Implantable active artificial larynx: timing evaluation of a laboratory prototype.

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***Abstract*— Total laryngectomy surgery consists in the removal of the larynx, and only allows to breath through a tracheostomy, where the trachea is permanently sewn on the anterior throat. Therefore, no air passes through the nose and mouth anymore, and restoring normal breathing would require to set the trachea back in place and to reproduce the closing mechanism of the trachea, which protects the airway during swallowing. In that regard, we seek to demonstrate the feasability of an *implantable active artificial larynx*, coupled with implanted sensors and real-time swallowing detection, and its speed constitutes the decisive aspect. Our previous works have shown that carefully chosen anatomical structure can provide qualitative signals and improved performances for a safe and early detection of swallowing. Therefore, as a proof a concept, the current paper focuses on its engineering aspects, that should allow to protect the trachea as fast as possible. We designed a laboratory prototype to estimate the operational uptime of such a system, and we showed that the real-time detection of swallowing, followed by the closure of the protective mechanism, can operate in less than 30ms seconds. We then discuss the main avenues that would improve the implantability of such a system.**

I. INTRODUCTION

In normal conditions, the primary roles of the larynx are to keep the airway open during breathing, to close it during swallowing, and to allow the phonation as it holds the vocal cords. But in case of advanced laryngeal cancer, total laryngectomy is the standard surgical treatment [1] and consists in the resection of the larynx, which causes the loss of its functions. To restore breathing, the surgery permanently separates the air passage from the bolus passage with the creation of a tracheostomy: the trachea is sewn on the anterior throat, and no air passes through the nose and the mouth anymore. Besides, the phonation can partially be restored with a tracheo-esophageal prosthesis, but the voice sounds low, and little modulation is possible. Finally, the swallowing is performed through the isolated pharynx [2].

The laryngeal functions are therefore partially and sub-optimally restored, which impact the patients physical integrity and self-esteem [3]. The desired possibility to set the trachea back in place would allow to close the tracheostomy and could open new avenues for improving the restoration of laryngeal functions, within the natural aero-digestive tracks (Figure 1). Therefore, this implies that the airway protective mechanism of the swallowing process should be the primary function to be restored, to guarantee the safety of the airway. In other words, no phonation and breathing through the natural track should be allowed with a permanently opened trachea. So, in that regard, our research focuses on the feasibility of an *implantable active artificial larynx* as a natural airway rehabilitation method, where an active protective mechanism would protect the trachea in real-time under the control of a real-time swallowing detection (Figure 1d). Such a system would require the measurement of physiological signals that should provide early and qualitative data about swallowing, to protect the trachea as early as possible, before the bolus puts the trachea at risks of aspiration.

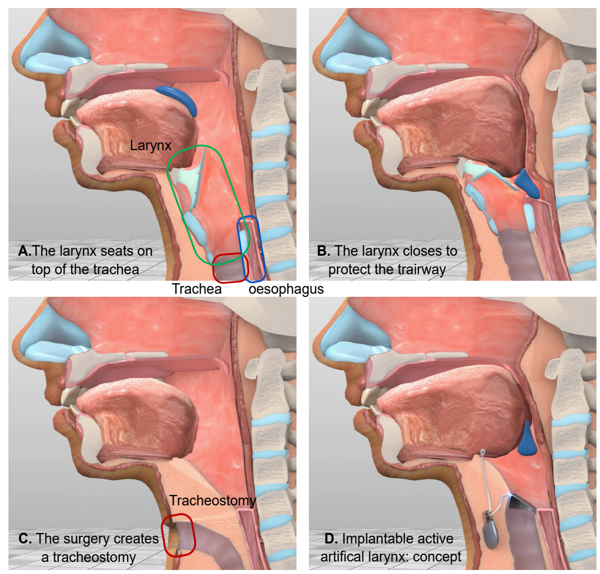

Fig. 1: **A.** and **B.** Normal functioning during swallowing. The larynx closes to protect the trachea. Breathing stops and resumes once the bolus has passed. **C.** Tracheostomy created during total laryngectomy surgery to allow to breath safely. **D.** *Conceptual view* of an implantable active artificial larynx that temporarily closes the trachea during swallowing.

Yet, previous reported works have already shown the possibility to implant a *passive* artificial larynx in humans [4], [5]. It allowed the patients to breath and swallow through the natural track again, but under medical control only. So, this relative success opens new possibilities, but the passive prosthesis had no active protection of the trachea, causing food residues to enter the upper part of the trachea because of imperfect sealing [6]. An active system would therefore considerably improve the reliability of such a prosthesis, since the airway would be forcibly and temporarily closed beforehand, with a dedicated mechanism.

In that regards, our previous works have already shown the viability of a real-time swallowing detection system that

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would measure physiological signals with implanted sensors. Especially, we first defined a temporal limit, after which the risk of food aspiration increases drastically and would require the trachea to be already protected [7], [8]. We provided a measurement method for that limit that we coupled with the electromyographic (EMG) measurement of the submental muscles, whose beginning of activity is known to mark the onset of the swallowing process [7]. These two meaningful time points allowed us to evaluate the temporal activity of key neck areas and we especially measured the stylohyoid and the posterior digastric muscles, with intramuscular EMG. So, we showed that the measurement of carefully chosen area can provide early [9] and dedicated [10] data about the swallowing process, *before the temporal limit*. Consequently, it allowed us to drastically improve the real-time swallowing detection performances [11], in comparison to common approaches, and both in terms of earliness and event detection.

But these results only demonstrate the viability of an implatable active artificial larynx from the perspective of the anatomy. So, future researches should be further justified by the evaluation of such a system from an engineering perspective. Indeed, it should process the acquired signals, run a detection algorithm, and actuate any protective mechanism before the temporal limit. Yet, the time it would take would obviously depend on the final system architecture, but it is possibility to estimate an operational uptime within a laboratory environment. So, as a proof of concept, we developed a laboratory prototype that emulates such a system, starting from the real-time signal acquisition, to the total closure of a protective mechanism. Its conception respects anatomical sizes and combines the followings: (i) a 3D printed structure that reproduces the tubular shape of the trachea, (ii) a closure mechanism that is actuated by a power circuit, (iii) a low-power microcontroller that implements a detection algorithm and commands the protective mechanism through the power circuit. This paper therefore intends to describe that prototype and provide an estimate of what would be the temporal capabilities of an implanted system.

II. MATERIALS AND METHODS

The functioning of an implantable active artificial larynx can be divided in tow part. The first one is the firmware part, that should acquire the signals, process them, and run any detection algorithm in real-time. The second one is the protective mechanism part, that should be actuated under the command of the first part. So, the following gives an overview of our laboratory prototype, followed by a description of these two parts.

A. Laboratory Prototype

The final prototype is visible Figure 2 and is composed of a low-power microcontroller that receives the signals' samples, one by one from the computer and at a fixed frequency, to emulate a real-time signal acquisition. It then runs the firmware part and, when a swallowing is detected, a digital output is set to 1, which operates a power circuit. Then, the power circuit converts the digital output into a power output, required to operate a solenoid that will in turn operate the protective mechanism. More specifically, the power circuit is first composed of a hardware driver board, that is the actual digital-to-power converter. Then, it is followed by a transistor-based circuit, able to output both a positive and negative voltage, which is required for the operation of the solenoid. Finally The protective mechanism consists in a valve that closes and opens under the control of the solenoid, whose linear movement is converted into a circular movement through a rack and pinion gear.

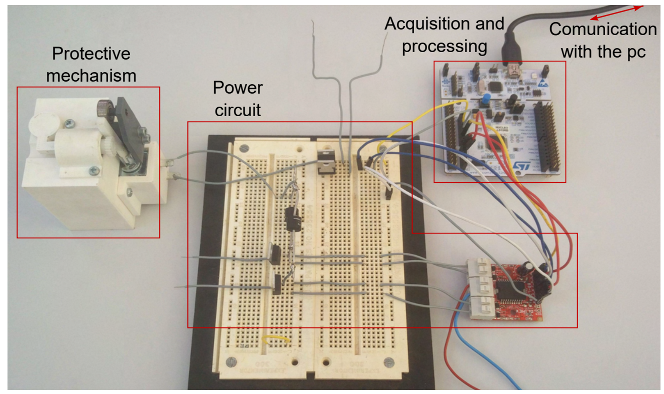

Fig. 2: Laboratory prototype of an implantable active artificial larynx. A processing unit drives a power circuit, that operates a protective mechanism and closes a valve.

B. Firmware

1) Real-time algorithm: In an implanted swallowing detection system, the signals would be acquired and sampled in real-time, which would result in each sample being stored in memory one after another and at a fixed frequency. Here, the signals have already been acquired and sampled in our previous works [7], but a real-time acquisition can be emulated by sending each sample from a computer to the microcontroller at a fixed frequency, which would reproduce the sampling frequency of the signals. To do so, on the computer side first, the samples are sent one by one with a Python program, which is built to precisely control the time elapsed between the sending of two samples. It uses a Windows Application Programming Interface (API) that allows to query the current time with a microsecond precision [12]. Then, on the microcontroller side, each sample is received through the UART (Universal Asynchronous Receiver Transmitter), which is a module that enables the serial communication with the computer. Then, the transfer of each sample to the memory is performed with a Direct Memory Access (DMA) module, which is specialized in data transfer and allows to relieve the CPU (Central Processor Unit), which can then focus on, and therefore speed-up, the signal processing and swallowing detection part.

The samples can therefore fill in the memory in a similar manner as an implanted system would do. Then, the CPU should, in turn, reproduce the real-time algorithm that processes the signals and runs a detection algorithm, using the newly stored samples. Classically, the data are first acquired within a temporal window (Figure 3), where the number $\mathbf{N_w}$ of samples it contains defines the temporal definition of the algorithm. Then, the data contained in a window defines an instance to be classified by the detection algorithm, and $\mathbf{N_w}$ is usually chosen to be shorter than the event to recognize, so that it can be detected before it is finished. Then, when a window has been processed, a new one is acquired, which can overlap (or not) the previous one, to further increase the temporal definition. The temporal distance between each windows is therefore defined by the number $\mathbf{N_b}$ of samples that seperates their beginning.

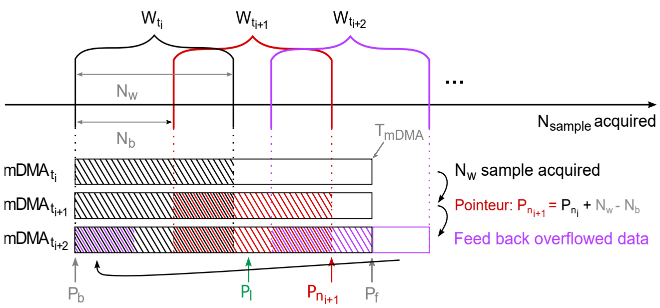

Fig. 3: CPU strategy to reproduce a real-time algorithm within the memory of the DMA (mDMA). $\mathbf{N_W}$: number of sample within a window. $\mathbf{N_b}$: number of sample between two windows. $\mathbf{P_b}$: pointer of the beginning of the memory. $\mathbf{P_f}$: pointer of the end of the memory. $\mathbf{P_l}$: pointer of the last sample received. The CPU should process a window before the arrival of the next one, to avoid any delay in swallowing detection, but also because new data will ultimately erase old ones, because of the finite size of the memory.

Besides, the CPU should no only reproduce the real-time windowing of the signals, but should also process a given window before the next one arrives. If not, delay would accumulate, leading to swallowing detection delay. Another consequence would be the processing of corrupted data. As the memory is finite, incoming samples would eventually be fed back at its beginning (Figure 3), mixing with old samples that the delayed CPU has to process. So, given a sample frequency f_s, the available processing time is $T_p = N_b/f_s$.

2) Configuration of the system: The strategy we described has been implemented in three low-power microcontrollers (Table I), using STM32 NUCLEO boards, to compare their performances. The first one provides little capabilities, while the other tow come with additional modules. A Floating Point Unit (FPU) module, which is specialized in calculations involving floating point numbers, allowing them to be executed faster. And a Digital Signal Processor (DSP) module, which is specialized in common signal processing methods and allows to accelerate them.

We used each of these microcontroller in conjunction with the signals that we recorded in our previous work [7], to reproduce the detection strategy that we developed [11], and that has shown increased performances in comparison to common practices. The signals consist in the EMG recording of 3 neck muscles, sampled at $2kHz$: the stylohyoid, the posterior digastric, and the submental muscles. However, the

TABLE I: Description of the three microcontrollers used.

	CPU	Max CPU clock (MHz)	Flash Memory (Kbytes)	consumption (μA/MHz)	FPU	DSP
L010RB	Cortex M0	32	128	93	✗	✗
F446RE	Cortex M4	180	512	100	✓	✓
U575ZI	Cortex M33	160	2000	19.5	✓	✓

✓: module available, ✗: module non available.

primary focus of our previous works being the stylohyoid and the posterior digastric, the work reported in the current paper first used only these two muscles, followed by a second implementation that used all 3 muscles, to compare the timing performances. In addition, to allow for further comparisons, common window parameters were used [13], where two window sizes of $100ms$ ($\mathbf{N_w} = 200$) and $200ms$ ($\mathbf{N_w} = 400$) were compared, with an interval of 50ms ($\mathbf{N_b} = 100$) between two consecutive windows, in both cases. Finally, these various configurations were applied on three detection algorithms: Linear Discriminant Analysis (LDA), Support Vector Machine (SVM), and Artificial Neural Network (ANN). A total of 12 commonly used features [11], [14] were computed per signals, to be fed into the classifiers. The firmware was developed in `C` within the STM32CubeIDE environment, using the STM32 `HAL` library, and the `CMSIS-DSP` library for the DSP module.

C. Protective Mechanism

Currently, no research is conducted on the development of an implantable active protective mechanism, and no specific mechanism capable of fast and reliable sealing of the airway has be reported. Therefore, the design of our prototype is voluntarily simple, to focus on its speed and to evaluate the future capabilities of such a system. Our mechanism can be summarized as follow: the linear movement of a solenoid is converted into a circular movement, which closes a valve that seals the trachea. Here, the trachea corresponds to a cylinder that goes through the main block. Besides, we used a *latching* solenoid (DSML-0630-12P, Delta Electronic), which can be activated with only a short positive pulse of current. So, unlike classical solenoids, it can hold its position without the need to maintain the source of power, and only requires a small negative pulse to get back to its resting position. This is beneficial to limit the consumption of the system. Then, the movement of the solenoid is transferred to a rack that sets a pinion in rotation, which then rotates the valve, connected through a shaft. The details can be seen on Figure 4.

Also, the components were chosen to respect anatomical sizes. The valve has a diameter of $15mm$, the pinion has a primitive diameter of $10mm$, and the solenoid was used with a course of $7.85mm$. This allowed to rotate the valve 90 degrees, from its vertical resting position to its horizontal closed position (Figure 4). Beside, the main block has been 3D printed with polyoxymethylene (POM). The valve, the rack and the shaft are also made of POM and can be found in any specialized store. The POM is chosen for its lightness and its solidity, which are key factors for such a system that should combine speed and robustness.

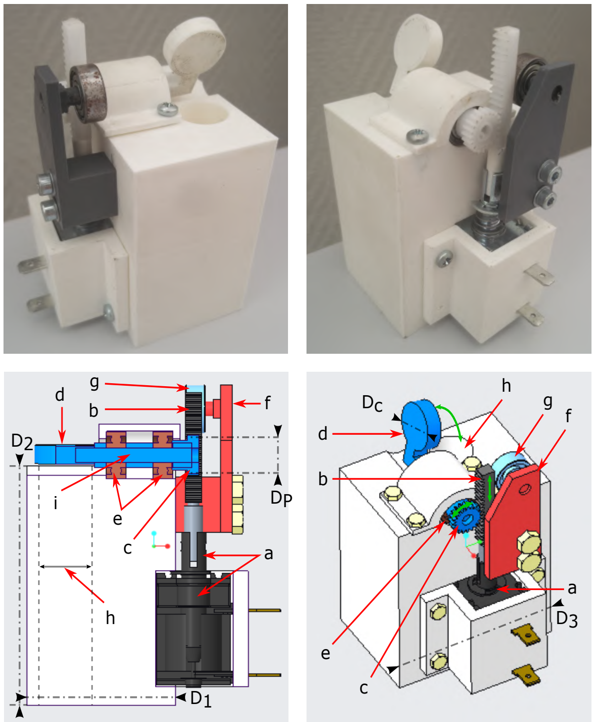

Fig. 4: Protective mechanism. Upper part: conception (left: perspective view from front side. right: perspective view from rear side). Lower part: 3D model (left: rear view. right: perspective view from rear side). **a**: latching solenoid. **b**: rack. **c**: pinion. **d**: valve. **e**: bearing. **f**: rack guide. **g**: rack guide bearing. **h** cylinder (diameter: $15mm$). **i**: shaft connecting the pinion and the valve. $\mathbf{D_1}$: main block width ($39mm$), $\mathbf{D_2}$: main block height ($65mm$), $\mathbf{D_3}$: main block depth ($55mm$), $\mathbf{D_p}$: pinion diameter ($10mm$), $\mathbf{D_c}$: valve diameter ($20mm$) – The valve rotates 90 degrees.

D. Evaluation of the System

The firmware part and the protective mechanism part were assessed independently to get a precise evaluation.

1) Firmware: two temporal markers were placed within the firmware, using `__HAL_TIM_SET_COUNTER(&time, 0)` and `__HAL_TIM_GET_COUNTER(&time)` functions from `HAL` library to get precise timing. The first one was set at the moment the CPU started to retrieve data from the memory to process the current window. The second one was set at the moment the detection algorithm outputs a decision.

2) Protective Mechanism: when the firmware part detects a swallowing, a LED is turned on on the microcontroller, right before it outputs a 1 on a digital output. Then, the power circuit operates the solenoid, which transmits its movement to the valve that rotates 90 degrees. The entire operation has been filmed with a high speed camera (Mikrotron® MotionBLITZ EoSens® Cube7) at a frame rate of 1000 images per second. Therefore, it allowed us to measure the time required to operate the mechanism with a temporal resolution of $1ms$. The starting point was the moment the LED turned on (which tooks less than a frame), and the finishing point was the moment the valve was completely closed.

E. Reproduction of our detection algorithm

For the sake of clarity, we provide a brief description of the most relevant aspects of our previously reported works, that we implemented on microcontrollers in the current work. First off, the signals were acquired on healthy people, within a clinical research protocol [7]. The stylohyoid and the posterior digastric were measured with needle EMG inserted within each muscle, and the submental muscles were measured with surface EMG. Other neck area were also recorded but are not relevant to the current paper and were therefore excluded. Each sensor were placed by an otolaryngologist surgeon. The participants performed 4 different types of swallowing tasks and 13 non-swallowing tasks. Then, the signals were used to evaluate the potential of each muscle for a real-time detection algorithm of swallowing. Both the LDA and SVM classifier were used and compared within a binary classification strategy, to differentiate swallowing tasks and non-swallowing tasks [11].

III. RESULTS

As for the configuration of the system, given the prerequisite that the processing time of a window should be finished before the next one arrives (in other word within $50ms$), the memory allocated to the DMA could be reduced down to the memory size required for the number of samples contained within only two consecutive windows (Figure 3). Besides, Only the LDA and the SVM were actually used in our previous work [11]. The additional ANN used in the current paper showed similar results in preliminary investigations, with one hidden layer containing 100 neurons and one output neuron for binary classification. This relatively small architecture allowed to reduce its memory usage while still maintaining detection performances.

Then, the timing performances of each configuration, implemented on all 3 microcontrollers, are visible in Table II. It should be noted that all 3 classifier require different computational load. The LDA is a linear classifier and is the least computational intensive. It essentially requires the computation of a dot product between the extracted features and the associated weights, where the result is compared to a threshold. Then, the SVM and ANN are both non linear classifier. The SVM uses representative instances of the training data, called *support vectors*, that are chosen during training. During classification, each support vector is compared to the new instance to be classified, through a non-linear transformation, or kernel, and we specifically used a Radial Basis Function (RBF) kernel. The SVM therefore requires to keep all support vectors in memory. As for the ANN, each of its hidden neuron basically uses the input features to compute a dot product and apply a transformation to it, called activation function, and we used the Rectified Linear Unit (ReLU) activation function. Then, neuron's result are combined in the output neuron to obtain a classification.

With regard to the microcontroller performances (Table II), the L010RB was meant to serve as a reference for comparison with the other microcontroller, as it has the lowest computing capabilities. However It actually performed poorly and only the more favorable configuration allowed to process a window within $50ms$, which used two signals out of three, the smallest window size of $100ms$, and the LDA classifier. So, because the latter is the least computational intensive classifier, the ANN and the SVM were not implemented in the L010RB microcontroller, and the F446RE was actually the one used as the reference. However, the SVM could not be implemented on the F446RE either, because of its memory requirement to store the support vectors. Their number were higher than expected and could not fit within the 512 kbytes of flash memory. Therefore, only the U575ZI microcontroller could be used to implement all 3 classifiers.

Besides, the F446RE and U575ZI microcontrollers provided a drastic improvement for the LDA and SVM classifiers, in comparison to the L010RB (Table II). These two microcontrollers allowed for a maximum processing time of $3.27ms$, and are the ones that possesses an additional FPU and DSP module. However, these two modules where actually not sufficient when using the SVM classifier, that processed a window in $135ms$, far beyond the required $50ms$ limit. Finally, while the F446RE and U575ZI provided relatively similar computational times, the U575ZI allowed for a significant improvement in consumption.

TABLE II: Real-time signal processing timing results

	classifier	Window size	signals	time* (ms)	consumption (mA)
L010RB	**LDA**	400	SH-PD	72.78	5.15
			SH-PD-SM	108.85	7.15
		200	SH-PD	38.18	5.44
			SH-PD-SM	55.26	3.93
	ANN	–	–	–	–
	SVM	–	–	–	–
F446RE ■	**LDA**	400	SH-PD	1.41	8.13
			SH-PD-SM	1.92	8.37
		200	SH-PD	0.76	7.91
			SH-PD-SM	1.13	8.03
	ANN	400	SH-PD-SM	2.31	24
	SVM	–	–	–	–
U575ZI ■	**LDA**	400	SH-PD-SM	2.69	1.93
	ANN	400	SH-PD-SM	3.27	1.95
	SVM	400	SH-PD-SM	135	3.5

■ classifiers non implemented. ■ FPU and DSP modules available.
* features computation + classification.

Regarding the functioning of the closure mechanism, the high-speed camera showed that it can be operated in $22ms$, from the moment a swallowing is detected to the complete closure of the valve, that rotates 90 degrees.

Then, to get an estimation of the total operational uptime of the laboratory prototype, the timing estimations of both the closure mechanism and the processing parts are added. We consider the worst working scenario (i.e excluding L010RB), that required $3.27ms$ (Table II), using the U575ZI microcontroller, the ANN classifier, a $200ms$ window size, and that used all 3 signals. Therefore, the prototype operates in $3.27 + 22 = 25.27ms$ from the moment the CPU starts to process a window to the complete closure of the valve.

IV. DISCUSSION

Total laryngectomy surgery removes the larynx and creates a tracheostomy, which comes with detrimental side effects. The desired possibility to set the trachea back in place would require to reproduce the protective mechanism of the larynx, and an *artificial* and *active* mechanism could effectively protect the airway, but no research have been reported on such a system so far. So, as proof of concept, we developped a laboratory prototype of an *implantable active artificial larynx* to validate experimentaly the faisability of such a system, and the current paper focused on its operational uptime, that should allow to protect the airway as soon as possible. So, we showed that it operates in $25.27ms$, from the moment it starts to process incoming physiologcal signals to the moment the protective mechanism is entirely closed.

While this value shows that a fast implantable system is a viable perspective, it should also be compared with the time available for a real-time protection of the airway during swallowing. The timings analysis of the stylohyoid and the posterior digastric swallowing muscle, in our previous works [9], [10], showed that both muscles always begin their activity *before the temporal limit* for the detection, with a significant amplitude, and that they activates 98.33% of the time $100ms$ to $1.1s$ before the temporal limit. In other words, the operational uptime of the laboratory prototype would allow to protect the trachea before the temporal limit in the vast majority of cases. Besides, both muscles activates at the beginning of swallowing [9], which implies that the mentioned timings are the earliest available. Therefore, while some swallowings would provide a sufficient amount of time to wait for the classifier to be confident of its output, other swallowings may require to be detected as soon as they start. However, no strategy that satisfies this constraint has been reported in the literature so far [11], [2], but the current laboratory prototype, coupled with our previously reported results, show the viable potential that an implantable active artificial larynx has to satisfy this requirement.

So, improvements have first to come from the real-time detection algorithm. First off, it should allow for the temporal windows to be the shortest possible, to minimize acquisition time from the start of a swallowing. Indeed, even with the current shortest size of $100ms$, in rare cases the processing may finish after the temporal limit. Besides, classifiers that requires a significant amount of memory are not appropriate for an embedded system that should operate as fast as possible. Especially, in the case of the SVM (Table II), not only the support vectors impose a large number of computation to compare them with the instances to classify, but they also require as much data transfer from the memory to be accessed. The latter point is a well known bottleneck in modern microcontroller architecture [15], where the CPUs are now capable of faster processing than what the memory can handle, leading to the CPUs mostly waiting for the data. Besides, the field of swallowing detection has essentially been relying on basic machine learning algorithms so far, and has failed to propose an algorithm that could be used in a daily basis, capable of adapting to the various conditions under which a swallowing occurs [2]. For an implantable active artificial larynx, the algorithm should be timely constrained and most likely should incorporate temporal modeling capabilities, and recent advances in time-series detection domains could be much inspiring [16], [17]. Also, the performances of any detection algorithm would greatly depend on the quality of the data measured in real-time. While neck muscles are the primary sources of qualitative data, other anatomical structures might provide complementary information. As an example, recently reported works have shown the possibility to access sensory inputs directly on the nerves [18], [19]. Coupled with the measurement of the motor output they generate on muscle, it might provide a more elaborated view of swallowing and its different sources of variations.

Regarding the protective mechanism, despite its simplicity, it is still able to protect the trachea before the temporal limit, in the vast majority of cases. Provided that a swallowing is detected early enough. So, these results encourage the initiation of a dedicated research, which would definitely improve the timing performances of such a system. Currently, no research is conducted in that regard, and the only artificial larynx previously implanted in humans only used a purely passive mechanism [4], [5]. It was composed of (i) an irremovable tubular-shaped prosthesis, placed on top of the trachea, with a porous titanium junction to be colonized by surrounding tissues, and (ii) a removable part, on top of the first one, composed of concentric valves that enabled inhalation and exhalation. So, its current imperfect sealing [6] would benefit from an active mechanism, that would force the trachea to be closed temporarily. Also, several other aspects have to be included. It should first incorporate any security that would forbid the definitive closure of the mechanism. Second, much like the natural larynx [2], and in addition to the active protection, a passive protection should still be incorporated to deal with food residues, drips from the nasal tracts, or any foreign body outside of a swallowing. Third, an effective design should seek to integrate these criteria while minimizing the size of the mechanism, to limit the mechanical constraints applied on it and on surrounding tissues. Fourth, the empty space left by the removal of the larynx causes the surrounding tissues to collapse, which would obstruct the entrance of the airway if it is not compensated for. Therefore, the tubular shape of the previous artificial larynx was intended to extend the trachea upwards, and was effective to hold the surrounding tissues. However, the titanium based structure also lacked flexibility and, more recently, the field of trachea reconstruction has shown encouraging results using bio-mechanical prosthesis, to allow for more mechanically compliant implants [20]. Especially, the use of cryopreserved aorta has shown great promise in the possibility to restore natural airway [21], which could potentially incorporate a protective mechanism.

V. CONCLUSIONS

We evaluated a laboratory prototype of an implantable active artificial larynx, that should detect a swallowing and protect the trachea in real-time. We especially focused on its operational uptime and, despite its simplistic design, it could be actuated in $25.27ms$ only. We showed that this timing is compliant with a real-time protection of the airway during swallowing, and we discussed several lines of research that would allow to develop both an effective real-time detection algorithm and active protective mechanism of the trachea.

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