

**CRADA Final Report
CRADA No.LB04-000251**

1. Parties:
 - a) Arthrocare Corporation
 - b) E.O. Lawrence Berkeley National Laboratory

2. Title of the Project: "Development of Plasma Ablation for Soft Tissue and Bone Surgery"

3. Summary of the specific research and project accomplishments:
(Were the goals of the CRADA achieved? Include relevant information but do not include proprietary or protected CRADA information.)

ArthroCare is a medical device company that develops, manufactures, and markets an advanced surgical tool, a plasma electro-surgical system for cutting and removing tissue. The hand-held electrical discharge device produces plasma in a biocompatible conductive fluid and tissue to which it is applied during surgery. Its products allow surgeons to operate with increased precision and accuracy, limiting damage to surrounding tissue thereby reducing pain and speeding recovery for the patient. In the past, the design of ArthroCare's plasma wands has been an empirical undertaking. One goal of this R&D program was to put the phenomena involved on a sound scientific footing, allowing optimization of existing plasma based electro-surgery system technology, and the design and manufacture of new and improved kinds of scalpels, in particular for the surgical cutting of bone. Another important related goal of the program was to develop, through an experimental approach, new plasma wand approaches to the cutting ("shaving") of hard bone tissue.

The goals of the CRADA were accomplished – computer models were used to predict important parameters of the plasma discharge and the bone environment, and several different approaches to bone shaving were developed and demonstrated.

4. Deliverables:

Deliverable Achieved	Party (LBNL, Participant, Both)	Delivered to Other Party?
Models of new "plasma wands" and associated electronics and other hardware, for bone shaving.	Both	Yes

5. Identify publications or presentations at conferences directly related to the CRADA?

There were no publications or presentations directly related to the CRADA.

6. List of Subject Inventions and software developed under the CRADA:
(Please provide identifying numbers or other information.)

There were no publications or presentations directly related to the CRADA.

7. A final abstract suitable for public release:
(Very brief description of the project and accomplishments without inclusion of any proprietary information or protected CRADA information.)

The primary goal of the project was to develop and demonstrate an atmospheric-pressure plasma tool that is suitable for surgical use for shaving bone in humans. This goal was accomplished, in fact with several different alternative plasma approaches. High bone ablation speeds were measured. The use of probes ("plasma wand" – the surgical tool) with moving active electrodes was also explored, and there are advantages to this method. Another important feature is that the newly-exposed bone surface have only a very thin necrosis layer; this feature was demonstrated. This CRADA has greatly advanced our understanding of bone removal by atmospheric pressure plasmas in liquid, and puts ArthroCare in a good position to develop the techniques for commercial (surgical) application.

8. Benefits to DOE, LBNL, Participant and/or the U.S. economy.

Benefit to DOE:

In other similar projects, LBNL-T1-006, LBNL-T2-0110, LBNL-T2-0110A, and LBNL-T2-0197, it has been demonstrated that the teams of the HCEI and LBNL can work together in very effective ways, benefiting both Russia and the US. The members of both teams know and respect each other. The success of prior projects is mainly visible by the impressive number of joint publications that resulted from the collaboration [see, for instance, E.M. Oks et al., Nucl. Instrum. Meth. Phys. Res., vol. B127 (1997) 779-781]. For the realization of its mission, the Department of Energy develops a broad range of technologies in the energy and materials sector. The development and application of plasma technologies for medical science provides a remarkable opportunity to enhance and broaden DOE-supported science into the medical arena.

Benefit to Participant:

Arthrocare's tissue ablation technology is applicable across many soft-tissue surgical markets. The systems are currently used to perform many types of arthroscopic surgery. The company strategy includes applying its patented Coblation technology to a broad range of other soft-tissue markets, including spinal surgery, neurosurgery, cosmetic surgery, ENT surgery, general surgery, gynecology, urology and various cardiology applications. With its soft tissue electro surgery system, Arthrocare operates within a worldwide market potential of \$2.8 billion. Implementation of the plasma electro-surgical system model for design of soft tissue systems will allow development of better products. This will no doubt accelerate the market penetration growth of the technology. Increasing the market penetration by 1% annually represents a revenue growth in excess of \$25M.

Benefit to U.S. Taxpayer:

9. This project, and possible follow-on work scope of a Phase II effort, has the potential to open up many new market opportunities. Most orthopedic or arthroscopic procedures involve bone cutting. The plasma electro-surgical tool will then replace a set of 3 tools: a bone "burr," a shaver, and a soft tissue ablation wand. This will allow surgeons to use the bone cutting system in a large number of knee and shoulder procedures, including sub-acromial decompression and anterior cruciate ligament reconstruction. Additional applications, such as endoscopic sinus surgery, will open up new market opportunities in cranial, spinal and open orthopedic surgeries and will lead to significantly less invasive surgery, providing faster patient recovery and less morbidity.
10. Financial Contributions to the CRADA:

DOE Funding to LBNL	\$1,395,000
Participant Funding to LBNL	\$0
Participant In-Kind Contribution Value	\$1,605,000
Total of all Contributions	\$3,000,000