System for Selective and Sparing Surgical Tissue Separation with a Water Jet

ERBE Elektromedizin GmbH: ERBEJET 2

The study on the savings potential of innovative medical technology was presented for the first time 23 October, 2008 at the Medical Technology Innovation Forum staged jointly by the German Industry Association for Optical, Medical and Mechatronical Technologies (SPECTARIS), the German Federal Ministry of Education and Research (BMBF), the Central Association of the German Electrical Industry (ZVEI) and the Federal Association of the Medical Device Industry in Germany (BVMed).

Status / area of application
The ERBEJET 2 is a water jet surgical device for the preparation and separation of tissue, suitable for preserving layering. The selective separation property of water supports the surgeon, for example in the dissection of parenchyma tissue (e.g. liver, spleen, kidney, brain) while sparing blood vessels and nerves. The area of application of ERBEJET 2 encompasses all techniques of selective dissection, primarily in visceral surgery, colon surgery, neurosurgery and gastroenterology.

Function
A fine water jet generated by pressure is used to separate the tissue. The ERBEJET 2 applicator produces a jet with a nozzle of 120 µm diameter. Sterile saline almost always serves as the medium for medical water jet dissection.

Once the water jet meets the tissue it is separated and flushed away. The water jet also forms an expansion space, whereby the liquid forces the tissue apart. The different sensitivity of various types of tissue (nerve tissue, connective tissue, blood vessels, organ parenchyma) with respect to the dissection jet and the possibility of regulating pressure and flow rate allows certain tissue types to be separated while preserving others. This effect is known as tissue selectivity.

Special features
Separation along anatomical layers is possible through the energy of water. This means less damage to the tissue and faster healing for the patient.
The “flushing” accompanying the water jet and the suction partly integrated preserves a clear overview of the surgical field and so allows faster surgery.

Technical description of the innovation
The construction of the ERBEJET 2 is compact and light thanks to a mechanical double-piston principle. The system includes a sterile pump unit for single use. This provides the connections for the applicators, as well as a Luer-Lock compatible connection linking to the separation medium via a regular infusion pump. ERBEJET 2 is also equipped with an ECB connection (ERBE Communication Bus) to connect with additional ERBE devices. There are currently six applicators available for ERBEJET 2 in total, some with a suction connection. The flow rate is adjustable between 1 and 55 ml/min, which corresponds to a pressure range of 1 to 80 bar for the current applicators. Modern regulation techniques allow the effect of the water jet on the tissue to be set in fine and precise steps.

Novelty content
The natural media used for tissue separation, such as physiological saline, do not burden the biological cell metabolism in any way. The application itself, i.e. the use of the liquid jet, does not cause any thermal side effects. The use of the water jet excels by virtue of its particularly high selectivity and represents one of the most sparing dissection methods. Through the novel principle of generating the water jet, it is possible to develop a compact, light and easy-to-operate system.

Improvements over existing solutions
ERBE has offered the Helix Hydro-Jet developed by Andreas Pein GmbH (later human med AG) for water-jet surgery since 2001. The experiences gained in the applications were utilized in the development of ERBEJET 2, which is based on a new technology. The new system concept allows the integration of additional devices (HF generators, argon plasma coagulators).

Individual data – indication-specific or for the respective operating surgeon – can be called up at the press of a button. The ReMode footswitch function, a “remote controller” from the operating table, allows the operating surgeon to change settings independently. The very high consistency of pressure from the new technology results in high precision. Unvarying and reproducible tissue effects can therefore be attained.
Qualitative benefit
The higher selectivity compared with conventional techniques spares blood vessels and nerves more effectively, which leads to lower blood loss. No thermal damage occurs in the surrounding tissue, which is why a higher percentage of residual, functioning parenchyma (organ volume) can be maintained. Scientific studies attest to short operation times (Rau et al.), as well as better and faster healing with significantly reduced length of hospitalization (Vollmer et al.). Ergonomic and light handpieces make work less fatiguing. Highly user-friendly and intuitive operation and uniquely matched accessories reduce the time spent in preparing the operation and training personnel.

Cost-benefit analysis
The cost-saving potential of using ERBEJET 2 is demonstrated with the example of a liver resection / partial liver resection. This compares the water jet technique, the ultrasonic aspirator and the “blunt” technique with mechanical instruments. Savings potential arises from shorter operation times, lower consumption of stored blood (both Rau et al.), lower procurement costs (up to 50%) and running costs (up to 11%), which also takes into account the wear on the handpiece calculated over two years. Furthermore, average costs of 50 € / operation minute and 75 € / stored blood are assumed. Approx. 21,000 in-patient operations on the liver are performed every year in Germany. (2004; InEK GmbH – Institute for the Hospital Remuneration System). Around a third of all these procedures are of relevance for the use of the water jet.

The overall saving potential with ERBEJET 2 amounts to more than 9 mil. Euro per year. Further savings potential exists from interdisciplinary use in fields such as urology, neurosurgery and gastroenterology.

Cost-benefit effect

<table>
<thead>
<tr>
<th></th>
<th>Blunt technique</th>
<th>Ultrasonic-technique</th>
<th>ERBEJET 2</th>
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</thead>
<tbody>
<tr>
<td>Costs of purchasing the device</td>
<td>0 €</td>
<td>61 600 €</td>
<td>35 000 €</td>
</tr>
<tr>
<td>Device costs per operation1</td>
<td>0 €</td>
<td>110 €</td>
<td>63 €</td>
</tr>
<tr>
<td>Material costs per operation</td>
<td>0 €</td>
<td>179 €</td>
<td>159 €</td>
</tr>
<tr>
<td>Operating time costs (per operation duration)</td>
<td>3 700 € (74 min.)</td>
<td>2 300 € (46 min.)</td>
<td>1 400 € (28 min.)</td>
</tr>
<tr>
<td>Costs for stored blood (per unit of stored blood)</td>
<td>375 € (x 5)</td>
<td>188 € (x 2,5)</td>
<td>113 € (x 1,5)</td>
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<tr>
<td>Saving potential operating time</td>
<td>2 300 €</td>
<td>900 €</td>
<td></td>
</tr>
<tr>
<td>Saving potential material costs2</td>
<td>40 €</td>
<td>142 €</td>
<td></td>
</tr>
<tr>
<td>Saving potential per operation</td>
<td>2 340 €</td>
<td>1 042 €</td>
<td></td>
</tr>
<tr>
<td>Number of operations per year</td>
<td>x 2 900</td>
<td>x 2 320</td>
<td></td>
</tr>
<tr>
<td>Total potential per year</td>
<td>6 786 000 €</td>
<td>2 417 440 €</td>
<td>9 203 440 €</td>
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</table>

1 For an amortization period of 8 years and an estimated 70 operations per device per year.
2 Savings in material costs = savings (stored blood / operating material costs / device costs.

Conclusion
Purpose
ERBEJET 2 is a water-jet surgical device for selective preparation of tissue, for example in the dissection of parenchyma tissue (e.g. liver, spleen, kidney, brain) while sparing the blood vessels and nerves. In water-jet dissection a very high pressure of max. 80 bar is generated by a fine water jet of 120 µm diameter, which is used to separate tissue.

Innovation
The water jet meets the tissue, which is separated and flushed away. The water jet also forms an expansion space in which the liquid forces the tissue apart. There exists a difference in sensitivity towards the dissection jet and the possibility arises through regulation of the pressure and flow rate of selectively separating certain tissue type while preserving others.

Saving effect
The overall savings potential in substituting existing devices with ERBEJET 2 amounts to more than 9 mil. Euro per year for visceral surgery. Further savings potential arises from interdisciplinary use in fields such as urology, neurosurgery and gastroenterology.

Water-jet dissection for parenchymal division during hepatectomy, (Vollmer et al.: HPB, 2006; 8:377-385)