# First Clinical Experience with a New Pre-Shaped Single A-V Lead for Permanent DDD Pacing

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**Summary**

*Even when combined with atrial OLBI stimulation, straight single A-V leads have demonstrated insufficient reliability for the primary target: permanent DDD pacing. Inconstant capture and/or occurrence of phrenic nerve stimulation, still present in about 20 % of treated patients, demonstrated this approach only to be acceptable for "back-up" atrial pacing in intermittent and mild chronotropic incompetence. A new single A-V lead (CCS mod. ATS), with a pre-shaped lobe in the atrial portion of the lead and a pair of half ring electrodes in the lobe apex, connected to a device allowing OLBI atrial pacing (Biotronik mod. EIKOS SLD), was submitted to clinical testing. The system was implanted in 15 pts, all with symptomatic AV block and without sinus node dysfunction. At implant, all atrial pacing configurations (unipolar, bipolar and OLBI) were tested and atrial pacing thresholds (APT) were measured. OLBI atrial pacing was performed during follow-up at discharge, 1 and 3 months. An exercise test and short term Holter monitoring were performed after 1 and 3 months to verify atrial capture (AC) and conversion between VDD and DDD modes. In each follow-up, occurrence of phrenic nerve stimulation was tested at highest pulse amplitude. APT values at implant were: unipolar 2.89 ± 2.55 V; bipolar 2.62 ± 1.34 V, OLBI 1.20 ± 0.82 V. At 1$^{st}$ month follow-up no AC was achievable in 2 pts. In the remaining 13 pts, mean OLBI APT was 3.16 ± 1.29 V in supine and 3.07 ± 1.15 V in standing position. At the 3$^{rd}$ month follow-up an additional pt was found without AC, but one of the previous two recovered capture. Mean OLBI APT values were: supine 2.53 ± 1.47 V and standing 2.41 ± 1.43 V. No PNS occurred in any pt at any time. In remaining 13 pts, mode conversion was perfect and AC stability as well. This first clinical experience in DDD pacing using the ATS pre-shaped AV lead shows promising results. Some initial failures were determined by the learning phase regarding the lead insertion technique. However, few additional improvements in lead design are required to achieve more stability of the atrial lobe, essentially during the first weeks after implant.*

**Key Words**

Single lead DDD pacing, pre-shaped lead, OLBI stimulation

## Introduction

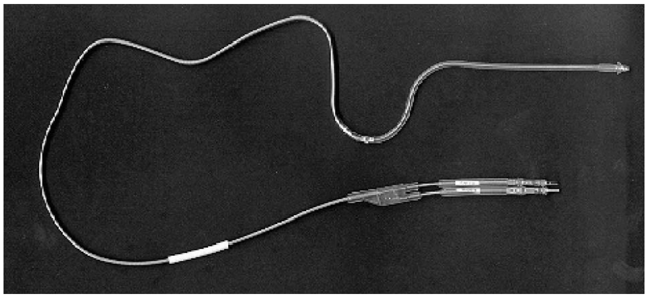

*Figure 1. CCS model ATS preshaped single AV lead.*

the phrenic nerve (PNS) and thoracic muscles, despite only intermittent capture of the atrial myocardium [2,3]. Many ideas have been proposed and some have been tested to find a solution to the problem [4-13]. DDD pacing with a single AV lead is seductive, yet satisfactory solutions have been or elusive or get only promising results which allows to foresee a potential way to solve the problem. This article reports preliminary results of a joined clinical investigation performed in the implant centers of Ferrara and Viterbo with a new preshaped single AV lead [14, 15] combined with an implantable pulse generator with OLBI atrial pacing capability.

The model ATS single AV lead (CCS, Inc, FL) has a complex preshaped body (see Figure 1). A first "S" curve is located at the level of the superior vena cava, just before its junction with the right atrium, and serves as fulcrum and stabilizer for the atrial portion of the lead that is shaped in a "lobe" in order to maintain the atrial electrode pair, made in polished platinum, in contact with the atrial wall. The atrial electrodes, spaced 5 mm apart, are positioned at the apex of the "lobe" and both have an half-ring surface oriented toward the atrial wall. This approach does not introduce critical changes in the electrode structure and allows stable positioning of the dipole against the atrial wall (see Figure 2), in a position far from the phrenic nerve.

## Methods

The ATS lead was implanted in 15 patients (pts), 11 males and 4 females, with at a mean age of 77.5 ± 5.7 years, all affected by symptomatic AV Block and without sinus node dysfunction. The leads, all with an A-V interelectrode spacing of 16 cm, were connected to an implantable pulse generator mod. EIKOS SLD (Biotronik GmbH, Germany) which permits atrial

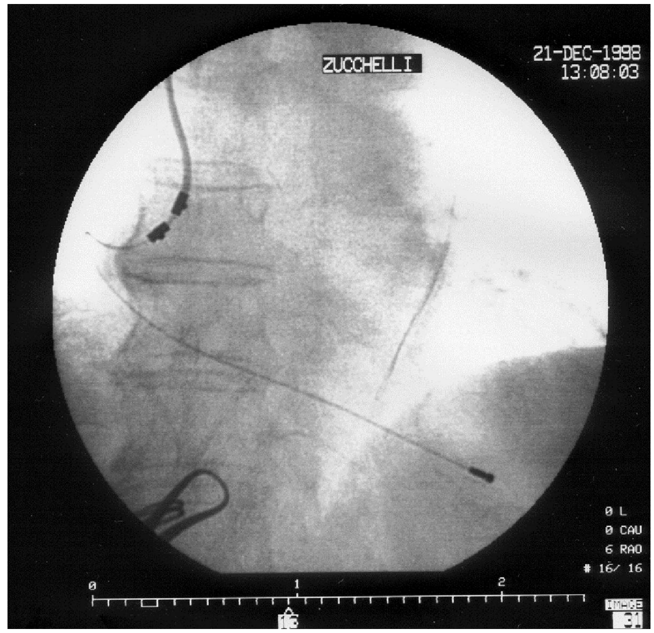


*Figure 2. Anteroposterior radiogram that shows the position of the atrial electrode pair in a septal-anterior position of the mid right atrium.*

OLBI stimulation. At implant the atrial pacing threshold (APT) was assessed at unipolar, bipolar and OLBI pulse configurations using a pacing system analyzer (PSA) mod. ERA 300B (Biotronik GmbH, Germany). At discharge, the OLBI APT was assessed using the pulse generator automatic threshold test During follow-up, performed at 1 and 3 months, APT (OLBI configuration only) was assessed in various body positions to verify lead stability. An exercise test with contemporaneous short term Holter monitoring were performed at 1 and 3 months follow-up to verify stability of atrial capture and conversion between VDD and DDD modes. In each follow-up, the occurrence of phrenic nerve stimulation was tested at the highest OLBI pulse amplitude. DDD pacing was temporarily programmed during follow-up only.

## Results

The parameters measured at implant (@ pulse duration 0.5 ms) with the PSA and values measured through the telemetry of the implanted device at discharge are shown in Table 1.

After discharge 2/15 pts had a major displacement of the atrial dipole and no atrial capture was detected at 1st month follow-up. In one pt, the dipole rised inside the

| | Implant | Discharge |
|---|---|---|
| P-wave ampl.(mV) | 2.42 (1.08) | 2.64 (1.47) |
| APT/unipolar(V) | 2.89 (2.55) | n.a. |
| APT/bipolar(V) | 2.62 (1.34) | n.a. |
| APT/OLBI(V) | 1.20 (0.82) | 1.83 (0.60) |
| V thresh(V) | 0.58 (0.27) | 1.30 (0.30) |

*Table 1. Parameters measured at implant and at discharge (± SD).*

superior vena cava, in the second the rotation of the atrial "lobe" was of about 80° clockwise (X-ray detection). In both cases, the P-wave amplitude was maintained at 0.5 and 0.8 mV respectively, assuring a reliable VDD pacing function. Since the two pt were the first implanted in each center, it seems reasonable to presume that the inconvenience should be attributed mostly to the learning phase of the new implant technique. A third pt showed no atrial capture at the 3rd month follow-up and, at X-ray examination, the dipole was found in superior vena cava. Also in this pt, P-wave detection was stable with a minimum value of 0.5 mV. This last pt reported to have been spent several days in performing heavy and stressing agricultural works during the month before last follow-up. Data collected in the remaining 12/15 pts are reported in Table 2.

An exercise test and the contemporaneous short term (range 45 - 75 minutes) Holter monitoring was performed at each follow-up in all pts showing atrial capture. Before the test, the pulse generator basic rate was programmed at a value 10 - 15 bpm above the pt intrinsic rate at rest and the OLBI pulse amplitude was settled at 0.5 V higher than APT (worst value between sitting and standing position). In all patients atrial pacing and sensing were 100% stable and the mode conversion from DDD to VDD occurred properly in both directions without atrial undersensing phenomena.

Occurrence of PNS was not observed in any of the 15 pts.

The preliminary data reported above can be commented as follows:

a) When the preshaped lead is positioned using a proper surgical technique, the atrial dipole remains stable during implant maturation.
b) APT shows the same course of contact electrodes, i.e. it increases during the first 4 - 6 weeks from implant and then decreases to stable chronic values during implant maturation.
c) Changes in body position slightly affected APT at both follow-ups. Thus, demonstrating that the shaped structure of the lead will correctly absorb all trusts generated by movements of the cardiac mass.
d) The relatively high values of APT during follow-up can reasonably be attributed to the quite old technology used in atrial electrodes (polished platinum). The use of new manufacturing techniques (e.g. fractal coating) will substantially improve the pacing efficacy of the electrodes.

Also lead encapsulation seems to take place in a reasonable short time. One of the two pts who lost capture during the first month after implant (the one with 80° "lobe" rotation) reacquired atrial capture at reasonable thresholds (3.2 V in supine and 2.9 V in standing position) at the third month. Since no evidence of additional movements of the atrial "lobe" were found at the X-ray fluoroscopy performed during the follow-up, the recovering of atrial capture may only be attributed to the lead encapsulation that kept the atrial electrodes close to the myocardium again.

| | 1 month | 3 months |
|---|---|---|
| Minimum P-wave amplitude (mV) | 2.37 (1.44) | 1.70 (0.94) |
| APT Supine - inspiration (V) | 3.33 (1.31) | 2.53 (1.47) |
| APT Supine - expiration (V) | 3.16 (1.29) | 2.43 (1.42) |
| APT Supine - left decubitus (V) | 3.38 (1.37) | 2.45 (1.41) |
| APT Supine - right decubitus (V) | 3.33 (1.31) | 2.55 (1.46) |
| APT Sitting (V) | 3.34 (1.22) | 2.55 (1.46) |
| APT Standing (V) | 3.07 (1.15) | 2.41 (1.43) |
| Ventr. Threshold (V) | 1.90 (0.60) | 1.53 (0.24) |

*Table 2. Parameters measured during follow-up (± SD) (@ atrial OLBI and ventricular pulse duration 0.5 ms).*

### Discussion

This first clinical experience in DDD pacing using the ATS pre-shaped AV lead shows promising results. Some initial failures were determined by the learning phase of lead insertion technique, which is quite different from that used to implant straight leads. However, few additional improvements in lead design are required to achieve more stability of the atrial lobe, essentially during the first weeks after implant.

Stimulation is quite a different challenge from sensing as it involves more problems concerning lead technology and other factors in relation to pacemaker electronics [16]. The consolidated clinical results achieved using straight AV leads and OLBI stimulation [6], that assure reliable DDD back-up pacing in more than 80% of treated pts, and the preliminary, but promising, results in using preshaped leads, as further reported by other authors [13], allow to foresee that primary DDD pacing with a single AV lead may not be so far in the future.

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