Szent István Egyetem

MECHANICAL SOLUTIONS IN UROLOGY

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Az iskolavezető jóváhagyása A témavezető jóváhagyása

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1. INTRODUCTION, GOALS

A significant part of the human urinary flow system diseases consist in retention and incontinence. By the civilized man the removal of urine and feces at a later age is not without problems. Not only health but also social aspects play a significant role in this seemingly natural process.
The number of the elder rationally rises with the rise of the average age in the developed and developing countries. 22% of the population is over 60 years old nowadays; this number will be over 30% in 2030.
20% of 65-69-year-olds are affected by problem to hold urine or to urinate; this number is 40% over the age of 70. It is significant with regard to the medical point of view that we talk about a group of people who suffer from illnesses in general, whose immune system is weaker from the average and whose movements are limited in most cases, therefore these diseases could unfortunately mean danger to their life beside the significant decadence of the quality of life.
For the solution of the outlined problems the medicine offers a number of options. I have analyzed the traditional and the nowadays used therapies and got to the catheters. My research and development work, then my doctoral thesis too was based on the development of a new catheter. The application of the catheter is logical and it comes from the simplified interpretation of the function and structure of the urine courses: *the faulty function of a relative simple tank-pipe used for storage and emptying of fluids must be corrected by relative simple technical solutions.*

As all medical appliances, the catheters have advantages and side affects, but undoubtedly they have more advantages. It is undermined that catheters are the only applicable therapeutic method in some cases (severe illness, immediate intervention).

After the description of the traditional catheter we have determined the requirements for the new catheter: side effects must be reduced by preservation of the function. According to this we analyzed the reasons of the side effects and we found out that the sizes of the catheters, their length and thickness were very important. We determined as a base requirement that the new catheter had to be as short and thin as possible. The short or partially short catheters correspond to this purpose, because

- they have fewer direct side effects
- they barely ruin the quality of life
- the danger of an ascendant infection is smaller if it ever could happen, because they do not have any contact with the outside world.

Aims

“The determination of the aim” is not so simply, either. At first I thought that I had to avoid the solely medical description, especially the “naturalistic” graphs. Then during an internal dispute it turned out that the indirect talk about the problem veils the clarity. The main thing got lost …
I wanted to develop not only “another better” catheter, but I wanted to permanently remove the 1.Figure status with an innovative technical solution and to make livable the diagnostic situation.

Fig.1. Patient with permanent catheter

The primer aim is: to develop a new, short catheter, to make a prototype.

Under the guidance of my supervisor I saw the possibilities of new theoretical considerations hidden in the technical development process, witch although start from the before outlined settings, but far-reaching. These theoretical considerations represent the backbone of the new scientific results of my doctoral dissertation.

The final goal: to create a technical mean that offer a new option for a significant problem in the medicine and that enriches the anyway by its complexity amazing biology with novel answers to yet not made up questions.

2. MATERIAL AND METHOD

It was obvious from the beginning on that it was not worth modifying the traditional catheters (e.g. Foley catheter). Something new had to be developed. The least expectation was to develop a short catheter. Therefore:

- the positioning and
- the problem of introduction and removal had to be solved in a new way, finally
- the catheter had to be provided with a closing structure, a valve.

I developed the harmonica structure as the solution for the first problem.
I made an additional appliance as the solution for the second problem.
I figured out the bioaffin closing valve as the solution for the third problem.

The device requirements were:

-the insurability of the normal biological conditions:

-**Manually opening mode**: a new short catheter with a valve that can be opened by hand,

-**Specified emptying time**: I maximized it in 2 minutes. I found that this is the time, which is still acceptable,

-**Stable pressure**: the pressure in the bladder is virtually stable under normal circumstances and does not change as the bladder gets full, either;
there are significant differences for each person (20-60 cm/water);
naturally this pressure rises while urinating, that's while I determined a pressure interval to the experiments: 50-175 cm/water;
the upper limit exceeded the physiological values significantly, but at list this much I held it necessarily for the testing of the security of the closing;

-**Appropriate total outflow**: the experience and the literature data show that it is 300- 400 ml.

-**Nature-identical model fluid**: we used tap water in the experiments. There is no significant difference between tap water and urine in the aspect of flowing,

-**Ease of use:** the manual opening and the subsequent emptying can be learned and proceeded easily.

Later:

- I conducted formal and structural experiments to improvement of the harmonica structures,
- I conducted structural experiments to an additional instrument design that helps the insertion and removal,
- I conducted functional experiments to optimize the design of the valve

During my work, therefore, I constructed an experimental layout to the adjustment of different pressures acting on the valve.

- with this experimental layout I tested the initial form and function of the valve, I measured the emerging pressure losses in the experimental layout,
- I measured the amount of water flowing through the valve under different pressures,

- Following this, the safety of the valve closing.

Although it turned out from the first experiments though that the pressure loss in the connecting tube can be neglected beside the pressure loss on the valve, to get more accurate measurements I extended the original layout with a new element.

I called this additional new element, due to its formal and functional similarity, bladder model, than

- in order to improve the flowing through the valves I repeated the experiments related to the flowing, but this time, with two valves made of a material with different hardness (Sh°40 and Sh°60), and
- since the quality of the manual opening is significant for the amount of the fluid lowing through the valve, I examined the valves in terms of the person who handles the valve. (At this examination we worked only with the valve with Sh°60 hardness, what I have kept better).

Finally I conducted experiments with the prototype, so

- I measured the extensibility of the prototype,
- I measured the amount of the flowing water within a period of time, and
- I analyzed the results of experiments with mathematical and statistical methods (where the measurement data set and structure size the opportunity to do so).

2.1. Formal and structural experiments

Triple folding structure, the solution for positioning

I have solved the problem of length-shortness and the dynamic adaptation by an innovation of the form: let's name it a **triple folding structure** (Fig.2. and 3.) This folding structure enables the size adaptation even every minute. Therefore, it will be able to adapt to the individual lengths and diameters and follow the habitual changes as well. The structure also enables the work with the properly decreased diameter when inserting and remove the catheter, so that the procedure is more acceptable for the patient.

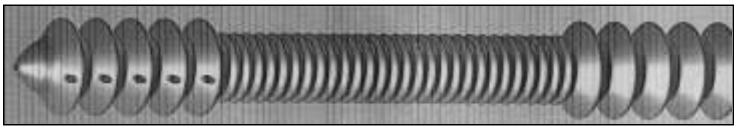


Fig. 2. Triple folding structure-released state (initial form)

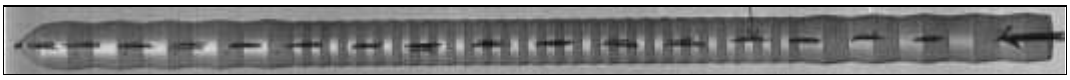


Fig.3. Triple folding structure-stretched state (initial form)

The design of the catheter, compared to the original imaginations, underwent some alterations in the course of the modelling and the manufacture of the prototype because of some practical problems. It was obvious that the short catheter designed by theoretical considerations has to be disassembled (taken to pieces), then the form, the thickness of the wall, the hardness and the extensibility have to be precisely defined in respect of its components. We conducted separate experiments with the components constructed in such a way, convenient for function, and we assembled the prototype of the short catheter from the components of the most favoured reaction (Fig.4).

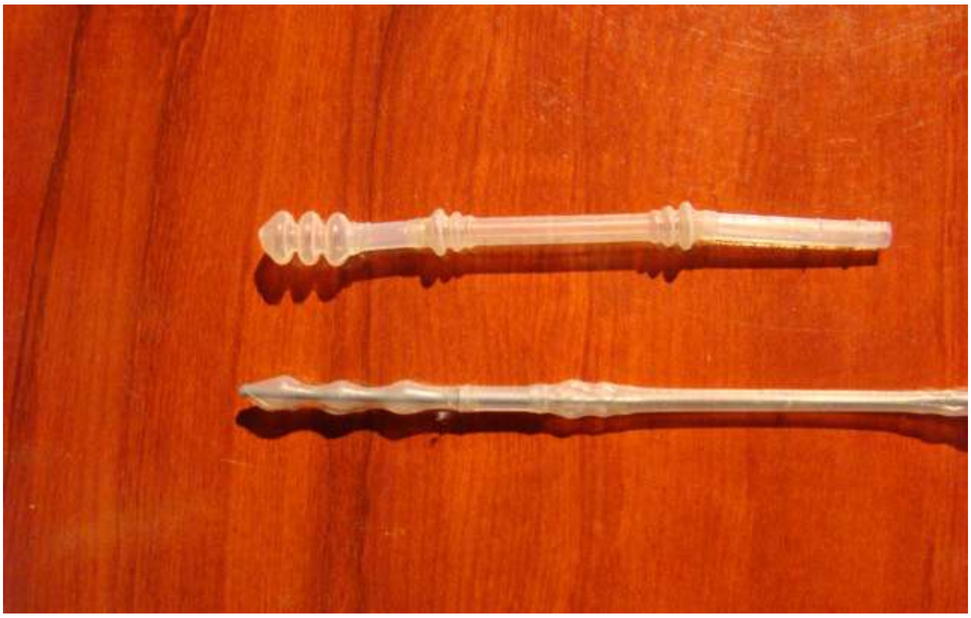


Fig.4. the prototype of the new short catheter

The solution for insertion and removal: development of an additional tool

It was obvious that the development of an additional tool, fitted to short catheter, is the solution to this problem. The difficulty consisted in the fact that by the short catheters the continuous eye-control is not possible. These catheters remain in the interior part of the urethra after introducing them, so they are not visible. We have to manipulate them accordingly. An important element by the short catheter is that the catheter can be introduced and removed as simple and safe as possible.

Closing structure-the bioaffin valve

The valve is the second innovative element. The advantage of the applied valve is its simplicity and the lack of moving parts.The operation of the valve is based on the analogy of the operation of the vein valves and lips. This is a special one-way valve (Fig. 5). The one-way valve can be characterized by the fact that it closes and opens depending on the pressure differential that affects on the both sides of the closing part. The valve can be operated a little bit differently from the usual one-way valves.

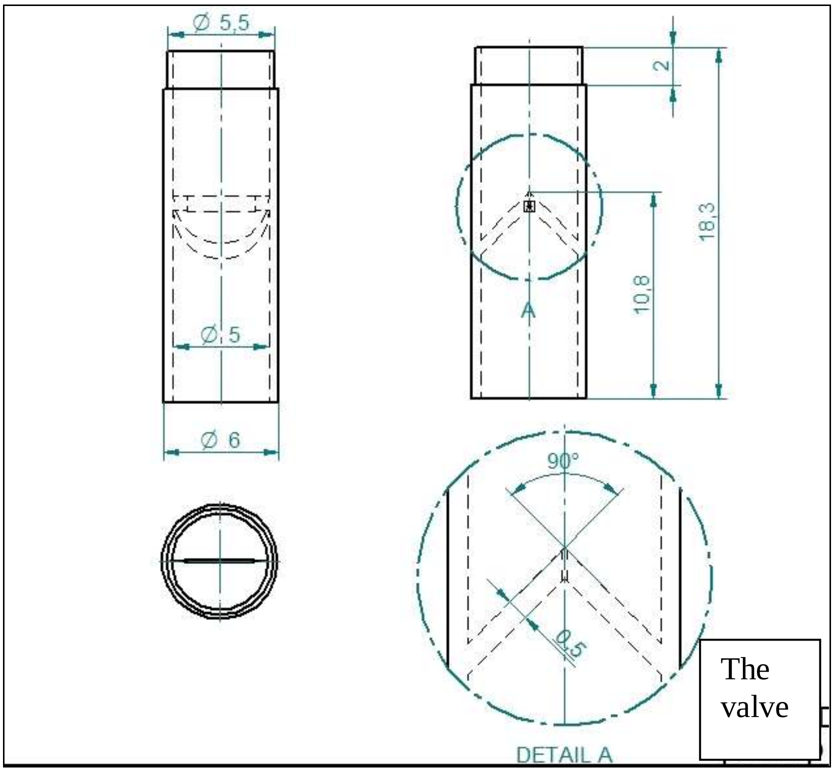


Fig.5. the valve of the short catheter

The formation, similar to a roof-crest, is the controlling part of the valve. The line of the crest is ripped up, but the split is held closed by the pressure that effects on the upper bladder side − side of the “roof”. The bigger the pressure, the better is the closing. To open the valve it is enough to effect pressure on the exterior side of the valve, that is perpendicular to the crest and the valve opens just like the human lips. The valve is connected to the end of the catheter that is next to the exterior. By the male patients, it is within the body. However, by the female patients it can be found out of the body, close to meatus of the urethra.
Due to the more complicated geometry of the structure and the coincidence of the opening of the valve, the flowing speed cannot be inferred from physical, hydrodynamic equations. So during the construction experimental examinations were needed step by step, and in the face of the experimental results corrections were necessary.
After setting the form of the valve the next question was the critical valve diameter, which meant what valve diameter would fulfill the required condition set by me: minimum 300 ml water had to be emptied within 2 minutes. This question was very important, because this diameter determined the maximum diameter of the prototype (catheter). Beside the determination “the smaller the better” that means: the diameter of the new small catheter cannot be bigger than the diameter of the catheters used nowadays: it is 8-24 Ch, which is 2, 4-7, 2 mm. We usually use a catheter with the diameter 18-20 Ch (5, 4-6 mm) for males. Therefore, the outer diameter of the valve must be between 5-6 mm.
An important consideration was also the manufacturability. The material (silicon) of the valve and its hardness (in case of the first valves it was Sh°40) also determined the diameter of the valves. The at least 0, 4-0, 5 mm wall thickness decreases the inner diameter. The rigidity (hardness) of the valve is very important as well, because it can preserve its original form during use and resist the outer pressure. This also results a bigger diameter. Accordingly we also accepted the 5-6 mm outer diameter.

We also needed to pay attention to the fact that the valve had to be groped by hand (through the wall of the penis for men) and opened when presses together. It would be difficult also under a certain size. In the face of this aspect, the 5-6 mm seemed acceptable again.
At examination of the valve we concentrated on two factors. One was the security of the closing. The other one was the speed of the emptying.

2.2. Functional experiments

Experimental layout to set different pressures

We joined the valve and the model of the urinary bladder to a plastic tube, which was filled with water and was 3 meters long and had 5,4 millimeters inner diameter. The other side of the tube was submerged in a dish containing 8 liters of water with a free surface of 800 square centimeters. The vertical projection *(h)* of the distance between the surface of the water and the valve means the pressure affecting the valve expressed in cmH_2O units.
(1 cmH_2O= 100 Pa) Fig.6.

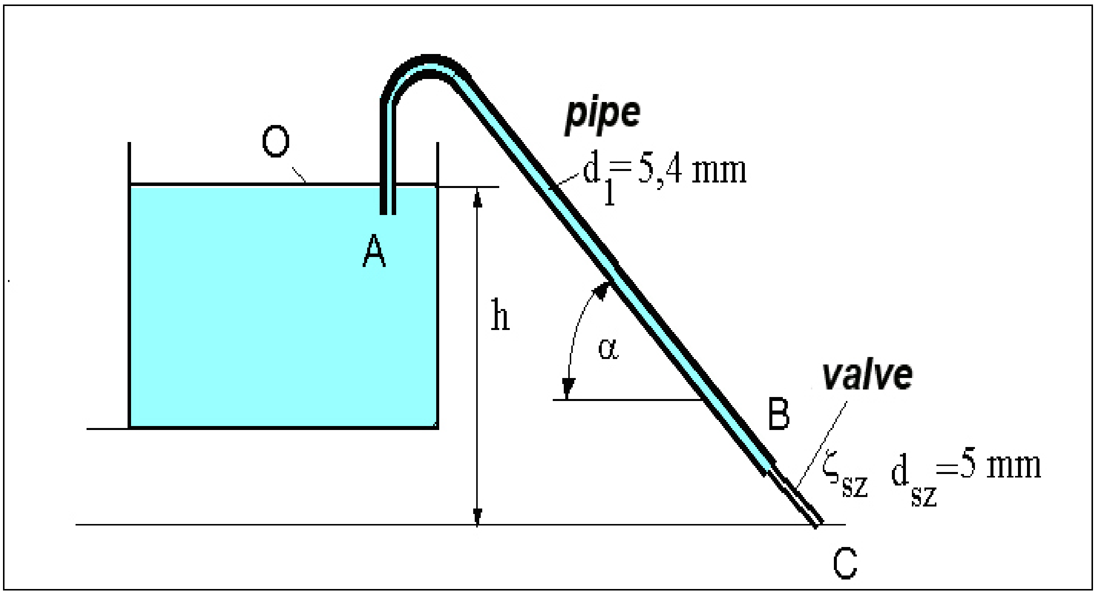


Figure 6: Experimental layout to set different pressures

The initial experiments were conducted with this experimental arrangement (Fig.6). Volunteers helped us conduct these experiments.

Experiments to the measurement of the pressure loss

We conducted the first attempt with 10 pieces of valves with 5, 4 mm outer diameter and Sh°40 hardness. Under different pressures we measured the quantity of the flowing water through the valves within a period of time. Out of it we counted the pressure loss in the connecting tube and the valve, and the hydrodynamic resistance of the valve.
We expected from the experiments that the results would empirically undermine our opinion about the diameter of the valve, and they would give initial experiences about the manual opening.

Experiments regarding flow time versus pressure

Under different pressures *(h=25-150 cm/water, and 2500-15 000 Pa)* we measured the minimal and maximal value of the average time, spreading of 100 ml flowing water. At that time we used the initial form of the valves (Sh°40 hardness, short-2 cm valve length) and the first experimental arrangement. Considering the fact that different persons will use the valve, the experiments were conducted by six patients in each arrangement. These experiments were conducted with a valve made of material Sh40. The average, the standard deviation, the minimum, and the maximum value of the flow time of 100 ml of water (t) under different pressures (h), where measured.
The standard deviation of flow time values depends on the" technique" by which the person conducting the measurement opens the valve, that is to say what extent cross section of the valve is to be opened.

Closing security

The test of the closing tightness was conducted under different pressures. The valve can close tightly under the pressure of 2500 Pa and 17500 Pa, that are equivalent to the pressure of a 25 cm and a 175 cm high water column.

The bladder model

We needed the bladder model to ensure the stable pressure. The originally 3 m long connecting tube described in the first experimental layout connects to a 1 liter volumetric closed dish, filled with water in the arrangement and it develops a stable pressure. Another short tube leads out of this closed dish and connects to the valve, and then to the whole prototype (Fig.7). So I could practice a constant pressure on the valve and prototype tested in the following attempts.

Figure 7: The bladder model

The effect of the valve material on the flow time

It is very important to record the hardness of the silicon the valve should be made of. The hardness of the valve influences the size and form of the split, which can be developed during use. It determines the flowing ability of the valve.
10 valves of different materials were tested: the softer Sh°40 and the harder Sh°60). In case of both types of valves the outflow times were measured on more than 500 occasions altogether. In each case the pressure was chosen to be 100 watercm. Five persons performed statistically appreciable experiments. 100 ml water was flowed through each valve 50 times with the five persons.
This time, on the contrary of the previous flowing examinations, I provided the valves with an additional 3 cm tube in the sake of a better manipulation (valves tested in the first attempts were hard to be held). This additional tube was made of a hard material (Sh°60) and it ensured an easier handling. Since the manipulation was a significant factor, the received results were much better than the ones at the first attempts.

Testing the valves from handling point of view

At the manual operating valve, the pressure in the right direction has an important role. The direction of the optimal pressure can be learned during a short period of time. The value of the flowing time greatly depends on the "technique" of the person who opens the valve, it means how big the flowing split is. Problems can occur at closing as well. Since the valve is self-closing, the more secure the closing is, the bigger the ram pressure is.
The flow time through the valves of Sh°60 were measured when different persons handled the valves. Five patients made statistically acceptable number of experiments.
In case of the given valve we regard the shortest flowing time as optimal that can be achieved by the person who handles the appliance. We assume that the size of the split is the biggest at this time and it is more or less similar under all examined pressures.

The functional examination of the new short catheter

During the development we formed the elements of the catheter one by one. We tested the valve separately in the aspect of function. At the end of the experiment series we put together the separate elements and we conducted more measurements on the prototype of the short catheter. Two identical catheter-prototypes were made.
5 person 90 times per person urinated 100 ml water with both catheter-prototype under 50 and 100 cm/water ($5 \cdot 10^3$ Pa, ill.10^4 Pa) stable pressure. In this case we also used the experimental layout with bladder model.

Experiments to test the extensibility of the new catheter

We tested the **extensibility** and **the flexibility** of the designed catheter during this experiment. They tested the tensile behavior of the circumferential ribs placed at the tip of the catheter and the double-circumferential ribs in the prostate stage. A quasi-rigid thick wall silicon tube connected the stages of circumferential ribs. Therefore, the expansion was performed by the shape change of the circumferential rib. A rigid extending stick produced the tension as it is done during the application. On measuring the catheter's extensibility the tensile force was determined by a digital scale.

To determine the tensile force we fixed a circular plate to the inferior ending of the stretching filament (Fig. 8).

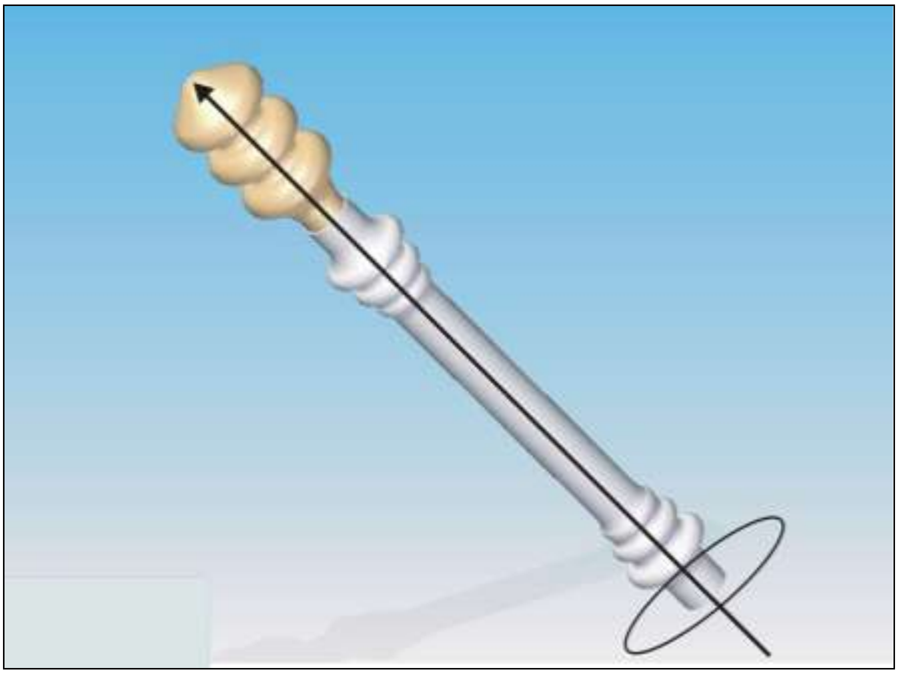


Fig. 8. Measuring the extensibility

2.3. Mathematical statistical methods

We used mathematical statistics to analyze the results of the experiments. One of the most important factors of the planned catheter is the patient himself, who is to use the instrument. The intentional and subjective meeting point of the patient and the catheter is the catheter valve. Opening it and keeping it open can be described just by random variables. Therefore, the applied mathematical statistics play outstandingly important role in the experimental method of the catheter.
We applied the following methods: *Lognormal distribution***,** where the H_0 hypothesis was checked by the Kolmogorov test at significance level $\alpha = 0.05$ and the *Bootstrap (resampling) method.*

3. RESULTS

3.1. The results of the development

Changes of the folding structures

The form of the circumferential ribs was developed. On the one hand, the curves had to be rounded. It reduces not just the harm of the urethra, but it also enhances the extensibility and the thinning of the stage, thus making the insertion and the removal easier. On the other hand it became clear, after some simple experiments, that it is needless to construct more than three so-called ribs (of the circumferential ribs item), they are completely sufficient for the positioning. Comparing the two forms (Fig.9. and 10.), we can see the differences.

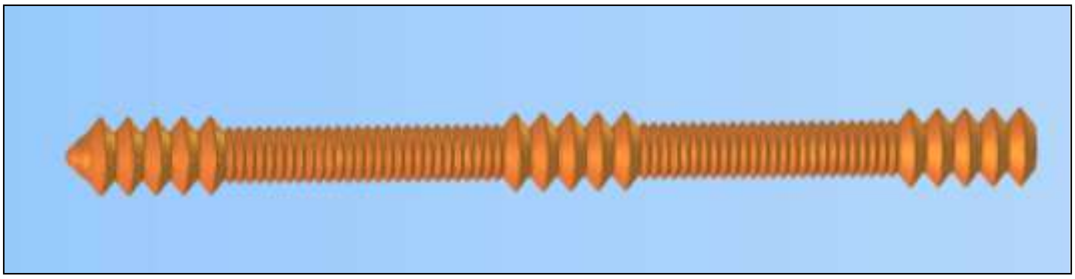


Fig.9. the initial form of the new short (male) catheter

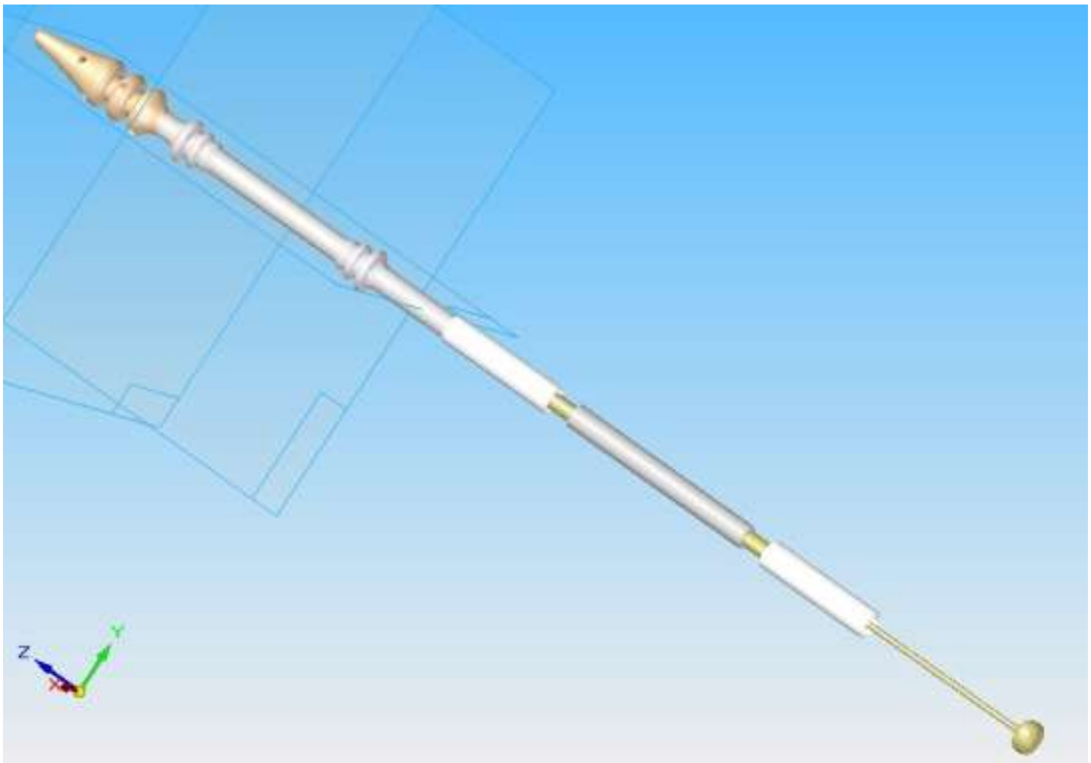


Fig.10. the final form of the short (male) catheter

Changes of the middle stage

As for the circumferential ribs, the other major change was that even the structure had to be changed in case of the middle stage. As regards the manufacture, the originally devised circumferential ribs shape of the middle stage cannot be solved, yet this stage also has to be dynamically changing. We solved the problem as follows: we used a tube for the 38 mm long part of the middle stage. Its outer diameter is 6 mm and this is the stage that is practically exposed to the highest exterior pressure because the prostate gland is around this tube. Consequently, we increased the hardness of this tube. We found a solution for the longitudinal adaptation: we constructed three ribs at the both ends of the middle stage (Fig.11.).

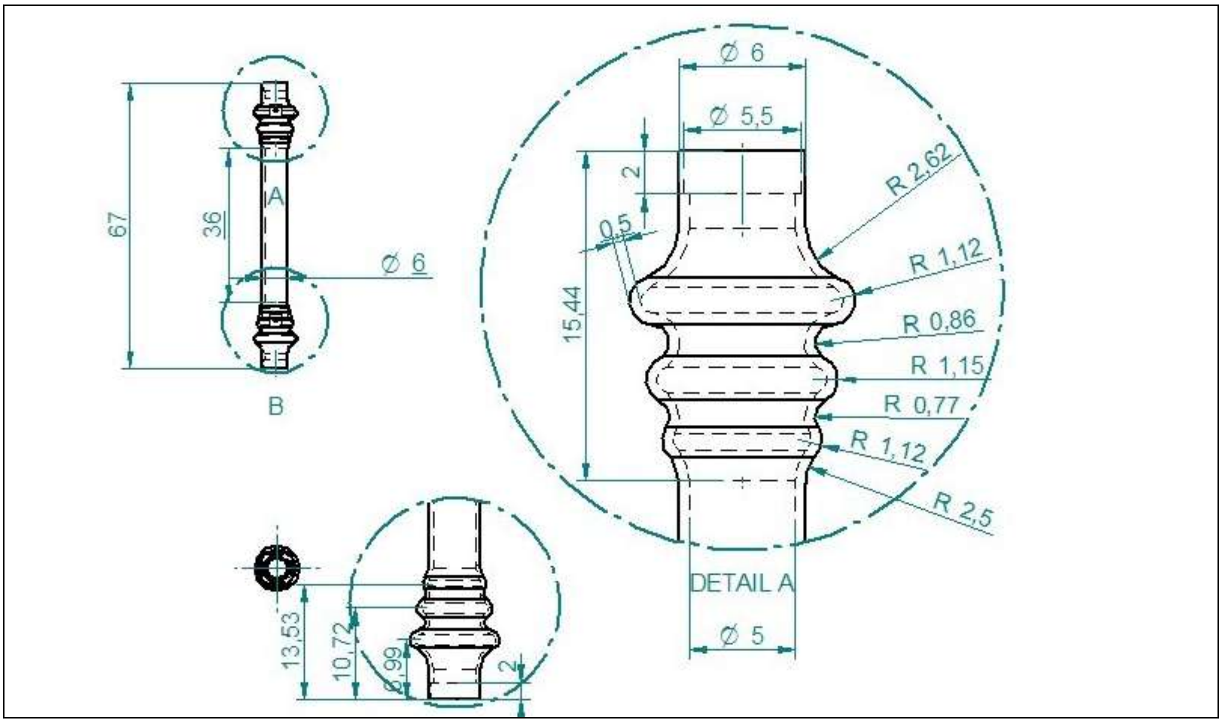


Fig.11. Short catheter- middle stage

The hardness of these transit parts is equivalent to the hardness of the circumferential ribs, which means that it was made of the softer material. The Sh°40, conical shapes fit better to the form of the prostate urethra, which rather resembles to a sand clock, than to a tube stage of equal diameter. Thus, the matter of dynamic adaptation has been solved too.

Changes in the catheters tip

The form of the interior circumferential ribs (the part getting into the bladder) also changed. Beyond the rounded ribs, we also rounded the end of it as well as we strengthened it inside in order to decrease the traumas while inserting (Fig.12.).

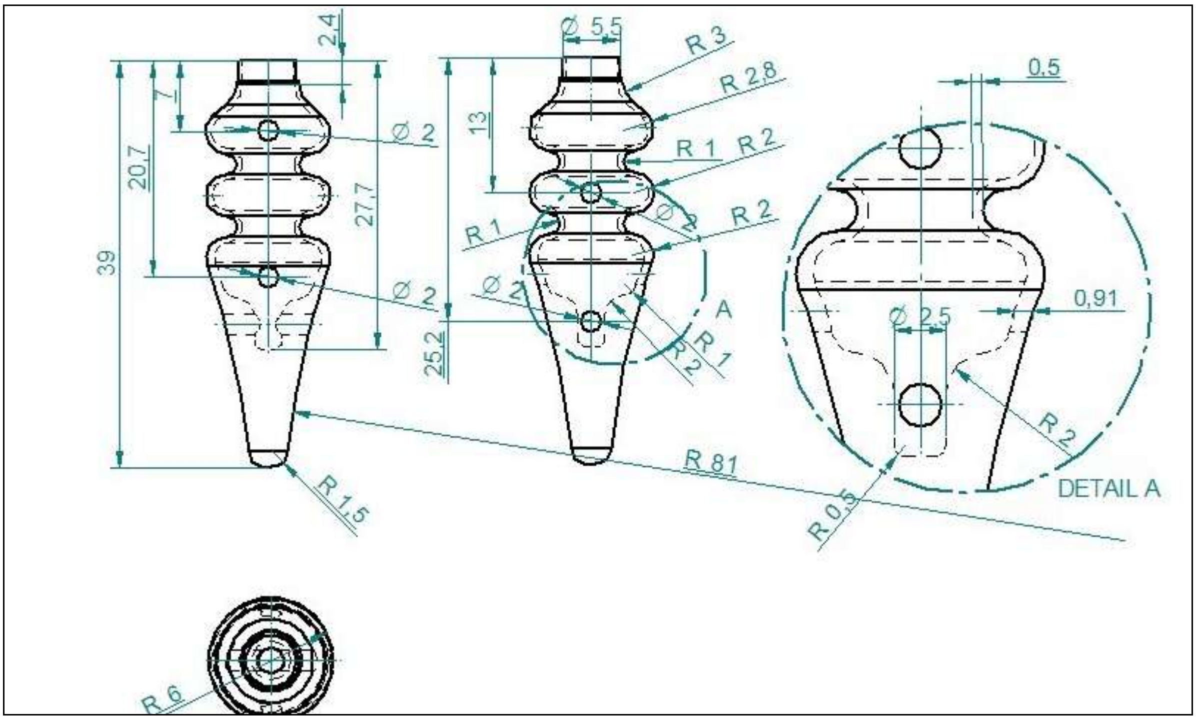


Fig. 12 The tip of the new short catheter

Positioning the valve

In respect of the form it was a change that the valve had to be put to a place where it could be operated easily by hand in case of the mechanical (by hand) catheter. It is not a problem for women (Fig.13.), because it is outside their body. The manual opening of the valve for male is only possible if it can be felt by hand. It means that the valve must be put farther from the prostate, in the part of the urethra which is distal from the stem of the penis. An additional catheter piece must be built in between the short catheter and the valve in the penis (Fig.14.). In the Fig. 13. and 14. the new short catheter without the additional part for women and the catheter with the additional part can be seen. The difference in length is noticeable.

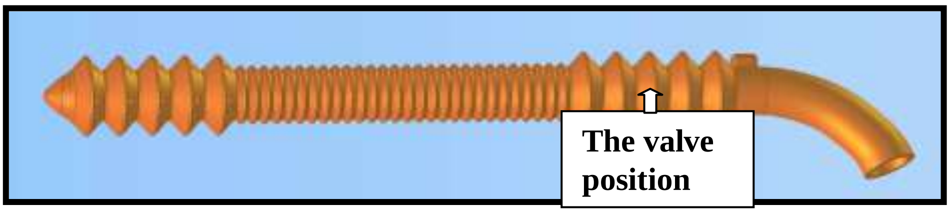


Fig.13. Female catheter (initial form)

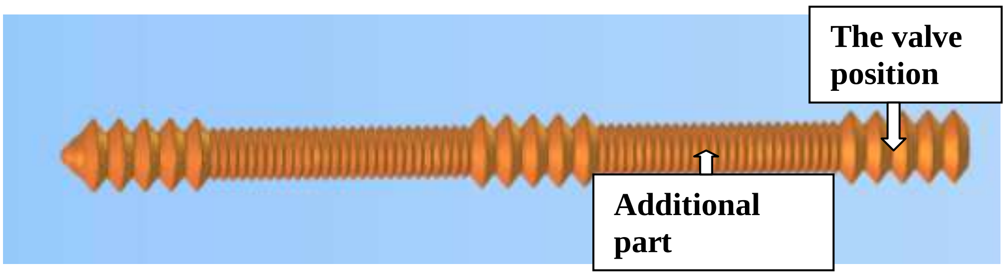


Fig.14. Male catheter with additional part (initial form)

The new short catheter

Finally we had contructed the protoype of the new short catheter. The technical design is presented on Fig.15. and the bild of the new short catheter in the Fig.16.

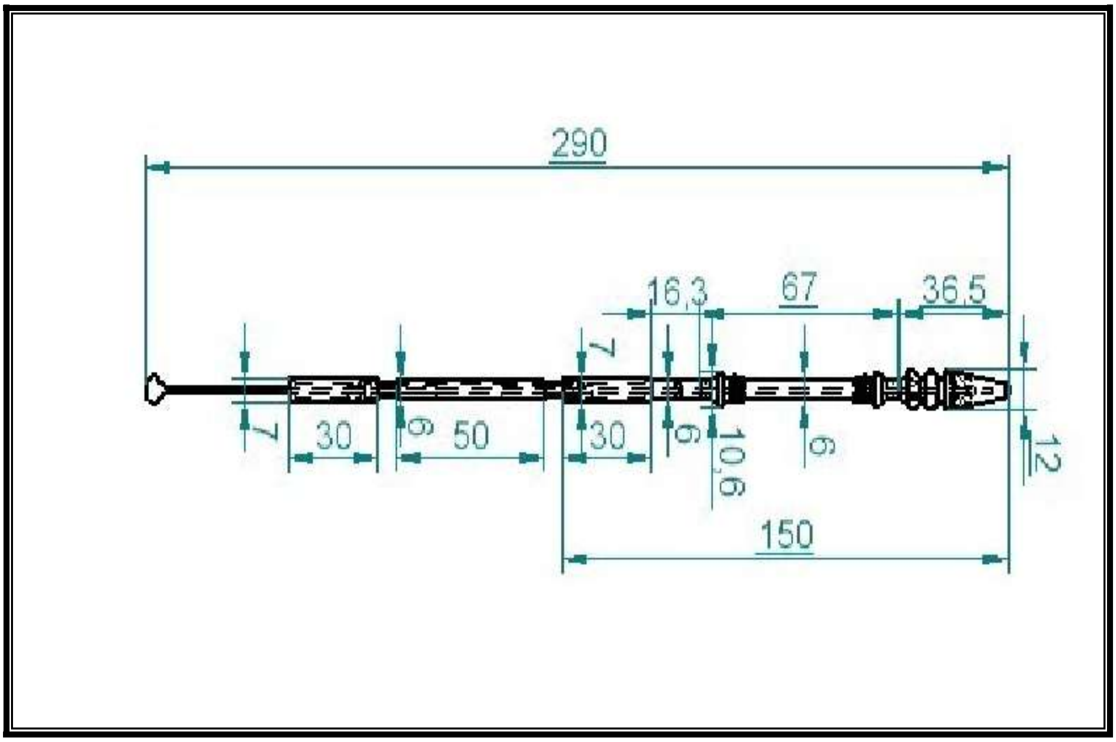


Fig.15. The new short catheter-technical design

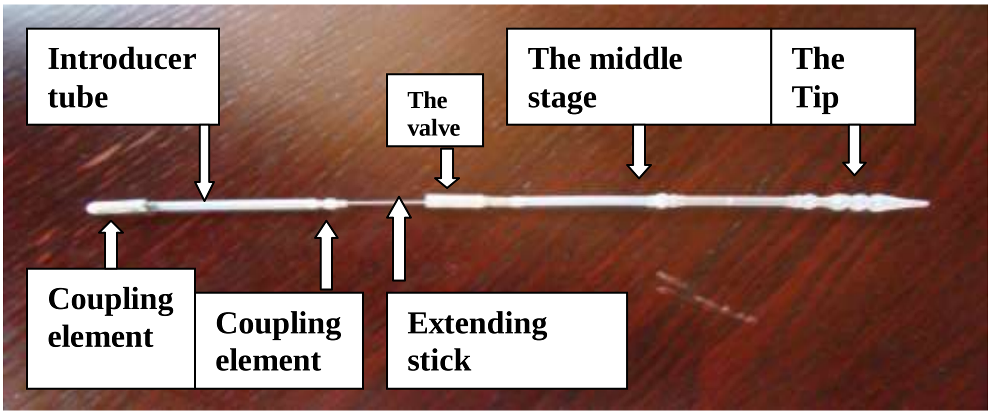


Fig.16. The prototype of the new short catheter

Insertion and removal

It is a significant element at the new, short catheter that the insertion and removal should be very simple and safe. The catheter is introduced with a special instrument (corresponding to external part), consisting from an introducer tube (Fig.17.), a coupling element (Fig.18.) a gripping spile (Fig.19.) and an extending stick (Fig.20.).

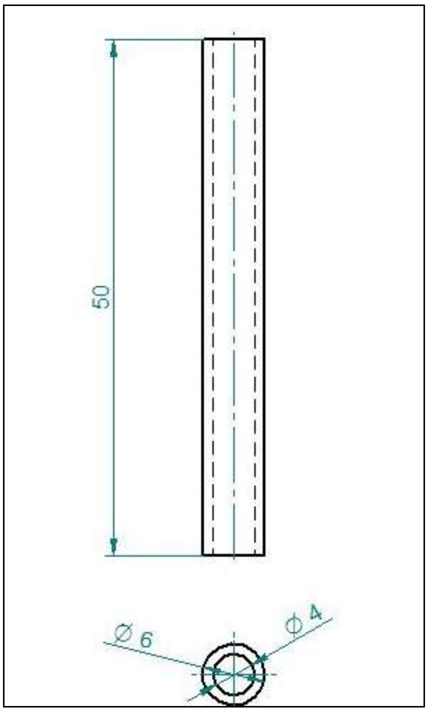


Fig.17. The introducer tube

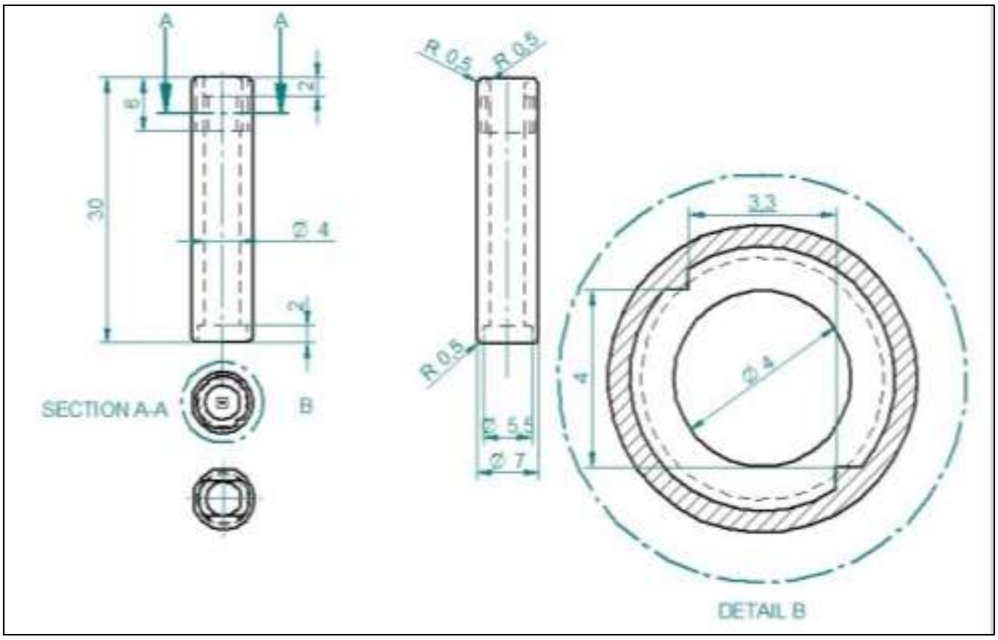


Fig.18. The coupling element

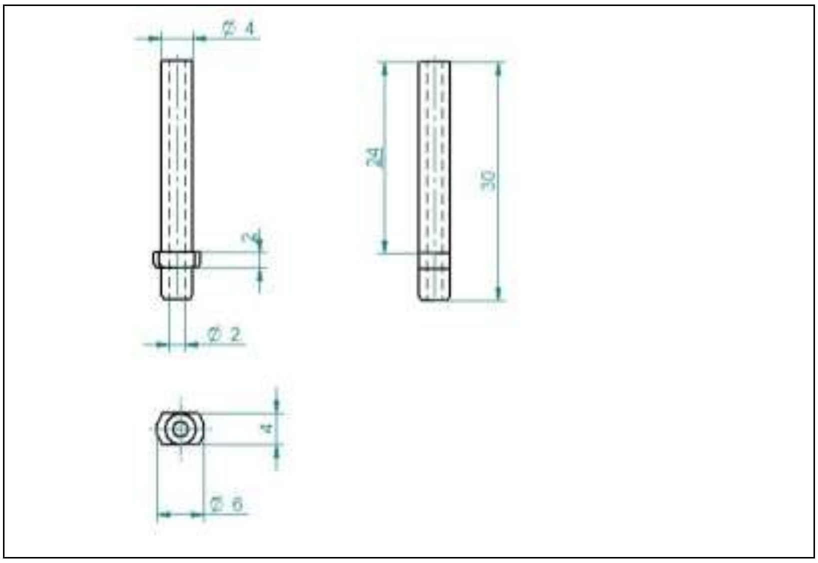


Fig. 19. The gripping spile

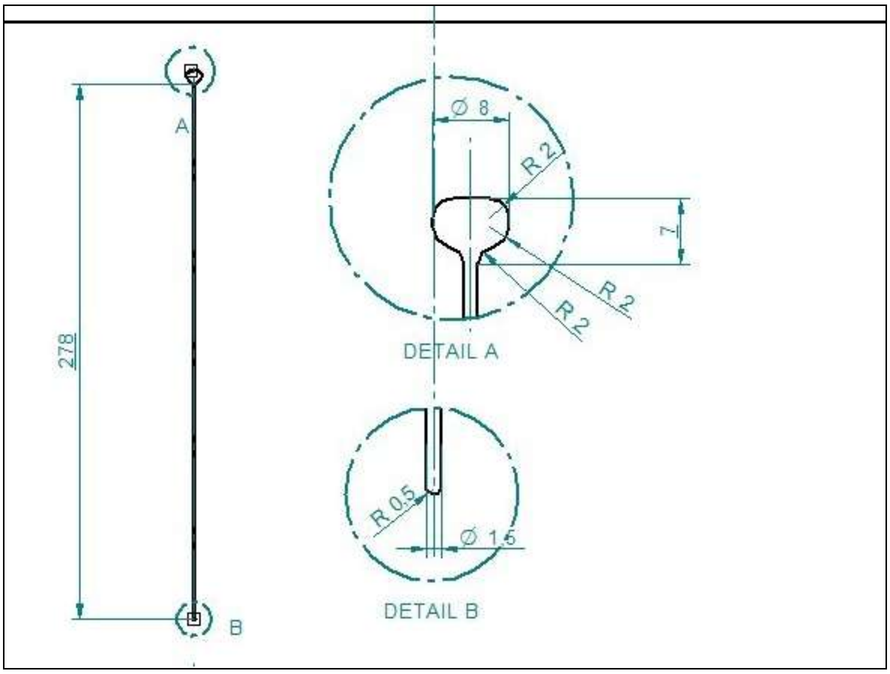


Fig.20. The extending stick

From the catheter differently, the additional part and the tube to be put up are made of polypropylene, not of silicon. The introducer tube is connected to the catheter with a solution that looks like a bayonet-lock, and then the extending stick can be lead into the catheter through it. The extending stick leans on the longest point of the catheter, on the tip of the foldings, and extends the folding structure by putting pressure on it. Therefore, their diameters decrease to a significant extent and the catheter can be introduced easily. The gripping spile is in connection with the proximal part of the introducer tube, so after stretching the extending stick can be fixed hear too.
The catheter in a stretched state, the tube to be put up, and the stretching part form one unit. This flexible unit can be pushed into the right position through the urethra. The conical form

of the top of the catheter is supposed to mild the trauma while inserting, and to help find the outer opening of the prostate urethra.

After we set the short catheter in the right position, we stop the stretching with the bayonet joint at the proximal end of the tube to be put up. The triple harmonica structures win back their original form. The distal (at the top) harmonica stays in the bladder, and the urine can flow into the catheter through its opening on the side. This top part is also a secure against slipping out. The middle and proximal harmonicas position and fix the catheter by leaning on both sides of the prostate. The conical form ensures the adaption of the dynamical size. Then we open the bayonet joint between the tube to be put up and the catheter. After this the short catheter will be able to function.

By removal, first we have to push the additional tube into the urethra. Due to its form it does not injure the urethra and it can directly connect to the bayonet joint at the distal end of the short catheter. Then we lead the stretching part to the top of the catheter, and we stretch the catheter. After a proper stretch we fix the stretching part to the bayonet joint at the proximal end of the tube to be put up again. At the end we remove the whole unit in one piece.

3.2. Results of the functional experiments

Results of the measurement of pressure loss

The results show that we can neglect the pressure loss falling in the connecting tube relative to the pressure loss falling on the catheter. Table 1. shows some results of measurements.

Table 1. The results of the flow measurements

h [m]	t [s]	q [ml/s]	v_k [m/s]	v_1 [m/s]	Re [-]	[-]□	h'_1 [m]	h'_k [m]	h'_1/h'_k
0.25	92	1.087	0.047	0.055	230	0.278	0.024	0.226	0.106195
0.5	71	1.408	0.061	0.072	298	0.215	0.031	0.472	0.065678
0.75	56	1.786	0.078	0.091	378	0.169	0.040	0.759	0.052701
1	46	2.174	0.095	0.111	460	0.139	0.048	0.951	0.050473
1.25	37	2.703	0.118	0.138	572	0.112	0.060	1.420	0.042254

We introduced the denotation of ”velocity reduction”. This shows to what proportion the valve resistance decreases the velocity in the catheter. Table 2. shows the results of the measurements.

Table 2. The velocity reduction for different heights

h [m]	t [s]	q [ml/s]	v_k [m/s]	[-]□	N [-]	Relative deviation [%]
0.25	92	1.087	0.047	0.021	46.7	-6.09
0.5	71	1.408	0.061	0.020	50.9	2.49
0.75	56	1.786	0.078	0.020	49.2	-0.99
1	46	2.174	0.095	0.021	46.7	-6.09
1.25	37	2.703	0.118	0.024	42.0	-15.55
Average					47.1	

According to the measurements, the velocity reduction was approximately 50 on average. The standard deviation of measurements changed depending on the person's valve handling skills and it was approximately 15%.

Flow time versus pressure-results

The average, the standard deviation, the minimum, and the maximum value of the flow time of 100 ml of water (t) under different pressures (h) are given in Table 3., where "h" is the height of the water column.

Table 3. Flow time of 100 ml of water depending on the height (average, standard deviation, minimum and maximum of flow time).

H (cm)	Average	Standard deviation	t_{min} (s)	t_{max} (s)
25	92	24	76	138
50	71	15	54	92
75	56	10	42	66
100	46	14	34	74
125	37	5	32	46
150	30	2	28	34

The standard deviation of flow time values depending on the" technique" by which the person conducting the measurement opens the valve, that is to say what extent cross section of the valve is to be opened. In case of the tested valves the shortest flow time is considered to be the best. This can be obtained with a right practice, if the person uses the valve properly. It is supposed that the actual cross section of the valve is the largest when the flow time is the shortest

Closing security measurement-results

The examination of the security of the closing occurred under different pressures. Corresponding to the pressure of a 25 cm and 175 cm tall water column from 2500 Pa to 17500 Pa the valves closed safely for several weeks. During more than one thousand conducted experiments we could observe that a deformation stayed back after the release of the thwart pressure on the valve in every second case in general. It leaked through this deformation. This leaking can be stopped within maximum three seconds by one, two, or three thwart slight rotation and mild pressurized effect, "rubbing". The fact that the valves are produced with industrial methods and the sharpness and accuracy of the tools at the cutting of the layers of the valve left barb could serve as an explanation.

The effect of valve material on the flow time-results

The summary of the results are presented in the Table 4. and Table 5.

Table 4. Test results with valves made of material Sh°40

Valve nr.	Average (s)	Sd (s)	min (s)	max (s)
1	39.3	13.2	23.3	75.5
2	31.7	9.9	18.9	64.2
3	36.3	9.7	23.0	59.7
4	21.3	5.2	12.7	36.6
5	33.6	7.2	23.3	59.2
6	35.8	12.9	17.8	62.9
7	26.6	9.5	19.3	68.8
8	39.1	12.9	15.6	78.6
9	42.8	11.2	20.5	72.6
10	30.9	11.0	20.2	58.7

Table 5. Test results with valves made of material Sh°60

Valve nr.	medium (s)	Sd (s)	min (s)	max (s)
1	22.2	5.4	12.4	33.1
2	17.3	3.4	11.5	25.2
3	19.7	6.5	10.8	39.3
4	20.5	5.4	16.5	50.4
5	19.0	8.3	11.4	54.5
6	14.8	3.7	11.0	26.2
7	16.5	2.5	12.8	22.4
8	15.7	3.0	11.0	23.9
9	16.0	2.7	11.7	26.7
10	14.7	2.1	11.6	20.0

The Table 4. summarizes the measured data of the valves with Sh°40 material, and the Table 5. summarizes the measured data of the valves with Sh°60 material. The number of the valve is listed in the first column of the table, the other columns show the average, the standard deviation, minimum and maximum of the measured flowing time in case of 50 flowing of 100 ml water.

At the choosing of the valve material of the final catheter it can be stated from this simply summary that the material with Sh°60 hardness should be chosen for the material of the valve. In the case of softer valves with Sh°40 the spreading of the time of emptying is longer, and even the difference between each valve is significantly bigger than at the Sh°60 valves.

From the point of view of the application, beyond the average flow rate or flow time, a more important question is that during the application of the certain valve in what percentage of the cases we can expect that the usual 300 ml urine can be emptied within 1, 1 to 2, 2 to 3, or more than 3 minutes.

Table 6. Outflow time for 300 ml water in percentage of all measurements, valve Sh°40

Valve number	Percent of all trials < 1	1 – 2	2 – 3	>3
	minute per 300 ml			
1	2%	57%	36%	6%
2	7%	76%	16%	1%
3	1%	68%	29%	2%
4	44%	56%		
5	1%	83%	16%	
6	8%	61%	26%	6%
7	18%	77%	5%	
8	4%	54%	32%	9%
9	0%	45%	46%	8%
10	11%	73%	15%	1%

Table7. Outflow time for 300 ml water in percentage of all measurements, valve Sh°60

Valve number	Percent of all trials < 1	1 – 2	2 – 3	>3
	minute per 300 ml			
1	38%	58%	4%	
2	80%	20%		
3	58%	41%	1%	
4	49%	51%		
5	63%	36%	1%	
6	93%	7%		
7	92%	8%		
8	93%	7%		
9	93%	7%		
10	99%	1%		

In order to determine the values it was analyzed by the Kolmogorov test, whether the measured 50 outflow times show lognormal distribution or not. The Kolmogorov test at significance level $\alpha = 0.05$ did not contradict this hypothesis in each case.

Testing the valves from handling point of view-results

It is visible from the determination of the mean and the deviation of the evacuation time values regarded to persons that there are no differences among the persons at simple error (Fig. 21).

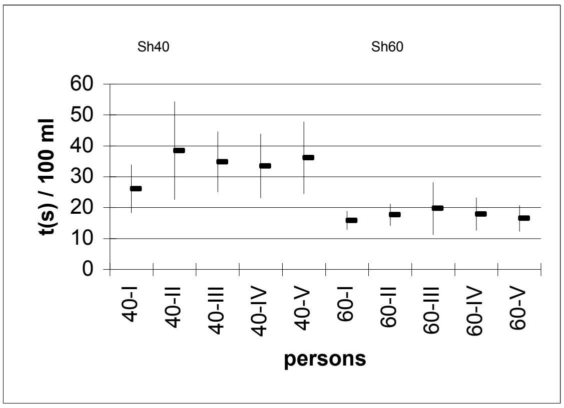


Fig. 21. 100 milliliters water evacuation time, mean and simple deviation in the case of Sh°40 and Sh°60 valves, by five test persons.

Just the same way, as it was done in the case of the valves, the distribution of the results of measurement was analyzed by the Kolmogorov test. The Kolmogorov test did not contradict the hypothesis of the lognormality of the distribution in any of the cases of the test persons. Accordingly, it was also determined in what percentage of the cases the test persons were able to accomplish the through flow of 300 ml of water within a given time interval (Table 8.).

Table 8. Flow time for 300 ml water in percentage of all measurements with different test persons, valve Sh°60

	Percent of all trials			
Person	< 1	1 – 2	2 - 3	>3
	minute per 300 ml			
Ba	88%	12%		
Cs	73%	27%		
Kl	59%	40%	1%	
Li	70%	30%		
Zs	80%	20%		

The results (Table 8.*)* show that two persons (Ba, male and Zs, female) of the five test persons were able to obtain a flow time within one minute, that is favorable result in 80 to 88 % of the cases.

The results of the functional testing of the new short catheter

The hypothesis of the lognormal spreading of each 450 measuring results by both catheter-prototypes and under both pressure values was neglected by the Kolmogorov-test. The Kolmogorov-test did not reject the lognormal assumption *in the group of the people* *conducting the measurement* – without exceptions. It also proves that the human parameters have a significant role in the development of the spreading

Table 9. The results of the measured emptying time under different pressure on both catheter-prototypes (A and B catheter). The measurements were conducted by five people, they are supplied the Roman numbers.

	Meam (s)	**stdev** (s)	*m*	*s*	< 45 s	45 - 60 s	> 60 s	RI_{45}	RI_{60}
A100 - I	46	4	3,82	0,08	42	58	0	58 ± 5	0 ± 0
A100 - II	48	5	3,87	0,09	25	74	1	75 ± 4	1 ± 0
A100 - III	44	5	3,78	0,11	59	41	0	41 ± 5	0 ± 0
A100 - IV	44	4	3,78	0,09	63	37	0	37 ± 5	0 ± 0
A100 - V	41	3	3,72	0,07	88	12	0	12 ± 3	0 ± 0
B100 - I	43	3	3,76	0,08	72	28	0	28 ± 4	0 ± 0
B100 - II	44	5	3,77	0,11	63	37	0	37 ± 5	0 ± 0
B100 - III	40	3	3,68	0,07	96	4	0	4 ± 2	0 ± 0
B100 - IV	44	7	3,77	0,16	60	38	2	40 ± 5	2 ± 1
B100 - V	44	5	3,78	0,12	60	39	0	40 ± 5	1 ± 0
A50 - I	55	5	4,00	0,09	2	84	14	98 ± 1	14 ± 3
A50 - II	52	6	3,95	0,11	10	81	9	90 ± 3	9 ± 2
A50 - III	54	8	3,98	0,14	11	68	21	89 ± 3	21 ± 4
A50 - IV	52	5	3,95	0,09	7	88	5	93 ± 2	5 ± 2
A50 - V	52	4	3,96	0,08	3	93	5	97 ± 1	5 ± 1
B50 - I	55	4	4,01	0,08	1	86	13	99 ± 0	13 ± 3
B50 - II	53	7	3,97	0,12	9	74	16	91 ± 3	16 ± 4
B50 - III	56	6	4,01	0,11	3	74	23	97 ± 1	23 ± 4
B50 - IV	54	4	3,99	0,07	1	92	7	99 ± 0	7 ± 2
B50 - V	56	4	4,02	0,07	0	87	13	100 ± 0	13 ± 3

Almost 100% of the patients are able to urinate 300 ml water within 1 minute with both catheter-prototypes under 10^4 Pa overpressure, which is obvious for physicians. If the overpressure is only $5 \cdot 10^3$ Pa, due to some severe deformation of the bladder, the patients still will be able to urinate in at least 75% of the cases within 1 minute.
It is important to mention that the urination greatly depends on the "skill" of the patient, on his actual mental state, so the patient has to be prepared for the use of the appliance.

The results of the tensile behavior of the new, short catheter

We presented the rate of the absolute stretching (S) formation on the horizontal axle of the diagram on the Fig.22. and the size of the power (P) developing the stretching on the vertical axle (90% confidence index). 100 gram "power" is 1 N power.

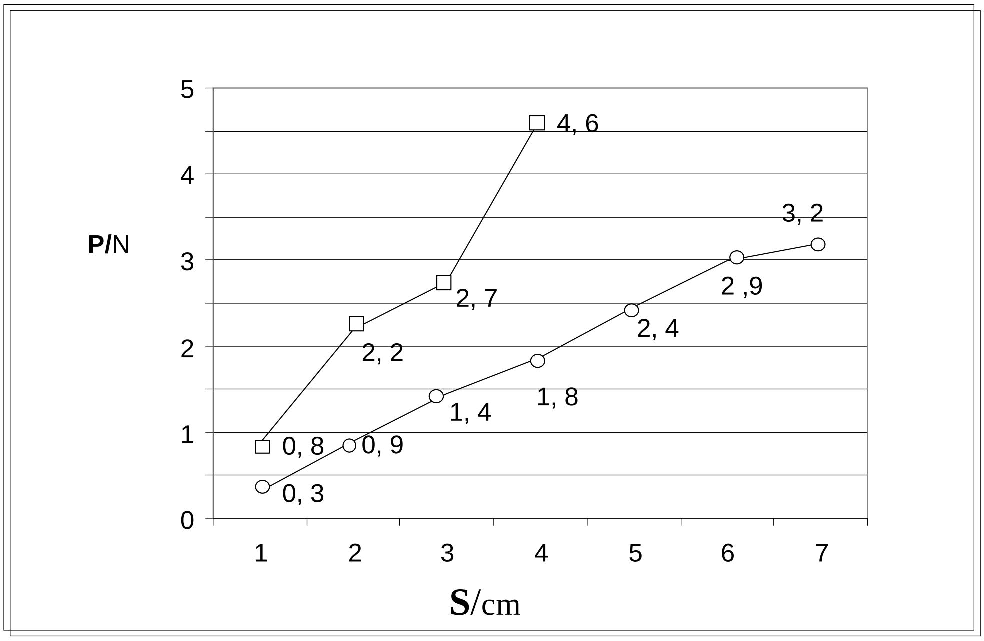


Fig. 22. The extensibility diagram-the absolute stretching related to power

The two curves show the tensile force versus deformation on of catheter circumferential ribs, made from silicon of different Shore hardness. The maximum deformation of the catheter of hardness Sh°40 was 7 cm. In case of the harder material, the maximum deformation is only 4 cm. The tensile force causing deformation is important. The force generating the maximum deformation was 3.2 N in case of the softer material (Sh°40) and 4.5 N in case of the harder material (Sh°60).

3.3. The summary of the results of the functional experiments

During the evaluation of the results we received the following consequences:

- **in the significant aspect of extensibility, during the use of catheter**, the material with Shº40 hardness is more appropriate for the folding, than the Shº60, because its extensibility is 134%.

The size of the power causing the extension is noteworthy. The power causing the maximal extension was 3.2 N for the softer material and 4.5 N for the harder. The structure of the triple folding made of a softer material follows easily the expected changes in size during the dynamical adaptation.

It is important from ergonomic aspect that we talk about slight powers which is suitable for the physician. The rate of the extension is important, because the physician makes it with the movement of his thumb during introduction. In case of folding made of Shº40 material, the 7 cm maximal push length is acceptable from this aspect.

- **In the aspect of the flowing time**, the valve with Shº60 material is a better solution that Shº40, because the flowing time on the valves made of harder material (Shº60) is significantly shorter.

- **The closing safeness of the catheter valves** is safe up to 175 watercm (=17500 Pa) overpressure, whether the valve is made of either Shº40 or Shº60 material.

- It can be observed that **the effectiveness of the valves built in the catheter improved significantly compared to the independently examined valves**. As long as 300 ml water emptying time is not more than 2 minutes for any experimental persons with Shº60 valve built in the whole catheter, the result of the valves with Shº60 material during the beginning phase of the development was much worse. The eventual turbulence during the flowing through the whole catheter can influence the flowing time barely negative, than the valve cuts made by the new technology positive. The factor of learning cannot be neglected either, and the manipulation of the whole catheter is easier.

- At the experimental results conducted with two whole catheters it is ostentatious that the results are greatly different in the handling of the two catheters in case of two experimental persons (An and Iz). Its probable reason is that these two persons at the examination of catheter B were indisposed during the conduction of the experiments, due to events independent from the experiment. **Their results proved though that the patient with decreased concentration ability could empty 300 ml urine within 2 minutes with 100% probability.**

- In the evaluation of the experimental results it has a significant role that it can be recognized and proved by the Kolmogorov-test that **the measurement results for groups of persons and valves show lognormal spreading**. Based on it, it can be examined what percentage of the cases the emptying of 300 ml water can be expected by the groups within the given time.

- The recognition of the lognormality made possible **the introduction of the emptying index and the determination of the fault of the emptying index**.

4. NEW SCIENTIFIC RESULTS

1. I introduced the definition of the biological rectification and the biological dual valves. Fact is that nothing happens without a determined reason in the biology and the presence of certain biological structures indicates functional characteristics. Studying the function of the upper urine tract and analyzing the process of fluids (urine, blood, lymph) and solid materials (food, defecation) in human and animal body I found that the rectification as a process should be generalized for these systems (heart and circulating system, lymph vein system, urine courses, main). I also found that for these the lack of rectification leads to diseases.
By analyzing the physiological processes (now partially) in the human body I got to the conclusion that the rectification occurs somewhere else too (e.g. nerve system) and most of the physical and chemical processes are rectified (e.g. cell membrane transport) as well. However, the human body is so complex that regarding this as a whole it is hard to make general statements. But it is certain that in respect of the urinary system, based on the technical and technological identity, the concept of rectification is appropriate and it is suitable for the interpretation of technical synergies. Although the conception of biological rectification is today only "a theoretical concept" it is expected that physician colleagues working in different fields undermine (or confute) this assumption.
The biological rectification (such as function) in my case fulfills through the biological dual valves (like structure). This definition is also a proven novelty in the biology. It is a guidance in the search for other similar structures (large vessel valves, heart valves, veins and lymphatic valves, cardia-pilorus valves, Bauhin-key) and in the generalization of operating characteristics.

2. I developed a technical-mechanical interpretation of urinary tract function. During the research, I formulated a new approach in the functioning of the urinary tract.

In this way, from technical aspects, nobody has yet analyzed the flow processes occurring in the urinary tract.It is especially important in the case of the upper urine tract, where there are a lot of uncertainties according to the actual theories.
It came up how much this new theoretical concept can be regarded as independent or whether it is only a form of the principle of the biological rectification applied on the urine tract. Although the principle of biological rectification includes the operating principle of the urinary tract, in witch is independent the explanation of rectification in urinary tract is that of technical-mechanical interpretation of an unidirectional process of pumping. In this case, to the specific morphological structures real function may be associate with, as long as the biological rectification already operates with abstract elements. Here, in a specific biological system, the technical analogy of a process control system provides assistance to correct the abnormal operation.

3. I introduced a mathematical model for the qualification of the appliances used in the medicina. During the research, analysis of the experimental results, the applied mathematical-statistic methods offered a new possibility. It turned out – abstracted from our experiments, but based on them - that they are suitable for qualification of the use of medical appliances. It means: it can be determined with a similar method how much a certain medical appliance is "use-friendly". This generalization gives answer to that simple question how much the patient or physician can use the given medical appliance according to its function, with other words how much chance they have to use it inappropriate. It is an important question, because it can decide whether the handling of the appliance can be done by the patient or the physician. If not, a separate handling staff is needed which results significant additional costs.

4. I created a patent-protected new short catheter. In comparison with today's catheters it can be stated that the prototype of the short catheter represents a completely new catheter type (third generation catheter). Such a catheter or similar to it has not been used yet. However, the therapeutic and technical aptitude benefits of use are obvious documented in my thesis. Analyzing of the similar inventions in this field I got to the conclusion that the prototype of the short catheter is the practical fulfillment of a completely new concept. It cannot be compared to any inventions. It is unique in its form and function. It can be produced and used. These two concepts cannot be separated from each other. However it is understandable that, particularly by the development of the medical appliances, what seems by useable must be able to be produced also. For example more inventions suggest a balloon solution (two or three balloon) to the positioning, which works well functionally, but due to difficult and complex manufacturability and the cumbersome insertion-removal it could not come to win the therapy. The great advantage of the short catheter is the maximal simplicity in the aspect of production (too). It does not contain any moving parts, the material used during production is proper in medical aspect, it can be form easily and it is cheap.
An important and fundamental formal novelty is the harmonica structure. It makes possible during stretching the unification of the originally different diameters and it ensures the dynamical adaption during use. This adaption is a requirement only by the short catheters. Here, however, it is so important that an invention, calculating with this dimensional problems, propose six different catheter sizes.
Regarding usability we have very positive initial experience. The short catheter can be handled simple and safe by the physician (caregiver) or the patient. The physician can insert or remove it without using additional appliance (cystoscop). This can be done without any danger by a well qualified assistant as well. Even the patient would be able to change the catheter. (The self-catheterization is a widespread method nowadays.)
From the patient's point of view is significant that, during the stretching, the diameter of the short catheter can be reduced to ca. 5-6 mm (further decrease will be prevented by the diameter of the valve). It is also important the formation of the top of the catheter because it make possible the easier insertion through the eventual narrow urethral part or the slowly widening. Another novelty is the additional part of short catheter used by males, which brings the catheter-valve into a position where it can be manipulated by hand.

5. . I developed a bioaffin closing valve to the new catheter. The valve is an unbearable part of the short catheter. There is no useable short catheter without the valve. The production of short catheters has been delayed due to lack of proper closure device. There is a suggestion to it among the inventions, but the suggested solution with balloon only complicates the production and the use. The simple valve applied for the prototype of the short catheter is a technically well known valve type (check valve), modified according to biological analogies (mouth-lips, cardiac vein). It can be produced and handled easily, so it corresponds to the expected requirements imposed by bio-hydrodynamics too. The diameter of the valve –as essential element of the emptied liquid per unit time – is that determines the smallest diameter of the short catheter (5-6 mm). It can be manipulated easily, however 300 ml fluid can be emptied within a reasonable time (2 minutes), which corresponds to the capacity of an average urinating.

5. CONCLUSIONS AND SUGGESTIONS

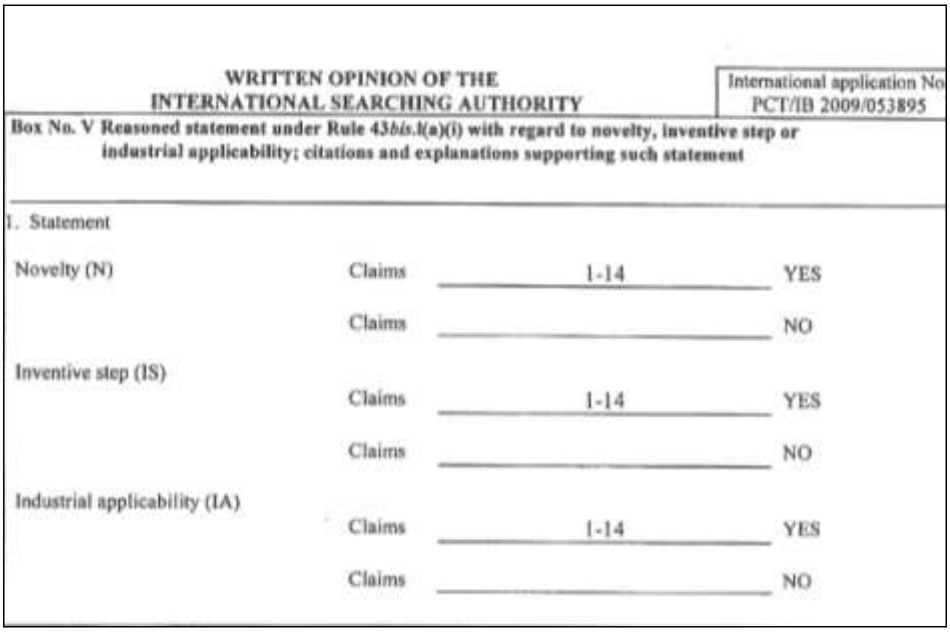
Biological rectification and biological dual valves
The practical value of this theoretical concept is widely presumed. In general we can hope that it can help understand the processes in the human body (in biology) better. If we can identify the dual valve structures ensuring the rectification, we can plan our outer interventions (e.g. surgeries) in the organ (nature?), so that the healthy rectification remains.

A new theory of the functioning of the urinary tract
The function of the urine tract is clearer with this explanation, but at the same time it does not have any contradiction from the current explanations. It does not expel the peristalsis characteristic to the independent function, but it completes it. The antireflux surgical methods applied in the urology prove the rightness of this new theory. The biggest practical benefit is that, moving the operation to a new light, significantly streamline the surgical technique.

The mathematical model for the qualification of the appliances used in the medicine
The practical benefit is that it predicts the handling faults of the medical appliances used by the patient (or doctor, caregiver or relative). According to this, the appliance or the instructions manual can be changed.

The new short catheter
We expect from the new short catheter a significant reduction of the side effects of catheterization. In other words, reducing the mechanical damage and infection. Beside this, the quality of life is also a main aspect. A catheter that cannot be noticed by another person or that makes possible to live sexual life would be a great achievement.

Finally, an objective opinion should be here instead of subjective qualification: The WIPO (World Intellectual Property Organization) gave the following positive qualification about the new, short catheter (International application No. PCT/IB 2009/053895) (Fig.23.)
application No. PCT/IB 2009/053895).



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/IB 2009/053895

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-14	YES
	Claims		NO
Inventive step (IS)	Claims	1-14	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims		NO

Fig. 23. The WIPO written opinion

6. SUMMARY

Technical solutions have been used in health care for a long time. The purpose of my researches was to find a new solution for some diseases of the human urinary system (retention, incontinence of urine). The urine maintenance and emptying problems affect 20% of 65-69-year-olds, it is 40% over the age of 70. It is significant with regard to the medical point of view that we talk about a group of people who suffer from illnesses in general, whose immune system is weaker from the average and whose movements are limited in most cases, therefore these diseases could unfortunately mean danger to their life beside the significant decadence of the quality of life.

There are more possibilities for the solution of the described problem. The traditional, nowadays used therapies have been analyzed one by one critically. I have experienced that the primate of the technical solutions dominates. The application of the catheter is logical and it comes from the simplified interpretation of the function and structure of the urine tract.

The base of the doctoral dissertation was given by the development of a new catheter. After the description of the traditional catheter I have determined the requirements for the new catheter: the new catheter must be as short and thin as possible.

Production of the short catheter brings three other problems: *positioning, insertion –removal* and *the incontinence of urine caused by the catheter*. The solution of these determines the form, size and structure of the short catheter.

During my research work, summarized in my doctoral dissertation, I have tried to fulfill the following goals:

- ***Development of a new short catheter regarding form and size, development of the prototype***
- ***Development of a suitable closing structure (valve)***

The final prototype has been developed as a result of the formal and structural experiments. The folding structure has been changed significantly, the valve has found its place. The procedure of insertion and removal is helped by an additional tool, which ensures the appropriate extension also.

I have clarified the hardness of the material of the catheter as a result of the functional experiments, and I have determined the necessary valve diameter. I have examined the secure of the closing under different pressure on the valve, and the whole prototype. The experiment was executed by several people, which made possible the perception of the personal differences and the generalization by the mean of mathematical statistic methods. This was analyzed under further aspects, because the number of the diagnostic and therapeutic supplies keeps rising, since they depend on the patient.

I expect from the new short catheter the significantly reduction of the side effects of catheterization. Beside the reduction of the mechanical injuries and infections, the quality of life is also a main aspect. A catheter that cannot be noticed by another person or that makes possible to live sexual life would be a great achievement.

During the above mention process new theories have been determined. One of them is the theory of the biological rectification, the other is the valve-mechanical explanation of the function of the urine tract. The generalization of the mathematical statistic methods belongs to this as well.

So far it's hard to determine the practical advantage of these theoretical conceptions. Generally we can hope that they can help us understand better the processes of the human body (the biology) and we can plan the interventions (e.g.: surgeries) of the body (nature?) in advance so that they do not disturb the healthy order of the body.

The generalization of the mathematic statistic methods predicts perfectly the handling problems of the medical appliances used by the patient (or the physician, caregiver, relative). According to this the appliance or the instruction manual can be changed.

PERSONAL PUBLICATIONS AND PATENTS RELATED TO THE TOPIC OF THE THESIS

M1. Publications regarding the dissertation

Publications in English:

DANI Á., SZENDRŐ P. (2009): Uro-mechanics: Technical Solutions in the Development of a New Urologycal Catheter.
Progress in Agricultural Engineering Sciences 5.Akadémiai Kiadó Bp., p:111-145

DANI Á., SZENDRŐ P. (2010): Short urinary catheter
Oradea Medical Jurnal, 2010. 1. pg.12-20

Publications in Hungarian:

DANI A., TÓTH E., KOVÁCS A., KOVÁCS I., BERTA K.(2010):Adatminősítés az orvosi eszközfejlesztés szolgálatában
Fizikai Szemle, 2010., 1.,p:10-13

Presentation in English::

DANI Á., SZENDRŐ P.(2009): Technical and biological synergies in the development of medical instruments
Synergy and Technical Development (International Conferences in Agricultural Engeneering

M2. Patents regarding the dissertation

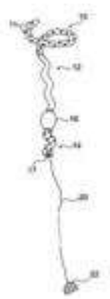
1. International application No. PCT HU2007/000062

WO/2008/010001) EQUIPMENT TO VOID BODY LIQUID

Pub. No.:	**WO/2008/010001**	**International Application No.:**	**PCT/HU2007/000062**
Publication Date:	**24.01.2008**	**International Filing Date:**	**09.07.2007**

IPC:	***A61M 1/00*** (2006.01), ***A61M 25/00*** (2006.01)
Applicant:	**DANI, Arpad** [HU/HU]; (HU).
Inventor:	**DANI, Arpad**; (HU).
Priority Data:	P0600601 19.07.2006 HU
Title:	EQUIPMENT TO VOID BODY LIQUID

Abstract: The invention is a device for the draining of body fluid, especially a urinary catheter, which is like a tube, and includes an internal section (10), with at least one lateral hole (11) for the body fluid, a central section (12) developed with a continuous wall, as well as an external section (14) equipped with an outlet hole (17). The invention is of the characteristic by that the internal section (10), central section (12) and external section (14) have a pigtail shape.



Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
African Regional Intellectual Property Org. (ARIPO) (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW)
Eurasian Patent Organization (EAPO) (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM)
European Patent Office (EPO) (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR)
African Intellectual Property Organization (OAPI) (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

2. International application No. PCT/IB 2009/053895

WO/2010/020971) CATHETER

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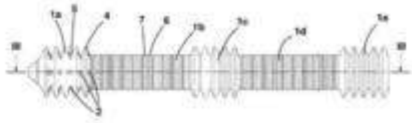

FIG. 2

Abstract: Catheter comprising a flexible and elastic, pipe-like body part (1, 11), the internal canal of which is connected to the bladder of the patient through one or several body orifices and, furthermore, with a bellow-shaped distal section (1a) located at the outlet of the patient's bladder when the catheter is in use, which fixes the catheter position, and an opposite, bellow-shaped proximal section (1c) which prevents the slipping in of the catheter; where in default case the diameter of both distal section (1a) and proximal section (1c) exceeds that of the outlet of the bladder but, stretched out horizontally, it is smaller than the diameter of the urethra and reduces to approximately the size of the below-shaped intermediate section (1b) connecting distal and proximal sections (1a, 1c), thereby allowing to introduce the catheter through the urethra until distal section (Ia) is located inside the bladder and, following the termination of the axial pulling pressure, sections (1a, 1b, 1c) revert to their original size, and thanks to its bellow shape, intermediate section (1b) flexibly adjusts to the size and shape changes ever and, furthermore, with a closing device designed in distal section (1a), made up by flexible membrane valve (13) openable by manual deformation, located at the external end of proximal section (1c).

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