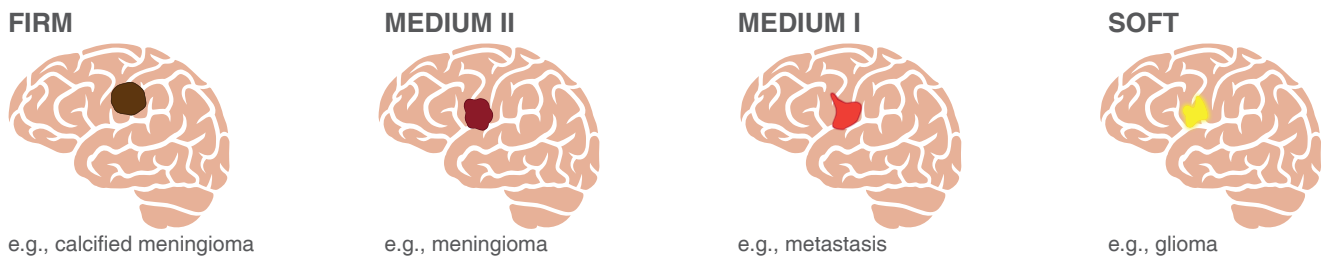


IN PRACTICE: Achieving optimal tissue effects in neuro surgery

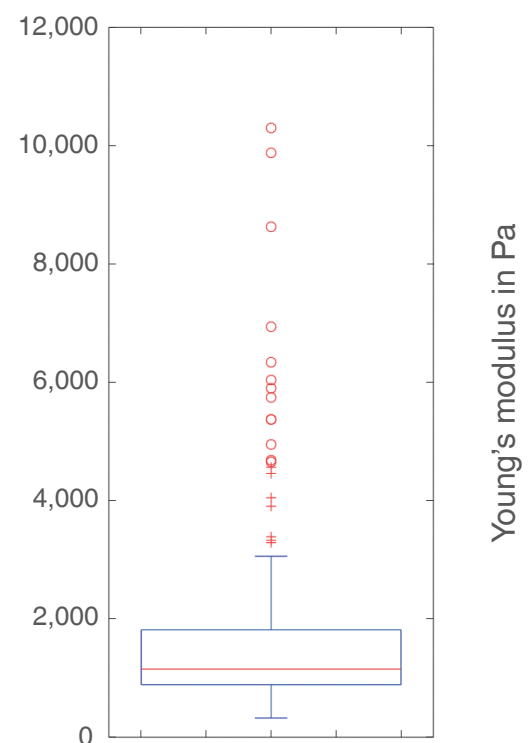
Description of tumour tissue: Young's modulus

Tumour resection using an ultrasonic aspirator aims to precisely and effectively remove all tumour tissue while sparing as much of surrounding healthy tissue as possible. A surgeon's choice of settings and consistency assessment are of utmost importance for tissue fragmentation. Tumour tissue can vary widely from viscous to calcified, with few quantitative data on mechanical tumour properties.



Söring therefore initiated together with the Department of Neurosurgery at the University Hospital Schleswig-Holstein (Lübeck campus) the "UltraLas" research project¹. A total of 232 human brain tumour samples were collected in 75 operations, the Young's modulus of the sample was measured intraoperatively and the tumour entity was then determined histologically.

The boxplot on the right confirms that the firmness of tumour tissue ranges widely. Most of the samples had a Young's modulus ranging from 300-3,000 Pa. Tumour tissue with this consistency is referred to as "soft" or "medium soft". Tumours with much firmer Young's moduli are also measured significantly less often. These tissue consistencies are described as "medium firm" to "firm" and require higher settings for efficient tissue fragmentation.



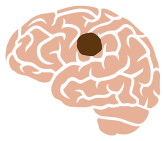
¹ Ref: ongoing prospective study, data on file

Boxplot¹ of Young's moduli measured in the 232 human tumour samples collected. The box includes the second and third quartiles of the recorded data. The red line indicates the median value, while the markers indicate the outliers.

Classification of brain tumour tissue

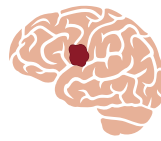
The data collected by Söring in cooperation with the Clinic for Neurosurgery, the Lübeck Medical Laser Center GmbH and the Institute of Biomedical Optics at the University of Lübeck enable descriptions such as "soft" and "hard" to be linked with quantitative values for Young's modulus for the first time.

There are four tissue classifications for ultrasonic fragmentation in neurosurgery:



FIRM

describes "firm"/"toughened" tissue with a Young's modulus greater than 6,000 Pa



MEDIUM II describes "medium firm" tissue with Young's modulus of up to 6,000 Pa



MEDIUM I describes "medium soft" tissue with a Young's modulus of up to 3,000 Pa

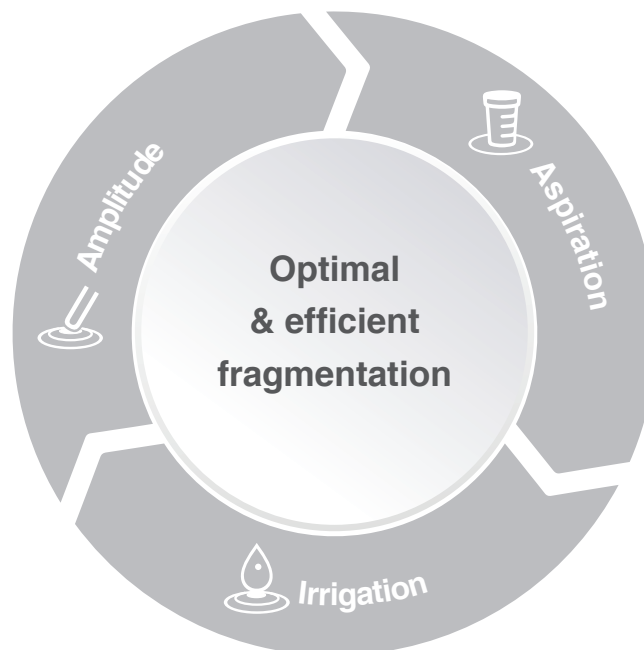


SOFT describes "soft" tissue with a Young's modulus of up to 1,200 Pa

Each tissue classification has specific mechanical tissue characteristics and consequently requires a specific range of setting combinations comprising amplitude (ultrasound setting), aspiration pressure and irrigation rate to achieve the desired extent of fragmentation. For tumours in the "soft" tissue classification, a range of low settings is sufficient to ensure

the desired tissue effect. Settings below this range are not sufficiently effective. Within the range, lower settings result in a slower fragmentation speed and higher settings result in faster fragmentation. Settings exceeding this range—with the same handling—no longer lead to a further increase in fragmentation speed.

Setting combinations for different tissue classifications



The correlation between amplitude, aspiration and irrigation

Each tissue class requires a specific minimum amplitude for fragmentation. High aspiration pressure alone does not result in the desired fragmentation if there is no sonotrode oscillation. Depending on the desired

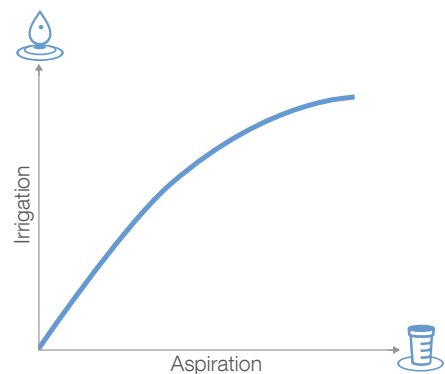
fragmentation speed, the ultrasound amplitude is selected based on the tissue and the aspiration pressure is adjusted accordingly. An appropriately selected aspiration pressure supports the fragmentation by the acting contact force and ensures the effective aspiration of secretions (tissue fragments, irrigation solution and blood). If the aspiration pressure is too high relative to the amplitude, the tissue can be aspirated or sucked in uncontrollably. Similarly, the irrigation rate must be adjusted to the selected amplitude. Only sufficiently high irrigation will lead to minimization of the thermal tissue load at a given amplitude.

Direct correlation between irrigation and aspiration

In order to achieve optimal tissue effects, the irrigation must be selected to ensure a sufficiently high fluid supply to the sonotrode. This results in cavitation, the sonotrode is cooled and the aspirated secretion is sufficiently diluted to minimise blockages. The function of irrigation directly correlates to the set aspiration pressure and is selected according to the following principle:

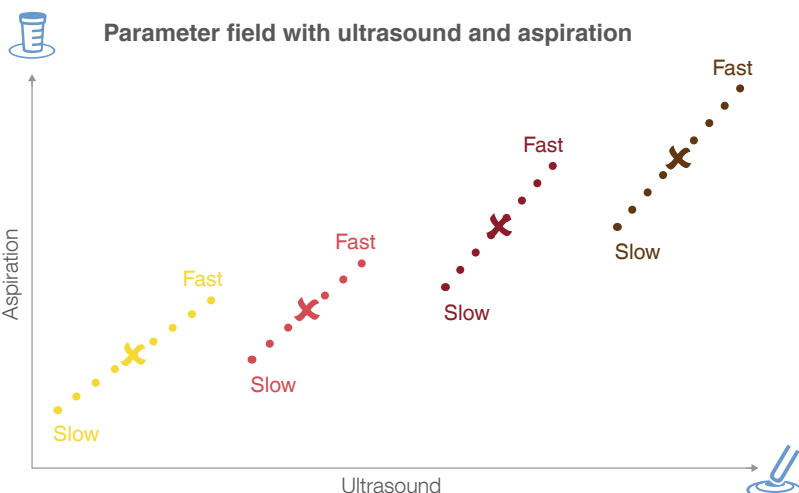
For a given aspiration pressure, the highest possible irrigation at which no mist occurs at the freely oscillating sonotrode tip should be selected.

Correlation between irrigation and aspiration



Optimal tissue effects can only be achieved by the combined and coordinated selection of the three settings.

With a slight variation in the three settings, the tissue effect can be further enhanced or reduced systematically—that is, the fragmentation speed (also known as removal rate) can be changed. For each tissue classification from “soft” to “firm”, there are setting ranges with variable fragmentation speed. The crosses show the setting combinations that lead to an average fragmentation speed. The table on the following page contains the exact setting values.



Tissue-dependant setting combinations for an average removal rate

	Aspiration 	Ultrasound 	Irrigation 
FIRM	0.54 bar	70%	9 ml/min
MEDIUM II	0.33 bar	50%	5 ml/min
MEDIUM I	0.21 bar	30%	4 ml/min
SOFT	0.15 bar	20%	3 ml/min

This recommendation does not replace the information given in the instructions for use. Please read the instructions for setting up the device and the safety instructions carefully. Setting combinations are for SONOCA 300 and LEVICS.

Expert opinions and practical experience

Dr. med. Lhagva Sanchin, BG Hospital Bergmannstrost Halle

Tumour consistency can vary greatly at different depths, particularly in large tumours (e.g., meningiomas), making it necessary to adjust the settings quickly. The settings for ultrasound intensity, aspiration pressure and irrigation rate should be calibrated to achieve the desired effect in the best possible way. My work has to be extremely precise, particularly in the vicinity of critical structures, so there must be no unwanted aspiration of tissue and nothing that can impair my view. I reduce all setting parameters when working near vessels and nerves: for example, for a tumour with medium consistency (Medium I consistency class), I reduce ultrasound intensity to 14%, aspiration pressure to 0.18 bar and irrigation rate to 4 ml/min.

