An Excerpt From:

8th ANNUAL INTERNATIONAL SYMPOSIUM ON TECHNOLOGY IN ARTHROPLASTY (ISTA) (FORMERLY ISSCP) FINAL PROGRAM

SAN JUAN - PUERTO RICO CERROMAR BEACH RESORT

WED. SEPTEMBER 27th - SUN. OCTOBER 1st 1995

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THE USE OF CARBON DIOXIDE GAS FOR PREPARATION OF BONY SURFACES IN CEMENTED TOTAL JOINT ARTHROPLASTY By

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Introduction:

There is a strong movement back to using bone cement as the primary fixation method in total joint arthroplasty. However, it is important to recognize its inherent biological and mechanical limitations. Because bone cement is a grouting agent and does not possess adhesive qualities, successful fixation is dependent upon the mechanical interface between cement, bone and implant.

Mechanical loosening is reported in approximately 70% of all hip replacement failures. Five to ten year results demonstrate a loosening rate as high as 25%. Clinical loosening of implants represents a significant problem and exposes the patent to the medical risks associated with revision surgery.

Current surgical techniques for implantation of cemented implants consist of shaping the bony cavity with hand and powered tools, followed by brushing and saline lavage. Suction and surgical sponges inserted into the cavity are utilized to dry the bone surface. Cement is then injected, under pressure, to assure interdigitation of cement into the prepared cancellous bone bed. In hip arthroplasty, a femoral plug is generally placed prior to cement introduction.

Cardiopulmonary dysfunction is a recognized risk factor associated with cemented arthroplasty procedures. This physiologic dysfunction is generally attributed to particulate, fat and marrow embolism. Thorough cleaning of fat, tissue and debris can help to reduce the incidence of embolic complications.

Purpose:

The CarboJetTM device delivers a pressurized flow of dry carbon dioxide gas to the bone surface, to clean and dry the area prior to cement implantation, This paper reviews the design concept and application, and reports results from clinical and laboratory testing of the CarboJetTM device, undertaken to evaluate its safety and effectiveness.

Methods:

The CarboJetTM device is used as a final step in bone preparation, employed immediately prior to cement introduction. The focused flow of gas aids in removing fat, liquids, and particulate debris from the bone, helping to improve mechanical interdigitation by reducing the volume of these materials which are otherwise interposed between cement and bone.

The CarboJet[™] device consists of a reusable handpiece and a variety of nozzles, along with a pre-set pressure regulator for use with standard C0, tanks.

The sterile CO, delivery tube set features quick-

disconnect fittings and an in-line microbial filter to assure sterility of the CO_2 .

In vitro testing was conducted on human cadaver bone to compare cleaning effectiveness of gas lavage to conventional pulsatile saline lavage preparation,

A prospective randomized clinical investigation was also conducted, comprising a total of 74 procedures done in 70 patents. Procedures performed included total shoulders, knees, hips, and elbows, and included both primary and revision surgery.

The investigational protocol included intra-operative monitoring of blood pressure, heart rate and end-tidal CO_2 .

Results:

Laboratory testing demonstrated significant cleaning and debris removal, with an improved penetration of cement into available intertrabecular spaces. Testing demonstrated that a moderate gas flow rate is sufficient to clean and dry the bone, with impact forces less than those delivered to tissue by pulsed saline. The CarboJetTM regulator delivers 50 psi of line pressure, with a resulting gas flow rate of approximately 25 LPM.

Clinical evaluations demonstrated a visible improvement in bone bed cleaning. Intra-operative monitoring was uneventful. Throughout the clinical experience, no complications relating to CarboJetTM use have been encountered.

Conclusions:

Subjective surgical impressions are that the CarboJetTM delivers improved or equivalent results in cleaning and local drying as compared to conventional techniques,

Successful long-term implant fixation relies upon solid mechanical interlocking between cement and bone. Thorough intra-operative cleaning and removal of fat, liquids and particulate debris prior to cement introduction helps to provide for intimate mechanical contact and may help to reduce the incidence of embolic complications arising from debris in the canal.

Mechanical and clinical testing has demonstrated that dry carbon dioxide gas lavage is a safe and effective method for bone bed preparation prior to cemented implantation of arthroplasty devices. Only additional testing and long-term clinical follow-up will demonstrate the CarboJetTM's potential contributions to clinical outcome.