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ICD-10-CM PCS Coordination and Maintenance Committee

Wednesday, March 19, 2014

CMS Headquarters

Baltimore, Maryland

Presentation Content

I. About Malignant Glioma

II. About Gliadel® Wafer

III. Gliadel® Wafer in Malignant Glioma Management

IV. Malignant Glioma Case Presentation

V. Rationale for new ICD 10 PCS Code

VI. Questions and Answers

INCIDENCE / MORTALITY

- An estimated 24,620 new cases of primary malignant brain and CNS tumors were predicted in 2013
- This represents 1.47% of all cancers
- An estimated 13,700 deaths in 2013 were attributed to primary malignant brain tumors
- Age of onset is between 45 and 70; median age is 45 for grade III and 60 for grade IV tumors

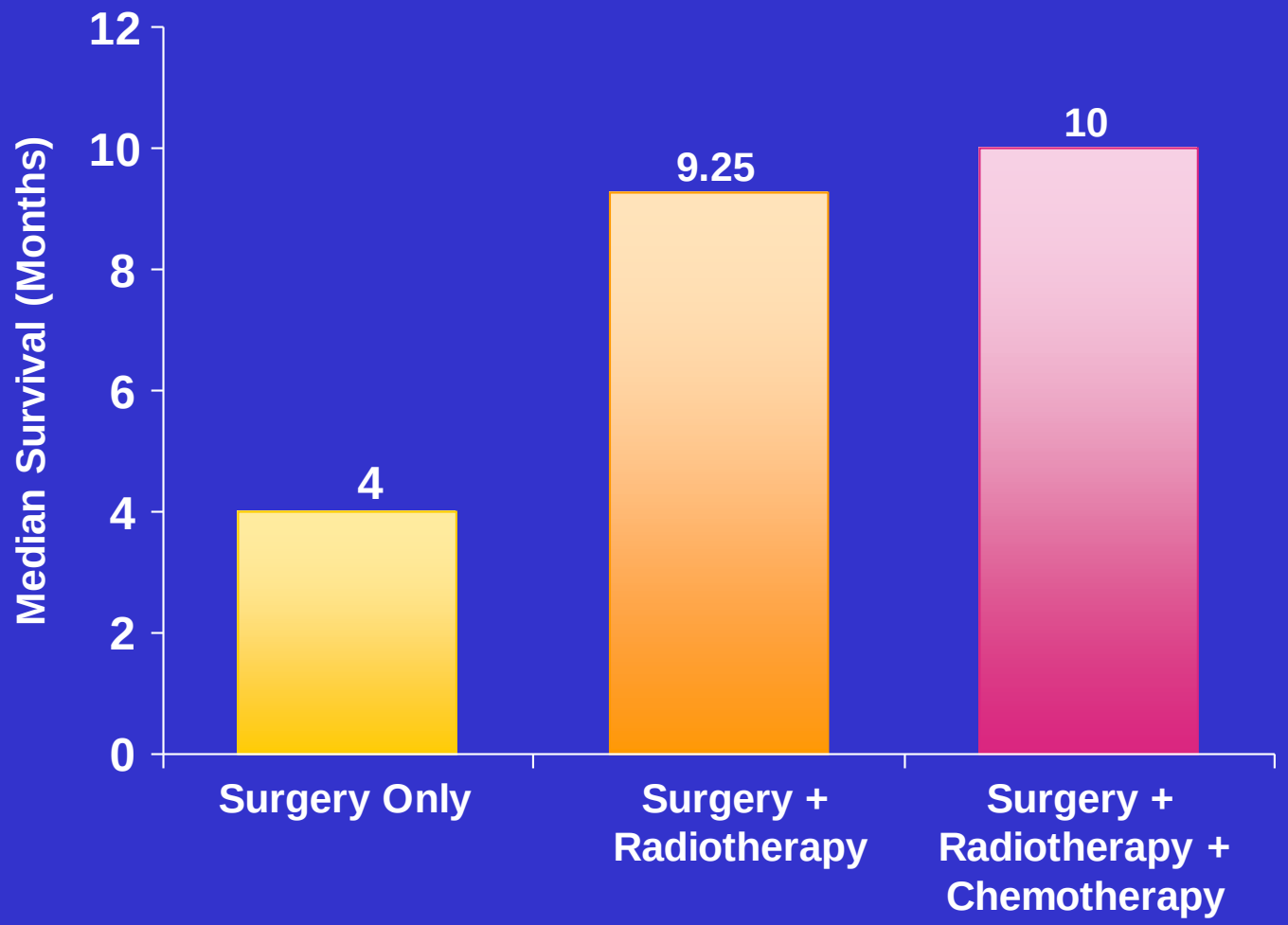
Central Brain Tumor Registry of the United States (CBTRUS) Fact Sheet 2013.
American Cancer Society: Facts & Figures 2014.
American Association of Neurological Surgeons: Patient Information 2012
Narayanan et al., ACNR 12 (4): 24-29, 2012

BRAIN TUMORS

- In 1984 – many systemic treatments had been tried with no benefit.

- The FDA had not approved any new therapy in over 20 years.

Glioblastoma: Treatment Outcome



McDonald JD, Rosenblum ML: In: Rengachary SS, Wilkins RH, eds. *Principles of Neurosurgery*. St Louis, MO: Mosby-Wolfe; 1994: chap 26.

Problem: Clinical effectiveness of new cancer therapies

Hypothesis: Better delivery of agents to target sites would improve outcome

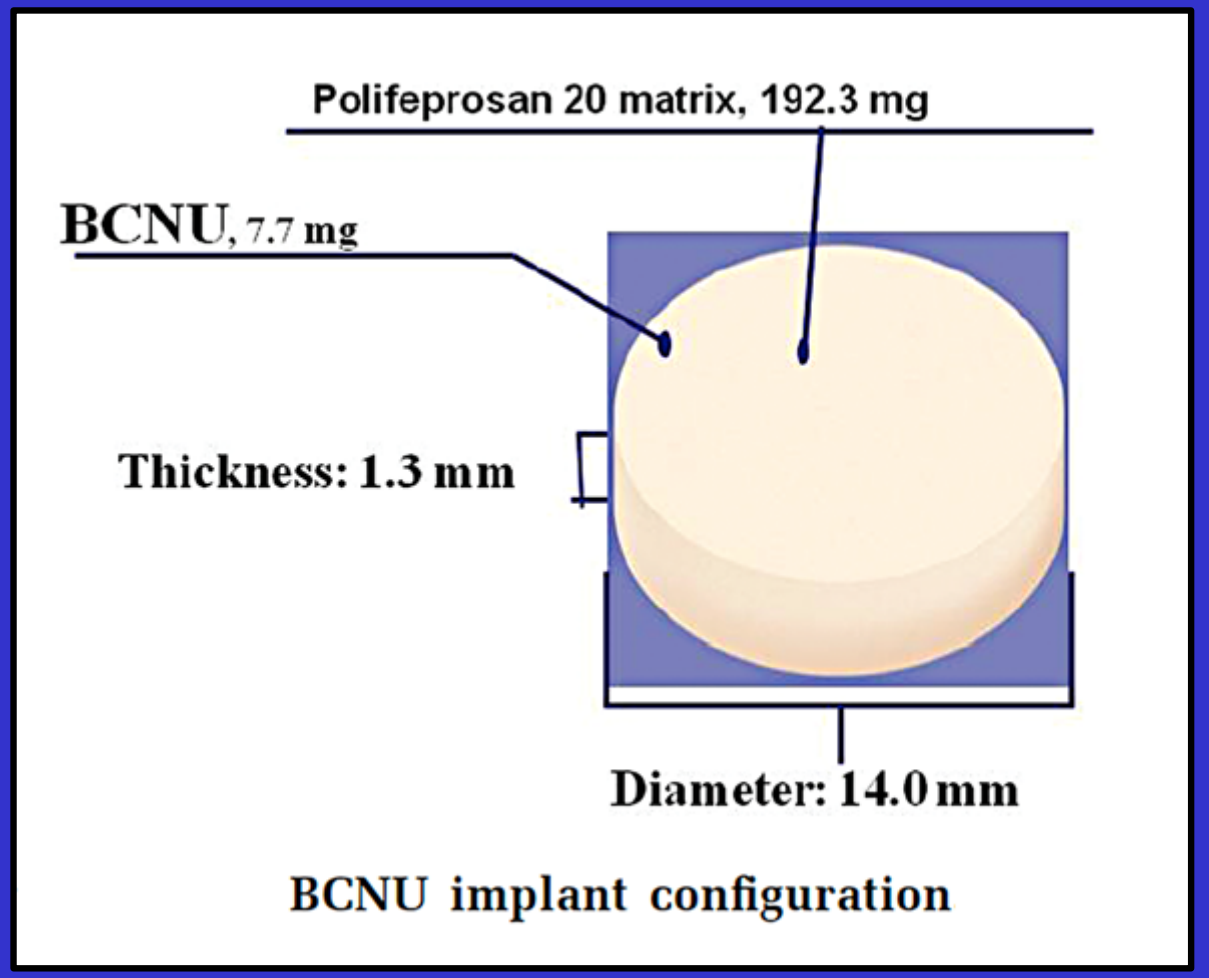
Solution: Targeted controlled delivery (polymers)

Rationale for Local Therapy

- Primary brain tumors usually recur within approximately 2cm of original tumor site
- Bypass the limitations of the blood-brain barrier
  - Delivers high local concentrations chemotherapy
  - Continuously releases chemotherapy over several days to weeks
- Limits systemic circulation
- Part of a multimodal management strategy for aggressive tumor types with high mortality rates and few available therapies

GLIADEL® Wafer

(carmustine implant)



BCNU implant configuration

GLIADEL® Wafer
(carmustine implant)

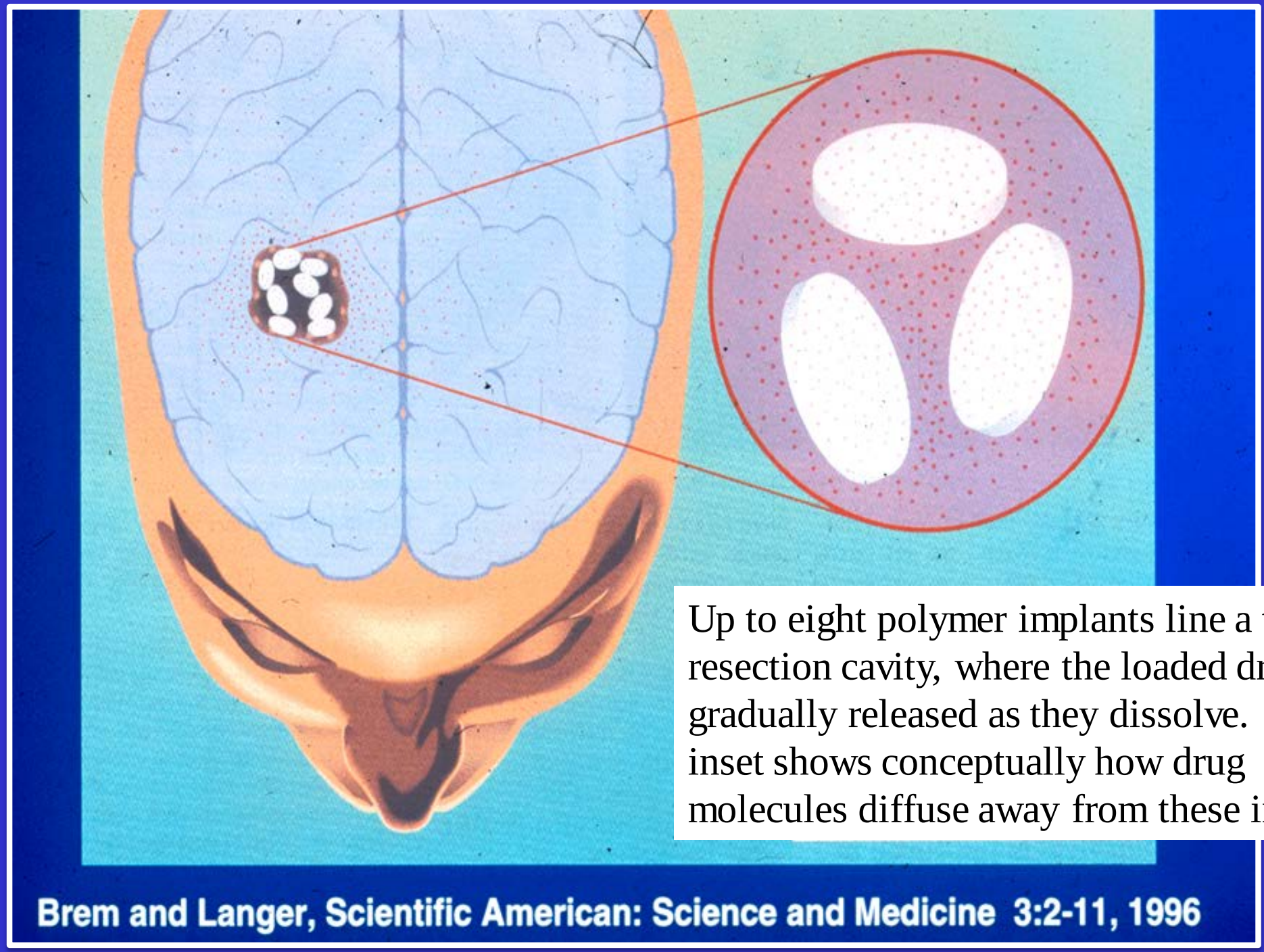
Mechanism of wafer release

- Released via surface erosion
- Hydrophobic monomers permit surface erosion for slow release & protect active agent from hydrolysis
- Copolymer degradation of 70% by 2-3 weeks

Surface Erosion

Time

Brem H, Langer R: Polymer-Based Drug Delivery to the Brain. *Science & Medicine*. 1996;3(4):2-11.



Up to eight polymer implants line a tumor resection cavity, where the loaded drug is gradually released as they dissolve. The inset shows conceptually how drug molecules diffuse away from these implants.

Brem and Langer, Scientific American: Science and Medicine 3:2-11, 1996

THE LANCET

Placebo-controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas

Henry Brem, Steven Piantadosi, Peter C Burger, Michael Walker, Robert Selker, Nicholas A Vick, Keith Black, Michael Sisti, Steven Brem, Gerard Mohr, Paul Muller, Richard Morawetz, S Clifford Schold, for the Polymer-Brain Tumor Treatment Group

Lancet 345:1008-12, 1995

Neuro-Oncology

A Phase 3 Trial of local chemotherapy with biodegradable carmustine (BCNU) wafers (Gliadel® Wafers) in patients with primary malignant glioma

Manfred Westphal, Dana C Hilt, Enoch Bortey, Patrick Delvault, Robert Olivares, Peter C Warnke, Ian R Whittle, Juha Jaaskelainen, and Zvi Ram

Department of Neurosurgery, University Hospital Eppendorf, Hamburg, Germany (M.W.)

Neuro-Oncology Vol 5, Issue 2: April 2003

Table 1 Selected Phase III Studies of Patients with Malignant Gliomas

				GBM (%)		Median Survival		
Phase III Trial	Malignant Glioma	Schedule	*n*	Treatment	Control	Treatment	Control	*P* value
Brem et al.[15] 1995	Recurrent	BCNU polymer vs. control polymer	222	66%	65%	31 wk	23 wk	.006
Valtonen et al.[17] 1997	New diagnosis	BCNU polymer + XRT vs. control polymer + XRT	32	69%	100%	14.5 mo	10 mo	.012
Westphal et al.[18] 2003	New diagnosis	BCNU polymer + XRT vs. control polymer + XRT	240	84%	88%	13.9 mo	11.6 mo	.03
Stupp et al.[35] 2005	New diagnosis	Temozolamide + XRT vs. XRT	573	93%	92%	14.6 mo	12.1 mo	< .001

Abbreviations: xrt, radiation therapy.

Current United States FDA-Approved Indications for Gliadel® Wafer

Indication	Date of Approval
Patients with recurrent glioblastoma multiforme as an adjunct to surgery	September, 1996
Patients with newly diagnosed high grade malignant glioma as an adjunct to surgery and radiation	February, 2003

IMPORTANT SAFETY INFORMATION

INDICATIONS GLIADEL® Wafer (carmustine implant) is indicated in patients with newly diagnosed high-grade malignant glioma as an adjunct to surgery and radiation.
GLIADEL Wafer is also indicated in patients with recurrent glioblastoma multiforme as an adjunct to surgery.

IMPORTANT SAFETY INFORMATION
GLIADEL Wafer (carmustine implant) can cause fetal harm when administered to a pregnant woman. It is recommended that patients receiving GLIADEL Wafer discontinue nursing. Female patients of reproductive potential should receive counseling on pregnancy planning and prevention. Advise male patients of the potential risk of infertility, and to seek counseling on fertility and family planning options prior to implantation of GLIADEL Wafer.

WARNINGS AND PRECAUTIONS

Seizures: Fifty-four percent (54%) of patients treated with GLIADEL Wafers in the recurrent disease trial experienced new or worsened seizures within the first five post-operative days. The median time to onset of the first new or worsened post-operative seizure was 4 days. Optimize anti-seizure therapy prior to surgery. Monitor patients for seizures postoperatively.

Intracranial Hypertension: Brain edema occurred in 23% of patients treated with GLIADEL Wafers in the initial surgery trial. Additionally, one GLIADEL-treated patient experienced intracerebral mass effect unresponsive to corticosteroids which led to brain herniation. Monitor patients closely for intracranial hypertension related to brain edema, inflammation, or necrosis of the brain tissue surrounding the resection. In refractory cases, consider re-operation and removal of GLIADEL Wafers or Wafer remnants.

Impaired Neurosurgical Wound Healing: Impaired neurosurgical wound healing including wound dehiscence, delayed wound healing, and subdural, subgleal, or wound effusions occur with GLIADEL Wafer treatment. In the initial disease trial, 16% of GLIADEL Wafer-treated patients experienced impaired intracranial wound healing and 5% had cerebrospinal fluid leaks. In the recurrent disease trial, 14% of GLIADEL Wafer-treated patients experienced wound healing abnormalities. Monitor patients post-operatively for impaired neurosurgical wound healing.

Meningitis: Meningitis occurred in 4% of patients receiving GLIADEL Wafers in the recurrent disease trial. Two cases of meningitis were bacterial; one patient required removal of the Wafers four days after implantation; the other developed meningitis following reoperation for recurrent tumor. One case was diagnosed as chemical meningitis and resolved following steroid treatment. In one case the cause was unspecified, but meningitis resolved following antibiotic treatment. Monitor postoperatively for signs of meningitis and central nervous system infection.

Wafer Migration: GLIADEL Wafer migration can occur. To reduce the risk of obstructive hydrocephalus due to wafer migration into the ventricular system, close any communication larger than the diameter of a Wafer between the surgical resection cavity and the ventricular system prior to Wafer implantation. Monitor patients for signs of obstructive hydrocephalus.

ADVERSE REACTIONS

The most common adverse reactions in Newly-Diagnosed High Grade Malignant Glioma patients (incidence >10% and between arm difference ≥4%) are cerebral edema, asthenia, nausea, vomiting, constipation, wound healing abnormalities and depression.

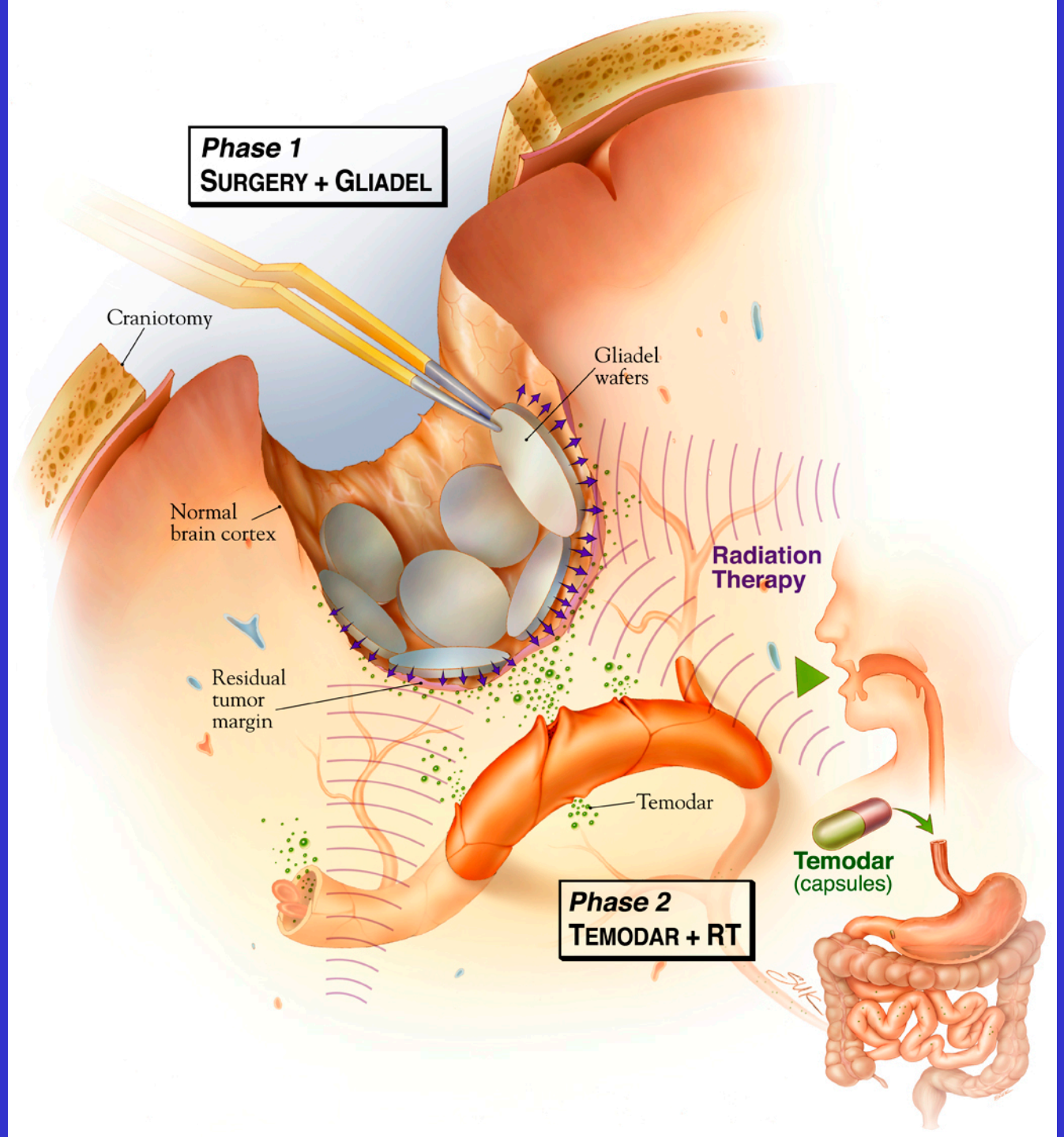
The most common adverse reactions in Recurrent Glioblastoma Multiforme patients (incidence >10% and between arm difference ≥4%) are urinary tract infection, wound healing abnormalities and fever.

Lessons from Clinical Experience with Gliadel® Wafer

- Gliadel® Wafer is safe and effective at initial presentation and recurrence
- Maximize debulking prior to inserting polymers wafer
- Small opening of ventricle does not preclude use
- Watertight closure of dura to eliminate CSF leaks and decrease infections

Lessons from Clinical Experience with Gliadel® Wafer

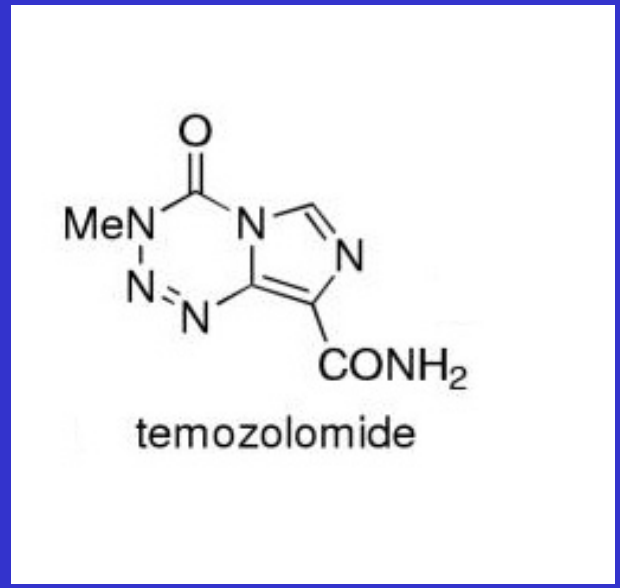
- Preoperative anticonvulsant medication
- Post operative AIR is routine on imaging studies
- High dose steroids (dexamethasone up to 20mg q4h) if post-op neurological compromise
- Steroids for at least 2 weeks post-op (during “chemotherapy”)


Phase 1
SURGERY + GLIADEL
Craniotomy
Gliadel wafers
Normal brain cortex
Residual tumor margin
Radiation Therapy
Temodar
Temodar (capsules)
Phase 2
TEMODAR + RT

Standard of Care Systemic Chemotherapy: Temozolomide (TMZ)

A novel alkylating agent which is:

- lipid soluble
- has modest toxicity
- active against melanoma, lymphomas, and primary brain tumors
- spontaneously chemically converted to its active methylating metabolite, the methyldizaonium ion, via hydrolysis

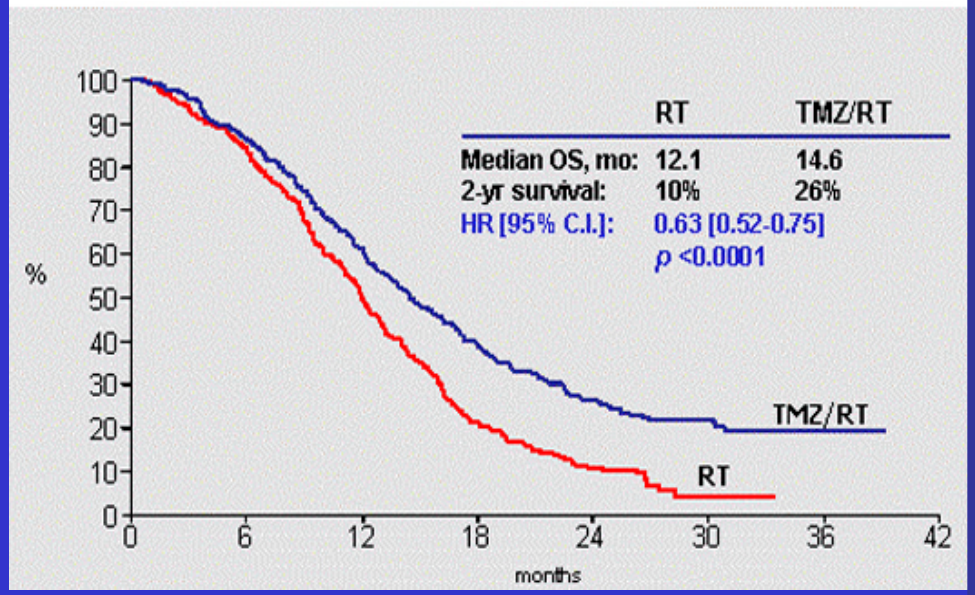


temozolomide

While systemic chemotherapy was included as part of a multimodal regimen in the pivotal trials involving Gliadel® Wafer, TMZ was not available at the time and therefore not included in the studies.

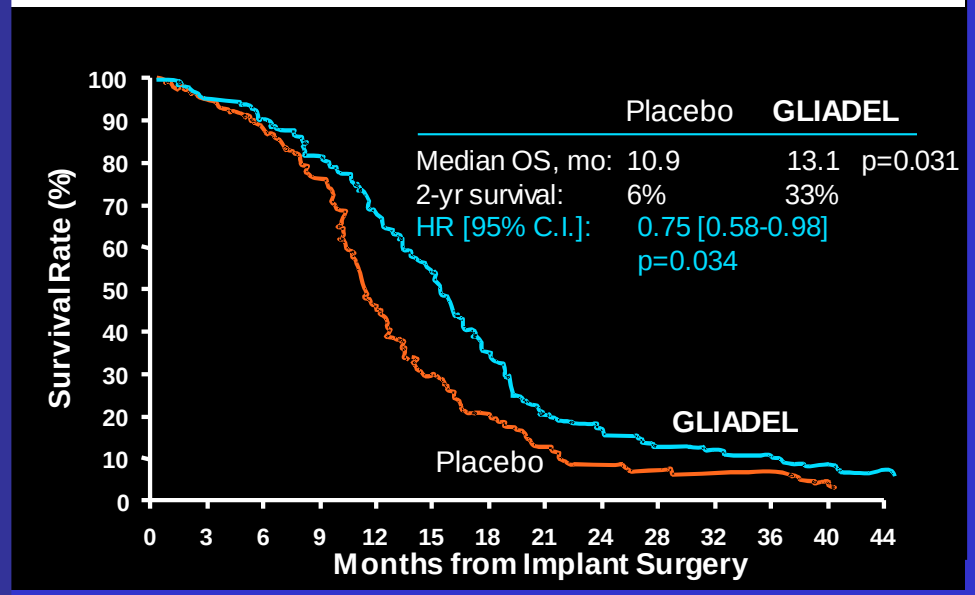
Gliadel® Implantable BCNU Wafers: Similar Survival to Temozolomide

TMZ Overall Survival



Stupp et al, ASCO, 2004 (www.asco.org).

GLIADEL Overall Survival



Meldorf M et al. AANS, 2003 (Abstract 1492).

Ann Surg Oncol (2013) 20:2065–2072
DOI 10.1245/s10434-012-2764-x

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – NEURO-ONCOLOGY

Implanted Carmustine Wafers Followed by Concomitant Radiochemotherapy to Treat Newly Diagnosed Malignant Gliomas: Prospective, Observational, Multicenter Study on 92 Cases

Julien Duntze, MD[1], Claude-Fabien Litré, MD, PhD[1], Christophe Eap, MD[1], Etienne Théret, MD[1], Adeline Debreuve[2], Nicolas Jovenin, MD[2,3], Emmanuèle Lechapt-Zalcman, MD, PhD[4], Philippe Metellus, MD, PhD[5], Philippe Colin, MD[6], Jean-Sébastien Guillamo, MD, PhD[7], Evelyne Emery, MD, PhD[8], Philippe Menei, MD, PhD[9], Pascal Rousseaux, MD[1], and Philippe Peruzzi, MD, PhD[1]

[1]Department of Neurosurgery, Hôpital Maison Blanche, Reims University Hospital, Reims, France; [2]Oncocha, Reims, France; [3]Department of Medical Oncology, Institut Jean Godinot, Reims, France; [4]Department of Pathology, Caen University Hospital, Caen, France; [5]Department of Neurosurgery, Marseille University Hospital, Marseille, France; [6]Department of Radiation, Polyclinique Courlancy, Reims, France; [7]Department of Neurology, Caen University Hospital, Caen, France; [8]Department of Neurosurgery, Caen University Hospital, Caen, France; [9]Department of Neurosurgery, Angers University Hospital, Angers, France

17 French centers with 92 patients treated with craniotomy, Gliadel, Temozolomide, RT

Progression free survival 10.5 months, median

18.8 month overall survival, median

TABLE 3 Adverse side events potentially related to temozolomide

Adverse side events	WHO toxicity grade	*n* (%)
Alopecia	1	5 (5.8)
Exhaustion	2	18 (20.9)
Epilepsy	3	3 (3.5)
Digestive disorders	2	4 (4.6)
Hematological disorders	2	2 (2.3)
Neurological aggravation	3	4 (4.6)

TABLE 4 Survival data from the main series on newly diagnosed gliomas treated by carmustine implants (carmustine) and/or radiochemotherapy plus concomitant and adjuvant temozolomide

Series	No. of patients	Carmustine	Temozolomide	Median progression-free survival	Median overall survival	Survival at 1 year	Survival at 2 years
Our series	92	Yes	Yes	10.5	18.8	70 %	37 %
Pan et al.	21	Yes	Yes	8.5	17	NS	39 %
McGirt et al.	33	Yes	Yes	NS	20.7	NS	36 %
Menei et al.	83	Yes	Yes	NS	20	NS	NS
Affronti et al.	36	Yes	Yes	NS	20.9	81 %	47 %
Stupp et al.	287	No	Yes	6.9	14.6	NS	26.5 %
Westphal et al.	120	Yes	No	5.9	13.9	59.2 %	NS

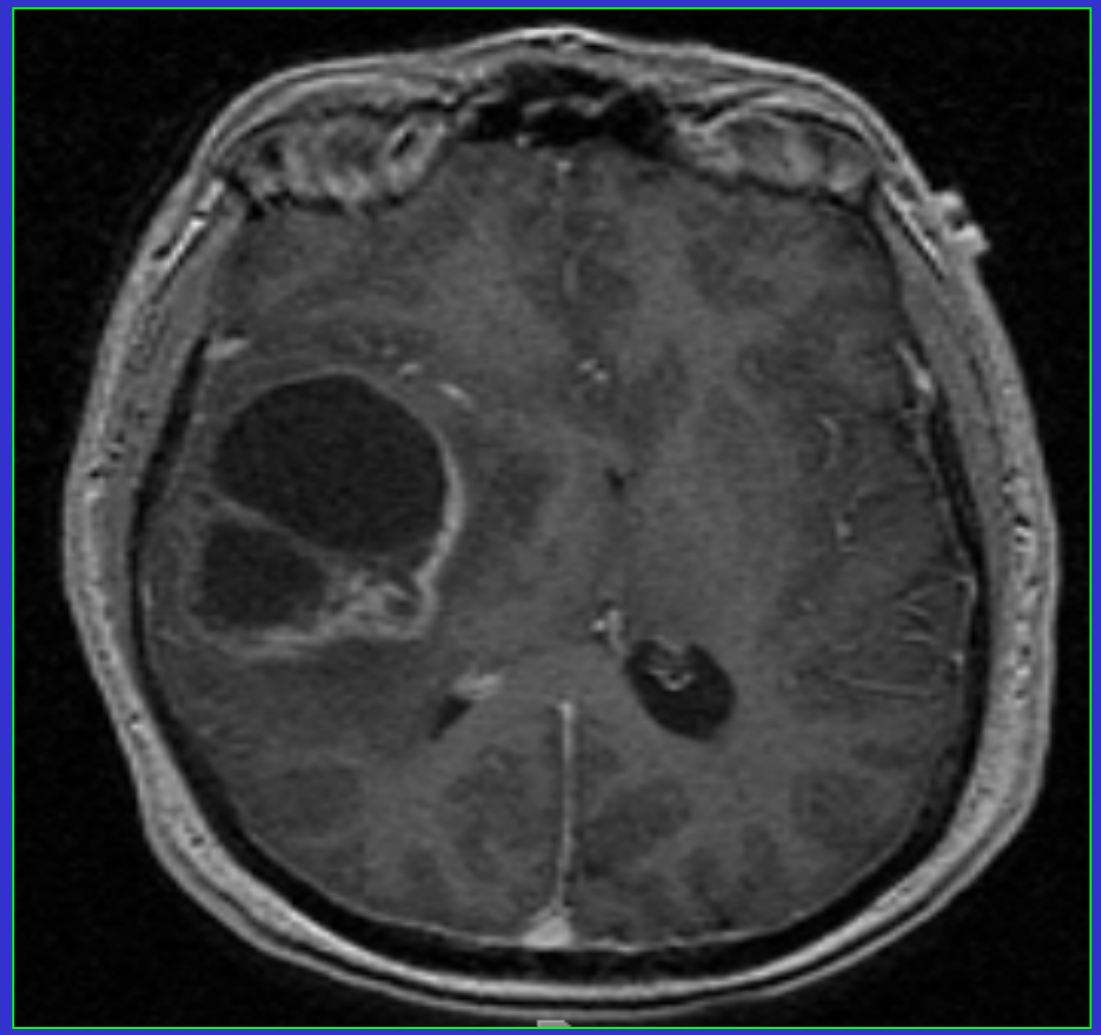
NS not specified

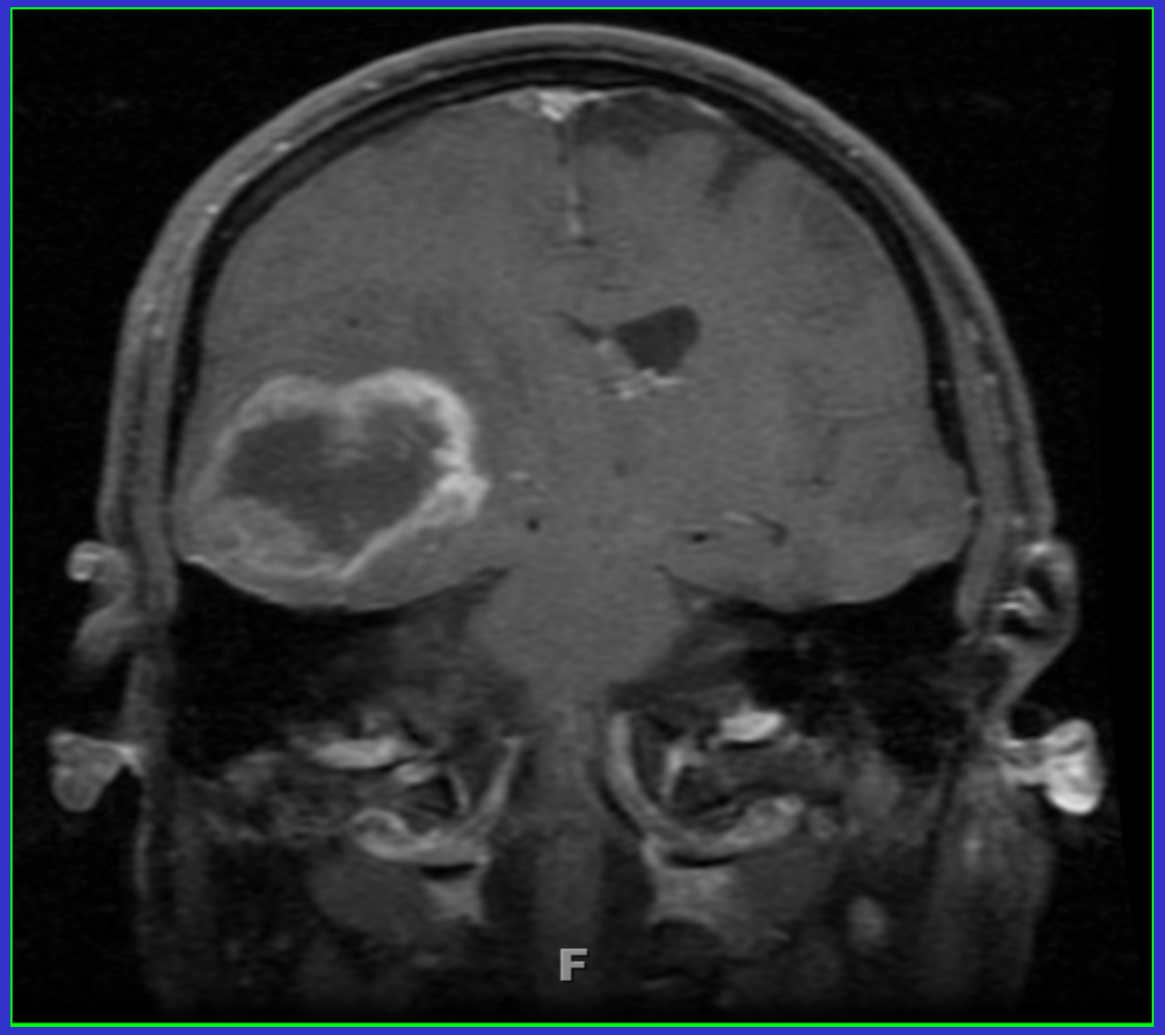
CASE PRESENTATION

DS: 52 yo ♂

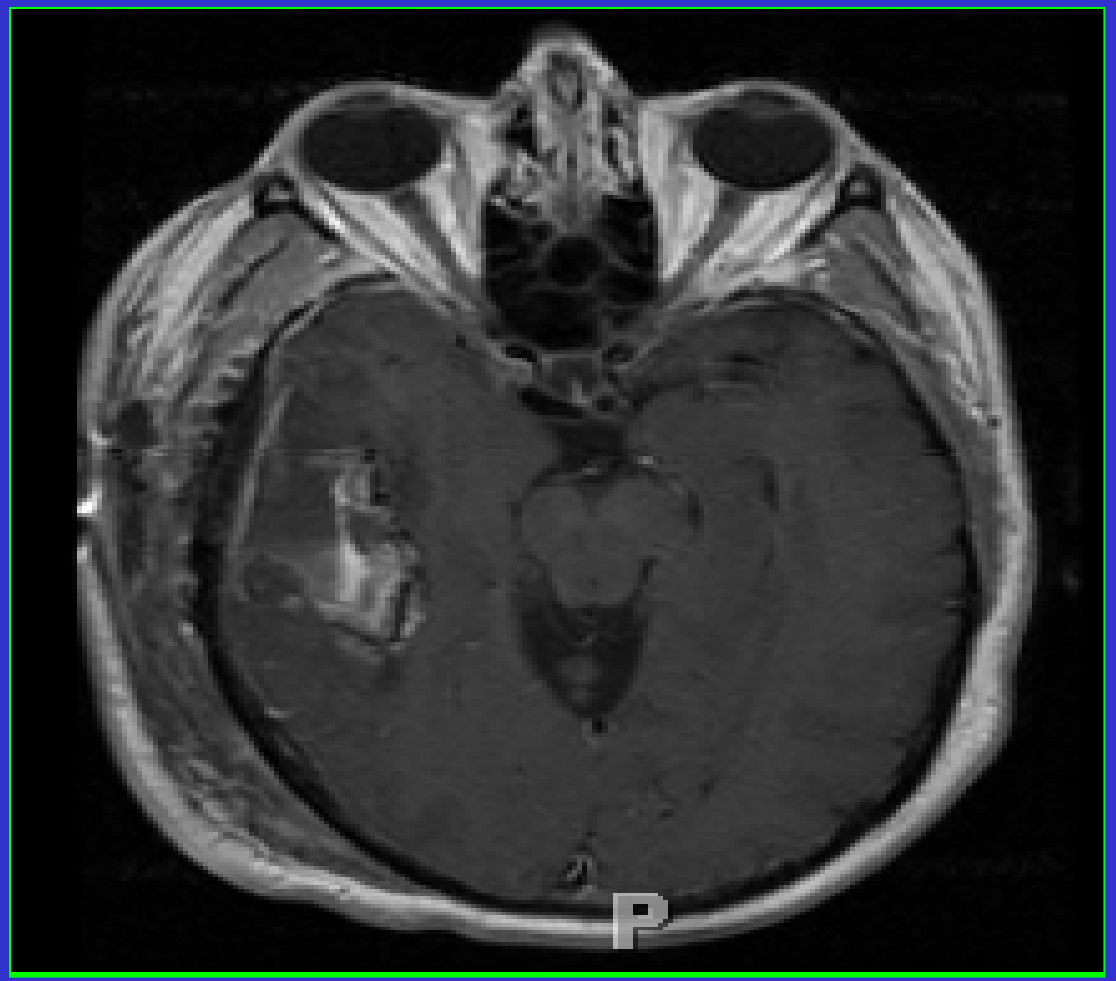
Presented with several week hx of severe HA's → PCP →MRI revealed ring enhancing mass

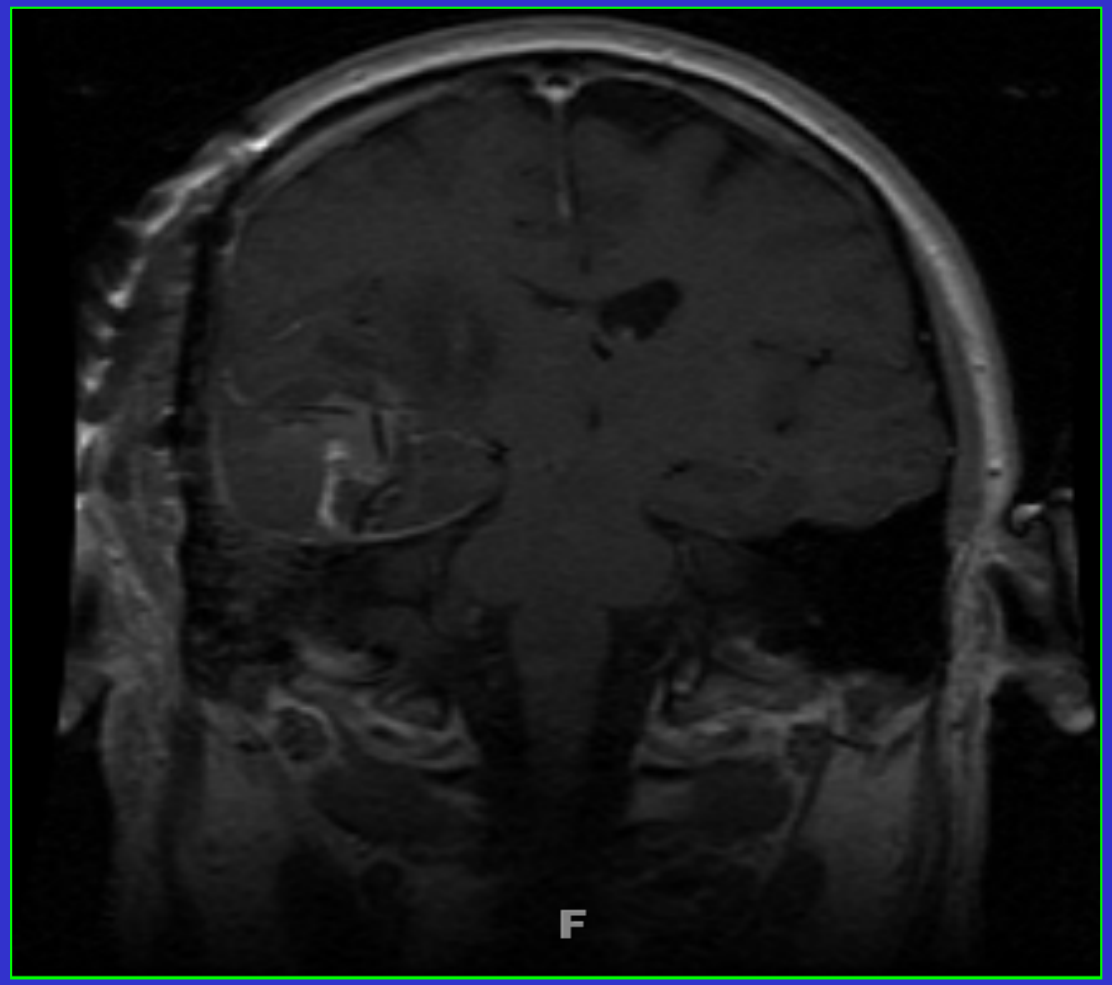
DS: Presenting MRI 09/18/2005





DS: Post Op Scan 09/20/2005





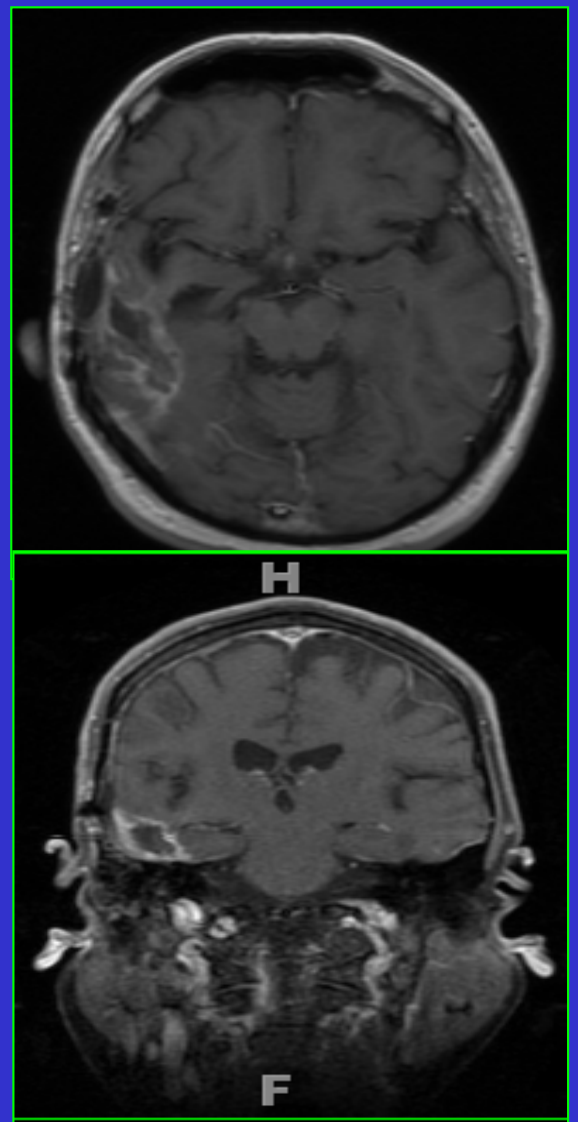
OR 1st crani 09/19/2005 → GBM → Resection + 8 Gliadel® Wafers

DS:

- XRT + Temodar (temozolamide/TMX)
  - IMRT 6000cGy 10/13/05-11/23/2005
  - Concomitant TMZ (75 mg/m² body surface area) was given 7 days per week during radiotherapy
  - Adjuvant TMX 150 mg/m²
    - Stupp Regimen:5 days on 23 days off times 6 cycles completed 08/2006
  - Watchful monitoring
    - Excellent QOL with RTW

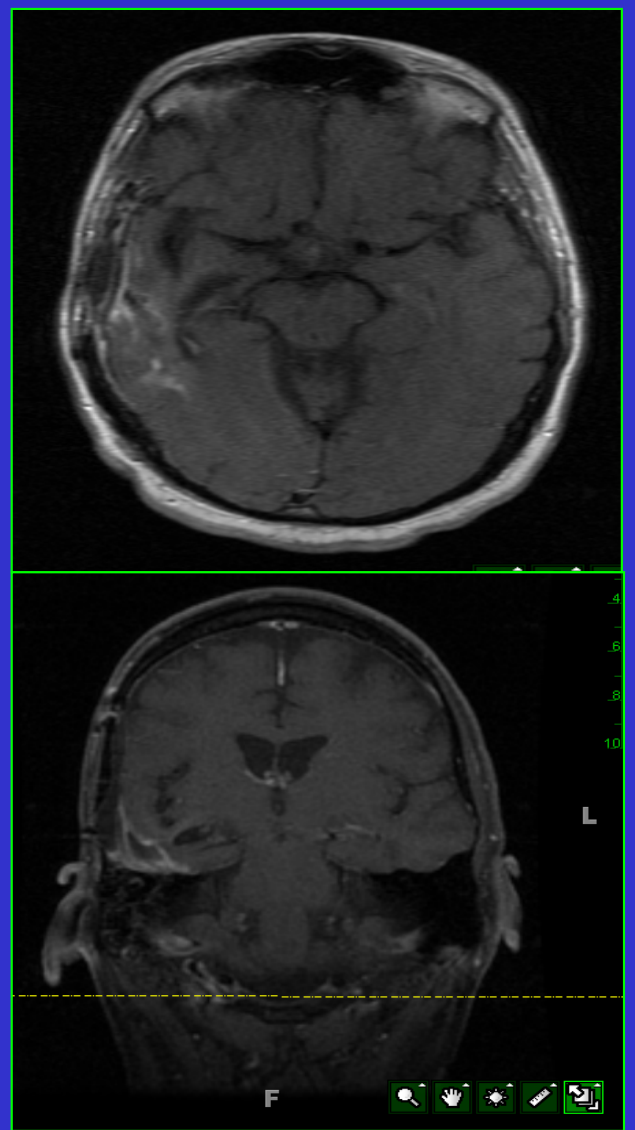
DS: Follow up scans

06/29/2006

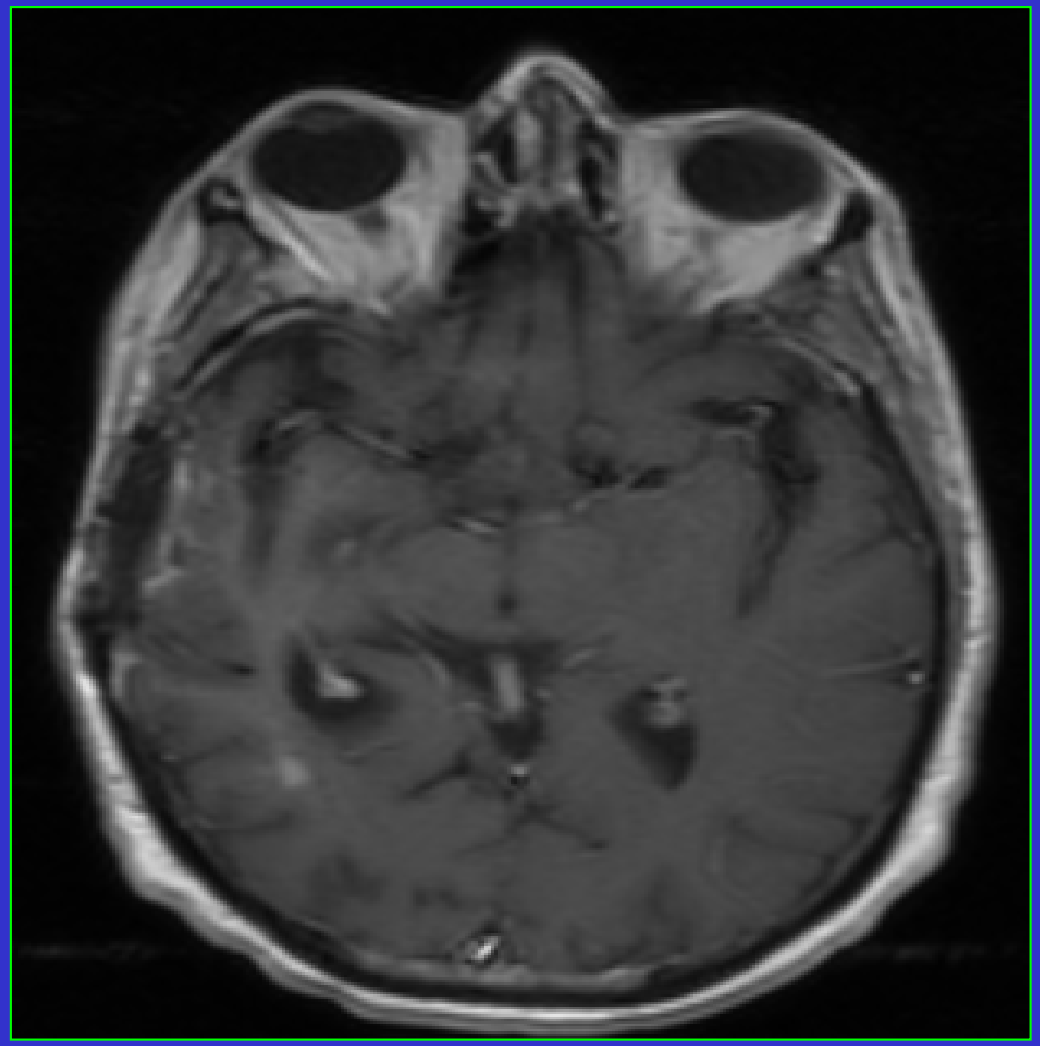


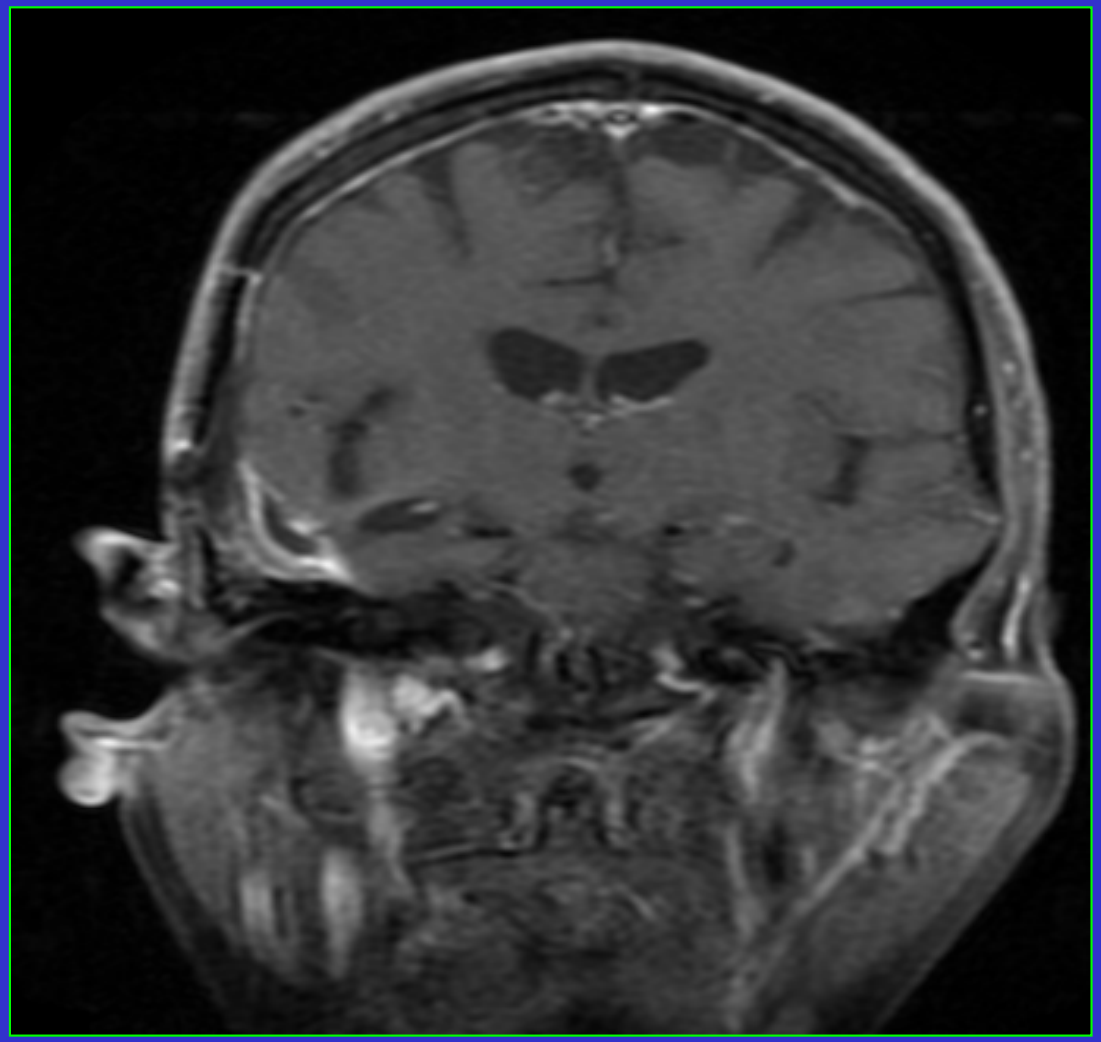
9 & 12 months out from
Gliadel® /XRT/TMZ

09/14/2006



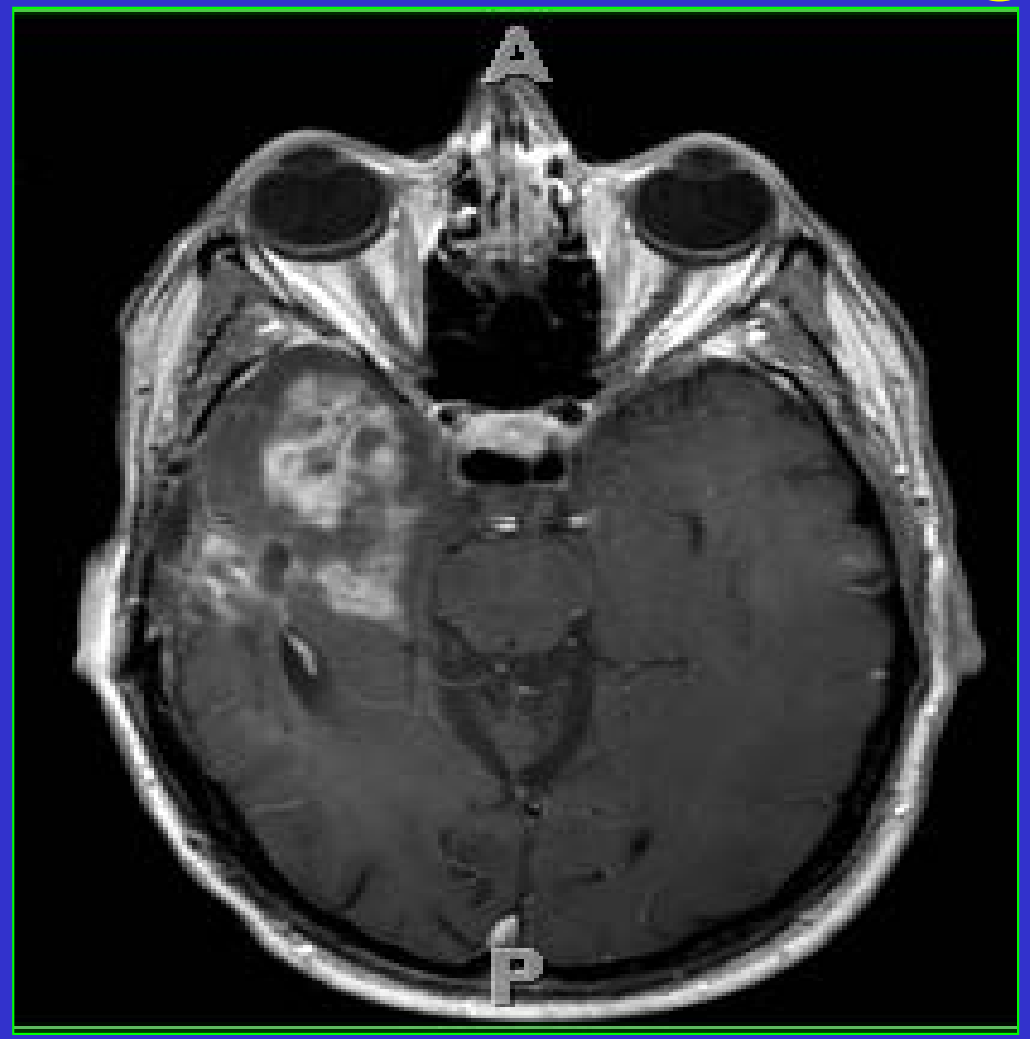
DS: Follow up scan 11/09/2006



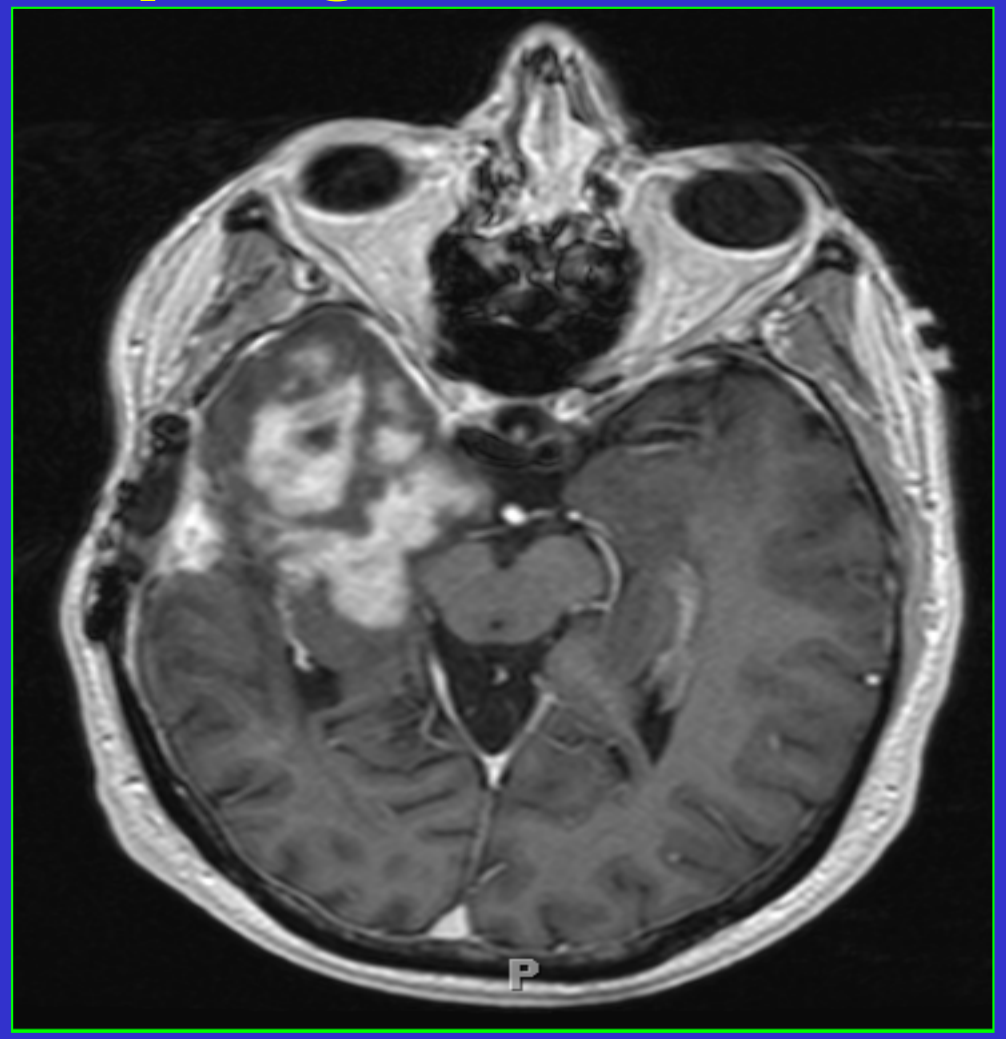


14 months from initial dx & treatment

DS: Routine 2 year f/u scan 09/2007 → radiographic progression

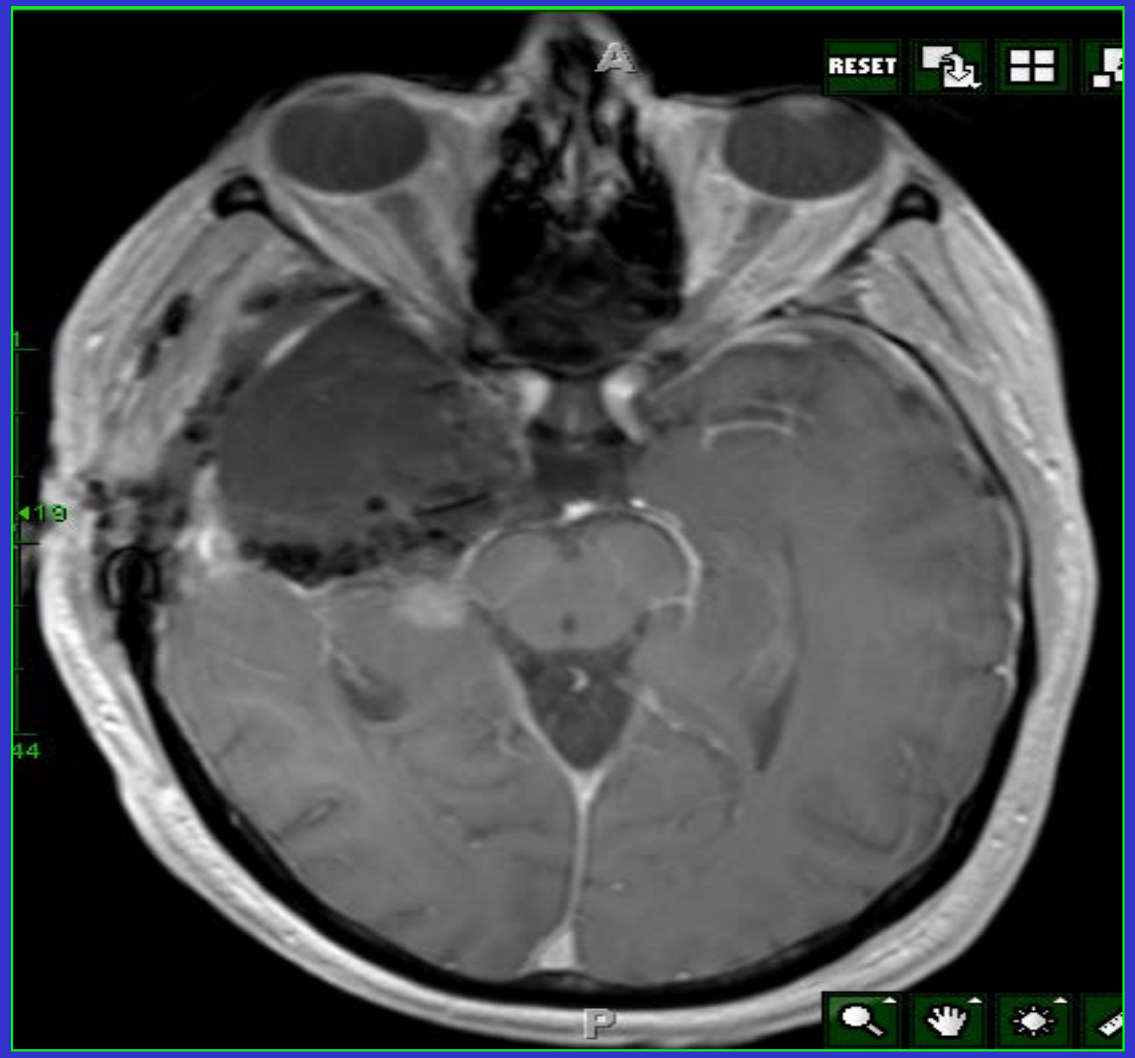


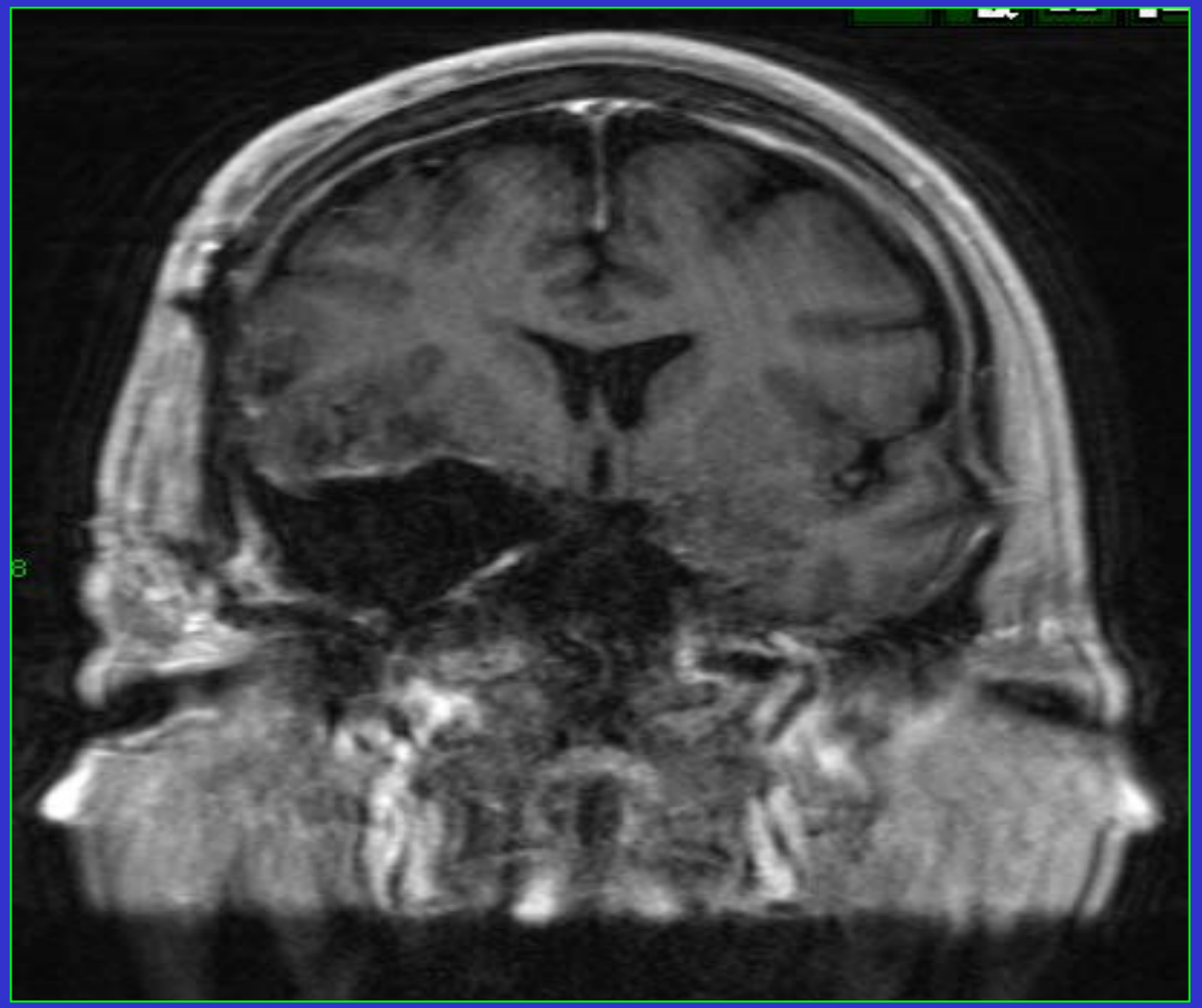
09/27/2007



10/28/2007

DS: Post Op Crani #2 + Gliadel® #2

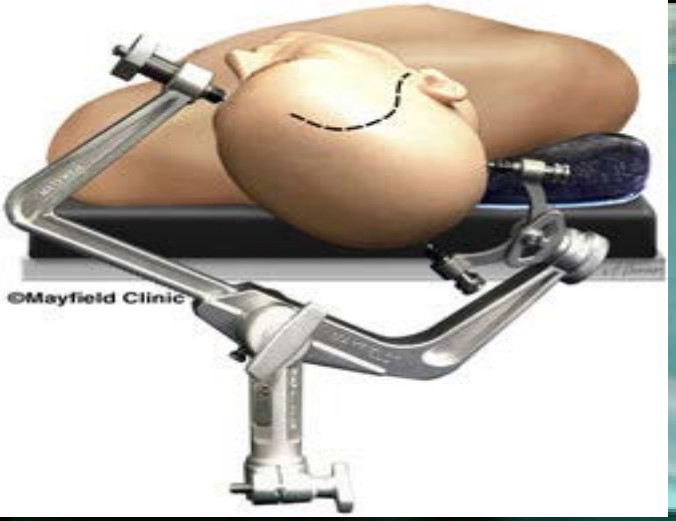


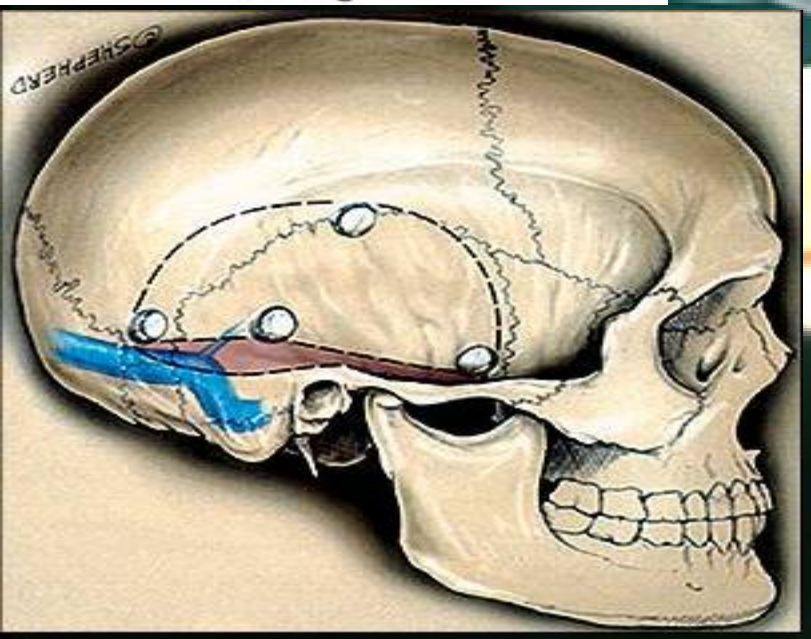


DS: Summary

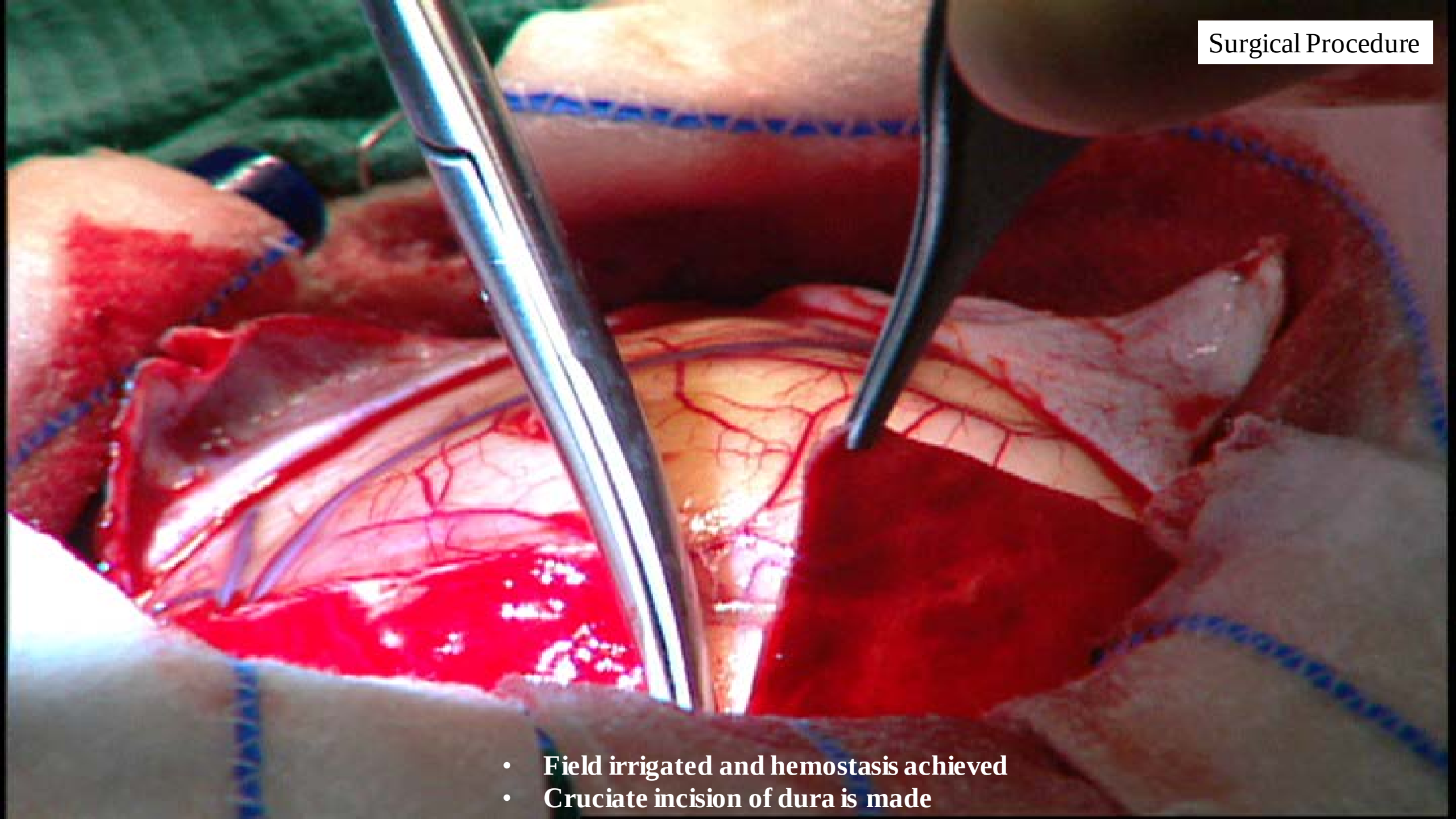
- Diagnosed with Glioblastoma at age 54 in September 2005
- Two craniotomies with Gliadel
- Survived 34 months

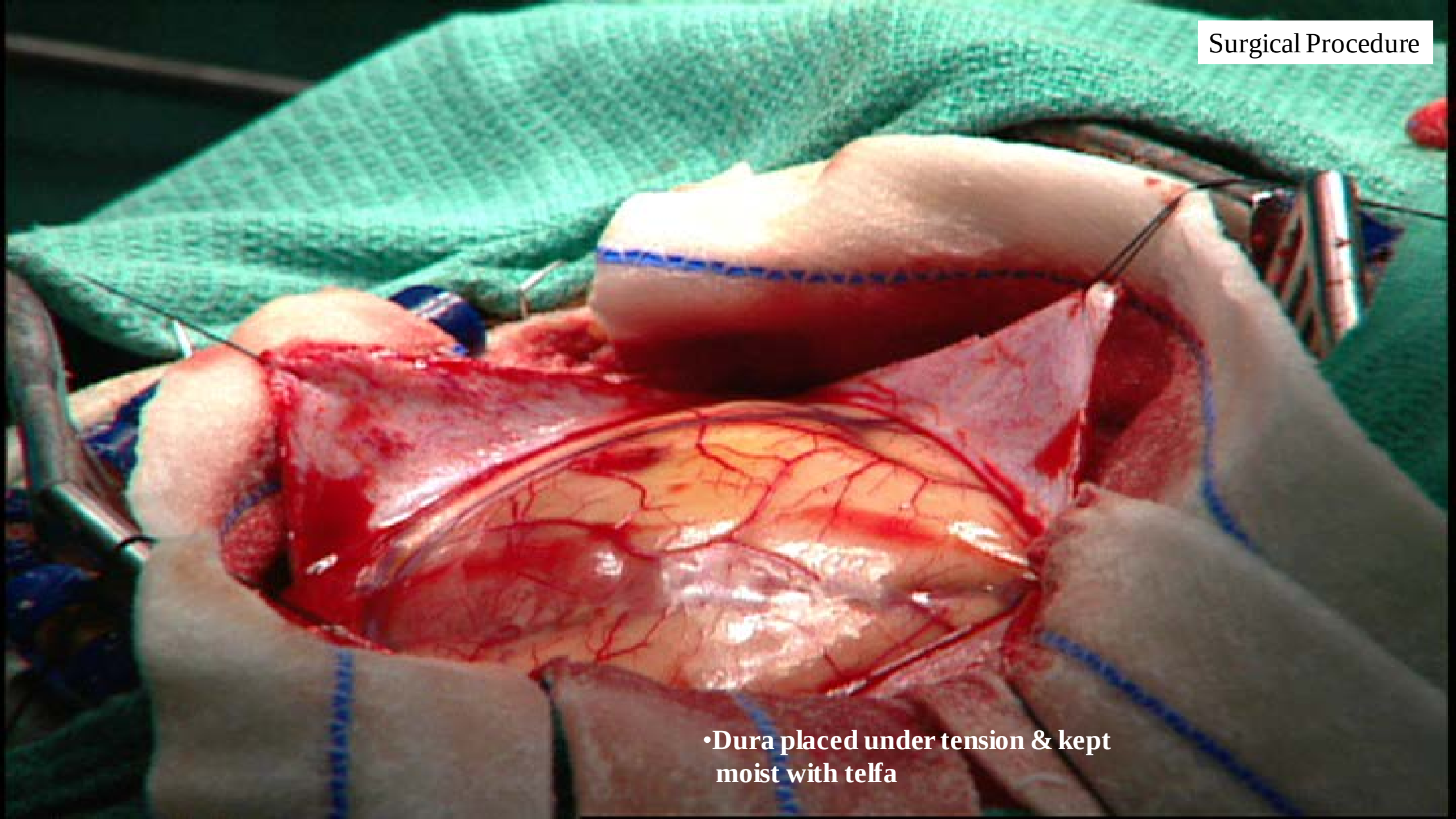
Surgical Procedure



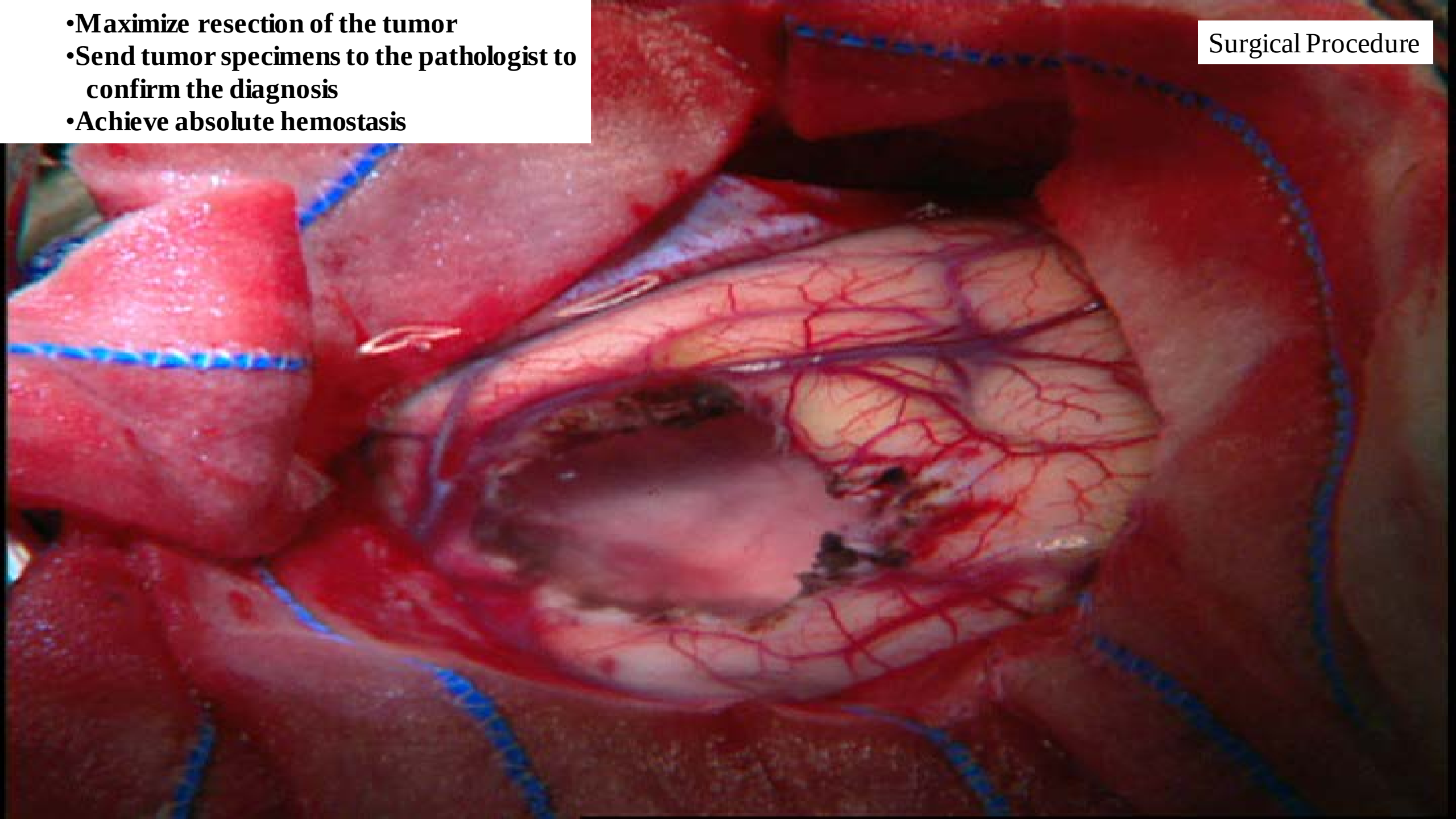


- Pt's head placed in clamp
- Neuro-navigational localization of mass
- Incision made
- Burr holes made, bone flap removed

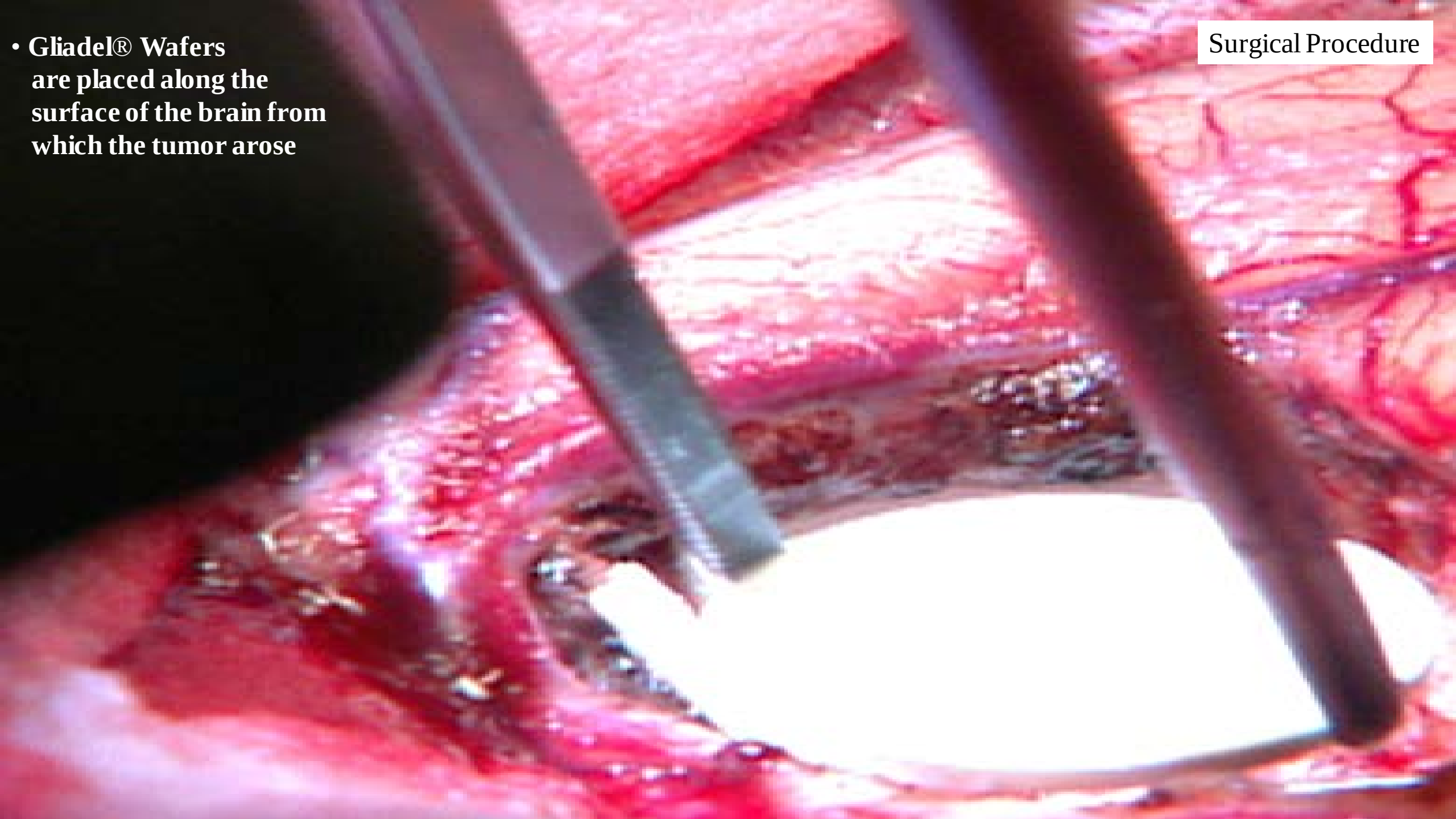

Surgical Procedure
• Field irrigated and hemostasis achieved
• Cruciate incision of dura is made


Surgical Procedure
•Dura placed under tension & kept moist with telfa

- **Maximize resection of the tumor**
- **Send tumor specimens to the pathologist to confirm the diagnosis**
- **Achieve absolute hemostasis**

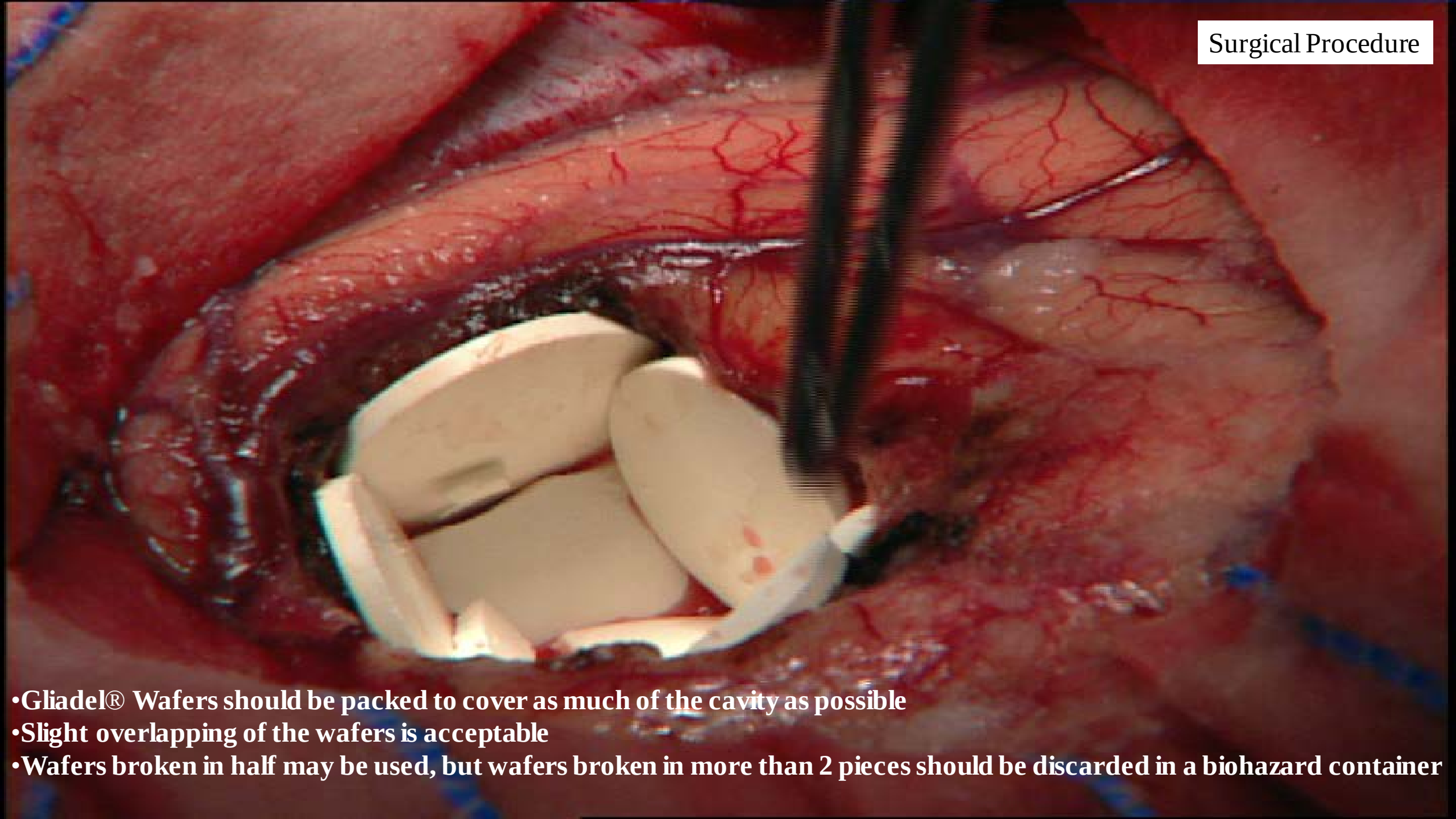


Surgical Procedure



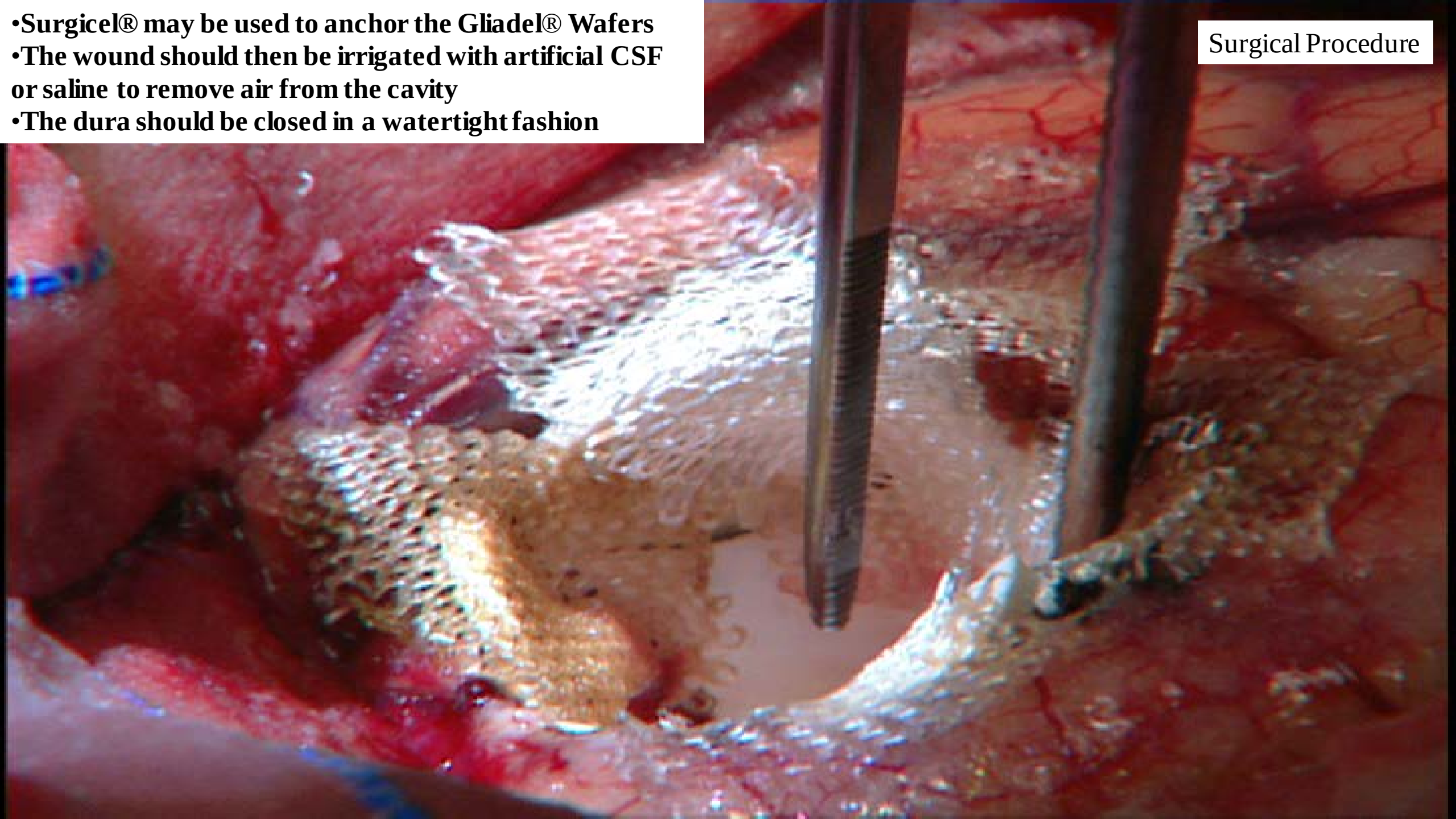
- **Gliadel® Wafers are placed along the surface of the brain from which the tumor arose**

Surgical Procedure

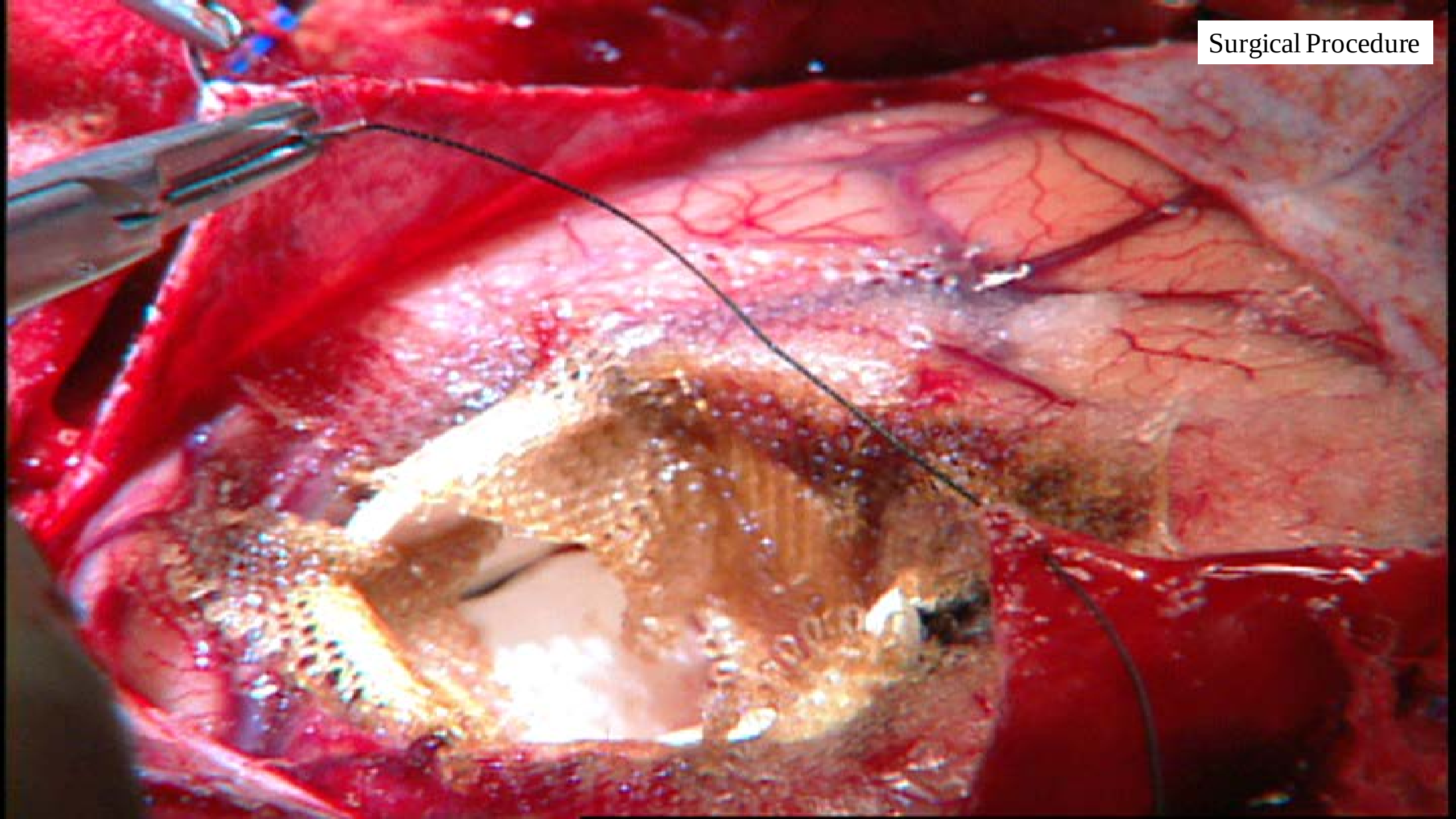


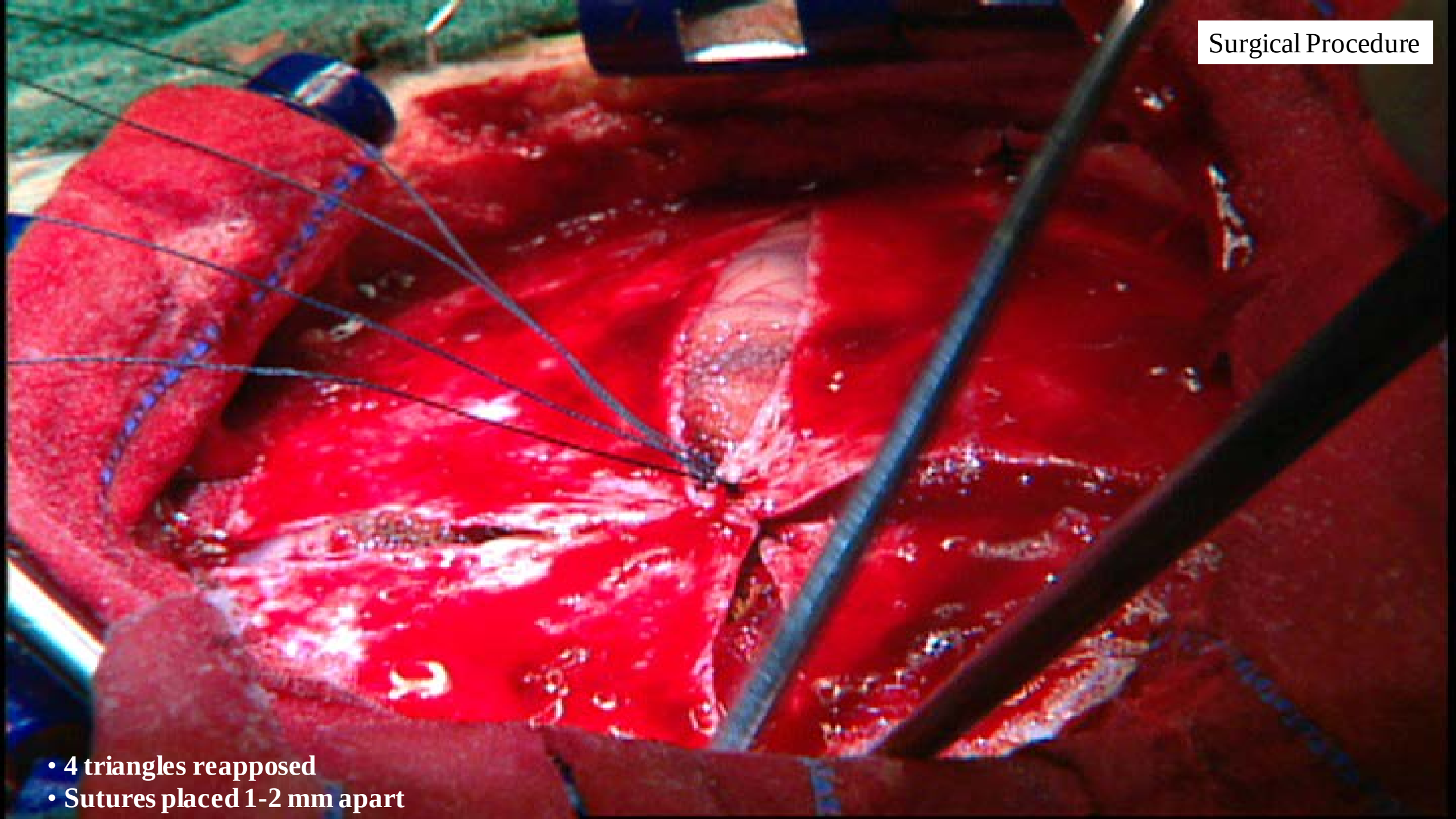
- Gliadel® Wafers should be packed to cover as much of the cavity as possible
- Slight overlapping of the wafers is acceptable
- Wafers broken in half may be used, but wafers broken in more than 2 pieces should be discarded in a biohazard container

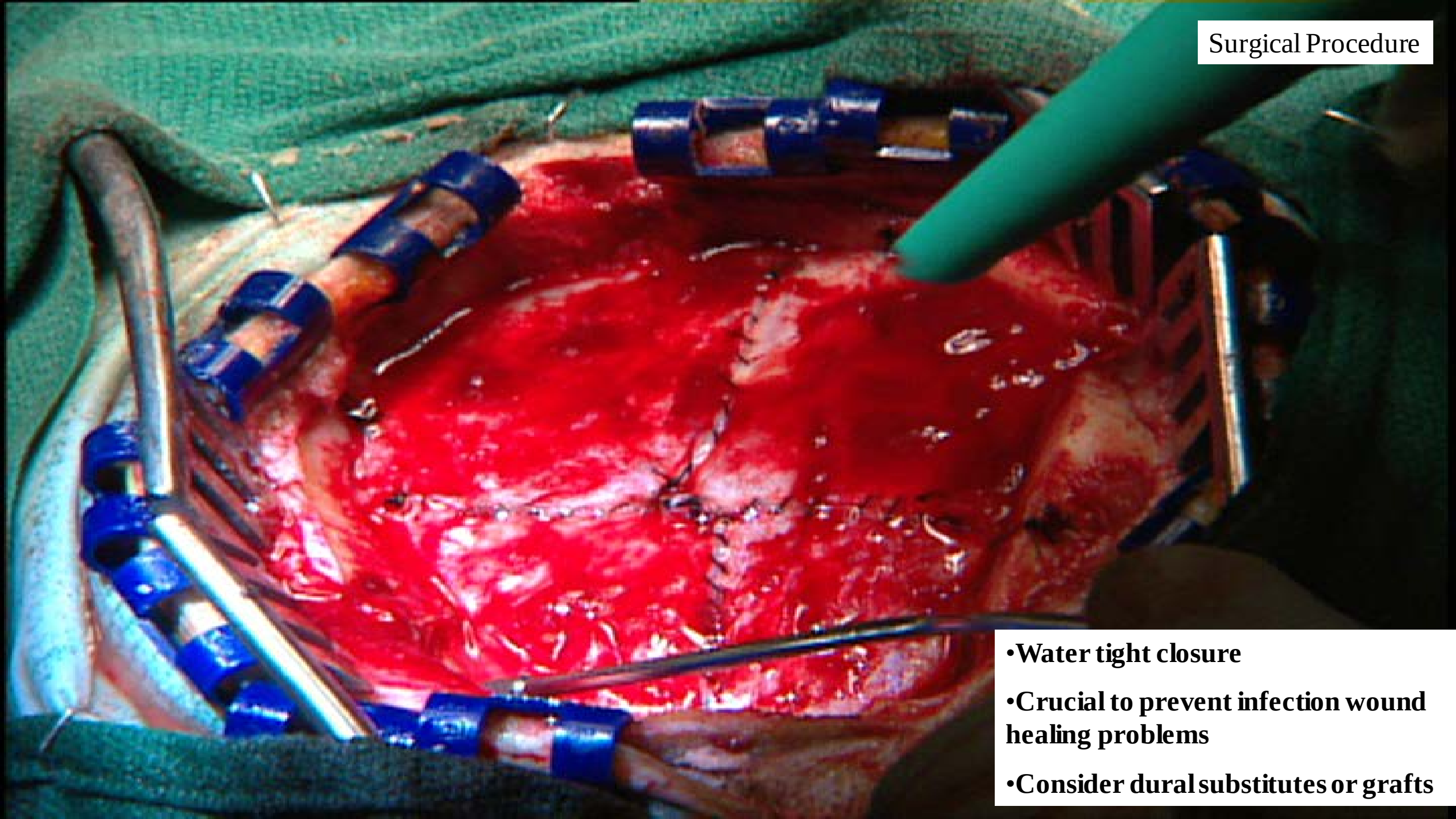
•**Surgicel® may be used to anchor the Gliadel® Wafers**
•**The wound should then be irrigated with artificial CSF or saline to remove air from the cavity**
•**The dura should be closed in a watertight fashion**



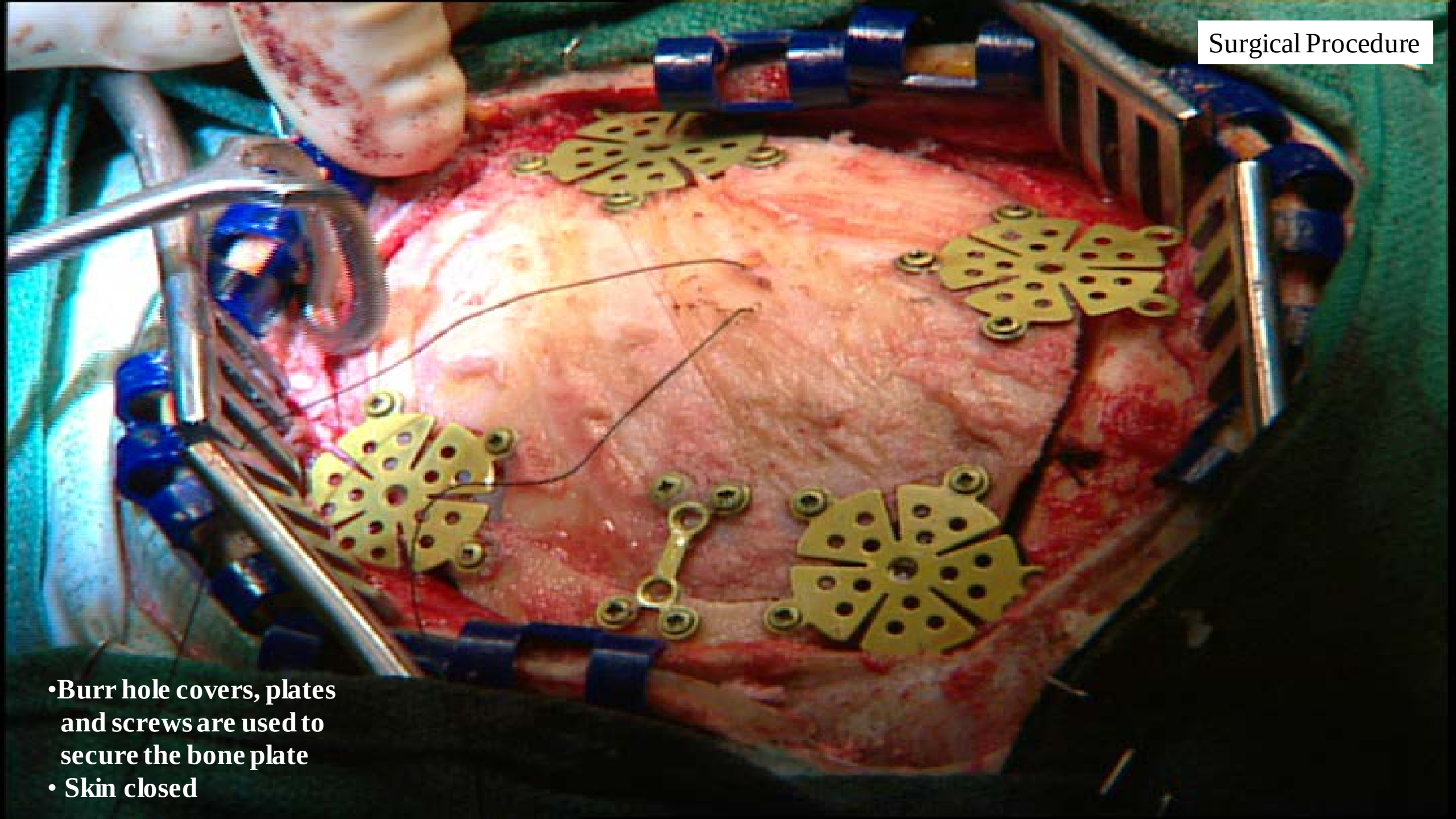
Surgical Procedure


Surgical Procedure


Surgical Procedure
• 4 triangles reapposed
• Sutures placed 1-2 mm apart


Surgical Procedure
•Water tight closure
•Crucial to prevent infection wound healing problems
•Consider dural substitutes or grafts

- Gelfoam placed over dura and secured in placed with tenting sutures
- Tenting suture carried up through bone


Surgical Procedure
•Burr hole covers, plates and screws are used to secure the bone plate
• Skin closed

SUMMARY

- In the management of patients with high-grade malignant glioma (HGG), it is essential to consider every treatment with a proven survival advantage.
- GLIADEL Wafer (carmustine implant) is the first and currently the only FDA-approved treatment that delivers an antineoplastic agent directly to the resected tumor environment while sparing the patient from systemic exposure to that agent.

Intra-operative Carmustine Wafer (Gliadel®) Guidelines for Anaplastic Gliomas and Glioblastoma

AANS/CNS Treatment Guidelines for Newly Diagnosed High Grade Gliomas:

- BCNU-impregnated biodegradable polymers are recommended in patients for whom craniotomy is indicated, on the basis of evidence taken from 2 well-designed comparative clinical studies:
  - Westphal M, et al. Neurooncol. 2003;5(2):79-88.
  - Valtonen S, et al. Neurosurgery. 1997;41(1):44-48.

NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®)*

- BCNU wafer recommended for patients where maximal safe resection is feasible and frozen-section diagnosis supports high-grade glioma (category 2B)

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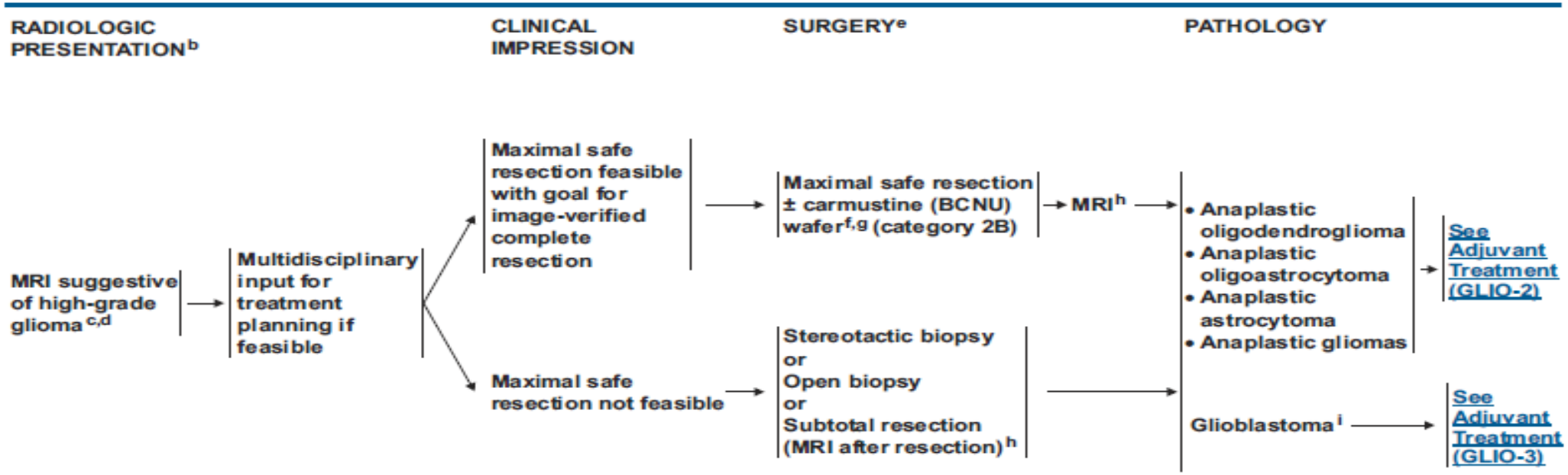
Anaplastic Gliomas/Glioblastoma[a]



[a] This pathway includes the classification of mixed anaplastic oligoastrocytoma (AOA), anaplastic astrocytoma (AA), anaplastic oligodendroglioma (AO), and other rare anaplastic gliomas.
[b] See Principles of Brain Tumor Imaging (BRAIN-A).
[c] Biopsy first if MRI compatible with CNS lymphoma.
[d] Consider a multidisciplinary review in treatment planning, especially once pathology is available (See Principles of Brain Tumor Management [BRAIN-E]).
[e] See Principles of Brain Tumor Surgery (BRAIN-B).
[f] If frozen section diagnosis supports high-grade glioma.
[g] Treatment with carmustine wafer may impact enrollment in some adjuvant clinical trials.
[h] Post-operative MRI should be done within 72 hours after surgery.
[i] This pathway also includes gliosarcoma.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

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PATHOLOGY	ADJUVANT TREATMENT	FOLLOW-UP[b]
Anaplastic oligodendroglioma Anaplastic oligoastrocytoma 1p19q codeleted	→ Fractionated external beam RT[j] and PCV chemotherapy (category 1)[k,l] or Fractionated external beam RT[j] and temozolomide chemotherapy[k,m] or PCV or temozolomide chemotherapy[k] (category 2B)	
Anaplastic oligodendroglioma Anaplastic oligoastrocytoma 1p19q uni- or non-deleted Anaplastic astrocytoma	→ Fractionated external beam RT[j] (category 1) or Fractionated external beam RT[j] and temozolomide chemotherapy[k] or PCV or temozolomide chemotherapy[k]	→ MRI 2-6 wk after RT, then every 2-4 mo for 2-3 y, then less frequently → See Recurrence (GLIO-4)
Anaplastic gliomas Poor Performance status (KPS < 70)	→ Fractionated external beam RT[j] (hypofractionated [preferred] or standard) or PCV or temozolomide chemotherapy (category 2B)[k] or Palliative/Best supportive care	

[a] This pathway includes the classification of mixed anaplastic oligoastrocytoma (AOA), anaplastic astrocytoma (AA), anaplastic oligodendroglioma (AO), and other rare anaplastic gliomas.

[b] See Principles of Brain Tumor Imaging (BRAIN-A).

[j] See Principles of Brain Tumor Radiation Therapy (BRAIN-C).

[k] See Principles of Brain Tumor Systemic Therapy (BRAIN-D).

[l] van den Bent MJ, Brandes AA, Taphoorn MJ. Adjuvant Procarbazine, Lomustine, and Vincristine Chemotherapy in Newly Diagnosed Anaplastic Oligodendroglioma: Long-Term Follow-Up of EORTC Brain Tumor Group Study 26951. J Clin Oncol 2012; Epub ahead of print.

[m] Wick W, Hartmann C, Engel C, et al. NOA-04 randomized phase III trial of sequential radiochemotherapy of anaplastic glioma with procarbazine, lomustine, and vincristine or temozolomide. J Clin Oncol 2009;27:5874-5880.

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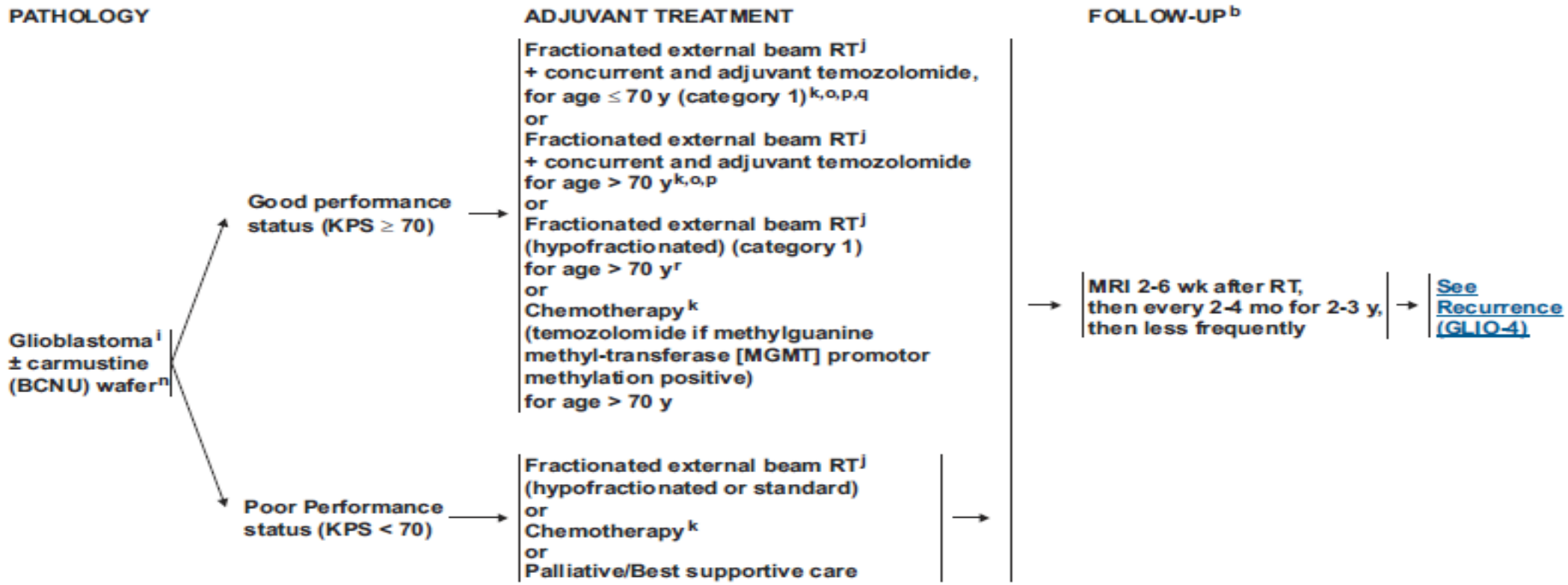

[a] This pathway includes the classification of mixed anaplastic oligoastrocytoma (AOA), anaplastic astrocytoma (AA), anaplastic oligodendroglioma (AO), and other rare anaplastic gliomas.

[b] See Principles of Brain Tumor Imaging (BRAIN-A).

[i] This pathway also includes gliosarcoma.

[j] See Principles of Brain Tumor Radiation Therapy (BRAIN-C).

[k] See Principles of Brain Tumor Systemic Therapy (BRAIN-D).

[n] Treatment with carmustine wafer, reirradiation, or multiple prior systemic therapies, may impact enrollment in some adjuvant clinical trials.

[o] Combination of agents may lead to increased toxicity or radiographic changes.

[p] Stupp R, Mason WP, van den Bent MJ et al. Radiotherapy plus concomitant and adjuvant temozolomide for glioblastoma. N Engl J Med 2005;352:987-996.

[q] Duration of treatment for glioblastomas beyond 6 months is unknown. Duration of therapy for anaplastic astrocytoma is unknown.

[r] Keime-Guibert F, Chinot O, Taillandier L, et al. Radiotherapy for glioblastoma in the elderly. New Eng J Med 2007;356:1527-1535.

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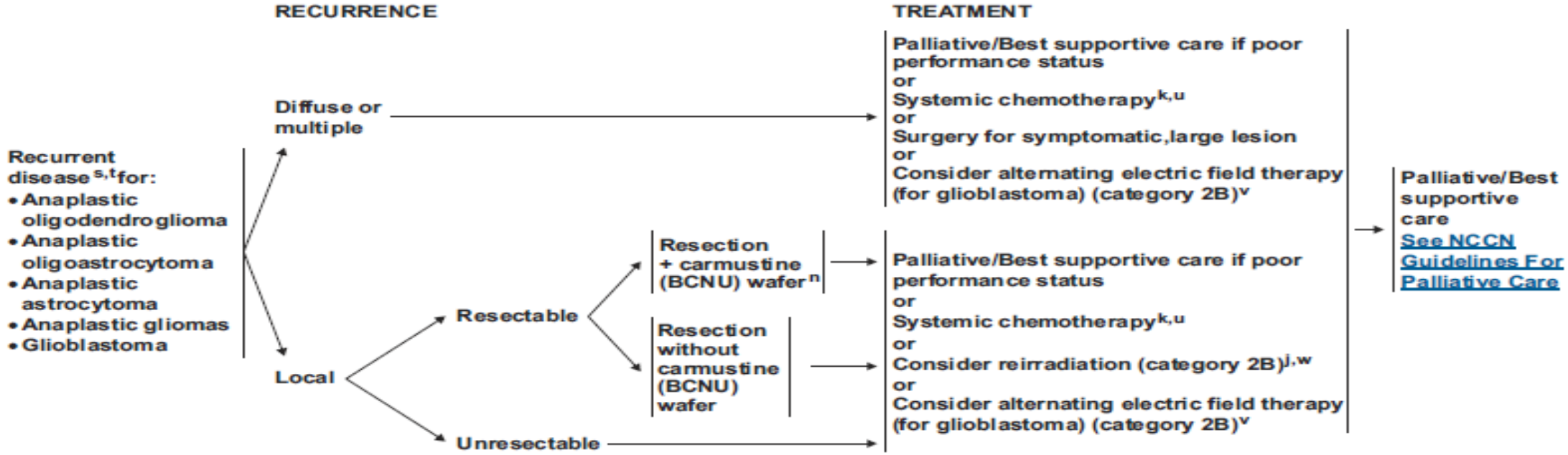

[a] This pathway includes the classification of mixed anaplastic oligoastrocytoma (AOA), anaplastic astrocytoma (AA), anaplastic oligodendroglioma (AO), and other rare anaplastic gliomas.

[j] See Principles of Brain Tumor Radiation Therapy (BRAIN-C).

[k] See Principles of Brain Tumor Systemic Therapy (BRAIN-D).

[n] Treatment with carmustine wafer, reirradiation, or multiple prior systemic therapies, may impact enrollment in some adjuvant clinical trials.

[s] Consider MR spectroscopy, MR perfusion, or brain PET to rule out radiation necrosis.

[t] Within the first 3 months after completion of RT and concomitant temozolomide, diagnosis of recurrence can be indistinguishable from pseudoprogression on neuroimaging. With pseudoprogression, stabilization or improvement should be expected within 3 mo of the end of radiotherapy.

[u] Anaplastic oligodendrogliomas have been reported to be especially sensitive to chemotherapy. Chemotherapy using temozolomide or nitrosourea-based regimens may be appropriate.

[v] Stupp R, Wong ET, Kanner AA, et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomised phase III trial of a novel treatment modality. European Journal of Cancer 2012;48:2192-2202.

[w] Especially if long interval since prior RT and/or if there was a good response to prior RT.

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Rationale for New ICD-10-PCS Code

The ICD-9-PCS code 00.10, *Implantation of chemotherapeutic agent*, did not transition to a unique ICD-10-PCS code.

Currently, under ICD-10-PCS there is not a unique procedure code that captures the procedure to insert chemotherapeutic wafer(s) into cranial cavity following open craniotomy for tumor excision.

Request: Create new code 3E0Q00_, effective 10/1/2014

- Administration 3 Administration
- Body System E Physiological System and Anatomic Regions
- Operation 0 Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products

Body System/Region	Approach	Substance	Qualifier
Q Cranial Cavity and Brain	0 Open*	0 Antineoplastic	_Chemotherapeutic Wafer*

*Approach:
Open approach (not percutaneous) is essential to capture surgical approach
Percutaneous approach as interim coding recommendation will create coding confusion and inconsistencies
*Qualifier
Add qualifier for chemotherapeutic wafer so that utilization, costs and outcomes can be captured,
Qualifier will differentiate for other types of antineoplastic agents

Discussion & Questions