Development of an Active Palpation Sensor Wearable on a Finger for Detecting Prostate Cancer and Hypertrophy

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Abstract

This paper is a study on the development of an active palpation sensor wearable on a doctor's finger for detecting the prostatic cancer and hypertrophy. The receptor of the sensor is a polyvinylidene fluoride (PVDF) film placed on a rubber base. For convenience, the structure is made up of two parts, sensor and vibro-machine. The sensor is worn on a doctor's tip of a finger and the vibro-machine is attached to the root of the finger. The sensor output is collected in case that the sensor part contact with the target by driving the vibro-machine. Fundamental characteristics and the verification for diagnosis of the conditions of prostate glands are investigated in the laboratory tests and in clinical test. These results shows that the output of the present sensor varies with the stiffness of prostate glands and the sensor is effective in diagnosing the condition of prostate glands, and the present sensor have a good correlation between doctor's palpation.

1. Introduction

The prostate is a gland that is present only in men. Prostate cancer and hypertrophy are common diseases that affect about one third of men over 50. Especially in America, prostate cancer is the most frequently diagnosed cancer among men and the second leading cause of cancer deaths. Recently, with the westernization of life style, the disease rate has also increased rapidly in Japan.

Nowadays, three tests are used to detect prostate cancer and hypertrophy in the absence of any symptoms: transrectal ultrasonotomography, screening blood tests and digital rectal examination. Of the three methods, digital rectal examination is the easiest and mostly used one, because it is performed by just inserting a finger into patient's rectum to touch his prostate and examine its size and stiffness. However, it is not an objective method because the result of diagnosis is greatly influenced by the doctor's experience and skill. The situation has drawn interest in the development of objectiveinstrumentation that measures and evaluates the stiffness of flexible soft materials [1-3].

The output voltage via osicilloscope from the polyvinylidene fluoride (PVDF) piezopolymer film takes the form of a brief potential wave at the onset of the pressure pulse and a similar brief wave at the termination, but there is no response during the stationary plateau of the applied pressure, the time variation of which is very similar to the response of the Pacinian corpuscle that is a sensory receptor in the dermis and particularly functional to the touch vibration of 250-300 Hz [4].

Recently, Tanaka *et al* proposed a palpation sensor as a substitute of a doctor's finger for digital rectal examination by PVDF film [5]. The measurements on the stiffness of sample prostate glands were compared with the diagnosis by a doctor's palpation, which confirmed that the active sensor well discriminates the stiffness and the various physiological states of prostate glands on the clinical test, non-invasively. Further, the optimum stiffness of the sensor base and driving frequency are investigated by FEM analysis and experiment [6]. However, in a clinical test a good contact between sensor and prostate cannot be guaranteed without help of ultrasonotomography because it is stick-shaped.

With this situation in mind, this paper is a study on the development of an active palpation sensor that is wearable on a doctor's finger for detecting prostate cancer and hypertrophy. A sensor, which receptor is a PVDF film assembled. For convenience, the structure is made up of two parts: sensor and vibro-machine. The sensor is worn on a doctor's finger tip and a vibro-machine is fixed at his finger root. The sensor is pressed against an object, such as a prostate gland and driven sinusoidally with a constant amplitude vibration. With this structure, the doctor can move his finger freely. The voltage signal from the PVDF film is integrated over the sampling period and is used as the output of the sensor for evaluating the stiffness of prostate gland. By using the present sensor, the laboratory tests were performed to investigate the functional characteristics. At last, clinical test was carried out in order to verify the sensor system. The results showed that the output of the sensor varies with the stiffness of prostate glands and the sensor is effective in diagnosing the condition of prostate glands.

2. Stick-shaped Active Palpation Sensor

At first, the stick-shaped active palpation sensor [5] is introduced. Figure 1 shows the sensor part of stick-shaped active palpation sensor. The tip probe is mounted onto a linear z-translation aluminum bar. It is fit into a cylindrical outer aluminum shell and driven by a micro-motor and crank mechanism. The mechanism of driving is essentially the same as that of an electric toothbrush.

The probe is positioned to the face to the prostate gland and oscillated at about 50Hz with constant peak-to-peak amplitude of 2mm. The probe is an assembly of layered media. The base is a thin circular aluminum plate with a diameter of 12mm, onto which a cylindrical sponge rubber of diameter 12mm, onto which a cylindrical sponge rubber, of diameter 12mm and thickness 4mm: a PVDF piezopolymer film of 6mm across and 28 μ m thick as the sensory receptor; and a thin acetate film, as the protective agent of piezopolymer film, are stacked in sequence. Furthermore, a convex sheet of vulcanized rubber of 3mm across was placed on the surface of the acetate film to enhance the sensitivity of sensor. The sensor head is pressed sinusoidally against the object and the output signal from the piezopolymer film is collected and sent to a digital storage oscilloscope. It is then further forwarded to a personal computer for data processing. The output voltage from the PVDF is proportional to the rate of the strain induced in the film, which means that the maximum amplitude of the signal from the sensor is rather superposed by noises from the measuring system

With this fact in mind, the following data analysis was performed using absolute output signal of the sensor integrated over the period of data collection, i.e.

$$I = \sum_{n=1}^{N} |V(n)|, \quad (1)$$

Here, I is the integrated output signal and N is the total number of data points collected for the term of measurement 100 ms.

A clinical test was conducted using the sensor. The subjects were 8 in total. One person was suffering from the carcinoma, four persons were patients with prostatic hypertrophy and two persons were suffering from prostatitis. The last person was diagnosed as having no definite lesions on his prostate gland. The stiffness of the prostate glands diagnosed this time was ‘elastic soft or elastic firm’, ‘definitely elastic firm’, or ‘hard’. The results obtained are presented in Fig. 2. The output on the prostate gland of diagnosis ‘hard’ is greater than the output of the gland of ‘ elastic firm’. However, a good contact between sensor and prostate cannot be guaranteed without help of ultrasonotomography because it is stick-shaped.

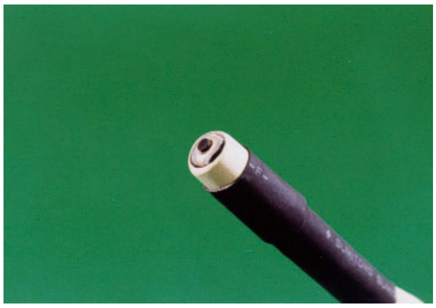

Fig. 1. Sensor part of stick-shaped active palpation sensor.

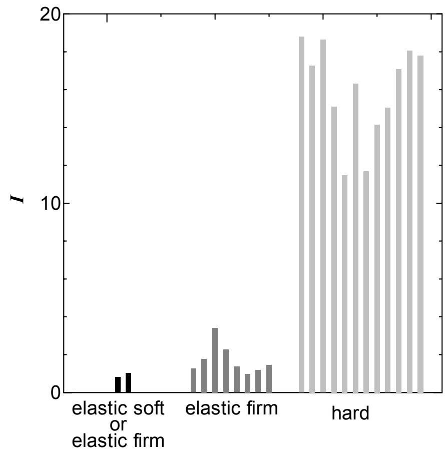

Fig. 2. The output of sensor on prostate glands of different firmness.

3. Wearable Sensor

In chapter 2, it is confirmed that the structure of the sensor and sensor system which is including the signal processing are effective to distinguish the stiffness of the prostate. Therefore the sensor wearable on a finger is assembled based on the sticked-shape sensor. This sensor enabled a doctor to examine the prostate with understanding the contact with it. However, the output from PVDF depends on the magnitude of contact force to the object. Therefore the mechanism for compensation of the contact force is necessary.

The geometry of sensor is presented in Fig. 3. A semiconductor strain gauge (KYOWA KSN-2-120-E4-16) that is used to detect the force is attached to a aluminum base (14mm×11mm×1mm). A layer of vulcanized rubber is placed on the metal base, and the PVDF film is placed on the rubber layer. Further, a small protrusion made of a vulcanized rubber with a diameter 3mm and thickness 3mm is fixed on the PVDF film in order to get better sensitivity. The vulcanized rubber (14mm×11mm×3mm) was used for the base material. Because it has been confirmed that the base material, which is the same hardness of cancer, is suitable to discriminate the prostatic hypertrophy and cancer, from the result obtained from FEM analysis.

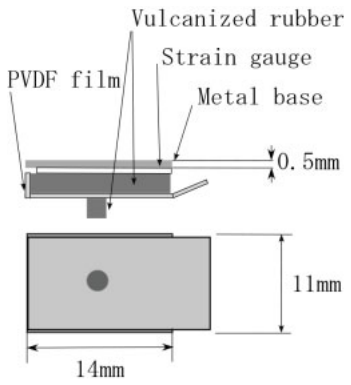

Fig. 3. Structure of the sensor

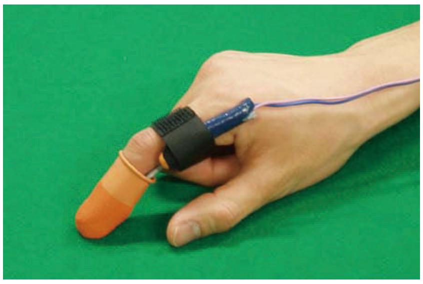

Fig. 4. Sensor and Vibro-motor

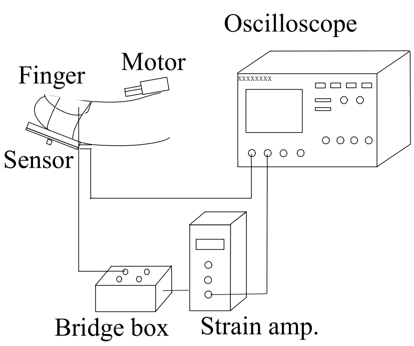

Fig. 5. Measurement system

According to the doctor's experience, it is easy to measure the object using the fingertip. Therefore the position of small protrusion of the sensor, which contacts with the object, is adjusted in order to locate on the fingertip. This sensor section is set in a finger stall in order to take stable contact between a user's finger and the sensor.

For convenience, the structure is made up of two parts: sensor and vibro-machine. The sensor is worn on a doctor's fingertip and a vibro-machine is fixed at his finger root. The miniature vibration motor (SICOH ϕ 4mm CORELESS MOTOR SE-4F) is used for the vibro-machine. With this structure, the doctor can move his finger freely. The sensor is pressed against the prostate gland and driven sinusoidally with a constant amplitude vibration by vibro-machine.

4. Measurement System and Signal Processing

Figure 5 illustrates the instrumentation for the measurement. The sensor part is pressed sinusoidally against the object by vibro-machine, and the charge in PVDF film is induced. The charge is collected via Digital oscilloscope (YOKOGAWA DL-1740). At the same time, the output from strain gauge is through bridge box (KYOWA DB-120P) and strain amplifier (MINEBEA DAS-406B), and is stored in the oscilloscope. The variable resistance of 50 kΩ is connected to the bridge box in order to reduce the offset. The measurement was performed for 100msec with sampling frequency of 100kHz. The outputs are then further forwarded to a personal computer for signal processing. The measurement was done by a gloved finger with the sensor and vibro-machine.

The output voltage from the piezopolymer film is proportional to the rate of the strain induced in the film, which means the maximum amplitude of the signal from the sensor is rather superposed by noises from the measuring system. With this fact in mind, the following data analysis was performed using the absolute output signal of the sensor integrated over the period of data collection, i.e.

$$I = \frac{1}{N}\sum_{n=1}^{N}\left|V(n)\right|, \quad N=10000 \qquad (2)$$

Here, $V(n)$ is the n-th quantified voltage value and I means the calculated average to the sampling number. Further, μ and σ shows the average and standard deviation of I to measurement times, respectively.

At the same time, in order to compensate the contact force to the object, the output from strain gauge is collected and evaluated. In this study, the value was set to the zero immediately before the sensor contact with the object, and after then the value was measured.

The relation between the strain gauge's output and contact force were investigated. The contact forces were set at 0.0196, 0.049, 0.098, 0.196, 0.49, 0.98, and 0.147N. The measurement was repeated ten times under each individual contact force. The output of strain gauge V_s is plotted in Fig. 6, with the contact force F taken as a parameter. In the figure, the vertical bars represent the variation of the ten data points collected, and the dots on the bars represent the averages. The full line is the least-square regression line for the ten distributed dots. From this relation, the strain output V_s [V] is transformed from the contact F(N) appropriately.

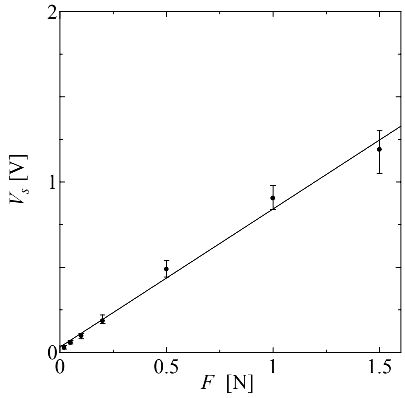

Fig. 6. The strain gauge output Vs against the contact force F .

Then the average force $\bar{F}[N]$ to the sampling time calculated from the following equation is used for the evaluation of the contact force.

$$\bar{F} = \frac{1}{N}\sum_{n=1}^{N}\left|F(n)\right| \;, \quad N=10000 \qquad (3)$$

Here, F (n) is the transformed value from n-th quantitized digital signal of strain gauge output $Vs(n)$ by the relation of Fig. 6.

5. Variation of Output Depending on the Contact Force

The fundamental characteristics of sensor were studied in the Lab. test. The rubber prostate models of training kit for the palpation were used as the measurement object. The states of the prostate model correspond to the normal healthy, prostatic hypertrophy, and prostatic cancer. Using the present sensor, palpation models of the prostates are measured.

The sensor outputs from PVDF on the each object were investigated in case that the contact force changes, in order to investigate the influence of the contact force for the evaluation of the stiffness and state.

The outputs of strain gauge amplifier were watched and the contact forces were adjusted. The contact forces were set 16 steps from 0.0 to 2.0N. The measurement was repeated ten times on the each object under each individual contact force level.

The relation between the average value μ of PVDf film and contact force $\bar{F}$ is shown in the Fig. 7. It is seen that the discrimination on the condition of normal, hypertrophy, and cancer can be done at the range of contact force from 0.2 to 0.8 N. Especially, at 0.5 N, the difference of the PVDF output of each condition takes the maximum, i.e. the contact force 0.5N is the optimum value. It is observed that there is no difference between the normal and hypertrophy when the contact force is not greater than 0.1N and the force is greater than 1.2N, i.e. it is difficult to evaluate the prostate conditions accurately.

These results mean that the discrimination of prostatic conditions is in dependent on the sensor user while contact force is controlled from 0.2 to 0.8N.

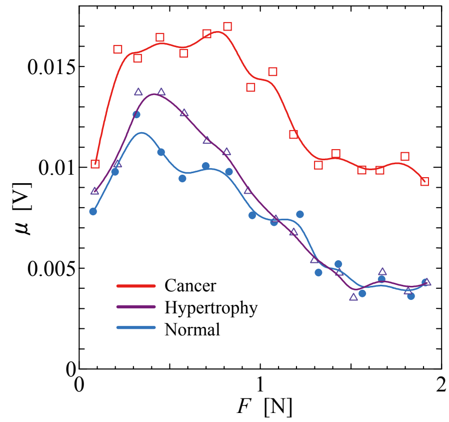

Fig. 7. The average μ of the sensor output on prostate models against contact force F.

6. Laboratory Test

The fundamental characteristics of sensor were studied first by fabricating six samples objects with different stiffness and measuring the variation of the sensor output with increased object stiffness. The sample objects are rubber blocks of 60mm×80mm×20mm, and fabricated with silicone rubber. Young's modulus of the rubbers is shown in Table 1. From the judgment of an urologist, the hardness of rubber D and rubber C correspond to that of the normal prostate and prostatic hypertrophy.

The finger tip with the sensor was applied to the rubber block and the vibro-machine was driven to obtain the output from the PVDF film. The contact force was kept almost 0.5N and the measurement was repeated ten times on each individual object.

Examples of sensor output are shown in Fig.8. It is observed that the output is harmonic and time variation is steady. It is shown that the amplitude of sensor output becomes larger as the sample target becomes harder.

The calculated value is shown in table 2. It is seen that the output becomes greater with the increase of the Young's modulus. The correlation |R| between sensor output and young's modulus was 0.9, and the relation is very sufficient. These results show that the wearable tactile palpation sensor evaluates the stiffness of the soft material accurately.

Table 1. Young's modulus of silicon blocks.

Silicon rubber	A	B	C	D	E	F
Young's modulus [$\times 10^5$ N/m^2]	7.58	5.61	2.84	1.43	0.84	0.45

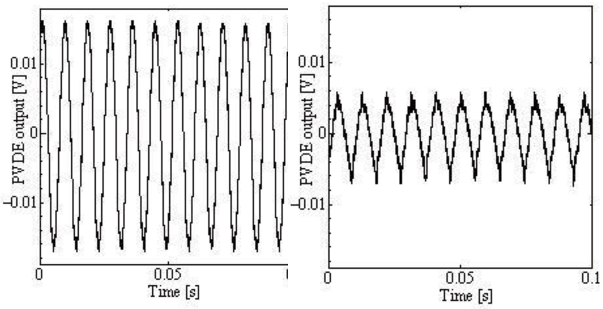

Fig. 8. The Sensor output on silicon blocks (A)(left) and (F)(right).

Table 2. Average μ, maximum I_{max} values and minimum I_{min} values and the standard deviation σ of the sensor output on silicon blocks

Silicon rubber	μ [mV]	I_{max} [mV]	I_{min} [mV]	σ [mV]
A	8.46	11.81	7.36	3.35
B	7.12	8.12	6.13	0.75
C	5.13	7.12	3.79	1.37
D	4.16	6.14	3.76	1.08
E	3.33	5.44	2.15	0.96
F	2.76	4.18	1.47	0.90

7. Variation of Output Depending on the Sensor User

A similar measurement was performed on the stiffness of the thenar of the thumb. According to the urologist's experience, the variations of the thenar from the opened to the closed state of hand are similar to the variations of prostate gland stiffness in various physiological situations. (X), (Y), and (Z) correspond to the state of the thenar on which the stiffness was diagnosed by a doctor as 'normal', 'prostatic hypertrophy' and 'prostatic cancer' , respectively. The measurement was performed ten times for each object.

Three sensor users (i-iii) measured on objects (X), (Y), and (Z). The measurement was done with the following two conditions. One condition is that the value of strain gauge was not checked and the measurement was carried out unconsciously without control of contact force. The other condition is that watching the value of strain gauge and controlling that the contact force were kept from 0.2-0.8 N by using the value.

Figure 9 shows the measurement result by three sensor users. It is seen that the every users can distinguish the each part, and especially, each difference of output between the part Y and Z is significant. And the result showed that the measurement is independent on the sensor user. Furthermore, the variation of the measurement output with control of the contact force became smaller than that without control of contact force. Especially, the difference of part Z is remarkable.

Thus, it is noted that the present sensor again discriminates the state of organs, regardless of the sensor user, and the sensitivity can be increased by controlling the contact force using the strain gauge output.

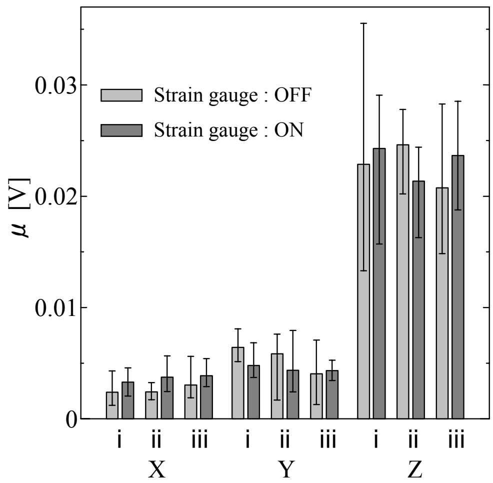

Fig. 9. The average of the sensor output on three parts of human hand（X,Y, and Z） measured by three sensor users（i, ii, and iii）.

8. Clinical Test

Finally, the sensor is testified clinically on prostate glands. Rectal palpation was carried out using the present sensor for the purpose of verifying the measurement of the stiffness and the diagnosing the condition of prostate glands. The clinical test was carried out by urologist with the present sensor. The total number of the subjects was 7 (A～G), with the age 58-79. The disease conditions are shown in table3.

The measurement on each part was carried out without ultrasonic tomography and looking for the disease part by the palpation mounted the sensor.

Table 3. Condition of prostatic glands of each subject

Subject	Condition of prostatic glands
A	Normal and healthy
B	Almost Normal and healthy
C	Between normal and prostatic hypertrophy
D	Under treatment of the prostatic cancer
E	Prostate stones in places
F	Prostate stones in places
G	Prostate stone

Table 4. Average Contact force F, average μ, maximum I_{max} values and minimum I_{min} values of the output data presented in Fig.10.

Patients	$\overline{F}$ [N]	μ [mV]	I_{max} [mV]	I_{min} [mV]
A	0.436	6.64	7.84	5.18
B	0.404	7.34	9.36	5.90
C	0.382	13.91	20.00	9.35
D	0.357	13.47	25.76	8.29
E	0.522	21.20	22.79	19.99
F	0.455	19.00	26.04	12.89
G	0.368	9.72	18.78	7.12

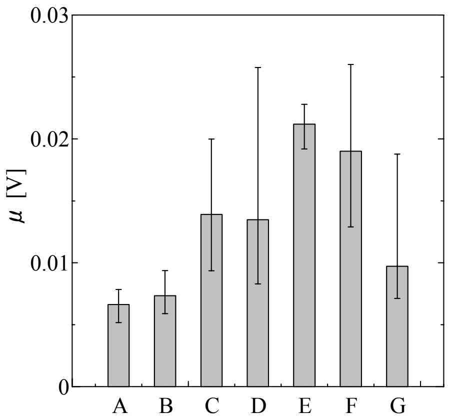

Fig. 10. Sensor output on prostate glands of subjects A-G.

Table 4 presents the average contact force from strain gauge, average , minimum and maximum output values from PVDF. Figure 10 shows the sensor output on each prostate gland.

It is seen that the outputs on subject A and B are much smaller the other's and the output of B is slightly larger than that of A. The difference corresponds to the difference of the disease A and B.

The sensor value on subject C is much larger than that of subject A and B. It means that the state of the prostate is closer to the hypertrophy. It is seen that the sensor output on subject D, who is under treatment of prostatic cancer, is closer to that of subject C. About the condition of subject D, the palpation result of the doctor without sensor could not distinguish the stiffness belongs to the prostatic cancer or hypertrophy. The result of the sensor output means the condition is closer to that of prostatic hypertrophy. The sensor output is effective to evaluate the disease conditions.

Subjects E and F have prostate stones in places, and the sensor output takes the maximum and much larger than the others'. Subject G has one prostate stone and it was difficult for the doctor to search for the part. Therefore the measurements were done many times and the fluctuation of the sensor output was large. From the doctor's diagnosis, the state of prostate except the stone part is prostate hypertrophy. Therefore the average value became the smaller than that of subject E and F. However, it is noticed the maximum value on subject G is large and the result means that it is unhealthy condition.

Further, the conditions of subjects were investigated using the ultrasound tomography. The enlarged prostate conditions of subject C and D were observed. The white marks, which correspond to the prostate stones, were observed in places on the prostate glands of subject E and C. However, the white mark could not be discovered on the prostate of subject G, by ultrasound tomography.

These results showed that the output of the present sensor varies with the stiffness of prostate glands and the present sensor output has a good correlation between doctor's palpation result. Further, it is said the sensor is effective in diagnosing the condition of prostate glands,.

9. Conclusion

An active palpation sensor wearable on a doctor's finger to guarantee good contact on the prostate for detecting the prostatic cancer and hypertrophy has been presented and its functions as a palpations have been studied in detail both in the laboratory tests and in the clinical trials. The obtained results are summarized as follows.

(1) The active palpation sensor wearable on a doctor's finger were assembled by using the polyvinylidene fluoride (PVDF) film and a strain gauge. For convenience, the structure is made up of two parts: sensor and vibro-machine. The sensor is pressed against the prostate gland and driven sinusoidally with a constant amplitude vibration. The sensor is worn on a doctor's finger tip and a vibro-machine is fixed at his finger root. With this structure, the doctor can move his finger freely.

(2) The results of fundamental characteristics of the sensor showed that the output strength of the sensor is strongly associated with the stiffness of

the object. Additionally, it is shown that the output of the sensor varies with the force to press the sensor against an object and begins to decrease when the force exceeds a certain value. The experiment performed by three people using the sensor showed that the result of measurement is independent on the sensor user.

(3) The sensor is testified clinically on prostate glands. The results showed that the output of the sensor varies with the stiffness of prostate glands and the sensor is effective in diagnosing the condition of prostate glands.

Acknowledgements

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