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CLINICAL ARTICLE

Association between meningioma consistency and surgical outcomes

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OBJECTIVE Tumor consistency, or fibrosity, affects the ability to optimally resect meningiomas, especially with recent trends evolving toward minimally invasive approaches. The authors' team previously validated a practical 5-point scale for intraoperative grading of meningioma consistency. The impact of meningioma consistency on surgical management and outcomes, however, has yet to be explored. This study aimed to determine associations between meningioma consistency and presenting symptoms, tumor characteristics, and postoperative outcomes.

METHODS A total of 209 surgically resected meningiomas were intraoperatively assigned a consistency grade according to a previously validated 5-point scale, ranging from extremely soft, suctionable tumors (grade 1) to firm/calcified tumors (grade 5). Presenting symptoms, tumor characteristics, postoperative complications, and surgical outcomes for these patients were prospectively collected. Tumor consistency was analyzed in three categories (grades 1 and 2, grade 3, and grades 4 and 5), using ANOVA, chi-square or Fisher's exact tests, and univariable logistic regression to evaluate associations between consistency and perioperative characteristics.

RESULTS The study cohort included 209 patients, of whom 48 (23%) were males with a mean age of 55.0 ± 13.7 years. Meningioma consistency distribution was as follows: grades 1 and 2 (n = 23, 11.0%), grade 3 (n = 88, 42.1%), and grades 4 and 5 (n = 98, 46.9%). The majority of meningiomas were skull base tumors (n = 144, 68.9%). Higher-consistency tumors were associated with lower rates of gross-total resection (OR 0.24, 95% CI 0.13–0.46; $p < 0.001$), increased invasiveness (OR 4.73, 95% CI 1.53–14.60; $p = 0.007$), tumor recurrence following resection (OR 3.30, 95% CI 1.25–8.66; $p = 0.016$), reoperation (OR 3.08, 95% CI 1.16–8.14; $p = 0.024$), and increased complication rates (OR 2.08, 95% CI 1.05–4.15; $p = 0.037$). No significant associations were identified with preoperative symptoms, tumor size (mean 4.04 ± 1.50 cm), or duration of surgery (mean 4.26 ± 1.60 hours) (all $p > 0.05$).

CONCLUSIONS Tumor consistency is associated with important meningioma characteristics and perioperative outcomes. A prior knowledge pertaining to meningioma consistency and tumor characteristics using advanced imaging is a priority and may provide surgeons with meaningful data to guide resection strategy and anticipate postoperative outcomes and complications.

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KEYWORDS meningioma; neurosurgery; consistency; outcomes; tumor; skull base

Meningiomas are the most common primary intracranial neoplasms in adults,[1] and they present a unique challenge in neurosurgical practice due to the various locations where they may arise. Originating from arachnoid cap cells,[2] these tumors can occur in anatomically complex regions along the skull base, where tumor growth can encompass important arterial supply to the brain and compress cranial nerves, leading to neurological deficits and subsequent morbidity. Technological breakthroughs, particularly in endoscopy, have improved visualization during resection of these lesions.[3] This increasing shift toward minimally invasive techniques, including tailored keyhole craniotomies and endoscopic endonasal approaches, strives to achieve definitive surgical treatment of complex lesions with improved postoperative recovery.[4–8] The success of these advanced surgical approaches depends on both a detailed knowledge of the relevant anatomy and the intrinsic properties of the tumor.[9–11]

Intrinsic properties of meningiomas play an important role in the prognostic assessment of these tumors. Among

ABBREVIATIONS EOR = extent of resection; GTR = gross-total resection; STR = subtotal resection.

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TABLE 1. Meningioma consistency grading system

Consistency Score	General Description	Capsule Characteristics	Exemplary Instrument(s) Used for Debulking
1	Extremely soft tumor	Easily folded or no capsule	Suction
2	Soft tumor; bulk of tumor freely suctioned; fibrous stroma remains	Easily folded following partial internal debulking	Majority done w/ suction; fibrous stroma resected w/ capsule
3	Average consistency; cannot be freely suctioned; requires some degree of mechanical debulking	Folds following sufficient debulking	Piecemeal resection; ultrasonic aspiration or other mechanical debulking device, often at low setting; sharp dissection
4	Firm tumor; requires mechanical debulking	Firm capsule; difficult to collapse despite tumor debulking	Piecemeal resection, ultrasonic aspiration, loop cautery, or other mechanical debulking, often at high setting; sharp resection or loop cautery
5	Extremely firm &/or calcified tumor; may approach density of bone; often requires en bloc resection	Rigid capsule that does not fold or collapse	Difficult to debulk even w/ ultrasonic aspiration, cautery loop, or mechanical/sharp dissection

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these, the physical consistency (also referred to as fibrosity or texture) of meningiomas is a critical factor that can influence both surgical approach selection and extent of resection (EOR).[12,13] Our team previously developed a comprehensive 5-point grading scale for assessing the intraoperative consistency of meningiomas, focusing on the surgeon's ability to manipulate and reduce the tumor mass burden.[12–14] This grading system demonstrated high reliability among users, establishing a foundation for its practical application.[13]

Application of this grading system to surgical outcomes has not yet been undertaken. Given the potential effect of tumor consistency on postoperative outcomes, we aimed to analyze the association between meningioma consistency and important clinical and neuroimaging outcome measures using a previously validated grading scale.

Methods

Data Collection

A database of 209 patients who underwent resection of meningiomas between January 2012 and July 2023 by the senior author (G.Z.) was prospectively collected. Tumor consistency was assigned intraoperatively, and additional data were retrospectively reviewed from the electronic medical record. This study included both index surgeries and reoperations for subsequent tumor progression or recurrence when indicated. Reoperation was defined as any patient who underwent a repeat surgery at our institution by the senior author, including patients whose index operation occurred at an outside hospital. Patients were not included if they received radiation therapy prior to surgery. Institutional review board approval was obtained in accordance with our institution's standards.

Patient demographic information was collected. Presenting symptoms were recorded, including headache, vision loss, and weakness of extremities. Tumor size and location were determined from preoperative MR images. Histopathology characteristics including Ki-67 index, presence of necrosis, and pathological invasion were reviewed from electronic pathology reports. Postoperative complications including intracranial hematoma, weakness, visual loss, CSF leakage, vascular incidents (e.g., venous infarction and stroke), infection, and retractor edema were also collected. EOR and tumor recurrence/progression were determined based on postoperative contrast-enhanced T1-weighted MR images interpreted by an independent neuroradiologist. Progression was defined as tumor growth following subtotal resection (STR), and recurrence was defined as tumor reappearance after gross-total resection (GTR). Progression-free survival was measured from the date of surgery. For patients who had tumor progression, survival was the time between the date of surgery and the date of progression. Patients not known to have tumor progression were censored for survival as of the last date of follow-up. GTR was defined as no remaining or residual enhancing portion of meningioma previously seen on preoperative imaging. Tumor invasion was radiographically determined using preoperative MRI with the assistance of a neuroradiologist. Meningiomas were considered invasive if the tumor eroded into the bone, invaded the brain parenchyma, or encapsulated adjacent vessels or nerves, similar to prior radiological studies on the subject.[15]

Consistency Grade Assignment

Tumor consistency was measured intraoperatively by the operating surgeon using our previously validated 5-point scale for consistency grading (Table 1).[13] This 5-point scale is arranged such that grade 1 meningiomas are soft and easily removed using suction alone, whereas grade 5 meningiomas are fibrous and/or calcified with a capsule that does not easily fold.

Statistical Analysis

For statistical purposes, tumor consistency grades were categorized into three groups (grades 1 and 2, grade 3, and grades 4 and 5). Categorical data were compared using Fisher's exact or chi-square tests. Continuous data were compared using ANOVA or t-tests. A univariable logistic regression analysis was used to determine associations between meningioma consistency and other tumor characteristics, postoperative complications, and surgical outcomes. Statistical analysis was performed using RStudio

TABLE 2. Demographics and presenting symptoms by consistency grade

	Consistency Grade				
	1 or 2	3	4 or 5	Total	p Value
Demographics					
No. of patients	23 (11.0)	88 (42.1)	98 (46.9)	209	
Male sex	4 (17.4)	20 (22.7)	24 (24.5)	48	0.765
Age, yrs	52.1 ± 16.4	56.2 ± 12.8	54.5 ± 13.9	55.0 ± 13.7	0.420
Presenting signs & symptoms					
Weakness	5 (21.7)	12 (13.6)	9 (9.2)	26	0.235
Visual loss	8 (34.8)	27 (30.7)	32 (32.7)	67	0.918
Headache	7 (30.4)	30 (34.1)	22 (22.4)	59	0.206

Values are given as number of patients (%) or mean ± SD unless otherwise indicated.

version 2022.12.0+353 (Posit). For all tests, a p value < 0.05 was considered statistically significant. Progression-free survival was analyzed using a log-rank test and plotted using the Kaplan-Meier method.

Results

Patient Demographics and Presenting Symptoms

Of the 209 patients with meningiomas who were included in the study, 23 (11.0%) patients had tumors with a consistency grade of 1 or 2, 88 (42.1%) patients had tumors with a consistency grade of 3, and 98 (46.9%) patients had tumors with a consistency grade of 4 or 5 (Table 2). Forty-eight (23.0%) patients were male, and the mean age at the time of surgery was 55.0 years. No significant differences in consistency were noted according to sex (p = 0.765) or age (p = 0.420). Preoperatively, 67 (32.1%) patients presented with vision loss, 59 (28.2%) patients presented with headache, and 26 (12.4%) patients presented with weakness. No association was observed between meningioma consistency grade and preoperative weakness (p = 0.235), visual loss (p = 0.918), or headache symptoms (p = 0.206).

Tumor Characteristics and Surgical Metrics

The mean tumor diameter for the cohort was 4.04 ± 1.5 cm, and it was not significantly associated with consistency (p = 0.116) (Table 3). No association was found between the Ki-67 labeling index (p = 0.100) or the presence of necrosis on histopathology (p = 0.257) with respect to meningioma consistency. Pathological invasion, however, was more common in consistency grade 4 and 5 tumors (p = 0.013). No significant association was observed between WHO grade and meningioma consistency (p = 0.492).

Of all the tumors, 144 (68.9%) were skull base meningiomas, 59 (28.2%) were convexity/parafalcine meningiomas, and 6 (2.9%) were intraventricular meningiomas (Table 3). Tumor location was not significantly associated with consistency (p = 0.347). The mean duration of surgery was 4.26 ± 1.6 hours, and it did not vary significantly in association with tumor consistency (p = 0.639); however, there was a trend toward higher-consistency tumors requiring longer operative times as follows: grades 1 and 2 (mean 4.03 ± 1.4 hours), grade 3 (mean 4.22 ± 1.5 hours), and grades 4 and 5 (mean 4.36 ± 1.8 hours).

Regression Analysis for Complications and Outcomes

GTR was achieved in 131 (62.7%) tumors, whereas 78 (37.3%) underwent STR. In the univariable regression analysis, relative to meningiomas with a consistency grade of 3, tumors in the grade 4 and 5 group were significantly less likely to undergo GTR (OR 0.24, 95% CI 0.13–0.46; p < 0.001). No association between GTR and tumors in the grade 1 and 2 consistency group was observed (OR 0.63, 95% CI 0.23–1.75; p = 0.375). Twenty-three (11.0%) meningiomas demonstrated radiographic invasion into surrounding tissues. Relative to tumors with a consistency grade of 3, tumors in the grade 4 and 5 consistency group were more likely to be invasive into adjacent structures, including brain or bone (OR 4.73, 95% CI 1.53–14.60; p = 0.007). No significant difference in invasion was observed between grade 3 tumors and the grade 1 and 2 group (OR 0.96, 95% CI 0.10–9.00; p = 0.968).

In total, 50 (23.9%) patients experienced at least one postoperative complication, with a higher likelihood of any complication occurring in patients with grade 4 and 5 tumors (OR 2.08, 95% CI 1.05–4.15; p = 0.037) (Table 4). No difference in complication rate was noted in patients with grade 1 and 2 tumors (OR 0.68, 95% CI 0.18–2.55; p = 0.562). Complication profiles based on tumor consistency are shown in Table 5.

Twenty-eight (13.4%) patients in this cohort underwent reoperation for the same tumor. Of these, 23 (82.1%) patients had initial surgery at an outside hospital and 5 (17.9%) had the index operation at our institution. Patients with consistency grades 4 and 5 were more likely to undergo reoperation (OR 3.08, 95% CI 1.16–8.14; p = 0.024). No difference in reoperation rate was observed between grade 1 and 2 tumors and grade 3 tumors (OR 2.88, 95% CI 0.74–11.20; p = 0.128). Thirty (14.4%) tumors recurred following GTR (n = 17) or progressed following STR (n = 13), and relative to grade 3 meningiomas, both grade 1 and 2 (OR 3.73, 95% CI 1.04–13.80; p = 0.043) and grade 4 and 5 (OR 3.30, 95% CI 1.25–8.66; p = 0.016) groups were more likely to experience recurrence/progression. Of these 30 tumors, only 5 (16.7%) underwent reoperation due to clinically significant recurrence/progression that warranted surgery. The remaining 25 (83.3%) were managed without surgery. Additionally, in a progression-free survival analysis, consistency grade 1 and 2 meningiomas (p

TABLE 3. Tumor characteristics, location, and duration of surgery by consistency grade

	Consistency Grade				
	1 or 2	3	4 or 5	Total	p Value
Tumor characteristics					
Diameter, cm	3.57 ± 1.1	3.95 ± 1.5	4.23 ± 1.5	4.04 ± 1.5	0.116
Pathology					
Ki-67 index, %	5.26 ± 4.01	4.50 ± 4.58	6.46 ± 6.1	5.50 ± 5.41	0.100
Invasion	2/22 (9.1)	6/88 (6.8)	21/98 (21.4)	29/208	0.013
Presence of necrosis	2/22 (9.1)	14/88 (15.9)	22/98 (22.4)	38/208	0.257
WHO grade					0.492
1	12 (52.2)	54 (61.4)	55 (56.1)	121	
2	10 (43.5)	34 (38.6)	41 (41.8)	85	
3	1 (4.3)	0	2 (2.0)	3	
Location					0.347
Convexity/parafalcine	10 (43.5)	23 (26.1)	26 (26.5)	59	
Convexity	7	16	17		
Parafalcine	3	7	9		
Skull base	13 (56.5)	63 (71.6)	68 (69.4)	144	
Sphenoid wing	1	11	16		
Olfactory groove	0	5	9		
Tentorial	1	9	13		
Tuberculum sellae	4	19	12		
Cerebellopontine angle	1	1	0		
Clinoidal	3	3	6		
Middle fossa	0	2	1		
Petroclival	3	9	8		
Planum sphenoidale	0	4	3		
Intraventricular	0	2 (2.27)	4 (4.1)	6	
Atrium of lat ventricle	0	2	4		
Surgery duration, hrs	4.03 ± 1.4	4.22 ± 1.5	4.36 ± 1.8	4.26 ± 1.6	0.639

Values are given as number of tumors (%) or mean ± SD unless otherwise indicated.

= 0.033) and consistency grade 4 and 5 meningiomas (p = 0.002) recurred more quickly after surgery compared with consistency grade 3 tumors (Fig. 1). The median progression-free survival for the cohort was 17.2 months (consistency grades 1 and 2: 33.8 months; consistency grade 3: 36.2 months; consistency grades 4 and 5: 9.12 months).

Discussion

Consistency, or texture, of meningiomas is an important tumor characteristic that affects surgical outcomes. Firmer or higher-consistency tumors, in particular, are often more challenging to resect, requiring mechanical debulking rather than suction alone for tumor removal.[16] Careful dissection of surrounding structures can also be more challenging in cases involving firm, calcified tumors, with a higher risk of intra- or postoperative complications. The current literature has not explored this subject in depth for patients with meningiomas; however, studies examining the effects of consistency on surgical outcomes for oth-

TABLE 4. Univariable logistic regression examining the association between meningioma consistency and postoperative outcomes

	Grades 1 & 2				No. of Grade 3 Patients (ref) (%)	Grades 4 & 5			
	No. of Patients (%)	OR	95% CI	p Value		No. of Patients (%)	OR	95% CI	p Value
GTR	16 (69.6)	0.63	0.23–1.75	0.375	69 (78.4)	46 (46.9)	0.24	0.13–0.46	**<0.001**
Invasion (radiographic)	1 (4.3)	0.96	0.10–9.00	0.968	4 (4.5)	18 (18.4)	4.73	1.53–14.60	**0.007**
Any complication	3 (13.0)	0.68	0.18–2.55	0.562	16 (18.2)	31 (31.6)	2.08	1.05–4.15	**0.037**
Recurrence	5 (21.7)	3.73	1.04–13.80	**0.043**	6 (6.8)	19 (19.4)	3.30	1.25–8.66	**0.016**
Reop	4 (17.4)	2.88	0.74–11.20	0.128	6 (6.8)	18 (18.4)	3.08	1.16–8.14	**0.024**

Boldface type indicates statistical significance.

TABLE 5. Complications by consistency grade

Complication	Consistency Grade			
	1 or 2	3	4 or 5	Total
Any complication	3 (13.0)	16 (18.2)	31 (31.6)	50
Cranial nerve palsy	2 (8.7)	4 (4.5)	6 (6.1)	12
Weakness	0	1 (1.1)	9 (9.2)	10
Vision loss	0	3 (3.4)	5 (5.1)	8
Stroke	1 (4.3)	3 (3.4)	3 (3.1)	7
CSF leak	0	3 (3.4)	3 (3.1)	6
SMA syndrome	1 (4.3)	1 (1.1)	1 (1.0)	3
Seizures	0	1 (1.1)	2 (2.0)	3
Arterial injury	0	0	2 (1.0)	2
Surgical site infection	0	0	1 (1.0)	1
Postop hematoma	0	0	1 (1.0)	1

SMA = supplementary motor area.
Values are given as number of patients (%).

er tumor types describe important outcome associations linked to tumor consistency.[17,18] Our study demonstrates significant associations between firm tumor consistency and EOR, tumor invasiveness, tumor recurrence, reoperation rate, and complication rate in patients undergoing resection of meningiomas. In the future, a prior knowledge of meningioma consistency using advanced neuroimaging may be utilized to tailor surgical approaches in an effort to minimize complications and maximize exposure and dissection utilizing meningioma consistency as one of several guiding features for surgical planning.

Our results also demonstrate that meningioma consistency is significantly associated with EOR, recurrence, and reoperation rate. GTR was less likely for firmer tumors, which likely reflects technical difficulties in manipulating or debulking tumor tissue. Lower rates of GTR may also be understood within the context of increased invasion, both radiographic and pathological, leading to tumor involvement of adjacent dural venous sinuses, cranial nerves, arteries, and brain parenchyma. Tumor resection was frequently limited in these areas to avoid injury to these structures. Firmer tumors were also significantly associated with increased tumor recurrence and reoperation rates following initial resection. Tumors with consistency grades 1 and 2 and grades 4 and 5 recurred more frequently and with shorter progression-free survival compared with grade 3 medium-consistency tumors.

Both the index surgery and reoperation were included for 5 (2.39%) patients in this analysis. Two (40.0%) patients demonstrated a decrease in tumor consistency in the second operation, from grade 4 to grade 3 (n = 1) and from grade 4 to grade 2 (n = 1). Two (40.0%) patients demonstrated the same consistency (grade 4) in both operations. One (20.0%) patient experienced an increase in tumor consistency, from grade 3 to grade 4. At this time, it is unclear which factors affect the tumor consistency of recurrent meningiomas, although future studies should explore the role of multiple surgeries, tumor genetics, and perioperative radiation therapy in this context.

Our results demonstrate that firmer meningiomas are also more likely to be invasive. Although this relationship has not been specifically explored in meningiomas, past literature has shown that from a mechanical perspective, constant generation of force by a stiffer tumor onto surrounding healthy tissue may promote tumor invasion into adjacent structures.[19] One potential mechanism underlying consistency change may be derangements in transforming growth factor–beta (TGF-β) signaling within tumor cells. While not specific to meningiomas, some existing litera-

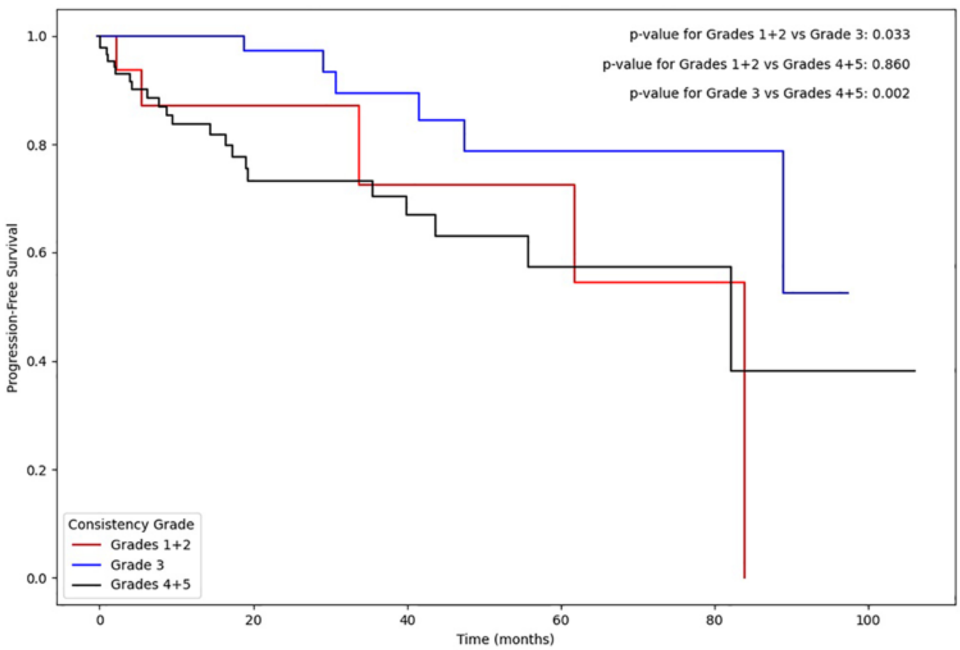

FIG. 1. Progression-free survival analysis by consistency grade. Figure is available in color online only.

ture has suggested that TGF-β dysregulation may increase the production of matrix-modifying enzymes, which can increase stiffness of the matrix in tumors.[19] Within meningiomas, TGF-β typically serves as a tumor suppressor, inhibiting growth of leptomeningeal cells.[20] Some studies have supported the notion that loss of TGF-β–mediated growth inhibition in the meninges results in meningioma pathogenesis and invasion, and therefore could contribute to firmer consistency.[20] Our observation that consistency correlates with EOR is consistent with our prior work on meningiomas and corroborates the principle established by other studies that softer tumors can be more easily resected in total.[21–23] In this study, softer tumors (consistency grades 1 and 2) also demonstrated a higher recurrence rate when compared with meningiomas of medium (grade 3) consistency. Exact mechanisms to explain this phenomenon are unclear but may reflect the ill-defined margins present in softer tumors.[24] Existing consistency classification systems are primarily dichotomous in nature, often categorizing tumors as soft or hard.[14,25,26] This binary system fails to capture nuances in tumor texture that may be clinically significant. Moreover, these existing classification methods are frequently derived from retrospective analyses and lack rigorous validation in terms of statistical and clinical relevance.

An increased frequency of at least one postoperative complication was noted for firmer meningiomas, of which cranial nerve palsy, weakness, and vision loss were the most prevalent (Table 5). This complication profile is in accordance with the current literature on complication rates following resection of skull base and convexity meningiomas.[27,28] The increased overall complication rate for grade 4 and 5 meningiomas is likely due to the more aggressive mechanical debulking required for resection of these lesions, along with their greater tendency for invasion into adjacent neurovascular tissue.

Meningioma consistency was not associated with preoperative presenting symptoms including headache, vision loss, or weakness. Likewise, tumor size and WHO grade were not associated with consistency, similar to the findings in the original study that established our consistency grading scale.[13] Of note, the meningiomas described in this study were largely located in the skull base (144/209, 68.9%), which is not representative of the general population.[4,29] Skull base meningiomas are more likely to be associated with critical neurovascular structures, which may result in an overall increased complication rate.[28] However, no significant difference was found with regard to tumors of a specific consistency arising in any particular location (i.e., convexity/parafalcine, skull base, or intraventricular). Additionally, although duration of surgery was not associated with tumor consistency, we noted a trend in increasing operative time with increased consistency as follows: grades 1 and 2 (mean 4.03 ± 1.4 hours), grade 3 (mean 4.22 ± 1.5 hours), and grades 4 and 5 (mean 4.36 ± 1.8 hours). This trend supports the idea that firmer meningiomas can be more challenging to resect and potentially require longer time in the operating room, an important factor to consider when proposing surgical intervention for patients.

While tumor consistency is associated with surgical outcomes, application of this knowledge in the preoperative setting is limited. To date, meningioma consistency can only be graded reliably during surgery, meaning this information is typically unavailable to neurosurgeons in the clinic, limiting the ability to counsel patients prior to surgical intervention. Recent studies have suggested that imaging modalities such as conventional T2-weighted MRI may help in predicting meningioma consistency preoperatively.[14,30–33] Such information would be invaluable in preoperative planning and to guide patient expectations on surgical outcomes. Indeed, future imaging studies are necessary to establish how radiographic features can predict physical properties of tumors. Exploration of imaging characteristics, in conjunction with the associations established in this study, may help neurosurgeons guide patients and families regarding expected outcomes based on tumor consistency, EOR, tumor recurrence rate, and postoperative complications.

Limitations

This single-center study is limited in several ways, including its retrospective nature and limited sample size. For example, of the 209 patients with meningiomas studied here, only 23 (11.0%) patients had consistency grades of 1 or 2, limiting our statistical power. Multi-institutional endeavors could overcome this limitation and improve generalizability of the results, particularly with regard to the location of tumors. In addition, a larger sample size would permit multivariable analysis with better control for potential confounders.

Conclusions

This retrospective analysis of 209 patients undergoing resection of meningiomas demonstrates significant associations between meningioma consistency and key surgical outcome parameters. Patients with firmer meningiomas were more likely to have invasive tumors, experience lower rates of GTR, and develop tumor recurrence requiring reoperation.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Shah, Chung, Cote, Briggs, Zada. Acquisition of data: all authors. Analysis and interpretation of data: Shah, Chung, Liu, Cote, Briggs, Gomez, Yang, Feng, Renn, Shiroishi, Hurth, Peterson. Drafting the article: Shah, Chung, Liu, Cote, Briggs, Guerra, Gomez, Yang, Feng, Renn, Shiroishi, Peterson. Critically revising the article: Shah, Chung, Liu, Cote, Briggs, Guerra, Gomez, Yang, Feng, Renn, Shiroishi, Peterson, Zada. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Shah. Statistical analysis: Shah, Chung, Cote. Administrative/technical/material support: Shah, Chung, Liu, Cote, Briggs, Gomez, Peterson. Study supervision: Shah, Briggs, Zada.

Supplemental Information

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