Proceedings of the 28th IEEE
EMBS Annual International Conference
New York City, USA, Aug 30-Sept 3, 2006

Development of a compliant device for minimally invasive surgery

P. Meier, S. Oberthür and M. Lang
Technical University Ilmenau, Faculty of Mechanical Engineering
PO 100565
98693 Ilmenau, Germany

***Abstract*- A Peristaltically Actuated Device for Minimally Invasive Surgery (PADeMIS) is being developed at Technical University of Ilmenau. PADeMIS will be manufactured from silicone rubber and its design is being optimized by finite element analysis (FEA). Due to the small dimensions of the device an extensively automated fabrication technology, based on lithography, is developed. Furthermore, a controlling unit is built up.**

I. Introduction

At present in minimally invasive surgery (MIS) the surgeon pushes rigid trocars through the tissue to the operation field. The trocar is used for guidance of optics and manipulation tools. Especially in sensitive areas, there is a high risk of injuries for patient or this technique is not practicable, e.g. inside the vertebral canal. A fully compliant structure without the risk of injuries for the surrounding tissue and self actuated crawling to the operation field, would be a great improvement. So it is the aim of our research to develop a peristaltically actuated device for minimally invasive surgery, whose primary application is the minimal invasive spine surgical treatment of herniated discs. The device moves actively like an earthworm and carries a hollow tube behind its back. The tube and PADeMIS are providing a canal to insert endoscopic tools and miniature cameras into the operating field as well as administering drugs in situ of the surgical target.

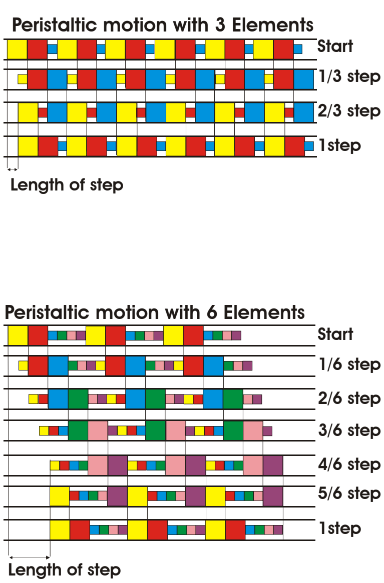

Fig. 1: Visualization of the locomotion principle for a device with 3 (top) respectively 6 (bottom) segments. With Δl difference between filled and unfilled segment length and filling time Δt, the resulting velocity for device with n segments results in $\frac{(n\text{-}2)\cdot\Delta l}{n\cdot\Delta t}$.

Fig. 2: PADeMIS (red) way in the vertebral cannel. The device runs a tube (green) for endoscopic tools.

PADeMIS consists of serial arranged segments. Each segment contains cushions, which can be filled hydraulically. Filling the cushions of different segments periodically leads to the desired peristaltic locomotion, see figure 1.

A possible progress of a spine surgery with PADeMIS is the insertion of the device at sacral bone (os sacrum), crawling to e.g. a herniated disc (see fig.2) inside the epidural space, removal of herniated disc through the inner opening, crawling to a second herniated disc, …, and at least extraction of the device. Thus, spine morphology and surgical requirements define the dimensions of PADeMIS. The outer diameter has to be alterable from 4 to 8 mm. In order to insert the endoscopic instruments an inner diameter of at least 2.5 mm has to be provided. Thus, the material has to endure large deformation and large strains periodically and must be medically proven. Hence, the liquid silicone rubber (LSR) MED 49xx from Nusil distributed by Polytec® is chosen. (xx indicates the shore hardness of the silicone rubber adjusted with silica filler by the manufacturer.)

The design of the segments is optimized by finite element analysis (FEA), an extensively automated technology for fabrication of the device monolithically and a controller for filling of the cushions is build up and these processes will be presented here.

II. Design optimization with FEA

The constitutive law for the FEA is determined experimentally by uniaxial and equibiaxial tension tests. Silicone rubber shows the Mullins effect and stress softening for successively tension tests. Nevertheless a hyperelastic Mooney- Rivlin- model is used as constitutive law. After some load cycles the LSR MED 49xx follows the pre- strained stress strain relation. Thus, the pre-stressed

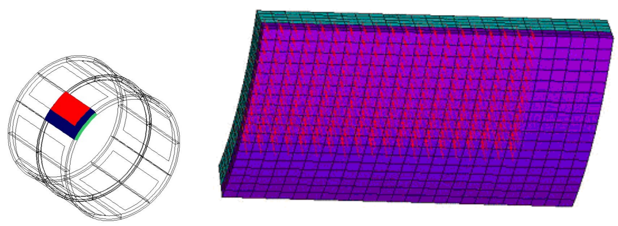

Fig. 3: Left: Worm segment with 6 cushions; the simulated section is colored, which can bee seen in the right part in detail. The different blue colors indicate the 2 silicone layers and in red the applied pressure is shown.

Med 49xx curve is used for the calculations concerning PADeMIS. Details of the tension test and evaluation of the constitutive law can be found in [1], [2].

The simulations are performed predominantly with Ansys® using the hyper58 element and the pre-strained constitutive law. To validate the results some simulations were performed with MSC.Marc® using a constitutive law including Mullins effect and stress softening.

A. Model of segment

Due to the manufacturing technology each segment is build up from two thin cylinders of silicone rubber. The cylinders are separated in the area of the cushions and connected to the rest of the structure. The model is build up as small as possible and will be complemented by boundary conditions. For steering of the worm at least 3 cushions on each segment are needed. Figure 3 shows a segment with 6 cushions and the simulated section.

B. Method

The filling of the cushions is simulated by increasing pressure in the areas of the cushions. The optimizations criteria are alterable outer diameter, remaining inner diameter and length increase in dependency from the applied pressure. For controlled crawling a steady length increase of the segment is necessary.

Parameters for the optimization process are the shore hardness and thickness of the LSR layers, number, arrangement, form and aspect ratio of the cushions. Due to the manufacturing technology no enhancement inside of the silicone layer and no partly thickening of the layer is possible.

C. Resulting design

Filling a cushion or a balloon with a surrounding tissue of rubber like material always causes a bubble like shape in the beginning and leads to a length decrease. By continuing the filling the tissue becomes strained and the length increases.

A segment made of MED 4950 built up with 3 cushions fulfills the criteria approximately (see fig. 4):

1. The outer diameter is alterable between 4 and 7 mm
2. The inner diameter remains larger than 2.5 mm.
3. The increase of the length occurs steady in dependency of increasing pressure

The thickness of the undeformed silicone layer is in the range of 100-300µm, the cushions have dimension of a few millimeters and the width of the supply tubes connecting the cushions are between 300-1000µm. Hence, an extensively automated technology for manufacturing the device monolithically with as few as possible hand operated mounting steps is needed.

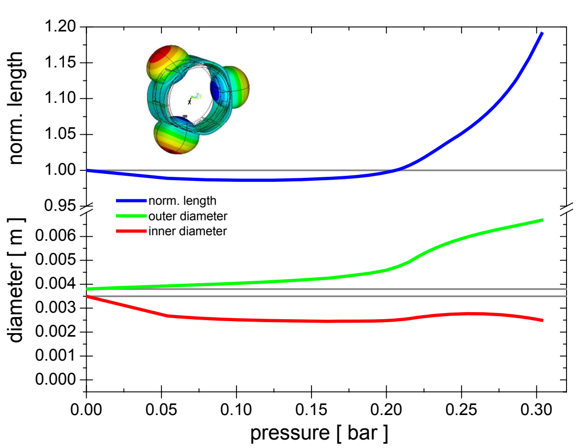

Fig. 4: Deformation in depending on the pressure. Inset shows corresponding design.

III. Lithographic facility

A facility adapting a lithographic process (see fig. 5) to silicone rubber is build up. For production of PADeMIS the following steps have to be performed:

1. Alignment of the substrate
2. Measuring diameter of the substrate
3. Application of separating photo resist (PR) layer to the substrate
4. Tempering of PR layer
5. Measuring thickness of PR layer
6. Application of LSR layer
7. Tempering of LSR layer
8. Measuring thickness of LSR layer
9. Application of photo resist (PR) layer
10. Measuring thickness of PR layer
11. Exposing and developing of PR layer to obtain cushions and supply tubes
12. Application of LSR layer
13. Tempering of LSR layer
14. Measuring thickness of LSR layer
15. Solving of resist of separating layer and inside cushions
16. Filling of cushions

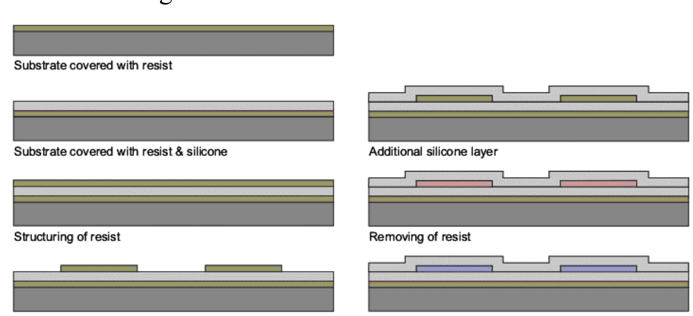

Fig. 5. Lithographic process for manufacturing of PADeMIS

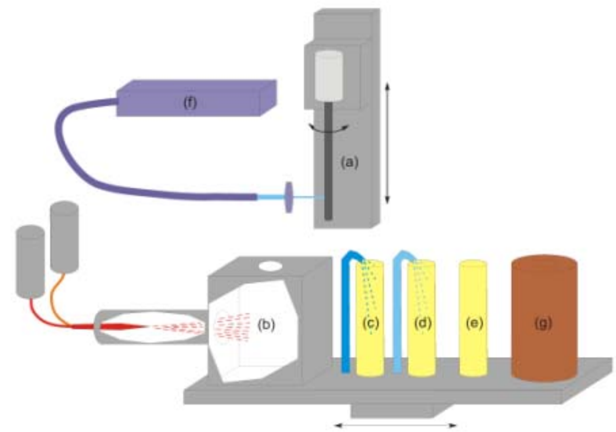

Fig. 6: Schematic Setup of lithography facility: a) Substrate; b) Spray-coating PR; c) Developing PR; d) Rinsing; e) Dip coating LSR; f) Exposing; g) Tempering

The steps are described in detail, consecutively. A schematic illustration of the facility shows fig. 6, the realized facility is shown in fig. 8.

A. Mechanical setup

Due to the cylindrical design of the device a rod with 3.5mm diameter is used as substrate. The thermal isolated substrate is mounted on piezoelectric motors, which are fixed to a rotating motor. The piezoelectric motors align the axis of the substrate and the rotation. The rotation unit is mounted at a linear motor performing a vertical movement.

Workplaces for PR and LSR coating, tempering, solving and rinsing are located on another linear motor performing a horizontal movement. The exposing unit is moved by a pressure cylinder toward the substrate. An optical measuring unit allows determination of the tilting of the substrate, determination of the actual diameter of the coated substrate

Fig. 7: Realized Setup of lithography facility

during the process and measurement of the distance between

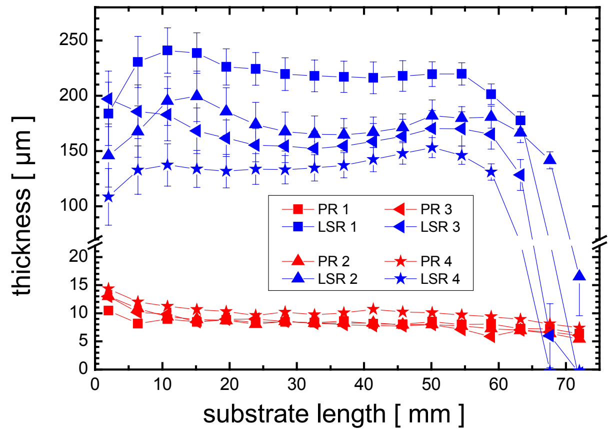

Fig. 8: Thickness of photo resist and liquid silicone rubber layer.

coated substrate and focusing lens. The facility is controlled by a LabView® program. Fig. 7 shows the realized Setup.

B. Spray coating of photo resist

In planar setups spin coating of photo resist is the most common technique. Unfortunately with the used cylindrical setup it is not possible. Also, in some preliminary tests dip coating proved out to be not practicable with PR on LSR. But, spray coating of the positive resist SX AR-P1250/12.2 mixed with thinner X AR 300-12/1 (both from ALLRESIST®) sprayed with automated spray nozzle Mikro3 from Krautzberger results in approximately homogenous layers of adjustable thickness. Normally, layers of 8-12µm ± 3µm thickness are used. (Admittedly, is the accuracy of the measuring setup 2-3µm also.) Fig. 8 shows the resulting PR layers.

C. Exposing and developing of photo resist

For exposing of the second PR layer a He-Cd-Laser (PLASMA HCL30Ymc) with a 10mm lens focusing the beam to approximately 30µm is used. The lens is adjusted according to the actual average thickness of the coated substrate, the beam is shut by a rotating magnet and the substrate is moved by the rotating and the vertical motor in front of the lens to obtain the desired structure.

Then the resist layer is developed (AR 300-26 mixed with deionised water) and rinsed in deionised water, afterwards.

C. Dip coating of liquid silicone rubber

The two components of MED 4950 are mixed and diluted in n-Hexane to obtain a low viscous fluid afterwards. Dip-coating is performed by lowering the substrate into the LSR solution at a constant velocity. Afterwards the substrate is pulled out with a ramped velocity profile. Viscosity of the solution and raising velocity affect thickness and homogeneity of the dip-coated layer significantly, as reported before [3]. After each dipping substep the n-Hexan is allowed to evaporate from the solution and partly cured. Then the dipping is repeated until the desired thickness of the LSR layer is reached. At least, the LSR layer is annealed completely. The resulting silicone layers are homogenous within 11%. Fig. 8 shows the resulting LSR layers.

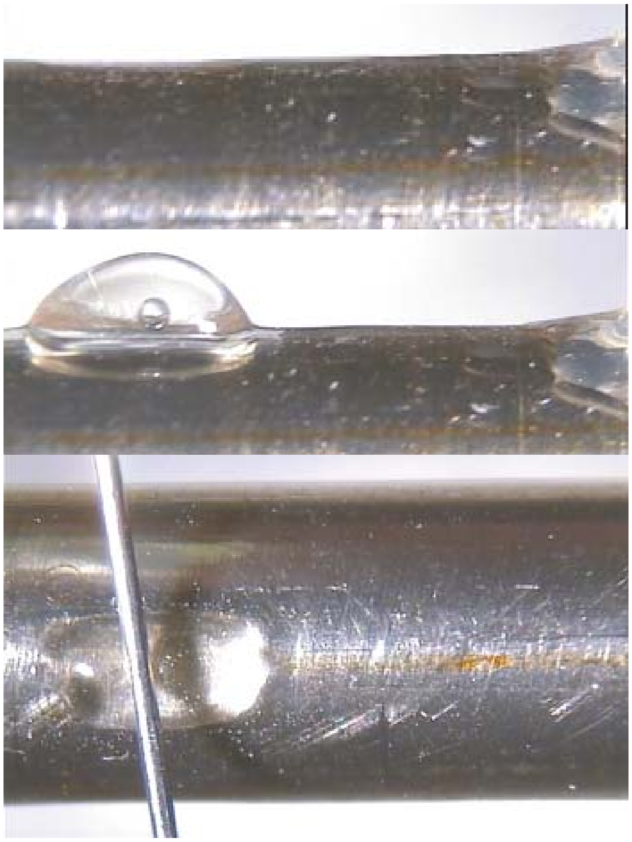

Fig. 9: Produced Test Structure with 1 cushion and supply tube. Top: Side view of unfilled cushion; Middle: Side view of filled cushion; Bottom: Top view of filled cushion with 300µm needle for size comparison.

D. Tempering of photo resist and silicone rubber

A tube furnace is made from 300W heating coils wrapping a aluminum pipe. The temperature can be adjusted within 5°C with a distribution of less then 5°C over the substrate length. Fig. 9 shows a test structure of one chusion with supply tube.

IV. Controller

The cushions of PADeMIS will be filled with physiological infusion solution to avoid injuries of the patient in the case of leakage. For the same reason the control unit works volume controlled and measures the pressure. To allow steering of the device at least 3 cushions per segment are needed. For the peristaltic locomotion at least 3 segments in serial arrangement are needed, but an arrangement of six segments moves twice as fast (assuming same time for filling). This 3 or 6 segment unit can be repeated serially to improve the wall contact of the device. Therefore a control unit piloting 18 ducts is built up. The 18 ducts are subdivided in three identical slave units, controlled by a master unit. Each duct is made up by an injection driven by a servo motor. The controller is shown in fig. 10, for details see [4]. Limited by the diameter of the supply tube the filling of the cushions takes at least 0.5 s and this will result in a locomotion velocity of approx. 5 mm/min.

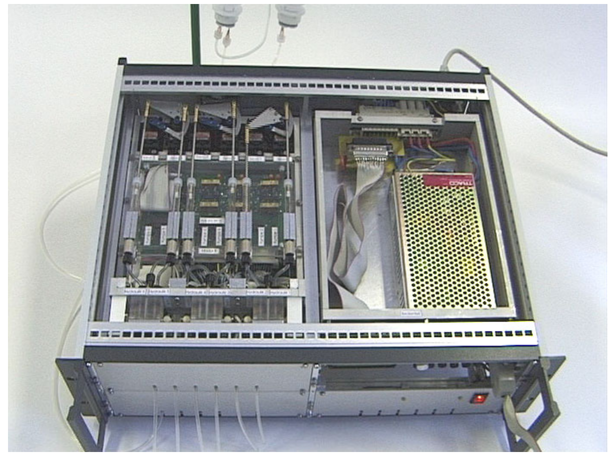

Fig. 10: Controller for a device with 18 ducts.

V. Conclusion

For a couple of incisions in MIS a compliant structure replacing the common rigid trocars would be preferable. Therefore a self crawling device is developed primarily for replacement of herniated discs. For fabrication of the device a lithographic facility is built up, allowing fabrication of cylindrical structures with medical proven material. For a short time, all process steps work satisfactory, so the first devices will be produced soon and have to prove PADeMIS practicability in animal tests.

Furthermore the technology allows production of similar devices with other applications, e.g. surgery inside the bronchia and also other devices like grippers, bending elements, etc made up from cylindrical basic form.

Acknowledgment

The authors thank Dipl. Ing. Roman Preuss for the starting design of the lithography facility and a couple of basic ideas. Alike we thank Dipl. Ing. Mike Stubenrauch for some ideas in the beginning and for revising the manuscript as well as Friedrich Meyer for performing preliminary tests with photo resist.

The authors thank Dr. H. Böhm, MD (Spine surgery, Zentralklink Bad Berka GmbH), for his inspirational input towards the project.

Furthermore we would like to thank the TKM (Ministry of Education of Thuringia) for financial support of the research group PADeMIS.

References

[1] P. Meier, S. Khader, R. Preuß, J. Dietrich and D. Voges, "Uniaxial and equi- biaxial tension tests of silicone elastomer", Constitutive Models for Rubber III, Busfield & Muhr (eds), Swets & Zeitlinger, Lisse, ISBN 90 58095665, pp. 99-106, 2003.

[2] P. Meier, M. Lang, S. Oberthür, "Reiterated tension testing of silicone elastomer", Plastics, Rubber and Composites, vol.34, p.372-377, 2005.

[3] C. J, Brinker and A.J. Hurd, "Fundamentals of sol-gel dip-coating", Journal de Physique III, 4, 1231-42, 1994.

[4] S. Oberthür, P. Meier, "Regenwürmer als Vorbild für medizinische Instrumente - Ansteuerung für eine peristaltische Sonde aus Silikon", Mechatronik F&M, Vol. 113, No: 11-12. p. 22-25, 2005.