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Reliability of start and stop control of hydraulic actuation for the insertion of electrode arrays

Abstract: Atraumatic insertions of electrode arrays (EA) into the cochlea aim to preserve natural structures and residual hearing. However, there is a limit as to how smooth and slow a surgeon can insert an EA. As a potential solution, we recently presented a tool (cochlea hydro drive, CHD) that makes use of an infusion pump to prompt and control the desired, continuous and very slow (< 1 mm/s) forward movement for such insertions. The present work further describes the onset, delay and cessation of the hydraulic actuation in response to different start and stop mechanisms, to better understand the safety of its application for cochlear implant surgery. *Methods:* Our previously designed tool was used to perform insertions of an EA into an artificial scala tympani model. The prototype is designed to hold an EA, which is then actuated by a standard infusion pump programmed to operate at 0.4 mm/s and 0.1 mm/s. A tubing system between the CHD and the pump includes a three-way valve. Ten insertions were operated using the functions of the pump and ten using the valve. *Results:* From the programmed start to the actual movement, we observed a larger average delay using the pump's start function (5 s at 0.4 mm/s; 17 s at 0.1 mm/s) vs. opening the valve (< 0.7 s for both velocities). Moreover, the average cessation of movement with the valve closure was almost immediate (0.7 s for both velocities; this corresponds to < 0.1 mm with the slower tested velocity), as opposed to 60–80 s delay when using the pump's stop function. *Conclusion:* The use of a 3-way valve facilitates motion cessation to the high accuracy level required for cochlear implant surgery. These promising findings support future clinical translation of our tool.

Keywords: cochlear implant, automated, soft surgery.

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1 Introduction

The rapid developments seen during the present century in the field of cochlear implants (CI) have led to an expansion of candidacy criteria to include patients with more residual hearing. This means that not only completely deaf individuals can benefit from a CI, but also those with less severe degrees of hearing loss who are especially challenged in the presence of background noise. When such residual hearing is preserved, patients have shown different functional outcomes that appear to be superior in comparison to those without any residual hearing or those who lose their residual hearing due to the trauma that CI surgery can cause. As a result, contemporary cochlear implant surgery seeks to be as atraumatic as possible, in order to preserve intracochlear structures and residual hearing.

Previous reports have described that a reduction of forces during the electrode array (EA) insertion in CI surgery produces less intracochlear trauma [1–3]. Likewise, slower EA insertions have consistently showed lower forces and consequently, very slow insertion velocities are desirable. However, there is a human limitation as to how slow an electrode array (EA) can be manually inserted, especially when a steady continuous movement is sought. Insertion velocities lower than 1 mm/s are not free from tremor, pauses and accelerations, even in the hands of experienced CI surgeons [1]. Automating the insertion of EAs could facilitate such slow continuous insertions. While several investigations have performed automated EA insertions in laboratory settings, such technologies have not been widely transferred to clinical settings and to date, only two robotic-assisted systems have been transferred to a clinical scenario.

In an effort to present an alternative to these complex robotic and electromechanical approaches, we recently described a tool that aims to reach multiple clinical settings

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that may not count with the infrastructure level required to implement the above-mentioned systems [2]. Our novel tool takes advantage of hydraulic actuation to facilitate the automation of EA insertions. Its design is simple and non-invasive, meant to merely hold an EA and indirectly respond to any infusion pump found in clinical practice. Given this use of already existing clinical infusion pumps (previously approved for human use, as opposed to new electromechanical systems), our tool's future transfer to a surgical scenario should be less challenging. However, it remains unclear how precise is the operability of our hydraulically-actuated tool for the particular insertion component within CI surgery. To better elucidate the performance reliability of the CHD as well as to understand the safety of its application for cochlear implant surgery, the present work describes the onset, delay and cessation of the hydraulic actuation in response to different start and stop mechanisms during insertion trials performed with the CHD.

2 Methods

2.1 CHD system design

Our previously designed tool was used to perform insertions of a straight EA (FLEX24, MED-EL, Innsbruck, Austria) into an artificial scala tympani model (aSTM). The CHD prototype is designed based on a standard disposable syringe equipped to hold an EA on its end [2]. On the other end, the syringe is then connected to a standard infusion pump (hereafter referred to simply as pump) used in multiple clinical settings. A tubing system between the CHD and the pump includes a three-way stopcock valve. The pump is programmed with different predetermined infusion rates to enable the hydraulic actuation at different resulting velocities.

2.2 Insertion test bench and trial design

The insertion trials performed with the CHD followed previously described methodology [2,3]. The CHD was mounted onto an insertion setup typically used for the measurement of insertion forces, positioned above the aSTM, which in turn was resting on a load cell (K3D35, ME-Meßsysteme GmbH, Hennigsdorf, Germany). The dimensions of the aSTM are based on an average sized human cochlea and project the first 480 degrees of the scala tympani. The cochlear lumen (with lateral wall length of 27 mm) was milled out of a polytetrafluoroethylene (PTFE, a.k.a. "Teflon") sheet and filled with saline solution for realistic friction conditions. At

the beginning of each recording, the tip of the EA was introduced into the aSTM until the full first electrode contact. A custom-made software read out the force sensor every 10 ms with a measuring amplifier (GSV-4USB-D37, ME-Meßsysteme GmbH) including analog-digital converter. One microscopic camera was positioned to capture the EA insertion into aSTM and the tip of the CHD; parallel to this a webcam recorded the activation of the pump or opening vs. closing of the valve.

Figure 1: Test setup: (a) CHD fixed to a platform; (b) aSTM; (c) force sensor; (d) microscopic camera; (e) infusion pump; (f) 3-way stop valve.

2.3 Insertion trial design

The pump was programmed to operate at either 170 mL/h or 46.8 mL/h, calculated to correspond to a hydraulic actuation of the CHD at 0.4 mm/s and 0.1 mm/s, respectively [2]. Two insertion protocols were planned for each velocity of interest. For *protocol 1*, the functions of the pump were tested: the insertion was run using the 'start' and 'stop' buttons of the pump leaving the valve open at all times. For *protocol 2*, the functions of the valve were tested: first, the infusion pump was set to start with the valve closed; second, the valve was opened to start the insertion trial; third, the valve was closed to conclude the insertion trial. Video and force recordings were stopped 90 seconds after each insertion trial concluded.

Figure 2: Each insertion trial was started and concluded either with the functions of the infusion pump— i.e. *Protocol 1* (a) or with the 3-way stopcock valve for *Protocol 2*(b).

3 Results

Twenty insertion trials were successfully conducted, ten for each tested insertion velocity. Then for each velocity, five trials were performed with each protocol. EA insertions at 0.4 mm/s showed a median delay from the programmed start to the actual movement of the EA that was larger when using the pump's start function (*protocol 1*: 5.3 s; 3.7 – 6.9s) than when using the valve (*protocol 2*: 0.1 s; 0.07 – 0.2 s). Likewise, a substantial larger median delay was observed between the operated conclusion of the insertion trial and the actual conclusion of movement with the pump's function (*protocol 1*: 66 s; 64 – 71 s) compared with the valve (*protocol 2*: 0.5 s; 0.5 – 0.7 s; Table 1, Figure 3).

Table 1: Time delays (seconds) in insertion trials operated at two insertion velocities using either the pump or the valve.

Velocity	Trial (#)	Pump:		Trial (#)	Valve:	
		start delay (s)	stop delay (s)		start delay (s)	stop delay (s)
0.4 mm/s	1	3.67	75	6	1.9	0.54
	2	6.87	70.8	7	0.03	0.50
	3	7.00	63.9	8	0.07	1.20
	4	5.30	65.8	9	0.10	0.70
	5	2.60	64	10	0.17	0.57
Median		5.3	65.8		0.1	0.6
(QR1-3)		(3.7 - 6.9)	(64.1-70.8)		(0.07 - 0.17)	(0.54 - 0.7)
0.1 mm/s	11	14.96	81.7	16	0.80	1.10
	12	16.20	82.7	17	1.5	0.87
	13	17.10	84.4	18	0.5	0.67
	14	17.53	85.73	19	0.27	0.80
	15	20.26	84.47	20	0.47	0.50
Median		17.1	84.4		0.5	0.8
(QR1-3)		(16.2-17.5)	(82.7-84.5)		(0.47-0.8)	(0.67-0.87)

Figure 3: Estimated time delays (s) between the operated stop and the actual conclusion of movement per insertion trial controlled with the valve or the pump.

The same pattern was observed for insertions performed at 0.1mm/s, with the trials operated with the 3-way valve (*protocol 2*) outperforming the infusion pump functions (*protocol 1*; Table 1, Figure 3).

Finally, the programmed insertion velocities corresponded to the resulting EA insertion velocity. To calculate this, we considered the insertion trial from the point the EA was first identified to move until the operated end of the trial (i.e. until the infusion was stopped with the pump function or with the 3-way valve). This method revealed the CHD effectively conducted insertions at 0.41 mm/s and 0.11 mm/s.

3.1 Insertion profiles

Given the limited EA samples available, insertion force results were of interest *only* to observe the presence of abrupt pauses or accelerations during the insertion trials performed with the CHD and to depict differences between the velocities, more than explore raw values. Analyses of friction effects, EA geometry and other variables pertaining to insertion forces are beyond the scope of the present work. Global insertion forces were considered to illustrate these results in Figures 4 and 5, with 100% indicating the maximum force observed across all trials. The CHD achieves its main purpose: facilitate very slow (< 0.1 mm/s) insertions that result in lower insertion forces (Figure 4).

Figure 4: Insertion forces for each insertion velocity operated with the CHD. Y-axis normalized based on global forces. *Please refer to Figure 5 to see median force profiles (without abrupt peaks).*

Trials operated with the pump functions produced at the *operated* stop a nearly immediate deceleration that progressed until the actual stop of movement was observed. This post-operated stop movement produced additional insertion forces until the actual conclusion of movement (Figure 5). In contrast, the use of the valve revealed an immediate drop in forces (corresponding to the conclusion of movement) that remained constant due to the presence of the EA within the aSTM.

Figure 5 clearly shows that the movement resulting from the hydraulic actuation can be stopped immediately using the valve, as required when the final insertion depth is achieved.

Figure 5: Median insertion forces per protocol and insertion velocity operated with the CHD. Y-axis normalized based on global forces.

4 Discussion

The insertion profiles obtained from the insertion trials further confirm that the CHD is able to successfully actuate an EA into a cochlea model without significant pauses or accelerations (Figure 5) and also without the need for corrections once the trials were started. Notably, our insertion tool can be reliably operated taking advantage of a 3-way valve to control the start and conclusion of the insertion. This operating method revealed a high-degree of accuracy that is reproducible throughout different trials at different velocity settings. Controlling the insertion driven by our tool (CHD) with the 3-way valve, the actual insertion starts within less than 3 seconds, a clinically acceptable waiting time. More importantly, concluding the insertion trial using the 3-way valve is very precise, with a median recorded delay ranging from 0.6 to 0.8 s, depending on the insertion velocity used. Importantly, this presumed delay manifested as additional movement is extremely hard to visualize even under microscopic visualization. In fact, one could argue this extra movement may not even be taking place and is rather an error resulting from our recording methods, in which despite video synchronization, the determination of movement cessation of the EA during the insertion trial is based on human visualization. Hence, in both possible conditions the results indicate a high level of precision on the operational plan identified for our insertion tool.

Considering the present work did not seek to evaluate raw force values resulting from the insertions (*see Section 3.1*), we were limited to report normalized values and rather observe behaviour trends. In general, we did not observe large abrupt peaks in the CHD force profiles, and despite our use of normalized values, it is clear that forces resulting from the slower tested velocity were lower compared to those resulting from the also very slow velocity of 0.4 mm/s (Figure 4). These are insertion velocities that the trained human hand cannot achieve successfully without brief pauses [1]. Although future studies accounting for other variables that impact insertion forces (e.g. friction conditions, EA and cochlear model properties) are needed, our results show the CHD facilitates the desired very slow insertion velocities and can reliably operate with a highly precise stop system. The precision of the valve stop system shown in Figure 5 is relevant also for instances in which the insertion may need to be paused based on surgeon's judgement or immediately aborted in case of an emergency. This has an impact on the CHD safety features.

5 Conclusion

The use of a 3-way valve facilitates motion initiation and cessation to the high accuracy level required for cochlear implant surgery. These promising findings support future clinical translation of our tool.

Author Statement

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