Piezoresistive Sensors for Medical Applications

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Abstract
Rectal manometry provide a useful method to objectively assess the physiology of defecation. We developed a probe with 10 embedded transducers for evaluating the dynamic rectal pressure profile. The innovation of the probe is to use small piezoresistive dice and reduce the packaging resulting in a very small assembly. The diameter of the probe is 9 mm with a length of 20 cm. The length could be extended up to 30 cm with 15 transducers. We performed measurement of the colorectal dynamic pressure profile in one healthy test person. We could detect pressure waves caused by the evacuation reflex at a frequency of 3 to 4 per minute with an pressure increase of 4-5 kPa. The diagnostic measurement of the dynamic rectal pressure profile may provide additional information in cases with colorectal disorders.

1. Introduction
Defecatory disturbances, including constipation and incontinence, are often difficult problems to diagnose and treat. Faecal incontinence may be multifactorial due to altered stool consistency, increased anorectal sensation, and neuromuscular or anal sphincter dysfunction [8]. Constipation is divided, with considerable overlap, into issues of stool consistency (hard, painful stools) and issues of defecatory behaviour (infrequency, difficulty in evacuation and straining during defecation). Constipation may be associated with anatomic abnormalities and with impaired colorectal motility.

In paediatrics, the Hirschsprung disease is an inborn disorder whose main characteristic is impaired intestinal function in which part of the colon lacks nerve cells and so is unable to relax. The result is chronic constipation and distention of the abdomen.

All above mentioned disorders are partly associated with motility abnormalities. The purpose of this study is to quantify the motility of the rectum up to the colon sigmoideum (see figure 1). As this paper is an interdisciplinary project of medical engineering a brief outline of the anatomy and pathophysiology is given in the following subsection.

The colon consists of longitudinal and circular musculature. Wave-like movements arise, consisting of alternating waves of relaxation and contraction in the muscular coat, by means of which the contents are propelled. This is called peristalsis. Contractions of the longitudinal and circular musculature during peristalsis are out of phase by 90 degrees. On distension of the lumen the longitudinal muscle contracts, followed by progressive contraction of the circular layer. The circular layer begins contraction when contraction of the longitudinal layer is half complete [9]. The reflex inducing peristaltic evacuation of the rectum is depicted schematically in figure 2.

Figure 1: Anatomy.

Figure 2: Peristalsis of evacuation.
At present, a rather large spectrum of different technical measurement devices for assessing the anal canal tonus and the motility of the rectum are being reported [5]. The most common measuring devices by which anorectal function is assessed today are the rectosphincter balloon, the water-perfused catheter assembly and the microtransducer tip catheter. The balloon and water perfused catheter are connected to external pressure transducer [1].

All devices are suitable to assess five parameters of the anorectal function: resting tonus, squeezing tonus and pressure profile of the anal canal, rectal capacity and the functional anal reflex. There are only a few studies dealing with the motility of the rectum [12].

Defecography is a diagnostic tool to visualise the rectal motility. A well-know procedure is the defecography using a contrast fluid with an x-ray image system (fluoroscope). Recently defecography is introduced applying magnetic resonance imaging (MRI). With these imaging technologies the evacuation is visualised and malformations like a rectocele (dilation of the intestinal wall, see figure 3) or an intussusception (intestinal wall is turned inside out) may be diagnosed. However, fluoroscopy suffers from x-ray exposition and MRI is time-consuming and cost-intensive. Hence we extended the classical manometry by a probe for assessing the dynamic pressure profile of the rectum.

2. Method

2.1. Construction of the probe

The aim of this study was to measure the dynamic pressure profile of the rectum and colon sigmoidum. In the following we like to focus on the construction of the probe in view of specifications required for medical devices.

The evaluated part of the colon is s-formed (see figure 1). Thus the probe has to adapt to this form. Additionally, the probe has to resist humidity in combination with intestinal fluids and mechanical stress. Further electrical safety aspects and bio-compatibility have to be considered.

Therefore we developed a probe with 10 pressure sensors with a distance of 2 cm each (see figure 4). This leads to a probe-length of 20 cm. The probe should be capable being extended up to 15 measuring points corresponding to a length of 30 cm. The innovation of the probe is to use small piezoresistive dice and reduce the packaging resulting in a very small assembly.

Figure 3: Defecography: Evacuation.

With our sensor probe a simultaneous measurement of the pressure profile combined with the defecography is possible. This would provide additional information in cases with neuromuscular disorders.

Figure 4: Probe with embedded sensors.

According to the above given specifications we developed an assembly with 10 rigid segments made from acrylic bio-compatible acrylic resin. Intervening elastic elements connect the rigid segments (see figure 4). After mounting the pressure sensor into the rigid segments the complete probe is molded with a pourable silicone elastomer (Dow Corning, Silastic MDX4-4210). The elastomer is designed for use in medical device encapsulating applications. It is particularly suitable for protecting the sensitive sensors against the intestinal fluid.

All used materials were tested for their bio-compatibility with an Agar-Diffusion test according to ISO Norm 10993, EN-DIN 30993-5. In order to protect the examined person from electrical hazard, an optical link between the recording PC and the amplifier was used. The sensors and the amplifier including a microcontroller producing a RS232 compatible signal are powered by batteries. For signal processing the software Labview, National Instruments was used (see figure 5).
The diameter of the probe is only 9 mm. This was possible using a very small piezoresistive die produced by SMI. Absolute measuring sensors were selected with a range of 200 kPa. A housing manufactured with low temperature cofired ceramics (LTCC) technology [3] was developed. This allows soldering the wires (d=0.1 mm) and to bond the die on different sides. The die, sunken into the ceramic, results in a very small package. The sensor dimensions have been reduced to a high of 1.4 mm and to an area of 4.5 to 5.5 mm [6]. The top ceramic layer is used as a border for the silicon rubber. This construction is highly robust due to very short bonds with pads lying in one level (see figure 6 and 7).

2.2. Measuring protocol

A bowel preparation was performed two hours before the investigation using a standard enema. The motility study was performed in squat position according to the following technique:
- enema of 500 ml warm water
- start of registration and insertion of the probe
- positioning of the first sensor exactly in the middle of the anal canal
- 2 minutes pause for adaption to the catheter
- performance of maximum consciously increase of intraabdominal pressure (Valsalva maneuver)
- registration of pressure profile while evacuation was inhibited voluntary
- registration of evacuation pressure profile
3. Results

The sensor probe was well tolerated in all positions. The preliminary results of a healthy test person without a history of intestinal disorders are shown in figure 8.

A tonus increase occurred due to the evacuation reflex (see double arrows in figure 8). Additionally a Valsalva maneuver – a consciously increase of the intraabdominal pressure – was performed (see arrow in figure 8). The maximum pressure of the Valsalva maneuver was four times higher than the rectal pressure waves.

In figure 9 we depict a section enlargement of the first pressure wave given in figure 8. Obviously, the pressure increase of the Valsalva maneuver (t=16 s) is exactly in-phase. The pressure increase from t=20 s to t=30 s was caused by the evacuation reflex. The test person felt an urge to evacuate, but this was inhibited consciously. The pressure waves recorded at different positions are slightly out of phase which is a hint at the peristalsis of the bowel.

4. Discussion

There are many studies dealing with the evaluation of the anorectal pressure. Three methods are commonly applied: balloon, water-perfused and micro-transducer catheter. But only a few studies are dealing with the rectal muscular activity. Shafig et al. performed simultaneous recording of the electrical and mechanical activity in healthy dogs [12]. They found that rectal contraction waves cause an increase up to 1.8-2.6 kPa compared to the resting tonus of 0.9-1.6 kPa. The frequency of these waves was between 5 and 14 cycles per minute depending on the rectal distension and the rectal pressure, respectively. We could detect waves at a frequency of 3 to 4 per minute with an pressure increase of 4-5 kPa. The peristaltic waves are not as obvious as expected. This might be due to the water filling in which pressure spreads out equally. A more viscous rectal filling (stool-like enema, e.g. instant mashed potatoes) would help detecting peristalsis more clearly. However, the diagnostic importance of these pressure waves is not validated yet [11]. Bell et al. suppose that the change in rectal tone might have important functional significance [2].

The diameter of our probe with 9 mm is small enough to subjectively provoke no irritation after inserting. However, a further reduction of the diameter would be of interest. Johnson et al. constructed a probe with 4 transducers embedded in a probe with 15 mm outside diameter [7]. Other researchers use microtransducer catheter with a diameter of 2 mm and less, but only with one sensor element [10]. Compared to this we realised a compromise between number of sensing elements and diameter.

Sundblath et al. found that neither the direction nor the position of the patient influenced the recording [13]. Based on this study we decided to measure at a certain point of the probe’s circumference in contrast to a more complex circular coupling with an oil-filled system. Nevertheless we placed the sensors oriented radially 90 degrees apart in order to...
avoid a systematically failure caused by contact of the probe with the intestinal wall.

Bielefeldt et al. concluded that anorectal manometry and defecography are complementary diagnostic tools in the investigation of patients with faecal incontinence [4]. With our method we can provide the measurement of the anorectal pressures as well as the dynamic pressure profile of the whole rectum. The rectal manometry performed simultaneously with defecography provides useful information of the visible defecation combined with the corresponding pressure profile.

5. Conclusions

Piezoresistive sensor elements mounted on LTC ceramics are suitable for medical applications, particularly, if a small assembly is required. The constructed probe enables one to record dynamic colorectal pressure profiles. Further studies are needed to evaluate the probe with a larger sample of test persons.

6. References


