# A NOVEL 3D PRINTED SENSORIZED SURGICAL INSTRUMENT TO CHARACTERIZE PITUITARY ADENOMA: DEVELOPMENT AND INITIAL VALIDATION

Giacomo Santona, Mauro Serpelloni, Antonio Fiorentino, Francesco Doglietto

Abstract— The pituitary adenoma (PA) is a tumor that grows in the sellar region, near the pituitary gland. PAs are usually removed surgically by expert neurosurgeons and otolaryngologists through the nasal cavities, with the so-called endoscopic transsphenoidal approach. One of the most challenging complications is that the consistency of PAs remains unpredictable until the surgeon approaches it during the surgery, thus meaning that surgeons must choose intraoperatively the most suitable technique to resect PAs. In this work is presented a novel and improved version of the solutions reported in the literature. The instruments consist of a body and a highly deformable tip fabricated through additive manufacturing technologies and a magnetoresistive sensor which measures the variation of the magnetic field when the tip is compressed due to the contact with the adenoma and then this system is capable of discerning soft tissues consistency. Two different tips with four arms were assessed, one with a 0.45 mm thickness and the other with a 0.75 mm thickness to find a trade-off between the stability of the tip and its deformability. Compression tests with samples of different Shore 00 hardness were conducted, to explore how the probe behaves with material with different hardness. Tests were conducted with specimens made of boiled egg white, which according to literature and expert surgeons, its consistency is similar to PAs. A preliminary value of hardness of 16.08 ± 2.02 for 0.45 mm tips and 16.17 ± 4.37 for 0.75 mm tips were measured for the boiled egg white. According to results, the 0.45 mm tips are more suitable for the application of the sensorized probe due to the lower uncertainties. In addition, force data measured during tests with the egg white specimen, are in line with data found in the literature about the force exerted during neurosurgical approaches. These results can be considered a preliminary analysis of how the probe would behave with a real PA.

Keywords— Pituitary adenoma, magnetoresistive sensor, 3D printing technologies.

## INTRODUCTION

The Pituitary Adenoma (PA) is a tumor that grows near the pituitary gland (or hypophysis), in the middle of the skull base, in the so-called sellar region, a protrusion of the back of the sphenoid bone. The dimensions of PAs change, they can be smaller than 10 mm, microadenoma, bigger than 10 mm, macroadenoma, or even greater than 40 mm, giant adenoma [1]. PAs are usually treated surgically by resection with the endonasal transsphenoidal approach which is a relatively new technique used by surgeons to access the sella turcica by passing through the nasal cavities [2]. One of the main difficulties of the operation is that the consistency of PAs is unpredictable until the tumor is exposed. PAs consistency can be soft or hard [3], [4]. In the literature different methods are available to preoperatively investigate the consistency of PAs, however, none of them has sufficient reliability in clinical use [5], [6]. Softer PAs can be aspired while harder PAs require an initial fragmentation [7], thus increasing the difficulties of the surgery as well as the risks connected to it [1]. Surgeons must therefore recognize the consistency intraoperatively and then decide which is the best strategy for the resection. A mechanical characterization of Pas, but also in general for soft anatomical tissues, is useful. Therefore ETA requires a high level of expertise which can be reached with a specific training approach and by performing numerous surgeries in the operating room [8]. The aim of this work is to develop a new sensorized surgical instrument that can measure the consistency of the PA intraoperatively. This will help surgeons determine the best strategies for PAs resection. The idea is to correlate the hardness of PAs with the variation of the magnetic field, caused by the displacement of a Nd magnet attached to a highly deformable tip. The magnetic field variation is measured by a commercial magnetoresistive sensor.

This paper presents an improved version of the sensorized probe designed in our former work [9]. Compared to the previous version, the new sensorized probe has a smaller diameter. Through a new design it was possible to reduce it by 33%, from 8.4 mm to 5.6 mm. The reduction in size is important because the aim is to fit the instruments into the nasal cavities intraoperatively during surgery. To explore the behavior of the sensorized probe, four different tips were studied, two with a nominal thickness of 0.45 mm and two with a nominal thickness of 0.75 mm. The idea is to explore different behaviors as a function of the thickness and to determine the most suitable design for the tip in terms of sensitivity. The four tips were mounted on four different probes and tests were performed with a magnetoresistive sensor together with a load cell. The advantage of using magnetoresistive sensors is that they are small and can be hermetically sealed, which is ideal for this application. This eliminates the contact with anatomical tissues, thus

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overcoming the problem of biocompatibility [10]. The behavior of the probes was evaluated indenting silicone samples having different hardnesses. Then, the same test was performed using a sample of boiled egg white, which, according to literature and expert surgeons, is a good reproduction of one consistency of PAs. A preliminary value of hardness for the egg white was then obtained.

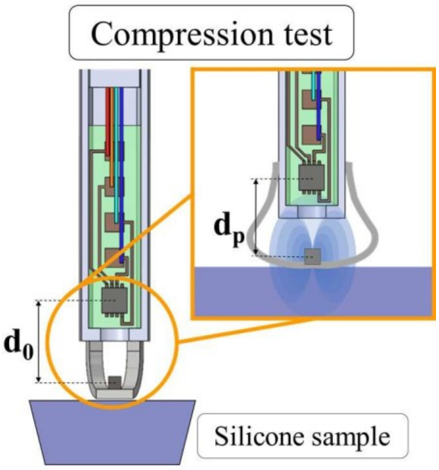
## MATERIALS AND METHODS

### A. The Concept

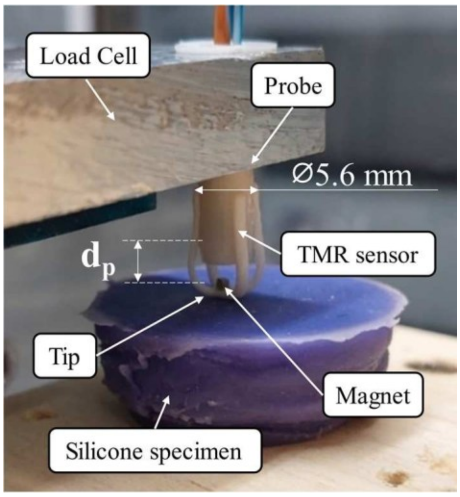
The concept at the base of the sensorized probe is to calculate the deformation of the highly deformable tip through the variation of the magnetic field measured by the magnetoresistive sensor placed inside the probe. In particular, the sensorized probe consists of: the sensor, the body and the tip. In addition, a 1 mm cubic-shaped Nd magnet is glued on the tip and the sensor measures the magnetic field which is correlated to magnet to sensor distance. The amount of deformation depends on the hardness of the surface that the tip indents. The deformation is calculated as the difference between the initial magnet to sensor distance, $d_0$, and the final magnet to sensor distance, $d_p$. This behaviour can be modelled as two springs in series with different stiffness, following Hooke's law, as shown in Fig. 1a. The magnetoresistive sensor measures the compression of the tip sensing the distance of the magnet and it is therefore possible to compare the hardness of different materials undergoing the same experimental procedure. Fig. 1a shows the concept of the compression test performed on the sensorized probe. The magnetoresistive sensor used to measure the variation of the magnetic field is a TMR2905S, an Ultra High Sensitivity TMR linear sensor (MultiDimension Technology Co., Ltd., China). It is soldered to a 4.16 mm width which is then inserted into the probe. The reduction of external diameter of the 33% compared with the previous version was possible thanks to an optimized design for the insertion of the board. An oval eyelet of 4.6 mm was designed to fit diagonally the sensor to prevent the rotation of the sensor once inserted into the body of the probe. On the top of the body a 3 mm cap was added to prevent the sensor from moving. The tip was designed with 4 arms as a trade-off between the reduction of the global volume of the probe and the stability of the system, so to prevent structural instability when pressed. In the middle there is a circular base with a diameter of 2.5 mm to facilitate the positioning of the magnet and, once the tip is folded around the body it will be the contact point with the specimens. The length of the tip is 28 mm and the width of its four arms is 1.25 mm. Two tips were designed, one 0.45 mm and the other 0.75 mm in thickness. The tip is designed so that once folded and attached to the body, the initial distance between the magnet and the sensor $d_0$ to be in the higher sensitivity trait, so to increase the sensitivity of the system during compression test. Fig. 2 shows the design of the tip. The main advantage of such design is the fact that the measurement of hardness is performed without friction because no relative movement of the parts of the probe occur.

### B. Fabrication

Both the probe and the tip were fabricated with an Ultimaker 3 Extended, a 3D printer developed by Ultimaker which prints with FFF (fused filament fabrication) technology. The body was 3D printed in PLA to give a rigid structure and to allow the interlocking of the board and for fixing the tip. Considering the small feature on the body of the probe, it was used a nozzle with a smaller diameter, the AA025 which has a diameter of 0.25 mm, and allows the fabrication of smaller features as the 4 grooves where the tip is mounted. The grooves are useful since they help in the positioning of the arms of the tip. The tip was printed in TPU with the AA04, the nozzle with a diameter of 0.4 mm and a layer height of 0.15 mm. Fig. 1b shows the probe once mounted.




(a) Concept of compression tests




(b) The probe

Fig. 1 (a) The TMR sensor measures the variation of magnetic field during compression tests which is correlated to the deformation of the tip, depending on the hardness of the specimen tested. (b) the probe mounted, $d_0$ is the initial magnet to sensor distance, while $d_p$ is the final magnet to sensor distance, obtained during compression tests.

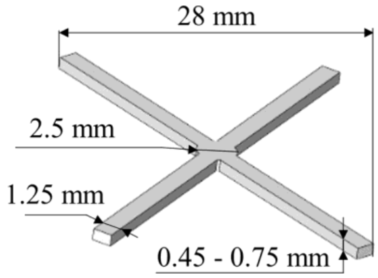



Fig. 2 Tip design The tip has 4 arms, with a width of 1.25 mm and a thickness of 0.45 mm (P1, P2) and 0.75 mm (P3, P4). In the middle a circular base with a diameter of 2.5 mm and a total length of 28 mm.

The samples used in this work are three silicones: Shamrock Elite Double 8 (Zhermack Spa, Badia Polesine, Italy), Silicon Mix SH A 12 Orange (ITALGESSI SRL, Castigliano, Italy) and Zhermack Elite Double 16 (Zhermack Spa, Badia Polesine, Italy) with a nominal Shore A hardness of 8, 12 and 16 respectively [9]. Two softer samples were added: silicone Dragon Skin™ 30 (Smooth-On, Inc., USA) with a hardness of 30 Shore 00 and a specimen with a Shore 00 hardness of 10. The Shore A values of the first three silicone samples were experimentally converted to Shore 00 hardness using a $3^{rd}$ degree linear regression model with two different data sets: C1[1]and C2[2]. Specimen were converted for comparison purposes only in sake of simplicity. The values of Shore 00 hardness of 45, 55 and 61 for the Shore A samples 8, 12 and 16 respectively. Fig. 3 show the $3^{rd}$ degree linear regression model used to determine the shore 00 hardness.

### C. Electronical Setup

The characterization setup has been designed and used to estimate the deformation of the tip when pressed in a controlled displacement condition to different specimens. The probe is locked on the micrometric slide which has an

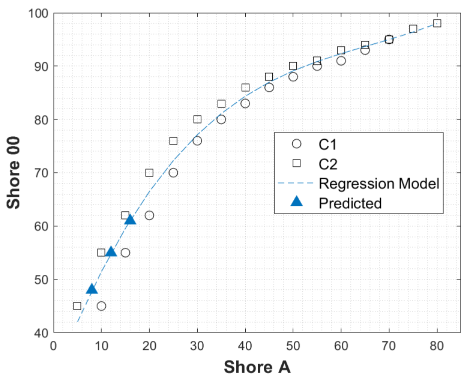



Fig. 3 Shore A to Shore 00 Calibration Curve To compare results, the values of the Shore A samples were preliminary converted into Shore 00 hardness using a $3^{rd}$ degree linear regression model using two different data set found: C1[1] and C2[2]. The values of Shore 00 hardness of 45, 55 and 61 for the Shore A samples 8, 12 and 16, respectively.

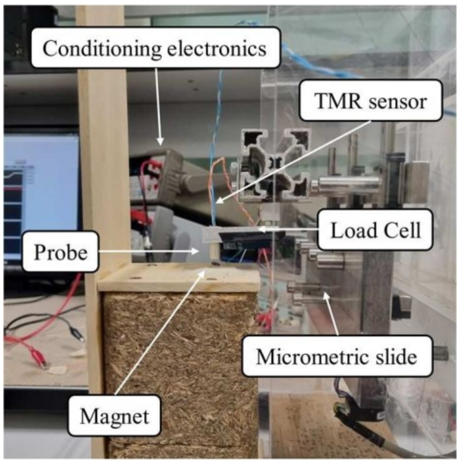



Fig. 4 The electronical setup A Load cell is embedded in a displacement controlled micrometric slide and it measures the resistance of the specimen to compression, while the TMR sensor measures the variation of magnetic field as a function of the displacement.

embedded load cell, data are then collected by a DAQ. The magnetoresistive sensor was alimented at 1 V, while the load cell at 10 V. Both sensors' data were measured by two HP34401a (Hewlett–Packard, Palo Alto, CA, USA) connected to a PC and interfaced with a LabVIEW program using 1 Hz as a sampling rate.

## RESULTS AND DISCUSSION

### *A.* Sensor Characterization

The magnetoresistive sensor was characterized as a function of distance in a specific designed test. The board was positioned inside the probe which was mounted on the micrometric slide. The tip was positioned on a flat surface right below the micrometric slide with the magnet attached to it. The characterization consisted of a movement between the magnet and the probe from 0 to 7.2 mm, Distancing phase (DP), with steps of 100 µm, 300 µm and 600 µm and then back to 0 mm, Approaching phase (AP). The resulting curves are

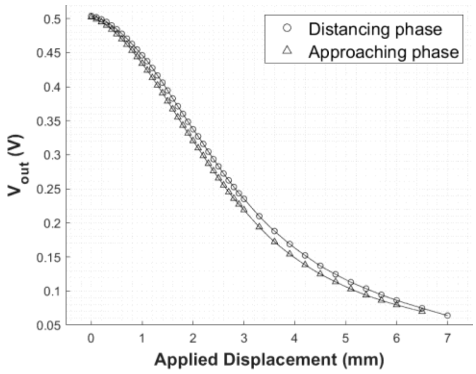



Fig. 5 TMR characterization The characterization consisted of a movement between the magnet and the probe from 0 to 7.2 mm, Distancing phase (DP), with steps of 100 µm, 300 µm and 600 µm and then back to 0 mm, Approaching phase (AP).

shown in Fig. 4. Both the DP and AP curves show a linear trend approximatively from 0.5 mm to 3 mm, which tends to flatten out at outer intervals. Additionally, both curve shows a hysteresis in the measurements. To overcome this problem, only the AP curve was considered for its congruity with compression tests.

### B. Compression Tests

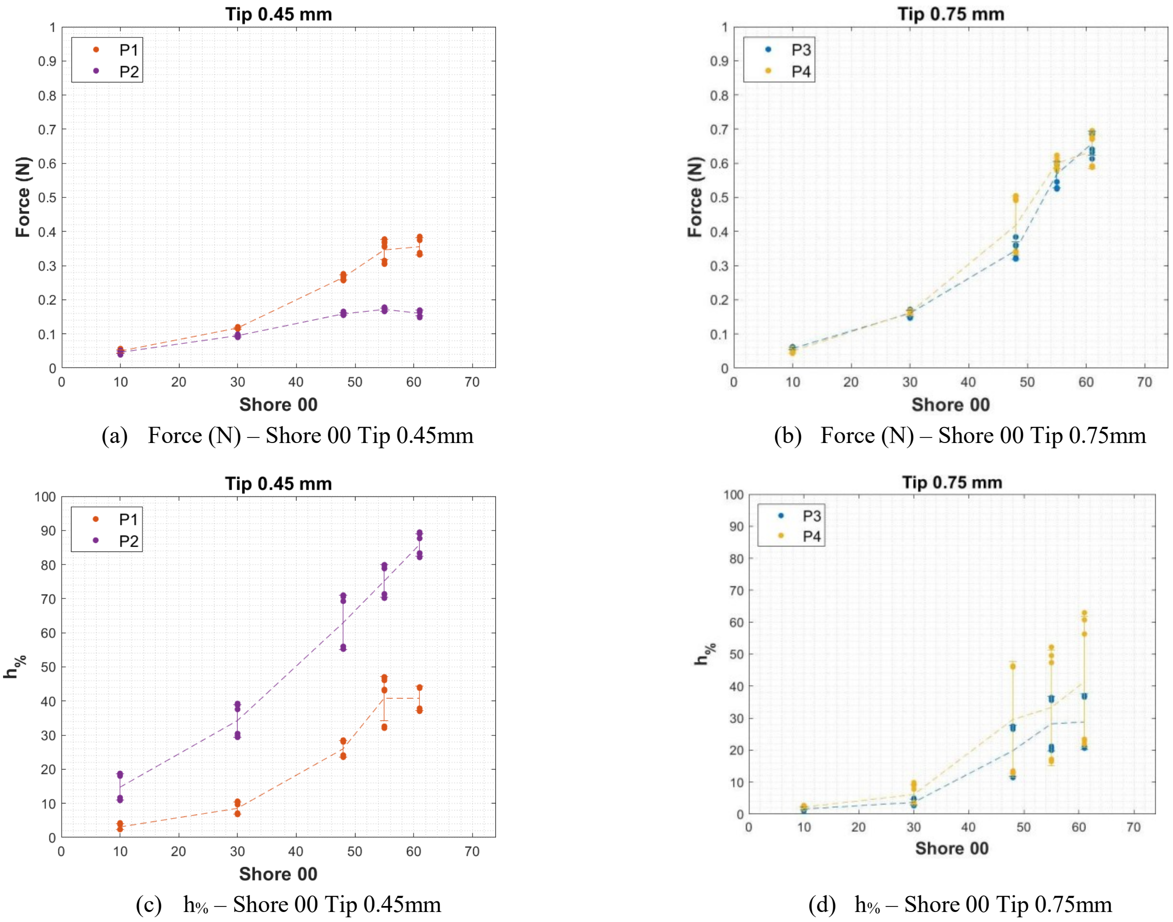
Compression tests were performed to explore a correlation between different Shore 00 hardness materials with the deformation of the four tips. They consist in a compression cycle of 3 repetitions with a displacement of 1 mm. From each tests the initial offset, $d_0$, was extracted, together with the value of the point of maximum indentation, $d_{pi}$, for each repetition of a single test, from both the load cell and the TMR sensor. Fig. 6a and Fig. 6b show Shore 00 data as a function of Force (N) for P1 - P2 (0.45 mm tips) and P3 - P4 (0.75 mm tips) respectively, what emerges is that 0.45 mm tip has a lower scattering, especially when testing materials with a lower hardness. Compression tests were performed twice for each combination of tip – specimen, for a total of 10 sets of proves for each probe.

TMR data were then converted into millimeters so the parameter $h_{\%}$ defined in our previous work was calculated for each point of maximum indentation [9]. Since the imposed distance, is equal to 1 mm, the formula of $h_{\%}$ can be simplified as follows:

$$h_{\%} = (d_0 - d_{pi}) * 100 \quad (1)$$

Fig. 6c and Fig. 6d show Shore 00 data as a function of $h_{\%}$ for P1 - P2 and P3 - P4 respectively. Data confirm that the thinner tips have a lower scattering, in addition they have a greater sensitivity which make them more suitable for the measurement of soft anatomical tissues, like PAs.

The same compression test was conducted with a boiled egg white specimen for each of the four probes, both the force, and the $h_{\%}$ values were determined for each test as well. By fitting a linear regression model between the Force (N) and the Shore 00 and analogously between $h_{\%}$ and Shore 00 hardness, it was possible to determine the Shore 00 values for the boiled egg white specimen measured with each probe. Force data present a better repeatability from P1 – P2 and P3 – P4, especially for lower hardness. Similarly, the Shore 00 values of the egg specimen were calculated from regression models obtained for each probe from force data, and a value of Shore 00 hardness of 16.96 ± 2.95 for P1-P2 combined, and 15.90 ± 6.37 from P3-P4 combined. The level of force reached while testing egg white specimen are similar to the forces found in literature reached when interacting with pituitary adenomas during a real transsphenoidal surgery in the range of 0.1 to 0.5 N when interacting with soft tissues [11], while a mean values of 0.68 N for neurosurgical




(a) Force (N) – Shore 00 Tip 0.45mm

(b) Force (N) – Shore 00 Tip 0.75mm

(c) $h_{\%}$ – Shore 00 Tip 0.45mm

(d) $h_{\%}$ – Shore 00 Tip 0.75mm

Fig. 6 The result obtained for the four probes: (a) and (c) report the result of P1 and P2 (probe with a 0.45 mm tip) for Force (N) and $h_{\%}$ respectively, analogously (b) and (d) for P3 and P4 (probes with a 0.75 mm tip). As a result, 0.45mm tips are more sensitive to lower values of hardness and their trend is closer to linearity than 0.75mm tips, making the former more suitable for the measurement of pituitary adenoma hardness.

approaches [12]. This can be a proof that the boiled egg white consistency is like the one of PAs. For the TMR sensor, the Shore 00 hardness values obtained for the egg white sample are: by averaging the results of P1 and P2 combined, $16.08 \pm 2.02$ Shore 00 was found, while a Shore 00 and for P3 and P4 combined, $16.17 \pm 4.37$ Shore 00. Fig. 7 shows the results for both the force data (circles) and TMR data (triangles). In addition, egg data measured during the first replicate with P4 were removed since they were considered outliers.

The low repeatability when comparing probes with the same tip thickness can be attributed to how the system was mounted, in fact, as shown in the TMR sensor characterization in Fig. 5, a minimal variation in $d_0$ corresponds to a large variation in sensor output. This variation is more visible with 0.75mm. In fact, there is a variation of the 23.9% between P3 and P4 while a variation of 10.0% between P1 and P2 when comparing force data while a variation of the 47.0% between P3 and P4 while a variation of 10.5% between P1 and P2 when comparing $h_{\%}$ data.

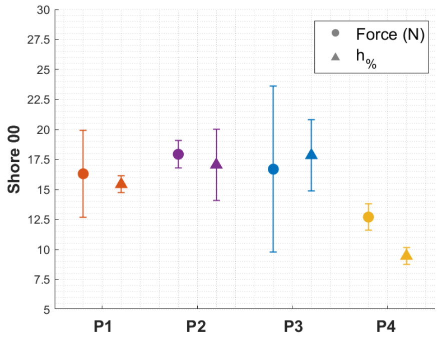



Fig. 7 Shore 00 Hardness of egg white specimen The plot displays the Shore 00 of the egg specimen measured with the four probes. With the circles are reported the value obtained from the load cell, while with the triangles the values of the TMR sensor.

## CONCLUSIONS

This work presents a novel and improved version of a sensorized probe to estimate the hardness of biological tissues. It consists of a rigid body in which the highly deformable tip is mounted, coupled with a magnet and a magnetoresistive TMR sensor. The system measures the deformation of the tip which depends on the hardness of the compressed surface. The innovative design reduces the overall dimension of the probe so to fit within the nasal cavities. In fact, the previous version had a diameter of 8.4 mm, while the new has a diameter of 5.6 mm. The two parts of the probe: the body, and the tip, were fabricated through FFF additive manufacturing technology, respectively in PLA for stability and TPU for deformability. Two different tips with a thickness of 0.75 mm and 0.45 mm were evaluated. In particular, the 0.45 mm tip revealed a lower scattering of the measures and the Shore 00 hardness for the egg white specimen was measured $16.08 \pm 2.02$. Future work will be focused on a study of the optimal tip design to enhance its sensitivity and accuracy, but also to overcome the repeatability in the mounting phase. This will include its geometry and the manufacturing process. Moreover, tests will be conducted with ex-vivo specimens to provide an estimation of PAs tissue hardness.

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