THREE PARAMETERS OPTIMIZING CLOSED LOOP CONTROL IN SEQUENTIAL SEGMENTAL NEUROMUSCULAR STIMULATION

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SUMMARY

In conventional dynamic myoplasties the force generation is poorly controlled. This causes unnecessary fatiguing of the transposed/transplanted electrically stimulated muscles and causes damage to involved tissues. We introduced Sequential Segmental Neuromuscular Stimulation to reduce muscle fatigue by allowing part of the muscle to periodically rest, while other parts work. In spite of this improvement we hypothesize that fatigue could be further reduced in some applications of dynamic myoplasty, if the muscles were made to contract according to need. This would also protect against damage to involved tissues. The first necessary step is to gain appropriate control over the contractile activity of the dynamic myoplasty. Therefore, closed loop control was tested on a sequentially stimulated neo-sphincter in order to strive for the best possible control over the amount of generated pressure. A selection of parameters was validated on optimizing the control. A control algorithm was created with the following built in variables: the frequency of corrections; the threshold for corrections and the transition time, during which no corrections were allowed. In dogs, neo-sphincters were created and stimulated to generate a closed loop controlled pressure. The accuracy of the generated pressure was measured while the values of the parameters were changed according to a protocol. Statistically significant optimum values were found for the tested parameters. Therefore we concluded that the frequency of corrections, the threshold for corrections and the transition time, are meaningful parameters in the controlling algorithm of the closed loop control in a sequentially stimulated myoplasty.

STATE OF THE ART

In dynamic graciloplasty the gracilis muscle is used to replace sphincter function. Outcome of this procedure has been variable /1,2,3/. Problems with muscle fatigue, ischemia, necrosis and fibrosis have been reported /4,5/. Current methods remedy fatigue using lengthy training protocols that transform the muscle from fatigue prone to fatigue resistant /7,8,9,10/. During this training period the muscles loose power and responsiveness and the patient does not benefit from the procedure. /6,7,8/. During training the patient is not experiencing benefit from he procedure and the muscles loose power and responsiveness. Additionally, as the result of constant performance, blood perfusion decreases, producing adverse effects on stamina and promoting fibrosis and necrosis.

In previous work we described Sequential Segmental Neuromuscular Stimulation (SSNS/ alternating stimulation) that improves blood perfusion during stimulation by allowing parts of the muscle to rest while other parts contract /9/. This improves the fatigue resistance of the muscle at the cost of a lower maximum power output, because only part of the muscle is stimulated at a time. In a graciloplasty dog model we found that SSNS significantly improved neo-sphincter blood perfusion and fatigue resistance during stimulation /10/. However, In spite of these improvements the neo-sphincter could not maintain contraction indefinitely and did go on to fatigue.

Based on our previous findings we decided to approach the problem differently. Rather than trying to optimize methods to maintain constant pressure around the urethra we decided to apply a more physiological approach and apply pressure only when it is needed to maintain continence. In the case of a normally functioning true sphincter control mechanisms regulate when and to what degree contraction occurs. This results in maintenance of continence without prolonged periods of maximum sphincter contraction. If we could apply the same principal to a neo-sphincter i.e. stimulate it precisely when and to the degree necessary to maintain continence we could minimize or eliminate muscle fatigue and oppose the reported fibrosis and necrosis of involved tissues.

Successful regulation of output using electrical stimulation with closed loop control has been reported in research concerning paraplegia /11,12/. In this study we tested the feasibility of using closed loop control to regulate neo-sphincter pressure. Herein we investigated the effectiveness of three separate parameters in the algorithm.

MATERIAL AND METHODS

Sixteen neo-sphincters were created in eight dogs using both gracilis muscles. These muscles were wrapped around compressible latex tubes containing fluid at a hydrostatic pressure of 30 cm H_2O and balloon dilatation catheters (BMX/8-3/5.8/120, Boston Scientific Corporation, Quincy, MA). An input/output device (CED 1401^{plus}, Cambridge Electronic Design, Cambridge, England) was used to generate a three-channel SSNS signal (mono-phasic rectangular block-pulse; frequency 30 Hz; pulse-width 500 μ-seconds; transition to next segment after 1.0 second). The amplitude of the stimulation signal was controlled for all individual segments by customized sequencer files and script files in Spike2 data acquisition software (version 2, Cambridge Electronic Design, Cambridge, England). Stimulation signals were isolated using linear stimulus isolators (A395's, World Precision Instruments, Sarasota, FL, USA) and thereafter led to the neo-sphincters using three pairs of Teflon coated stainless steel wire electrodes (∅ 0.007 inch; Medwire®, Mount Vernon, NY). Pressures generated by the neo-sphincters were picked up by balloon dilatation catheters and captured by pressure-transducers (P23 ID, Gould, Statham, USA). The generated pressure signals were amplified using CED1902's (Cambridge Electronic Design, Cambridge, England) and recorded with the CED 1401^{plus} (Fig. 1).

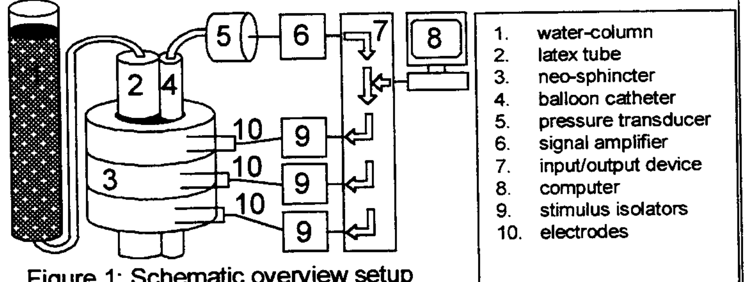

Figure 1: Schematic overview setup

All neo-sphincters were stimulated to generate 30 cm H_2O. After reaching 30 cm H_2O pressure, this pressure was maintained for 15 seconds. During these 15 seconds, the actually generated pressure was measured and the average (from 150 samples) of the standard deviations was recorded to verify accuracy. This procedure was repeated 24 times with intervals of 6 minutes. Adjustments were made in the algorithm of the closed loop control with every repetition according to a protocol. In this protocol three parameters of the algorithm were evaluated for eight discrete values. Correction frequency: The number of corrections conducted by the closed loop control was varied from 1 per second up to 8 per second in steps of one (1-8 Hz). Allowable deviation: The threshold for the algorithm to conduct a correction by changing the amplitude of the signal was varied from 1% deviation of the goal pressure of 30 cm H_2O to 2%, 3%, 4%, 6%, 8%, 12% and 16%. In the SSNS every step to the next segment was started with a transition time. This transition time, in which no corrections were conducted, was varied from 0.0 up to 0.7 seconds, with steps of 0.1 seconds. This protocol of adjustments was constantly rotated to avoid bias in the measurements caused by fatigue of the neo-sphincters.

Statistical analysis of the data was performed using Friedman Repeated Measures Analysis of Variance on Ranks (RM ANOVA) and All Pairwise Multiple Comparison Procedures (Dunnett's Method).

RESULTS

The standard deviations generated with the 8 discrete values of the frequency of corrections showed a minimum at 4Hz (Fig 2). Differences with all other frequencies were statistically significant ($p<0.05$). For the 8 values of the allowable deviation, a minimum standard deviation was found when the allowable deviation was 4% of the requested pressure of 30 cm H_2O (Fig. 3). Again, differences with all other values were statistically significant. A transition time of 0.3 seconds produced minimal standard deviations (Fig. 4). At this transition time the difference in standard deviation was not statistically significant when compared to 0.2 or 0.4 seconds, but all other values showed significantly higher standard deviations.

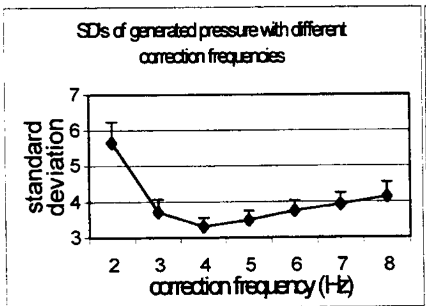

Figure 2

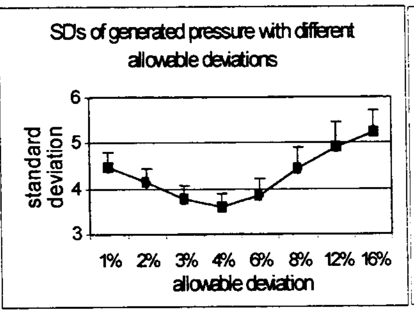

Figure 3

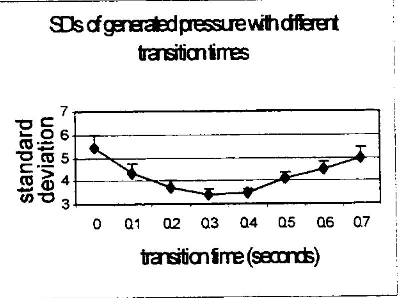

Figure 4

DISCUSSION

In dynamic myoplasties like dynamic graciloplasty major progress can be achieved if generation of output could be controlled and immediately adjusted according to necessity. Closed loop control using biofeedback is a useful means of acquiring this control. This approach was elaborated in the above described experiment: A neo-sphincter squeezing an artificial urethra containing a hydrostatic pressure of 30 cm H_2O and a balloon sensing the pressure generated by this neo-sphincter (biofeedback). With a specified frequency, this generated pressure was evaluated and when the specified threshold was exceeded the amplitude was proportionally corrected (closed loop control). Efficiency of the controlling algorithm was evaluated by calculating the average standard deviations during functioning. The frequency of corrections was evaluated on efficiency and showed an optimum value at 4Hz. At lower frequencies, corrections were relative late allowing greater deviations. At higher frequencies, adaptation of the muscle on changed stimulation amplitudes was too slow to react efficiently. This led to over-correction of the amplitudes and overshooting of the goal-pressure. The threshold for corrections showed an optimum in efficiency at a value of 4%. With lower thresholds the system over-reacted for the minimal corrections necessary, leading to over-correction. With higher thresholds the system was more indifferent to deviations allowing inefficiency. The neo-sphincter was divided into three segments and sequentially stimulated to improve perfusion during stimulation and thus endurance. The algorithm controlled these three segments as if three neo-sphincters were working in a sequential fashion, each having its own amplitude and individual correction of this amplitude. When switching from one segment to the next, the muscle and the biofeedback did procrastinate. Therefore, it was possible that a correction in amplitude was executed on a just starting segment, with biofeedback information referring to the previously stimulated segment. This faulty information led to poor corrections in amplitude of the stimulation signal. Therefore, a transition time in which no corrections were fulfilled was introduced. An optimum was found around 0.3 seconds. Lower transition times showed interference of segments and their biofeedback, resulting in higher standard deviations.

Higher transition times also resulted in less efficiency caused by the lack of corrections during stimulation.

It is concluded that closed loop control and sequential segmental neuromuscular stimulation can be combined in a system that control generated output. The frequency of corrections, the deviation allowed before corrections are effectuated and the transition time when switched to the next segment prove to be useful parameters in optimizing the efficiency of this closed loop control. The actual optimal values will probably differ between different muscles and different applications.

Efficient control of generated output of dynamic myoplasties will reduce fatigue and the necessity to train the muscle extensively. It will prevent ischemia and compromise of involved tissues and broaden the application area of dynamic myoplasty.

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