Body Sensors Applied in Pacemakers: A Survey

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***Abstract*—This paper presents a survey of the body sensors applied in pacemakers and recent advances in modern pacemaker systems. New features of modern pacemakers that are commercially available are briefly described. Body sensors incorporated in pacemakers are illustrated with their rationales, sensing signals, advantages, limitations and applications. Their further improvements are needed to better serve patients.**

***Index Terms*—Biomedical sensing, biosensor, implantable sensor, pacemaker, physiological response, power consumption, reliability.**

I. Introduction

CARDIOVASCULAR diseases are major causes of morbidity and mortality in the developed countries. Early diagnosis and medical treatment of heart diseases can effectively prevent the sudden death of a patient. It is well known that implantable cardiac devices such as pacemakers are widely used nowadays. They have become a therapeutic tool used worldwide with more than 250, 000 pacemaker implants every year [1]. A pacemaker is a medical device that uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. Its primary purpose is to treat bradycardia due to sinus node or atrioventricular conduction disorders and to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in its electrical conduction system. It can help a person who has an abnormal heart rhythm resume a more active lifestyle [2].

Modern pacemakers are externally programmable and allow cardiologists to select the optimal pacing modes for individual patients. The complexity and reliability of modern pacemakers have increased significantly, mainly due to developments in and use of sensing technologies. Therefore, modern pacemakers with sensors are applied not only for pacing but also for other functions such as obtaining diagnostic data and providing continuous cardiac monitoring and long-term trended clinical information.

Many problems exist regarding pacemakers in the treatment of a number of conditions. One of them is the diagnosis of cardiac abnormalities. This is because serious but infrequently occurring arrhythmias can be difficult to detect and analyze [3]. To solve them, various types of sensors, such as activity, metabolic and dual sensors, have been used to detect body activity, and measure some consequence of a physiological change during exercise or facing environmental or emotional changes, e.g., temperature and posture changes.

Sensors have four main components: sensing, processing, communication, and energy/power units. Body sensor networks, owing to the sensing units' proximity to each other, might have a base station that handles all the processing, communication, and power delivery. Body sensors fall into two main categories, implantable and wearable. The former measure parameters inside the body and mostly operate as interfaces to relatively small software components attached to or implanted into human bodies. They provide bidirectional communication interfaces between a person and a remote information system that provides healthcare services, diagnosis, or upgrades [4]. Wearable sensors, although not as invasive as their implantable counterparts, nevertheless must withstand the human body's normal movements and infringe on them as little as possible.

Next, we provide a brief introduction to the recent advances and features in modern pacemakers. Our focus is on the review of various body sensors applied in them. The contribution of this survey is to present a summary research and comparison of various sensors with their rationales, features and applications. By comparing different types of body sensors, we conclude the signals they can sense, advantages, limitations and application conditions. This survey intends to benefit the readers interested in biomedical sensing technology. Section II briefly describes the new features of modern pacemakers. Section III illustrates the main categories of body sensors in pacemakers and compares their features. Finally, the last section presents conclusions and future research directions.

II. Modern Pacemakers

A. Basic Functions

Pacemakers are used to treat arrhythmias that are problems with the rate or rhythm of a heartbeat, maintain an adequate heart rate by delivering electrical stimuli (paces) to the chambers of the heart, and prevent human from being harmed by low heart rate. During an arrhythmia, a heart can beat too fast (tachycardia), too slow (bradycardia), or with an irregular rhythm and may not be able to pump enough blood to the rhythmic electric impulse to the heart muscle in order to restore an effective heart's rhythm to meet the oxygen needs of the body. A pacemaker can determine when stimuli must be delivered by calculating the timing of incoming contraction events.

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A modern pacing system consists of at least three main parts, a pacemaker with body sensors, pacing leads carrying pacing impulses, and a programmer. Its programming normally includes demand pacing and rate-responsive one. The former monitors the heart rhythm and sends only electrical pulses to the heart if it is beating too slowly or if it misses a beat. The latter speeds up or slows down the heart rate depending on how active the patient is. It monitors the sinoatrial node rate, breathing, blood temperature, and other factors to determine the activity level. A variety of sensors appropriate for rate-responsive pacing have been developed.

B. New Features

Modern pacemakers have many technological advances of functions, including various modes of dual-chamber pacing, rate-responsive algorithms with dual sensors for optimum physiological response, cardiac resynchronization therapy, arrhythmia-prevention algorithms, antitachycardia pacing, hemodynamic monitoring, rest rate and sleep rate limits, and remote monitoring [5]. They automatically self-adjust the energy output required to pace the heart per the needs of each individual patient. Through actively monitoring the heart on a beat-by-beat basis, they provide pacing only when needed to allow the patient's own heart rhythm to prevail whenever possible, which is beneficial to a patient's cardiac health. The feature of rate response automatically adjusts the heart rate to match the level of activity. Special sensors detect changes in the body other than heart rate and allow the pacemaker controllers to increase or decrease the heart rate accordingly.

The automaticity features of pacemakers with body sensors enable continuous or intermittent monitoring of various pacemaker parameters including pacing impedance, sensing levels, pacing thresholds, and daily activity log. The benefits include increased patient safety, improved quality of life, increased battery longevity, cost effectiveness, and remote device interrogation including data monitoring as well as patient alert functions for device malfunction.

To illustrate the details of the new features in modern pacemakers, several representative ones are introduced next. The Adapta pacemaker offers the Medtronic-exclusive pacing mode called Managed Ventricular Pacing (MVP), which enables it to be programmed to deliver pacing pulses to the heart's lower right chamber (ventricle) only when necessary. The Accent RF pacemaker features daily wireless remote monitoring, providing timely notification of actionable events and flexible remote follow-up scheduling through Merlin.net Patient Care Network. Victory pacemakers offer an important combination of features, including optimized settings to save time at implant, Ventricular Intrinsic Preference (VIP) technology to minimize ventricular pacing, the FastPath summary screen to speed follow-up exams, and advanced technologies to extend the life of the device in patients. The company provides a suite of algorithms designed to make it easier for physicians to manage patients with atrial fibrillation (AF). AF is the world's most common cardiac arrhythmia that results in a very fast, uncontrolled heart rhythm caused when the upper chambers of the heart (atrial) quiver instead of beating. An Evia pacemaker system integrates wireless remote monitoring with smaller size. It is able to provide home monitoring for patients with some sensors. With Closed Loop Stimulation (CLS), Evia responds to changes in the autonomic nervous system on a beat-by-beat basis. CLS is one of the most advanced and physiologic rate regulation sensors. For standard motion-based rate-adaptation, Evia is also equipped with an accelerometer located within the pulse generator. This sensor produces an electric signal during physical activity of the patient.

Although modern pacemakers offer a range of advanced pacing features mentioned above, serious but infrequently occurring arrhythmias can be difficult to detect and diagnose. Hence, a body sensor system incorporating physiological information to aid diagnosis is also an important research field for implantable pacemakers. In rate-responsive pacemakers, some of new physiological parameters are sensed and utilized for diagnosis, such as body vibration or movement, respiratory rate, electrocardiograph (ECG), heart rate, physiological impedance, temperature, and venous oxygen saturation.

III. Body Sensors

A body sensor is a device for the detection of an analyte that combines a biological component with a physicochemical detector component. It normally consists of three parts:

1) the sensitive biological element (biological material, a biologically derived material or biomimic);
2) the transducer or detector element works in a physicochemical way that transforms the signal resulting from the interaction of the analyte with the biological element into another signal (i.e., transducers) that can be more easily measured and quantified;
3) the associated electronics or signal processors that are primarily responsible for the display of the results in a user-friendly way. This sometimes accounts for the most expensive part of a sensor device.

As the sensing technology advances, pacemakers have been able to detect various kinds of physiological variables as well as cardiac signals. Now body sensors are incorporated in most pacemakers as a programmable option. In addition, the role of sensors has been expanded to include functions other than rate augmentation such as the detection of atrial and ventricular capture, and monitoring of heart failure, sleep apnoea, and haemodynamic status [6]. Through the utilization of sensors to monitor cardiac haemodynamics, right ventricular pressure has been found to be a good estimate of pulmonary arterial diastolic and capillary wedge pressure. A fully implanted device has been used to reduce heart failure hospitalization [7].

Body sensors fall into those that detect only body activity and so react only to movement (accelerometers) and those that measure some consequence of physiological change during exercise or other conditions (QT interval, respiration, temperature, and venous oxygen saturation). Table I illustrates the categories of sensors for adaptive pacemaker systems. We conclude specifications, sensed signals, advantages, limitations and application conditions for activity sensors, metabolic sensors, blended sensors, closed loop stimulation (CLS), dual

TABLE I
CATEGORIES OF SENSORS FOR ADAPTIVE PACEMAKER SYSTEMS

Physiological parameter	**Speed of response**	**Sensor reliability**	**Representative sensors**
Body vibration or movement	fast	high	accelerometer; piezoelectric crystal
Respiratory rate	moderate	high	minute ventilation; blended sensor
Heart rate	fast	high	PEA; blended sensor
Physiological impedance	slow	moderate	CLS; minute ventilation
Temperature	slow	moderate	right ventricular blood temperature
Venous oxygen saturation	moderate	moderate	mixed venous oxygen saturation
Blood pressure	slow	moderate	rate of change of right ventricular blood pressure (dP/dt)
Electrocardiograph	moderate	moderate	QT interval

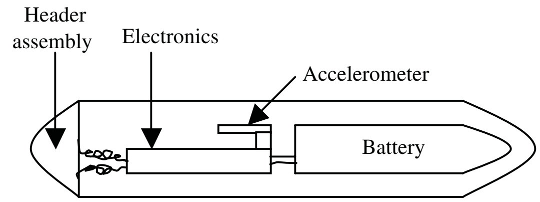

Fig. 1. Accelerometer sensing system [14].

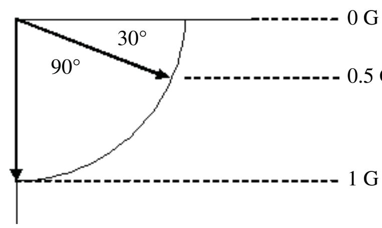

Fig. 2. Acceleration of gravity derived from the angle [16].

sensors, and new diagnostic sensing systems, as shown in Table II [8].

A. Activity Sensor

Chronotropic incompetence is defined as the inability of a sinus node to react adequately with an increase in heart rate to exercise or other movement. For patients suffering from this disease, rate-response pacemakers were invented [9], [10]. It represents a significant advance over constant rate demand ventricular pacing when first introduced in the 1980s, which relies on sensors to detect a patient's activity [11]. The key element of such pacemakers is their activity sensors. Such sensors have been almost universally applied because of their technical simplicity and relative lack of incorrect responses.

Activity sensors, which offer rapid response to exercise by assessing body vibrations or movements, are old and widely used. The working modality is based on the relationship between activity and heart rate. Activity may be recognized by an accelerometer that identifies the postural changes and the body movements related to physical activity [12].

A simple but robust solution for activity sensing is the use of an accelerometer to register body movement. An accelerometer placed in a pacemaker detects movement and patient's physical activity and generates an electronic signal that is proportional to physical activity. Because it is non-invasive (the sensing device is placed inside the pacemaker without direct contact with the human body), this is the preferred technique used in most rate-responsive pacemakers sometimes complimented with sensors for other parameters such as ventilation rate, venous O_2 saturation, or body impedance [13]. An accelerometer evaluates amplitude representing a movement force and also a signal frequency, which is a rate scale factor of movement. It responds to a particular range of vibration frequencies, reducing unwanted external vibrations.

In some models [15], the accelerometer detects the movement of a magnetic ball to obviate rate acceleration caused by direct pressure on the pacemaker. It has proved to deliver an acceptable pacing rate profile in daily life through customized programming by physicians. Movement that is perpendicular to the plane of the sensor generates an electrical signal that is then used to alter the pacing rate. Instead of counting signals above a certain threshold, the accelerometer integrates the voltage that arises from the piezoelement. The pacemaker then differentially "weights" deflections of large amplitude, which allows a more proportional rate response to a given level of exertion to be achieved. Schematic drawing of how an activity sensor using an accelerometer positioned within the pulse generator is shown in Fig. 1. The accelerometer is mounted on the hybrid circuitry of the pacemaker and is independent of the mechanical forces of the surrounding tissue but dependent on patient motion. Scanning a patient's position and movement is necessary to think about what kind of accelerations are scanned.

The principle is grounded on scanning a statical change of acceleration towards gravity acceleration. The sensor has to be always placed on the measured body – one axis is parallel and others perpendicular to the direction of gravity acceleration.

It is possible to scan the position of a top part and a lower part of a patient's body – independently from each other. For walking, running or other kind of movement, scanning of dynamical acceleration is used. It is a change of power working on mass body – human body. The testing results suggest that the most suitable way is to place one sensor on a patient's thigh and the second one on the sensor on patient's chest [17].

With a 3-axis accelerometer sensor, the acceleration can be measured in x, y, and z-axis directions in a three-dimensional space [18]. Based on the acceleration of gravity, the tilt angle of an object and its direction of movement can be detected. The gravitational accelerometer is based on the angle of inclination of the Earth's gravity, where the orthogonal acceleration of gravity is 1G. Therefore, the acceleration of gravity is shown in Fig. 2.

Accelerometer sensors are used most often due to their low cost and ease of programming. Unfortunately, they have

TABLE II

FEATURES OF MAIN BODY SENSORS

Type of sensor		Bio-signal	Description of measured data	Advantage	Limitation and application
Activity sensor (Accelerometer)		Body vibrations or movements, postural changes	Measurement of acceleration/movement forces in a 3-D space	Rapid response to exercise; Simplicity, low cost, and ease of programming; Relative lack of incorrect responses	Less physiologically accurate; Lack of acceleration in the case of increased metabolism without vibration of the body; Possible mismatch between exercise intensity and rate increase; Improper response to increased workload in daily activities; For patients having chronotropic incompetence or doing short exercise
Metabolic sensor	Minute ventilation	Variations in transthoracic impedance	Measurement of volume of air inhaled or exhaled from patient's lungs in one minute	Physiological and excellent correlation with metabolic demand; Enable paced heart to mimic normal cardiac response to increased workload	Slow to respond to onset of exercise; Lower reliability in patients with obstructive pulmonary disease, interference with cardiac monitors and posture or false positive reaction in hyperventilation
	QT Interval	QT interval	Measurement of interval between pacing spike and evoked T-wave	Ease of calculation; Important ECG diagnostic parameter; Supply increase of sensor-driven heart rate during post-exercise recovery to balance oxygen debt	Not be stable chronically, affected by cardiac drugs, acute myocardial ischaemia, electrolyte disturbances and increased circulating catecholamine; For patients with risk of ventricular arrhythmia, but not patients with acute myocardial infarction
	PEA	Peak of myocardial vibrations during ventricular contraction	Index of myocardial contractility	Fast and appropriate pacing rate responses in different conditions; Effective and rapid respiratory rate	Sensitive to inertial forces generated by myocardium movements; For patients with heart failure or during atrial fibrillation
Blended Sensor		Changes in motion and minute ventilation	Dependent on its sensing mechanisms	Physiologic response to movement, breathing and restoring chronotropic competence	Providing a physiologic response to movement and breathing and restoring chronotropic competence and providing Life Adaptive Pacing
CLS		Changes in intra-ventricular impedance	Measurement of changes in cardiac contractility(inotropy), impedance increase during systole and decrease during diastole	Less sensitive to parameter changes as compared to open-loop systems; Physiological sensor	Affected by changes in posture; Unstable if certain conditions are neglected; Patients with acute mental stress
Dual sensors		e.g., peak of myocardial vibrations and body vibrations	Dependent on its two sensing devices	Control each other and pacing rate only be changed if both or a predominant sensor agrees; Fully use of dual sensors' advantages and eliminate defects	Higher power consumption; Reduced lifespan; Higher price; Patients with dual-sensor pacemaker need follow-up visits more often
New diagnostic sensing system		Intracardiac ECG signal	Measurement of ECG to analyze pole-zero of phase error between abnormal ECG and entrained YNI-response	Intelligent; Replacement of complex sensor system; Set up to individual patient	Innovative tendency in future development for patients with bradycardias and tachycardias

some disadvantages, e.g., lack of acceleration in the case of increased metabolism without vibration of the body. Joining two different types of sensors in a single pacemaker to fully use their advantages and eliminate deficiencies can solve this problem.

Activity sensors allow for instance to tailor the rate response to the individual patient with proper treadmill protocols [19]. Fast reaction to terminate short exercise represents further advantage of activity sensors. However, after longer exercise, an oxygen debt may require a sustained rate to increase, which is not provided by activity sensors during recovery because they are unable to acknowledge the oxygen debt. Moreover, the fact that they do not respond to the activity not related to body movements (e.g., isometric exercise, mental stress, or metabolic inadequacy consequent to pathologic conditions), and the possible mismatch between exercise intensity and rate increase, represent their main limitations [12].

Activity-controlled pacing with vibration detection remains the most widely used form of rate adaptation because it is simple, easy to apply clinically, and rapid in onset of rate response. The piezoelectric crystal is bonded to the inside wall of the pulse generator "can".

As the body moves and generates low-frequency vibrations that are transmitted to the torso, the piezoelectric crystal is slightly deformed. With the slight deformation the piezoelectric crystal produces a weak electrical current, which is then used as the basis of the algorithm to adjust the pacing rate. The generated electrical currents from the piezoelectric crystal are "counted" based on the size of the output and whether it is large enough to cross a specified threshold. The number of outputs counted, i.e., the number that will meet criteria to alter the heart rate, is therefore a function of both the "size" of the signal (in turn dependent on the extent of movement) and the sensitivity to which the sensor threshold is programmed. Various sized signals are processed based on how the threshold of the sensor is programmed and whether a given signal or oscillation crosses the sensor threshold [14]. This sensor results in a very fast almost immediate response time, requires no special lead, and at present is the most widely used type of sensors for adaptive-rate pacing. However, its main limitation is the lack of proportionality with physical activity. Also, stimuli other than dynamic exercise such as isometric exercise, mental activity, and emotional stress are unable to stimulate it.

B. Metabolic Sensor

Metabolic sensors, based on minute ventilation, QT interval or peak endocardial acceleration, provide pacing rates more closely and specifically related to physical and mental stress requirements.

Minute ventilation, the product of respiratory rate (the number of breaths per minute a person is taking) and tidal volume, is one such sensor that has an excellent correlation with metabolic demand, including body oxygen consumption and cardiac output [20]. Tidal volume is the lung volume representing the normal volume of air displaced between normal inspiration and expiration when extra effort is not applied. It satisfies the following equation:

$$\dot{V} = R \times T \tag{1}$$

where $\dot{V}$, R, and T represent minute ventilation, respiratory rate and tidal volume. Its typical values are around 500ml or 7ml/kg bodyweight [21].

Minute ventilation measures variations in transthoracic impedance signal, the volume of air inhaled or exhaled from a person's lungs in one minute, by delivering frequent low-amplitude electrical pulses from the pacemaker. These impedance measurements are used to calculate minute ventilation that is then translated into an indicated pacing rate [20].

As shown in Fig. 3, minute ventilation increases sharply at exercise onset, then increases further as exercise continues and workload increases. Pacing rate, controlled by the magnitude and frequency of electrical impedance variations, also increases during exercise after a one-minute delay.

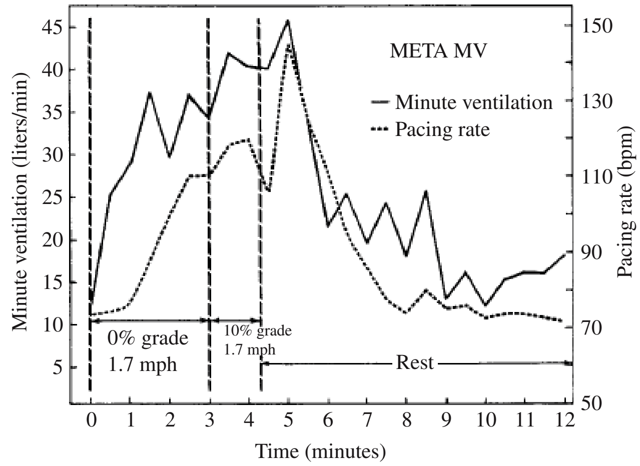

Fig. 3. Minute ventilation for control of pacing rate [22].

The patient continues to hyperventilate for about a minute following exercise, then minute ventilation and pacing rate decrease towards resting values. Minute ventilation is a particularly useful sensor at low levels of exertion where increase in respiration is brought about by increased depth of respiration with increases in ventilatory rate occurring at higher levels of exercise. With the ability to vary the heart rate with changes in minute ventilation, minute ventilation rate-responsive pacemakers enable the paced heart to mimic the normal cardiac response to increased workload.

Telectronics Meta 1254 minute ventilation rate-responsive pacemaker (now owned by St Jude Pacing Company, Sylmar, CA, USA) [23] is the successor of the first minute ventilation rate-adaptive pacemaker marketed. This particular pacemaker has been implanted in a significant number of patients worldwide.

However, this kind of sensors cannot provide higher reliability in patients with obstructive pulmonary disease, interference with cardiac monitors and posture [24] or false positive reaction in hyperventilation.

The QT interval, shown in Fig. 4, reflects the total duration of ventricular myocardial repolarization. It measures the interval between the pacing spike and the evoked T-wave as the sensor and this interval shortens with exercise. Despite improvements in the algorithm employed to determine the pacing rate the speed of onset remains relatively slow. The QT interval may not be chronically stable due to a variety of cardiac drugs and may be affected by acute myocardial ischaemia. The interval may vary chronically with time necessitating frequent medical intervention to maintain optimal rate response [25], [26].

Since the faster the heart rate, the shorter the QT interval, it may be adjusted to improve the detection of patients at the increased risk of ventricular arrhythmia. Modern computer based ECG can be used to calculate a corrected QT easily, but this correction may not aid in the detection of patients at the increased risk of arrhythmia.

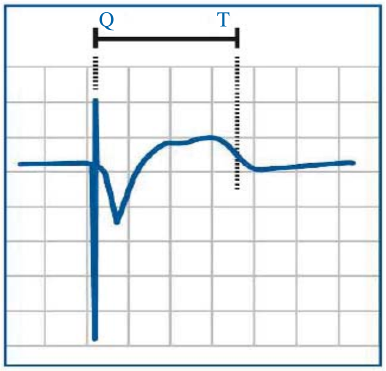

Fig. 4. QT interval.

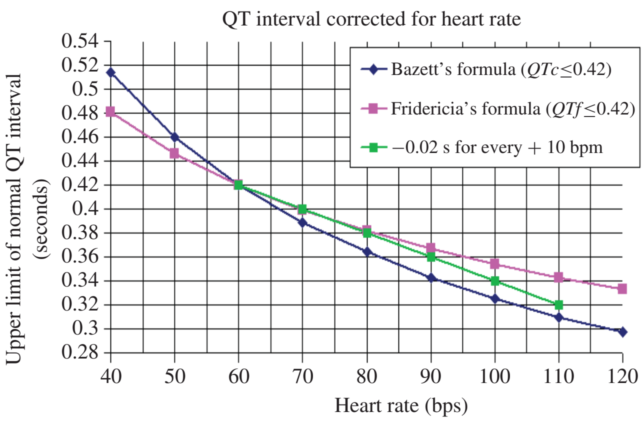

Fig. 5. QT interval corrected for heart rate [25].

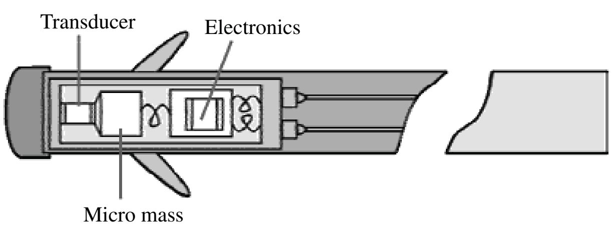

Fig. 6. PEA sensing system [14].

The standard clinical correction is to use Bazett's formula [27], by calculating the heart rate-corrected QT interval

$$Q_{cor} = \frac{Q}{\sqrt{I}} \tag{2}$$

where Q_{cor} is the QT interval corrected for heart rate, and I is the interval from the onset of one QRS complex to the onset of the next QRS complex, measured in seconds, often derived from the heart rate as 60 bpm.

Definitions of normal Q_{cor} varies around being equal to or less than 0.40 s (≤400 ms), 0.41 s (≤410 ms), 0.42 s (≤420 ms) or 0.44 s (≤440 ms) in Fig. 5. However, this nonlinear formula over-corrects at high heart rates and under-corrects at low heart rates. Fridericia [28] has established an alternative adjustment

$$Q_F = \frac{Q}{I^{1/3}}. \tag{3}$$

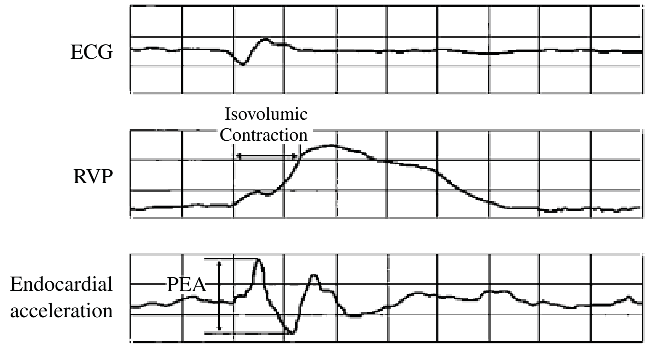

Fig. 7. Simultaneous electrocardiograph (ECG), right ventricular pressure (RVP) curve, and peak endocardial acceleration (PEA) waveform [14].

Sensors using QT interval variations are based on the finding that physical activity and circulating catecholamine produce shortening of the QT interval, since a prolonged QT interval is a risk factor for ventricular tachyarrhythmias and sudden death. This interval is an important ECG diagnostic parameter for cardiologists. Prolonged QT interval on the ECG is associated with an increased threat for arrhythmia and sudden death.

This type of sensor detects the increase of heart rate during recovery after exercise. Nevertheless, since the QT interval is affected by drugs, electrolyte disturbances and increased circulating catecholamine, these sensors cannot be used in patients with acute myocardial infarction, following which congestive heart failure may occur as complication.

A peak endocardial acceleration (PEA) sensor is more widely used in recent years based on its rapid and appropriate heart rate response in different conditions. It utilizes a micro-accelerometer inside a hermetically-sealed capsule incorporated in the tip of the pacing lead as shown in Fig. 6. The sensor is a micro-accelerometer housed inside a rigid, perfectly hermetic capsule within the distal portion of the lead. An associated electronic circuit preprocesses the signal to ensure its correct transmission through the catheter. The rigidity of the capsule allegedly makes the sensor totally insensitive to ventricular pressures and to fibrosis on the lead tip, such that the sensor is sensitive only to the inertial forces generated by myocardial movement. The micro-accelerometer measures the amplitude of mechanical vibrations that are generated by the myocardium during the isovolumetric contraction phase of the cardiac cycle. The signal obtained is directly related to contractility of the myocardium and peak-to-peak values of the signal are measured, i.e., peak endocardial acceleration in Fig. 7 [14]. The PEA is represented by the peak-to-peak value of the endocardial acceleration signal measured inside a time window containing the isovolumic contraction phase.

A micro-accelerometer is placed at the tip of a standard unipolar pacing lead at the right ventricular apex for the chronic measurement of the peak of the ventricular endocardial acceleration during the isovolumic contraction phase. The peak of these myocardial vibrations recorded during ventricular contraction is known as PEA [29]. It is an index of myocardial contractility whose directional changes mirror very closely changes in left ventricular peak dp/dt [30]. The sensor assesses mechanical vibrations generated by the myocardium during the isovolumetric contraction phase.

PEA is related to the first heart sound, which reflects cardiac contractility and is proportional to metabolic demand. When the myocardium contracts isometrically, it generates vibrations that have audible components, responsible for the first heart sound. Both audible and non-audible spectra of these vibrations can be measured with an implantable endocardial accelerometer. It measures changes in cardiac contractility and it is also influenced by left ventricular filling. The rigidity of the capsule prevents the generation of artifacts that may arise from the compression of the electrode by cardiac muscle during contraction. Therefore, the sensor is sensitive to only the inertial forces generated by myocardium movements.

A significant and stable correlation has been confirmed between heart rate acceleration during exercise and changes in PEA in subjects in normal sinus rhythm. Hence, PEA measurements can be used to drive a rate-responsive pacemaker with an appropriate algorithm.

The sensor system allows the monitoring of myocardial function by means of PEA, which is identified as an expression of cardiac contractility. A CRT-P device equipped with an implantable PEA sensor is developed to monitor cardiac function and guide CRT programming in patients [31].

Experimental data indicate that PEA monitoring provides fast pacing rate responses with long term performance of sensor lead and effective and rapid respiratory rate, also in patients with heart failure, and it is feasible during atrial fibrillation [32].

C. Blended Sensor

A blended sensor provides a physiologic response to movement and breathing, restoring chronotropic competence and providing Life Adaptive Pacing. The blended sensor can detect changes in motion and minute ventilation (respiratory rate and tidal volume). Note that an accelerometer senses changes in motion but cannot respond appropriately to increased workload in daily activities such as carrying groceries, walking upstairs and household chores [33].

For any given stage of exercise, the percentage of metabolic reserve P_{MET} and heart rate reserve P_{heart} tested in the blended sensor are equal to:

$$P_{MET} = \left[\frac{(M_s - M_R)}{(M_P - M_R)}\right] \times 100\% \tag{4}$$

$$P_{heart} = \left[\frac{(R_{heart\_s} - R_{heart\_R})}{(220 - A_{year} - R_{heart\_R})}\right] \times 100\% \tag{5}$$

where M refers to metabolic equivalents of oxygen consumption, its subscript s as a variable represents any given stage of exercise, R rest, P peak exercise, R_{heart} heart rate, and A_{year} age in years.

The value of M_s refers to an estimated metabolic level at the stage of exercise, M_R an estimated metabolic level at rest, M_P an estimated metabolic level based on peak treadmill stage, and R_{heart_s} heart rate at the stage of exercise.

D. Closed Loop Stimulation

Future devices may provide the opportunity to use physiologic sensors to monitor a cardiac function and to adapt the pacemaker function to assist therapy for associated disorders.

The Closed Loop Stimulation (CLS) is a physiological impedance-based pacemaker rate-response sensor, which relies on changes in intra-ventricular impedance to dictate heart rate. By using CLS, pacemakers are integrated with the natural cardiovascular system. CLS creates a negative feedback loop, such that the changes in pacing rate have a direct effect on myocardial contraction dynamics. Specifically, the pulse generator monitors and processes the intracardiac impedance signals associated with myocardial contraction dynamics. Changes in the waveform of this impedance signal are associated with changes in the contraction dynamics of the patient's heart due to the heart's inotropic response to exercise and acute mental stress. By translating these changes into appropriate pacing rates which are specific to the patient's individual physiologic demands, CLS emulates a healthy sinus node, the human heart's natural pacemaker. Sensors that could be used in a closed loop system, indicating whether heart rate is adequate to a given metabolic situation, are endocardial accelerometers and those using impedance derived ventricular signals.

The CLS system measures changes in cardiac contractility (inotropy), and the impedance (resistance) increases during systole and decreases during diastole. It may be affected by changes in posture. It is an auto-optimising sensor and can be programmed to low, medium or high levels depending on patient activity [34]. It is also the only rate regulation sensor that is proven to pace effectively and provide appropriate heart rate response during periods of acute mental stress. Its technical feasibility and clinical reliability must be tested before it is implemented in cardiac pacemakers and implantable defibrillators or biventricular pacemakers.

E. Venous Oxygen Saturation

Mixed venous oxygen saturation (S_vO_2) measured in the pulmonary artery is an average of the venous oxygen saturations of the body. It reflects the balance between oxygen supply and demand and might be used for diagnostic decisions, therapeutic guidance, prognostic prediction and, in combination with oxygen uptake and arterial oxygen saturation to determine cardiac output. It is demonstrated that an S_vO_2 sensor is a physiologically acceptable sensor [35].

S_vO_2 reflects cardiac output and tissue oxygen utilization, which has several features that are attractive as a rate control parameter. These include its perceived proportionality to metabolic demand, its prompt response to changes in exercise workload, and its potential diagnostic value in terms of hemodynamics [36]. Oxygen saturation of venous blood decreases as oxygen utilization increases. Low workloads cause considerable changes in oxygen saturation, although workload changes above 100 watts yield additional changes. Oxygen saturation of hemoglobin can be estimated from the ratio of light absorption at 605 nm (sensitive to oxygen saturation) and at 880 nm (not sensitive to oxygen saturation).

It consists of red (660 nm) and infrared (880 nm) light-emitting diodes, hermetically sealed in a sapphire capsule [37]. The reflectance of the light from each is received and measured by a photodetector to generate a relative reflectance ratio that varies in proportion to changes in S_vO_2. The use of a reflectance ratio instead of reflectance from a single wavelength is shown to reduce the variation in S_vO_2 determination resulting from fibrin coating, intrasystolic variation, velocity of blood flow, ventricular wall proximity, and changes in hematocrit [38]. However, several technical challenges have marked the evolution of this sensor. Of greatest concern has been the long-term stability of the optical sensor when implanted in the harsh environment of the human heart. The potential for positive feedback in which the decrease in S_vO_2 may result in an increase in the pacing rate with subsequent development of myocardial ischemia and a further decline in the control parameter has been documented in feasibility trials.

The pacemaker (OxyElite, model 8007, Medtronic Inc) is based on an activity-sensing DDDR pacemaker from the same manufacturer (Elite II, model 7086). It can be programmed to provide rate response using either a right ventricular S_vO_2 sensor or a piezoelectric activity sensor. The pacemaker features both activity and S_vO_2 telemetry (in real time), and it also collects data for programmer display and storage of S_vO_2 values.

Continuous telemetry link with the pacemaker is established by placing the telemetry head of the programmer over the pacemaker using a special harness over the chest of the patient. The S_vO_2 data are sampled and stored on a floppy disk for subsequent analysis. Using the Fick principle for oxygen uptake,

$$CO = \frac{Vo}{(SaO_2 - SvO_2) \times 1.34 \times h_e} \tag{6}$$

where CO = cardiac output, Vo = oxygen consumption (in mL/kg), and SaO_2 and SvO_2 are the percentages of arterial (from pulse oximeter) and mixed venous (from pacemaker telemetry) oxygen saturation. Assuming hemoglobin level (h_e) remaining unchanged during exercise, CO can be derived (in units) using the above equation with Vo and oxygen saturation values alone. SvO_2 has been shown to be a useful indicator of CO, particularly if normalized for oxygen uptake and hemoglobin level. SvO_2 has been suggested to be an alternative physiologic parameter to gauge oxygen delivery and uptake. The development of implantable sensors for rate augmentation has now made an implantable SvO_2 sensor possible.

F. Dual Sensors

Ideally a sensor should be physiologic, quick to respond, and able to work well with the minimum energy demands or current drain. The ideal sensor would be able to increase the rate proportionally to the patient's need and metabolic demand, work compatibly with the rest of the pacemaker, reproduce sinus node behavior in all the different activities of daily life, and be easy to program and adjust. It would not require any additional lead system to work.

Nowadays, various types of sensors have been used to control pacemakers. The proliferation of alternate sensors is a clear indication that no currently available single sensor approaches the characteristics of an ideal sensor. In the absence of an ideal sensor, the combination of dual sensors has been investigated. Crosscheck between sensors is used to avoid inappropriate rate increase. During crosscheck both sensors can control each other and the pacing rate will only be changed if both or a predominant sensor agrees. After administration of a drug that shortens the QT interval, a QT interval sensor would indicate the need for rate increase, but the pacing rate would not change because the activity sensor is not activated. Conversely, passively tapping on the device would activate the activity sensor and indicate a rate increase, but the pacing rate would not be modified because the QT-interval sensor would not be activated by this maneuver.

The most common combinations include association of an activity sensor giving a rapid response for light or short duration exercise, and a metabolic sensor, e.g., PEA sensor is usually combined with activity sensors; minute ventilation or QT interval that provides a delayed but proportional and stable acceleration to sustained exercise and deceleration during recovery [39].

Another option in rate response devices is to obtain circadian heart rate variation with two different hourly mean rates during day and night. Physiologic sensors and activity ones can provide rate variations based on signal sensor solicitation. Two lower heart rates are programmed for day and night. When the sensor is constantly solicited, the daytime lower rate is used. On the contrary, when the signal sensor level is low for a consistent period of time, the device switches to nighttime lower rate.

Presently, many companies offer this kind of solutions. An example pacemaker is the Pulsar Max DR model 1270 (Guidant, USA) [40], which is equipped with dual sensors (accelerometer and minute-ventilation) that work together. This type of devices should theoretically ensure more physiological steering of the frequency of heart rhythm than the traditional rate-response pacemakers with accelerometer sensors only [8]. The disadvantages of this solution are higher power consumption, reduced lifespan, and higher price. Additionally, patients who have these types of pacemakers implanted need follow-up visits more often.

G. Other Body Sensors

Temperature of right ventricular blood is affected by physical activity and emotional stress, and increases with workload because about 80 percent of the energy expended in skeletal muscles is converted to heat. At the onset of exertion the blood temperature in the right ventricle falls as cold peripheral blood reaches the central circulations. Increased flow in peripheral blood vessels during exercise and emotional stress may cause a transient decrease of up to 0.5° in central blood temperature, because an increased portion of the total cardiac output perfuses cooler peripheral tissues and enters the central circulation at hypothermic levels. As with normal heart rate, blood temperature varies diumally and reflects fever and baths. Right ventricular blood temperature is a byproduct of activity from all parts of the body and reflects a composite of autonomic, biochemical, metabolic, circulatory, respiratory, and cardiac influences. The sensor requires for temperature measurements is an electrical resistor making use of a semiconductor whose resistance varies with temperature. Clinical studies [41] show that temperature-based pacemakers restore rate response during a large number of activities typically associated with heart rate increases. However, temperature changes are not confined to physical activity, since blood temperature can be also affected by several other parameters such as emotion, external temperature variations, hot baths and infections. In addition, temperature changes are higher than in those more physically fit in elderly patients, probably due to reduced heat dissipation related to more pronounced reduction of blood flow to the skin during exercise.

Blood pressure is a clinically important measurement. This kind of sensors measures the rate of change of right ventricular blood pressure (dP/dt) as an indicator of the force of contraction. As increases in venous return further distend the ventricle, the myocardial fibers contract with greater force (Frank-Starling law). Because dP/dt is affected by the dynamics of contraction, intrinsic and paced beats result in different level signals. During exercise the right ventricular pressure waveform increases in amplitude with a decrease in duration. Thus, the first derivative of pressure with respect to time (dP/dt) increases, having a strong correlation with the sinus rate. Apart from technical problems, the main concerns with the sensor system are the influence on the pacing rate of nonexercise stimuli such as posture changes and the longevity of the sensor which may be affected by fibrin coating or by burying within the cardiac trabeculae.

In addition, for avoiding many problems of interference both with blood and with external electromagnetic fields, fiber-optic technology has been proposed for several technical purposes and, in medicine, for purposes such as respiratory monitoring. Fiber-optic force sensors have been extensively used for numerous medical applications, especially for recording the movements of the myocardial wall within the heart. Their primary principle of operation relies on modulation of light. The fiber is inserted into a pacemaker lead or an elastic catheter, positioned inside a heart chamber. Only the end of the fiber outside the heart can be used for coupling the light into and out of the fiber. Therefore the end within the heart is provided with a mirror to reflect the light [42].

A fiber-optic sensor can be divided in three main components: the light source, the light modulator element and the optical detector. The optical fibers are the elements used to transmit and receive the light. The modulated light uses the receiving optical fiber to reach an optical detector where the light is transformed to an electrical signal and it is amplified. The voltage output can then be correlated to the force. Fiber-optic light modulation sensors fall into two categories [43], extrinsic and intrinsic sensors. The former are responsible in delivering light to and receiving light from the light modulator element. However, the optical fibers in intrinsic sensors are responsible for delivering and receiving the light while the modulation of the light occurs inside the optical fibers [44].

In Table III, the specifications of fiber-optic force sensor are summarized. Compared with others, a fiber-optic force sensor has several advantages. It is very small and can be integrated in the leads of pacemakers or in catheters without any problems. Because of the extremely small mass and the high degree of flexibility of the thin fibers, the mechanical characteristics of the leads are not influenced. On the other hand, to avoid disturbances from movements outside the heart, a special fiber has to be constructed, with low sensitivity outside the heart and high sensitivity within the lead chambers [42]. From the comparison of typical sensors' specifications as shown in Table IV, fiber-optic sensor has smaller size, less weight, moderate power consumption and high reliability. Additionally, compared with accelerometer in larger size, a metabolic sensor cannot provide higher reliability.

TABLE III
FIBER-OPTIC FORCE SENSOR SPECIFICATIONS

Characteristics	Specifications
Size	< 2.5 mm in diameter
Working range	0–0.5 N
Sensitivity	high sensitivity to minimal touch
Resolution	0.005–0.01 N
Linearity	linear behavior
Hysteresis	low

TABLE IV
SPECIFICATION COMPARISON OF TYPICAL SENSORS

Sensor	Average size	Average weight	Reliability	Average power consumption
Accelerometer	<5.0 mm (in length)	<5.0 g	high	<1.0 mW
Metabolic sensor	<3.5 mm (in length)	N/A	moderate	<0.8 mW
Temperature sensor	<2.5 mm (in diameter)	<3.5 g	moderate	<1.5 mW
Pressure sensor	<10 mm (in length)	<5.0 g	moderate	<1.5 mW
Fiber-optic sensor	<2.5 mm (in diameter)	<2.5 g	high	<1.0 mW

Although a temperature sensor requires the average power consumption of less than 1.5 mW and provides moderate reliability as a pressure sensor, it has the advantage of less weight for implantable pacemaker systems.

H. Future Development

As mentioned previously, the resulting combined sensors require a complicated lead system to work and consume high energy in a pacemaker. Instead of a multi-sensor method, our previous research [3] was based on intracardiac ECG waveform and YNI (Yanagihara, Noma, and Irisawa) model to analyze the pole-zero characteristics of the phase error between abnormal ECG and entrained YNI-response. This intelligent diagnostic sensing system for a pacemaker, which can replace the complex sensor system, set up to an individual patient and is then checked and adjusted periodically, would be also an innovative tendency in the development of body sensors.

At present, many of pacemakers relay stored information to a server, which then makes the distilled data available to clinicians, in some cases via web browsers. They communicate with PCs to upload stored information and may soon communicate with devices such as smartphones. All these conveniences may come with possibility that hackers could break into the pacemakers' communications and either send harmful commands to the devices or steal private patient information and even reprogram their devices [45]. Hence, researchers and manufacturers are required to design a sensor with security features that protect a patient's data.

IV. Conclusion

This paper has attempted to survey the body sensors applied in pacemakers. Firstly, the new features and advances of modern pacemakers that are commercially available for utilization are introduced. Further, the advancement of varieties of body sensors incorporated in pacemakers is presented with their rationales, features and applications. Though the pacemaker systems whose controlled heart rate adapts to only one physiological variable are dominantly used so far, one sensor is not enough to calculate heart rate and could not simulate a normal sinoatrial node function in all aspects. Combining different kinds of sensors can more closely mimic intrinsic heart rate, if the chosen sensors are complementary. Hence, to take fully dual sensors' advantages and eliminate defects, combining sensors for optimal rate adaptation is a leading trend in the development of sensing technology applied in pacemakers. They may control each other and the pacing rate is changed only if both or a predominant sensor agrees.

Providing more accurate diagnostic analysis with a less complicated lead system and lower energy to work will be another important and developing field in the future pacemakers. Moreover, researchers are required to design a body sensor with security features that protect a patient's data from hackers. Hence, improvements on sensor systems are still necessary for modern cardiac pacing systems.

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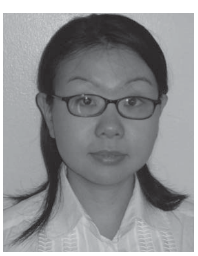

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