowing.

**UNMET NEED** Up to 16.5M senior citizens experience dysphagia, decreasing quality of life. Inpatient healthcare costs exceed $547 mil annually. If the current therapy options (swallow exercises, diet changes, drugs) fail, there is no device able to replace swallowing functionality.

**Youngjae Chun, PhD,** Industrial Engineering. **Neil Gildener-Leapman, MD,** Otolaryngology.

### Adipose Tissue Harvest and Graft Device – 2013

**DESCRIPTION** This specialized surgical instrument would facilitate fat grafting, an emergent reconstructive technique for natural and minimally invasive repair of tissue defects. It consists of two telescoping tubes which rotate to adjust cannula aperture size and shape incrementally.

**UNMET NEED** The fat grafting market grew 19% to 68k procedures and $113 mil in revenue in 2011. Current fat extraction cannulas are not designed for grafting, resulting in needlessly complex and risky transitions between removal and re-insertion of fat.

**Mark Gartner, PhD,** Bioengineering. **Peter Rubin, MD,** Plastic Surgery.


**DESCRIPTION** An implantable device outfitted with WiFlow microchips would communicate with an app via external receivers. A) Doppler Coupler system would monitor free flap perfusion as an anastomotic coupler. B) SmartStent system would integrate microchips with standard vessel stents to monitor flow and patency.

**UNMET NEED** A) After surgery resulting in a free flap, patients are tethered to a bedside monitor by a transcutaneous wire, which is cumbersome and poses risks of infection and vessel damage. B) Patients with vascular stents need to be monitored for restenosis, narrowing of stents by 50-80% in the first two years.

**Michael Rothfuss, MS,** Electrical Engineering student. **Michael Gimbel, MD,** Plastic Surgery.
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<td>Wounds can lose the ability to clear infections and regenerate tissue and vasculature. Pressure ulcers are a common chronic wound, with 28% incidence in long-term and home care. Current products seek to keep wounds moist and sterile while providing a generic scaffold for cell growth not tailored to the individual wound.</td>
<td>Curostem would be a smart topical gel aimed at curing chronic wounds. By incorporating human mesenchymal stem cells into space-filling bioengineered polymer gel, it would be rich in healing components and able to recruit more, responsive to the wound, and topical.</td>
<td>Minimally invasive surgeries have grown enormously to about 3 million cases per year. All laparoscopic procedures require a light source, attached to the lens via a fiberoptic cord. The distal end of this cord becomes very hot and poses a burn risk.</td>
<td>This disposable plastic sheath would fit onto standard endoscopic fiberoptic light cords, advancing automatically when the cord is removed from the lens. By isolating the heated end of the cord, burn risk to patients, OR staff and infrastructure would be eliminated.</td>
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<td>Brain-originating tumors have an incidence of 20K cases per year in the US, and brain metastases affect over 100K patients. The best outcomes follow maximal safe surgical resection, but resection for deep-seated tumors can cause unacceptable brain damage.</td>
<td>Designed to minimize the disruption of overlying brain tissue during surgical access to deep brain regions, this device would improve neurological outcomes. The proximal end of the catheter would be compatible with standard image-guidance technology familiar to surgeons.</td>
<td>During laparoscopic abdominal organ removal surgery, the organ to be removed is often larger than the incision sites in the abdominal wall. Current morcellators mince and suck out the organ, which can spread malignant cells and needlessly injure other tissue.</td>
<td>This device would replace current bladed morcellators with a multi-bag system. By quickly removing organ pieces created manually by the surgeon instead of automated mincing action, the dependence on cameras and the risks would be cut without costing extra time.</td>
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| Early diagnosis of acute myocardial infarction (MI) enhances its treatment and vitally increases patient survival. NSTEMI is deadly because it affects over 1 mil patients annually and is much harder to detect. More sensitive detection methods are urgently needed. | NSTEMI (non-STE acute myocardial infarction) can be better detected with spatial and temporal ventricular repolarization dispersion (S/T-VRD). The SPEED algorithm would automatically flag incoming ECGs of likely NSTEMI patients en route to the hospital. | Early diagnosis of acute myocardial infarction (MI) enhances its treatment and vitally increases patient survival. | The device improves upon ventriculoamniotic shunting for feti 95790a7ed00c4360a1f960802b42a9a3
### Fade to Clear High Visibility Sutures – 2014

**DESCRIPTION** Sutures coated with a bio-soluble dye would be easy for the surgeon to see during the procedure, and fade to clear within a few hours after the procedure to improve the appearance of the patient’s surgical site.

**UNMET NEED** Clear polymer is used for very superficial sutures so they are not visible through the skin after surgery. But they are also harder for the surgeon to see during the procedure, increasing fatigue and eyestrain.

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### PerioMag GBR Barrier Membrane – 2014

**DESCRIPTION** The PerioMag GBR barrier membrane for dental prosthetic bone grafts would be safely degradable, and have the mechanical strength and stability of the Ti-PTFE membranes it aims to replace. It has also been shown to stimulate better bone growth.

**UNMET NEED** Americans receive 500,000 prosthetic tooth implants each year. 60% of these prostheses require bone grafting prior to placement, supported by non-degradable barrier membranes removed during a later procedure. Unfortunately, the costs and risks of these multiple procedures are typically borne by the patient.

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**DESCRIPTION** Combining a wearable motion capture wristband and a web-based software application, this device would facilitate patient engagement with their stroke treatment goals and communicate progress to clinicians. Monitoring would focus on wrist angle.

**UNMET NEED** Stroke affects about 800K patients annually in the US, resulting in weakness of one hand. The disabled hand contributes to the overall loss of independence, an expensive problem predicted to cost $241 bil by 2030. Current therapy, relying on repeated task practice to regain function, is limited by the lack of objectivity and tracking.

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### A Motorized, Flexible Arm Retractor for Open Abdominal Surgery – 2014-2016

**DESCRIPTION** A long arm, fixed to the operating table and holding movable retractors, would be throttled between rigid and flexible using a foot pedal. Surgeons would find these controls much easier to use during the stages of surgery.

**UNMET NEED** Open abdominal surgery presents several challenges: anatomic complexity, field depth, and technical issues exacerbated by morbid obesity. Current retractor technology is bulky, obstructive, inefficient, and hasn’t notably progressed in 30 years.

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### Reducing Alloimmunization and Sickle Crisis in Sickle Cell Disease Patients – 2014-2016

**DESCRIPTION** A procedure for minimizing the remaining sickle hemoglobin and maximizing donor normal hemoglobin encapsulated in the red blood cell membranes would improve the effect of sickle cell disease treatment.

**UNMET NEED** Hemoglobinopathy, most commonly sickle cell disease, is caused by a gene for defective hemoglobin molecules. Abnormally shaped RBCs cause gradual, eventually fatal damage to all organs. Donation and transfusion of normal RBCs prolongs life, but must be repeated due to the re-accumulation of abnormal hemoglobin.

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### Diagnosis of Aggressive Prostate Cancer Via Detection of MMP9 in Biological Fluid – 2014

**DESCRIPTION** The ACES (Autocatalytic Enzyme Screen) assay is designed detect MMP9 (matrix metalloproteinase 9), a biomarker found in blood, urine, and tissue that is useful for lung, bladder, breast and prostate cancer, and particularly well correlated with aggressive cases.

**UNMET NEED** Prostate cancer (Pca) leads to the death of 30k men annually. Post-treatment monitoring Pca is performed using the prostate specific antigen test (PSA), which is hard to interpret due to several variables. Other diagnostic techniques have proven expensive and risky.

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### GREK Smartband: Interactive Wearable System for Remote Cardiac Monitoring – 2015

**DESCRIPTION** A smart wristband with a sensor array and a sensitive analog to digital converter would provide real-time electrical potential measurements and accurate heart rate and rhythm information, and the means to obtain EEG.

**UNMET NEED** Undiagnosed arrhythmias pose a significant risk for patients, providers and healthcare systems. Possible consequences include heart attack and stroke. Atrial fibrillation (AF), an example of an arrhythmia that can occur without detection and lead to stroke, is estimated to affect 2.5 mil in the US, and up to 12 mil by 2030.
### Design of Artificial Polymeric Vascular Grafts with Tunable Luminal Topography – 2015

**Description:** An improved artificial polymer vascular graft would suppress platelet adhesion in a wider variety of situations, maintaining graft patency (blood flow) for years instead of months.

**UNMET NEED:** Cardiovascular disease remains the costliest and deadliest health problem in the Western world. Vascular grafts can bypass blocked arteries, but existing synthetics show poor long-term patency, especially with small diameter, non-laminar flow, and external mechanical stress. Graft failure causes hyperplasia and thrombosis.

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### Prevent Bedwetting in Children by Foot Neuromodulation – 2015

**Description:** Electrodes placed on the skin surface of the foot would provide neuromodulation during the day, modulating bladder reflex activity during the night.

**UNMET NEED:** Nocturnal enuresis, bedwetting at night affecting children older than five on a recurring basis, is a very common pediatric problem. Bedwetting can have dramatic psychological and social impacts on a child's life. It can also lead to significant sleep disruption and financial stress within a family.

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### Self-Cleaning Smart Antibacterial Surfaces – 2015

**Description:** New nanostructured surfaces for patient-contacting or implanted devices would combine mechanical and chemical defense against bacterial adhesion. The first application will be to glaucoma drainage implants (GDIs).

**UNMET NEED:** One of the most pervasive problems afflicting healthcare facilities is the threat of pathogen contamination, made harsher by the proliferation of antibiotic-resistant strains in facilities. New antifouling, bactericidal surfaces are needed for a variety of applications, most urgently implanted devices.

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### Controlled Release, Gel-based Ear Drops for Treatment of Otitis Media – 2015

**Description:** By adapting an existing ocular drug delivery system, a thermoresponsive hydrogel drop with extended release activity, for use in the ear, otitis media drugs can be administered with less repetition and discomfort.

**UNMET NEED:** Acute OM accounts for 20 mil pediatrician visits annually in the US, with one third of children experiencing six or more cases before age 7. OM is responsible for the greatest number of antibiotic prescriptions in children, with a huge economic impact. Poor medication adherence makes surgery more likely.

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### Esophocclude: Temporary Esophagus Occlusion for Intubations – 2015

**Description:** The Esophocclude is an encapsulated self-expanding stent resembling a pill attached to a guidewire. It would be swallowed by patients so the expanding stent could clear the way for intubation, blocking gastric acids.

**UNMET NEED:** Gastric aspiration is a devastating complication of intubation and other clinical scenarios. An estimated 3.5% of intubations result in aspiration. 9-10% of affected patients die, and others experience repeated lung infections. Worse, it is underreported and misdiagnosed.

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### Electrotargeted Vascular Access: A Novel Way to Place IV Catheters – 2015

**Description:** ThreadRite IV, a detection unit with disposable catheter units, is designed similarly to standard catheters, adding insulating plastic that leaves only the tip exposed to act as an electrode. The detector is able to determine when the electrode is approaching blood.

**UNMET NEED:** Peripheral IV drug delivery is a mainstay of modern healthcare. Virtually all ER and hospital patients get pIV lines. Yet under half of attempted placements are successful. With 1.2 bil pIVs purchased in N. America last year, this represents massive waste and risk.

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### Minimally Invasive Delivery of Therapeutic Cells to Abdominal Aortic Aneurysm – 2015

**Description:** This system, which consists of iron nanoparticle-loaded therapeutic cells, mixing and delivery, guidance, and implanted magnetic catheter, would induce healing of small abdominal aortic aneurysms (“aneurysm” is ballooning and weakening) to prevent or delay surgery.

**UNMET NEED:** 7-10% of US males are affected by such aneurysms. A rupture is life-threatening, currently the 13th leading cause of death in the US. Large aneurysms can be treated with surgery, but there is no existing treatment for small aneurysms, which grow over time, except monitoring.