ACCELERATION EXPERIENCED BY
THERMAL CONVERTER IMPLANTED IN CALVES

COO-2208-8

TECHNICAL REPORT

MASTER

PREPARED FOR THE U.S. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION
UNDER CONTRACT E(11-1)-2208

February, 1976

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1.0 SUMMARY

The objective of this study was to determine acceleration levels experienced by the ERDA thermal converter unit implanted abdominally in a calf.

A full-scale weighted mock-up of the thermal converter was fabricated containing a triaxial accelerometer. The mock-up was implanted in calf cadavers which were subjected to falls from an operating table. Highest acceleration recorded was 34 g.

The mock-up was implanted in living animals and acceleration measurements made under various maneuvers including walking, standing from a laying position, walking up and down stairs, jumping, and falling from a standing position. Maximum acceleration recorded was 8 g and occurred in the falling maneuver.

2.0 INTRODUCTION

Animals with a total artificial heart implant have been routinely living over a month. Most of the total artificial hearts have the pumping chambers in the chest cavity and a driving unit external to the body.

The ultimate goal for long-term applications is a totally implantable system in which both the power source and the pumping chambers are inside the body to eliminate potential problems such as infection at the skin penetration and the inconvenience of external hardware.

ERDA has been developing such a totally implantable artificial heart. It consists of two main components, a blood pump (BP) and a thermal converter (TC), connected by a flexible drive shaft.

Anatomical fit of the BP for intrathoracic location, for men and calves, have been studied and its acceptability reported (1,2). Implantation of BP with motors in the abdomen revealed over one week's survival in a calf (3). These studies are indicative that a totally implantable artificial heart, as is developed by ERDA, has been getting closer to reality, including the nuclear energy source. Therefore, TC is required to be reasonably resistant to possible shock loading. The fuel capsule has been tested separately for such requirements (4). It is also necessary to document how much shock load the TC will experience under various experimental activities, since acceleration induced to TC affect the design and fabrication of it in terms of component stress, lubrication system function, and control stability.

The main objective of this study is to assess the maximum acceleration and its duration induced to TC under various conditions, when implanted in the experimental animal. The abdominal implant location has been defined previously by the University of Utah as preferable for the present stage of development.

3.0 EXPERIMENTAL METHOD

3.1 INSTRUMENTATION

Thermal Converter Mock-Up: A mock-up of the thermal converter was constructed of wood to the dimensions of the IVBM mock-up obtained from Westinghouse. The overall shape is shown in Figure 1a, having a height of 22 cm with a crankcase, nominally a 9 cm cube. To obtain the correct mass and center of gravity for the mock-up, lead plugs were inserted at various points. The final mass of the completed mock-up was 2.2 Kg. To mount the accelerometers, a space was milled out at the center of gravity of the device. Various methods were used to seal the unit against penetration by body fluids. For the cadaver studies, the unit was first coated with polyurethane varnish and then with epoxy paint. The point where the accelerometers were installed was sealed with RTV adhesive sealant. For the first in vivo study, in addition to the previous treatment, the entire unit was coated with silicone adhesive. This proved adequate for the first trial approximately one week after implantation, but leakage caused a failure after one month. For this reason a better method for sealing the unit was sought for the second in vivo experiment. In this case epoxy adhesive was coated over the entire device. Medical grade silicone rubber was then applied to the unit, and the entire assembly, including the electrical leads, was covered with dacron velour fabric to allow surrounding tissue to attach to the unit. This proved adequate, but body fluid leakage into the external electrical connector caused a failure after approximately one month in the animal.

Accelerometers: As sensors for the acceleration measurement, three Endevco miniature piezoresistive accelerometers model 2264-150 were used. They were mounted perpendicular to each other on a block of aluminum. This block was then mounted within the space made at the center of gravity in the thermal converter mock-up. The accelerometers are rated at 150 g full-scale with frequency response extending from D.C. to 1200 Hz.

ACCELERATION
REFERENCE DIRECTIONS

FIGURE 1a

General shape of Thermal Converter Mock-Up showing directions of positive acceleration component vectors.

FIGURE 1b

Location of implanted TCM in calf in left upper extraperitoneal region. TCM implanted with accelerometer axis, as shown.

Recording System: As an excitation source for the accelerometers, three Hewlett-Packard model 8805 B carrier amplifiers were used, providing a 2400 Hz. carrier at 5 VRMS. The output of the carrier amplifiers was fed to a Hewlett-Packard model 8820 A low-gain DC amplifier which was used for buffering the signal for input to the recorder, which was a Sanborn model 650 T direct writing optical oscillographic recorder. System frequency response extended from D.C. to 850 Hz., which was more than adequate for this purpose because, as expected and later observed experimentally, there was little high frequency (>100 Hz.) acceleration component. Calibration of the system was performed by using sensitivity factors for the accelerometer along with calibration circuitry in the carrier amplifiers and verified by using the acceleration of gravity as a reference 1 g.

3.2 EXPERIMENTAL ANIMALS

Studies In Calf Cadavers: Cadaver studies were conducted to obtain information regarding highest acceleration induced to TCM under the most violent situation, i.e., fall from an operating table. Two calf cadavers were subjected for this study within one hour post mortem.

The cadaver calf was placed on right lateral position. The left paramedian skin incision, approximately 3.0 cm left to the midline, was made longitudinally extending from the xyphoid process to the pubic area. The anterior sheath of the rectus abdominis muscle was split longitudinally. By bluntly dissecting the rectus muscle, the posterior sheath was reached. A dissection plane between the posterior sheath and the peritoneum was developed and extended posteriorly to create a pouch big enough to contain the TCM. Following positioning the TCM and adjusting its direction for acceleration reference (Figure 1b), the TCM was fixed to the overlying muscle and skin by two umbilical tapes passed around the flywheel housing and the right angle gearbox. Position of the TCM was in the left upper abdomen. The wound was closed with three umbilical tapes passed through the entire layer of the muscle and the skin. The lead from the TCM was introduced through the operative wound and connected to the recorder.

The height of the operating table was adjusted and the cadaver was exposed to falls to the bare concrete floor while recording acceleration.

Studies In Live Animals: Two calves, weighing 83 Kg and 88 Kg, were subjected for this study. Fluothane (4%) in pure oxygen (4-5L/min) was used for induction and for maintenance (1.2%). The animal was intubated and the respiration controlled by a Bennett respirator. No anesthetic drugs were employed.

The animal was placed on right oblique position. The left lower thorax and the upper abdomen were prepped and draped for a sterile procedure.

The left paramedian incision, from the xyphoid process down to the pubic area, was made and the subcutaneous tissues dissected until the anterior rectus sheath. The anterior sheath and the muscle were split longitudinally to expose the posterior sheath. Since the peritoneum is thin and vulnerable to trauma, a dissecting plane was established over the fascia of the transverse abdominis muscle by peeling the muscle off as the dissecting plane went dorsally. Bleeding spots were either electrocoagulated or clamped and tied. A big pouch was created extending cranially under the rib cage. The xyphoid process was dissected free from the surrounding tissue. The substernal leg of the diaphragm was penetrated just enough to pass the driving shaft into the anterior mediastinum.

The TCM was placed in the pouch and the driving shaft was anchored to the xyphoid process with sutures of 2-0 silk. The instrumentation leads from the TCM was brought out of the pouch through a separate stab wound. The operative wound was closed in layers.

The animals were extubated approximately an hour after surgery. They were brought back to the pen on the day of surgery and were allowed free access to water and food.

Loridine, 1.0 gm i.m., b.i.d., for five days were the only medication administered.

4.0 EXPERIMENTAL RESULTS

4.1 ACCELERATION IN CADAVERS

Calf 75-C, 102 Kg: The animal was first struck by hand several times in the area where the TCM was implanted to check the operation of the accelerometers. Impulse accelerations of up to 19 g were observed at this time. The cadaver was then shoved off the table from a height of 80 cm landing first on the back and then rolling onto the left side where the TCM was implanted. On the initial impact maximum acceleration was 17 g, while on the direct impact the recorder went off scale with a reading in excess of 26 peak acceleration. Subsequent analysis of the recorder trace allowed extrapolation to an estimated value of 34 g. At this point it was decided to change the recorder scale to 200 g full-scale in order to reach the peak value on subsequent falls. The animal was dropped two more times from the same height to try to reproduce the peak encountered in the first drop. However, the cadaver did not fall directly on the device in either fall, so that peak acceleration reached a value of only 20 g on these trials. The device was removed and calibration rechecked.

Calf 430, 75 kg: Acceleration measurements were carried out essentially the same as Calf 75-C. The height of falls were varied between 80 and 108 cm. One fall was made on a hard rubber mat in which the highest maximum acceleration of 34 g was obtained.

The magnitude of the maximum acceleration vector (calculated from the three measured components) from these two cadaver series, as well as each recorded component, are tabulated in Table 1. A representative acceleration recording is depicted in Figure 2.

4.2 ACCELERATION IN LIVE ANIMALS

Experiment No. 75012, Calf No. 199, 83 Kg: The animal recovered from surgery within 24 hours. The following morning it was standing up, eating, and drinking. On the second postoperative day accelerations induced to TCM were measured under the following situations:

TABLE 1
ACCELERATION STUDIES (CADAVER)

Calf No. (Weight)	75c (102 kg)			430 (75 kg)			
Height of Fall (cm)	80	80	80	100	108	108*	80
Maximum Acceleration (g)	>27#	21	13	18	32	34	28
X (g)	>26#	15	10	4	-10	-15	-9
Component Y (g)	8	15	8	17	29	30	26
Z (g)	--	--	--	2	7	5	6

Convertor : Wooden model of ERDA unit. Weight: 2.2 kg

Accelerometers : Three Endevco 150 g accelerometers
mounted at center of gravity

Implantation : Left upper extraperitoneal submuscular space

Mode of Falls : Supine position on a concrete floor

* Fall on a hard rubber mat

Off scale reading, estimated at 34 g

FIGURE 2

Accelerations recorded during fall of 108 cm from operating table to hard rubber floor mat.

1. Walking
2. Standing : When it stood up from the sitting position.
3. Stairs : When it was forced to go up and down three stairs, each stair having the height of 18 cm.
4. Jumping : When it was forced to jump from a 54 cm deck to a concrete floor.
5. Falling : When its legs were pulled sideways and the animal was forced to fall down on his side on a concrete floor.

Exposures to these motions were repeated to show essentially the same magnitude of acceleration induced to TCM under individual motions. The maximum acceleration induced by these motions are tabulated on Table 2. Tracings of accelerogram during each motion are shown in Figure 3 through Figure 6.

The animal was kept for an additional three weeks in a pen.

The above series of experiments was scheduled to be repeated on the 21st postoperative day; however, after making the instrumentation connections, a sudden movement by the animal caused damage to the leads in the animal necessitating removal of the TCM for repairs. The animal was sacrificed.

Experiment No. 75030, Calf No. 121-C, 88 Kg: Five days after surgery the animal was put on a treadmill at varying speeds of 0.5, 1.0, 1.5, and 2.0 MPH. At each rate, following several seconds of walking, the treadmill was abruptly stopped. Acceleration was measured through the entire period. In all instances, the maximum recorded acceleration did not exceed 2.0 g. The X-axis recording always had noise derived from the motor of the treadmill.

The animal was subsequently kept in a pen for 31 days after surgery. During this period, starting from the second week, the wound developed infection. On the 28th day he was put on the treadmill again; however, it was found that the accelerometers did not function properly due to fluid entering the external electrical connector. He was electively sacrificed on the 31st day. The autopsy revealed the infection surrounding the TCM and the instrumentation cable. The abdominal cavity however was free of infection.

TABLE 2
ACCELERATION STUDIES (IN VIVO)

<u>Activity</u>	<u>Maximum Acceleration (g)</u>
Walking	1.4
Standing	2.5
Stairs (Three 18 cm steps)	
Going up	2.0
Going down	4.5
Jumping (53 cm)	4.5
Falling down on right side	8.0

FIGURE 3
Accelerations recorded two days after implantation. Calf walking on concrete floor

FIGURE 4

Two days after implantation. Calf in process of standing up from a laying position.

FIGURE 5
Two days after implantation. Calf jumping off a 53 cm high deck to a concrete floor

FIGURE 6

Two days after implantation. Calf forcibly knocked off its feet falling to its right side.

5.0 DISCUSSION

The goal of this study was to determine the acceleration levels which may be encountered by a thermal converter implanted in the experimental animal, the calf. The abdominal implant location attempted to duplicate the planned method of implanting the system for in vivo experiments. While this method is quite convenient for implanting the blood pump in the thorax connected to the thermal convertor in the abdomen, it offers relatively little protection to the thermal convertor to forces and impacts from the surroundings external to the calf. Immediately after implantation there is relatively little thickness of tissue and skin covering the thermal convertor. In addition, the tissue is relatively soft without muscle or bone in the vicinity to absorb forces from outside. In planning these experiments, the objective was to cover most of the normal maneuvers as well as the most severe cases that might be encountered. The most severe case envisioned was the animal falling from the operating table in a relaxed anesthetized state, caused either by dropping during handling of the animal or due to a convulsive movement in the animal. We elected to use calf cadavers to simulate this condition. By vectorally summing the three acceleration components, the maximum magnitude obtained was 34 Gs in these drop tests. This magnitude was obtained only when the thermal convertor implant location made contact with the floor. As expected, the duration of the accelerations are quite short, on the order of 50 - 100 milliseconds for the entire event. In the in vivo studies acceleration magnitudes are considerably less. A maximum of 8 Gs was obtained when the animal was forcibly upset from standing position onto his right side. The magnitude of the 34 g maximum acceleration experienced may at first seem high, but when the TCM was dropped on a hard surface table from a height of six inches, the maximum accelerations measured were in the range of 20 to 30 Gs.

In general, therefore, it can be concluded that the magnitude and duration of the accelerations expected to be experienced by the thermal convertor in future animal experiments is relatively low. In utilizing the acceleration data, it must be borne in mind that the unit was

constructed of wood and that the accelerometers were mounted near the center. The elasticity of the wood may cause lower acceleration readings than might be experienced in a more rigid structure. In addition, local forces and accelerations in a non-solid structure such as the actual thermal convertor might be considerably higher. However, the order of magnitude measurements made in these experiments should be useful in the development of the thermal convertor to estimate forces on individual components of the unit.

We had originally planned to make measurements of the accelerations a few weeks after implantation of the thermal convertor in the two calves. However, this was not possible in both cases due to failure of the electrical leads. However, from our past experiences with implants we are confident that the additional fixation and encapsulation of the thermal convertor in the animal's abdomen would tend to reduce the level of acceleration experienced by the unit as compared to results made soon after implantation. Therefore, the data presented here, measured soon after implantation, represents the worst case, which is probably the most meaningful data desired from these experiments.

6.0 REFERENCES

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