

Beyond liposuction – the new human med AG

With last year's takeover of human med AG we have fundamentally changed the course of the company. Today our goal, as the former manufacturer and marketer of a liposuction machine, is to establish water-jet technology in various medical disciplines and fields of application. Our current work focuses on the realisation of new product ideas.

Human med has a long tradition in water-jet surgery. We have been able to establish ourselves in this field by offering an innovative solution that holds obvious benefits for both the doctor and the patient. These benefits are always based on the advantages offered by water as a more intelligent and physiological approach to separating tissues. Water does not cut. It pushes apart sheets of cells at their weakest point. This allows the operator to separate various types of tissues or "cut" along lines of differing tissue densities. The operator is able to follow the existing anatomical structures.

In liposuction the fan-shaped water-jet has another advantageous effect. It infiltrates the surrounding fatty tissue, transforming it into a gelatinous state. This tissue can then be suctioned off more effectively and in a manner that is less stressful for the patient than conventional procedures.

application for water-jet technology. In this issue of our Hydro Surgery News we have dealt with the most advanced of these concepts.

On the following pages, you will read about how the use of the fan-shaped water jet for the removal of sweat glands and the mobilisation of facial skin during facelifts can greatly improve the safety of these procedures. In both applications the operators had the same experience: When separating tissues with the help of a diffused stream of water the instrument tends to remain within the desired tissue layer. The water-jet separates tissues at the appropriate site. Surrounding structures, especially lateral blood vessels supplying the skin, remain intact, while underlying vessels and bands of tissue are cleanly exposed for subsequent steps of the procedure.



New wound debridement cannula

Our new product design for wound debridement and irrigation is being presented at the 2007 IPRAS Congress in Berlin. Here, we have succeeded in developing a technology with which surfaces can be effectively cleaned without producing the harmful aerosols. Set-up and clean-up times are minimal. The doctor guides the instrument simply like a pen in which the aspiration is integrated (see picture). Because all parts of the system, except the supply tubing, can be resterilised the costs remain within limits.

The multitude of new ideas which we have been able to pursue in such a short period of time confirms our belief that the use of water-jet technology in the medical field has a great potential which is still largely unrecognised.

We invite you to participate in the development and testing of our new concepts. As a medical technology company our primary task is to listen to your ideas and work with you to turn them into new products. Feel free to contact me personally with any questions and input you may have!

Arnd Kensy
CEO
Human med AG

Together with our users we have now assessed several new fields of

Significant reduction of Pain and Ecchymosis after Water-Assisted Liposuction (body-jet®) compared to Traditional Liposuction

"Comparison of Power Water – Assisted and Traditional Liposuction: A Prospective Randomized Trial of Postoperative Pain" Araco, A., Gravante, G. et al. In: Aesth. Plast. Surg. 31: 259-265, 2007

In a prospective randomized clinical study including 60 patients, the authors have found that pain and ecchymosis was significantly reduced by water-assisted liposuction (WAL) with the body-jet® compared to traditional liposuction. After 4 days 87% of the WAL patients were completely free of pain versus 3.6% in the group of patients treated with traditional liposuction. Also ecchymosis was significantly reduced in the WAL group. Operation time was also significantly reduced in the WAL group.

Study Results:

"A total of 60 patients were analyzed; 28 for the traditional liposuction and 32 for the power water-assisted liposuction. The eligibility criteria included all patients with a body mass index (BMI) of 25 to 30 with excessive pathologic fat located in the outer and inner thighs, knees, abdomen, flanks, chest, arm, ankles, chin and buttocks." "No significant differences existed between the two groups except for the operating time, which was longer for the traditional liposuction group than for the power water-assisted group (p<0.05). Comparison of the pain measurements showed a significant difference, with average values 4.8-fold

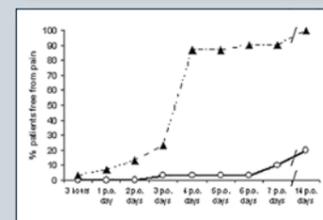
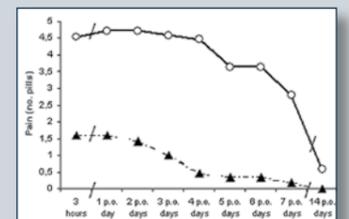
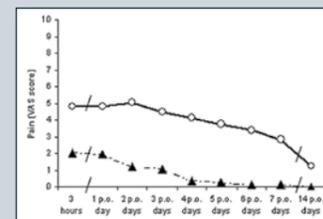
lower for power water-assisted than for traditional liposuction (p<0.05). Additionally, after 4 days, 87% (28/32) of the patients treated with power water-assisted liposuction were completely free of pain versus 3.6% (1/28) of those treated with traditional liposuction.

Ecchymosis measurements also were significantly lower for the patients who underwent power water-assisted rather than traditional liposuction (p<0.05)." As shown in the Fig., both techniques showed a dramatic bruising reduction at postoperative day 5. However, the scores were significantly lower for the power water-assisted liposuction in every assessment during the first 5 postoperative days.

For all these reasons, the hypothesis that less trauma is produced for tissue nerves and blood vessels with power water-assisted liposuction than with traditional liposuction is consistent. With a fine jet of water that follows anatomic structures without damaging them, whose pressure can be adapted to different connective tissue structures, it is possible to selectively remove fat cells while sparing blood vessels and nerves.

Conclusion:

Postoperative pain is an important factor that needs to be analyzed when new techniques in cosmetic surgery are introduced. This study gives clear proof that power water-assisted liposuction is an almost painless procedure as compared with tumescent liposuction.



Pain assessment. Left upper panel: Visual analog score (VAS). Right upper panel: Number of daily analgesic pills required. Lower panel: Percentage of patients completely free of pain. Circles represent traditional liposuction, and triangles represent power water-assisted liposuction.

Water-Jet Assisted Face Lifting with Aqualift®

An Interview with
Dr. med. T. B. Tork

hydro surgery news: Aqualift® with the Water-Jet: What is the concept behind this method?

Dr. Tork: Throughout its developmental history for medical applications, water-jet technology has been used in cases where the top priority was a dissection of the target structure with minimal tissue damage as well as minimal irritation of the surrounding vessels, nerves and sheets of connective tissue. Furthermore, depending on the shape and pressure of the water-jet, it can also be used for loosening solid structures, such as scars, and for cutting adhesions with minimal tissue trauma.

hydro surgery news: In which areas do you use water-jet technology with the body-jet®?

Dr. Tork: In the lower half of the face and the chin/neck area, the adhesions and band structures mentioned earlier are the reasons for the development of "marionette" wrinkles and, subsequently, for the typical development of sagging skin owing to the effects of gravity on the soft tissues of the cheek.

Furthermore, in many cases, the aging phenomena are associated with the development of a double chin, which can be treated at the

same time using a suction cannula instead of a cannula designed for dissection only.

hydro surgery news: In your experience, can water-jet technology also be used for fat transfer procedures, otherwise known as "Lipo-Shifting", for example, in cases where the patient has a thin neck?

Dr. Tork: In more slender patients with thin necks and mobile cervical skin structures the surgeon generally chooses not to remove moderate submental fat deposits by means of liposuction but to mobilise the fat cells by means of fat transfer, or "Lipo-Shifting". This helps producing a more youthful appearance by filling out the ventral cervical areas of skin.

Using a special fan nozzle with a diameter of 2.4 mm and a V-shaped water beam it is possible to remove these adhesions without doing serious damage to tissues. The tissue mobilisation is accomplished in a criss-cross technique using fan-shaped movements under constant monitoring of the dissection level by the guiding hand.

hydro surgery news: Why do you consider the water-jet assisted Aqualift method to be especially gentle on tissues?

Dr. Tork: The gentle nature of this technology is demonstrated by the low incidence of haematomas and postoperative swelling from the release of histamine. An additional indication is the rapid healing and the completely natural-looking postoperative flexibility and mobility of the cheek structures. A sufficient mobilisation has been achieved if, when pulling gently on the cheek skin parallel to the line of the chin, the tissue all the way to the tip of the chin exhibits a uniform flexibility. Adhesions above the jawbone connecting the jawbone with the corner of the mouth can be successfully mobilised with very visible results. When conventional techniques are used in such cases a high degree of tissue trauma with the classic clinical symptoms such as swelling and the development of haematomas is practically unavoidable.

Using a fine 2.4mm cannula and a pulsating jet the tissue dissection is easy to direct, and a safe method of operation can be guaranteed by constantly assessing the dissection depth using the guide hand.

hydro surgery news: What risks, in your opinion, are associated with the Aqualift method?

Dr. Tork: Inexperienced operators

could underestimate the dissection energy of the water-jet and, therefore, perform a more intensive dissection than planned. However, when used properly, the technology offers a reduction in the known risks. This fact is substantiated by the nature of the technology itself and justifies its potential use, for example, in neurosurgery.

hydro surgery news: Dr. Tork, can I ask you for a final word?

Dr. Tork: In my view hydrodissection and the Aqualift® concept represent a highly effective, time-saving tool.

hydro surgery news: Thank you for your time!

Dr. Thomas B. Tork

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The photographs show a 57-year-old patient, from upper left, preoperatively, on the 3rd postoperative day, after stitches were removed on the 8th postoperative day and 6 months after the procedure.



Before and after photographs of a 51-year-old patient with drug-induced Cushing Syndrome, preoperatively and 4 weeks after treatment, which included Aqualift®, liposuction of the chin area and upper eyelid blepharoplasty.

„Water-jet assisted liposuction in combination with subcutaneous submentoplasty“ (from face No. 2, June 2007)

Dr. med. T. Lorentzen

Dr. Thomas Lorentzen: "The combination of WAL with submentoplasty represents a gentle and fast treatment method for the rejuvenation of the submental region."

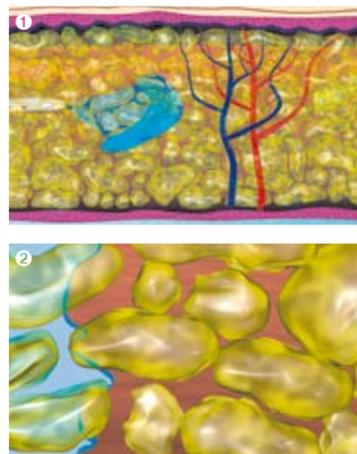
Method: "The combination of water-jet assisted liposuction (WAL) and submentoplasty (based on Watson 2005) is effective in tightening and contouring the cervicomental angle through the removal of excess fat and the shortening of the platysma muscle in the midline. The main goals of this method are a rejuvenation of the neck in order to restore well defined, youthful contours, a recreation of the cervicomental angle as closely as possible to the youthful ideal of 105° to 120° and the prevention of large scars in the head and neck area."

Procedure: "The body-jet® from human med is the only device currently approved for water-jet assisted liposuction. This device possesses a special fan nozzle for applying the high pressure water-jet as well as an integrated

vacuum system. With the simultaneous jet and suction technology the fluid infiltrated with the water-jet is immediately aspirated. The operator can select from five levels water pressure, meaning that the pressure can be optimally adjusted to the treatment area and procedure. The operation is performed either under a local anaesthetic or with analgesia and sedation. The patient lies in a supine position with the head tilted back."

Results: "Water-jet assisted liposuction (WAL) offers a number of advantages for both the patient and the operator. The operator benefits from a much better view of the treatment area and is able to make corrections during the operation, meaning that the treatment can be performed with greater precision and that, as a result, fewer corrective operations are required. Even transition regions and smaller anatomical areas can be shaped with especially high precision. An effective anaesthesia can be achieved by means of pressure infiltration with minimal

quantities of tumescent solution. Because a preoperative inflation of the tissue with fat-dissolving liquid is no longer necessary, there is no drastic deformation of the anatomical regions. Therefore, it is much easier to assess the treated areas and contours during the procedure. An additional advantage is the reduction of total operation time by 50 percent. Overall, liposuc-



1 Local infiltration for anaesthesia and fragmentation

2 Selective fragmentation of adipose tissue

tion using WAL technology is well tolerated by patients. It is less stressful for the patient, it requires fewer concomitant medications and it does not leave larger quantities of fluid in the body. Furthermore, the tissues are not subjected to thermal influences, and the overall tissue trauma is extremely low. The development of swelling and haematomas following the treatment is minimal.

In 10 operations that were performed using WAL in the neck/chin area in combination with submentoplasty none of the patients developed complications. Patient satisfaction was, without exception, very high, especially owing to the immediately visible results and the short recovery periods."

Dr. med. Thomas Lorentzen

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58-year-old patient preoperatively and the same patient postoperatively (small picture)

Water-Jet Assisted Sweat Gland Removal with the Body-jet®: Gentle Procedure with Permanent Results

Hyperhidrosis is often experienced as embarrassing and socially debilitating. It is estimated that up to 2 million people in Germany suffer from this condition.

Conservative Treatment Methods with topical agents often fail owing either to bothersome accompanying symptoms, such as skin irritations, or to poor patient compliance.

Surgical Methods: The partial or total skin excision with reconstructive flap surgery must be seen as a last resort and is not appropriate for cases of "simple" hyperhidrosis.

Mechanical Curettage: With a low initial success rate of only 50-70%, this procedure is often futile and, especially owing to the high complication rate, disadvantageous. The main problem is the risk of partial or total necrosis.

Paravertebral Neurotomy is a very effective treatment. However, the procedure is highly complicated, and the associated risks are correspondingly high.

Botulinum Toxin: Injections of botulinum toxin offer an effective alternative. However, this treatment is quite costly and must be repeated in several-month intervals.

Water-Jet Assisted Sweat Gland Removal

In the search for an alternative treatment with permanent results and low risks, water-jet assisted sweat gland removal was developed. First the sweat-producing area is marked by means of an iodine-starch test. Then, under local anaesthetic and using a procedure which has been further developed and perfected by Dr. Meyer, the lower layer of dermis, where the sweat glands are located, is exposed using a liquid jet in a more selective manner than previously possible.

Then the apocrine glands are scraped out using a sharp curette with a special design.

Previous techniques for mechanical removal were associated with unsatisfactory permanent success rates and frequent complications in the form of partial or complete necrosis because the subdermal and intradermal vascular plexus had to be destroyed in order to reach the gland-containing layer. The fine line between radical sweat gland removal and preservation of the skin perfusion was very narrow indeed.

With the new technique it is possible to expose the relevant layer of dermis with minimal damage to the surrounding structures, so that the perfusion of the treatment area through transversal connections remains at least marginally guaranteed. The result is a drastic reduction in the risk of necrosis along with an increase in effectiveness. Surgical access is provided by a one-centimetre incision. The resulting scar is minimal and inconspicuous.

Success Rate

The initial success rate for 193 patients over a 30-month treatment period was 87% (based on the results of a patient survey). Only 3 cases of surface erosion, in the form of partial necrosis, were reported.

Duration of the Procedure

Ambulatory surgery using the water-jet assisted method only takes about 45 minutes for both axillae. The application of the liquid jet is completely painless and is well tolerated by all patients. The applied medications are equivalent to the composition of a tumescent solution with the goal of

anaesthetisation and vasoconstriction. The actual tumescent effect, however, is not required because there is no need for liposuction. The subsequent mechanical curettage can therefore be performed in a completely pain-free manner with practically no bleeding. Haematomas can be effectively prevented by applying local compression for the first few days after treatment.



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- 1 Colour test for verification of the treatment area
- 2 Dissection cannula
- 3 Detached dermis
- 4 Curettage of the sweat glands
- 5 Follow-up colour test performed 3 months postoperatively on patient shown in Fig. 1

Water-Jet Assisted Liposuction for Patients with Lipoedema and Lymphoedema – No Hazard Posed to Lymph Vessels!

No traces of lymphatic endothelium in the aspirate of 20 subsequent Lipoedema patients.

Lipoedema is a symmetrical fat distribution disorder which occurs almost exclusively in women and usually manifests in the thighs and lower legs but can also affect the arms. The result is an extreme disproportion between the enlarged legs and the typically slender to thin torso.

Primary lymphoedema is rarely a symmetrical condition. This disorder, which is caused by a defect in the lymph conducting pathways, can also lead to a progressive increase in leg volume.

Until just a few years ago surgical procedures such as liposuction had been rejected by the scientific lymphological societies. This position was based on the results of cosmetic liposuction procedures, which were usually performed using a criss-cross technique. As numerous lymph vessels were damaged by the mechanical shear forces lipoedema sufferers experienced a worsening of the already existing high-volume lymph transport insufficiency, and in many cases lipoedema developed into lipo-lymphoedema.

After ground-breaking papers were published in the early 90s liposuction was recognised as a treatment for lipoedema. Such procedures must be carried out with strict consideration of the anatomy of the lymphatic structures so that there are no detrimental effects on the lymphatic system. The guidelines of the German Society for Phlebology name liposuction as a method for reducing adipose tissue in patients with lipoedema. Procedures focused on the preservation of lymphatic structures did not lead to a worsening of the oedema. On the contrary: The symptoms were significantly relieved, and the positive effects were still noticeable several years after the liposuction treatment.

Proof of the Structural Integrity of the Lymph Vessels

Contrast radiography was once the only means of proving the macroscopic-anatomical integrity of the lymphatic vessels after liposuction. Recently, however, a new method of immunohistological analysis has been developed which looks for lymphatic endothelial cells in the aspirate by means of vascular endothelial cell markers and is therefore able

to detect the presence of cells from lymphatic vessels. This test is far more sensitive than comparable anatomical methods. The liposuction aspirate were examined for general vascular endothelial cell markers (CD 31 antibodies) as well as selective markers for lymphatic endothelium (D2-40 antibodies).

For a total of 22 liposuction patients whose treatment area included the inner knee, the aspirate that was removed from these knee zones was sent to the Institute for Dermatohistology of Drs. Krahl where it was examined for the presence of the above named markers. This region on the inside of the knee represents a particularly vulnerable area owing to the relatively high lymphatic vessel density of the ventromedial lymphatic bundle.

Traces of lymphatic endothelium were found in the first two samples. However, after modifying the aspiration technique and adjusting the pressure, the subsequent 20 samples showed no evidence of aspirated lymphatic endothelium.

These results have proven that water-jet assisted liposuction poses no hazard to the lymphatic vessels when guidelines related to lymphatic system anatomy are followed. This refutes the assertion that water-jet assisted liposuction causes lymphoedema.

WAL for Patients with Primary Lymphoedema

As these results were so positive, I also performed a liposuction treatment for the first time on a patient with primary lymphoedema who had exhausted all conservative treatment options.

The aspirated area comprised the entire lower leg and the distal thigh. Again, samples of liposuction aspirate from the vulnerable zone on the inside of the knee collected from the beginning to the end of the procedure were sent in for immunohistological analysis.

Even in this case of primary lymphoedema with large quantities of aspirate, no traces of lymphatic endothelial cells could be detected.

Conclusion:

In light of these first studies it can be concluded that, even for this indication, water-jet assisted liposuction (WAL) represents a gentle treatment method. Until now, patients for whom conservative methods had brought little or no relief had few surgical options available to them for reducing the movement-restricting layer of connective tissue. With water-jet assisted liposuction (WAL) we now have a broader

spectrum of treatment options for lymphoedema at our disposal. I am aware of the need for additional tests and long-term studies. Nevertheless the use of WAL for both lipoedema and lymphoedema offers an extremely promising expansion of the therapeutic options.



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Water-Jet Assisted Liposuction

"WAL shortens surgery times significantly"

Dr. A. Z. Taufig

From the book: Liposuction, Principles and Practice. Edts. M. A. Shiffman, A. DiGiuseppe. Springer 2006, chapter 49, 326 – 330.

In the book "Liposuction, Principles and Practice" Dr. Taufig concludes in his article that "the technique of water-jet liposuction is a safe, gentle and targeted method to remove subcutaneous fat build-ups. It offers a very good way for moulding the tissue during the operation."

"Apart from the solution for the water jet no additional drugs are required; therefore, drug-related side effects are not to be expected. The method is simple, easily explained to the patient and quickly learned by the surgeon".

"WAL shortens surgery times significantly", finds Dr. Taufig.

Risk of the tumescent technique

"While liposuction has steadily been gaining popularity worldwide, the risk of the tumescent technique has been very much neglected. Alongside local complications like overcorrection or undercorrection as well as dents and steps, other side effects caused by the drugs contained in the tumescent solution are a problem. The chief ingredient of the solution used for tumescent liposuction is the local anesthetic lidocaine, which can only be absorbed by the body up to a certain limit.

There are no side effects from local anesthetic with the water-jet technique since local anesthetic tumescence is not used. The water-jet technique uses an isotonic sodium chloride solution with an additive of adrenaline in the ratio of 1 ml to 3l of sodium chloride solution, which is suctioned off

almost at the same time as the dissolved fat particles; therefore, no side effects are caused by the solution that is used as with the tumescent technique."

Precise correction

"The simultaneous suction of the fat tissue allows the surgeon to determine, at any time, the magnitude of the fat tissue that is to be removed. Borders and margins can be harmoniously aligned by adjusting the pressure of the water jet. The tumescent method does not allow such a precise correction of margins because the area that is being worked on loses its original shape owing to the tumescent solution.

The postoperative leakage of fluid from the incisions with the tumescent method is largely reduced if not even stopped..."



Time to Rethink Tumescent Liposuction

Availability of faster, safer and more predictable techniques are poised to blow outdated practices out of the water

Statistical Data

"During the period from October 1999 until March 2003, 280 patients were treated with this new method of liposuction."

Results

"It has been noted by the author that surgery times can be reduced by more than 40%. This is mainly caused by the fact that the phase for the instillation of tumescent solution and the period until it takes effect with the tumescence

technique does not apply for the water-jet technique. A large part of the saving in time rises from the fact that immediately after inserting the cannula and starting the water-jet the suction process is started.

The removal of fat tissue and the molding of the surrounding area can start right from the beginning of the operation. Compared with other methods only little fluid remains in the tissue, which is perceived by the patient as being very pleasant."

Please order your body-jet® Information-Package

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