DIGITAL TECHNOLOGY IN DAILY CLINICAL CARDIAC PACING PRACTICE

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The new digital C-series and T-series pacemakers from Vitatron, are the first in the world to process heart signals digitally, and are better at analyzing the signals and diagnosing them than their analogue predecessors that are currently the standard in the pacing community. Although digital technology has been around us for some time in consumer electronics and PC's, achieving the specific design challenges to incorporate this technology in an implantable device represents a significant step forward bringing important advantages to the daily practice of pacing clinicians.
The biggest design challenge in converting from analogue to digital was to keep power consumption down in the new digital devices. The challenge of microchip power consumption becomes apparent when the pacemaker chip is compared to the Pentium 4, the chip at the heart of the newest generation of PCs. The leakage current alone from these consumer electronics is ten times higher than the current that is needed to operate a pacemaker.

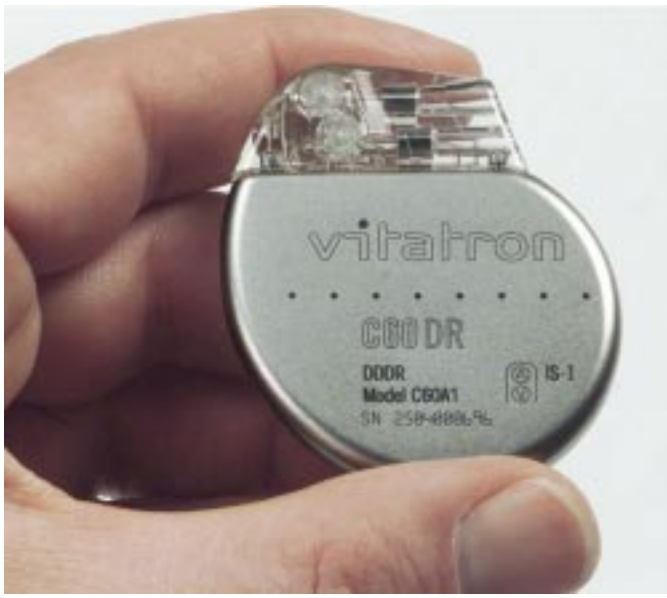

Figure 1. *C 60DR; familiar physical shape and size, but containing a new technology for implantable pacemakers.*

A patented design of the digital signal processor incorporated has implemented the field of cardiac pacing.
In daily clinical practice, the new digital pacemakers offer substantial benefits.
Communication between the implanted digital pacemaker and the external computer takes a matter of seconds, rather than minutes in the case of most analog pacemakers. The report produced by the digital pacemaker is also much clearer and easier to interpret by the clinician.
In addition, the added »Therapy Advisor« functionality analyses, alerts, and suggests programming recommendations in the first seconds of follow-up if needed, reducing follow-up time, and eliminating the need for the clinician to examine all diagnostic data for trouble-shooting.
The digital pacemaker samples the intracardiac signal 800 times per second as compared to the current analog standard of 125 Hz. The processor parts of the chip are designed to measure and compare each signal against the preceding signal extremely quickly, a mandatory requirement for a chip used for intracardiac signal analysis.
The ability to store these high-resolution intra-cardiac signals much more precisely, make the diagnostics much more reliable, and therapy adjustments can be made with more confidence by the clinician.
Since the digital storage of intra cardiac signals in a fully digital device consumes less than 1% of battery capacity, compared to 20% for a analog device, it can be left on during the complete lifetime of the device.

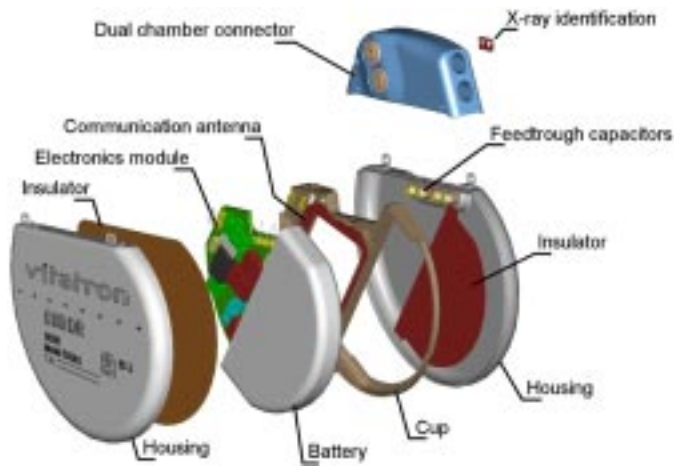

Figure 2. *Exploded view of the digital C-series pacemaker with the electronics module that incorporates the digital signal processor.*

Storage of historical data and subsequent trending of data in the C- and T-series allows the clinican to monitor treatment success, including the efficacy of administered drugs.
Especially in the field of atrial arrythmias there has been a clinician's demand for more specific and more precise atrial sensing and signal interpretation. This need is met to large extent in the digital Vitatron T-series variant, where automatic analysis of atrial arrhythmia's and automatic advice on the programming of preventive pacing therapies greatly reduces the workload of clinicians for these difficult to treat patients.
Recent clinical data has identified that reduction of ventricular pacing to a necessary minimum, reduces the risk on deve-

loping atrial fibrillation and heartfailure in bradycardia patients. Automatic analysis of AV conduction development over follow-up periodin the new digital devices by may lead to the suggestion to switch a reduced ventricular pacing algorithm on, if applicable.
Additonally, the digital design is much more robust to handle electronic interference from the day-to-day world a patient lives in.

Conclusion

The new digital technology now applied in cardiac pacemakers today, allows to make the daily practice of pacemaker clinicians faster, and with more confidence. In the future, further development of digital pacemaker software will open up exiting fields of clinical research. Continuing our long tradition for research with cardiac clinicians from Slovenia and other countries worldwide will lead to the delivery of new diagnostics for physicians and new therapies for their patients.

BEAT BY BEAT AUTOCAPTURE™ PACING SYSTEM

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Background

St. Jude Medical's ventricular AutoCapture™ algorithm verifies capture on a beat-by-beat basis to ensure the highest patient safety available. It combines several years of clinical experience with ease of use to become the premier algorithm of choice. AutoCapture™ insures maximum patient comfort with programmable polarity (unipolar or bipolar) for the higher output back-up pulse. AutoCapture™ provides safety on a beat-by-beat basis by automatically adjusting the ventricular output to the patient's changing threshold needs. The AutoCapture™ algorithm effectively controls the device output therefore increasing longevity and potentially decreasing the number of replacement devices needed by the patient. AutoCapture™ saves time during follow-up. There is no need to measure, calculate, and program ventricular pacing threshold safety margins.

Methods

After the pacing pulse, an initial waiting period of approximately 14 ms is followed by an Evoked Response Detection Window of approximately 47 ms in length. If the device senses an evoked response in this detection window, capture is confirmed. The timing cycle is reset, and pacing resumes at the Automatic Pulse Amplitude and the programmed pulse width.
The absence of an evoked response during the detection window (47 ms) results in the delivery of a 4,5 V back-up safety pulse within 80–100 ms of the primary pacing pulse.
It is the algorithm's method of determining the current capture threshold. It is automatically initiated after 2 consecutive loss of capture beats, every 8 hours, after magnet and/or telemetry wand removal and as desired via the programmer. During a threshold search, the AV/PV delay shortens to 50/25 ms respectively in a dual chamber device, and the pacemaker automatically adjusts the output to determine the new capture threshold. When capture is confirmed for 2 consecutive beats, a 0,25 V working margin is then added to the new threshold value.

Results

	Implantation	Discharge	1 month	3 months
Patients	134	131	116	60
Paced events	4472	3709	2721	1314
Loss of capture	176	168	232	133
Loss of capture followed by safety pacing	176	168	232	133
Success rate	100%	100%	100%	100%

* This report is based on PMA data corresponding to the FDA report dated December 23, 1996, and summarizes the results of the Microny SR+, Model 2425T and Regency SR+ model 2400L clinical investigation conducted in North America.

Conclusions Steven Greenberg et al. at Cardiostim 2000

1) AutoCapture™ provides enhanced longevity when compared to conventional pacing systems.
2) Cost savings per year for single and dual chamber pacemaker were 52% and 28% less, respectively.
3) AutoCapture™ shows a clear benefit in cost/patient/year when compared to conventional pacing systems while providing enhanced safety and similar efficacy.
4) AutoCapture™ appears to be the most cost-effective form of pacing at present.

TO STIMULATE OR NOT TO STIMULATE

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The very first implanted pacemaker used the VOO mode for stimulation. With this method of pacing there was 100% stimulation. Soon this system was improved and the VVI mode was used in the majority of patients. The percentage of pacing reduced to a lower value, off course completely dependent on the conduction and intrinsic rhythm of the patient. Most manufacturers started to develop features and special algorithms to decrease the percentage of stimulation to reduce energy consumption, and secondly, to improve hemodynamic effects. In the late 70-ties, atrio-ventricular synchrony maintenance gained special attention in pacemaker design.
Early study results showed improvements in cardiac output, blood pressure, and ejection fraction. Maintaining AV synchronization (Atrial based pacing) was considered superior to VVI (Ventricular based) pacing.
Early studies showed that atrial based pacing might reduce mortality especially after longer periods. Recent studies (PASE, MOST, CTOPP) have however failed to show this.
In patients with Sinus Node Disease, studies now focus on the prevention of stroke, and the reduction of Pacemaker syndrome, atrial fibrillation, quality of life and Heart Failure (HF).
In the modern approach we have to take into consideration that stimulation might have a direct impact on the development or progression of Heart Failure. Therefore, the crucial dilemma in the pacemaker treatment is currently: to stimulate or not to stimulate.

The MOST study demonstrated a progressive risk for HF hospitalizations in proportion to the cumulative percentage of ventricular paced beats. The result is the application of features to reduce the number of ventricular stimulated beats or "Pacing avoidance".
Right ventricular stimulation results in the same depolarization pattern as left bundle branch block (LBBB). A feature that gives priority to the intrinsic rhythm is "Rate hysteresis". This allows the intrinsic rhythm to be slower than the pacing rate. Only if there is an episode with a need for stimulation, the pacemaker will start pacing at the lower rate limit. A search mechanism prevents pacing for a too long episode.
In a dual chamber system a patient might develop fusion of pseudo fusion beats. First of all, this is a waste of energy, secondly this might lead to an inappropriate depolarization of the ventricles. In clinical practice, a normal approach is the extension of the AV delay.
However, this has an influence on the upper rate behaviour. The system will show the 2:1 block at a lower atrial rate, possibly resulting in a potentially reduced exercise capability of the patient. The solution is AV hysteresis (preferably with a search mechanism) to avoid fusion beats, but to be able to stimulate with an appropriate AV delay when necessary. In modern devices a feature called "Early Detection" can prevent the occurrence of fusion beats by extending the sensing window upon early sensed cardiac signals.

In the devices for Cardiac Resynchronization Therapy (CRT) especially in patients with a LBBB, the goal is synchronous stimulation of both ventricles with an optimized AV delay and optimized ventricular timing (VV offset). This synchronization is mandatory, even during episodes of atrial fibrillation with conduction to the ventricles.
The "biventricular trigger" mechanism will stimulate the left ventricle in case of a sensed event in the right ventricle, to ensure synchronization. Ventricular Rate Regulation (VRR) stabilizes the ventricular rate during episodes of AF. Together with the biventricular trigger it restores biventricular pacing as much as possible.
In some of the current CRT devices there is no, or limited use of left ventricular sensing. This might lead to the induction of ventricular arrhythmia due to stimulation in the vulnerable period of a left ventricular premature ventricular contraction (PVC). A feature like "Left Ventricular Protection Period" (LVPP) will prevent left ventricular stimulation after a left sided PVC.

In conclusion, in the last 40 years, pacemaker therapy has changed from 100% pacing to the avoidance of pacing when applicable. Nevertheless, when there is a real need for stimulation, all the tools for pacing optimization with improved safety features are now available.