STANDARDISATION OF SHOCK WAVE LITHOTRIPTERS

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Abstract

There is an urgent requirement to develop global standards for the calibration of biomedical equipment, for better healthcare, as per WTO (World Trade Organisation) norms. National Physical Laboratory of India is actively involved in the development, maintenance and establishment of primary standards for the country, for both electrical and non-electrical parameters. It is planned to extend the facility for maintaining and developing the standards for the calibration of biomedical equipment, devices and systems.

The ultrasonic lithotripters are in common use, these days, in the hospitals, for the removal of the stones present in the kidney or gall bladder, without surgery. It is, however, lacking to standardise the dosage level and duration, for a particular treatment. Due to the high intense shock-waves generated by the lithotripters, namely ESWL (Extra-corporeal Shock Wave Lithotripters), there are side effects on the soft biological tissues in the human body. Even the delicate nerves and fibres in the surrounding of the kidney or the gall bladder, are damaged. It is, therefore, important to standardise the output parameters of the lithotripters, from time to time, preferably on site. In order to have the facility for calibration of such high power lithotripters, a new smart portable acoustic power dosimeter is developed for the measurement of power output of the lithotripters. The design and development of this smart sensor is given in the present paper. Other techniques for the optimisation of the performance of the lithotripters are also discussed, in brief. The establishment of the new facility for the standardisation and calibration of shock wave lithotripters will assist in the better treatment of the patients suffering with the presence of stones in the kidney or gall-bladder. Additionally, it will help in maintaining proper safety for the patient as well as the doctors or operators of the machine.

1. Introduction

The removal of renal calculus and the gallbladder stone by using extracorporeally induced shock waves has become a very popular procedure these days, world wide. The shock waves are generated by the lithotripter, like Extracorporeal Shock Wave Lithotripter (ESWL), which generate acoustic pulses with pressure rise time of several nanoseconds duration [1-6]. The mechanism of stone destruction is not yet completely understood, although it has been assumed that the repeated tensile wave reflection and spalling, and the acoustic cavitation might play an important role in this process. Since biliary lithotripsy is burdened with a high rate of continuous treatments due to an incomplete fragmentation, further understanding of the procedure of stone disintegration should improve the success of fragmentation results. In order to obtain a more detailed analysis of shock wave effects on the human stones, several techniques are in use. In one technique, high-speed films at 10, 000 frames per second of shock wave action on kidney stones and gallstones have been used. Also, scanning electron microscopy (SEM) of human gallstones has been utilised after the shock wave treatment [5]. As said above, kidney stone disintegrators, like ESWL (Extra-Corporeal Shock Wave Lithotripters), are currently in routine use in the hospitals for the removal of kidney stones, non-invasively and non-destructively. However, proper standardisation of such systems is still required for better safety purpose, and for better health care. Acoustic power output or intensity level of the lithotripter transducer is, generally, measured by using conventional devices like PVDF (poly-vinyl-di-fluoride) hydrophones which have their limitation of sensitivity, stability and durability. In order to overcome such problems, a new smart silicon sensor is developed, in the present work, to characterise and calibrate the acoustic or electro-magnetic lithotripters for their output parameters like ultrasonic power output and/ or intensity level to enable the doctors to use the lithotripters in a more effective manner, with proper dosage level, for a particular treatment. with better safety.However, the treatment effect with the shock waves depends upon the acoustic power/ intensity level available from the ESWL apparatus. These days, conventional piezo-electric type or pvdf (polyvinyl difluoride) hydrophones are, generally, used to monitor the acoustic power output of the lithotripsy transducer [6]. These power measuring devices have, however, limitation of sensitivity, resolution, stability and even durability. The devices are even found broken after a specific number of shocks. In order to solve these problems, a new smart silicon lithotripsy sensor has been developed in the present work, with better stability and better durability, for the standardisation of the lithotripters.. These days, there is an urgent need to develop and establish standards and calibration facilities for biomedical equipment in the country, for better healthcare, as there is no such facility available presently for proper diagnosis and treatment of the diseases of the patients. A new programme on the 'development and establishment of standards and calibration facilities for electro-medical equipment' is initiated in this Laboratory, for better health care in the country. As is aware, these days, the human body is being exposed to different types of radiations and there are well established ill effects on the soft tissues. The safety limitations of say, ultrasound dosage are established on the basis of the basic findings. The study would help the clinicians to use ultrasound machines with proper dosage level and proper duration for a particular human body or tissue to be treated. Biological tissues are characterised for ultrasonic, thermal and physical properties to enable develop 'safety standards' for avoiding side effects on the surrounding delicate nerves and fibres. High power acoustic lithotripters are in extensive use, these days, to disintegrate renal calculi, non destructively. It is investigated first time that acoustic stimulation assists in the enhancement of stone disintegration in lithotripters, used for the removal of kidney stones, without surgery. In the present study, safety limits of lithotripter intensity on the human tissues are studied and discussed, by giving comparative data on the laboratory samples of renal calculi, in vitro.

2. Design and Fabrication

The semiconductor lithotripsy sensor chip has a four-arm Wheatstone bridge of silicon strain gauges with the associated electronic circuits of signal conditioning and amplifier etc. on the chip itself. The chip has been developed using conventional bipolar IC process, in association with bulk micro-machining process [7-10]. The standard 5 ohm-cm p-type (100) silicon material was used as the starting material. The size of a particular chip was 3 mm square and the size of the anisotropically etched diaphragm was 1.0 mm x 1.5 mm x 20 micron (thickness). The sensor device chip was fabricated by using the DIMES-01 (Delft Institute of Microelectronics, TU-Delft, the Netherlands) bipolar process. First, the alignment marks were required by the wafer stepper, as used for most of the lithotripsy steps, were patterned on the wafers by a double oxidation step with a lithography step in between. The first mask of the present chip layout, the BN mask (buried n-type layer) was used to create the n^+ buried regions. The Sb^+ ion implantation was used, that was then followed by long and high temperature anneals. Then with the 4 μm, 0.5 ohm-cm resistivity, As^+ doped epilayer was grown. The deep p-type (DP) isolation diffusion and the n-type (DN) collector plug diffusion completed the first part of the process. At this stage, all the oxide was removed and a thin 400 A channelling prevention oxide was thermally grown. Through this oxide, an additional implantation step (As^+, 150 keV, $5X10^{15}$ /cm^2) was performed (option 1: SN mask) to improve the contact to the epilayer. The field oxide of about 3300 A was then grown, and through this oxide, both intrinsic (BW mask) and extrinsic (WP mask) base surfaces were implanted. The boron dose for the intrinsic base was $1x10^{14}$/cm^2, while for the extrinsic one was 4.85 x 10^{15}/cm^2. At this point, a 1500 A silicon-rich nitride, used as masking layer during the etching of silicon in the KOH solution, was deposited by LPCVD (option 2). The nitride was totally removed on the front side of the wafer and, at a later stage of the process, was patterened on the backside through the KOH mask.

Local reduction of the oxide thickness on the membrane areas (except on the piezo-resistors) with the field oxide thickness of about 3300A was preserved through the OX1 mask (option3). The oxide was etched to about 1000 A in order to reduce the stress of the silicon membrane. The last part of the basic process consisted of the emitter implantation (WN mask), the contact windows opening (CO mask) and the metallization (IC mask). An 0.6 μm Al/1% Si deposited by sputtering was then used as metal interconnection material.

After the alloy step, the bulk micromachining process module was applied. The mask containing the membrane areas (KOH mask) was exposed on the back side of the wafer and aligned with the structures present on the front side of the wafer in a backside aligner. The nitride in the windows was plasma etched and the wafer was ready for the electrochemically-controlled etching of silicon. The completely processed wafer was coated with resist on the front side and mounted in a specially design wafer holder with a spring loaded contact used to passivate the epilayer with a positive voltage. The wafer was etched in 50% KOH solution at T = 89 C, resulting in a silicon etch rate of 1.7 μm/min. The negative electrode of the cell was a platinum electrode. The cell current and voltage were continually monitored and recorded together with the solution temperature and the etching time.

3. Measurements

The fabricated sensor was assembled as a gauge pressure sensor and its basic characteristics were measured. The piezo-resistors-bridge was initially designed for 1000 ohms, and the chip size was 800µm x 20µm, but finally it gave resistance of 908 ohm in each arm.

The sensor chip was encapsulated in a stainless steel chamber having two parts, pressure housing and electronic circuitry housing. The pressure housing was used to monitor the pressure amplitudes of the shock wave apparatus of the lithotripter by filling it by distilled/ gas free water. The pressure sensitivity was found to be 10 µV/mm Hg pressure, with non-linearity of 0.20% full scale and the thermal stability less than +_ 1.5% over a temperature range -50 to 300°C. Thus the present smart silicon sensor, was found to have better sensitivity and better resolution, and useful in monitoring of the acoustic intensity level and pressure amplitude (in MPa range) of the shock waves generated by ESWL or some other similar lithotripter.

In order to balance wide bandwidth with durability, a hydrophone for lithotripsy research was developed by using a special multi-element sensor chip. Each element was stretched across a mounting frame. In case of failure of an element, it was possible to quickly replace it. In order to avoid the need for recalibration with each replacement, the use of hysteresis poling ensured constant sensitivity of elements. Electronics located in the frame included a wide-bandwidth preamplifier and gating circuitry to prevent saturation, say by the electromagnetic pulse from a spark-gap lithotripter, if used. The proposed design would provide the needed bandwidth to resolve shock wave frequency components beyond 100 MHz, as well as the durability and spatial resolution to map the acoustic field within a lithotripter.

4. Conventional Lithotripters

The comparision is made for the measurement [10-13] of some basic physical parameters in the under water acoustic field of an extracorpporeal shock wave lithotripter provides information which is useful in comparing the performance of these machines and then side effects. The lithotripters reffered here are those manufactured by Dornier Medical System GmbH (Doctor HM3), Richard Wolf GmbH(pizolith 2200), Siemens(lithostar), Technomed International (Sonolith 2200)and EDAP(Lt-01). The shock wave can be described in terms of range of frequencies with a fundamental frequency around 0.5 MHz in most ESWL machines and a number of higher harmonics. The measured pressure parameters(p+ and p- in M Pa0), pressure rise time(t_r, ns), occuring at the focal regiion in which pressure is higher thanthe half of the peak focal pressure(r and z,16 cm), G , and the shock parameter, X , of ESWL systems calculated from measured parameters. These machines employ a focussed shock wave which leads to higher pressure occurring in a region near the stone by abrupt release of energy in the small space.According to physical laws of acoustics, these waves propagate and are transmitted through a medium with low attenuation. Shock wave lithotripsy also require some form of analgesia because the summation of wave imppulses, both at the skin level and within the focal point, stimulates cutaneous and vicera; sensory afferents.Without analgesia, patients perceive a “Slapping or shock liike” pain which is unpleasent, especially since the length of the treatment time varies from 30 min to 90 min, and larger stones require longer treatment and more shock waves.

5. Biological Effects of Shock Wave Lithotripsy

The effect of radiation from lithotripters on biological specimens is mainly due to rise in local temperature.A thermo-couple tempreture-probe is used to monitor the rise in temperature due to high energy radiation.In vitro biological samples are studied [1-13] experimentally in the laboratory.Some of the techniques and results of earlier work show that in ESWL systems, rapid and high voltage underwater spark discharge within an ellipsoid reflector to generate a shock wave, which is foccused and transmitted through water.This high energy wave travels at supersonic speed through body tissues with slight attenuation.The impact of wave against the stone liberates short-term high energy mechanical stress at the focal point. This stress overcomes the tensile strength of the calculus and caused disintegration.The voltage across the electrodes determines the each shock waves delivered.The low frequency ultrasound waves with positive pressure compressive amplitudes have good tissue penetration.Some of the effect of high energy shock wave lithotripsy to biological media are given below :

(a) Damage of soft tissues :

(1) Effect on serum parameters : An increase in the white blood cell count(WBC), lactric dehydrogenase (LDHI), serum gultamic oxaloacetic transminase (SGOT), creatinine phosphokinase(CHK), and bilirubin was observed.A decrease in analyse, platelets, alkaline phosphate, and hematocrit was also recorded.
(2) Effect on urine: The urine becomes slight pink or dark red indicating the presence of blood after the application of shock wave energy.
(3) Anatomic changes in kedneys: The ppatients treated with shock waves have been reported to suffer from peri-renal bleeding.
(4) Animal pathologic studies:Five shocks were delivered to the kidney stones and the kedney demonstrated some pathologioc changes after the application of high energy shocks.
(5) Clinical studies of renal changes : The sevierity of swelling after lithotripsy increase as the number of shock waves is increased.With shock wave energy, sub capsular bleeding is observed.

(b) Effect on Human Spermatozoa, In Vitro :

A gradual decrease in the spermatozoa is observed with the increase in the number in shock waves.Decrease in sperm motility is also observed.

(c) Effect on Urological Prosthesis and Endoprosthesis :

There is an epidemic of injuries to the upper urinary tract epithelium with the application of shock wave causing damage to prosthesis.

(d) Effect on Lung Haemorrhage :

One of the serious side effects of shock wave is lung damage due to bleeding.

(e) Effect on L 120 Cells :
Lukemia mouse cells (L 120) irradiated with different number of shock waves were found to suffer secondary effects caused by serve cellular damage.

(f) Kidney Haemorrahage by Shock Wave :
It has been observed that shock waves up to 120 waves caused haemorrahage in tissues. However, the number of shock waves used for stone destruction varies between several hundred and several thousand waves and many cause severe dammage.

6. Safety Aspects

(a) A metal sievins may be used between the transducer and the place where shock wave to be applied.
(b) A special type of radiation -proof medical kit or or chemical should be used on the skin of the patient for safety purposes and for better coupling.
(c) Operators responsible for the equipment should stay away from the radiation area to avoid the radiation hazards.
(d) The exact site of the stone should be detected properly with imaging techniques used.
(e) Focussing of shock wave should be exactlyy on the renal calculi to be disintegrated in order to avoid damage to surrounding tissues.

7. Conclusion

Safety standards of lithotripters have been studied and analysed. A new smart pressure sensor with improved sensitivity and resolution has been developed to be used as a hydrophone for the study or map the acoustic field of an electromagnetic or extracorporeal shock wave types of lithotripters. The pressure sensitivity has been found to be 10μV/mm Hg pressure, with nonlinearity of 0.20% full scale and thermal stability less than +_ 1.5% over a temperature range –50 to 300°C, for a particular case. The sensor is adaptable to a durable and wide-bandwidth lithotripsy hydrophone, by using in multi-element array form.

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