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Experimental Study

A Biomechanical Evaluation of the Epidural Neurolysis Procedure

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Background: The epidural lysis of adhesions (ELOA) procedure supposedly has a biomechanical component in addition to the targeted injection of medications into the epidural space. It is assumed that the catheters used for the ELOA procedure can release epidural scars and adhesions.

Objectives: To evaluate the possible biomechanical effects of the typically used catheters and to put these effects into clinical perspective.

Study Design: Experimental study.

Setting: The biomechanical laboratory of an academic orthopedic surgery department.

Methods: Experimental setups were devised that allow for the measurement of the 3 main forces that can be exerted by manipulating a catheter in the epidural space or by injecting fluids through such a catheter: axial forces, torsional forces, and hydraulic effects.

Results: The maximum axial forces measured under extremely tight catheter guidance were 7 newton (N), whereas the maximum forces under conditions that more likely reflect a real treatment situation were between 1 and 2 N. The maximum torsional forces measured were 0.3 N under extremely tight catheter guidance and 0.01 N under more realistic conditions. The maximum flow that could be achieved through the typical catheter using normal saline and the maximum possible thumb pressure onto a 5 mL or a 10 mL Luer-Lock syringe was 0.48 mL/ s. Given these results and other data available to us, it appears impossible that the ELOA procedure with typically used catheters has any relevant mechanical effect.

Limitations: Like with any experimental study, the realities of an in vivo situation can only be modeled to a limited degree. The main limitation of our study is that we cannot calculate, measure, or simulate neither the flow resistance between an epidural adhesion pocket and the open, local epidural space nor the flow resistance between the open, local epidural space and the larger epidural space as well as the retroperitoneal space.

Conclusions: According to our findings and arguments, the ELOA procedure is predominantly a method for the highly targeted application of epidural medications and possibly also has a lavage effect. A mechanical lysis of scars or adhesions appears unlikely.

Key words: epidural lysis of adhesions, epidural neurolysis, epidural neuroplasty, biomechanical, experimental, epidural, catheter, back pain, sciatica

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The epidural lysis of adhesions procedure (also called "epidural neuroplasty" or "epidural lysis of adhesions and spinal injection via catheter," hereafter shortened to ELOA) is a popular therapy for sciatica with and without low back pain, caused by postsurgical scarring, postinflammatory epidural scars or by epidural adhesions of other origin (1-10). In a previous paper, we examined some of the

pharmacological aspects of the particular combination of drugs employed for this procedure (6). The study presented here is a laboratory evaluation of the other aspect of the ELOA procedure: the biomechanical component of releasing epidural adhesions or scars. The clinical relevance of epidural adhesions (postsurgical or of other origin) and of the changes in epidurographic filling defects with ELOA is controversial (7,8). While the existence of postsurgical and postinfectious epidural scar tissue (also called epidural fibrosis) is universally accepted and the proof is often evident during revision spinal surgery, the existence and the clinical relevance of epidural adhesions from other origins are much less so. Nevertheless, the original descriptions of the procedure clearly imply a mechanical component as being part of the ELOA procedure (9,10) and a fair number of other studies deal with this particular phenomenon. Since no data characterizing the biomechanical aspects of the catheters typically used for ELOA were available, we decided to investigate what forces can be generated when manipulating such a medical device in the epidural space, what the potential biomechanical effects would likely be, and whether it is probable that mechanically relevant scars or adhesions could be released by doing so. Based on the original description of the ELOA procedure and the properties of a typically used catheter, we defined 3 different types of forces that could possibly have a biomechanical effect in the epidural space and that were to be evaluated separately. First, there is the force transmitted by the catheter tip onto the adjacent tissue when a catheter is pushed forward in an axial direction – hereafter termed "axial force." Second is the force transmitted by the catheter tip onto the adjacent tissue when a catheter with a bent tip is torqued (rotated) around its longitudinal axis – hereafter termed "torsional force." The authors are aware that this torsional mechanical effect is not part of the original description of the technique. But since it is a possible distinct mechanical effect of manipulating the catheter inside the epidural space, it was decided to include it in the study for reasons of completeness. Third is the distending pressure and/or shear force that is generated between the dura and adherent tissues by forcefully injecting a fluid volume into a pocket of adhesions via the catheter, hereafter termed "hydraulic effect."

Objective

To evaluate the potential biomechanical component of the ELOA procedure in an experimental setting.

Methods

Catheters

All catheters used for these experiments were standard Tun-L-XL catheters (Epimed, Gloversville, NY), obtained through the official German distributor. The axial and torsional force measurements were performed with the guide wire lodged firmly inside the catheters, whereas for the hydraulic effect testing, the guide wires had to be removed.

Force Transducer

We used an S2/20N force transducer to measure axial and torsional forces (Hottinger Baldwin Messtechnik GmbH, Darmstadt, Germany).

Testing Setup for Axial and Torsional Force Measurement

When a long, flexible catheter is axially advanced against resistance, it has the tendency to flex and coil, which limits the amount of force that can be transmitted via the catheter tip onto the material that offers the resistance. The amount of flexing and coiling that can occur is mainly determined by the size and the shape of the space through which the catheter passes, as well as the free length of the catheter within this space. Since the epidural space has a very complex configuration and since its size and shape have great interindividual variability, it can only be modeled in a simplified fashion. The underlying principle, however, remains that a catheter can exert the most force when it is guided very tightly and the least force when it is allowed to flex and coil. Since we were interested in the range of forces that can be expected between the extremes of a very loosely and a very tightly guided catheter, we decided that a simplistic surrogate canal would be an acceptable model for this specific purpose. We therefore chose tubes of different internal diameters (1.15 mm, 3 mm, 7.7 mm and 15.8 mm) in order to simulate a wide range of anatomical situations. The length of these tubes was measured as being 15 cm from an anatomic spine model (Sawbones Europe AB, Malmö, Sweden) as the anatomical distance inside the spinal/sacral canal between the sacral hiatus and the disc level L4/5 as the most common location for discogenic pathologies. A special testing setup was constructed to allow for the exact and reproducible pushing of the catheter tip through one of the 4 different tubes against the force transducer, which was attached at a 00 angle for axial force measurements and at a 900 angle for torsional force measurements. For torsional forces mea-

surements, the catheter tip with the indwelling guide wire was bent at an angle of 30° precisely one cm from the tip, using a specially made bending template. The catheter tip was then pushed against the force transducer by torquing (rotating) the catheter (and the guide wire) inside the respective tube (Figs. 1 and 2). To examine whether manual control over the catheter is influenced by wearing surgical gloves, we performed the first series of experiments (axial force measurements) while wearing latex surgical gloves and then without gloves. Based on the results of the axial force measurements, the torsional force measurements were only performed while wearing latex gloves. To control for variability, a set of n = 40 measurements was acquired for each measurement point.

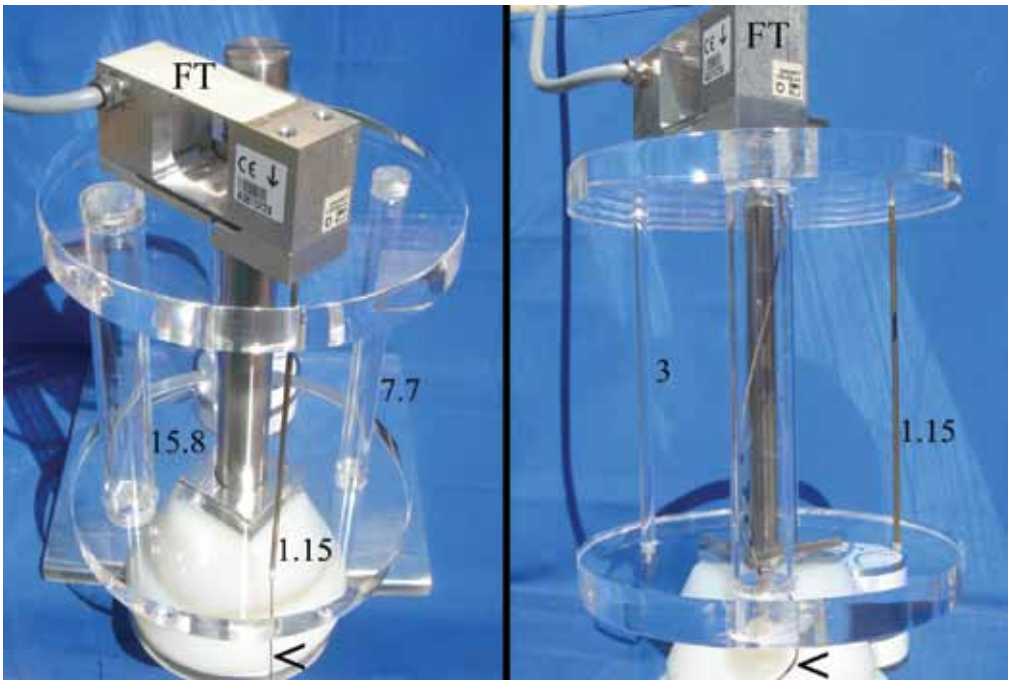

Fig. 1. *The dedicated apparatus that was used for guiding the catheters (<) through different diameter tubes of 15 cm length against the force transducer, which is mounted in the position for axial force measurements. The tubes are labeled with their internal diameter (1.15 mm, 3 mm, 7 mm and 15.8 mm). In the left half-image, the catheter is tightly guided through the tube with 1.15 mm internal diameter. In the right half-image, the catheter can be seen flexing inside the widest (15.8 mm) tube.*

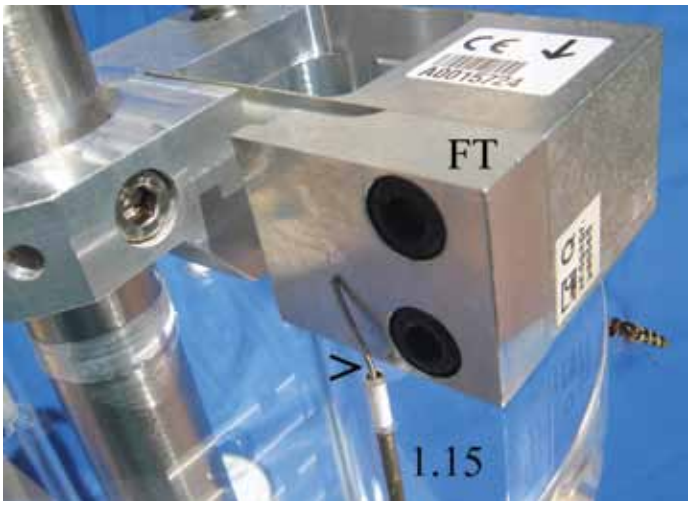

Fig. 2. *A close-up view of the same apparatus with a prebent catheter (>), tightly guided inside the 1.15 mm tube and being torqued against the force transducer. Note Phil, the lab fly.*

Thumb Force Determination

Since no literature data were available as to what forces could reasonably be expected from a thumb pressing onto a syringe plunger, we performed a preliminary study with n = 40 volunteers (all between 18 and 45 years old with one exception in the 55 to 65 years age group, a man to woman ratio of 34:6, the ratio of orthopedic surgeons to other professions 19:21). All volunteers were asked to perform a single uninterrupted forceful flexion (maximum force possible) with their dominant thumb using a specially constructed apparatus with a syringe grip and plunger and a spring scale to measure forces.

Testing Setup for Hydraulic Effect Measurement

The hydraulic effect of forcefully injecting a fluid through a catheter into a more or less enclosed space (such as an epidural adhesion pocket) depends on a large number of variables. On the catheter side, the most important of these are length, internal diameter, internal surface structure, and flow characteristics (laminar versus turbulent). On the side of the fluid, its viscosity and the pressure by which it is forced through the catheter are most important. The latter is in turn dependent on the size of the syringe used and on the force that is applied onto the syringe plunger. A testing setup was constructed to allow for prefilled syringe catheter-assemblies to be mechanically "injected" by a biomechanical testing machine (Z010/TN2A, Zwick GmbH & Co. KG, Ulm, Germany) while the applied pressure and the resulting flow were automatically registered and saved into a database by means of an attached computer workstation and a dedicated software package (TestExpert Version 12.1, Zwick GmbH & Co. KG, Ulm, Germany). Luer-lock syringes (Becton Dickinson, Germany) with 5, 10 and 20 mL volume were used for this experiment in order to test the most common clinical options. For the testing fluid, we decided on normal saline because we were interested in determining the highest possible flow through the assembly and because a low-viscosity fluid will perform better in this sense than a high-viscosity fluid (e.g., contrast medium). One hundred seventy data pairs (force versus flow) were acquired for the evaluation of the flow characteristics of the syringe-catheter combination. The forces measured in this experiment were later used to interpret the findings in the hydraulic effect experiment.

Statistical analysis

Results are presented as the mean ± standard error of the mean (SEM) unless stated otherwise. Since this was an investigation for principle and no specific hypothesis was to be tested, we decided to present our results using descriptive statistics only.

Results

Axial Forces

The measured axial forces using the 4 different tubes are displayed in Fig. 3. It is obvious from this data that wearing latex surgical gloves allows for a more forceful and controlled manipulation of the catheter. As can be seen, the absolute maximum axial force of 7 newton (N) was generated when the catheter (with indwelling guide wire) was guided by a very narrow tube of 1.15 mm internal diameter and 15 cm length. This force would translate to 700 g of weight in the Earth's gravity field. With wider tubes and their lesser guidance for the catheter, which is more realistic in relation to the anatomical situation in the caudal and spinal canal, the measured forces were considerably lower. Assuming that a tube with an internal diameter of between 8 and 16 mm probably comes reasonably close to many clinical situations, axial forces of between 1 and 2 N (equivalent to between 100 and 200 g of weight) are to be expected when a catheter is advanced with force against tissue resistance.

Torsional Forces

When the catheter (with indwelling guide wire) was torqued, the forces measured where the bent catheter tip pressed against the force transducer were minimal and never exceeded 0.3 N, which is equivalent to 30 g of weight (data displayed in Fig. 4). Even these minimal forces could be measured only when using the narrowest tube (internal diameter 1.15 mm). The forces measured when using the tube with 3 mm internal diameter never exceeded 0.01 N (equivalent to one g of weight) and no forces at all could be measured when using the 2 larger tubes.

Thumb Forces

The thumb forces that were recorded with the syringe-plunger apparatus were higher for the orthopedic surgeons group, averaging 71 N ± 12 (SEM) and with a range from 40 to 100 N. The group with other professions generated a slightly lower average thumb

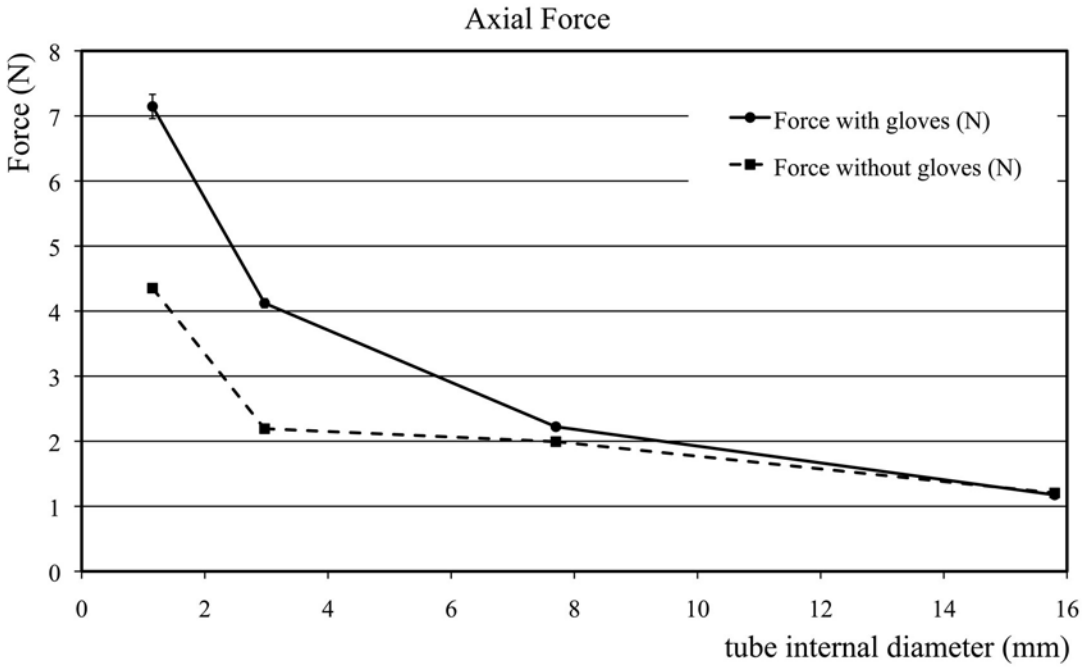

Fig. 3. *The forces generated by axially pushing the catheter against the force transducer using different diameter tubes and with surgical gloves or without surgical gloves. Error bars represent the standard error of the mean, but for most data points are too small to be displayed.*

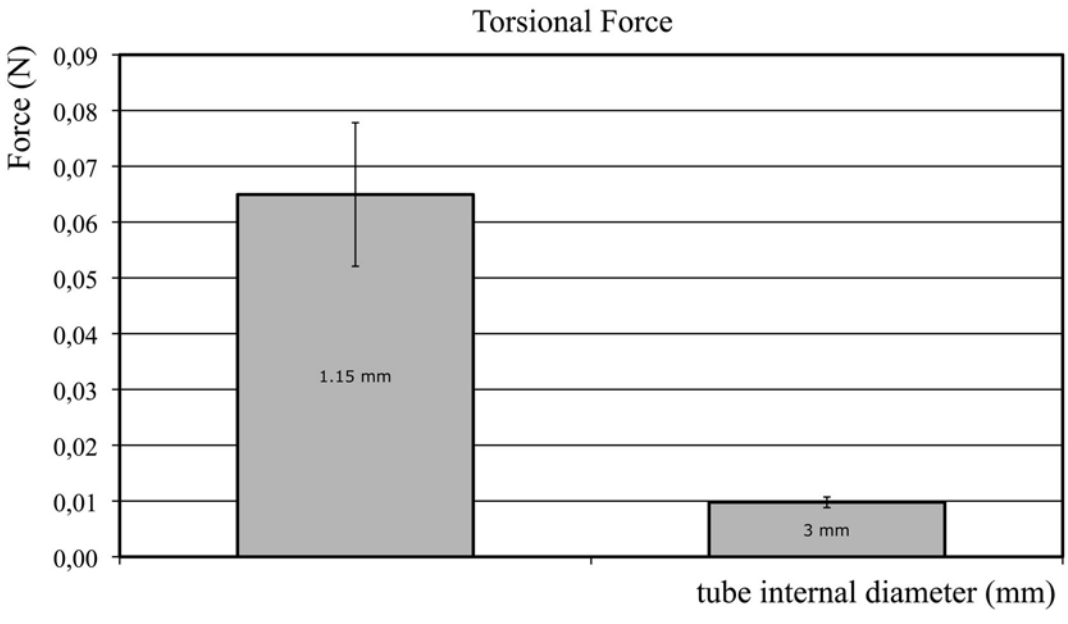

Fig. 4. *Shows the forces generated by torquing the bent catheter tip against the force transducer using different diameter tubes and with surgical gloves. Error bars represent the standard error of the mean.*

force of 56 N ± 16 (SEM) and with a range from 35 to 80 N. All of these forces represent a true maximum effort on behalf of the participating individuals and are probably considerably higher than the forces that the same individuals would be applying in a clinical situation. Nevertheless, these results indicate that for the purpose of our study, thumb forces of around 71 N need to be considered.

Hydraulic Effects

Figure 5 displays the data generated when testing a 10 mL Luer-Lock syringe attached to a catheter, with varying forces applied and with repeat measurements. When displaying the data points in a dot plot, it becomes clear that at lower pressures there is a linear relationship between the pressure applied onto the syringe and the flow. Starting at around 0.4 megapascals (MPa), the curve flattens out in an asymptotic fashion, which means that higher pressures no longer generate a higher flow. The maximum volume flow that could be generated was 29 mL/min and this was achieved only with 5 mL and 10 mL syringes, where the maximum orthopedic thumb force fell into the asymptotic section of the pressure/flow - curves. When putting the measured thumb forces into perspective to these measurements, and when relating them to the pressure / flow – curves of the different syringe sizes (Fig 5, Table 1), it becomes obvious that somewhat less than 0.5 mL per second can be injected through such a catheter under the best of circumstances and only when using a low-viscosity fluid. Obviously, smaller flow volumes are to be expected when using a more viscous fluid, such as contrast medium or when using more reasonable thumb pressures.

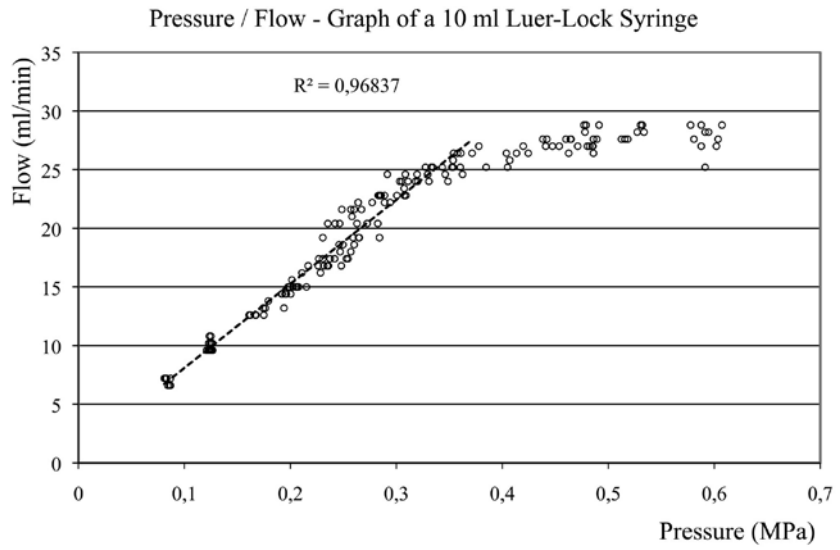

Fig. 5. *Dot plot of the flow/pressure relationships when using a 10 mL Luer-Lock syringe filled with normal saline and attached to a Racz Tun-L-XL catheter. N = 170 data pairs were acquired. From about 0.4 MPa on, there is no longer an increase in flow with increasing pressure. The maximum flow achievable is 29 mL/min for normal saline, equating to somewhat less than 0.5 mL /s. R2 is the coefficient of determination, where a value of one represents an ideal linear relationship between 2 variables. Our calculated R2 of 0.96837 therefore indicates a near perfect linear relationship between pressure and flow for the linear section of the curve.*

Table 1. *Pressure/Flow – Relationships for Different Syringe Sizes.*

Syringe Volume (mL)	Plunger Diameter (mm)	Plunger Surface Area (mm2)	Force (N)	Pressure (MPa)	Flow (mL/min)
5 mL	12.3	118	71	0.60	27.6
10 mL	15.6	190	71	0.37	26.4
20 mL	18.9	281	71	0.25	17.4

Table 1 calculates the pressures generated inside a typical 5, 10 and 20 mL Luer-Lock syringe when pressing onto the plunger with 71 N (average maximum thumb force measured with orthopedic surgeons). These pressures were then correlated with the experimental pressure/flow curves (as shown for a 10 mL syringe in Fig. 5) and the corresponding volume flows were read. According to our measurements, the largest volume flows can be achieved with 5 mL and 10 mL syringes and in both cases, they are on the asymptotic end of the curve. This means that higher pressures (greater thumb forces) cannot generate higher flows. The flows measured are representative only for water-like, low-viscosity liquids. Highly viscous contrast medium will generate much smaller flows.

Discussion

It is the declared goal of the ELOA procedure to go beyond the epidural injection of medications and to exert mechanical effects in the epidural space, which supposedly are capable of releasing postsurgical scars and epidural adhesions from other origins. Based on an analysis of the potential nature of such effects, we defined and subsequently studied 3 types of forces in the framework of a biomechanical testing setup: axial forces, torsional forces, and hydraulic effects. Any in vitro experiment inevitably has the limitation of more or less imperfectly modeling the realities of a clinical situation inside a living human body and this study is no exception. While our model simplifies the way a catheter behaves in the human epidural space and the way by which flexing and coiling is limited in a real anatomical setting, we believe that our experiments nevertheless provide good data on what axial and torsional forces can reasonably be expected. The most significant limitation is probably not being able to assess the speed, the flow, and the resistance of fluid exiting the spinal epidural space via the neural foramina into the retroperitoneal space and of fluid escaping to adjacent levels of the epidural space (cranially and caudally). It would be extremely difficult to model such a situation and very large interindividual variations are to be expected based simply on the large anatomical differences between patients. We therefore cannot know for sure whether the passageway from an epidural adhesion pocket into the local "open" epidural space or the passageway from the local "open" epidural space into the larger epidural space and into the retroperitoneum represents the main point of resistance. In our view, however, it seems very likely that the exit area from a local epidural adhesion pocket would be the point of greatest resistance. Having said that, an opening from such an epidural adhesion pocket that offers less flow resistance than the catheter itself will effectively prevent the generation of any significant pressure inside the pocket. Given the length of the catheter and its internal resistance, such an opening could even be smaller in diameter than the internal diameter of the catheter and still be effective in that sense. This is why we do not believe that the small volumes that can be injected rather slowly (at an absolute theoretical maximum of 0.48 mL/s) through such a catheter would ever lead to a relevant hydraulic effect. To better understand these implications, it may be helpful to imagine the complete system from the syringe all the way to either the "open" epidural space (or the retroperitoneal space for that matter) as a closed hydraulic system. In such a system, the highest resistance will to a large extent determine the total flow. The more important fact though is that when a lower resistance follows a higher resistance, there is no pressure being built up in front of the lower resistance. The maximum axial force measured in our experiments was 7 N, but this measurement was performed using extremely tight guidance for the catheter, which cannot reasonably be expected to parallel a real life situation. The forces that likely can be generated under more realistic conditions range between 1 and 2 N (100 to 200 g in Earth's gravity field). Our measurements suggest that it is near to impossible that the axial forces transmitted by the catheter would be capable of releasing real scar tissue in the epidural space. The torsional forces we measured were minimal as expected and we did not expect any meaningful mechanical effect from torqueing the catheter beyond directing it to either side. Anyone experienced with revision spinal microsurgery knows how tough and resistant these collagenous scars are and that in many cases, serious traction and a sharp blade are required to remove them from the epidural structures and from the thecal sac. There is very little experimental data on the tensile strength of scar tissue and none of the published studies specifically examined human epidural scar tissue. The data that are available, however, indicate that the forces required to rupture 4- to 10-week-old scar tissue in pig skin are in the range of 60 to 90 N (11,12). Another biomechanical experiment on 6-week-old skin scars in rats found that in 50% of cases, specimen rupture did not occur at the suture line, but rather through the uninjured skin (13). So on the background of that data, and given the measurements that we obtained, it

appears unconceivable that the catheters typically used for the ELOA procedure can physically modify mature epidural scar tissue in any meaningful way. As far as (nonpostsurgical) epidural adhesions are concerned, the prevalence, origin and the exact anatomical characteristics of such adhesions have not yet been studied in a way that would silence critics. The existence of such adhesions has been postulated by some authors based on the observation of an increased contrast medium spread when comparing the epidurograms obtained before and after performing an ELOA procedure. While such observations will remain a subject of interpretation until hard data become available, there are possible explanations other than implying that adhesions must have been present and that these must have been resolved by the procedure. It is just as well conceivable that after lavaging the epidural space with considerable amounts of fluid, areas within the epidural space that had been comparably "dry" prior to the procedure are wetted after the procedure and therefore offer less flow resistance toward the highly viscous contrast medium than prior to the procedure. The use of hypertonic saline solutions might also temporarily reduce the volume of epidural tissues by extracting water from them, thus transiently generating more space for fluids to flow through. Other data supporting the existence of such adhesions originate from transhiatal epiduroscopies with low-resolution, flexible endoscopes (2,14-19). First, it is well understood, that contrast medium, like any fluid, will follow the path of least resistance and that therefore the complete epidural space may not necessarily fill up with contrast medium when contrast medium is injected at one specific location. Second, under normal and healthy anatomical conditions there may be fine connective tissue septa oriented parallel to the neural axis, linking the dural sac to the osseous spinal canal and thus subdividing the epidural space and the epidural fat when it is present (20,21). With the limited optical capabilities of low-resolution flexible fiberscopes, such naturally occurring septa or their remnants might by misinterpreted as epidural adhesions while representing normal anatomy. Beyond that point though, only one of the studies mentioned above exclusively included patients without previous surgical interventions (16) while one other study included patients with, as well as without, previous spinal surgery (15). Only the paper by Igarashi et al (16) includes exemplary images and only one of these low-resolution images displays a very thin, localized connective tissue bridge between the dura and surrounding epidural structures. Both of the above studies, however, used the targeted injection of a steroid and of a local anesthetic in addition to the "mechanical breakage of adhesions," so that no conclusions can be drawn as to the relative effectiveness or ineffectiveness of the mechanical part of the procedure. Considering in addition that no studies so far have correlated either of the observations mentioned above with an anatomical structure (for example during surgery or as part of an anatomical study), the evidence supporting the existence and the clinical relevance of such adhesions (not of postsurgical scarring) as a source of pain remains thin. The consideration of whether the ELOA procedure might be capable of breaking these structures of questionable existence and clinical relevance would therefore be pure speculation. However, since the volumes of liquids that are injected into the epidural space during the ELOA procedure are much higher than those injected, for example, with transforaminal nerve root blocks, an additional lavage effect reducing the local concentration of proinflammatory cytokines seems conceivable and some literature points into that direction (22-24). Such a lavage effect has also been implicated in the discussion surrounding the effects of (sham) knee arthroscopy in osteoarthritis ever since the Moseley trial (25). It should be extremely interesting to compare the clinical effects of the ELOA procedure to an equivalent (by means of number of injections and dosage of medications, but with different total injectate volume) series of transforaminal nerve root blocks in a prospective, controlled and observer-blinded study.

Conclusion

In summary, our data suggest that the ELOA procedure is primarily a very targeted method of injecting medications into the epidural space and not a mechanical tool.

An additional lavage effect, reducing the local concentration of proinflammatory substances seems possible.

A true mechanical lysis of postsurgical adhesions (i.e., scar tissue) by means of the ELOA procedure appears to be impossible.

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