34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Towards minimally invasive monitoring for gastroenterology –An external Squamocolumnar Junction Locator

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Abstract— **Transient lower oesophageal sphincter relaxations (TLOSRs) occur frequently and are the main mechanism of acid reflux. The only means of currently detecting TLOSRs is intra-luminal manometry and the probes themselves may stimulate TLOSRs. The squamo-columnar junction moves 4-5 centimeters proximally during TLOSRs and this provides a means of detecting such episodes. The objective of this work is to develop a sensor system capable of detecting the movement of a miniature magnet attached to the squamo-columnar junction from outside the body and thus allow detection of TLOSRs without the artifact associated with intraluminal detection probes. A GaAs Hall effect sensor was selected and an alternating current supply was developed with a combination of filters and a Phase Sensitive Detector, to detect the magnet. The oscillation frequency of the current was chosen in order to reduce electronic noise, and filtering outside this frequency means the signal to noise ratio was greatly improved. The phase sensitive detector was employed to accurately convert the amplitude of the sensor's output to a DC signal. With the addition of paired Flux Concentrators increases the range up to 10.2 centimetres, an improvement of 580% over commercial Hall effect sensors. The AC circuit and flux concentrator device far exceeds the sensitivity of the current Hall effect sensors supplied in the market, by rejecting noise and providing accurate measurement over significantly larger distances. The development of this sensor has applications beyond this specific medical device.**

I. INTRODUCTION

Gastro-Oesophageal Reflux (GER) is a very common complaint in the western world [1], however the mechanism of this condition is not fully understood. Reflux occurs when gastric contents retrograde into the oesophagus and can cause a burning sensation in the chest, a symptom commonly know as heartburn. Extended or frequent retrograde episodes of this type may cause Oesophagitis, Barrett's Oesophagus or Adenocarcinoma. The Gastro-Oesophageal Junction (GOJ) is the transition between the stomach and oesophagus, maintenance of which provides reflux protection. This antireflux barrier, working to oppose the gastro-oesophageal pressure gradient, consists of the Lower Oesophageal Sphincter (LOS), the stomach Flap Valve and the Diaphragmatic Crura. The LOS and Crura maintain a sphincteric pressure of 10-35 mmHg [1] in the healthy population. The LOS can relax to release trapped gastric gas in the form of a belch, or to allow the contents of a bolus of swallowed food to pass from the oesophagus to the stomach, the former action is termed a Transient Lower Oesophageal Sphincter Relaxation (TLOSR).

The Squamo-Columnar Junction (SCJ) is the epithelial tissue type change between the columnar epithelium of the proximal stomach and squamous epithelium of the oesophagus, which is above the GOJ [1]. Both high-resolution manometric data and the pH step-up point can identify the transition between stomach and oesophagus, and in much of the literature this is assumed to be the location of the SCJ. This may provide the location of the SCJ within several centimetres during periods of solid sphincter tone in healthy subjects, however during TLOSRs or in non-healthy population, this assumption is no longer applicable due to a distal portion of columnar lined oesophagus [1]. Manometry is capable of detecting a TLOSR when sphincter tone is lost, however details of the SCJ or GOJ movement is unknown during this period [2]. The only published paper measuring the magnitude of SCJ movement used fluoroscopic imaging, whereby a radio-opaque endo-clip is endoscopically placed at the SCJ then a small number of 30 second screenings may be recorded [3].This method is likely to underestimate the proximal movement of TLOSRs because the initial movement will be missed as fluoroscopic recording may only be started after the onset of a TLOSR has started.

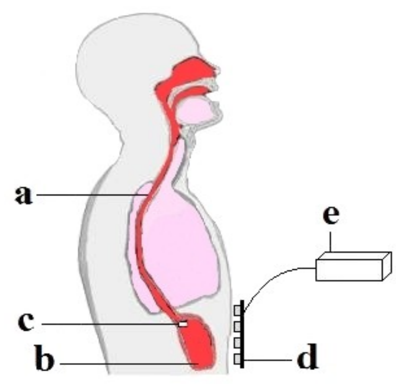

Figure 1. Illustration depicting the anatomy and technology described in this paper. Where (a) the oesophagus, (b) the stomach, (c) clipped magnet, (d) Hall Effect Sensors and (e) AC circuitry.

As the stomach contents are often strongly acidic, up to pH 1-3 [1], reflux of gastric content can cause damage to the sensitive oesophageal squamous epithelium. Positional knowledge of the SCJ with respect to acid along the

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oesophagus during reflux episodes shows the duration and strength of acid exposure on the squamous oesophagus.

The Hall effect is the voltage change across a semiconductor when a magnetic field is applied [4]. The magnitude of the output voltage (V_H) is proportional to the current flowing through the semiconductor (I) and the magnitude of the magnetic field (B), as in (1). Where d is semiconductor thickness, N is the carrier density and q_0 is the charge on an electron

$$V_H = \frac{IB}{q_0 Nd} \qquad (1)$$

Previous work led to the development of a high-resolution Hall effect sensor based catheter probe consisting of an encapsulated array of A1395 Hall effect sensors (Allegro Microsystems, USA) placed on a flexible printed circuit and external microprocessor which measured the magnet from in the oesophageal lumen with an accuracy of 1 centimeter [5]. This technology allowed the user to accurately measure movement of the SCJ due to breathing, swallowing and TLOSRs over extended periods, both pre and post-prandial.

Recent papers by Mittal and Noordzij [6,7] have suggested the very presence of oesophageal luminal devices affect the behavior of the sphincter and may artificially induce extra TLOSRs by way of laryngopharyngeal mechanoreceptor stimulation. As a significant number of reflux events occur as the result of TLOSRs, the therapeutic objective is often to minimize the number or TLOSRs [2], however since the presence of an intraluminal probe increases the frequency of TLOSRs, the focus of this research is towards developing a non-luminal tool which measures the movement of the SCJ. Previous magnet tracking devices have been used in humans, however have used larger magnets than is appropriate for attaching to the SCJ [10] or external apparatus such as MRI [11]. This device is required to operate from outside the patient or volunteer, to avoid increasing TLOSR frequency due Mittal's mechanoreceptor event, and provide a tool capable of reliably measuring TLOSRs without triggering them, conceptually shown in Fig. 1.

II. Materials and Methods

A. Constant Current Hall Effect Sensor

Sensitivity is an accurate term for describing sensor efficacy, however in this application, the important factor is range; the distance over which the magnet can be detected, as the magnet is merely a marker for the SCJ, therefore although the sensitivity is increased, this paper will use range to describe the sensor. For the purpose of clarity, all bench-top tests will use a 1789 Gauss Samarium Cobalt disc magnet of 3mm diameter and 2mm length, in ideal orientation.

An initial Direct Current (DC) system was developed, showing high levels of noise and drift, therefore a regulated 5 Volt constant current source of 5 milliamps was used to supply the Hall effect sensor. This increased the sensitivity by reducing internal heating therefore thermal drift and with the addition of shielding, decreased noise greatly.

B. Alternating Current Hall Effect Sensor

In order to advance the current SCJ locator probe technology [5], the equipment must be redesigned in order to measure the magnetic clip externally, which provides new problems whilst removing others. Where the luminal probe was severely restricted by size, both of the sensors and the flexible circuit board on which they were mounted, the new non-luminal probe will have no such restraint, as it will not be employed nasally, therefore resolution and complexity may be significantly improved. This is fortunate, as the distance over which the magnet needs to be detected increases significantly with the new design criteria.

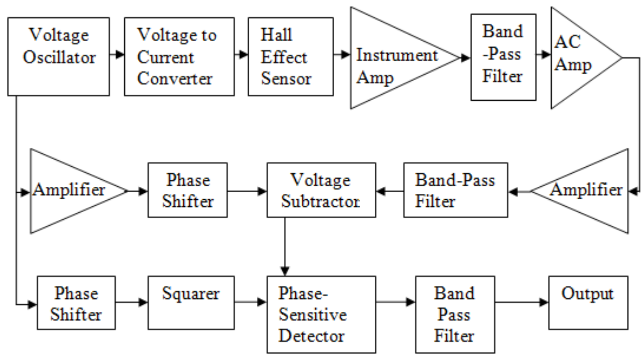

Figure 2. AC Circuit Schematic

In order to further the device, a range of high sensitivity Hall effect sensors were tested and the AHS P15 GaAs sensor (AHS, UK) was used to improve the overall performance where a DC driving circuit was employed. To increase the system's magnet detecting range, an Alternating Current (AC) driving system was designed, as shown in Fig. 2. The system works by supplying AC to the Hall sensor at 1.59 kilohertz, the output of which is proportional to the product of the AC and the presence of a magnetic field. The output is amplified and band-pass filtered at the driving frequency then subtracted from a phase matched driving AC signal, producing a sine wave with amplitude proportional to the magnetic field. A Phase-Sensitive-Detector (PSD) is employed to accurately measure this sine wave. The printer circuit board is shown in Fig. 3.

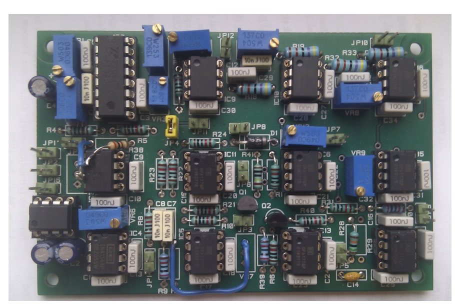

Figure 3. Printed Circuit Board of the AC schematic

C. *Flux concentrator simulation and testing*

The limiting factor of Hall Effect sensor sensitivity for large signals is the sensors transduction ratio [8] as seen in (2), where S_A is the sensor sensitivity.

$$S_A = \left| \frac{V_H}{B} \right| \tag{2}$$

Therefore there methods of increasing sensitivity are to reduce the output noise, for example with good conditioning electronics, and amplify the measured field without adding noise. Flux concentrators (FC) may be employed to passively amplify the magnetic field, whereby a ferromagnetic material is placed in-between the sensor's hall element and the magnetic field source, amplifying the magnetic field at the sensor. With novel flux concentrator design [8] very high gains have been shown in simulations.

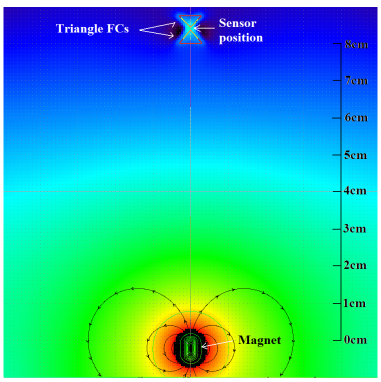

Figure 4. Vizimag Simulation Output of paired triangular flux concentrators showing a color contour plot of field amplification 8cms from the magnet.

Simulations were performed using *Vizimag 3.17* magnetic field software, testing a variety of FC shapes, with a constant relative permeability of 2000 and a magnet of 1800 Gauss, demonstrated in Fig. 4. Where the FCs were placed in front of and aligned with the sensor, the closest edge of the FCs was 8 centimetres from the face of the magnet, which was in ideal orientation with the north face pointing towards the FCs. The FC dimensions for simulations were 5 millimeters wide and 4 millimeters high, however the FCs used in testing were 3 millimeters wide and 10 millimeter long Ferrite rods (Fair-rite USA).

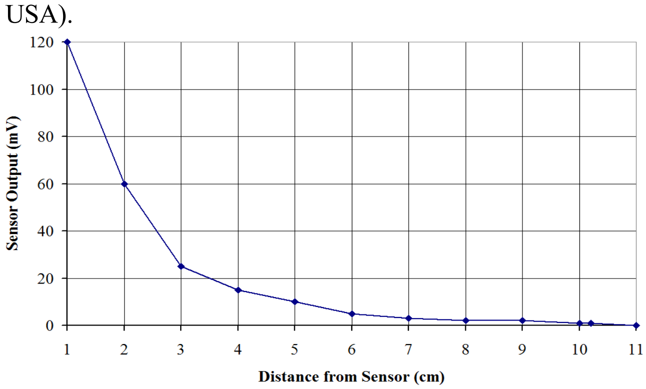

Figure 5. Output of the AC sensor with FCs with increasing distance between sensor and magnet.

Bench-top testing of the actual FCs was performed with the same rules, in order to evaluate simulated with actual results, and instead of measuring the field at the same point, the magnet was moved away from the FC and sensor until its field could no longer be detected. Gain was calculated for each experiment to allow comparison.

III. Results

A. *Constant Current Hall Effect Sensor*

The improved DC system with P15A sensors, a constant current source and shielding is improvement on standard hall sensors available, due to the higher field sensitivity, low drift and noise rejection qualities respectively. The range at which a magnet could be detected with the DC system was 2.4 centimetres, an increase of 60%.

B. *Alternating Current Hall Effect Sensor*

The range of the sensor is up to 6.3 centimetres, when measured with an RMS-to-DC converter which measures the Root-Mean-Squared amplitude of a sine wave and translates it to a DC signal, a very significant improvement of 320%. Without the RMS-to-DC converter, the accuracy was limited due to manually reading the amplitude from an oscilloscope.

Improvements were then made to the device by adding a subtractor circuit, which removed the driving voltage, when there was no magnet present, the output was 0 volts, but when a magnetic field was present, a small sinusoidal voltage was created, which can be amplified and filtered for greater accuracy. This improved the range up to 8.2 centimetres, an increase of 447%. The PSD allows the detection of the magnet at 8.9 centimetres, an increase of 493% when compared to the commercial Hall effect device previously used [5].

C. *Flux concentrator simulation verses actual*

Table 1 shows the gain with the different types of FCs, comparing the simulated gain with that measured in testing. For the simulations, the gain was calculated using the increased field strength with the FCs compared to the gain with no FCs present, as shown in table 1.

The triangle paired FCs showed the best theoretical and bench-top gain, an increase of 76.1%, improving the total range to 580% compared to the commercial sensors. The output voltage with respect to distance of the Hall sensor and FC system is shown in Fig. 5.

TABLE 1. Comparison Simulated and Experimental Flux Concentrators

Concentrator Type	Simulation Gain	Experimental Gain
No Concentrator	0.00	0.00
Square Behind	5.00	3.43
Triangle Behind	5.87	4.90
Triangle Fronted	13.00	10.78
Paired Triangles	22.07	14.70

IV. Discussion

The limitations of the DC system restricted the range at which the sensor could accurately detect a magnetic field as the signal-to-noise ratio was poor, even with shielding.

The shortest distance between the oesophagus and the skin is far greater than this, approximately 6-10 centimetres upon visual inspection of MRI data, therefore the range at which the magnet can be detected needs to be greater than this distance.

The AC system was designed for its noise rejection quality, and its increased sensitivity due to the increased current which can be supplied through the sensor without internal heating. Since the driving frequency of the hall sensor was 1.59 kilohertz, all other frequencies can be filtered out, including low level background magnetic field as well as electronic sources of noise, for example mains power and computer interference.

The device was able to measure the magnet near the required biological distance, however further circuitry employed a PSD to enable detection of the magnet at even greater distances. The PSD can detect very small sinusoidal voltages even in situations where levels of signal to noise are very low and the signal appears completely lost within the noise [9]. This is possible due to the advantage of driving the circuit with a known frequency, all other frequency components of the signal can be removed by multiplying the sine wave with an equivalent square wave of the exact frequency and in antiphase of the driving signal, and filtering out high frequencies, leaving only a DC component proportional to the field strength of the magnet, allowing it to be multiplexed or sampled by a microprocessor.

The discrepancy between simulated and actual gain values for FC amplification can be attributed to the non-ideal performance of the magnetic field, as well as differences in gap and FC misalignment on the bench-top, highlighting the importance of FC alignment. The relative permeability of the simulated and experimental FCs differed due to the poor availability of high relative permeability material for retail, adding a source of discrepancy. For the paired triangle test, the gain was proportionally lower due to the difficulty in machining fragile ferrite and producing the tapered triangle. Despite the difference in dimensions of the FCs between simulation and testing, the triangle or tapered concentrator is shown to produce the highest gain, direct comparison is not drawn, rather the simulation allows for highlighting geometries of highest amplification, agreeing with the literature [8]. If the ability to model more complex shapes were possible with available software then more direct comparisons could have been made.

The range of 10.2 centimetres with the Hall effect sensor and flux concentrator combination is an increase of 580% detection range over the commercial Allegro A1395A Hall effect sensor with the same magnet.

The importance of this much improved Hall effect sensor and circuitry leads to a potentially very accurate and reliable method of detecting the magnet at the squamocolumnar junction, allowing for the first time, detecting the number of TLOSRs over a period of time without the presence of a luminal catheter based probe.

As a significant number of reflux events occur as the result of TLOSRs, the therapeutic objective is often to minimise the number of artifactual TLOSRs, however since Mittal and Noordzij [6,7] suggest the presence of an intraluminal probe increases the frequency of TLOSRs, the number of TLOSRs must be measured via a non-luminal means, such as this device. This technology is small enough to be portable and ambulatory, offering significant advantages over previous magnetic motility equipment [10,11]. The importance of significantly higher sensitivity and range goes beyond this device and indeed application, and could provide valuable for any work performed with magnetic fields and their measurement due to the hugely increased sensitivity.

Acknowledgment

The lead author would like to thank his supervisors for their leadership and motivation, and his colleagues for their support. The author also thanks the EPSRC for a Medical Devices Doctoral Training Centre Studentship that supported this work.

References

[1] P. T. Chandrasoma and T.R. DeMeester, *GERD: Reflux to esophageal adinocarcinoma.* Burlington, MA: Elsevier, 2006.

[2] S. Roman, F. Zerbib, K. Belhocine, S. Bruley des Varannes and F. Mion, "High resolution manometry to detect transient lower oesophageal sphincter relaxations: diagnostic accuracy compared with perfused-sleeve manometry, and the definition of new detection criteria" *Aliment Pharm Ther.*, vol. 34, June 2011 pp. 384-393.

[3] J. E. Pandolfino, Q. Zhang, S. K. Ghosh, A. Han, C. Boniquit, and P. J. Kahrilas, "Transient lower esophageal sphincter relaxations and reflux: mechanistic analysis using concurrent fluoroscopy and high-resolution manometry". *Gastroenterology*, vol. 131, Sept. 2008, pp 1725-1733.

[4] E. Ramsden, *Hall effect sensors: theory and application*. Burlington, MA: Elsevier, 2006.

[5] Y. Y. Lee, J. P. Seenan, J. G. H. Whiting, E. V. Robertson, M. H. Derakhshan, A. A. Wirz, D. Smith, C. Hardy, A. Kelman, P. Connolly and K. E. L. McColl. "Development and validation of a probe allowing accurate and continuous monitoring of location of Squamo-columnar junction" *Med Eng Phys.*, vol. 34, April 2011, pp 279-289.

[6] R. L. Mittal, W. R. Stewart and B. D. Schirmer, "Effect of a Catheter in the Pharynx on the Frequency of Transient Lower Esophageal Sphincter Relaxations" *Gastroenterology*, vol. 103, Oct. 1992, pp 1236-1240.

[7] J. P. Noordzij, R. K. Mittal, T. Arora, N. Pehlivanov, J. Liu, J. F. Reibel and P. A Levine, "The effect of mechanoreceptor stimulation of the laryngopharynx on the oesopho-gastric junction", *Neurogastroent Motil*., vol. 12, Aug. 2000, pp 353-359

[8] P. Leroy, C. Coillot, A. F. Roux, and G. M. Chanteur, "High Magnetic Field Amplification for Improving the Sensitivity of Hall Sensors", *IEEE Sens J*., vol. 6, June 2006 pp. 707-713.

[9] M. L. Meade, *Lock-in amplifiers: principles and applications*. London, UK: Peter Peregrinus Ltd, 1983.

[10] J. Worsoe, L Fynne, T Gregersen, V Schlageter, L. A Christensen, J F Dahlerup, N. J. M. Rijkhoff, S Laurberg and K Krogh," Gastric transit and small intestinal transit time and motility assessed by a magnet tracking system", *BMC Gastroenterol.*, vol. 11(145), Dec 2011.

[11] L. A. Szarka and M Camilleri, "Methods for measurement of Gastric Motility" *Am J Physiol Gastroinest Liver Physiol*, vol 296, Mar. 2009, pp G461-G475.