

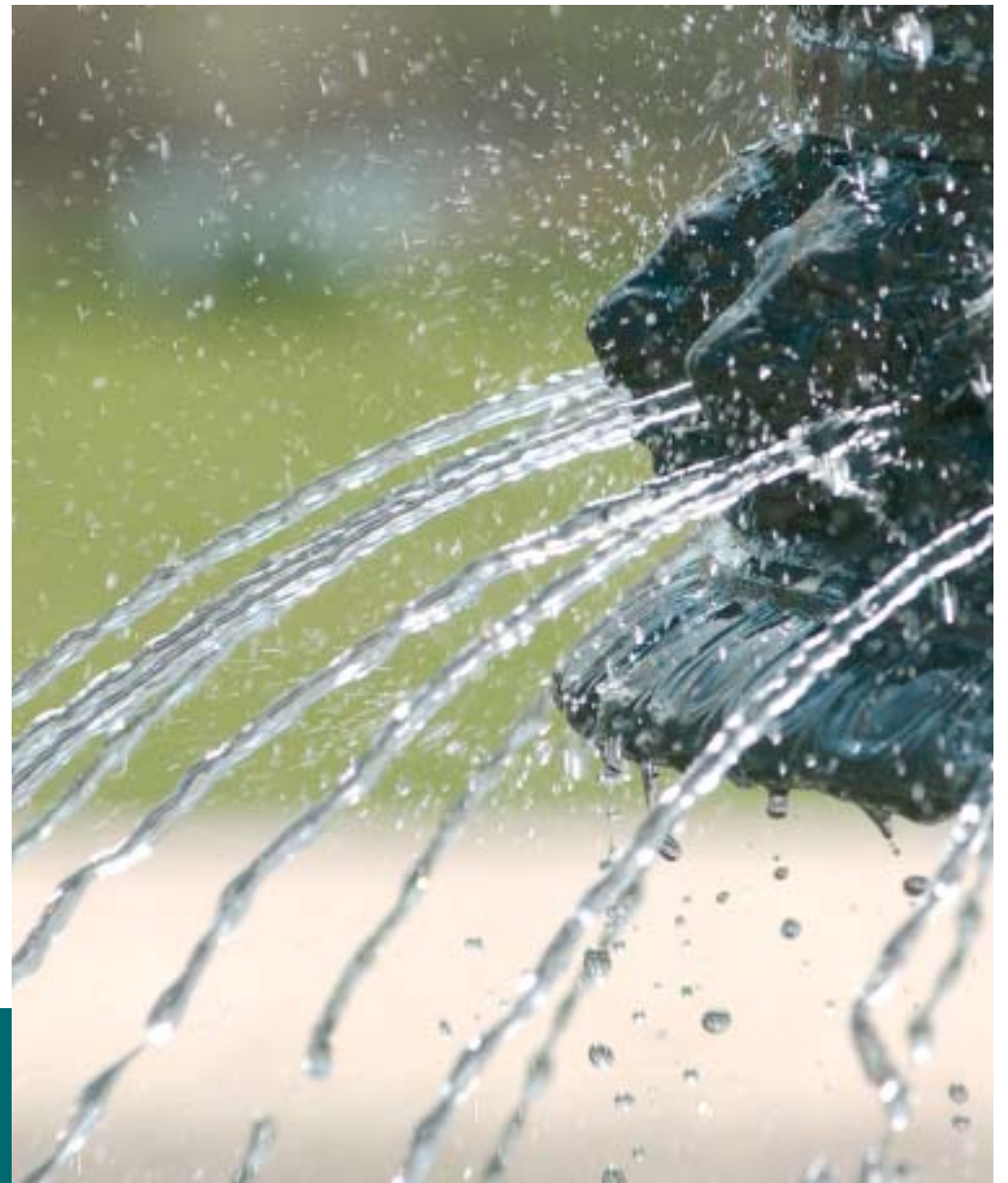
The Force of Water



Water is one of the central elements in our life. The flowing force and kinetic energy of water enables streams and rivers to carve their way through the hardest rock.

This is how the miracles of nature on our planet Earth have been created over thousands of years, like the Grand Canyon, for example. The coastlines of our oceans illustrate how much force, energy and strength can be found in this medium which often appears so gentle to us.

The use of water with the aid of pumps and valves makes it possible to give water shape and form, which has been expressed in art and architecture as well as in technology. By using this principle, it has been possible to successfully create a tool, which was first used in industry for cutting steel. The precise dosing and shaping of the water jet has also made it possible in medicine to use the effect of water for gently dissecting parenchymal organs.



The Force of Water – Fascination and inspiration for innovation and perfection

The transformation of Water

into a gentle precision tool of advanced medical technology

Human Med designed a unique technology to transform water into a laser-fine, pressurized rotating laminar jet which forces softer tissues to separate while blood vessels, nerves and fibrin-rich structures are preserved. The unsurpassed gentle water-jet surgery was invented in Germany 1988. In 2001, after 13 years of clinical experience, system approvals and registration work the first water-jet surgery device – the helix hydro-jet® – was launched by Human Med. After 400 systems sold, Human Med follows its mission to equip all major hospitals around the globe with water-jet technology, within 10 years from now!

A couple of years later the body-jet® was launched! A fundamental new method for liposuction, better described as liposculpting or body contouring. The body-jet® was designed for simultaneous water-jet infiltration, irrigation and aspiration of subcutaneous fatty tissues and eccrine glands, thus providing a safer and less traumatizing method of liposuction.

Because of increased patient safety and handling efficiency water-jet assisted liposuction with the body-jet will be the future standard in liposuction.

●●helix hydro-jet

●●body-jet

General Surgery helix hydro-jet®

For nearly all kinds open and laparoscopic surgery; removal of tumorous/cancerous tissues, metastases

- High tissue selectivity and sensitivity
- Minimum risk and less complications
- Minimum tissue trauma
- No thermal damage of tissues
- Preservation of vessels, ducts and nerves
- Significant reduction of blood loss
- Less blood transfusions
- Organ saving resection (e.g. in living donor liver programs and brain resections)
- Reduction of post-operative side effects (e.g. loss of continence and potency)
- Better recovery



- Visualization of vital structures – clear vision at the site of operation
- Safe and easy handling with special hand pieces and sterile application sets
- Shorter procedure time and hospital stay

Aesthetic and Plastic Surgery body-jet®

For safer liposuction, treatment of lipoedema, perspiratory gland removal

- Safe procedure in local anesthesia
- Better intra-operative assessment and better results due to much less intraoperative swelling
- 70% less tumescent solution required in pre-infiltration – less exposure to analgesics – less complications
- No waiting time after infiltration
- Reduced pain-related impairment due to continuous application of analgesics during irrigation and aspiration
- Reduced tissue trauma and hematoma
- Reduced procedure time per patient
- Better recovery



- Significant reduction of revision rate
- Better patient satisfaction levels
- Safe and easy handling with special hand pieces and sterile application sets

Dissecting with the high-pressure water-jet

"Cutting with a high-pressure water jet is a development which has been used primarily in industrial engineering. At the tip of the nozzle, the water jet reaches hypersonic speeds at up to 20 000 bar pressure, with which wooden and even steel panels can be cut very precisely, effortlessly and without any heat development. In order to use this technique in general surgery, the water jet and pressure parameters first of all had to be adapted to the structural characteristics of parenchymatous organs. Due to the mechanical and physical effect of the water jet on tissue, the more resistant duct structures are separated from the parenchyma and are thus made visible."



Prof. Rau in a programme about hepatic tumour excision with the helix hydro-jet, shown by ZDF on 08.02.2006

Munich stated: "The use of dissection techniques has transformed over the years. After preliminary experimental work, we were able to introduce the "water-jet-cutting" technique into clinical practice in 1990. After the first commercial devices became available in late 1995, there was a gradual increase in the frequency that the technique was used and nowadays it is our standard dissection method. Our choice of the helix hydro-jet is based on the data of 591 patients in a clinical comparison study, the results of which have been published continually.

The significant differences in dissections techniques (water-jet cutter/helix hydro-jet, ultrasound aspirator/CUSA and blunt dissection) involve loss of blood, the dissection time and/or Pringle time.

Loss of blood

The loss of blood per resection area was significantly lower when the water-jet cutter was used at 10.57 ± 15.35 ml/cm² than when the ultrasound aspirator was used (18.26 ± 30.13 ml/cm²) or when blunt dissection, which had the poorest result of 72.72 ± 497.26 ml/cm², was used. This is also reflected in the necessity for transfusion which was only half as high in the water-jet cutter group at 0.012 ± 0.06 ery-

throcyte concentrates (EC)/cm² as when the ultrasound aspirator (0.024 ± 0.054 EC/cm²) was used or with blunt dissection (0.095 ± 0.806 EC/cm²). These differences were significant in the Kruskal-Wallis test at $p=0.002$.

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Resection time

The water-jet cutter dissection technique has proven to be significantly faster in practice. This was also proved by determining the resection time in relation to the resection area. At 0.29 ± 0.67 min/cm², this technique is significantly faster than the ultrasound aspirator at 0.48 ± 0.85 min/cm² and blunt dissection at 0.77 ± 1.75 min/cm².

Pringle Time

Confirmation of this was also provided in the comparison of the Pringle time per resection area, which was less than half as much with the water-jet cutter at 0.13 ± 0.18 min/cm² compared to when the CUSA (0.29 ± 0.47 min/cm²) or blunt dissection (0.23 ± 0.56 min/cm²) were used.

Postoperative complications

As far as the postoperative complications are concerned, there were no differences regarding the amount of biliary fistula and subhepatic abscesses in the groups."

(from: H.G. Rau, A. Zimmermann, C. Wardemann, F.W. Schildberg: Standards of Surgical Techniques in Liver Metastases. Chirurgische Gastroenterologie 2003; 19:333-339)

Indications

Surgery

Liver resection | Split-liver resection (living donor) | TME (total mesorectal excision) | Laparoscopic cholecystectomy | Spleen resection

Urology

Partial nephrectomy | Open prostatectomy | Lymph-Node dissection

Orthopedic Surgery

Percutaneous discotomy | Arthroscopic synovectomy

ENT

Parotid surgery | Tongue surgery

Neurosurgery

Brain tumor resection | Epilepsy surgery

Water-jet dissection for hepatectomies – higher efficacy and safety with helix hydro-jet®!

In their new publication of October 2006, Vollmer, Dixon et al. are stating that "the thin laminar liquid-jet effect" of the helix hydro-jet "provides precise, controllable, tissue-selective dissection with excellent visualization and minimal trauma to surrounding fibrous structures".

The "results are equivalent to, or better than those from our contemporary series of resections performed with ultrasonic dissection."

"Patients and Methods: The efficacy of the Water-jet system for hepatic parenchymal dissection was examined in a consecutive case series of 101 hepatic resections (including 22 living donor transplantation resections) performed over 11 months. Perioperative outcomes, including blood loss, transfusion requirements, complications and length of stay were assessed.

Results: Three-quarters of the cases were major hepatectomies and 22% were cirrhotic. Malignancy was the most common indication (77%)...

The results (regarding blood loss, transfusion requirements, complications and length of stay) were equivalent to, or better than, those from our contemporary series of resections performed with the ultrasonic dissection.

Conclusion: This initial experience suggests that this precision tool is safe and effective for hepatic division, and compares favourably to other established methods for hepatic parenchymal transection."

C.M.Vollmer, E. Dixon, A. Sahajpal et al.: Water-jet dissection for parenchymal division during hepatectomy. HPB : Official Journal of The International Hepato Pancreato Biliary Association. Vol. 8, Number 5/October 2006, 377-385



helix hydro-jet is demonstrated on an orange in order to show the way in which it works

The helix hydro-jet makes use of a high-pressure liquid jet with pressures of between 10 and 150 bar and a jet diameter of 0.12 mm. A jet of this quality allows vascular and bile duct structures to be rinsed out of the parenchyma according to their degree of hardness.

Professor Rau, head of the Transplantation Programme at the University Teaching Hospital of

helix hydro-jet® is the Best Device for Hepatectomies in Living Donors

"We find that the Water-Jet-Dissector is the best instrument for hepatectomies in living donors because it causes only a minimal necrotic seam."

This is the result reached by W.C. Meyers et al., Drexel University College of Medicine, Philadelphia, USA, in their overview "Sorting through methods of dividing the liver (Eur Surg (2004) 36/5:289-295).

Y. Ume, J. Uchino, K. Ogasawara et al. published similar results back in 1989:

"Compared to the CUSA, the water jet leaves a smoother cut surface and little hepatic degeneration or necrosis at the borders." (Liver resection using a water jet. Cancer Chemother Pharmacol 23 (Suppl): S74-S77)

New Comparative Study

from Canada about Living Organ Donors in favor of the helix hydro-jet®

In a major Canadian study, a partial hepatectomy was carried out on 101 living donors for transplantation with the Helix Hydro Jet and the Caviton Ultrasonic Aspirator (CUSA Excel). Due to findings made in the course of the study, the ultrasonic aspirator device was removed from the study after only 21 operations, and the Helix Hydro Jet was used exclusively for the last 80 operations!

"The shortage of deceased organ donors has created a need for right lobe living donor liver transplantation in adults. Concerns regarding donor safety, however, necessitate continuous assessment of donor acceptance criteria and documentation of donor morbidity. ... Overall morbidity rate was 37%; all complications were either grade 1 or 2, and the majority occurred during the first 30 days after surgery. There were significantly fewer complications in the later half of our experience. All donors are well and have returned to full activities."

Due to findings made in the course of the study, the Caviton Ultrasonic Aspirator device (CUSA Excel), which was also initially used, was removed from the study after only 21 operations, and the Helix Hydro Jet was used exclusively for the last 80 operations!

"There were significantly fewer complications in the later half of our experience. ... A bile leak developed in three donors during our initial experience, but none in the last 80 donors. ... It is difficult to account for this low rate of biliary complications but several factors may be involved. First, the Hydro-Jet dissector, which we have used in the last 80 donors, facilitates meticulous dissection and identification of smaller bile ducts that can be either ligated or clipped before division."

(S. A. Shah, D. R. Grant et al.: Analysis and Outcomes of Right Lobe Hepatotomy in 101 Consecutive Living Donors. American Journal of Transplantation 2005; 5:2764-2769)

*„Dual power principle –
new devices in the product family”*

Treatment of Rectum Carcinoma

The helix hydro-jet® dissector significantly facilitates total mesorectal excision

Professor Dr. F. Köckerling, Head of the Department of Surgery and Center for Minimally Invasive Surgery, Hanover Hospital, has introduced the Helix Hydro Jet dissector into his surgical routine for the treatment of rectal cancer. In his new book publication he points out, that "the Hydro-Jet dissector significantly facilitated total mesorectal excision."

"Background: The introduction of total mesorectal excision (TME), in particular, has resulted in a dramatic decrease in postoperative functional disorders. Strict adherence to the dissection planes "The particular feature of this technical aid is that it permits the rapid early development of the embryological plane between the pelvic nerves and the mesorectal fascia, without doing damage to either of them. This leads to optimal radi-



Professor Dr. med. Köckerling

cality and maximum preservation of the autonomic nerves." Described above, is the prerequisite for good oncological and functional outcome. To facilitate dissection, we have introduced the high-pressure water jet dissector into our surgical routine for the treatment of rectal cancer. Below, we describe the technique of total mesorectal excision we employ in our department and present our perioperative surgical results.

Methods: We performed total mesorectal excision for rectal cancer in 49 patients, comprising 32 males and 17



females aged between 34 and 88 years. 38 patients underwent low anterior resection of the rectum and 11 patients abdominoperineal resection.

Results: The mean operating time was 282 min, mean intraoperative administration of red cell concentrates was 0.55 units. The mean postoperative stay in the ICU was 1.92 days. ... **Conclusion:** The perioperative results are comparable to those of centres of excellence in the international literature. The Hydro-Jet dissector significantly facilitated TME. The particular feature of this technical aid is that it permits the rapid early development of the embryological plane between the pelvic nerves and the mesorectal fascia without doing damage to either of them. This leads to optimal radicality and maximum preservation of the autonomic nerves. ..."

Prof. Köckerling is also demonstrating the use of the Helix Hydro in a special Video ("OP-DVD Helix Hydro Jet"), available at Human Med AG. (F Köckerling, C. Yildirim et al.: Total mesorectal excision with the water-jet dissection. Technique and results. In: Techniques in Coloproctology, Springer Milan, Vol. 8, Suppl. 1/2004, 217-225)

Nerve-sparing Prostatectomy with the helix hydro-jet® – the Water-jet maintains Potency and Continence

Removing the prostatic gland can result in incontinence and impotence if the nerve vascular bundle is damaged. Through the selective effect of the fine water jet, the prostatic gland is gently taken out of the tissue bed. The force of the water pressure is set in such a way that vessels and nerves can withstand the jet but muscles and organ structures are ablated. The feared injuries to the nerve vascular bundle on the prostatic gland, which may lead to incontinence or impotence, are to a large extent avoided.

In a clinical study carried out by Dr. S. Fernandez De La Maza, the use of the Helix Hydro Jet reduced loss of blood by 36%, to an average of 830 ml, and operating time by 20%. For three months after the operation, only 56% of the men operated by using the conventional method were potent while the potency of almost 80% of the patients who had been operated by using the helix hydro-jet remained intact.

Significant Reduction of Blood Loss during Water Jet Resection in Renal Surgery

Bleeding is one of the most common problems during transection of renal tissue. Already in the year 2000, Basting et al. have demonstrated that water jet technology with Helix Hydro Jet is an applicable tool for transection of renal parenchyma in patients with renal cell carcinoma and nephrolithiasis. They stated that "it has been shown to reduce the risk of blood loss significantly compared to other techniques." ("However, reduction of blood loss by use of the ultrasound aspirator (CUSA) is still far from satisfactory.")

Results: "By means of water jet resection tissue was dissected effectively avoiding damage to the vascular structures, which were then ligated selectively. Resection time was between 14 and 30 minutes with a minimal intraoperative blood loss. No significant problem was seen postoperatively." The authors emphasized the "safe and simple use (of the Helix Hydro Jet) without any particular training".

(R.F. Basting et al.: Use of Water Jet Resection in Renal Surgery: Early Clinical Experiences. Eur Urol 2000; 38:104-107)



Retention of the neurovascular tract during radical retropubic prostatectomy

(S. Fernandez De La Maza, Early clinical experience with water-jet dissection (helix hydro-jet®) during nerve-sparing radical retropubic prostatectomy. Min Invas Ther & Allied Technol 2002; 11(5/6):257-264)

Highlights in Neurosurgery

„Water-jet Dissection versus Ultrasonic Aspiration in Epilepsy Surgery” – significant reduction of blood loss and better preservation of intraparenchymal blood vessels with helix hydro-jet®!

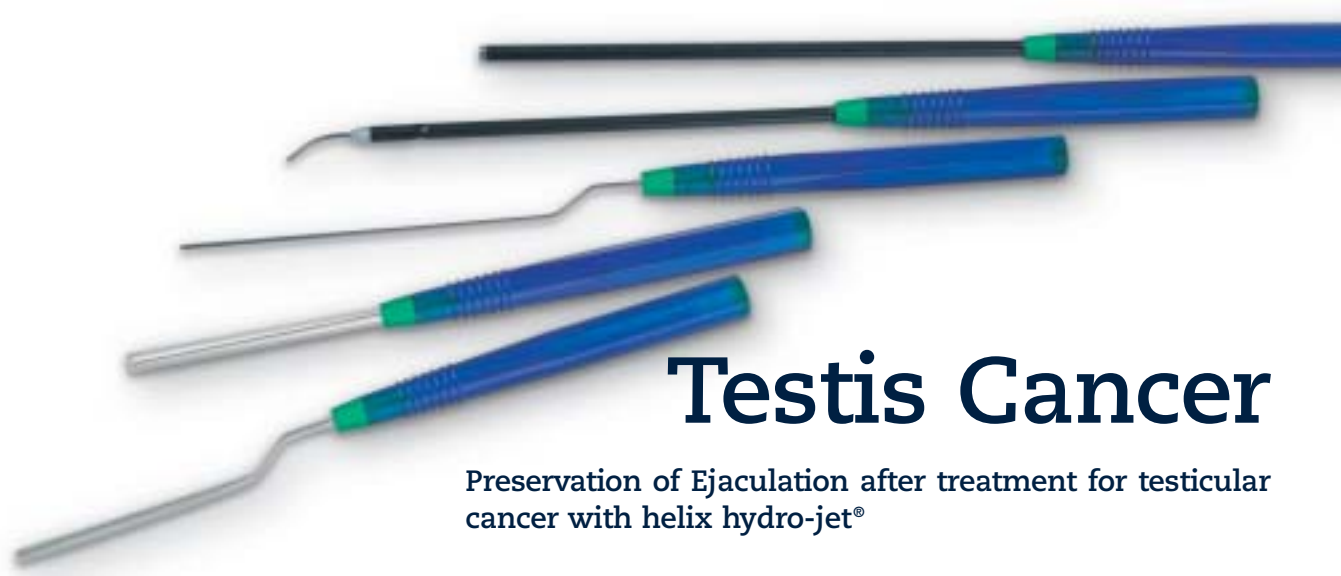
Methods: The authors applied the water-jet device in a prospective randomised study in comparison with the ultrasonic aspirator. 30 patients received a tailored temporal lobe resection. Intraoperative vessel preservation, intraoperative blood loss, surgical complications, and epilepsy outcome were evaluated. All patients were followed at 3-month intervals.

Results: During surgery, both instruments were easy to handle. Only with the water-jet dissector, however, even small intraparenchymal blood vessels were preserved.

Intraoperative blood loss was significantly reduced with the water-jet (mean 70±46 ml) compared with the ultrasonic aspirator (mean 121 ± 48 ml). However, no difference occurred in the necessity for blood transfusion, operation time or surgical complications and outcome.

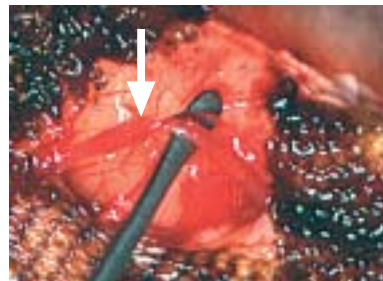
Conclusion: The water-jet dissector enables a significant reduction of intraoperative blood loss in the investigated setting.

From: J. Oertel, M.R. Gaab, U. Runge, H.W.S. Schroeder, J. Piek: Neurosurgery. 56(1) Operative Neurosurgery Supplement 1:142-146, January 2005.



Testis Cancer

Preservation of Ejaculation after treatment for testicular cancer with helix hydro-jet®



Conservation of fine blood vessels (arrow) during the removal of a brain tumour

“The water-jet allows a safe and complete removal of lymphatic tissue, leaving vulnerable anatomic structures intact. The water-jet was able to remove lymphatic tissue easily and atraumatically. At pressures of 20 bar, the lymphnode capsule remained completely intact, thus avoiding tumor-cell spread. Antegrade ejaculation could be preserved in all patients, who, to date, show no evidence of disease.”

This is the conclusion of a clinical

study on 18 patients with clinical stage I and stage 2 testis cancer by Stefan Corvin, M.D. and Wolfgang Sturm, M.D. of the Eberhard-Karls-University of Tübingen, published in 2005.

(S. Corvin, W. Sturm et al.: Laparoscopic Retroperitoneal Lymph-Node Dissection with the Water-jet is Technically Feasible and Safe in Testis-Cancer Patients. Journal of Endourology. Sep 2005, Vol. 19, No. 7: 823-826)

Water-jet resection of brain metastases

First clinical results with 10 patients. helix hydro-jet® is particularly suitable for soft, poorly demarcated metastases.

The water-jet technique enables precise tissue dissection without thermal damage and with preservation of vessels in general surgery. In neurosurgery, these qualities could help to avoid damage of intact brain parenchyma in tumour resections. The present study reports our first results with this technique in brain metastases.

Ten patients with intracranial metastases underwent surgery with the aid of the water-jet. Resection was performed in combination with

conventional neurosurgical methods. The follow-up consisted of neurological examination and MRI studies.

Intraoperatively the device was easy to handle. No complications due to the device were observed. Vessels were preserved at pressures below 20 bars. Six of the tumours consisted of soft tissue which was poorly demarcated from the surrounding brain. In these tumours, the water-jet was very helpful. It enabled tumour debulking by aspi-

ration and – more important – precise separation of tumour and brain parenchyma.

In conclusion, the water-jet can be applied in surgery of brain metastases without complications. The device appears particularly suitable for soft, poorly demarcated metastases.

From: J. Oertel, M.R. Gaab and J. Piek: European Journal of Surgical Oncology 2003; 29: 407-414.

„Water-jet dissection in neurosurgical procedures: clinical results in 35 patients.”

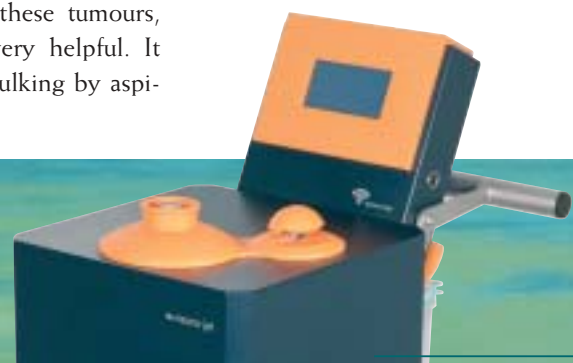
helix hydro-jet® appears to be particularly suitable for the dissection of highly vascularized gliomas or normal brain tissue.

Methods: Thirty-four patients with gliomas (Grades II-IV), cerebral metastases, temporal lobe epilepsy, or cerebral hemangioblastomas, and one patient with internal carotid artery stenosis were treated surgically with the aid of the water-jet. Intraoperatively, the water-jet was easy to handle, and no complications due to the device were observed. Dissection of tissue was possible for all pathological conditions, and pressures between 3 and 45 bars were used.

Conclusion: Water-jet dissection has been shown to be a promising new method for precise dissection of normal brain parenchyma and various brain tumours in the supra- and infratentorial hemispheres.

This device appears to be particularly suitable for the dissection of highly vascularized gliomas or normal brain tissue, in which tissue dissection with sparing of blood vessels can be achieved.

From: J. Piek, J. Oertel, M.R. Gaab: Journal of Neurosurgery 96:690-696, 2002



Surgical Challenge – 35th World Congress of the International College of Surgeons from 25.-29. Oktober in Pattaya

“Surgical Challenge” – this was the title of the “35th World Congress of the International College of Surgeons” (ICS), which was held from 25–29 October 2006 in the exotic location of Pattaya in Thailand. The ICS is the world congress which has the richest tradition for surgery in the International College of Surgeons, which the host, Thailand, entered 52 years ago. The programme offered scientific lectures by renowned speakers from all over the world as well as interesting symposia sponsored by industry.

Human med used the congress to increase publicity for its helix hydro-jet® and neuro-jet water jet dissectors and to increase its presence in particular in Asia through new contacts. Human med’s appearance was organized jointly with the GTS partner company, which has recently taken on selling the products in the Asian territory. GTS would like to resume the sales success of Erbe, the former human-med sales partner, which has been able to sell more than 20 helix hydro-jet® systems in China alone.

Indication lipoedema

Reliable therapy for long-term improvement in quality of life by "Liposculpture" with the body-jet®

Hydro Surgery News: Dr. Stutz, please tell us briefly about the main focus of your specialist clinic.

Dr. Stutz: We have been treating lipoedema patients for more than ten years. These patients are exclusively women. Lipoedema is a symmetrical fat distribution disorder which occurs mostly in the upper and lower thighs and sometimes even on the arms. Thickening appears on the outer thighs (jodhpurs) and the inner knees during puberty or pregnancy. Over the years, the fat spreads to the ankles and gives the legs a pillar-like shape. The cause is not yet known.

Hydro Surgery News: So, this is not just a matter of purely aesthetic treatment but rather a clinical picture which causes great suffering to the women affected?

Dr. Stutz: That is correct. The upper body of these patients is disproportionate to the legs, which means that these patients mostly have quite a slim upper body; some of them are even cachectic but the legs remain unchanged. In the fat pads on the legs it is not a question of stored fat reserves as in the case of obesity: lipoedema fat has an entirely different structure and cannot be reduced through exercise or dieting. It is not a matter of excess weight, nor is it a lymphatic drainage disorder; it is a separate clinical picture and for this reason it is also defined in the statute book. Lipoedema is a clinical diagnosis and the patients suffer not only from the way it looks but also from the symptoms.

Hydro Surgery News: Does that mean that these symptoms are painful too?

Dr. Stutz: The patients are severely prone to swelling, particularly in the summer months and there is often extremely unpleasant tenderness and pain. Even the smallest amounts of pressure lead to bruises and a hematoma which is much greater than normal.

Hydro Surgery News: Do the national health insurance companies now pay the costs of either the entire treatment or part of it?

Dr. Stutz: The costs are paid for non-surgical treatment, which consists of two components: these are manual lymph drainage and the



permanent provision of compression with elastic stockings and tights which are flat-knit. As far as I am aware, the health insurance companies do not pay for surgical treatment for lipoedema, which consists in removing diseased fat cells.

Hydro Surgery News: Does that mean that these patients have to be given permanent treatment for life, so to speak, with all the costs which are involved, because lasting treatment is not reimbursed?

Dr. Stutz: That is what the current situation is. Life-long physical treatment is required which involves the patient wearing a pressure garment that has to be renewed every six months all her life. If the diseased fat cells are removed with the aid of water jet liposuction during an operation in the early stages, it is possible to completely omit the above method of treatment. In every case improved quality of life, a reduction of the degree of pressure and avoidance of manual lymph drainage can be expected.

Hydro Surgery News: In the meantime, you have made water-jet-assisted liposuction (WAL) – which you call "Liposculpture" – standard treatment in your clinic. Why has WAL with the Body-Jet proven itself to such a degree in your work?

Dr. Stutz: We have made treatment of the symptoms of lipoedema into our specialist field; we perform nearly no cosmetic operations. For this we needed a particularly gentle procedure because in its later stages, a consequence of lipoedema is often lymphatic disease. Naturally, we wanted to apply a method which is particularly gentle to the lymphatics and the tissue, and in my opinion, the WAL has particularly proven itself.

Hydro Surgery News: Why is this process so gentle?

Dr. Stutz: The main reason is definitely that a) we do not require any tumescence, which means that it is no longer necessary to make the tissue bloated and b) it is more of an indirect process; it is not so much suction but a rather washing out process. We wash the fat cells out of the fibrous tissue and in this way, there is practically no destruction to the important structures. That is what makes this process so gentle in comparison to other methods of removing fat cells.

Hydro Surgery News: How can the effect of water jet assisted liposuction with the Body-Jet be explained to a non-expert?

Dr. Stutz: I explain it to my patients in the following way: if you wish to replant an exquisite rose-bush, you can dig the plant out with a spade. You will damage a few roots while doing so. If you want to do it in a particularly gentle way, you can use a water jet to rinse out around the root until it has been rinsed completely free. You do not injure the roots with the water jet. This is exactly how you can imagine the effect of the water jet in the body.

Hydro Surgery News: So only the fat tissue is selectively removed.

Dr. Stutz: Yes. A further really significant advantage of water jet assisted liposuction is the constant control. Since we have no tumescence, we do not need to make the tissue bloated, we do not need to double the tissue's diameter or to increase it by three times and thus have exact control of the area drawn off by suction and the neighbouring area. In this way, the operator has constant control of the process and can make permanent assessment of the extent that the fat has already been drawn off by suction.

Hydro Surgery News: So, less solution is brought into the body? Does that mean that less medication, that can possibly cause hemodynamic side effects and other side effects, is applied?

Dr. Stutz: In principle, one can say that we require roughly a tenth of the tumescence fluid in the body that is used in other processes in order to sufficiently eliminate pain and in this way, anybody can easily imagine that if a tenth of the quantity of fluid brought into the body

is used, the drug effects must also be drastically lower.

Hydro Surgery News: Is the operation performed under general anaesthesia?

Dr. Stutz: That depends on the therapist and his/her philosophy. We perform liposuction only under local anaesthesia. The patients remain awake during the operation; they can cooperate, for example, turn over or tense the muscles. This is simply an enormous safety factor.



Hydro Surgery News: So, the patient does not feel any pain and she feels well during the operation?

Dr. Stutz: We ensure that the patient does not feel any pain throughout the entire operation and can therefore endure the procedure in a relaxed state.

Hydro Surgery News: What happens after the operation? When can the patients go home again?

Dr. Stutz: We proceed in the following way: As soon as the liposuction is completed and the residual fluid has been pushed out of the tissue, the patient – after receiving a corset – can go or drive home again.

Hydro Surgery News: Can she drive directly after the operation herself?

Dr. Stutz: She can drive herself if she has been given no additional sedative.

Hydro Surgery News: What are the long-term results like? Should a patient expect that the fat cells which have been drawn off by suction, will reform?

Dr. Stutz: We can track the results of lipoedema treatments in our clinic over the last 8 years.

Interview ●●●●●●●●

Josef J. Stutz M.D., surgeon and lymphologist in his clinic for treatment of lipoedema

Liposuction has, of course, been around for much longer. The fat cells do not reform again. Fat cells which are drawn off by suction are removed permanently, which is why a permanent result can also be expected, although if there is a large weight gain, the lipoedema can deteriorate again. If the patient is very resolute and maintains the weight which she has achieved, no new fat cells will form. In this respect, it is a permanent result.

Hydro Surgery News: How long have you been carrying out water jet assisted liposuction (WAL) with the Body-Jet in your clinic?

Dr. Stutz: We started using the WAL over two years ago. In the initial phase we still liked to try different combinations, merely to learn the treatment and we tried other forms such as ultrasound-assisted liposuction. Since we have mastered the Body-Jet, no additional treatment is necessary any more. Nowadays we make exclusive use of the WAL with the Body-Jet in all forms of operating.

Hydro Surgery News: Do you receive feedback from your patient? Are they happier after the operation?

Dr. Stutz: We do, of course, receive feedback. We give our patients a check-up after 6 weeks, 6 months and after one year and also see in Internet forums how the patients exchange messages and give each other information.

When we ask our patients to visit us, we receive positive messages, such as, for example, that they visit swimming pools with their children again or are finally able to buy a pair of trousers or a suit again. The patients are very satisfied indeed. Aside from the fact that the symptoms have been eliminated and that they now have no more pain and hardly ever have swollen legs in the summer months, the quality of life improves enormously. At the end of the day, what is important is the patients' satisfaction with the changes to their appearance and the harmonisation of the body's silhouette which makes the patients very, very happy.

Advance in Liposuction techniques

More safety and better results with the body-jet

- Not only a new technique but a whole new concept.
- Results from 800 treatments



„Water Jet-Assisted Liposuction“

A new approach

Introduction

Since the publication of the tumescent method under local anesthesia by J. Klein several mechanical methods for the infiltration of the fluid and for the aspiration of the fat have been developed further. All of them need the application of sometimes considerable quantities of fluid for liposuction to be carried out. This causes side effects associated with the medications of fluid. Aside from volume-related electrolyte shifts and resultant circular reactions, the analgesics added can produce several effects. These effects can appear even days after the procedure. The number and severity of complications for procedures carried out under anesthesia in combination with tumescence use. Therefore, the dilemma for all forms of liposuction remains in the seemingly unavoidable side effects associated with the use of tumescent solution. This provided the idea of developing a new method that would minimize the drawbacks of tumescence use.

Background/Characteristics of body-jet®

Water jet assisted liposuction (WAL) uses a thin, targeted, fan-shaped jet which is channeled into the adipose tissue, in order to loosen the structure and release the adipocytes. This is an active process, which replaces the previous mechanism of passive entry of fluid through diffusion and osmosis. A pressure system was developed, which directs the infiltration solution through a closed tubing system, via a piston pump into a very thin application cannula. This is surrounded by an external cannula, which can have different diameters and arrangements of openings, depending on its purpose. The flow

rate of the infiltrate, as well as the application pressure, can be selected from different levels by a software. For technical reasons, a pulsating jet is produced.

The effective jet has an impact power comparable to a powerful shower head; therefore, there is no possibility of a traumatic „tearing up“ effect.



Modified infiltration solution

To provide maximum anesthetization for as long as possible, with minimal side effects, a two-stage concept was developed. Pre-infiltration produces a rapid anesthetization and vasoconstriction in the entire treatment area. Aspiration then is carried out using a „rinsing solution“ that contains only small quantities of analgesic, in order to increase the analgesia and vasoconstriction that was already given. This two-stage process is achieved by using two different tumescent solutions. The infiltration solution consists of a relatively short-acting analgesic with rapid uptake, combined with a long-acting analgesic with slow uptake. In addition, epinephrine is used for vasoconstriction. Because it is continually added and almost immediately aspirated again during liposuction, the concentration in the rinsing solution can be reduced.

Preparation phase

The patient is prepared for the procedure in the usual way.

The authors have carried out more than 800 treatments of water-jet assisted liposuction (WAL) since 2001. They come to the conclusion that the use of WAL with the body-jet® under local anesthesia represents a new and safer method that is suitable for all types of liposuction.

Risk of serious side effects reduced

In previous methods of liposuction, serious side effects have been caused due to the fact that sometimes considerable quantities of fluids containing medications had been needed. Aside from volume-related electrolyte shifts and resul-

tant circular reactions, the analgesics added had produced side effects even days after the procedure.

In water-jet assisted liposuction (WAL) with the body-jet® these risks are much reduced as only 28% of the tumescent solution used in conventional liposuction procedures were required with WAL. Meyer and Man concluded that „in particular, patient safety has increased considerably, even in extensive procedures“.

Differences in Histology

According to Meyer and Man, „Histology shows significant difference between WAL and PAL

effects to cell membranes. Tumescence effects are not seen in WAL. Fat cells are aspirated more selectively with less collateral damage to other structures. Very few cells are disrupted.“

H. Meyer: Water-jet assisted Liposuction – not only a new technique but a new concept. In: D. Panfilov, State of the Art in Aesthetic Surgery, Springer Verlag Berlin, 2006

It is unnecessary to wait before starting the aspiration process (aside from the inevitable time taken to perform the infiltration). Anesthetization and vasoconstriction take place over a shorter period of time due to controlled high infiltration and simultaneous suction.

After the infiltration cannula has been swapped for the suction cannula, the aspiration process starts immediately. As a general rule, the fluid leads the way; the cannula simply follows it and penetrates „soft areas“. The functional structures are displaced by the jet and are thereby protected from mechanical trauma. The whole procedure is generally tolerated without any problems, even by sensitive patients.

Results

In total, the authors have carried out more than 800 treatments since 2001. The following lists an overall summary of the results:

- In relation to the quantity used in conventional liposuction methods, an average of 20 to 30% of the tumescent solution was used in pre-

infiltration, depending on the individual findings of the authors

- The length of time it remains in the tissue, and the resulting absorption times are all considerably lower for the recommended infiltration solutions, compared with all other tumescence-based liposuction techniques.
- Patients satisfaction with both, the procedure performed under local anesthesia, and the final outcome increased to over 94%.

Conclusion

Use of water jet assisted liposuction under local anesthesia shows that:

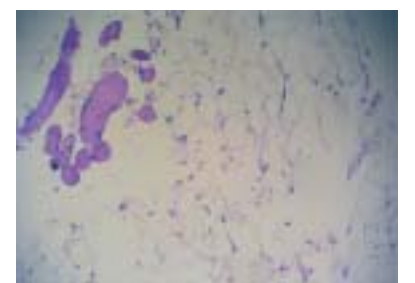
- In almost all cases, WAL makes it possible to use pre-infiltration of modified tumescent solution to create analgesia that is suitable for the performance of painless or near painless liposuction. Therefore, liposuction under general anesthesia or sedation, which suppresses consciousness, is no longer necessary.
- Considerably less intraoperative swelling allows the surgeon to better realize the target result.
- WAL presents a new and safe

method that is suitable for all types of liposuction.

In particular, patient safety has increased considerably, even in extensive procedures.



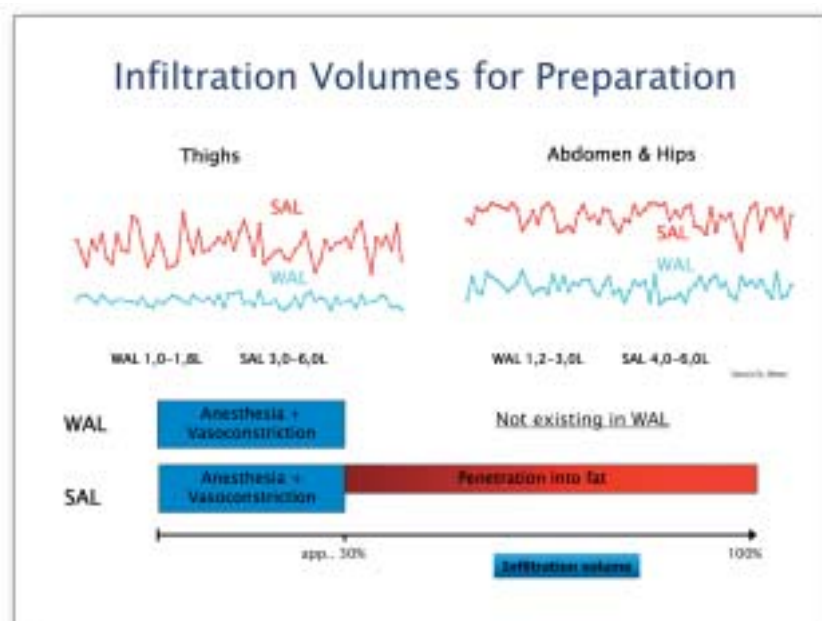
picture 1



picture 2

Histology shows significant difference between WAL and PAL effects to cell membranes. Tumescence effects are not seen in WAL. Fat cells are aspirated more selectively with less collateral damage to other structures. Very few cells are disrupted (picture 1).

In picture 2 damage to other cell structures by PAL can be seen.



H. Meyer et al: Water-jet assisted Liposuction – a new concept. In: Ch. Yamaguchi, 2nd Annual Meeting on Aesthetic Surgery, Sao Paulo, August 2006

H. Meyer et al: Water-jet assisted Liposuction – a new approach. In: K. Ohmori, Minimal invasive procedures in Aesthetic Surgery, Tokyo 2007 (prepared)

Replacement of the power assisted method of liposuction with the water-jet assisted method (body-jet®), in Vienna

Prof. Dr. med. P. Hernuss, in his presentation during the 1st European Congress on Anti-Aging Medicine – 16th Congress on Menopause Andropause Anti-Aging, October 18 – 21, 2006 in Vienna



Prof. Dr. med. P. Hernuss

“Since the American Jeffrey Klein first published his tumescent anaesthesia method for fat removal at the end of the 1980s, liposuction has developed to become one of the

most commonly performed cosmetic operations worldwide.

We at the Tagesklinik Wien have replaced the vibration powered method of liposuction with the water jet powered method because the same degree of local anaesthesia is achieved with half the tumescent fluid. Obviously this is beneficial for the patients haemodynamics and sharply reduces the drug requirements. In addition the fat cells are mostly destroyed (detached) and washed out by the water jet and thus can be removed more easily. The residual nerves and vessels are even more protected and preserved. Excision of only the superficial skin layer reduces the wound area extremely and thus makes it possible for the patients to return to work after a couple of days. An overnight hospital stay is no more necessary.”



The 13th asean congress of plastic surgery

The most important regional congress for cosmetic and plastic surgery in Southeast Asia took place from 16–18 October 2006. The conference was held in the culture centre of Chiang Mai, approximately 750 km north of Bangkok.

The congress attracted a large number of plastic surgeons and dermatologists in the region, whose participation was rewarded with a first class specialist programme and varied cultural events.

An international speaker, Dr. Hartmut Meyer, plastic surgeon from Hamburg and the most experienced user and joint developer of the body-jet, gave a lecture at the main event of the congress on the

topic of water jet assisted liposuction techniques. This was his response to a personal invitation by the president of the “Society of Plastic and Reconstructive Surgeons” as well as the “Society of Aesthetic Plastic Surgeons of Thailand”. The large crowds at the human med body-jet stand following his lecture showed how positive the response was.

Northeast Asia has taken on a pioneering role in adapting the technology, which is still new, by installing over 30 body-jets in the beauty markets of Japan and Korea this year alone. The congress in Chiang Mai should be used to extend this success to southeast Asia.

International Workshops for Doctors with Application Training

International workshops are being offered for new users in order to provide support in the safe use of the body-jet. The aim of these practice-oriented intensive training workshops is to give personnel training in using the device and to give the practising doctor proof of training.

Body-jet workshops have been carried out this year in countries including Korea, Japan, Thailand and Brazil.

Human med sees the workshops as an essential quality assurance instrument resulting from a sense of responsibility towards the customer and the patient.

The workshops are of a practical nature and are normally carried out in local conditions and in the usual operating environment.

The content of the workshops include

- An introduction into water jet technology and the way that water effects fat tissue – presentation and discussion.
- Applying the body-jet and its accessories including the procedure for sterilisation and disinfection.



- Assessing and preparing the patient, marking out the area etc.
- Presentation and discussion of concepts of anaesthesia, formulation of the tumescence solutions, medication.
- Performing one to two operations, detailed instructions into water jet assisted liposuction (WAL) operating techniques.
- Postoperative measures, pressure treatment, cooling, follow-up examination.

A certificate confirming successful participation is issued at the end of the workshop/training.

The workshops are organized in collaboration with the local human med partners. Experience has shown that several workshops are required in each country before a local training partner can take over the task. Aside from carrying out local workshops, human med also offers the possibility of training in Germany.



Large interest in international body-jet workshops



Sterile application system

Indications

- Liposuction
- Liposculpting/Body contouring
- Treatment of Lipodemas
- Perspiratory Gland Removal
- Fat tissue transplantation

human med AG

Water is Carving its Way

human med AG relies on 16 years of experience in the development of water jet dissectors for surgical applications.

After a change of main shareholders at the beginning of 2006, human med AG consequently started to implement new product lines and expanded its international distribution activities.

The main shareholders now are Roger Dullien and Bernd Lindner. Roger Dullien held top management positions in Tyco Healthcare for as long as 28 years, at last as President International. Bernd Lindner looks back at more than twenty years of general management in medical companies and is the founder of EnviteC Wismar GmbH. He is also the chairman of human med AG, together with Arnd Kensy. Arnd Kensy was vice president of a worldwide leading producer of medical products in the field of cardiology / cardiac surgery before he joined human med AG, and brings international experience of sales and marketing into the organization.

Arnd Kensy states: "We will only achieve a strong distribution of water jet technology in the field of classic and plastic surgery by cooperating more closely with our users, the doctors. The water jet opens up diverse possibilities to the user for improving his/her operating methods. However, as in the case of the classic scalpel, there is no standard set of instructions for the water jet. Doctors are our partners in researching the indications and they provide the stimulus for further development of our products.

Our worldwide sales partners find this aspect to be of particular importance because they are the link to our users. Together with our partners we train our customers and offer them a forum for discussing their results with us and with their colleagues on a scientific basis.

In this process, the everyday application of our helix hydro-jet and



the body-jet is comparatively straightforward and the advantages are easily recognisable. For example, water jet assisted liposuction (WAL) reduces the volume of pre-infiltration by approx. 70% compared to the methods currently applied. Consequently, the risk factor of the operation is lowered, the doctor is given the possibility of maximising his result intra-operatively and furthermore reducing his/her costs due to the lower time required for each patient. This is a rare combination in technical reform in medicine."

Another convincing area is the use of the water jet in general surgery, as is impressively demonstrated by the selection of users' opinions printed in this Hydro Surgery News.

Therefore, it is our aim to offer surgeons a technical option for using the water jet in surgical procedures where it is superior or complementary to existing instruments: during selective and vessel-sparing dissection of parenchymal tissue. A cooperation with a strategic partner from the field of electromedicine is also being considered.

There is no other manufacturer worldwide who has such a wide range of expertise in the medical application of water jet technology at his disposal. An important point is that our products have already proven themselves and are used worldwide. The water jet is no longer "new territory" and it enables a rapidly growing group of users to give their patients more precise and

gentler treatment. On the basis of this experience, we are working continuously on expanding the application spectrum of the water jet in the near future. The results are very promising.

The potential of this technology has not yet been exhausted. Water is carving its way.

- High tissue selectivity
- Less complications
- Minimum tissue trauma
- No thermal damage
- Preservation of vessels and nerves
- Significant reduction of blood loss
- Visualization of vital structures
- Shorter procedure time
- Safe procedure in local anesthesia
- Better intra-operative assessment – no bloating
- 70% less tumescent solution required in pre-infiltration – less exposure to analgesics – less complications
- Minimum tissue trauma
- Reduced pain-related impairment due to continuous application of analgesics during irrigation and aspiration
- Reduced procedure time per patient
- Better patient satisfaction levels

●●helix hydro-jet

●●body-jet

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