



**Position Statement
on
Appropriate Uses of Paraffin Sections in Association with Mohs Micrographic Surgery
(Approved by the Board of Directors: August 1, 2011; Revised November 5, 2011;
Revised August 9, 2014)**

According to AMA/CPT, Mohs micrographic surgery is a technique for the removal of complex or ill-defined skin cancer with histologic examination of 100% of the surgical margins. It requires a single physician to act in two integrated but separate and distinct capacities: surgeon and pathologist. If either of these responsibilities is delegated to another physician who reports the services separately, these codes should not be reported. The Mohs surgeon removes the tumor tissue, maps and may divide the tumor specimen into pieces and each specimen or piece is embedded into an individual tissue block for histopathologic examination. While this is typically done with frozen sections, it can be done on paraffin sections in selected cases. The Mohs surgeon then interprets the frozen (or paraffin) section for each piece and indicates on a map where tumor remains, if any. This position statement is not intended to contradict the foregoing description of Mohs surgery; however, it addresses the issue circumstances when the physician performing the Mohs surgery may need to obtain, in addition to his/her frozen or paraffin section slide interpretation, a pathologic consultation on the paraffin sections derived from Mohs tissue (either the paraffin sections made during the conduct of Mohs, or paraffin sections derived from tissue that has already had frozen sections taken from it).

When Pathology Consultation or Paraffin Sections are Compatible with Mohs Surgery

Mohs surgery with frozen section tissue processing is highly effective for the delineation of tumor margins. In a small minority of cases, paraffin (formalin-fixed) section pathologic evaluation of Mohs-derived tissue may be necessary for optimal patient care. This may occur before, during, or after the Mohs procedure. Examples include, but are not limited to, the following:

- (1) A second opinion consultation is required during surgical treatment of melanoma;
- (2) Further tissue processing is required to assess features of an aggressive, deep or histologically unusual tumor;
- (3) Paraffin section evaluation is used to confirm a diagnosis other than what was found on a prior pathology report, upon which Mohs surgery was done;
- (4) Further tissue analysis is necessary to complete the staging of a tumor so that the need for additional therapy, such as radiation or chemotherapy, can be determined;
- (5) Unusual findings during frozen section evaluation, or during other portions of the Mohs case, lead the physician to conclude that a second pathologic opinion is necessary.
- (6) Despite proper processing technique, frozen section interpretation is not sufficient to assess the tissue margin with a high degree of reliability.
- (7) A biopsy specimen of tumor not previously biopsied is obtained and assessed by frozen section immediately before commencement of Mohs; the pathologic diagnosis is then confirmed by paraffin section.
- (8) Special stains are required that are not done on frozen sections but are on paraffin sections.

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Each of these situations is discussed in Appendix 1.

Criteria for Mohs Surgery are Not Met

In certain circumstances, sending paraffin sections for pathologic evaluation is not compatible with Mohs surgery. In general, this occurs when one or more of the tasks that must be performed by the operating surgeon are delegated to another physician.

- (1) When all excised specimens during the course of Mohs are sent to a pathologist for initial interpretation by either frozen sections or paraffin sections, then Mohs is no longer being performed. Instead, the physician removing the tissue should characterize that process as an excision and document it as such.
- (2) When a separate physician, such as a pathologist, reads the slides made from tissue removed by the Mohs surgeon during a particular stage of Mohs surgery, and the Mohs surgeon does not first interpret frozen sections, this will constitute “delegation of responsibility” and as such, makes it incompatible with Mohs surgery. This differs from the permissible case where, during a particular stage of Mohs surgery, the physician obtains and processes all the tissue, and reads all of the slides for margin assessment, but then obtains additional second opinion pathologic consultation on a portion of these slides.
- (3) Routine primary interpretation by another physician (e.g. a pathologist) of histopathologic features of a tumor being treated with Mohs is not compatible with Mohs surgery. In general, pathologic consultation should occur in a rare number of cases.

For additional information on meeting the criteria for Mohs, see Appendix 2.

Conclusions

In most cases when Mohs surgery is performed, no tissue specimen is sent for paraffin sectioning and pathologic assessment. However, infrequently, it is appropriate (before, during or after) to send tissue for paraffin sections and second opinion pathologic assessment.

Importantly, the key elements of the Mohs procedure, including excision and primary evaluation of the frozen section slides, must be done entirely by the Mohs surgeon, who must act as both surgeon and pathologist. None of these functions may be delegated to another physician, such as a pathologist or a physician extender. It is considered good medical care that before, during, or after Mohs surgery, paraffin sections from an area that is through the same operative wound, may be sent for evaluation as a second opinion consultation to a pathologist without affecting the integrity of the Mohs procedure.

It is important that any practice expend appropriate efforts to understand and use proper CPT coding for the services it provides and that its coding is verified by an authoritative entity such as the local Medicare carrier or relevant private payer.

APPENDICES
Appendix 1

Second Opinion Consultation is Required during Treatment of Melanoma

When melanoma is treated by Mohs, a second opinion consultation is required in a higher percentage of cases. This reflects the requisite high standard of care for melanoma treatment given the higher associated risks. Commonly, the central melanoma area may be sent for paraffin serial sections to assess the depth of invasion, or a slide(s) on a given stage may be sent for pathologic consultation. Additionally, when Mohs surgery is used as a treatment for melanoma in situ, Kinonen & Reddy (2010; citing Dawn, Dawn & Miller 2007) recommend: "A final margin can then be taken from around the tumor and sent for paraffin sections to confirm the initial frozen section margin assessment."¹

Further Tissue Processing is Required

In complex Mohs cases, tumors may be unusually aggressive, deep, or otherwise histologically unusual. In these cases, paraffin section processing and pathologic analysis may be required for evaluation of these tumors' unusual histologic features:

- * Unusually aggressive tumors would include poorly differentiated tumors.
- * Deep tumors include tumors penetrating into bone and requiring processing of the same, which cannot be done with frozen sections.
- * Special stains with paraffin sections may be required for confirmation of clear margins for rare and uncommon nonmelanoma tumors that are treated with Mohs surgery, such as Merkel cell carcinoma (CK-20), or dermatofibrosarcoma protuberans (CD-34).
- * Histologically unusual tumors may also include those with a diffuse inflammatory infiltrate that makes interpretation of frozen sections unreliable.
- * Interdisciplinary management may be needed to improve cure rate for certain tumors with a potentially high metastatic rate or high likelihood of local recurrence. For instance, for dermatofibrosarcoma protuberans, an algorithm has been reported that combines Mohs and paraffin section evaluation (Kimmel Z, Ratner D, Kim JY, Wayne JD, Rademaker AW, Alam M. Peripheral excision margins for dermatofibrosarcoma protuberans: a meta-analysis of spatial data. *Ann Surg Oncol*. 2007 Jul; 14(7): 2113-20).

1 Dawn ME, Dawn AG, Miller SJ (2007). Mohs surgery for the treatment of melanoma in situ: a review. *Dermatol Surg*. 2007; 33:395-402. Cited in Kinonen & Reddy 2010.

Kinonen C, Reddy VB (2010). The Skin. In J Taxy, A Husain, & A Montag (Eds.) *Biopsy Interpretation: The Frozen Section*. (p. 270-302) New York: Wolters Kluwer.

Confirmation of New Diagnosis is Required

Prior to the initiation of Mohs surgery, a biopsy specimen is obtained to establish diagnosis.

- * The original biopsy specimen may not be representative of the entire tumor. Thus, when removing a tumor, a more representative section may occur for which second opinion consultation is required. Obtaining such a consultation does not negate the Mohs procedure.
- * Collision lesions can also occur. In a typical collision lesion, two unrelated tumors may be physically proximal or even overlapping. The prior biopsy specimen leading to initiation of Mohs may have diagnosed one of these tumors, but not detected the adjacent tumor. For instance, a basal cell carcinoma undergoing Mohs may be proximal to an amelanotic nodular melanoma, which may require different treatment. When suspecting a collision lesion, paraffin sections should be sent for pathologic examination.

Staging or Grading is Required

Very aggressive tumors may require additional therapy. On occasion, this may become apparent during Mohs surgery, when extensive tumor invasion is detected for the first time. For instance, during Mohs surgery, it may become apparent that perineural, vascular, or lymphatic invasion is present. Such invasion may in turn suggest the need for additional radiation therapy, lymph node biopsy or dissection, or enrollment in a chemotherapy protocol. For the Mohs procedure to be valid, the physician must remove the tumor tissue and examine it pathologically by frozen section to confirm margin negativity. Additional confirmation of staging or grading may be appropriately obtained by a dermatopathology consultation or by paraffin sections sent for pathologic examination without invalidating the Mohs procedure.

A Second Opinion is Required

The decision to send paraffin sections for pathologic examination should be guided by:

- ✓ the acceptable standard of care;
- ✓ good medical practice;
- ✓ the need to avoid patient harm; and
- ✓ the need to ensure patient benefit.

In addition to the above itemized situations, special circumstances may arise when it is necessary and in the patient's best interest to send a paraffin section out for evaluation.

The use of consultations and second opinions are longstanding patient safety measures employed by all medical specialties. No policy, procedure or coverage determination should be in place that jeopardizes patient safety by limiting the use of a second opinion or consultation services.

When Frozen Section Interpretation is Not Sufficient

It is generally accepted that frozen sections are, in some instances, of lesser quality than paraffin sections. In 1991, the College of American Pathologists' Q-study probe found that for frozen sections, there existed a 4.2% deferral of diagnosis rate and discordance with paraffin section diagnosis of 1.7%

(Novis, Gebhardt & Zarbo 1996, as cited in Montag 2010).² This “deferral” refers to instances in which frozen sections are of insufficient quality for diagnosis, and in which tissue is sent for paraffin section and pathologic analysis. In these instances, it is undeniably the standard of care to obtain pathologic consultation. If, despite proper processing, frozen sections cannot be interpreted, recuts and restaining, or other adjustments in the frozen section laboratory, may be sufficient to remedy this problem. If such further frozen section processing is impractical or insufficient, paraffin sections may appropriately be sent for second opinion consultation.

Appendix 2

Meeting Criteria for Mohs Surgery

According to the 2011 CPT Coding Definitions under Mohs Micrographic Surgery, the following description is given:

“Mohs Micrographic Surgery...requires a single physician to act in two integrated but separate and distinct capacities: surgeon and pathologist. If either of these *responsibilities is delegated* to another physician who reports the services separately, these codes should not be reported” [emphasis added].³

As per communication from members of the committee of the American College of Mohs Surgery that drafted the above CPT description of Mohs Surgery around 1982 when the codes were changed from 17300-17302 to 17304-17310 (Richard Bennett, personal communication, 2011), the definition was never meant to exclude paraffin section pathologic examination under circumstances of difficulty in interpretation of frozen sections.

Rather, it was meant to exclude a pathologist from collaborating with a surgeon to perform Mohs surgery. A pathology consultation with a paraffin section for a small percentage of the slides examined by the Mohs surgeon should not be viewed in the same light.

The integrity of the Mohs surgery is not affected so long as all aspects inherent to Mohs surgery are performed under the supervision of the Mohs surgeon as the surgeon and pathologist: tumor resection, slide creation, slide interpretation, issue of a written report and medical decision making based upon the results of the interpretation. The use of a pathology consultation in conjunction with Mohs surgery supplements the work of Mohs surgery; it does not replace the work of Mohs surgery.

2 Novis DA, Gebhardt GN, Zarbo RJ (1996). College of American Pathologists, Interinstitutional comparisons of frozen section consultation in small hospitals: a College of American Pathologists Q probes study of 18,532 frozen section consultation diagnoses in 233 small hospitals. *Arch Pathol Lab Med.* 1996; 120(12): 1087-1093. Cited in Montag 2010.

Montag AG. (2010) The Frozen Section: Historical Background and Quality Assurance. In J Taxy, A Husain, & A Montag (Eds.) *Biopsy Interpretation: The Frozen Section*. (p. 1-11) New York: Wolters Kluwer.

³ *Current Procedural Terminology: Standard Edition* (2011), 4th Ed. Chicago: American Medical Association. p. 58.

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The operational rule is that a pathologist should neither prepare nor read the frozen section slides at the time of Mohs surgery. This definition does not preclude a pathologist from reading a paraffin section slide at some later point as part of a second opinion consultation; there would be no 'delegation of responsibility' in this instance.

This Position Statement is provided for educational and informational purposes only. It is intended to offer physicians guiding principles and policies regarding the practice of dermatology. This Position Statement is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual practice arrangements.