Translating Fecobionics Into a Technique That Addresses Clinical Needs for Objective Perineal Descent Measurements

Z. Zhuang, MEng[1], H.Y. Hung, MD, PhD[2], S.C. Chen, MD[1], K. Futaba, MD, PhD[1] and H. Gregersen, MD, PhD[1]

INTRODUCTION: **Perineal descent is a phenomenon associated with anorectal dysfunction. It is diagnosed by defecography but subjected to manual measurements on the images/videos and interobserver bias. Fecobionics is a simulated feces for assessing important physiological parameters during defecation. Here, we translate Fecobionics into a new method for estimation of perineal descent based on electronic signals from the embedded inertial measurement units (IMUs).**

METHODS: **A displacement measurement method by a combined zero-velocity update and gravity compensation algorithm from IMUs was developed. The method was verified in a robot model, which mimicked perineal descent motion.**

RESULTS: **The method correlated well with the reference ($R^2 = 0.9789$) and had a deviation from the peak displacement (range 0.25–2.5 cm) of -0.04 ± 0.498 cm. The method was further validated in 5 human experiments with comparison to the benchmark defecography technology ($R^2 = 0.79$).**

DISCUSSION: **The proposed technology is objective, i.e., electronic measurements rather than by fluoroscopy or MRI. The development may impact clinical practice by providing a resource-saving and objective technology for diagnosing perineal descent in the many patients suffering from anorectal disorders. The technology may also be used in colon experiments with Fecobionics and for other gastrointestinal devices containing IMUs such as ingestible capsules like the Smartpill.**

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INTRODUCTION

Anorectal disorders and symptoms related to impaired defecatory function are very common (1,2). Anorectal disorders and symptoms may be associated with excessive perineal descent (also termed increased perineal descent or descending perineum syndrome). This is typically described as ballooning of the perineum several centimeters below the bony outlet of the pelvis during straining. Excessive and repetitive straining is believed to be one of the main causes of perineal descent. Other possible causes are weakness of the pelvic floor muscles caused by either neuropathic degeneration of muscle that accompanies old age, trauma to the pelvic floor muscles or their nerve supply during pregnancy and childbirth, or connective tissue disorders (3–7). Perineal descent is a common condition. Because it is often associated with fecal incontinence and obstructed defecation (8,9), it is important to have an objective, valid, and easy-to-use test not based on radiation.

A variety of technologies including manometry have been used in the gastrointestinal tract to evaluate function and mechanisms that lead to dysfunction (10,11). For example, anorectal (defecatory) function is commonly tested using pressure measurements and imaging technology including endoanal ultrasonography and defecography. The latter is the benchmark clinical technology for assessment of perineal descent, but it suffers from subjective measurements and interobserver variation (12–15). A variety of physiological tests and diagnostic procedures such as anal squeezes and straining are conducted during the testing. Because discrepancy exists between anorectal tests and the diagnostic accuracy of some tests is low (16,17), we developed a simulated stool named Fecobionics that combines anorectal manometry with the balloon expulsion test (18–20). Fecobionics has pressure sensors and contain inertial measurement units (IMUs) for measurement of orientation (Figure 1). The 2 IMUs in Fecobionics are used for computing the bending of Fecobionics. Hereby, it can assess the anorectal angle during defecation.

The availability of lightweight microelectromechanical system sensors has enabled the use of IMUs to determine physiological

[1]Department of Surgery, the Chinese University of Hong Kong, Shatin, Hong Kong; [2]Department of Imaging and Interventional Radiology, the Chinese University of Hong Kong, Shatin, Hong Kong. **Correspondence:** H. Gregersen, MD, PhD. E-mail: hag@giome.org.
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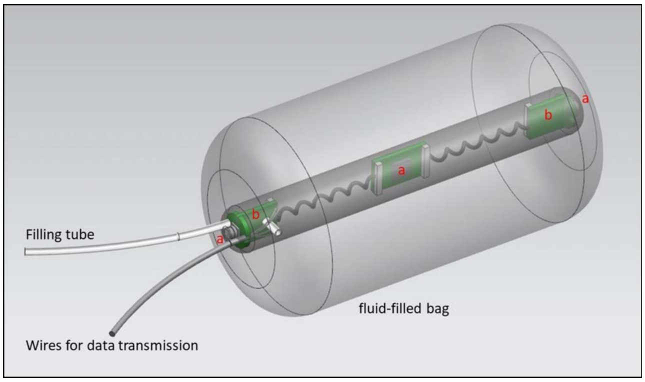

Figure 1. Sketch of the Fecobionics device for assessment of anorectal physiology. Fecobionics contained pressure sensors at the front, rear, and inside the bag (**a**) and 2 inertial measurement units (IMUs) (**b**) at the front and rear. In previous studies, the IMUs were used for computing the bending of Fecobionics. In this study, the front IMU is used for assessing perineal descent.

parameters. For example, displacement and deformation using imaging technology or gyroscopes and accelerometers were used for fall detection and gait analysis (21) and monitoring cardiac motions to detect myocardial dysfunction (22). IMU is a fused accelerometer and gyroscope. Low-cost microelectromechanical system IMU has demonstrated the potential in measuring displacement in inertial tracking systems (23). IMUs are also embedded in some ingestible capsules such as the Smartpill.

IMUs are prone to drift. Direct numerical double integration of acceleration leads to drift because of accumulation of errors. The colored noise in accelerometer readings causes a drift quadratically while the white noise causes drift proportionally to $t^{1.5}$ (24). In a study of accelerometer sampling at 300 Hz, the root mean squared error in displacement was 0.8 cm in a 1.68-s test (24). Zero-velocity update (ZUPT) is a solution to reduce drift of displacement caused by double integration. By setting the acceleration and velocity during stationary conditions (no movement) to zero, the drift can be reduced. The acceleration measured by accelerometers consists of both linear acceleration and gravitational acceleration. To measure displacement, linear acceleration must be separated from gravitational acceleration. In other words, the gravitational acceleration must be compensated. In this article, we present an algorithm combining ZUPT and gravity compensation, which can reduce the error caused by integration and enable displacement measurements in a motion with rotation.

The aim of this study was to develop the framework for computation of displacement during anorectal procedures and perineal descent using the IMU in the novel Fecobionics device. We provide validated data from bench experiments as well as human data from maneuvers such as push, anal squeeze, and defecation of Fecobionics. The translational impact is to obtain an objective electronic measurement of abnormal displacements and perineal descent.

MATERIALS AND METHODS

Zero-velocity update

The ZUPT method reduces the drift caused by integration when the IMU is stationary. We implemented ZUPT by the generalized likelihood ratio test. GLRT tests the hypothesis that the IMU is stationary based on the sum of kinetic energy generated by angular velocity and linear acceleration without gravity. If the likelihood falls below the threshold γ, the algorithm decides that the IMU is stationary; otherwise, the IMU is moving (25). It is defined as:

$$T_k(a,\omega) = \frac{1}{N}\sum_{n=k}^{k+N-1}\left(\frac{1}{\sigma_a^2} a_n - g\frac{\bar{a}}{\bar{a}}^2 + \frac{1}{\sigma_\omega^2}\omega_n^2\right) \le \gamma \qquad (1),$$

where $\boldsymbol{a}$ is the acceleration vector($\boldsymbol{a}\in\mathbb{R}^3$), ω is angular velocity vector($\omega\in\mathbb{R}^3$), σ_a , $\sigma_\omega$is the standard deviation of acceleration and angular velocity in a window of N, $\bar{a}$ is the mean acceleration, and g is the magnitude of gravitational acceleration.

Gravity compensation

The gravity compensation method by gyroscopes (GYRc) was proposed to determine the displacement in movements with rotation (22). The general principle of gravity compensation is to transfer the alignment of the gravitational acceleration vector to the sensor frame by the angular velocity acquired by gyroscope. This can be calculated as:

$$g_t = q_t g_0 q_t^{-1} \qquad (2),$$

where $\boldsymbol{q_t}$ is the rotational quaternion that are updated by the angular velocity and $\boldsymbol{g_0}$ is the initial gravitational vector. After the alignment is transferred, the actual linear acceleration of the sensor is calculated by subtracting the gravitational vector from the net acceleration by the following formula:

$$a_{linear} = a_{net} - g_t \qquad (3),$$

where $\boldsymbol{a_{linear}}$ is the actual linear acceleration. $\boldsymbol{a_{net}}$ is the net acceleration with gravitational and linear acceleration component. $\boldsymbol{g_t}$ is the gravitational vector aligned with the sensor frame.

We introduced a combined GLRT and GYRc algorithm to measure displacement. First, the GLRT method provides acceleration with zero-velocity update. Next, the GYRc method provides the update of gravitational acceleration aligned with the sensor frame. After subtracting $\boldsymbol{g_t}$, actual linear acceleration $\boldsymbol{a_{linear}}$ was obtained. $\boldsymbol{a_{linear}}$ was integrated to obtain velocity and double integrated to obtain displacement.

Robot model experiments

To evaluate the displacement determination algorithm, a robot system was constructed. To mimic the conditions *in vivo*, the robot system performed linear and rotational movements. A 10-cm long linear ball screw slide (Manmeirui, GGP 1610, Yancheng, China) with a precision of ±0.05 mm was used. The speed of the slider was controlled by the 57*56 step motor. To control the sensor to move smoothly, the step motor accelerated and decelerated with constant acceleration and deceleration. A metal gear servo (Tower Pro, MG90S, Shenzhen, China) was fixed on the slider that controlled the rotational movement. The MPU 6050 6-axis IMU sensor (Invensense, San Jose, CA) was fastened to the servo as shown in Figure 2.

Human experiments

The algorithm was applied to data obtained previously using the Fecobionics device. The subject made push procedures, i.e., attempting to defecate Fecobionics by increasing the abdominal pressure instantly. Finally, a study was performed on a normal human subject and 4 patients with chronic constipation (3F/2 M ranged 26–75 years) where push procedures were performed during simultaneous Fecobionics measurement and

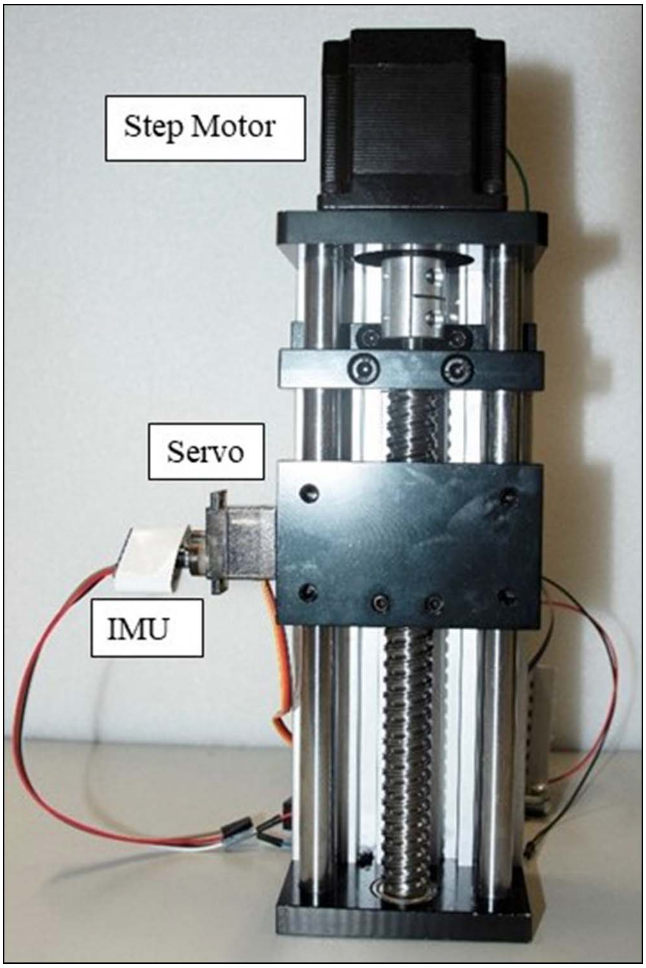

Figure 2. Photograph showing the robot system. It consisted of a step motor, a slider, a servo, and the inertial measurement unit sensor being tested.

defecography for validation. A small amount of contrast fluid was injected into rectum before inserting Fecobionics for improved radiographic visualization. Anal squeezes and defecation of Fecobionics were also performed. The sampling rate was 30 Hz in the Fecobionics experiments. The normal subject had no defecatory symptoms and fecal incontinence severity index and Wexner constipation scoring system scores within the normal range. The 4 constipated subjects had constipation scoring system scores between 12 and 21. One patient had constipation symptoms for 18 months, whereas the others had symptoms for 6–20 years. Constipation symptoms were described as stable. All patients used laxatives on a regular basis (agiolax, lactulose, or both) without much relief of symptoms. Two of the subjects had balloon expulsion technology studies performed during the past 2 years and were not able to expel the balloon.

Statistical analysis

Statistical analysis was performed by MATLAB R2019 (Mathworks, Natick, MA). Most data were normal-distributed as verified by the Kolmogorov-Smirnov test. The correlation between the reference and measured displacement was analyzed by linear regression. The goodness of fit was evaluated by the coefficient of determination, $R^2 \in [0, 1]$. In addition, Bland-Altman analysis was performed to investigate how well the predicted displacement agreed with the reference (26). *P* values were obtained from the Student *t* test. $P < 0.05$ was considered statistically significant.

RESULTS

Results from the robot model experiments

In the robot experiment, the IMU was moved upward and downward in the range of 0.25 to 2.5 cm with 0.25-cm increments. The servo was programmed to rotate 30 degrees and simultaneously move vertically with an acceleration of 1 m/s^2. For each displacement, the experiment was repeated 20 times (n = 200). The IMU sampling rate was 155 Hz. Data were collected and analyzed by the proposed combined GLRT and GYRc method. The reference displacement was labeled by the programmable speed of the step motor, and the computed displacement was compared with the reference. Figure 3 shows an example of acceleration, velocity, and displacement profile where the sensor was moved 2 cm downward followed by 2 cm upward after 2 s. Each motion was performed in 0.4 s. The left panel of Figure 3 shows the unfiltered acceleration, whereas the right panel shows the filtered signal with moving average with a window size of 5. Although the acceleration was noisy, the integrator acted as a low pass filter (27). Therefore, the velocity and displacement tracings were much smoother as shown in the upper panel of Figure 3. Hence, filtering the acceleration data was not necessary. In the example shown in Figure 3, the computed displacement fitted the reference well, i.e., the deviation of the peak displacement from reference was 0.05 cm.

The displacement in the robot experiment was analyzed by linear regression. Figure 4 shows the linear regression between the mean of computed displacement and the reference. The mean of computed displacement and reference displacement showed very good correlation with slope 1.01 ($P < 0.001$) and R^2 of 0.9789. The error was quantified as the root mean squared error (RMSE). A systematic increasing RMSE was found between the computed and reference displacement when the displacement was increased. The agreement between measured and real values was also studied using Bland-Altman analysis. The bias was close to zero, and SD was below 0.5 cm. During 200 displacement tests in the range of 0.25 to 2.5 cm, the average deviation between the computed displacement to the reference was -0.04 ± 0.498 cm.

Results from *in vivo* experiments

Human experiments were conducted using the Fecobionics device. Data were obtained from the front IMU (closest to the anus) and 3 pressure sensors. The subject was instructed to do push procedures and anal squeezes several times, and the displacement was computed by the proposed method. Figure 5 shows an example of displacement analysis during 1 push and 1 anal squeeze. The displacement was computed to be -1.6 cm in the push and 0.9 cm in the anal squeeze, which is in the physiological range. Negative values indicate the downward direction, and positive values indicate upward direction.

The final validation experiment was performed in the 5 human subjects with simultaneous defecography and Fecobionics. Several push procedures and anal squeezes were performed in each subject with empty or filled Fecobionics bag before the subject was asked to defecate Fecobionics. The normal subject felt urge at 60-mL bag volume, whereas all patients reached the 80 mL maximum before feeling urge, indicating hyposensitivity. One patient could not expel the Fecobionics probe within the 2-

MOTILITY

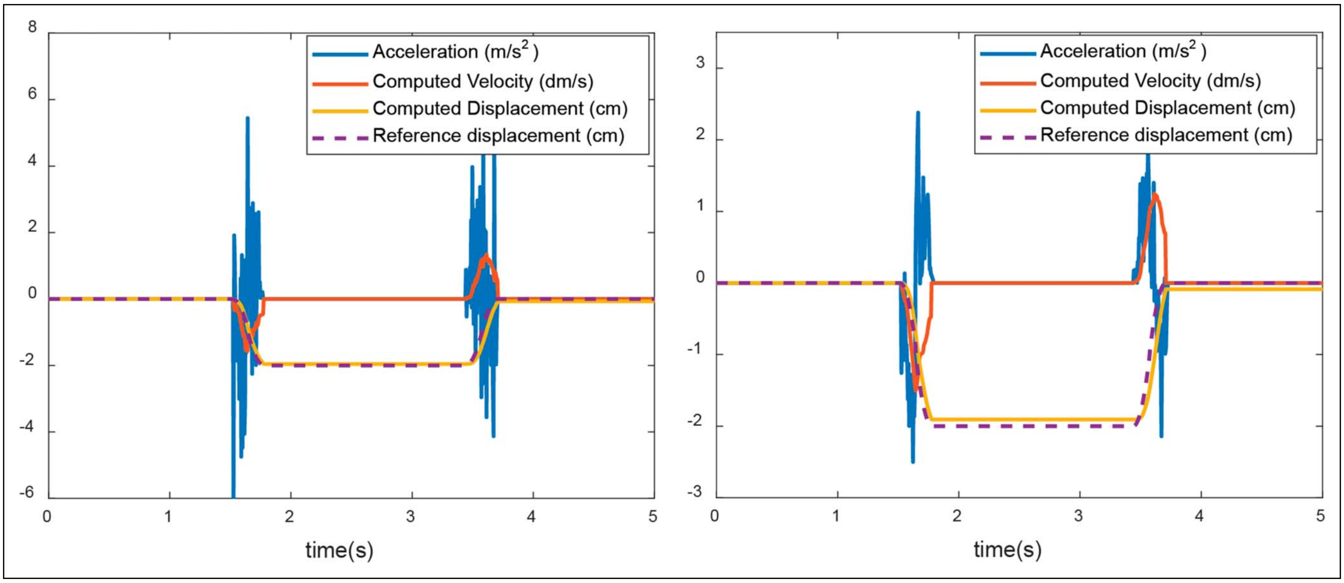

Figure 3. Representative velocity and displacement analysis in the bench test. The colored tracings are explained in the figure. Left: unfiltered acceleration. Right: acceleration filtered with moving average with window size of 5.

minute limit, whereas 2 subjects unintentionally expelled it during the push procedures. The normal subject showed more displacement than the patients for anal squeezes and push procedures. Figure 6 shows defecographic images before and during push and anal squeeze and comparative data. Good agreement was found between distances measured with IMU and defecography. The slope was 0.83 ($P < 0.001$). R^2 was 0.79. If defecations were included in the analysis, the agreement was even better ($R^2 = 0.89$). The Bland-Altman plot showed minimal bias that clearly was within the confidence interval.

DISCUSSION

In this study, algorithms were developed for computation of displacement using IMUs embedded in a Fecobionics device for anorectal testing. Through several iterations, we were able to obtain acceptable measurements that fitted well to reference values. The algorithms were applied to previously obtained Fecobionics data that showed displacement data in the expected range (13–15,28). The final validation experiments in human subjects with simultaneous defecography and Fecobionics demonstrated agreement between the 2 methods.

Clinical aspects

Fecobionics is a novel anorectal function test that provides measurements of pressures, bending angle (anorectal angle) and geometric profiles (18–20). It has proven useful for assessment of anorectal physiology. In addition to pressure

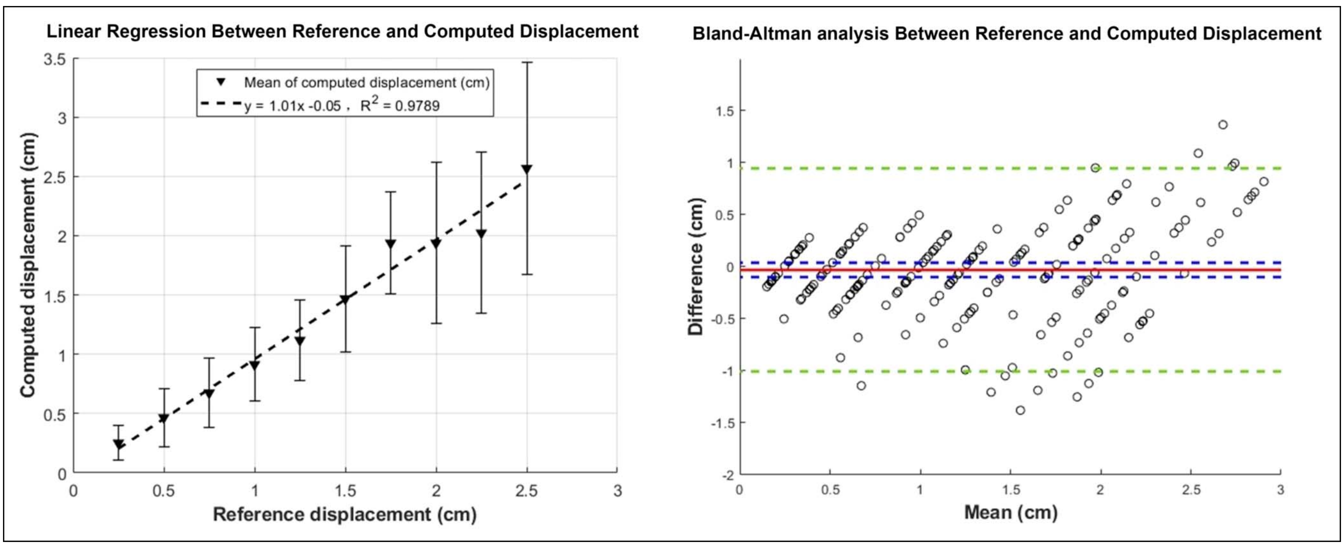

Figure 4. Left: linear regression analysis for robot experiments. Triangles are the average of computed displacement. The error bars show the SD. Right: Bland-Altman analysis. The red line is the average. The blue and green lines illustrate the confidence intervals and ±1.96 SD of the difference.

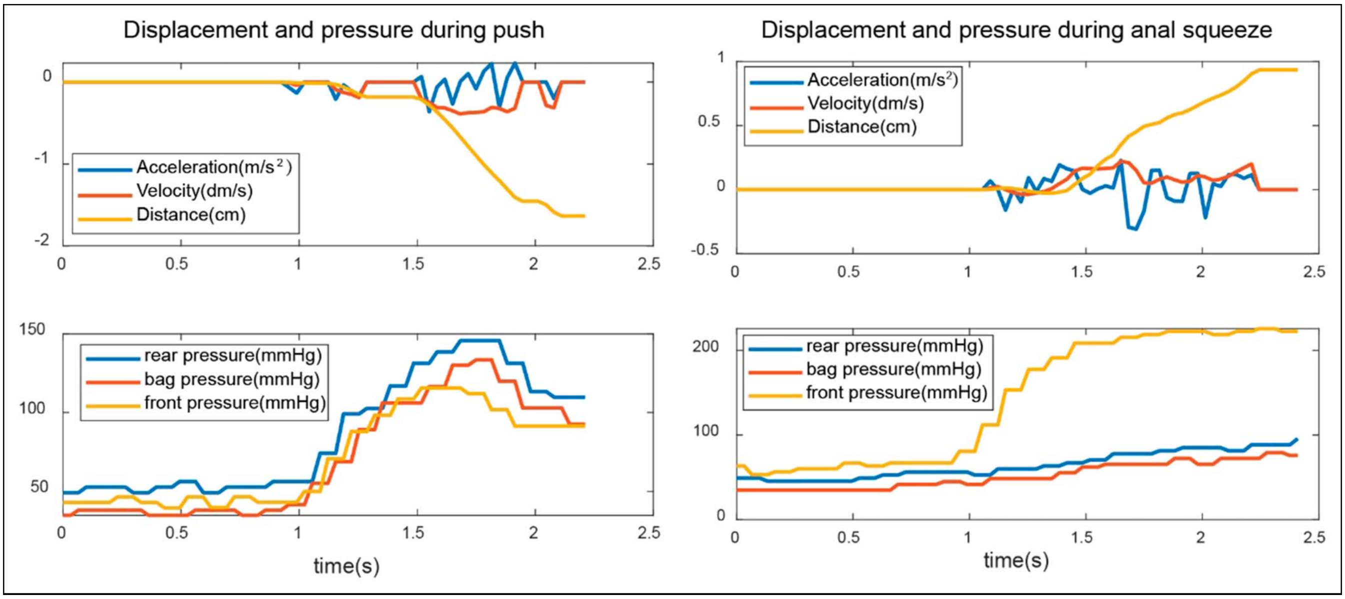

Figure 5. Velocity and displacement analysis for the *in vivo* experiment. Left: representative of displacement and pressure profile during a push. Right: representative of displacement and pressure profile during a squeeze. The colored tracings are explained in the figure.

measurements in the direction of the trajectory, it also provides an electronically measured anorectal angle. Fecobionics has been validated in bench testing (19) and used in normal human subjects and patients (18–20,29–31). In this study, we pursued additional use of the IMU data for analysis of acceleration, velocity, and displacement of movements. The specific aim was to develop an electronic test of displacement including perineal descent that occur during push and straining. However, it will not be able to detect rectal prolapse or stationary descent (1,2,12).

Perineal descent is typically described as ballooning of the perineum several centimeters below the bony outlet of the pelvis during strain. Descent can also occur at rest. Excessive and repetitive straining is believed to be 1 of the main causes. This straining forces the anterior rectal wall to protrude into the anal canal and creates a sensation of incomplete defecation and weakness of the pelvic floor musculature. Other possible causes reported are weakness of the muscles of the pelvic floor caused by either neuropathic degeneration of muscle that accompanies old age (3–5), trauma to the pelvic floor muscles, or to their nerve supply during pregnancy and childbirth or connective tissue disease (4,6,7). Abnormal movements and perineal descent have been described in relation to anorectal disorders including constipation and fecal incontinence. Perineal descent is a common condition associated with fecal incontinence and obstructed defecation (8,9). Because it is associated with anorectal symptoms, it is important to have a valid easy-to-use test without radiation involved. In this study we demonstrated that the new technology is comparable with the benchmark clinical standard defecography. The big advantage of Fecobionics is that the IMUs provide an objective measurement of displacement including perineal descent, whereas defecography suffers from manual measurements on images and interobserver variation. Furthermore, in versions of Fecobionics that also measures cross-sectional areas and shape (18), rectal and anal diameters can be assessed. These have also be found to be comparable with diameters measured by defecography.

Methodological aspects

In this article, we used GLRT as the ZUPT method. Several ZUPT methods have been proposed before, including decision tree filtering method, Hidden Markov Model, and GLRT (32–34). Decision tree filtering method requires routine calibration of acceleration (32). Hidden Markov Model uses only the gyroscope for determine the movement and cannot determine a motion with no rotation (33). Therefore, these methods are not suitable for evaluation of displacement during defecatory testing, which is a dynamic process with small rotation. Good results have been reported for applying GLRT in foot-mounted systems (34). A limitation of GLRT algorithms is their threshold-based activation behavior, which is sensitive to motion type. The detection may fail if the user changes its motion type or intensity. Adaptive threshold methods by support vector machine classifier (35) have been proposed to detect multiple motion types. An adaptive threshold method could further reduce the estimation errors.

The current displacement estimation error comes from 2 sources: modeling error and measurement error. The modeling error can be reduced by choosing better models (e.g., ZUPT algorithm with a higher accuracy). The sensors themselves introduce the measurement error. This error depends on the gyro drift rate, frequency and magnitude of acceleration maneuvers, and accelerometer precision and accuracy (23). For the Gaussian white noise model proposed by Thong et al. (24), the RMSE of displacement was given by:

$$RMS(s(T)) = \frac{1}{2}\frac{\sigma_d}{\sqrt{f_s}}T^{1.5} \qquad (4),$$

where σ_d is the SD of noise of accelerometer, which is 400 $\mu g/\sqrt{Hz}$ from data sheet, f_s is the sampling frequency, and T

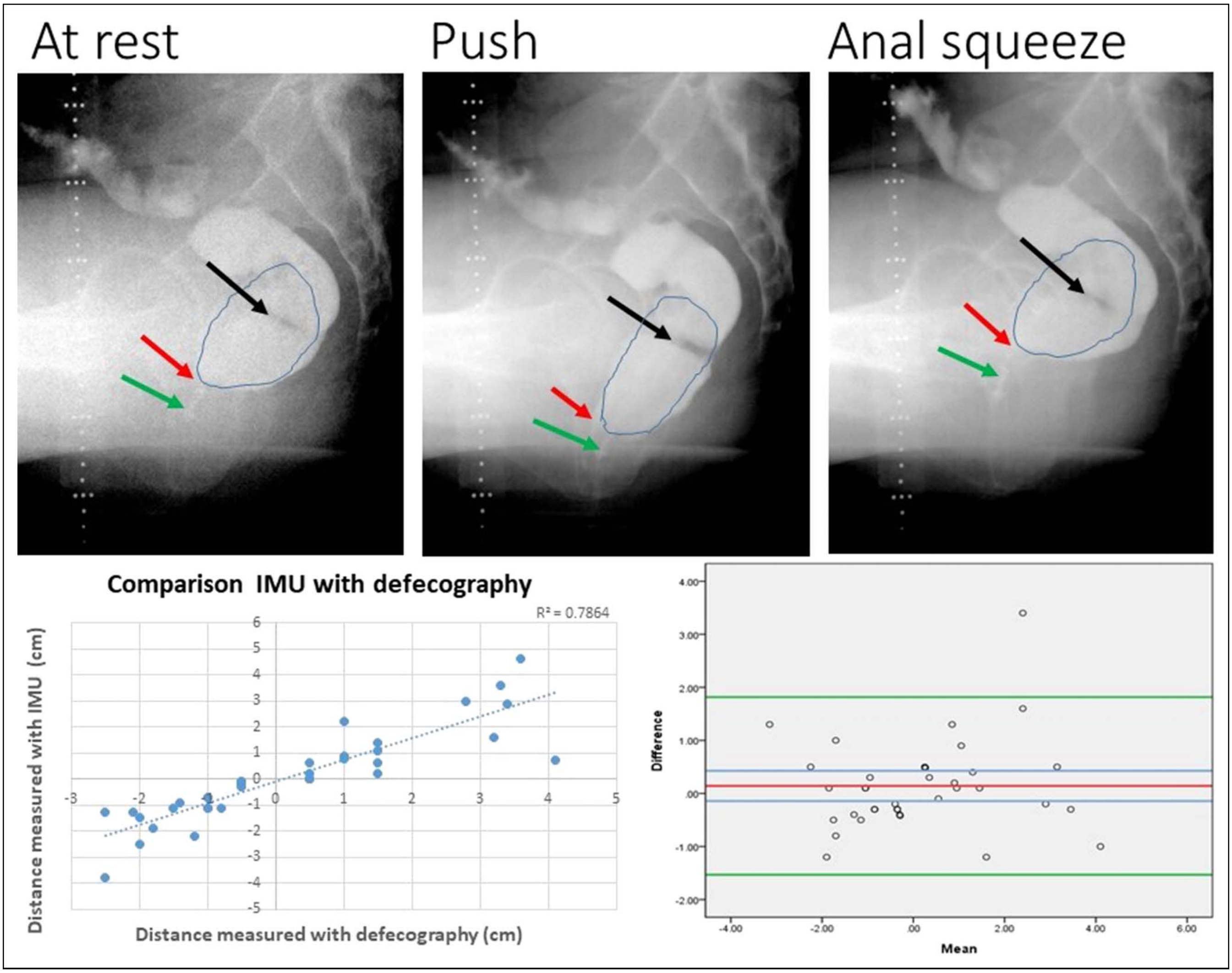

Figure 6. Top. Defecographic images of anorectum at rest and during push and anal squeeze procedures in the normal human subject. The red arrow marks the anorectal junction. The green arrow marks the front of Fecobionics. The black arrow marks the mucosal fold. The blue area indicates the location of the bag on Fecobionics. Bottom. Regression plot and Bland-Altman plot from multiple anal squeezes and push procedures in the 5 subjects. The negative values in the regression plot are the anal squeezes, whereas push procedures are positive values. In the Bland-Altman plot, the red line is the average. The blue and green lines illustrate the confidence intervals and ±1.96 SD of the difference. IMU, inertial measurement unit.

is the integration time. The error increase inversely with sampling rate and proportional to $T^{1.5}$. To verify the effect of sampling frequency and integration time on the error, we conducted robot experiment where the IMU was moved 2 cm up and down. Keeping the integration time constant, the RMSE was 0.55 cm at sampling frequency 155 Hz, whereas RMSE was 1.18 cm (increased by 115%) at sampling frequency 64 Hz. Keeping the sampling frequency constant, RMSE was 0.62 cm at integration time 0.4 s, whereas RMSE was 1.55 cm (increased by 150%) at integration time 0.8 s. Hence, high sampling frequency and short integration time is required to obtain an accurate estimation of displacement. The human experiments were performed at a considerable lower frequency. Therefore, results can be further improved by using better IMUs and higher data transmission rate.

Our results from the robot experiments showed the combined GLRT and GYRc method was able to accurately predict displacements ranging from 0.25 to 2.5 cm in a movement with rotation. It demonstrated the potential of measuring the displacement of perineal descent *in vivo*. However, we found the SD to be 0.498 cm in the computed displacement. This means multiple inspections are required to obtain a precise measurement of displacement. By using the mean displacement from multiple inspections, the error can be greatly reduced.

As expected, we showed agreement between defecography as the benchmark reference and the new IMU-based technology. However, the sampling frequency used in Fecobionics was merely 30 Hz. According to Eq. 4, the RMSE is inversely proportional to the square root of the sampling frequency. Therefore, the results could have been even better with a system based on higher frequency.

CONCLUSIONS

In this study, we provide bench test validation and found a high degree of agreement between defecography and IMU-based measurement of movements of the pelvic floor. With further improvement in technology including using better IMUs and higher sampling frequencies, the test may prove useful for addressing the critical medical need for objective evaluation of displacements during defecation and perineal descent. Another highly relevant translational impact is application of the technology to passage of Fecobionics in colon (36) or to ingestible capsules that contain IMUs.

CONFLICTS OF INTEREST

Guarantor of the article: Hans Gregersen, MD, PhD.
Specific author contributions: All authors participated in the experimental work, commented on the data, and read and approved the final manuscript. Analysis was performed by Z.Z., H.Y.H. and H.G.. Study design and planning were performed by Z.Z., H.G., and K.F. H.G. drafted the manuscript.
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Potential competing interests: H.G. invented the Fecobionics device and filed patent applications.

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Study Highlights

WHAT IS KNOWN

- ✓ Perineal descent is traditionally measured from defecographic images
- ✓ Defecography is subjected to interobserved bias

WHAT IS NEW HERE

- ✓ A method for electronic measurement of perineal descent using inertial measurement units was developed
- ✓ The technique was validated *in vitro*, and human experiments correlated well with defecographic assessment

TRANSLATIONAL IMPACT

- ✓ The development may impact clinical practice by providing an easy-to-use, resource-saving, and objective technology for diagnosing perineal descent in the many patients suffering from anorectal disorders.
- ✓ The technology may be used in devices placed in colon or ingestible capsules for evaluation of gastrointestinal physiology.

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