

# Multicentric Medical Registry on The Use of the Plasma Surgical PlasmaJet® System in Thoracic Surgery

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## Objectives

The medical registry was designed to evaluate the interest, efficacy and safety of the PlasmaJet® system (neutral plasma surgical device developed by Plasma Surgical Limited) in open and video-assisted thoracic surgery within the normal, daily practice of the participating centers. The ability of the PlasmaJet® system to coagulate tissue and to stop air leaks was studied. The patients' post-op evolution was measured in terms of air leakage and drainage duration as well as in terms of complications and was compared to that of patients operated by traditional means. The system's ergonomics and ease of use were also evaluated.

## Patients and Methods

In total 54 patients were included prospectively between June 2007 and April 2008. The series included slightly more men than women, aged 63 years on average (42-83), with a rather good general physical condition (ASA 2, OMS 1) and respiratory function (VEMS at 80% of the norm, more than 70% without notable dyspnea). 65% of the patients suffered from primitive bronchopulmonary cancers, 20% presented with pulmonary metastases and 15% presented a benign or congenital dystrophy. One third of all patients had antecedents of chemotherapy, radiotherapy or both.

All of the patients requiring an open or thoracoscopic surgery for primitive cancer, metastases, bullous / emphysematous dystrophy or pulmonary biopsy were included in the medical registry in the order of their hospitalization date in the different participating centers, without any randomization or other specific inclusion criteria. The patients were followed up postoperatively for the length of their hospital stay and/or of their re-hospitalization for those who incurred a complication which required their readmission in the department.

## Results

6 of the 54 patients included in the registry (11%) had a video-assisted operation. 5 patients were operated by wedge resection / pulmonary biopsy, one had a superficial metastasis resected. 4 of the 6 video-assisted surgeries also had a mini thoracotomy.

48 patients had an open thoracotomy. The lungs were normal and supple in 57% of the cases. 77% of all surgical procedures were performed on a totally or partially excluded lung. The main procedures included 9 metastasectomies (most often multiple and superficial), 14 wedge resections /

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pulmonary biopsies and 35 complementary procedures in the course of planned resections (opening fissures, peeling, treatment of depleuralized zones).

In most of the procedures the application of the PlasmaJet® was complemented by the use of clips and/or endo-GIA type staplers (4 out of 6 video-assisted procedures, 20 out of 23 responses for thoracotomies).

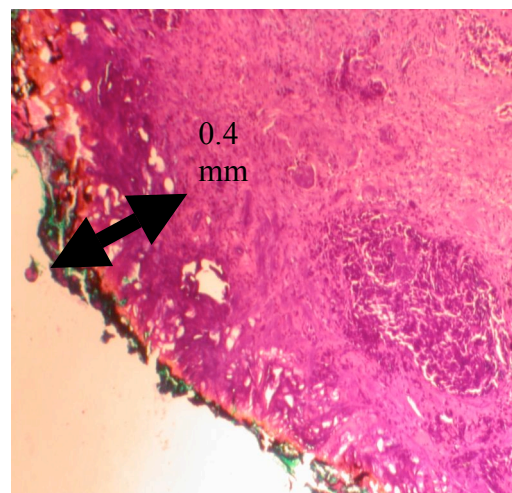
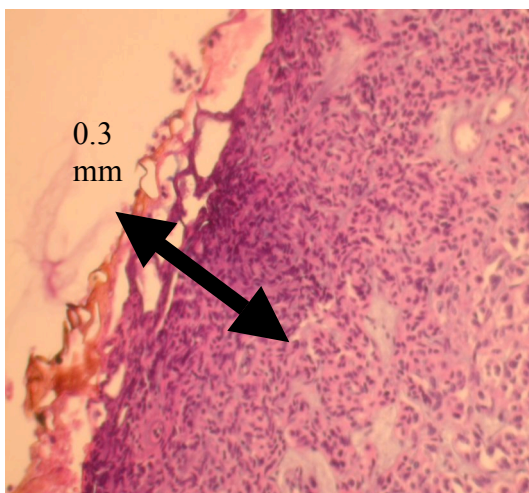
The PlasmaJet® was rated as very easy to use by the surgeons and the O.R. nurses. Most of the handpieces used were 5mm in diameter and 7 or 12cm in length. The average power setting used was 50%. Plume smoke was underlined as a drawback in 28 cases (52%).

Use of the PlasmaJet® provided complete and immediate aerostasis in 75% of the cases. It provided for a good hemostasis in 29 patients (54%). Hemostasis was deemed insufficient in 8 cases (21%).

The average length of post-op air leakage was between 0 and 2 days for patients operated by thoracoscopy. It was 3 days for patients operated by thoracotomy. The average length of post-op drainage was less than 2 days for patients operated by thoracoscopy and 6 days for patients operated by thoracotomy. 7.4% of the lobectomies experienced prolonged air leakage (>7 days) ; a percentage one may compare with the 8.7% reported in the national database Epithor. Post-op follow-up was uneventful in 40 patients (74%) and complicated in 13 (24%). 3 patients (5.5%) required readmission. In no case were the complications attributed to the use of the PlasmaJet® system.

## Conclusion

The PlasmaJet® is a sophisticated surgical tool that has a valuable place in the thoracic surgical suite, mainly for aerostasis. It is simple to use, very efficient and very rapid in treating large depleuralized surfaces. It may be used in open surgery as well as in video-assisted procedures. Because of its inherent technical characteristics (the generation of a pure, electrically neutral gas plasma), it generates no tissue damage away from the target (see histological slides below) and incurs no accidental overpressure in video-assisted surgeries (gas flow < 0.7l/min).



Depth of necrosis after PlasmaJet® application  
Histology findings on tissue resected by wedge esection and metastasectomy  
(Courtesy of Dr. Charpentier – Military Hospital Lavéran)

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Ref: CAB-PJ-THO01

The PlasmaJet® system does not have any abrasive effect on the parietal pleura. Its efficacy on blood vessels is quickly limited (clips are a better alternative) and fissures that are too thick should be dealt with automatic staplers.

In open surgery its main applications are:

- the treatment of depleuralized zones (quick on large surfaces, it is even more efficient when the target is superficial. Several applications are sometimes necessary. The treated zones remain air-tight after lung reinflation. The system may be used under a thin layer of water)
- peelings
- opening closed fissures as long as they are not too thick

While the intended use of the PlasmaJet® system is for coagulation, in this study it was also used to cut the soft tissue of the lung. In thoracoscopy, the participants in the Registry found that the PlasmaJet® is very easy to use to:

- do a biopsy or a wedge-resection
- resect metastases with a good safety margin
- ablate emphysematous bullae, blebs and all types of adhesions

In conclusion, this first, multicentric medical registry has demonstrated that the PlasmaJet® system has a real value in thoracic surgery, and complements other devices which are routinely used. Consumables are cost competitive, and the system may be shared with other surgical departments within the same hospital (such as gynecological surgery, liver surgery, orthopedics, and plastic surgery).