AUTOMATIC SCREWING OF CAPS TO SPIKE CONNECTORS ON APD PERITONEAL DIALYSIS LINES

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Key words: hemodialysis, peritoneal dialysis, APD, CAPD, manual caps screwing, automatic caps screwing,

Abstract: Around 3 million people worldwide with end stage renal disease regularly need to use one of the established dialysis methods. The most common is haemodialysis but less invasive is peritoneal dialysis where peritoneum takes the role of artificial kidney /1/.

Using APD – Automatic peritoneal Dialysis, PD dialiser executes the whole cycle of successive charging and dialysis fluid discharging during the night. Connection of lines, solutions and patient to PD dialyser is done by use of connectors which are protected with caps that must be unscrewed sterilly before use. In the production of disposable PDL lines the caps are screwed to connectors manually or automatically. Automatic screwing guarantees controlled and repetitive screwing conditions, as well as higher throughput. In the article we describe such a machine that we built. It is fully automatic and needs to be occasionally refilled with material and reset to define new material lot. Process, as well as production, parameters are put-in through user friendly touch screen.

Avtomat za vijačenje kapic na konektorje linij za avtomatsko peritonealno dializo

Kjučne besede: hemodializa, peritonealna dializa, APD, CAPD, ročno vijačenje kapic, avtomatsko vijačenje kapic,

Izvleček: Dandanes se je nekaj manj kot tri milijone bolnikov s stalno ledvično odpovedjo prisiljeno redno zatekati k eni od uveljavljenih metod dialize. Gre bodisi za hemodializo, oz.krvno dializo, kjer bolnika trikrat tedensko priključimo na umetno ledvico, ali pa za peritonealno dializo, kjer vlogo (umetnih) ledvic prevzame bolnikova potrebušnica, peritonej /1/.

Pri kontinuirani peritonealni dializi (CAPD - Continuous Ambulatory Peritoneal Dialysis) bolnik štirikrat dnevno ročno prazni in nato polni močno prekrvavljeno trebušno votlino z ustreznimi raztopinami. Pri avtomatski peritonealni dializi (APD - Automatic peritoneal Dialysis) pa to funkcijo prevzame PD dializator.

Priključitev linije in vrečk z raztopinami na dializator bolnik opravi s pomočjo ustreznih konektorjev. Le-ti so zaščiteni s čepki, ki jih mora bolnik predhodno pazljivo sterilno odviti.

V proizvodnji dializnih linij za enkratno upoprabo se vijačenje čepkov na konektorje izvaja ročno ali avtomatsko. Ročno vijačenje ima določene slabosti, kot so:

- nekontroliran navor privijanja, ki posledično lahko povzroči težave bolniku pri odvijanju, če so čepki preveč priviti ali pa netesnost linije, če so čepki premalo priviti
- dolgotrajno ročno privijanje zaradi ponavljajočih se gibov lahko povzroči bolečine v prstih in rokah delavcev.

Avtomatsko privijanje na drugi strani zagotavlja kontrolirane pogoje privijanja in višjo produktivnost. Delovanje avtomata je v veliki meri samodejno, saj ga je potrebno le občasno posluževati z materialom, kakor tudi vnašati proizvodne parametre za posamezne lote materiala. V prispevku opišemo konstrukcijo in delovanje avtomata za privijanje čepkov. Po začetnem testiranju je naprava začela delovati v proizvodnji ter dosegla vse planirane parametre : kapaciteto nad 8.000 privijanj/izmeno ter navor privijanja v željenem oknu od 3Ndm do 8Ndm.

1. Introduction

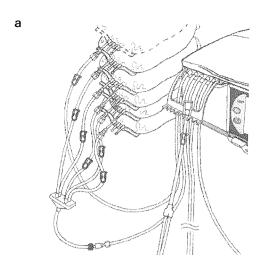
Around 3 million people worldwide with end stage renal disease need to regularly use one of the established dialysis methods. The most common is haemodialysis, which needs to be done three to four times a week where the patient is dialysed by use of artificial kidney. Less invasive is peritoneal dialysis where peritoneum takes the role of artificial kidney /1/.

Using CAPD – Continuous Ambulatory Peritoneal Dialysis, the patient needs to manually discharge and charge the peritoneal cavity four times a day with suitable solutions. On the other hand with APD – Automatic peritoneal Dialysis, PD dialiser takes over the whole cycle of successive charging and discharging during the night.

Connection of lines, solutions and patient to PD dialyser is done by use of suitable connectors, figure 1 and figure 2. These connectors are protected with caps which must be unscrewed sterilely before use. Cap colour defines to which type of dialysis solution the line connector must be connected to.

In the production of disposable PDL lines the caps are screwed to connectors manually. Manual screwing has several disadvantages like:

- uncontrollable screwing torque which may lead to problems during cap unscrewing by patient due to too tight force, or on the other hand, leakage of the whole line due to too light force
- continuous repetitive manual screwing may cause operator finger and handaches.



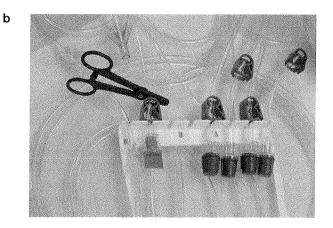


Fig. 1: a) connection of APD line to solution bags; b)Part of an APD line with five connectors

Automatic screwing guarantees controlled and repetitive screwing conditions, as well as higher throughput. The machine is fully automatic and needs to be occasionally refilled with material and reset to define new material lot. Process, as well as production, parameters are input through user friendly touch screen.

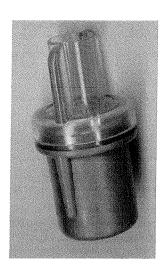
2. Machine design

2.1 General

The idea was to construct a machine that could replace a human operator for screwing caps onto connectors of PDL lines. Torque should be controlled within the broad range of 1 Ndm to 10Ndm with central value of 5±1 Ndm. Machine capacity should be more than 8.000pcs/shift.

Basically the machine consists of the *cap feeding system* which feeds the caps to the *cap transport mechanism*. When caps arrive close to the holder the *cap feeding arm* takes the caps and puts them into the *screwing holder*. On the opposite side of the machine connectors are fed from *connector feeding system* which feeds connectors to the *connector transport mechanism*. When connectors arrive close to the holder the *connec*.





a b

Fig. 2: a) cap (bottom) and spike (up) separated; b) cap screwed on spike

tor feeding arm takes the connectors and puts them into the screwing holder. Three screwing heads with motors are downloaded to screw the connectors onto the caps by using appropriate software driven algorithm. Once screwed, the holder opens and connectors with cap fall into the material box.

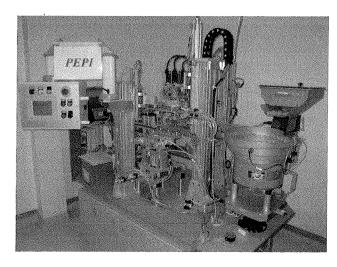


Fig. 3: Machine

2.2 Machine hardware and software

Heart of the machine are screwing heads with servo motors and microprocessor closed loop control of torque and rotation speed. These two parameters are inserted by operator through the control panel.

The process consists of two steps:

 screwing up to predefined torque of 3Ndm, rotation speed is variable and should be inputted via control panel

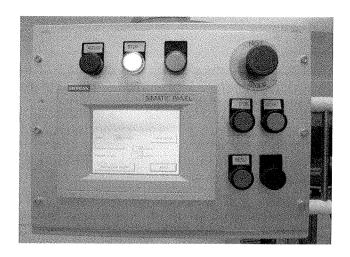


Fig. 4: Machine control panel

screwing with lower rotation speed of 10RPM, final torque is variable and should be inputted via control panel

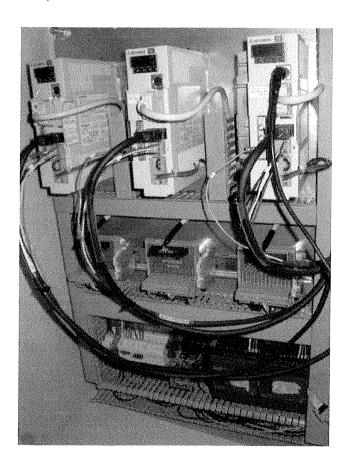


Fig. 5: Servo controllers and DA units

2.2.1 The program flowchart and explanation of the speed/torque control

The flow chart of the screwing procedure is presented in figure 7. The process is intentionally divided into two phases, so that optimum between speed and accuracy can be reached without remarkable overshooting in torque.

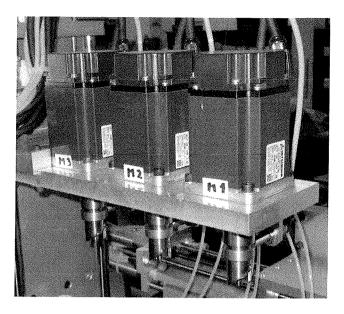


Fig. 6: Servo motors with screwing heads

Control signals for adjusting the speed and torque from PLC to servo controllers are provided by analogue signals with 0 to +10V reference. The resolution of the system is 12 bit. Theoretically we can adjust the torque with accuracy better than 0,005 Ndm, which is more than enough in this particular application.

When the routine starts the servo regulator works in a "speed control mode", in order to perform quick and reliable positioning of the screwing heads in home position. Just before the screwing procedure starts, the servo regulator switches into the "torque control mode" where it is able to provide the specified torque.

In this particular mode the servo regulator follows torque and speed reference from superior PLC. However the speed reference can be followed and carried out, only if the torque reference value has not been exceeded. When load reaches predefined torque value the speed of servomotor begins to fall and eventually it reaches zero.

The signal of motor zero speed is also the crucial signal in the control program and represents the condition for jumping to next programming sequence.

The time graph of the screwing sequence in torque control mode can be seen on figure 8. The "ON" signal line represents the control signal from superior PLC to servo regulator, it has two states (HIGH state energizes the servomotor and LOW state deenergizes it). There is a clear point of speed drop when the torque reaches its maximum. This graph was recorded during the second phase of screwing procedure.

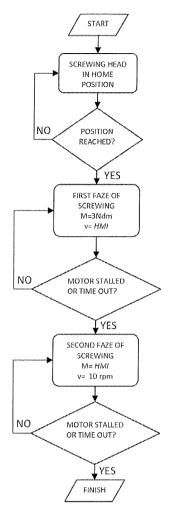


Fig. 7: Flow chart (simplified)

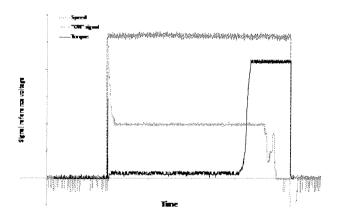


Fig. 8: Screwing sequence time diagram (phase 2)

2.3 Check of system linearity and accuracy

Before the servo system was installed into the machine, some basic tests were made in order to check the linearity and accuracy of the motor torque output as a function of torque reference. This was also a base for system calibration.

On figure 9 schematic drawings represent the system calibration procedure. The procedure is considered as a static

measurement. The torque of servomotor was "weighted" with known masses on a light rope, which was connected to the light pulley of known perimeter. The pulley was directly connected to the servo motor axis. The servo controller is capable of providing feedback information of the servo motor's momentary torque output.

The data was acquired when the outer torque with respect to mass gravity force and the servo motor torque were in equilibrium. The condition of a constant angular velocity must be met in order to use the equation's below:

$$\sum \vec{M}_i = 0, \omega = 0$$

$$\vec{M}_{F_g} + \vec{M}_{SM} = 0$$

$$\vec{M}_{SM} = -\vec{r} \times \vec{F}_g$$

$$M_{SM} = F_g \cdot \frac{d}{2}$$

Based on upper equation we were able to calculate the theoretical torque, which was compared to servo controller feedback.

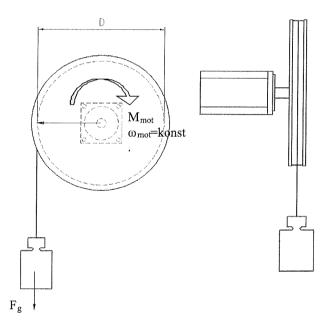
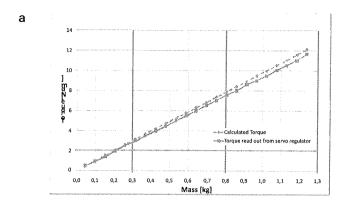


Fig. 9: Scheme of a torque measurement procedure a) front view; b) side view

The graphical representation of the results can be seen on figure 10a. In general there is a constant 5% difference between calculated value and the feedback from servo controller. This difference can be successfully compensated in the software of the control PLC.

In order to assure precise control of the torque on the connector screwing machine, the linearity measurement of the DA converter from the PLC was carried out. The graphical representation is on figure 10b. The R² factor of the data has a value very near 1, which gives us a great confidence in DA converter linearity.



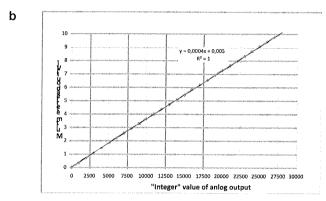


Fig. 10: Graphs of torque measurement and voltage output – a) Theoretical and servo controller feedback torque; b) Linearity of the DA converter

3. Results

3.1 Machine operation

Machine has been in operation for several months and besides some minor mechanical and software changes it has been performing according to expectations.

3.2 Machine throughput

Planned throughput of 8.000pcs/shift has been reached very soon. Today, the machine throughput is in the range of 9.500pcs/shift.

3.3 Determination of torque window

Torque window within which the cap should be screwed on the connector was determined in the following way:

a)if minimum torque is applied the line should still not leak through the connector cap

By use of graph shown on figure 11 the minimum torque required before the line starts to leak was determined to be 2Ndm. As can be seen on figure 12, line leakage through the connector screwed with less than 2Ndm becomes substantial.

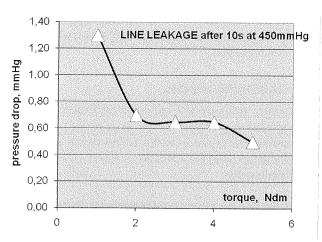


Fig. 11: Line leakage versus torque

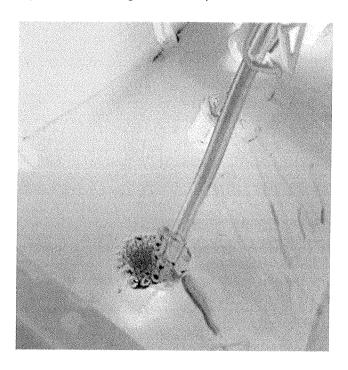


Fig. 12: Cap to screw leakage

b)if maximum torque is applied it becomes impossible to unscrew the cap manually without the appropriate tool. Several people were asked to unscrew the caps and subjectively classify the force they had to use. The results are shown in the Table 1. Obviously, torque above 8Ndm is already too high and it becomes impossible to unscrew the cap.

Table 1, force needed to unscrew the cap, subjective rating

torque, Ndm	unscrewing, subjective rating
3	easy
4	easy
5	not so easy
6	difficult
7	almost impossible
8	impossible
20	impossible

From above experiments the acceptable torque window was defined to be between 3Ndm and 8Ndm with central value around 5Ndm.

3.4 Screwing results

Validation of screwing was executed by torque measurement needed to unscrew the cap. To do so we prepared a measurement accessory similar to the actual machine's screwing head used for automatic screwing but with added dynamometer.

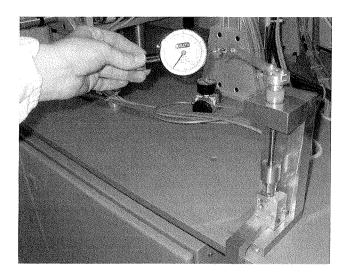


Fig. 13: Torque measurement

To execute the measurement the subassembly must be positioned in the holder, the measurement head lowered and the dynamometer arm forced to open the cap.

The force is read and the torque needed to unscrew the cap calculated.

The data acquired for the torque needed to unscrew the caps and spikes is represented on figure 14. The calculated mean value of the torque is 5,2 Ndm with standard deviation of 0,9 Ndm (based on population of 336 samples). Shape of the histogram is very close to theoretical normal distribution N (5.2;0.9).

4. Conclusion

The machine for automatic screwing of caps to spike connectors was constructed and built. Due to its high throughput it successfully replaced several manual operators with which we also avoided problems of long term operator fin-

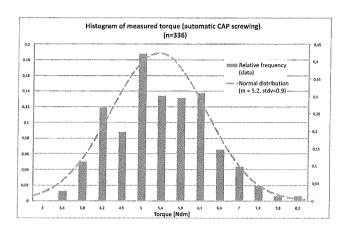


Fig. 14: Histogram of torque measurements

ger and handaches, as well as we obtained good control of screwing process. Long term results of torque measurements show almost 30 % better accuracy of automatic system over the manual assembly. Operator friendly user interface allows easy machine set up and control of main process parameters.

Although main goals of machine operation and process control were met, there is still room for further development and research, especially in shortening cycle time and lowering standard deviation of the unscrewing torque.

5. References

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