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Expert control of the arterial blood pressure during surgery

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Abstract

During and after many surgical procedures the patient's arterial blood pressure must be artificially decreased to a lower than normal level. Although there are alternatives, infusion of the drug sodium nitroprusside (SNP) is frequently the preferred technique to achieve this controlled hypotension. The fast action of the drug and the danger of a too low pressure make manual control of the SNP infusion flow rate, even if done by an expert, a difficult and demanding task. This is mainly due to an occasional large unpredictable variability over time of the patient's sensitivity to SNP, and to the fact that a multitude of other factors also influence the arterial pressure. Due to these and several other causes, current automatic controllers cannot handle all cases equally well.

A new expert system based SNP controller [3] was designed to perform well for all patients, regardless of their characteristics. It monitors and adjusts its own performance, employing a number of heuristics derived from a careful study of the properties of the arterial pressure signal, the effects of SNP and other clinical provocations on the arterial pressure, and the ways in which expert clinicians manually manage the SNP infusion. Expert systems technology allows the new controller to access and employ this type of *expert medical knowledge,* resulting in expert-level performance.

The controller was tested on 30 patients undergoing cardiac surgery, both before, during and after bypass. It was safe, needed little attention, and performed well in all cases.

Introduction

During some types of surgical procedure the patient's arterial pressure needs to be controlled at a lower than normal value. Usually the drug sodium nitroprusside (SNP) is infused to lower the arterial pressure. An earlier study [2] into the dynamic and static characteristics of this drug shows that application of the drug is often difficult due to little *a priori* knowledge of the patient's sensitivity, the change of the patient's sensitivity in time, a pronounced non-linearity, a significant and possibly changing delay time in the control loop and a frequently bad quality of the measured arterial pressure signal. Manual control is often difficult and requires close attention to the patient's response. Existing closed loop controllers often do not cope well with non-average patients. An automatic controller thus far is not a good alternative for manual control, since those cases which are the most difficult to treat manually are as yet impossible to control automatically. The goal of this research was to realize a robust, unconditionally stable automatic controller that can be used either as a stand-alone system or integrated in an infusion pump, a liquid management system or a work station.

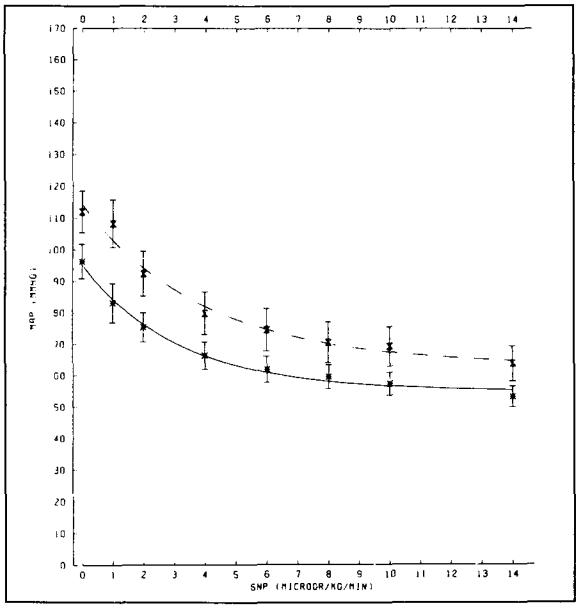

Fig. 1. Average normalized static characteristic of SNP in pigs. The lower curve was obtained at the beginning of the experiment, the upper curve approximately six hours later.

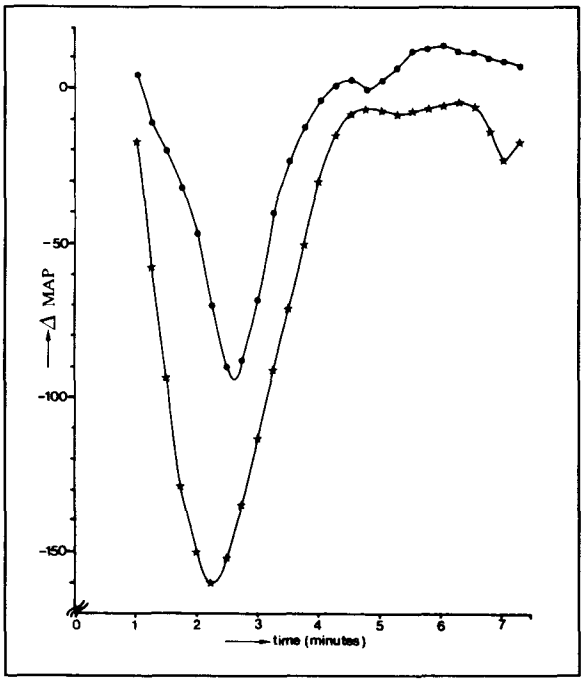

Fig. 2. Typical dynamic (impulse) characteristic of SNP in pigs. Both curves were obtained at the same mean arterial blood pressure, the upper curve about 90 minutes later than the lower one.

SNP characteristics

To gain a better understanding of the variability of the response to SNP, experiments with 19 Yorkshire pigs were done [2]. Surgical and anesthetic procedures were standard. The arterial blood pressure was measured in the abdominal aorta and SNP was administered by means of an IMED 929 computer controlled isovolumetric infusion pump. Data were acquired and processed by a PDP11/03 based data acquisition system [1], which also controlled the pump.

Static characteristics were obtained from dose-response measurements. Infusion rates of 0, 1, 2, 4, 6, 8, 10 and 14 μg/kg/min of a standard solution of 100 mg SNP in 400 cc glucose 5% were administered until a new steady state was reached, which usually took 5 to 10 minutes. This procedure was performed both at the beginning and at the end of the experiments, which lasted from 5 to 8 hours. The static curve, shown in Fig. 1, was generally non-linear. In only 11% of the dose-response curves a straight line was a fair approximation, while all curves could be fitted well with an exponential function. The coefficients that describe each individual curve showed a large variation, however, and could not be related to any of the observed physiological variables (other measured variables, body weight, etc.). The characteristics were not stationary either. In the course of the 5 to 8 hours of the experiments, in 83% of the animals the curve shifted upward significantly. This upward shift showed a large variation, between 8 and 58% of the initial pressure, and could not be related to any of the observed physiological variables.

Dynamic characteristics were obtained continuously by correlating the mean arterial pressure (MAP) measurements with the SNP infusion rate while either of three controllers was in effect: manual control (i.e. the anesthetist specified the infusion rate), an automatic controller designed by Sheppard [9] and a prototype version of a new adaptive controller. The Extended Kalman Filter [5] was used to continuously estimate 30 impulse response points at 15 second intervals, representing a total impulse response time of 7.5 minutes. The

estimation procedure was made adaptive, so that changes could be tracked. This attempt to establish the patient's sensitivity from a correlation between input (SNP flow rate) and output (mean arterial blood pressure) was only partly successful; although frequently a sufficiently accurate sensitivity estimate was obtained, the estimate often proved to be unreliable due to the bad signal-to-noise ratio: the arterial pressure was often much more influenced by other events than by a change of SNP flow rate. The dynamic (impulse response) characteristic, shown in Fig. 2, was found to be composed of a delay time of between 15 and 60 seconds followed by a second order response, reaching an extremum after about two minutes followed by a fast decay (see also Slate and Sheppard [11]. The impulse response never lasted more than 6 minutes. In general, the amplitude of the extremum decreased at lower pressures (which can be explained by the nonlinearity of the static curve) and towards the end of the experiments (which may be due to increasing baroreceptor reflex action). Inter- and intra-animal amplitude (sensitivity) variations of up to a factor of 80 were observed.

Controller characteristics

An automated sodium nitroprusside infusion system for blood-pressure control should have certain performance characteristics; some of these have been established by consensus. These include, after a step change in setpoint, a 20 percent settling time[1] of less than 10 minutes, a maximum overshoot of less than 10 mmHg, and a steady-state error of less than 5 mmHg. Along with these performance characteristics, the controller also has some clinical constraints. The first of these is a maximum allowable infusion rate, a function of patient weight and drug concentration, to prevent cyanide toxicity. Another constraint is that incremental increases in infusion rate should be limited to prevent rapid decreases in pressure which can cause diminished blood flow or circulatory collapse.

The controller must also be able to handle a wide variety of patient types and a wide range of patient characteristics; the largest number found in the literature concerning the patient's sensitivity variability, for instance, is 48-fold [6], while we found a factor of 80 in animals. Furthermore, the patient's characteristics can change during the course of the operation. Thus, the controller must be able to identify the characteristics of the patient it is controlling and then adapt to any changes that might occur. The performance of the controller must be guaranteed, even during episodes in which no valid measurements are available.

Another complication is that large 'noise' levels may occur in the arterial pressure signal. In the ICU, this noise may be due to sudden changes in the patient's emotional state or level of activity in which case the controller must take appropriate steps to regulate the arterial pressure. Arterial pressure is not always stable in the operating room either. Surgical stimulation during light anesthesia, bleeding, rapid fluid infusion, administration of other vasoactive drugs, and respiration maneuvers can dramatically influence blood flow and arterial blood pressure. However, routine procedures such as the taking of blood samples or the flushing of a catheter give readings which are not real and must be disregarded.

In view of the problems of conventional modelling and estimation methods for this particular problem, we decided to have a better look at the (rather successful) clinical practice of ad hoc adjusting the infusion flow and to investigate the use of a simple but robust controller combined with an expert system to monitor the controller's behavior and adjust its parameters if necessary. The SIMPLEXYS real time expert systems toolbox [3], especially developed for this type of application, was used to implement the system. Robustness was considered to be the key issue for the control system.

[1] The time required to bring the pressure toward the setpoint, within a margin of 20% of the setpoint change.

Arterial pressure characteristics

Many disturbances can cause the measured signal not to reflect the true arterial pressure: transducer calibration (zeroing), blood clotting, air bubbles in the line, flushing the arterial line, sampling of blood, electrocautery etc. If these disturbances can cause an incorrect computation of the mean pressure, they must be detected, as well as transducer, catheter and amplifier failure. We therefore designed a signal validation algorithm that, for each heart period, computes the mean arterial blood pressure value and sets a validity flag, which indicates whether this value reflects the true mean pressure or not. The validation algorithm [3] incorporates four categories of knowledge regarding the arterial pressure:

1. morphological knowledge concerning the possible shapes of a correctly measured period of the signal;
2. information content knowledge, i.e. which 'features' of the signal (systolic, diastolic, mean and pulse pressures, period duration, systolic dP/dt, etc.) are clinically meaningful;
3. knowledge concerning the numerical values that these features can have under physiological conditions;
4. the knowledge that subsequent arterial pressure periods are nearly identical in shape.

The latter assumption excludes use of the controller during certain therapeutic procedures (e.g. when employing a balloon pump that supports only one beat out of every two or three) and for some patients (e.g. when the patient's cardiac rhythm shows a persistent bigeminy). Otherwise, the validation algorithm is conservative; whereas it considers an acceptable period as invalid once in a while, especially during and after sudden mean pressure level shifts, it never considers a period containing a significant artifact as valid.

Other disturbances reflect the true arterial pressure, but are due to instabilities due to e.g. surgical events or administration of other drugs with a vasoactive effect. The arterial pressure is also influenced by a multitude of other physiological processes; an example is breathing. These 'normal' variations must not disturb the controller's actions.

Once in a while a large *transient* can be observed in the mean arterial pressure. A transient is a sudden large in- or decrease of the pressure which, even if not acted upon, disappears after a short time. However, when a sudden large in- or decrease of the pressure appears, the control system has no way to 'look ahead' to establish whether it will be a transient or not. It is most prudent to temporarily assume the worst case situation.

Positive transients can be tolerated if they do not last too long. These positive transients are often caused by pain stimuli. Insufficient pain suppression may cause large increases in arterial pressure that last as long as the pain stimulus occurs and subside when the pain stimulus is over or when pain suppression medication is increased. Such a pressure increase should not be suppressed by SNP, because SNP is not a pain killer. If it were suppressed by SNP, a large pressure undershoot might occur after the pain ends. Since too low a pressure is more dangerous than too high a pressure, a control strategy of, at least temporarily, not responding to a large sudden pressure increase seems best.

Negative transients are dangerous; they can indicate a state of shock.[2] SNP infusion should stop immediately and should only be resumed when the arterial pressure is approximately at the setpoint again. However, if the negative transient was due to an artifact of some sort, the expected after-effect of temporarily stopping the SNP infusion would be a pressure overshoot.

The above mentioned *interpretations* of what causes transients, i.e. pain and shock, will often be incorrect, as transients may have other causes. The control strategy that is followed after such transients was chosen for the sake of patient safety and appears reasonable also if the cause should be different.

Transients needs to be detected for more reasons. The controller simply cannot compensate for transients: they are too fast and too large. Moreover, such an attempt to compensate for a transient

[2] This interpretation is probably more appropriate in the intensive care unit than during bypass surgery. Yet the appropriate control decision is the same.

would cause a large change of flow, but without much immediate effect. But when the transient is over, the controller must recover and bring the flow back to the pre-transient level; this takes time and may result in a severe over- or undershoot. It is therefore better to detect transients and select a different control regime until the transient is over.

The control system

A diagram of the blood pressure control system is shown in Fig. 3. The system communicates with the outside world in three ways: it acquires the analog arterial blood pressure signal from the AD-converter, it communicates with the infusion pump through an RS-232 interface, and it communicates with the user through the computer's keyboard and display.

The controller has a cycle time of 5 seconds. An algorithm averages the output from the validation algorithm over a 5 second interval; values which are flagged as invalid are, of course, not included in the average. If no valid beats are found in the 5 second interval, a 'pressure not valid' flag is set by the algorithm. Thus the expert system controller is provided with a new input every 5 seconds, consisting of a MAP value and a validity flag.

The controller has two control modes: manual and automatic. It is meant to be switched to automatic as soon as the arterial pressure measurement becomes available and to remain in control until the end of the case. The controller starts up in manual mode with a zero flow rate and a setpoint equal to the MAP at this time. Pressing one of the keyboard's function keys decreases the setpoint, in steps of 1 mmHg, between limits; the new setpoint depends on the number of times the key is pressed or the time during which the key is kept depressed (the keys have auto-repeat). Another key similarly functions to increase the setpoint. In manual mode, other function keys allow the infusion flow rate to be increased (up to the maximum value allowed) or decreased (down to zero flow); the new flow rate takes effect immediately. If the system is in manual mode, it can be switched to automatic mode, which then takes over starting with the flow rate that was

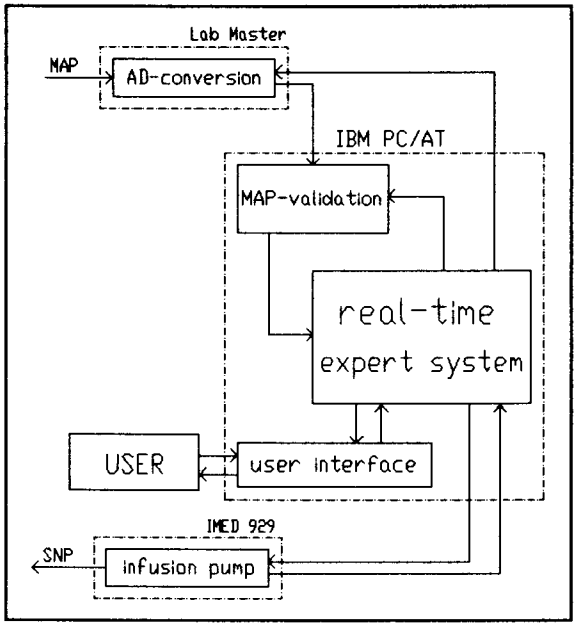

Fig. 3. The blood pressure control system.

set in manual control. For the sake of safety, an 'emergency stop' key can force a zero flow condition immediately.

Under certain conditions (air in line; occlusion; low fluid; malfunction), the infusion pump will stop delivering fluid, give an alarm, and will not obey further commands till the problem is resolved. The controlling system needs to know these facts and act appropriately. Handling pump errors is done as follows: if in automatic mode, the system first switches to manual mode; next, the fact that the actually delivered flow rate is zero and not any more under control of the system is recognized, and lastly the appropriate alarm message is displayed. After repair of the alarm condition, which may take any time interval, control can be resumed with a single key-press.

Due to instabilities in the arterial pressure signal caused by all kinds of artifacts, the signal can be invalid for periods (much) longer than 5 seconds. Feedback control is then impossible and feedforward (open loop) control is, for safety reasons, allowed for only a short time. The following 'hold mode' solution is chosen for the controller:

- control continues using a MAP equal to the last valid value if the signal is lost during at most 30

seconds, or during 60 seconds if the last valid pressure measurement was less than 20 mmHg from the setpoint;
- if the signal is lost for a longer time, the system gives an audible alarm and control returns to manual mode with a flow rate identical to the last valid flow rate given. To resume automatic mode, the signal must be valid again; one keypress is then sufficient.

Knowledge implemented in the control system

Several types of knowledge must be incorporated into the control system. First, how to control under normal circumstances; this determines the basic controller. Second, how to perform any required type of adaptation to the patient's characteristics; this determines the adaptation mechanisms. Third, how to react in special circumstances; it must be specified how control must proceed when transients are detected. Fourth, how to incorporate any additional safety features.

Knowledge verification

Due to its robustness, we decided to use a PID-controller as the basic controller. Initial tests during 33 cases were performed to provide a verification of the animal data about the dynamic SNP response in patients and to translate these findings into PID-terminology. Table 1 provides the relevant observed parameters, together with the ranges that we decided the controller was to be able to handle. If the controller's nominal gain is chosen to be -0.2 mmHg/(mg/hr), equivalent to -0.04 mmHg/(μg/kg/min), the relative control gain varies between 1/9 to 9, the total control gain being equal to nominal gain times relative gain.

The basic controller

Simulations established the best (most robust) values for the control parameters. Optimal design parameters could be chosen in such a way that if any single control parameter was a factor 2 off from the counterpart patient parameter, control would still give good performance, while a factor 3 off would still give reasonable performance.

Table 1 shows that the controller's time constant and delay time can be fixed at an optimum value, but also that its gain needs to be adapted. As a basis for this adaptation, the patient's sensitivity as well as the controller's relative gain, is classified into one of five groups, as shown in Table 2, and a number of gain adjustment mechanisms is introduced which monitor the controller's performance in various ways and can adjust the control gain in steps of a factor 3.
These considerations led to the following control formula for the basic controller:

$$SNP_k = SNP_{k-1} + G \star [I \star (SET_k - MAP_k) + P \star (MAP_k - MAP_{k-1})]$$

with

SNP	=	flow rate	[ml/hr] = [mg/hr]
SET	=	setpoint pressure	[mmHg]
MAP	=	mean arterial pressure	[mmHg]
G	=	relative control gain	(1/9, 1/3, 1, 3, 9)
I	=	I-parameter, 0.0960 to 0.0720	[(ml/hr)/mmHg]
P	=	P-parameter, 0.0056 to 0.0036	[(ml/hr)/mmHg]

Table 1. Dynamic SNP parameters. Extremes from 33 cases and the ranges that the controller was designed to handle. Very short delay times were found only rarely.

	minimum found	maximum found	design optimum	design range	
relative gain	0.6	4.0	1	0.1–9.0	
delay time	15	75	50	25–100	seconds
time constant	30	100	60	30–120	seconds

where the control interval is 5 seconds, and SNP_k and MAP_k are the *current*, SNP_{k-1} and MAP_{k-1} the *previous* sodium nitroprusside flow rate and 5 second averaged mean arterial pressure respectively. Moreover, the flow increment $SNP_k - SNP_{k-1}$ is limited to 7% of SNP_{k-1}; this provides for a relatively 'smooth' control that clinicians find intuitively appealing. The P- and I-parameters are allowed to vary, because simulations demonstrated that in regulation different values were appropriate than in stabilization. If the offset is 100 mmHg or more, the lowest values are used; at smaller offsets, the parameters proportionally grow to their highest values. For instance, if the offset is 50 mmHg, the actual P- and I-parameters are halfway between the two values given above.

Adaptation to the patient's sensitivity

For safety reasons, the system starts to control at a very low gain (1/9), as it initially assumes a very sensitive patient. In many cases, however, the control gain will be too low. Optimally, the controller's gain should be inversely related to the patient's sensitivity.

The most important conditions that provide an estimate of the patient's sensitivity and thus can be used to adjust the controller's gain are:

- In a steady state condition (the mean pressure is or should be approximately constant), the controller's gain is increased if the offset (the difference between the actually measured pressure and the pressure setpoint) is, on average, significantly different from zero for too long a time.
- In a steady state condition the controller's gain is decreased if the offset is, on average, zero, but shows oscillatory behavior.
- If the pressure changes too slowly following a setpoint modification, the controller's gain is increased.
- If the pressure changes too rapidly following a setpoint modification, the controller's gain is decreased.
- Due to the non-linearity of the SNP dose-response curve, the gain is decreased if a large setpoint increase is ordered, since this might mean a move to a region of higher sensitivity. This mechanism anticipates; it becomes active before the MAP shows any effects due to the setpoint change. In some cases the gain decrease will be inappropriate, and then a gain increase action may reverse its effect after some time.

Table 2. Sensitivity and gain ranges.

patient's sensitivity	relative control gain
very insensitive	9
insensitive	3
normal	1
sensitive	1/3
very sensitive	1/9

Safety features

Cyanide is produced when SNP is metabolized [8]. Blood thiocyanate is an intermediate product; thiocyanate levels above 150–200 mg/l exceed the detoxifying powers of the body, and acute anoxia may result. This action is reversible, but only if recognized early. Cyanide toxicity should be suspected in any patient who requires a flow rate greater than 10 μg/kg/min; recommended 'safe' infusion rates are less than 2.0 μg/kg/min. This sets an upper limit to the average SNP flow rate. Another reason to limit the flow rate is that if, due to some unexpected occurrence, the infusion flow rate ever reaches a very high value, the controller will not be able to immediately reduce it to the correct level. For both reasons an upper limit must be set for the flow rate. In the experimental stage of the blood pressure controller it was decided to limit the infusion flow rate to this 'safe' 2 μg/kg/min, a factor 2.5 to 4 lower than the maximum rate mentioned by others [4, 7, 10], but in agreement with standard practice (much used manual settings of the SNP flow rate that we observed were 0.2, 0.4, 0.8, 1.6 and only occasionally 3.2 μg/kg/min; intermediate values were seldomly used). It is therefore to be expected that the controller will not be able to sufficiently depress the pressure in less sensitive patients.

Cyanide may also accumulate; toxic blood levels may occur if more than 1 mg/kg is given over a period of two or three hours (rates greater than 4 μg/kg/min for more than 2 or 3 hours may be unsafe). The 'safe' maximum dosage has been reported by others to lie between 3.0 and 3.5 mg/kg. This sets an upper limit to the total SNP dose allowed. The method is sometimes abandoned because the patient is considered resistant, i.e. if a satisfactory low pressure does not follow infusion of 50 mg over 30 minutes; this occurs mainly in young patients. A cumulative dose limit or alarm was not implemented in the system; it was considered sufficient to continuously present the cumulative dose on the display.

Clinical evaluation

The control system was evaluated during cardiac surgery procedures, mainly bypass cases. Bypass surgery has three stages. During the first stage access to the heart is made, and blood vessels are resected from a leg. During the second stage, these vessels are used to replace defective coronary arteries. The heart is inoperative and blood circulation and oxygenation are provided by a heart-lung machine (perfusion); the resulting arterial pressure signal is almost flat. The MAP is mainly controlled by the heart-lung machine and is at an exceptionally low level (around 40 mmHg). During the third stage the heart is reactivated, the chest is closed and the MAP is allowed to rise again to its pre-perfusion level.

Clinical tests proceeded in three phases. During the first phase all signal processing and display functions were tested, including the data validation. During the second phase (33 cases) the system was tested under 'open loop' conditions; although control was still manual, an SNP flow rate was computed by the expert system. The first and second phases also provided extra information on the ways in which clinicians controlled the SNP flow rate. The second phase was mainly used to debug the system, to correct the knowledge base where necessary, to gain sufficient confidence in the system's performance, and to familiarize the clinicians with the system. The third phase (30 cases), closed loop control, was started when we thought the system could be trusted under all conditions; during this phase (30 cases) the knowledge implemented in the control system remained unchanged.

Performance of the expert system controller

Several aspects of the controller's performance need to be discriminated: how the controller works under manual control, because this determines whether any errors exist in the software surrounding the controller itself, such as signal acquisition, signal validation and the display of the data; how well adaptation is performed; how well control proceeds under special circumstances; and how safe and convenient the overall system is.

Signal acquisition and validation performance

The pulsatile and perfusion validation algorithms were tested separately. They were shown to perform adequately: all significant artifacts were detected. A small percentage of acceptable periods was flagged as invalid, but not enough to significantly influence control actions. This is due to both the 5 second averaging algorithm which delivers a valid MAP as long as at least one period[3] within the 5 second interval is valid, and to the fact that missing up to twelve successive 5 second average values has an negligible impact on the controller's performance.

Control performance

A major aspect of the controller's performance can be assessed by measuring the offset, the difference between MAP and setpoint, over time. An assessment of the quality of manual control during a total of 33 cases (85889 5 second MAP averages), and of automatic control during 30 cases (60970 5 second

[3] During perfusion, the signal was segmented into artificial 1 second 'periods'.

MAP averages, manual control episodes not included) is shown in Table 3. The results are presented by noting how often the offset stayed within a zero-centered band. Table 3 shows that automatic control is consistently better.

Averages and standard deviations of the offset distributions computed for the same data are presented in Table 4. On average, both clinicians and controller keep the MAP close to the setpoint. The controller's standard deviation is smaller, however, indicating that in automatic control the MAP is less often far from the setpoint.

The results suggest that automatic control is slightly better than manual control in keeping the MAP close to the setpoint. In the interpretation of these results, however, several factors are important to consider. In the first place is it, both for the clinician and for the controller, impossible to control the pressure if the setpoint is above the MAP (no negative flows can be given), or when the imposed maximum value limits the flow rate. In the second place, clinicians were sometimes during manual control too preoccupied with other matters to promptly mention the new setpoint that they considered appropriate in a new situation. Third, it is not always the control system's highest priority to keep the MAP close to the setpoint, e.g. when transients occur; the same is undoubtedly true for the clinician. Fourth, manual control episodes during an automatic control regime were disregarded; on average, one such episode occurred during a case, lasting less than 20 seconds but influencing the pressure over a longer period. Fifth, the numbers of cases compared are too small to allow definitive pronouncements.

Table 3. Percentages of the offset in zero-centered bands in manual versus automatic control.

offset band	manual	auto
± 5 mmHg	30%	33%
± 10 mmHg	55%	61%
± 15 mmHg	70%	78%
± 20 mmHg	81%	88%

Performance of the complete system

The implemented knowledge proved to be correct. The controller proved to be safe and could handle all cases well, except when its maximum flow rate needed to have been exceeded. Transients, both positive and negative, were recognized and processed correctly (on average, two per case). The gain adaptation worked correctly as well but was overly cautious in some cases: when the flow rate had been (almost) zero for some time, the gain was decreased, assuming a possible increase of the patient's sensitivity. This is probably unnecessary in most, maybe in all, cases.

Switching back to manual control with an audible signal after a one minute signal loss worked correctly. Usually the clinician just activated automatic mode again when the signal was restored.

The controller was generally switched to automatic soon after the arterial pressure measurement became available, and remained in control at all times, before, during and after perfusion. Only occasionally (once per case, on average) did the clinician consider the controller's response to be too slow; manual control was then selected, the correct flow rate was set, and automatic mode was returned to within seconds. The only criticism by the clinicians was, in fact, that in some cases the system reacted too slowly. The clinicians considered its safe and cautious behavior, a design criterium, to be more appropriate in an intensive care environment than in cardiac surgery. As a result we will, in the future, evaluate the system in an intensive care setting. More research seems required to adapt the knowledge base to the severe conditions that apply during cardiac surgery.

The controller was almost never confronted with a steady state situation. So many other factors influence the arterial pressure during cardiac sur-

Table 4. Evaluation of control regimes during manual and automatic control.

	manual	automatic	
average offset	− 0.8	− 1.1	mmHg
standard deviation	18.1	12.6	mmHg

gery, that the controller is only one more factor, and a slow one compared to e.g. the heart-lung machine's flow setting. Yet, it was an unproblematic one, accepted and trusted by the clinicians.

Conclusions

The controller is based a model which is partly black box, i.e. founded on a mathematical description of the input-output relation of the system, and partly mechanistic, i.e. based on knowledge of the internals of the system. Such intermediate models lead to unique controllers which are often not optimal in a theoretical sense (they do not try to optimize some performance criterium), but robust (they are adequate under wide operating conditions despite imprecise knowledge about the system to be controlled). As a consequence, their performance is often difficult to measure. The difference between MAP and setpoint is one measure, but not the only one, since the pressure need not be kept at a fixed level but can be allowed to fluctuate within reason, depending on surgical needs. The controller takes into account other criteria as well. One constraint is that, for reasons of safety, incremental increases in infusion rate are limited. Another is, that under exceptional conditions a different type of control is required. Also, overdosage has to be avoided at all costs.

The automatic blood pressure controller functioned correctly in all respects, according to its design criteria. It is impossible to decide whether we encountered 'difficult' cases in the closed loop control phase of this study; except for the somewhat overly cautious behavior of the controller (in a cardiac surgery context), no uncontrollable situations were discovered. The system is simple to interact with, unproblematic in use, and in occasional special cases manual control can temporarily take over without much effort.

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