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Towards the development of an automatic maxillary expansion appliance

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To my grandmother Etelvina and to my uncle Carlos,
who saw the beginning of this academic journey,
but won't witness its ending.

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Everyone I want to acknowledge is Portuguese, so all the acknowledgements are written in my native language.

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Resumo

A expansão do maxilar superior consiste na abertura da sutura palatina mediana, separando os dois ossos que o constituem, com o objetivo final de aumentar a dimensão transversal do maxilar. Este tipo de tratamento é realizado maioritariamente quando o maxilar superior é mais estreito que o inferior, não proporcionando o devido encaixe entre os mesmos.

A expansão é realizada através da utilização de aparelhos que proporcionam a aplicação de forças transversais à linha da sutura, levando à abertura da mesma. Atualmente, diversos tipos de aparelhos podem ser utilizados para o mesmo fim, mas um dos mais utilizados entre os médicos dentistas é o aparelho cuja expansão é feita através da rotação manual de um parafuso de expansão. Sempre que o parafuso é rodado existe um pico de força aplicada, cuja magnitude vai diminuindo ao longo tempo, mas que aumenta assim que o parafuso é rodado outra vez. Deste modo, quanto maior a frequência de ativação do aparelho, maior a força gerada em menos tempo. Assim sendo, com este tipo de aparelhos é possível realizar quer uma expansão lenta ou rápida, controlando então a frequência de ativação. Contudo, as ativações manuais dos aparelhos trazem algumas desvantagens, uma vez que estes aparelhos são mais utilizados por crianças que não têm responsabilidade suficiente para realizá-las, ficando este processo ao cargo dos pais. Para além disso, quando as ativações são mais frequentes, o aparelho gera forças de elevada magnitude (podendo chegar ao 100 N), o que causa alguma dor e desconforto ao utilizador.

Desde a criação do primeiro aparelho com parafuso de expansão, em meados do século XIX, este tipo de aparelhos não sofreu uma evolução significativa, principalmente no que diz respeito ao método de ativação, uma vez que continuam a ser meramente mecânicos. Portanto, com este trabalho pretendeu-se dar início ao desenvolvimento de um aparelho de expansão maxilar automático, que retire partido das novas tecnologias existentes hoje em dia, deixando de requerer ativações manuais por parte do utilizador. Para além disso, sendo que as ativações são automáticas é possível aumentar a frequência de ativação, tornando a aplicação de forças mais contínua. Deste modo, a utilização do aparelho torna-se mais confortável.

Inicialmente, começou-se por realizar o desenho do aparelho proposto. A automatização passa pela utilização de um microcontrolador que irá controlar um micromotor e respetivo atuador para exercer a força pretendida. Uma vez que não se dispõe de muito espaço, os componentes escolhidos possuem tamanhos na ordem do micrómetro. Para além destes componentes, é necessário selecionar uma bateria para os alimentar. Assim sendo, o foco deste projeto foi o estudo da bateria mais adequada e eficiente para o meio em que o aparelho irá funcionar, uma vez que o meio intraoral não possui as mesmas características

que o meio ambiente e por isso nem todas as pilhas serão apropriadas. A escolha recaiu sobre as pilhas Zinco-Ar devido às suas reduzidas dimensões e considerável capacidade energética, mas também por não possuírem constituintes de elevada toxicidade, como o mercúrio, que poderiam por em risco a saúde do utilizador. Contudo, estas pilhas necessitam de oxigénio para que a reação eletroquímica ocorra, pelo que a sua performance depende diretamente da quantidade de oxigénio disponível no meio em que se encontra. Para além disso, o seu bom funcionamento também depende da temperatura e da humidade relativa. Uma vez que se pretende utilizar estas pilhas dentro da boca, onde a quantidade de oxigénio pode variar e a humidade relativa é elevada, é necessário testar o seu funcionamento sob essas condições.

Num estudo anterior, as pilhas Zinco-Ar já haviam sido testadas de forma a estudar a viabilidade de serem utilizadas em aparelhos médicos intraorais. A performance das pilhas fora estudada num ambiente intraoral artificial, através da utilização de saliva artificial. As pilhas, devidamente isoladas com um invólucro, foram sujeitas a um teste de descarga, ao mesmo tempo que o invólucro era submerso na saliva durante 2 segundos a cada 2 minutos. O tempo de descarga da pilha foi, em média, 80 horas, apenas menos 3 horas que o tempo de descarga determinado pelo fabricante das pilhas, considerando as mesmas correntes de descarga e em condições ambientais mais semelhantes às do meio ambiente. Tendo em conta estes resultados, concluíram que as pilhas zinco-ar poderiam ser, de facto, uma possível solução energética a utilizar dentro do meio intraoral. Contudo, a fiabilidade destes resultados pode ser posta em causa, uma vez que só foi simulada a produção de saliva, não tendo sido em conta a temperatura e as condições do meio. Assim sendo, este projeto teve como objetivo testar a performance das pilhas num meio intraoral real.

Os testes foram divididos em duas partes. A primeira tinha como objetivo a análise do perfil de descarga de uma pilha quando sujeita a determinadas condições de descarga e a segunda tinha como objetivo analisar a capacidade das pilhas alimentarem o aparelho de expansão maxilar automático, fazendo uma aproximação do consumo do aparelho durante um tratamento.

Para realizar os testes dentro do meio intraoral foi necessário desenvolver primeiro um dispositivo para testes. Esta etapa incluiu o desenho dos circuitos eletrónicos dos dois tipos de teste e o desenho do invólucro para isolar a eletrónica do ambiente intraoral, não esquecendo as entradas de ar necessárias para as pilhas funcionarem. Estas entradas foram cobertas por membrana de Teflon de forma a evitar a entrada de saliva para dentro do invólucro sem comprometer a passagem de ar. Para ser possível colocar o invólucro na boca, recorreu-se à fixação do mesmo a um aparelho de contenção removível. Antes de realizar os testes, um médico dentista realizou o molde da boca dos participantes (4 no total), de forma a criar então esse aparelho de contenção.

Com os primeiros testes foi possível verificar que as pilhas dentro do ambiente intraoral não suportam as mesmas correntes quando expostas ao meio ambiente ou às condições criadas *in vitro*. Por exemplo quando sujeitas ao mesmo circuito de descarga utilizado nos testes *in vitro*, a pilha descarrega rapidamente, uma vez que os níveis de humidade relativa reduzem a performance da pilha e o oxigénio que entra na pilha não é suficiente para suportar os pulsos de corrente. Quando retirada da boca a pilha consegue recuperar a sua tensão rapidamente, o que evidencia a influencia destes dois factores na performance da pilha.

Considerando que as pilhas estavam a ser sujeitas a correntes elevadas, tendo em conta o ambiente intraoral, o circuito de descarga foi alterado de forma a reduzi-las, nomeadamente a corrente de base contínua foi removida, permanencendo apenas os picos de corrente. Com estes novos testes, foi possível verificar que nestas novas condições a pilha consegue manter a sua tensão constante, indicando que, de facto, as correntes a que estavam sujeitas anteriormente eram elevadas para o ambiente em questão e que nestas condições a pilha, entre pulsos, tem tempo para armazenar oxigénio suficiente de forma a suportar os picos de corrente. Contudo, ao longo dos testes verificaram-se algumas falhas das pilhas, nomeadamente durante a altura em que os sujeitos a realizar os testes estavam a dormir. Esta falha era acompanhada pela recuperação da tensão das pilhas quando os sujeitos acordavam. Inicialmente, considerou-se que o problema estaria na posição das entradas de ar do invólucro utilizado, uma vez que estas eram facilmente tapadas pela língua, impedindo a entrada de oxigénio na boca. Porém, depois de se fazerem alterações ao invólucro, o mesmo problema persistia, indicando que a falha existente poderá estar relacionada com a respiração do sujeito durante o sono. Por fim, realizou-se um teste em que as pilhas foram sujeitas a correntes que simulavam o consumo do motor juntamente com o microcontrolador. As pilhas conseguiram manter a sua tensão constante, mesmo com pulsos de corrente mais elavada e com maior duração.

Em suma, este estudo demonstra que as Zinco-Ar têm potencial para serem utilizadas no meio intraoral tendo em conta os consumos do aparelho, apesar de serem necessários mais testes.

Palavras-Chave: Expansão Maxilar Automática, Pilhas Zinco-Ar, Testes *in vivo*, Ambiente Intraoral

Abstract

Nowadays, the maxillary expansion appliances with expansion screws still require manual activations. In this project work, an automatic maxillary expansion appliance is proposed. The appliance comprises a microcontroller controlling the activation of a micro motor and its actuator. In order to power these components, an adequate and efficient power source for the intraoral environment is necessary, specifically a non-toxic battery with small dimensions and a good capacity. The Zinc-air cells fit these features and have already been successfully tested *in vitro* through the use of artificial saliva. However, since the intraoral environment is difficult to model, those results might not be reliable. Thus, in this study we intend to test the Zinc-air (Zn-A) cells *in vivo*, that is, inside real mouths.

The tests had two main goals. The first one was to evaluate the Zn-A cells performance inside the intraoral environment and the second was to test the capability of the cells to power an automatic maxillary expansion device considering its power consumption during the treatment. Before performing the tests, we developed a test device suitable for the intraoral environment, including the electronic circuits and a casing with entrances of air covered with a Teflon membrane to allow the air to reach the cells. To place the casing inside the mouth, we decided to fix it to a removable mouthguard. The mouthguards were created through the cast of the participants' teeth and palate with the help of a dentist.

The results from the first tests showed that the high levels of Relative Humidity (RH) and the slow oxygen diffusion have a great influence on the performance of the cells. The limiting current of the cell is lower in the intraoral environment than in the outside, and consequently, the cells can not handle pulse loads as well. Besides that, it was observed that when the cells were removed from the intraoral environment, their voltage recovered rapidly, evidencing the influence of those two cited variables. Nonetheless, when the average load current of the discharge circuit was decreased, the cells were able to maintain their voltage constant during an undetermined time. When considering the current consumptions of the automatic device, which involved higher pulse currents with a longer duration, the cells were also able to support those currents. Thus, this study supports the use of Zn-A cells in the intraoral environment.

The limitation of this study was a problem detected during sleep, that is, in the majority of the tests, the cells failed when the subject was asleep, only recovering after waking up. This observation doesn't invalidate the use of the cells in the intraoral environment, but more studies must be done.

Keywords: Automatic Maxillary Expansion, Zinc-Air Cells, *in vivo* tests, Intraoral Environment

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Abbreviations

Zn-A Zinc-air

HPT High Power Test

SME Slow Maxillary Expansion

RME Rapid Maxillary Expansion

ADC Analog-to-Digital Converter

RH Relative Humidity

Li-ion Lithium ion

PCB Printed Circuit Board

PWM Pulse-Width Modulation

MOSFET Metal Oxide Semiconductor Field Effect Transistor

RPM Revolutions Per Minute

PLA Polylactic acid

PTFE Polytetrafluoroethylene

List of Symbols

O_2	Oxygen
H_2O	Water
OH^-	Hydroxide ion
Z_n	Zinc
Z_n^{2+}	Zinc ion
$Z_n(OH)_2$	Zinc hydroxide
Z_nO	Zinc oxide
e	Electron
$\rightarrow$	Net forward reaction
E^0	Standard reduction potential

Chapter 1

Introduction

1.1 Motivation

In the orthodontic branch of dentistry, posterior crossbites are common malocclusions with a prevalence of 7% to 23% [1, 2]. This problem is usually corrected by performing a maxillary expansion, which involves the utilization of an orthodontic expander on the maxillae.

Nowadays, to carry out a maxillary expansion, several appliances with different activation methods can be used. These methods can vary between the use of springs, screws, magnets or other materials, all of which being capable of applying sufficient force to provide the maxillary expansion, but with different magnitudes which lead to different treatment durations [3]. From the diversity of appliances, the most used and the ones which can provide a faster treatment have a screw-type activation. The screw is activated by turning a key, which will allow the expansion of the appliance, thus opening the suture and separating the bones. After a few weeks, this will result in the desired maxillary expansion.

The first use of the appliance with an expander screw was in the mid-19th century [4]. Since then, this type of appliance has not been improved significantly, staying merely mechanic and depending on a manual activation to perform the expansion. This latter feature is one of the major disadvantages of the appliance. Moreover, due to the mechanical nature of the expander, there is the need to go to the dentist more often to make some adjustments or to replace some of its parts.

Therefore, it is necessary to design a new device which removes the need for a manual activation and that exploits the new existent technologies, namely related to mechanics and electronics. Nowadays, we have already motors of small dimensions, in the millimeter-order, denominated by micro motors. Thus, the use of this motor, along with a microcontroller, controlling its activation, makes it possible to develop an automatic maxillary expander.

1.2 Objectives

The principal goal of this thesis is to work towards the development of an automatic maxillary expansion appliance. This appliance will be comprising a microcontroller and a micro motor, which will allow the automatic activation of the device by being controlled by the first one.

Before designing and prototyping the appliance is necessary to study the best energetic solution, that is, an appropriate battery to power the components since the device will not function as desired without an efficient solution. In this case, the battery constitutes a problem, because the intraoral environment conditions differ from the ones in which the batteries are designed for, that is, the ambient environment. In addition, the battery has to be small due to the limited space inside the mouth. Thus, the major focus of this thesis is going to be the selection and testing of an adequate battery for the intraoral environment in order to power an automatic maxillary expansion appliance.

Some couple of years ago, Amaral et al. [5] have studied the viability of using Zinc-air (Zn-A) cells in intraoral devices, testing them in an artificial intraoral environment. Their results have shown that using these cells in that environment is an adequate solution.

Although the results pointed to the possibility of using the Zn-A cells in an intraoral device, these cells were not tested in a real environment. Therefore, the primary goal of this project work is to continue the study started in [5] by testing the Zn-A cells in a real intraoral environment. This way, it is going to be possible to conclude whether those cells are in fact an efficient and adequate solution to power the electronics of the device, inside a mouth.

Two different experiments are going to be made to achieve this:

- Evaluate the performance of a cell in a real intraoral environment.
- Test the capability of the cell to power the automatic maxillary expansion appliance.

A test device needs to be developed to perform these experiments in a real intraoral environment. This device needs a casing capable of partially isolate the cells and the electronics from the oral cavity, to avoid the direct contact between them. After having the test device, the tests are going to be performed with the help of an orthodontist that will be applying the device on the participants' teeth.

1.3 Contributions

The Zn-A cells were never tested inside a real intraoral environment, so this project work will provide new knowledge about the performance of those cells *in vivo*. Also, an article was written to be submitted for Journal of Medical Devices from The American Society of Mechanical Engineers.

1.4 Thesis Outline

This thesis is divided into six chapters, this introductory chapter and five more.

The chapter 2 is dedicated to the maxillary expansion. The chapter begins with a brief anatomical introduction of the maxillary bones to understand when the maxillary expansion is needed. Then, the treatment itself is explained, addressing the biology processes behind it. Also, different appliances used to perform the expansion are described, giving particular focus to the one with screw-type activation.

Considering one of the disadvantages of the cited appliance, in chapter 3, an improved device is proposed, specifically an automatic maxillary expansion appliance. Besides the concept, the design of the appliance is proposed, taking into account the expansion mechanism and all the components needed. As explained in the previous section, in this thesis, the power source of the device is going to explored, particularly the use of Zn-A cells. The specifications of these cells and the possibility of using them in an intraoral environment are discussed. Finally, the tests which are going to be performed to evaluate their performance in a real intraoral environment are proposed.

Since the tests are going to be performed inside human mouths, in chapter 4, the device which is going to be used to perform the tests is described, including the electronic circuits which are going to be used, the casing and the final assembly of the used appliance.

Then, in chapter 5, all the tests performed are described and the respective results are presented and discussed.

Finally, the conclusions are made in chapter 6, as well as the discussion of possible future work.

Chapter 2

Maxillary Expansion

This chapter addresses the concept of maxillary expansion. In the first section (section 2.1), a brief anatomical introduction is made to understand the need of performing such expansion. The second section (section 2.2) is dedicated to the biological response which occurs during the procedure. Lastly, in the third section (section 2.3), different types of appliances are distinguished.

2.1 Maxillary bone

The maxillary bone is a facial bone located between the orbit and mouth cavities, articulated with other bones, either facial bones - such as the nasal, lacrimal, palatine and zygomatic - or cranial bones, such as the frontal, sphenoid and ethmoid. This bone comprises a body, pyramidal in shape, and four processes: the zygomatic, the frontal, the alveolar and the palatine process, which are identified in Figure 2.1.

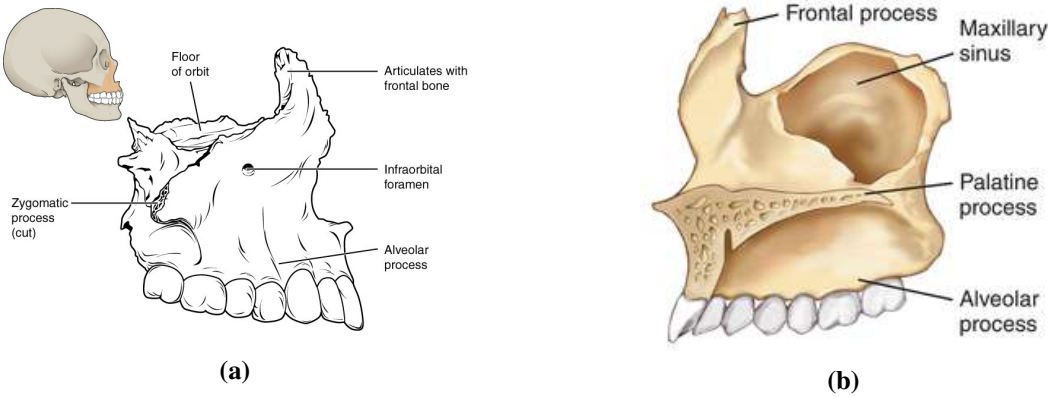


Figure 2.1: Maxillary bone. **(a)** Location of the bone and close-up lateral view. **(b)** Medial view.

- The zygomatic process is a triangular eminence where the maxillary bone articulates with the zygomatic bone.
- The frontal process, which is projected upwards, medialward and backward, forms part of the lateral

wall of the nasal cavity through its medial surface, where it articulates with the ethmoid bone. The upper border of this process also articulates with the frontal bone and the anterior border with the nasal.

- The alveolar process, in the inferior surface of the maxilla, has eight cavities, the teeth sockets, responsible for supporting the roots of the superior teeth.
- The palatine process is a horizontal medially directed projection, which has an upper surface forming part of the nasal cavity and an under surface forming part of the roof of the mouth.

Two lateral maxillary bones, the maxillae, form the upper jaw, which is represented with green in Figure 2.2, and meet through the palatine processes. Theses processes are joined by a suture named median palatine suture, forming the roof of the mouth (the palate), as shown in Figure 2.3 [6]. The articulation of these two bones also forms the alveolar arch or maxillary arch, where the superior teeth are housed (also seen in Figure 2.3).

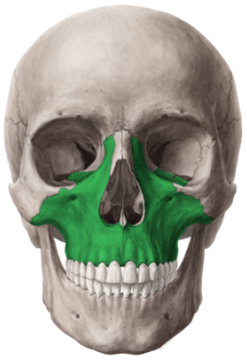


Figure 2.2: Upper jaw (green). ([7])

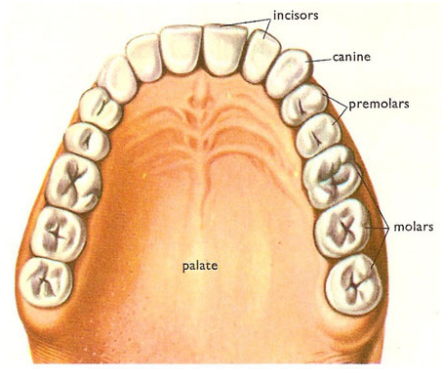
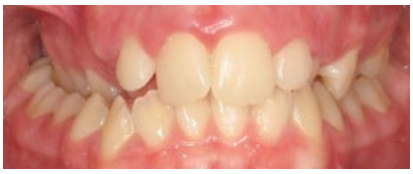


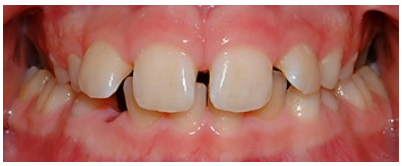
Figure 2.3: Roof of the mouth (palate) and identification of the upper teeth ([8])

The lower jaw, the mandible, also has an alveolar process, forming the mandibular arch, where the inferior teeth are held. Although the maxillary bones are not articulated with the mandible, they are related through the dental arches. In normal conditions of bone growth, the superior dental arch is a bit wider and larger than the inferior one, to provide a proper occlusion when closing the mouth. However, skeletal discrepancies can occur due to deficiencies during bone growth, giving rise to skeletal malocclusions [9]. One example is the transverse maxillary deficiency, which can lead to a posterior crossbite when the upper jaw is narrower than the lower one.

The posterior crossbite is the most common transverse malocclusion with a prevalence of 7% to 23% [1, 2, 10]. When the discrepancy between the jaws is only present in one of the lateral sides of the maxilla, it is named unilateral posterior crossbite (Figure 2.4a). On the other hand, when the discrepancy is present at both lateral sides, it is called bilateral posterior crossbite (Figure 2.4b).



(a)



(b)

Figure 2.4: (a) Unilateral ([11]) and **(b)** Bilateral ([12]) Posterior Crossbites

This type of malocclusion can constrict the nasopharyngeal airways, which makes it difficult to breathe through the nose, leading to mouth breathing and causing difficulties associated with mastication. Thus, correcting this condition is not only important on an aesthetic level, but even more in a functional level [13]. The correction of this type of malocclusion passes through the widening of the palate, that is, a maxillary expansion. In the next section, this treatment is described.

2.2 Maxillary expansion treatment

The maxillary expansion consists in increasing the width of the upper jaw by separating the two maxillary bones through the application of forces. The first reference to this kind of treatment was made in 1860 by Angell [4], who introduced the concept of maxillary expansion through the separation of the maxillary bones using a screw-type maxillary expansion appliance. This appliance, illustrated in Figure 2.5, was fixed to the superior teeth and was capable of applying sufficient forces to expand the palate. The expansion was verified by the appearance of a diastema [1] between the upper central incisors after two weeks of treatment.

Figure 2.5: Appliance used in [4]

Because the underlying processes and its consequences were not known at the time, this expansion generated some skepticism. However, with the increase of knowledge about this treatment, more dentists supported this technique and nowadays is a common procedure to correct transverse maxillary deficiencies and other conditions, such as upper teeth crowding.

2.2.1 Timing of treatment

The maxillary expansion should be performed as soon as the malocclusion is diagnosed, since, at an early age, the maxillary bones are not fused yet. This process only occurs after the median palatine suture,

[1] space between teeth

which joins the bones through connective tissue, suffers some morphological changes during the cranial and facial growth [14].

Melsen [15] verified that the suture, during the infantile period, reveals a Y-shape in the frontal section, as illustrated in Figure 2.6A, with the surface of the vomer forming the V-shape. During the juvenile period, the Y-shape of the suture is lost, acquiring a more sinuous course due to the formation of bone spicules on the margins (Figure 2.6B). These bone spicules become more interdigitated during adolescence, creating an interlocked course, as seen in Figure 2.6C. Only later in time, in adulthood, the suture is fused by obliteration of the connective tissue fibers with calcified tissue [15, 16].

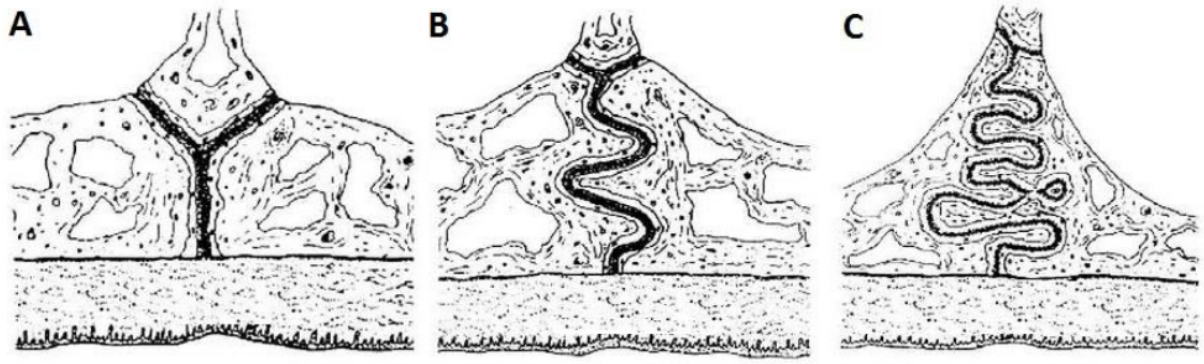


Figure 2.6: Illustration of different stage of the maturation process of the median palatine suture. **(A)** infantile period **(B)** juvenile period **(C)** adolescence period. Adapted from [16]

Therefore, the expansion should be performed within the first stages of the maturation, since there is less resistance to the expansion due to the presence of less calcified tissue. This way, the separation of the suture can be achieved by the application of forces transversal to the suture through the use of an appliance attached to the teeth [17]. Also, the applied forces will move the bone, instead of the teeth. The Figure 2.7 illustrates the way that the suture opens due to the application of such forces. Since the resistance to the expansion is lower in the anterior region of the suture, because there are lesser bone structures, the maxillary bones separate with a V-shape. In the end, the expansion creates a diastema at the incisor teeth as observed in [4].

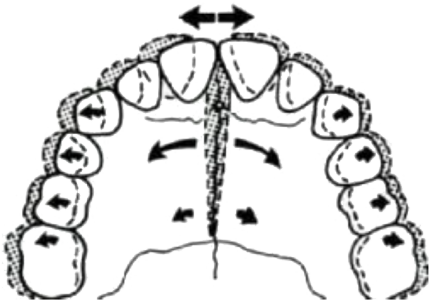


Figure 2.7: Illustration of the opening of the suture during a maxillary expansion. The white part illustrates the initial position of the teeth and the gray the final.

As the stage of the maturation of the suture advances, the resistance to maxillary expansion increases. The higher the resistance to the separation of the maxillae, minor changes occur at the skeletal level (orthopedics), increasing the occurrence of dentoalveolar modifications (orthodontics), when using a maxillary expansion appliance [18]. When the application of forces through the appliance is not sufficient to move the bones, it is necessary to perform surgery to cut the bone, denominated osteotomy, to provide the separation and new bone growth [19].

2.2.2 Biological response to the expansion

When sufficiently high forces are applied, that is, forces which exceed the limit needed for sutural resistance, changes in the sutural connective tissue are induced [20]. Moreover, the median palatine suture is a bone growth site, that is, a region where the formation of new bone occurs in response to external stimuli, such as the application of external forces [14, 21, 22]. Thus, new bone growth will occur to fill the suture's gap created with the separation.

In the first hours, right after the first application of forces, some trauma occurs within the sutural area, leading to disruption of collagen fiber bundles and cell death, such as the death of fibroblasts (fiber-forming cell of the connective tissue, which secrete collagen) [21, 23]. During the next 3 to 4 days, the process of bone formation begins through the pre-existing and undamaged osteoblasts (bone-forming cells) at the suture margins. These cells then form concentric layers of bone along the suture margins. During the following 1 to 2 weeks, the formation of new bone continues, as well as the development of collagen fibers [23]. According to the applied tension, the collagen fibers and cells become aligned transversely across the suture [21].

After completing the desired expansion, bone and suture remodeling occurs until the normal morphology is reached. A retention appliance should be used to promote the conclusion of the bone and suture remodeling in order to avoid the relapse of the expansion. This appliance will also allow the dissipation of residual forces accumulated during the treatment [24].

2.2.3 Types of treatment

If the surgery is not needed, two types of expansion can be performed: Slow Maxillary Expansion (SME) or Rapid Maxillary Expansion (RME). The main characteristics of both treatments are summed up in Table 2.1.

In the SME, the forces involved throughout the treatment are lower than in RME. To achieve the same expansion, the SME treatment will take more time than in the RME.

The higher forces in the RME allow more orthopedic changes, but the process of separating the bones can cause more trauma in the affected tissues than when performing a SME.

Although there are differences between them, both treatments can correct the posterior crossbites. Thus the choice of performing a SME or a RME is made by the dentist, taking into account which one is more convenient for the patient condition, including suture's stage of maturation, and its preference [20].

Table 2.1: Comparison between rapid and slow maxillary expansion treatments using a screw-type appliance

Rapid maxillary expansion	**Slow maxillary expansion**
Applied forces with magnitudes up to 100 N [19, 25]	Applied forces with 2 to 20 N of magnitude [19, 25]
1 to 3 weeks of treatment [19, 25]	7 to 15 weeks of treatment [26]
Maximum skeletal movement [20, 27]	Produce more orthodontic modifications [27]
Microtrauma may arise [20]	Better tissue adaptation [27]

2.3 Maxillary expansion appliances

Different types of appliances are used today to perform the maxillary expansion. Considering their activation method, they can be divided into four categories [3]:

- spring-type appliances: composed by springs. One example can be seen in Figure 2.8.

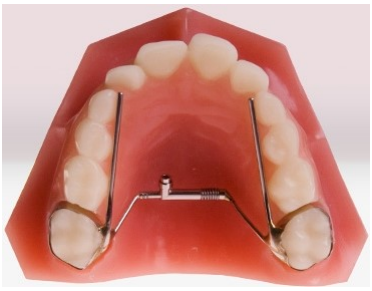


Figure 2.8: Spring-type appliance.

The spring will be compressed and when applied on maxillae, it will exert an opposite force to that deformation, perpendicular to the line of the median palatine suture. The applied forces may vary between 2.4 and 3.9 N decreasing its magnitude with the displacement, as shown in Figure 2.9. Thus, if the resultant expansion is still not the one desired, the appliance has to be adjusted to provide more expansion [3].

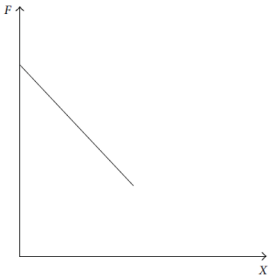


Figure 2.9: Applied force throughout the expansion with a spring-type appliance [3]

- magnetic appliances: with incorporated magnets which will apply opposing forces, perpendicular to the line of the median palatine suture, allowing the maxillary expansion [28]. It can generate forces of 2.5 to 5 N, which will also decrease with the expansion, as shown in Figure 2.10 [20].

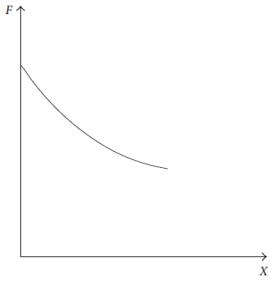


Figure 2.10: Applied force throughout the expansion with a magnetic appliance [3]

- shape memory alloy appliances: consist of alloys which can be deformed at a temperature lower than its transition temperature. When the temperature is higher than the transition temperature, the alloy returns to its original shape, exerting constant forces that will allow the expansion.

  Some of these appliances are composed by nickel-titanium, such as the one represented in Figure 2.11. This material has a transition temperature of $34\,^{\circ}\mathrm{C}$, adequate for the intraoral environment [29].

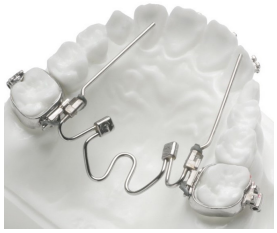


Figure 2.11: Shape memory alloy appliance composed by nickel-titanium [3]

- screw-type appliances: comprise an expansion screw, that expands the device when the person rotates it with a specific key, as illustrated in Figure 2.12.

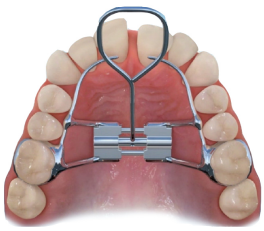


Figure 2.12: Illustration of a screw-type appliance being activated with a specific key [30]

The treatment consists of activating the expansion with a determined frequency depending on the clinical case. The screw-type appliances provide a different force-displacement relation compared

to the previous ones. As the screw is rotated, the force increases (magnitude peaks shown in Figure 2.13a). Within the next hours the force decreases, but as the screw is rotated once more the applied force increases again, now with accumulated forces. Thus, a higher frequency of activation, will lead to greater applied forces.

(a) **(b)**

Figure 2.13: Applied force by a screw-type appliance throughout the expansion. **(a)** Applied force by a screw-type appliance over the time. **(b)** Expansion provided by a screw-type appliance over the time. [3]

The first three devices are used when the dentist wants to perform a SME because the appliances can't produce forces of high magnitude. In the screw-type appliances, the activation of the screw can be controlled. This way, it is possible to perform either a SME or a RME. In the first case, the screw is activated two to three times a week, while, in the second case, the activations increase to two times a day.

Due to its versatility, the screw-type appliance is the most used among dentists. Thus, they will be the focus of this thesis. The next section is dedicated to the evolution of this type of appliances.

2.3.1 Evolution of Screw-type appliances

As referred earlier, the first reference to the concept of maxillary expansion was in [4], where the first screw-type maxillary expansion appliance was introduced. The appliance, illustrated in Figure 2.5, comprised a jackscrew that could be rotated by a specific key to provide the application of forces.

Although the concept of maxillary expansion was introduced through this study, namely the RME, the popularization of this method was done some years after with the studies of Haas [31, 32]. In 1961, Haas [31] improved the appliance proposed in [4]. It consisted of an expansion screw activated by a key as well, but instead of having the appliance only anchored to the teeth, the author suggested a dento-mucosal support, that is besides the dental support, the appliance also had an acrylic plate covering the mucosa of the palate (Figure 2.14). This way, the appliance besides applying force on the teeth, applied force on the bone as well.

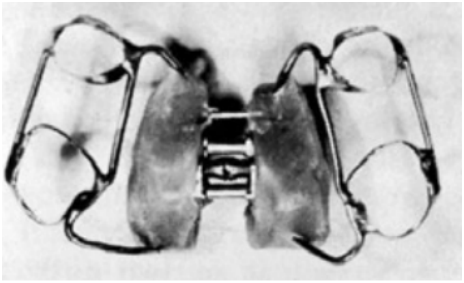


Figure 2.14: Appliance used in [31]

In [31], the author tested the new appliance in 45 individuals (9 to 18 years old) with maxillary insufficiencies. The treatment consisted of activating the appliance twice a day (each activation: 1/4 turn $\approx$ 0.2 a 0.25 mm) until reaching the needed expansion. After that, the appliance was retained for 3 months without activations to allow the bone formation at the suture and to avoid relapses. During the expansion, the participants reported some pressure at the alveolar processes and palate. The pressure was higher during the activation of the appliance, then, after some minutes, it was dissipated. Regarding the results of the expansion, after 10 to 14 days the distance between the second/third molar teeth was 5.5 mm, maximum, and 1.5 mm, minimum. The expansion resulted in the separation of the upper central incisors, forming a diastema. Also, some adverse reactions in the soft palate, such as moderate hypertrophy, due to the direct contact between the acrylic plate and the palate.

In 1964, Isaacson and Ingram [24] carried out a study about the forces present when using a Haas-type appliance. Five participants (8 to 15 years old) used this appliance together with a dynamometer to measure the applied forces throughout the expansion. When the appliance was first activated (1/4 turn like in [31]), forces with magnitude from 1.36 to 4.53 kg of force were generated, reaching 10 kg (100 N) of force after 15 days, due to force accumulation. The authors considered that this accumulation is the origin of the pressure felt by the participants all over the face, including the nose. Besides that, the load produced per activation was lower in the younger participants than, the older ones, which indicates that the resistance to expansion is higher as the person grows. Thus, a lower applied force would be sufficient to perform the expansion in the younger.

Posteriorly, the Haas-type appliance was considered as unclean, since the acrylic plate covers the palate making it difficult to clean. Also, sometimes adverse reactions occured in the soft tissue of the palate. Considering this problem, in 1968, Biederman [33] developed an appliance named Hyrax (Hygienic appliance for rapid expansion). The activation method of this device is similar to the one in [31], i.e. it uses an expansion screw, but instead of being dento-mucosal supported, it is only dental supported, as shown in Figure 2.15, which facilitates the cleaning process.

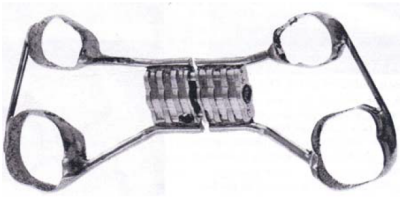


Figure 2.15: Hyrax appliance [34]

The concept of this appliance is similar to the Haas-type appliance. Thus, the results obtained by both appliances regarding the increase of the maxilla doesn't seem to differ significantly [35, 36]. Some values obtained using these appliances are shown in Table 2.2.

Table 2.2: Short time expansion (right after the expansion) and long time expansion (two or more years after the retention period) verified in different studies. The expansion value corresponds to the difference between the molar teeth (intermolar distance).

Expansion type	Appliance	Short time expansion	Long time expansion	Reference
Slow	Haas	5.3 mm	4.0 mm	[25]
Slow	Hyrax	4.7 mm	3.6 mm	[25]
Rapid	Hyrax	8.0 mm	3.6 mm	[37]
Rapid	Haas	4.4 mm	N/A	[38]

Over the time, other appliances similar to the Hyrax and Haas-type have emerged, only changing their support. For example, in 1973, Cohen and Silverman [39] constructed an appliance with dental support using acrylic covering the teeth (Figure 2.16). This way, teeth inclination during the expansion process is avoided, which sometimes happens when using the other appliances. In addition, the placement is more simple with this appliance compared to the others [20]. In 1977, Mondro and Litt [40] came up with a better solution to place and to remove the appliance, which involved only the expansion screw and acrylic. In this case, the wires between the expander and the acrylic didn't exist. The acrylic involved the teeth and was extended to the middle of the palate where the expander was incorporated.

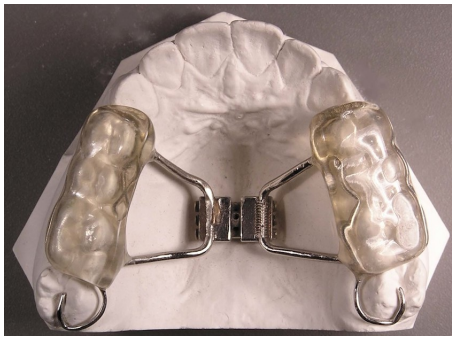


Figure 2.16: Appliance with the Cohen and Silverman design [41]

Later, in 2004, Wichelhaus, Geserick and Ball [42] proposed an appliance similar to the Hyrax, but with wires of nickel-titanium instead of stainless steel, to reduce the application of forces with high magnitude. The authors tested the appliance in the Instron universal testing machine and observed that when the appliance was activated six times a day, the magnitude of the force applied was between 12 and 14 N [43].

More recently, in 2011, Halicioğlu, Kiki and Yavuz [43] tested an appliance with the same characteristics as the one in [42], in five individuals, with a mean age of 12.88 ± 0.76 years old. The treatment consisted in activating the screw with 2/4 turn (0.4 mm) 3 times a day. The mean time of the treatment was 7.52 ± 1.04 days, with a retention period of 6 months. After this time, zero relapses were registered. Thus, the authors considered that this way of combining a rapid expansion (regarding the treatment time) and slow (related to the applied forces) produce similar results compared with the other appliances, but in less time ($\approx$ 1 week).

Nowadays, the Hyrax appliance and its variants are the most used [3]. Although improvements have been made, namely related to the applied forces and the support, these appliances still have a common disadvantage, which is the manual activation of the screw. These appliances demand the user to keep track of the activations performed to follow the recommended treatment. Thus, if the patient forgets to activate the appliance, the results can be compromised. Moreover, the user usually is a child, so the parents have to be in charge of the activation. Therefore, creating an automatic appliance would remove the intervention of the user/parent, facilitating the treatment. The next chapter is dedicated to this type of appliances.

Chapter 3

Automatic Maxillary Expansion Appliance

In this chapter, the concept of an automatic maxillary expansion is introduced (section 3.1). In section 3.2, an automatic maxillary expansion appliance is proposed, giving particular attention to its power source in section 3.3.

3.1 Concept

As the name implies, an automatic maxillary expansion appliance should be able to be expanded automatically, allowing a maxillary expansion without the user intervention. Since the automatic apparatus removes this intervention, the frequency of activation can also be increased, so the applied forces per activation can be decreased, allowing a more comfortable expansion for the user.

At the moment, there aren't automatic maxillary expansion appliances in the market, but Sharizli et al. [44, 45] have proposed one appliance with such characteristics. The schematic of the appliance proposed by the authors is represented in Figure 3.1. As seen, the Hyrax screw is integrated with a micro motor, micro gear and a microcontroller to transform its activations into automatic. The expander activates the screw through the micro motor, which in turn is controlled by a microcontroller. This way, the user doesn't need to activate the appliance and with the micro motor it is possible to control the applied forces, in such a way that these can become lighter and more continuous.

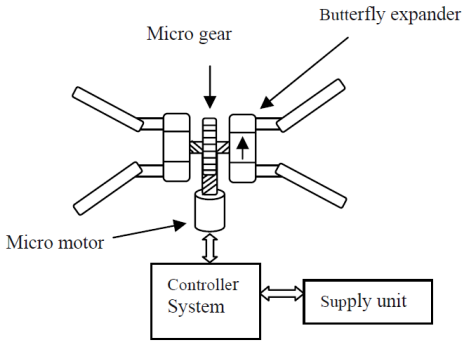


Figure 3.1: Schematic of the automated rapid maxillary expander [44].

The authors divided the construction of the prototype in five different phases ([44]):

1. Preliminary design: deciding how to activate the screw without a manual activation and deciding the materials to use, including the micro motor, the micro gear and the microcontroller.
2. Mechanical modifications: changing the Hyrax appliance to incorporate the micro gear.
3. Design of the microcontroller system: design of the Printed Circuit Board (PCB) with the components required to control the expander.
4. System integration: Integration of all components: microcontroller system, micro motor and the modified Hyrax - Figure 3.2.
5. Testing the prototype.

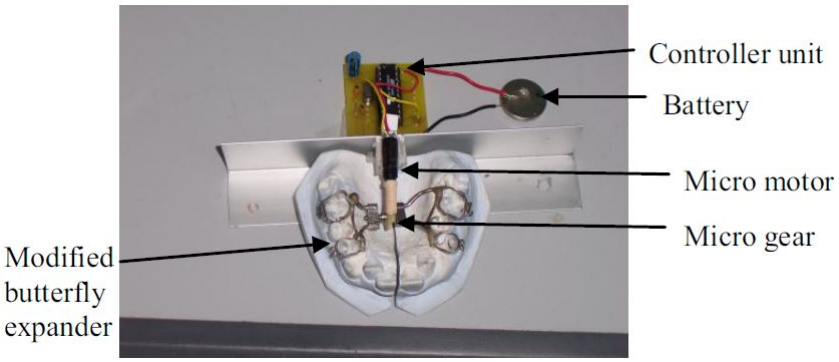


Figure 3.2: Automated rapid maxillary expander [44]

In 2009, the first tests of the prototype were performed in a maxilla model (the one shown in Figure 3.2). The tests consisted of applying forces in one direction (x direction), which resulted in a translation in the same direction. The force applied to the four teeth in which the appliance was anchored (upper first premolar and molar teeth) was measured. Each test had a duration of 5 days in which 10 activations (twice daily) of 90° were performed. Ten tests were carried out with the results showing that the force was constant throughout the days between 0.3 and 0.4 N [45].

3.2 Proposal

Considering the previous study as a proof of concept, we decided to improve the automatic maxillary expansion appliance. The concept is similar, that is, we intend to use a microcontroller and a micro motor with the adequate gear to allow the automatic expansion, but without using the Hyrax screw.

Our proposal comprises an automatic expansible casing which will be anchored to the teeth (tooth-borne) through the use of wires (of stainless steel, for example). The housing can be fixed to four teeth, the two superior premolar and two molars, just as in a Hyrax or Haas appliance (Figure 2.14, Figure 2.15).

This way, as the casing starts to expand, the device will apply forces transversely to the line of the suture, which will lead to the desired expansion.

The Figure 3.3 represents our design proposal for the automatic maxillary expansion appliance designed with SolidWorks. The expansible casing comprises two parts which will slide against each other to provide the expansion. This casing will also support the components of the device and isolate them from the intraoral environment.

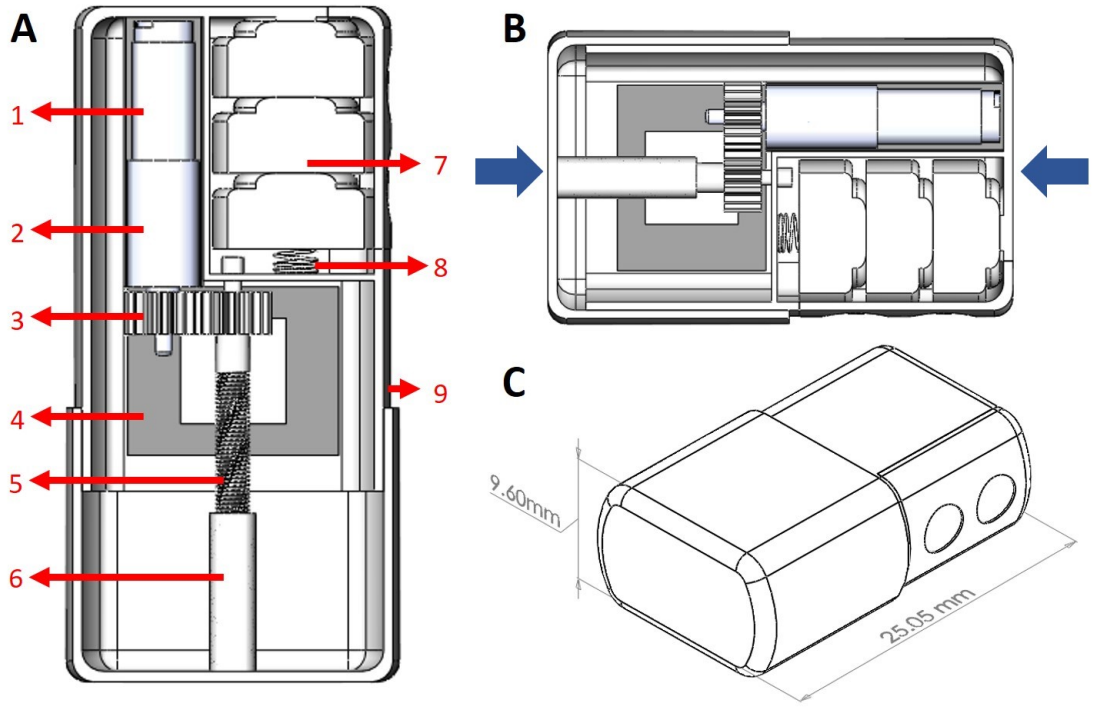


Figure 3.3: Automatic maxillary expansion appliance design. **(A)** Top section view (appliance expanded) **1.** Micromotor (0308B Faulhaber) **2.** Gearhead (03A) **3.** Micro gears **4.** Microelectronics (PCB) **5.** Screw **6.** Cylindrical nut **7.** Battery **8.** Spring to fix battery **9.** Casing. **(B)** Top section view (appliance closed). The blue arrows indicate the region where the wires can be placed to anchor the appliance to the teeth **(C)** Isometric view.

The dimensions of the appliance are 25.05 x 15.84 x 9.60 mm^3, which increases to 32.05 x 15.84 x 9.60 mm^3 when expanded. The linear actuator used here allows an expansion of 7 mm, but this can be increased according to the expansion needed. Moreover, in Figure 3.3B, it is possible to see the region where the wires can be placed to anchor the appliance to the teeth (indicated by blue arrows) and in Figure 3.3C are represented two holes that were designed taking into consideration the performance of the cells selected in section 3.3.

Regarding the material in which the casing as to be constructed, it has to be one compatible with the intraoral environment, in particular, one metal with good corrosion resistance. We suggest the use of austenitic stainless steel, which is a non-magnetic stainless steel with 18% chromium and 8% nickel. Its composition enhances the corrosion resistance. This metal is also referred as surgical stainless steel, which is used for biomedical implants and is already used in dentistry for dental crowns, for example,

[46]. Although there are other metals with greater resistance to corrosion, such as gold or platinum, the costs involved are higher.

In the CAD model, we have a micro motor (1) with its gearhead (2) attached to a micro gear (3). To minimize the dimensions of the appliance, the micro motor is not centered, but we added spur gears to align the linear actuator (5/6) with the center of the appliance. This way, the applied force is well distributed to allow the two parts of the appliance to slide against each other easily. The expansion is possible because the casing of the appliance is composed of two parts. One that houses all the components and the second one with a nut (6) which will be connected to the screw (5) of the linear actuator. When the motor is activated the screw rotates and the nut, which is fixed to the other part of the casing, will move linearly along the screw, providing the expansion.

The microelectronics (4) comprise a PCB with a motor driver and a microcontroller needed to control the motor. The powering of all components is ensured by a battery (7). These components, including the motor as well, will be described in the following subsections.

3.2.1 Motor (1)

The motor is needed to perform the automated expansion. In this case, as we are designing an intraoral medical device, we need to take into consideration the limited space inside the mouth. Thus, a motor with small dimension is required, namely a micro motor. For our application, we are going to use the brushless DC micro motor 0308B from Faulhaber which was previously chosen by the team working on this project. This motor, shown in Figure 3.4, is a 3-phase motor, has a diameter of 3 mm, a length of 8.4 mm and weights 0.31 g.

Figure 3.4: 0308B micromotor from Faulhaber [47]

This motor can be powered by batteries, having a nominal low voltage of 3 Volts, which allow us to avoid high voltages inside the mouth. The brushless motors have permanent magnets which rotate around a fixed armature, as illustrated in Figure 3.5. When electrical current powers a permanent magnet, the motor will move, so no physical commutator (brush) is necessary. An electronic controller can be used to continually switch the phase to the windings to keep the motor turning [48]. This technology increases the reliability and lifetime of the motor since it is less susceptible to mechanical wear [49].

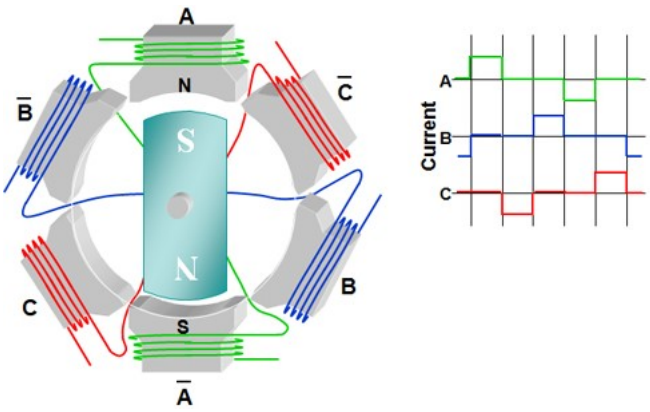


Figure 3.5: Mechanism of a brushless motor.

Another advantage of the brushless DC motor is their high torque per weight ratio (sensitivity). The 0308B micromotor can reach a torque of 0.023 mNm (miliNewton meter) at 15000 Revolutions Per Minute (RPM). Adding a linear actuator, with a gearhead of 125:1 reduction ratio, the motor can provide a force up to 2.8 N or 4.2 N in continuous or intermittent mode, respectively. The Figure 3.6 shows the motor with its linear actuator. In this configuration, the maximum diameter is 3.4 mm and the length is 22.85 mm.

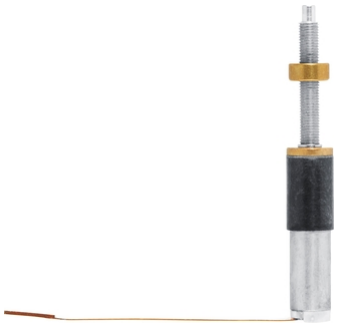


Figure 3.6: 0308B micromotor from Faulhaber with its linear actuator [47]

3.2.2 Microelectronics (4)

To control the motor previously described, we need a motor driver and a microcontroller.

3.2.2.1 Motor driver

In order to move the motor, it is necessary to provide power to each phase in a correct sequence. We can program the desired sequence in a microcontroller, but it doesn't have the necessary current per pin used by the motor. Thus, to simplify the problem, we can use a driver that can control the power to provide to the motor and, at the same time, generate automatically the sequence for each phase. A possible motor drive that can be used is the MTD6505 from Microchip, which is a 3-phase full-wave sensorless driver for brushless DC motors. The Table 3.1 describe the principal characteristics of this driver.

Table 3.1: Specifications of the motor driver

Power Supply Voltage	$2 - 5.5\ V$
PWM Input Frequency	$1 - 100\ kHz$
Maximum Output Current	$750\ mA$
Max Standby Current	$40\ \mu A$
Max Power Supply Current	$10\ mA$
Dimension	$3 \times 3 \times 0.5\ mm$

The rotational speed and direction of the motor will be controlled by digital input signals (PWM and DIR, respectively). The speed of the motor can be adjusted by changing the Pulse-Width Modulation (PWM) duty cycle and the rotation depends on the DIR pin state. Another digital input pin, the R_{PROG}, is used to configure the electro-mechanical coupling coefficient of the motor ("motor constant") according to the used motor. Through a digital output pin, the FG, it is possible to provide information to an external controller about the speed and phase of the motor.

3.2.2.2 Microcontroller

A microcontroller is an integrated circuit comprising not only a microprocessor but also programmable input/output peripherals, analog-to-digital converter, timers and memory, which allows the information to be read and written in order to store it. One of the microcontrollers' advantages is their low power consumption ($\approx mA$) and their ability to enter a sleep/wait mode which allows a consumption even lower ($\approx \mu$A). This feature is particularly interesting for our application, since we are designing a battery-driven device and because we will only need to activate the motor for a duration of time, cyclically.

There are several microcontrollers available, such as the ones from Intel®, Atmel, and others. The microcontroller available and selected for this project was the MSP430 from Texas Instrument, which has a 16-Bit central processing unit (CPU). The major advantages of these microcontrollers are the ultra-low-power operating modes and their low costs. In particular, the microcontroller selected was the MSP430G2553 [50], which can be powered with 1.8 to 3.6 V, has a 10-Bit Analog-to-Digital Converter (ADC), a flash memory of 16 KB and RAM of 512 B. During its active mode the consumption is about 230 μA, achieving 0.1 μA in its lowest power mode. Depending on the version of the microcontroller, it can have 16 or 24 programmable input/output peripherals. Its size can also vary, for example, the 32-pin version, represented in Figure 3.7, is the smallest one, having the following dimensions: 5 x 5 x 0.9 mm. In this case, the dimension is a critical feature, so this version would be ideal for the application.

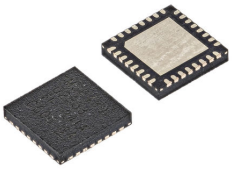


Figure 3.7: MSP430G2553 - 32-pin version [51]

Using the timer of the microcontroller, we can configure it to generate automatically a PWM output to control a DC motor. The activation of the motor is programmed to be periodic and with a determined duration. The microcontroller will control the motor through the motor driver using the pins PWM and DIR.

3.2.3 Battery (4)

To power all the electronics, a battery with a voltage similar to the nominal voltage of the components is recommended. Since the appliance is going to be used inside the intraoral environmental, its selection has to be carefully done taking into account:

- its composition, to avoid toxic materials;
- its size and capacity, because we have limited space but still need to have sufficient capacity to power the electronics;
- the environment conditions in which the battery is going to operate (intraoral) since some conditions may influence its performance.

As the power source is such an important component of this appliance, the next section of this chapter is dedicated to it.

3.3 Power Source

A wide variety of medical devices, such as hearing aids, cardiac pacemakers and other implantable devices, is powered by internal batteries [52]. Over the years, these devices have been designed to be smaller and lighter to minimize the user's discomfort. Since the battery is responsible for occupying a large fraction of the device's volume, from 25 to 60% [53], the design of smaller devices, inevitably, passes through the selection of batteries with a high volumetric energy density [54]. Usually, the Lithium and Lithium ion (Li-ion) batteries are selected because they have high energy density, both gravimetric (small) and volumetric (light) and a reasonable lifetime [55].

When dealing with battery-powered intraoral medical devices or systems, the device's size is also an important consideration to take into account during its design, because a bulky device will affect the user's phonetics and mastication. The lithium technology has also been used in this type of devices as

shown in Table 3.2, but the possibility of using coin shaped Zn-A cells as batteries for intraoral medical devices was exploited in [5].

Table 3.2: Batteries used in intraoral medical devices and wireless systems (including some prototypes)

Device	**Reference**	**Battery type**	**Dimension** mm^3	**Nominal Voltage** V	**Typical Capacity** mAh
Automatic Mandibular Distraction	[56]	Li-ion (Rechargeable)	21 x 31 x 3.7	3.7	120
Tongue Computer Interface	[57]	Li-ion (Rechargeable)	11.5 x 18 x 2.8	3.7	20
Intraoral Tongue Drive System	[58]	Li-ion (Rechargeable)	18 x 24 x 3.5	3.7	110
Arch-Shaped Intraoral Tongue Drive System	[59]	Li-ion (Rechargeable)	12 x 15 x 5	3.7	50

Although these cells are not rechargeable and have a shorter lifetime than the Lithium ones, considering an automatic maxillary expander, the device doesn't need a lifetime as high as a pacemaker needs, because the usage is limited to a period of time [60]. Thus, in these cases, it is possible to abdicate from a higher lifetime in order to choose a smaller and lighter battery, since the Zn-A cells have a higher volumetric and gravimetric energy density than the majority of primary (see Figure 3.8) and Li-ion (secondary) batteries. The last ones have an average volumetric and gravimetric energy density of 400 Wh/l and 150 Wh/kg, whereas the Zn-A cells have 1500 Wh/L and 400 Wh/kg, respectively.

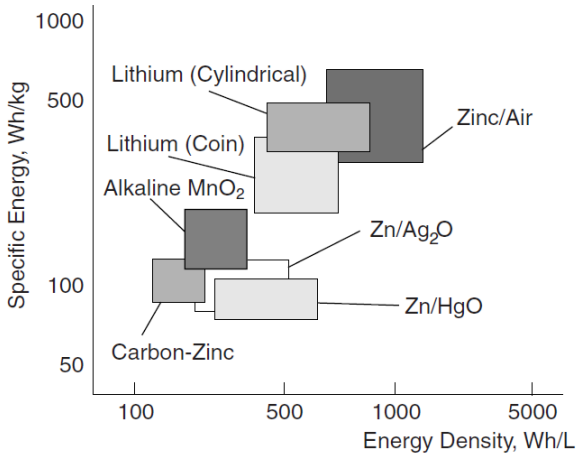


Figure 3.8: Energy density comparison between different types of primary batteries [60]

Considering these features of the Zn-A cells, in the following subsections, the characteristics of the Zn-A cells are described and the possibility of using these cells in the intraoral environment is also discussed.

3.3.1 Zinc-Air Cells

The Zn-A cells are primary cells which, as the name implies, can provide electrical power through the interaction of the zinc, inside the cell, and the atmospheric oxygen. These cells have been used in some medical devices, namely in hearing aids, and in telemetry devices [60].

Overall characteristics of the Zn-A cell [60–63]:

- Light. Has one of the highest gravimetric energy densities ($\approx$ 400 Wh/kg) compared with other cells (Figure 3.8), making the cell light.
- Small. Has a volumetric energy density of $\approx$ 1500 Wh/l, because the cell volume is almost filled only by zinc. This feature allows the construction of a cell with small dimensions. In Table 3.3 the dimensions of the coin shaped Zn-A cells are registered, as well as some other specifications.

Table 3.3: Zinc-air cells specifications

Type	**Model**	**Diameter**	**Height**	**Weight**	**Nominal Voltage**	**Nominal Capacity**
	(ANSI)	(mm)	(mm)	(g)	(V)	(mAh)
10	7005ZD	5.8	3.6	0.3	1.4	70 a 100*
312	7002ZD	7.9	3.6	0.6	1.4	134 a 180*
13	7000ZD	7.9	5.4	0.9	1.4	260 a 300*
675	7003ZD	11.6	5.4	1.8	1.4	600 a 650*

* Range based on the values of the following manufacturers: Duracell® [60], Rayovac® [60] and Power one [64].

- Discharges with constant voltage. Has a constant internal resistance.
- Long shelf life. With the tab sealing the holes (that is, without entrance of air and other gasses), it loses 2% of its capacity in one year (store at $+21\,^{\circ}\mathrm{C}$).
- Short lifetime. When activated, the constant air exposure and the environmental conditions will discharge the cell, even when in open circuit.
- Limited power output. A higher air disposal, will allow a higher output power, but a shorter lifetime. Thus, it is important to establish a trade-off between the two variables.
- Safe and ecological. The zinc is fairly non-toxic and the quantity inside the cell is small.
- Low cost.
- Dependent on environmental conditions. Its performance varies with temperature and Relative Humidity (RH).

The Zn-A cell comprises:

- Anode: zinc powder and electrolyte;
- Cathode: catalyzed carbon;
- Electrolyte: Potassium hydroxide.

The cathode case has air entrances (identified as air hole in Figure 3.9), which are sealed by a tab. When this tab is removed, the atmospheric oxygen flows into the cell. Then, the oxygen diffuses through a Teflon membrane and comes in contact with the cathode, which reduces it. Afterward, the reduced oxygen interacts with the anode, releasing electrons (Equation 3.1). From the global reaction, theoretically the cell produces 1.65 V, but in practice, this value is approximately 1.4 V [60].

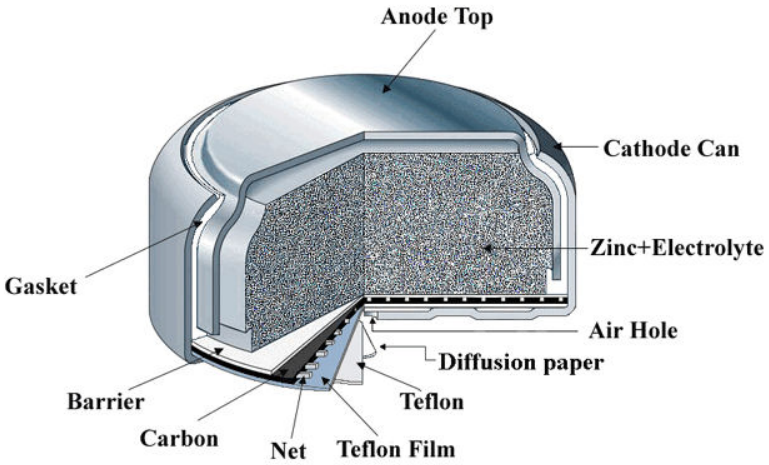


Figure 3.9: Zinc-air cell components. Adapted from [65]

$$
\begin{aligned}
&\text{Cathodic Reaction:} && \frac{1}{2}O_2 + H_2O + 2e \rightarrow 2OH^- && E^0 = 0.40V \\
& && Z_n \rightarrow Z_n^{2+} + 2e && \\
&\text{Anodic Reaction:} && Z_n^{2+} + 2OH^- \rightarrow Z_n(OH)_2 && E^0 = 1.25V \\
& && Z_n(OH)_2 \rightarrow Z_nO + H_2O && \\
&\text{Overall Reaction:} && Zn + \frac{1}{2}O_2 \rightarrow Z_nO && E^0 = 1.65V
\end{aligned}
\tag{3.1}
$$

The oxygen consumption is a major factor for the cells' operating current, being directly proportional. The oxygen transfer rate is dependent on the air holes' dimensions so larger holes would allow a higher operating current capability. However, due to other gasses transfer, namely water vapor, which has a degradable impact, usually, these holes are small, to balance both transfer rate. Another variable regulating the oxygen and water vapor transfer rates is the porosity of the diffusion membrane, which together with the holes' size set a maximum continuous-current capability for the cells (limiting current) [60]. Thus,

the limiting current is dependent on air availability and the environmental conditions, mainly the relative humidity, which will influence the water vapor transfer rate (more details in the next sections).

The cell discharges with a constant voltage if the average current doesn't exceed the limiting current even with pulse currents higher than that value. The cell supports these currents because when the load is lower than the limiting current, a reservoir of oxygen builds up within the cell, which allows it to handle higher currents during the pulse. However, the pulses duration must not be too long to avoid oxygen-starvation. In order words, if a single applied pulse has high current and long duration, the electrochemical reaction occurs at a faster rate than the rate at the reservoir of oxygen builds up within the cell; consequently, the cell runs out of oxygen and the voltage declines. Also, if the limiting current is exceeded the cell becomes oxygen-starved and the voltage decreases [60].

3.3.1.1 Effects of environmental conditions

As stated before, the performance of the Zn-A cells depends on the environmental conditions, namely the temperature and humidity levels.

The temperature will influence the performance of the cell as follows: low temperatures reduce the ionic mobility, diminishing the capacity of the cell (Figure 3.10). In addition, the voltage also varies with temperature. Fixing the current, if the temperature is lower than the optimal temperature, the cell's voltage is going to decrease, as seen in Figure 3.10. The optimal temperature to discharge the cell is between 10 and $40\,^{\circ}\mathrm{C}$ [60].

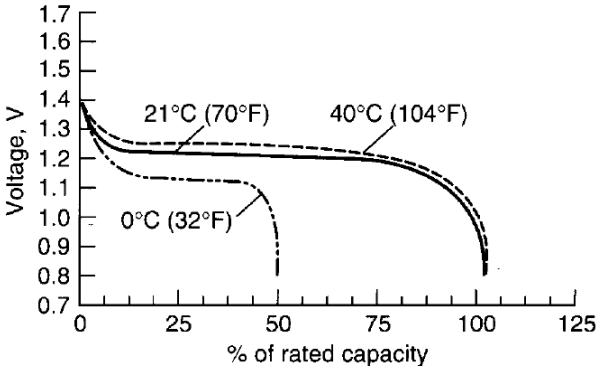


Figure 3.10: Temperature effect on Zn-A cells [60]

Regarding the humidity, extreme levels (either too high or too low) affect the cell's performance negatively. Considering a typical electrolyte (potassium hydroxide concentration of 30%), the cell will lose water if the RH is lower than 60% and will accumulate water if it's higher than 60% (Figure 3.11), decreasing the lifetime of the cell or its power. The loss of water increases the concentration of the electrolyte, making it difficult to maintain the discharge reaction. Also, the gain of water dilutes the electrolyte, decreasing its conductivity [60].

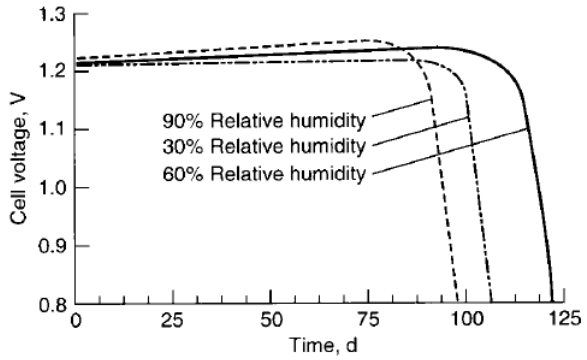


Figure 3.11: Relative Humidity effect on Zn-A cells (at +21ºC) [60]

3.3.2 Zinc-air cells in an intraoral environment

The intraoral environmental conditions vary throughout the day mainly due to the secretion of saliva, which can reach 2 liters per day with a higher flow rate in the afternoon than in the morning [66].

The RH varies from 80% to 95% throughout the day, depending on the mouth region [67]. For example, Saraiva et al. [68] verified that the RH is higher in the molar site (RH $\approx 90.8\%$) than the incisor site (RH $\approx 84.8\%$). Regarding the temperature's variation, it also varies throughout the day between 30 and 36 °C [69, 70].

Comparing these values with the optimal values of temperature and RH of the Zn-A cell, the temperature of the intraoral environment is not going to influence the discharge profile. The same doesn't happen when analyzing the RH of the mouth because it's much higher than the optimal value. Thus, the water vapor transfer rate will influence the performance of the cell negatively, decreasing its limiting current and the capacity of the cell as described previously.

3.3.2.1 *in vitro* intraoral environment

In order to preview the discharge profile of the Zn-A cells under an intraoral environment, some *in vitro* tests were made in [5]. This project work had the goal of studying the feasibility of using these cells in intraoral medical devices. The authors started by analyzing the discharge profile of 312 Zn-A Rayovac® cells performing the HPT:

1. under three different levels of RH: 50, 70 and 90% at 37 °C. The levels of RH and the temperature were controlled by a climatic chamber.

2. at ambient temperature and RH, but placed inside a metallic holder with an air entrance covered by a Teflon membrane.

3. the same as the last one but with the presence of artificial saliva. The holder was submerged in the artificial saliva for 20 seconds every 2 minutes to simulate the intraoral environment and the secretion of saliva.

According to the manufacturer, the cell needs 83h to discharge performing the HPT under a RH of 50% at +21 °C [71]. In the first test, the authors verified that the mean time to discharge 4 cells was similar between the RH level of 50 and 70% − 80 and 84 hours, respectively − and, as expected, with 90% of RH the cells take less time to discharge − 65 hours −, since this value is more deviated from the optimal value (60%).

The last tests demonstrated that the necessary time to discharge the cell in the presence of saliva (≈ 80 hours) or in ambient environmental conditions (≈ 83 hours) didn't differ that much. However when observing the graphics in Figure 3.12, it is possible to see more voltage fluctuations in the first case (blue line) than in the second (black line). With these results, the authors concluded that, in fact, the Zn-A cells are a suitable solution for powering medical devices inside the intraoral environment.

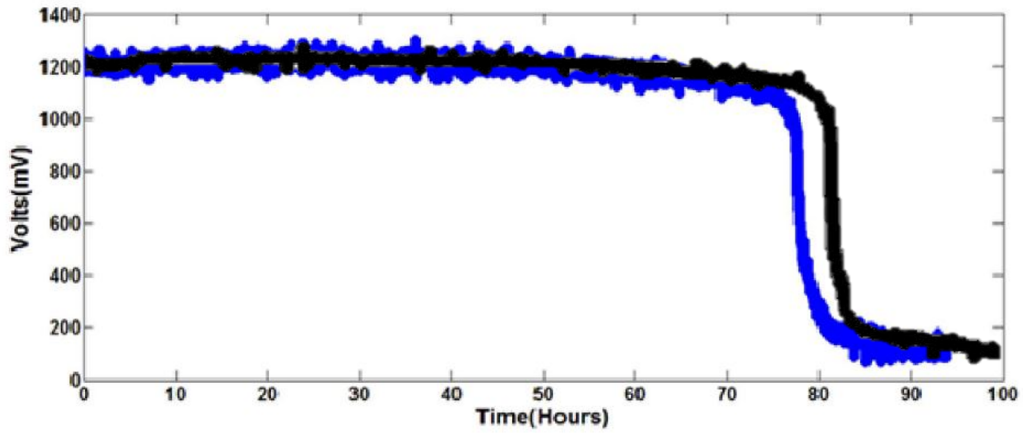


Figure 3.12: Discharge profile of Zn-A cells inside the holder in ambient environmental conditions (black) and in the presence of saliva (blue). Adapted from [5]

3.3.2.2 Proposed Tests

Although those tests were a good preview of the performance of the cells under an intraoral environment, the artificial environment used in [5] is not a true replication of what happens. As described at the beginning of this subsection (3.3.2), the secretion of saliva and the intraoral temperature varies a lot during the day, as well as the RH levels, which also vary between regions in the mouth. In addition, these variables vary between individuals too, which increases the difficulty of modeling this environment. The oxygen availability in the mouth was also not taken into consideration. Thus, it is necessary to perform the same test under a real intraoral environment, i.e. testing inside a human mouth, to validate the earlier findings.

In order to be able to compare the results, we decided to select the 312 Zn-A cells (see Table 3.3), which have been used in the previous study ([5]). More specifically, the cells chosen were the 312 zero mercury from the same manufacturer (Rayovac®) as well, which have a nominal capacity of 180 mAh and the entrance of air is allowed by the existence of three small holes.

To test if the Zn-A cells are suitable to use as a battery for the automatic intraoral appliance, two types

of test are going to be made:

1. Evaluation of the Zn-A cell performance in the intraoral environment using the same discharge circuit as in [5].
2. Evaluation of the capacity of these cells to power the automatic maxillary expander, simulating its current consumption (Simulation test).

The design of these tests is described in the next chapter, as well as the device developed to perform them.

Chapter 4

Test Device Development

In this chapter, the development of the test device used for the two tests proposed previously is going to be described. In section 4.1, the designed electronic circuits used for each test are explained. The section 4.2 is dedicated to the device's casing and finally, in section 4.3, the assembly is described.

4.1 Electronic Circuit

The goal of the electronic circuits is to register and to store the information related to each test. These electronics are going to be used in the mouth, so they need to be small to minimize the discomfort during the performance of the tests. Additionally, they should not have any physical connection to the exterior.

4.1.1 Circuit 1

To evaluate the discharge profile of the cells under intraoral conditions, in this first type of test, we considered the discharge circuit of the High Power Test designed by the cells' manufacturer to allow a more direct comparison of the Zn-A cells performance *in vivo*, *in vitro* and in the ideal conditions. The test consists in discharging the cells with a constant background current of 2 mA and pulses of 10 mA during 100 ms every 2 hours, registering the voltage of the cell over time.

The schematic of the circuit used for this test is represented in Figure 4.1. The circuit is based on the one designed previously in [5]. The cell's discharge circuit is highlighted with red in the schematic. The positive side of the cell will be connected to VCC1 and the negative to the ground (GND). The resistor R1 will be drawing 2 mA of current from the cell during the test. In parallel with the resistor R1 is the R2 which together will draw 10 mA.

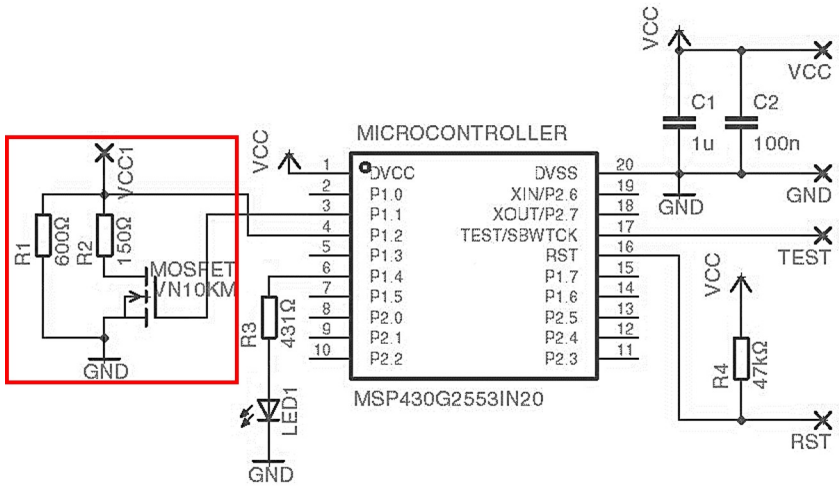


Figure 4.1: Schematic of the electronic circuit for Test 1. Highlighted with red is the part correspondent to the discharge circuit of the cell.

Since we only want to draw 10 mA every 2 hours, to create the pulses of 100 ms, a N-channel Metal Oxide Semiconductor Field Effect Transistor (MOSFET) and a microcontroller were added. The semiconductive properties of this transistor allow the commutation of signals, that is, it can function as a switch. The application of an electric potential difference between the source terminal and the gate of the MOSFET higher than the threshold voltage (V_{GS}) will allow the current to flow in a third terminal, the drain. The MOSFET also has a fourth terminal, the body, but usually this one is connected internally to the source and works as a heat sink. The gate of the MOSFET is connected to a digital pin of the microcontroller and when the pin is activated, that is when the output changes from low to high, the current will also flow through the resistor R2. The activation time is controlled by using the timer of the microcontroller.

The microcontroller selected was the MSP430G2553 [50] described previously in chapter 3, but in this case, we used the 20-pin version suitable for a PCB. This one is a bit bigger than the one suggested earlier, having the following dimensions: 6.6 x 4.5 x 1.05 mm^3.

As we had limited space (and limited funding), we decided not to add more electronics in order to monitor the voltage during the test, such as Bluetooth. Instead, we just added a LED to the circuit, which allows us to have some feedback related to the voltage of the cell throughout the test. The right side of the circuit (Figure 4.1) is the recommended circuit for the good functioning of the microcontroller. The VCC, GND, TEST and RST pins are the ones needed to program it.

After designing the circuit, two PCBs were printed and the result is present in Figure 4.2. The PCB has 15.3 mm of length and 14.3 mm in width. The height of the PCB itself is around 3.4 mm but increases to about 7 mm with the connectors.

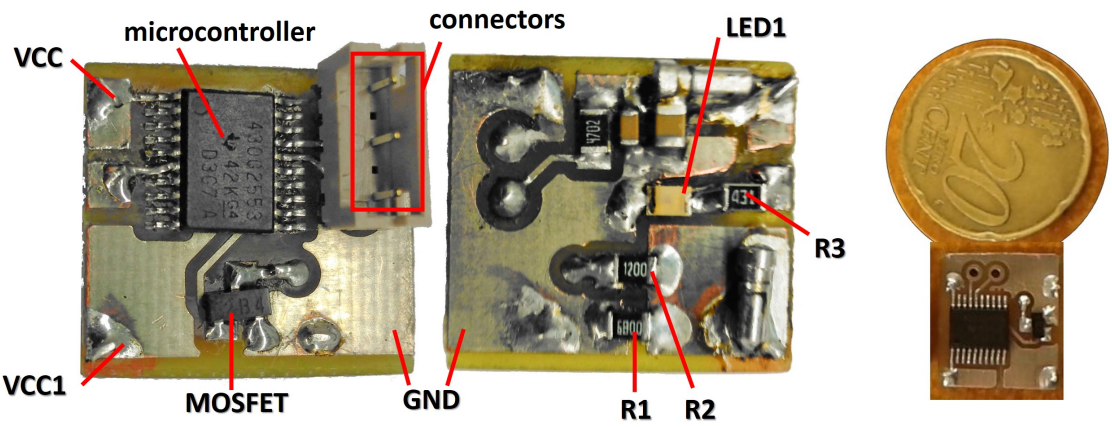


Figure 4.2: PCB of the circuit in Figure 4.1 including the components and connectors needed to program the microcontroller and its comparison with a 20cents coin.

4.1.1.1 Microcontroller Powering

To power the microcontroller we decided to use the same cells, that is, 312 Zn-A cells. The microcontroller can be powered with a voltage between 1.8 to 3.6 V, but for a good operation of every element, such as the flash memory, it should be powered with 2.2 V or higher. Since we don't know how the cells will perform in the intraoral environment, to ensure that there is sufficient voltage to power the microcontroller, we decided to use 3 Zn-A cells.

We placed the 3 cells in series to create a battery. In order to minimize the space, the best configuration is the one illustrated in Figure 4.3. Although at first, it seemed that this arrangement would cover the holes of the cells necessary for the entrance of air, that doesn't happen because the cell is designed in such a way that the negative surface only contacts through a point on the positive one.

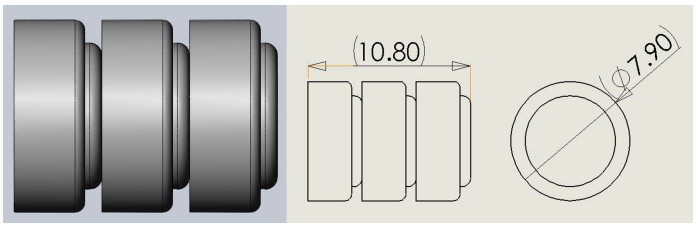


Figure 4.3: Configuration of the battery to power the microcontroller and its dimensions (in mm).

To support the cells, a heat shrink sleeve was used. To confirm that this configuration was, in fact, viable, we measured the voltage at the terminals of 2 Zn-A cells, in series, in series with a resistor. As seen in Figure 4.4, the current was able to pass trough the cells.

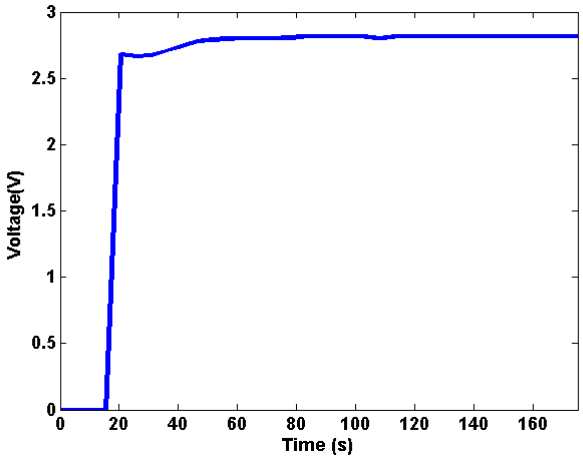


Figure 4.4: Voltage at the terminals of 2 Zn-A cells, in series, in series with a resistor. The transition in the voltage represents the instant when the voltage at the cell's terminals started to be measured.

The final circuit with the PCB integrated with the Zn-A cells is presented in Figure 4.5.

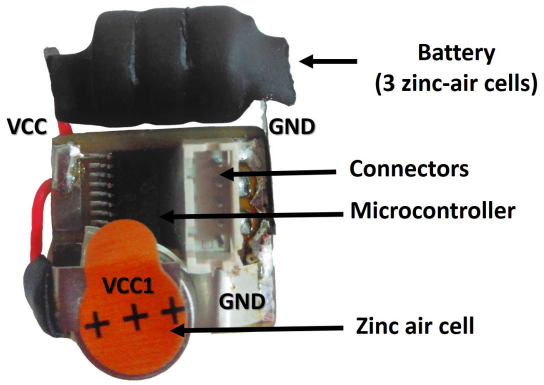


Figure 4.5: PCB integrated with the Zn-A cells.

4.1.1.2 Microcontroller Programming

The software used to develop and debug the application for this test was the Code Composer Studio™ Integrated Development Environment and the hardware used was the MSP-EXP430G2 LauchPad, which allows the connection to the PC through a USB cable.

The microcontroller was programmed to set the MOSFET pin to high, cyclically, for a determined period of time and after that period set it to low. Besides controlling the activation of the MOSFET, we used the microcontroller to analyze the voltage of the Zn-A cell being discharged. Through the ADC of the microcontroller, it is possible to measure the voltage of the Zn-A cell and to convert it to digital to allow its storage. The microcontroller has different options for the reference voltage of the ADC, such as VCC, 2.5 V, 1.5 V and others. In this case, as the cell voltage is not higher than 1.5 V, we can set the

reference voltage to that value. This way, we get a resolution of:

$$\frac{1.5\ V}{2^{10}-1} \simeq 0.0015\ V. \tag{4.1}$$

The conversions of the ADC are also activated cyclically. During the cycle, the value of the pin connected to the positive side of the cell is converted to hexadecimal and then is written at an address of the flash memory. This address is then incremented so it is not overwritten in the next cycle. Since the values are written with the same interval of time between them, in the end, we can obtain the discharge profile of the cell.

To monitor the voltage, every time a value is written, the pin connected to the LED is set to high/low a determined number of times according to the value itself. The number of times the LED blinks is specified in Table 4.1.

Table 4.1: Number of times that the LED blinks accordingly to the voltage of the Zn-A cell measure during the test 1.

Nº of blinks	**Voltage (V)**	**Nº of blinks**	**Voltage (V)**
1	0	6	]1.0,1.1]
2	]0,0.25]	7	]1.1,1.2]
3	]0.25,0.5]	8	]1.2,1.3]
4	]0.5,0.75]	9	]1.3,1.4]
5	]0.75,1.0]	10	]1.4,1.5]

4.1.2 Circuit 2

As one of the objectives of this thesis is to test the capacity of the Zn-A cells to power the automatic maxillary expander proposed, a test simulating the Zn-A cells powering that device was designed.

For this test we are going to consider the motor selected in chapter 3, but instead of using the real motor, we are only going to estimate its current consumption and use a resistor to simulate the motor. Although the current's consumption of a motor is not constant, we decided to make this approximation to simplify the circuit design. Taking into consideration the specifications of the motor present in Table 4.2, the resistor value to simulate the current consumption was estimated. We started by calculating the stall current (I_S), which is usually the maximum current that the motor will draw:

Table 4.2: Specifications of the motor (0308B Faulhaber)

Nominal Voltage (U_N)	**Output Power** (P_{2max})	**Efficiency** (η_{max})	**Stall torque** (M_H)	**Torque constant** (k_M)
3 V	0.04 W	16.94%	0.024 mNm	0.289 mNm/A

$$I_S = \frac{M_H}{k_M} \simeq 83.0\ mA. \tag{4.2}$$

Then, knowing that the motor won't be drawing the maximum current, we decided to approximate the current consumption as the mean of this value with the necessary input current. Considering the maximum efficiency of the motor and its maximum output power, the input power (P_1) and the respective input current (I_1) was determined as follows:

$$I_1 = \frac{P_1}{U} = \frac{\frac{P_{2max}}{\eta_{max}}}{U} = 65.6\ mA, \qquad (U = 3.6\ V). \tag{4.3}$$

The calculation of the resistor value is in Equation 4.4. The resistor value available in the market more close to $48.5\ \Omega$ is $47\ \Omega$. Thus, we are going to approximate the current consumption of the motor to a resistor of $47\ \Omega$.

$$R = \frac{U}{\frac{I_S + I_1}{2}} = \frac{3.6}{74.3} = 48.5\ \Omega \tag{4.4}$$

After determining this value, the circuit was designed. The circuit is similar to the previous one, but in this case, the battery powering the microcontroller is going to be powering the "motor" as well. In a real situation the microcontroller would be controlling a motor driver to activate the motor, but in this case, we have a MOSFET. The schematic of the circuit is represented in Figure 4.6 and the respective PCB in Figure 4.7.

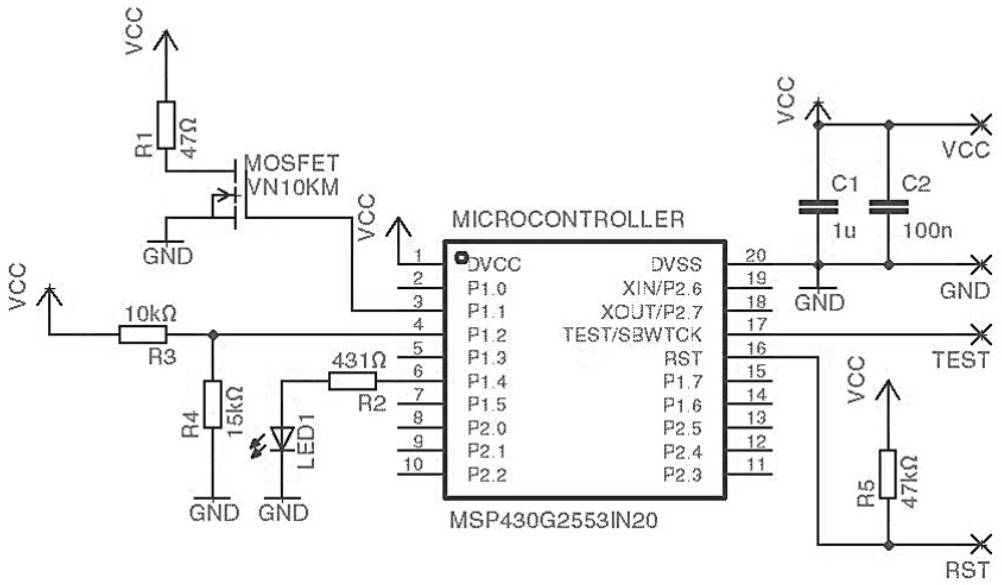


Figure 4.6: Schematic of the electronic circuit for Test 2.

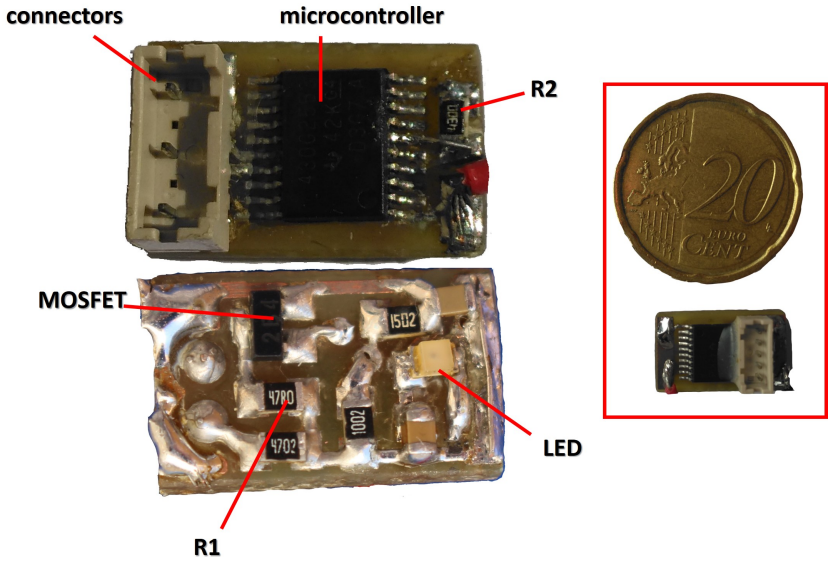


Figure 4.7: PCB of the circuit in Figure 4.6 including the components and connectors needed to program the microcontroller and its comparison with a 20 cents coin.

4.1.2.1 Microcontroller Powering

As described in section 4.1.1.1, the microcontroller is powered by 3 Zn-A cells in series. Here the three cells are necessary not only for the good operation of the microcontroller but also for powering the "motor", which has a nominal voltage of 3 V.

4.1.2.2 Microcontroller Programming

In this test, the microcontroller is programmed as described in section 4.1.1.2. The main difference is the configuration of the ADC, specifically the reference voltage used. None of the options available for the reference value suited the value of the battery. We couldn't set it to the VCC, because it's the value that we want to measure and the other two values (2.5 and 1.5 V) are too low compared to the battery voltage when fully charged (can reach 4.2 V). To overcome this problem, we set the reference value to 2.5 V and added a voltage divider, which is represented in Figure 4.6 by the resistors R_3 and R_4. Defining $R_3 = 10\ k\Omega$, the value of R_4 was determined as follows:

$$2.5 = \frac{R_4}{R_3 + R_4} \times 4.2 \Rightarrow R_4 = \frac{25 \times R_3}{17} \simeq 14.7\ k\Omega \quad (with\ R_3 = 10\ k\Omega). \tag{4.5}$$

The resistor value available more close to 14.7 Ω is 15 Ω. Although the real ADC resolution is 0.0024 V (see Equation 4.6), after converting the values accordingly to the voltage divider, we get a resolution of 0.0041 V (see Equation 4.7).

$$\frac{2.5\ V}{2^{10} - 1} \simeq 0.0024\ V. \tag{4.6}$$

$$\frac{2.5 \times \frac{R_3 + R_4}{R_4} V}{2^{10} - 1} \simeq 0.0041\ V. \tag{4.7}$$

Just like in the previous test, we used one LED to monitor the voltage during the test. In Table 4.3, the number of times the LED blinks accordingly to the voltage measured is distinguished.

Table 4.3: Number of times the LED blinks accordingly to the voltage of the Zn-A cell measure during the test 2.

Nº of blinks	**Voltage (V)**	**Nº of blinks**	**Voltage (V)**
1	0	6	]2.2,2.6]
2	]0,1.0]	7	]2.6,3.0]
3	]1.0,1.4]	8	]3.0,3.4]
4	]1.4,1.8]	9	]3.4,3.8]
5	]1.8,2.2]	10	]3.8,4.2]

In this case, as we are using the ADC and writing information in the flash memory, the microcontroller will have a higher current consumption than it would have if we were only using it to activate the MOSFET. Also, the voltage divider and the LED draw some current as well. Thus, although we are trying to simulate the current consumption of the real automatic maxillary expander, the current's consumption of the microcontroller when not performing any activation of the "motor" will be higher than it will be in the device.

4.2 Casing

Since it is not convenient to have the PCB and the cells in direct contact with the mouth, a casing was designed for both tests. The CAD model of the casing is shown in Figure 4.8 and it is composed by two parts forming a box. During the design, we took into consideration the necessary space for the PCB and cells and that we needed an entrance of air to ensure that the air flows to the inside since the cells will need the oxygen to activate the chemical reaction. The entry of air is ensured by the hole present in one of the parts, which was designed considering the design of the casing used in [5], as it showed to be sufficient for the proper functioning of the cell.

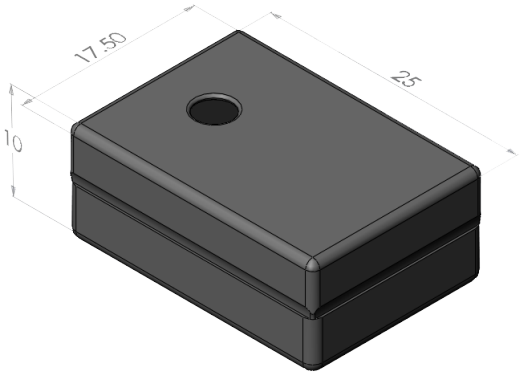


Figure 4.8: CAD model of the casing with the following dimensions: $25 \times 17.50 \times 10\ mm^3$.

The final result of one part of the casing can be seen in Figure 4.9. The part with the hole was 3D printed with austenitic stainless steel (316L) because it is going to be in contact with the mouth. The choice of this material has been already discussed in chapter 3. The second part was printed with Polylactic acid (PLA) since it will be isolated from the intraoral environment. With this material, it is possible to create transparency to see the LED blink throughout the tests.

To avoid the entrance of water/saliva, the hole is going covered by a Polytetrafluoroethylene (PTFE) membrane filter, as shown in Figure 4.10, which still allows the air to flow, as also verified in [5]. The PTFE membrane filters, commercially known as Teflon, are biologically inert and hydrophobic, not having any affinity to water. For our application, we chose a membrane with 0.22 µm of pore size, which filtrates particles bigger than that, but allows the air to pass easily through the pores. The membranes used, represented in Figure 4.11, were from Sterlitech Corporation having a thickness that varies between 102 and 152 µm.

Figure 4.9: 3D printed casing.

Figure 4.10: Teflon membrane covering the hole.

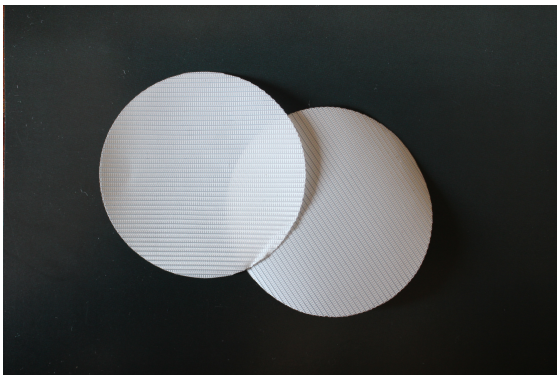


Figure 4.11: PTFE membrane. Diameter: 47 mm and Pore size: 0.2µm (Sterlitech Corporation)

4.3 Device assembly

The assembly of the device consists of different steps:

1. Programming the microcontroller;
2. Creating the battery described in section 4.1.1.1;
3. Integrating the cell and the battery with the PCB accordingly with the test that is going to be performed (as shown in Figure 4.2, for test 1);
4. Placing everything inside the casing.

As mentioned in the previous section, the initial idea was to perform the tests inside the mouth anchoring the device to the teeth. However, instead of using a fixed appliance, to facilitate the process, we decided to follow another approach which involves a removable appliance, creating an acrylic mouthguard of the maxilla. To build this mouthguard, first, it was necessary to make a dental impression to create a cast of the palate and teeth. Only then the mouthguard was produced. An orthodontist follwed this process. A cast with the respective mouthguard can be seen in Figure 4.12.

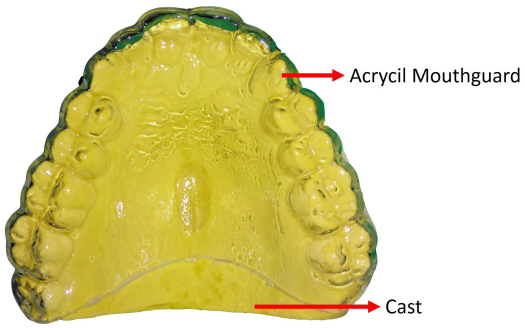


Figure 4.12: Cast and Acrylic Mouthguard of one of the participants.

Then, the casing was fixed to the mouthguard using acrylic resin, which solidifies when it polymerizes. The placement of the acrylic resin was made in order to close the casing in order to isolate the inside from the outside. After the polymerization, the appliance is ready to be placed on the teeth. In Figure 4.13 it is possible to see one of the appliances used for one test and in Figure 4.14 the appliance fixed to the teeth of one of the participants.

(a) **(b)**

Figure 4.13: Example of a final appliance used to perform a test. **(a)** inferior view: the casing is involved by acrylic resin and covered by teflon membrane **(b)** superior view: it is possible to see the PLA part (black) of the casing. The PLA has some transparency allows the user to see the LED light.

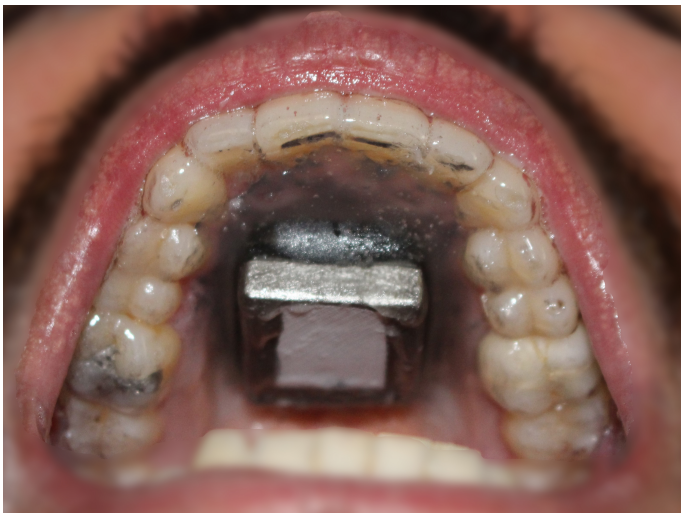


Figure 4.14: Example of the appliance fixed to one of the participants teeth.

This process has to be done every time a test is performed. At the end of the test, the casing is opened in order to access the PCB and read the flash memory of the microcontroller, where the values are being stored.

Chapter 5

in vivo Tests

In this chapter, all the tests performed and the results obtained are described, as well as their respective discussion. In the first section (section 5.1) we tested the Zn-A cells discharge profile using the circuit described in section 4.1.1. Some alterations were made throughout the tests to observe differences in the performance of the cell. In the second section (section 5.2) the performance of the Zn-A cells when powering the automatic maxillary expansion appliance is analyzed. The chapter ends with an overall discussion of the results obtained (section 5.3).

5.1 Zinc-Air Cells Performance Tests

As described earlier, the first proposed test consisted of using the discharge circuit designed by the cells' manufacturer (section 4.1.1) to evaluate the discharge profile of the cells under intraoral environment conditions. We started by repeating this test, but with a cycle duration of 200 ms instead of 2 hours to observe the influence of the pulse load and the oxygen-starvation phenomenon. Then, according to the results, we changed some variables such as the cycle duration and the background current of the discharge circuit to reach the best conditions for the performance of the cell. The casing used was also changed in some tests.

5.1.1 Test I

5.1.1.1 Material and Methods

In this test, we used the circuit described in section 4.1.1 and programmed the microcontroller to activate the MOSFET every 200 ms during 100 ms. This way, we increased the average current from approximately 2 mA to 6 mA.

Before performing the *in vivo* test, this discharge circuit was tested in an ambient (not controlled) environment condition. Two tests were performed and the results (see Appendix A) showed that the average current didn't exceed the limiting current of the cell and that the pulses duration and current were not high enough for the cell to become oxygen-starved in that environment. The cell only discharged after approximately 23 hours.

The device described in the previous chapter (section 4.3) was used.

5.1.1.2 Results

The appliance remained in the mouth about 20 hours. At that time the cell had already a voltage between 0 and 0.25 V. Besides that, the intensity of the LED was weak, indicating that the voltage of the battery powering the microcontroller had decreased as well.

Then, the casing was opened in order to access the flash memory of the microcontroller. The discharge profile of the Zn-A cell during this test is present in Figure 5.1. However, the values stored didn't correspond to the time elapsed from the beginning to the end of the test ($\approx$ 20 hours), since we only obtained information from the start of the test ($\approx$ 3 hours).

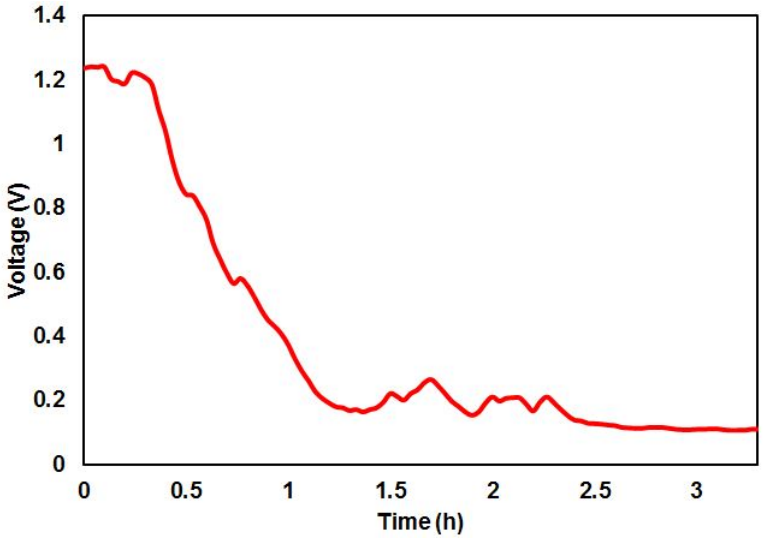


Figure 5.1: Zn-A cell discharge profile during test I *in vivo*. (Subject 1)

5.1.1.3 Discussion

Analyzing the graphic of Figure 5.1, we can see that the Zn-A cell immediately started to discharge. The environment itself could have caused this behavior, that is, the high levels of RH, which negatively influence the performance of the cell, reducing its conductivity. Also, considering that the air availability is lower in the casing, the interval between the pulses might not be long enough for the cell to recover, that is, there is no time for the cell to have sufficient oxygen to handle the pulses. Hence, combining these two factors, which influence the limiting current negatively, the cell becomes oxygen-starved rapidly. This observation is supported by the results obtained when performing the same test outside the intraoral environment (discharge time $\approx$ 23 hours), where the cells are exposed to environmental conditions more similar to the ideal ones and the limiting current is higher.

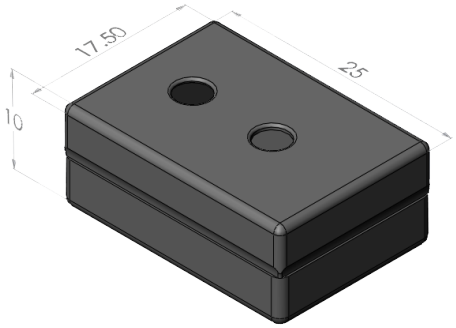
As stated, some information (Zn-A cell's voltage) was not stored in the microcontroller. This is related to the decrease of the voltage of the battery powering the microcontroller because the process of writing

information to the flash memory only occurs with a power supply higher than 2.2V. One condition that might have influenced the bad performance of the battery was the lack of oxygen inside the casing because the current consumption of the microcontroller is about 0.5 mA, so it was expected that the cell could support that current.

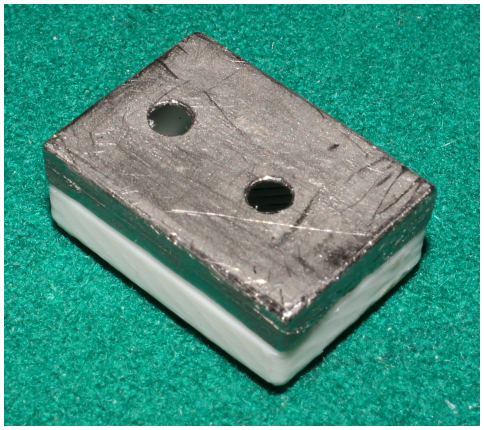
5.1.2 Test II

5.1.2.1 Materials and Methods

To test if the failure of the battery was related to an oxygen deficiency, we added an entrance of air, as shown in Figure 5.2. In this second test, only the casing was changed, the discharge circuit and cycle remained the same.



(a)



(b)

Figure 5.2: Casing used for test II. **(a)** CAD model of the Casing. Dimensions in millimeters. **(b)** 3D printed model.

5.1.2.2 Results

The Figure 5.3 shows the discharge profile of the Zn-A cells. Right after placing the appliance in the mouth, the cell started to discharge. After 2 hours, through the feedback of the LED, the voltage was already too low, so the appliance was removed from the mouth. When it was in the outside environment, the voltage increased, but as it was placed back in the mouth, it started to decrease again. The same behavior was observed when the appliance was removed again. These moments are identified by the dashed lines present in the graphic. In this test, all values were stored in the flash memory and variations in the intensity of the LED were not observed.

5.1.2.3 Discussion

The extra entrance of air didn't seem to influence positively the performance of Zn-A cell being discharged, since its voltage started to decrease right after the beginning of the test, just like in the previous one. This confirms that we are not giving sufficient time between pulses for the cell to recover, as explained before.

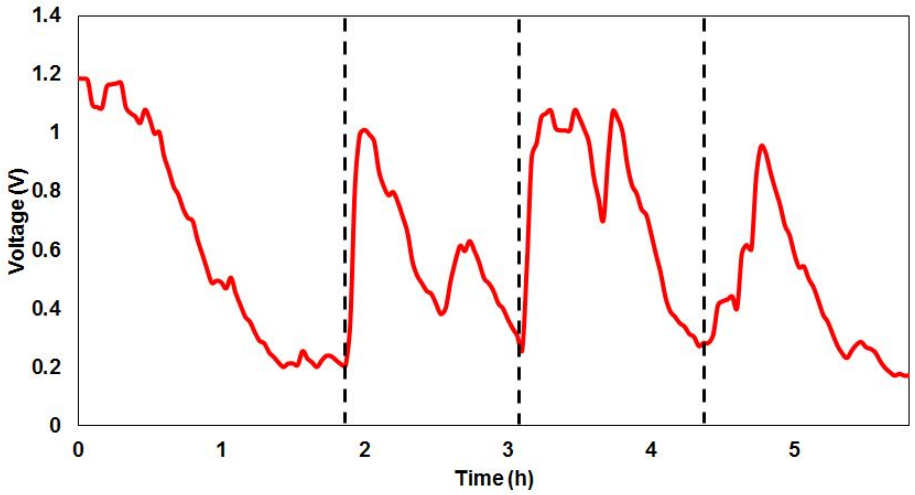


Figure 5.3: Zn-A cell discharge profile during test II. The dashed lines indicate the moment when the appliance was removed from the intraoral environment and then placed in the mouth again. (Subject 1)

Moreover, in Figure 5.3 it is possible to see that the Zn-A cell recovers easily when outside the intraoral environment, where the air availability is higher, and the RH levels are lower, favoring the oxygen transfer rate. As the appliance is placed in the mouth, the oxygen available decreases and the water vapor transfer rate has a higher influence in the cell, worsening its performance. Thus, considering those sequence of events, we can confirm that the intraoral environment conditions decrease the limiting current which the cell can support.

5.1.3 Test III

5.1.3.1 Materials and Methods

From the previous test, we concluded that the fast discharging of the cell is related to the exceeding of the limiting current in the intraoral environment, which is influenced by the RH levels and the air availability. Since there were no problems associated with powering the microcontroller, in this test, we decided to use the same casing (Figure 5.2). Instead, we increased the cycle of activation of the pulses to 2 hours, as in the original HPT, to decrease the limiting current to approximately to 2 mA to observe if the cell supports it.

5.1.3.2 Results

The Figure 5.4 show the discharge profile of the Zn-A cells. In the first 2 hours the cell had a constant voltage, but then it started to decrease. After some hours, observing that the voltage had declined, the appliance was removed.

The voltage of the battery didn't seem to change and the microcontroller was able to store all the data.

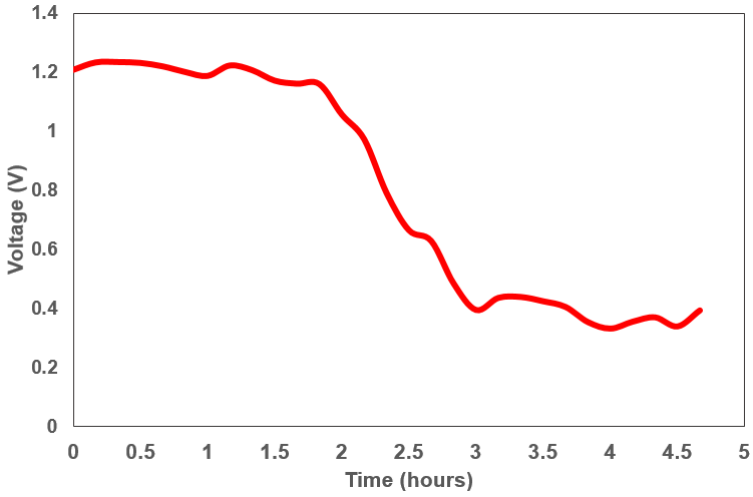


Figure 5.4: Zn-A cell discharge profile during test III. (Subject 1)

5.1.3.3 Discussion

Comparing with the discharge profile from Figure 5.3, this time, the cell could maintain a constant voltage for a bigger period, although it is still not significant (2 hours) when compared with the capacity of the cell.

As the results didn't vary from the previous ones as much as expected, but there were no problems associated with the storage of values at the microcontroller, the average load current of 2 mA seems to be still too high for the cell to have capability of handling the pulses of 10 mA. Between pulses, the cell should be able to build up a reservoir of oxygen to handle it, what doesn't seems to happen. Thus, the cell becomes oxygen-starved.

In this test, the battery powering the microcontroller didn't seem to fail, since we didn't observe variations of the LED intensity throughout the test and all the values were stored.

Moreover, comparing this result with the *in vitro* results and the manufacturer ones, it is possible to observe that the intraoral environmental conditions, in fact, reduce the performance of the cells.

5.1.4 Test IV

5.1.4.1 Materials and Methods

Considering the results from Test III, the Zn-A cells' performance in the intraoral environment is far from the performance described by the cells' manufacturer. However, instead of concluding that these cells are not adequate to power the intraoral device, we decided to continue to analyze in which conditions the cell improves its performance.

We started by changing the background current of 2 mA to 0 mA, only remaining the pulses of 10 mA. This way, we can test if the fast decline of the voltage in the previous tests was only related to the pulse load or the background current already being too close to the limiting current of the cell. Also, this

alteration was made already considering that the automatic maxillary expander will consume currents in the order of μA when asleep, that is, when is not activated. In this test, we decided to change the cycle duration to 30 minutes. The current and the duration of the pulse remained the same. Thus, the average load current of this test is approximately 0.5μA. The casing used was the same.

5.1.4.2 Results

During the test, through the observation of the LED, the Zn-A cell didn't discharge maintaining its voltage constant, so the subject slept with the appliance. However, after waking up the LED was not blinking meaning that the microcontroller was not functioning well. Thus, the appliance was removed from the mouth, but after a while, the LED started blinking.

As expected through those observations, the microcontroller wasn't able to store all the information. Taking into account what happen during the test and the data stored, we determined approximately the moment when the microcontroller failed and its duration. The result can be seen in Figure 5.5. The part (1) of the graphic corresponds to the values measured *in vivo*, part (2) to the period of time with no information about the voltage and part (3) to the values measured outside the mouth.

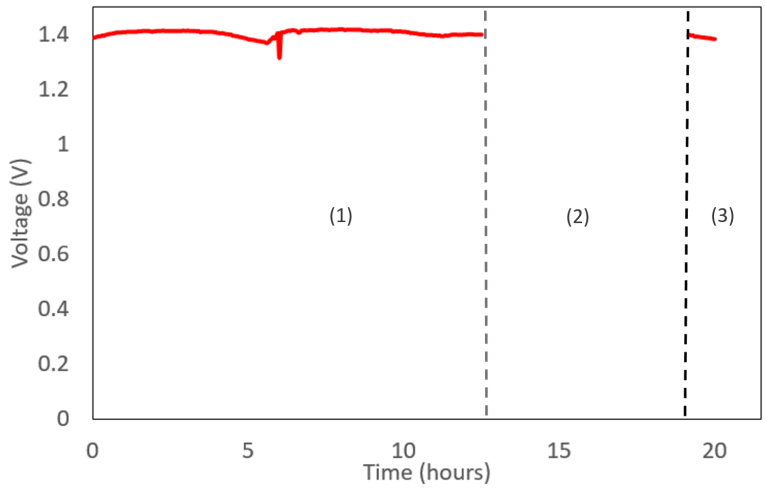


Figure 5.5: Zn-A cell's voltage measured during test IV. (1) and (2) *in vivo*; (3) outside the mouth. During part (2), the microcontroller wasn't able to store data. (Subject 1)

5.1.4.3 Discussion

In this test, the Zn-A cell maintained approximately a constant voltage for about 12 hours and 30 minutes. After that time, the microcontroller couldn't store more values. Since this period corresponds to the moment when the participant was sleeping, this might be related to the fact that during sleep, the tongue can be blocking the entrances of air of the casing, which become easily in contact with the tongue due to its position. During the day, the subject can have more control of its tongue, avoiding blocking the entrances. After removing the appliance from the mouth, the battery recovered and the values stored indicate that the individual Zn-A cell still had not discharged.

This result showed that with a lower average load current, the cell has a performance more similar to the one described by the manufacturers, that is, the cell discharges with a constant voltage if the average load current doesn't exceed the limiting current. Also, this result demonstrates that the bad performance of the cells in the previous tests was mainly related to the background current. Now, between pulses there is time for the oxygen to enter the cell in order to build the necessary reservoir for the applied pulses, avoiding the oxygen-starvation. Thus, when considering the use of these cells in the intraoral environment, the current consumptions of the devices have to be well studied to avoid the failure of the device due to pulse currents higher than the ones the cells can support.

5.1.5 Test V

5.1.5.1 Materials and Methods

Since the changes made in the previous test resulted in positive results, we decided to decrease the pulse cycle to 15 minutes to observe if the cell could support a higher average load current. In this case, it is approximately 1μA. The casing and the circuit were not changed, only the programming of the microcontroller was adjusted to decrease the cycle of activation of the pulses. The test was only performed during 24 hours in order to observe possible changed from the previous test.

5.1.5.2 Results

During the test, through the analyses of the LED, the voltage of the Zn-A cell was kept approximately constant. However, the data stored in the microcontroller showed that during the test the microcontroller failed. This failure occurred after about 10 hours, corresponding to the moment when the subject was sleeping. Taking into account the duration of the test, we assumed that the microcontroller failed during about 1 hour. The Figure 5.6 shows the registered Zn-A cell's voltage during the test.

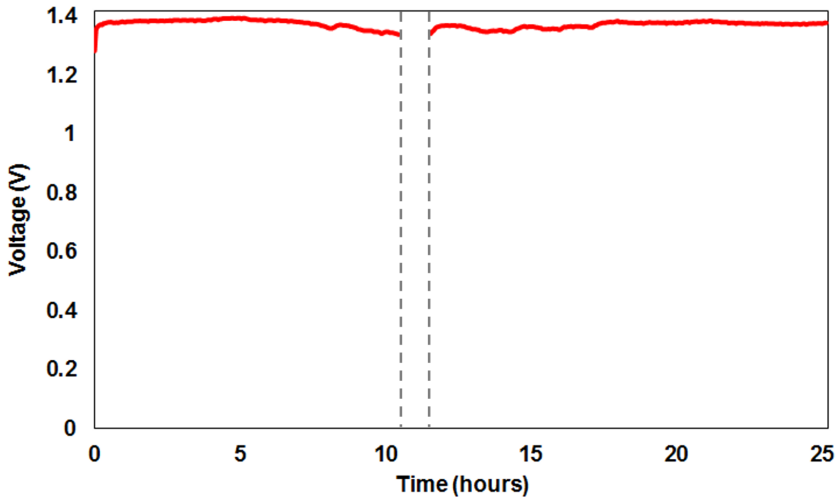


Figure 5.6: Zn-A cell's voltage measured during test V. The dashed line limits the moment when the microcontroller failed. (Subject 1)

5.1.5.3 Discussion

The Figure 5.6 shows that the Zn-A cell's voltage maintained constant during the test. However, the microcontroller failed to store data during the night. Considering that in the previous test it also failed when the subject was sleeping, we assumed that the tongue might be influencing the entrance of air into the casing, that is, the tongue is blocking the entrances.

Taking into account that in both tests (test IV and V) the battery powering the microcontroller decreased its voltage, but the Zn-A cell didn't, we can conclude that the demanded currents to this cell were low. These results are consistent with the average load currents involved in each case, that is, the battery has an average load current of approximately 0.5 mA and the cell being tested, 1 μA. Thus, if there is a lack of oxygen caused by the blocking of the entrances of air the battery will be affected first, that is, will become oxygen-starved more rapidly.

5.1.6 Test VI

5.1.6.1 Materials and Methods

Based on the results of the previous tests (IV and V), we decided to perform the last test on different subjects in order to analyze if the failure persisted only during the night when sleeping. The casing used in this test is the one described previously on section 5.1.2, that is, with two entrances of air. Also, the cell is being discharged only by pulses of 10 mA every 15 minutes. The test was repeated in more three subjects with a duration of 24 hours. All subjects gave informed consent (see Appendix B) to participate in this study.

5.1.6.2 Results

The Figures 5.7, 5.9 and 5.8 show the Zn-A cells' voltage measured during the different tests. In the test performed with subject 3, the Teflon membrane suffered some damaged as shown in Figure 5.10b. In the other two, there were no damages registered.

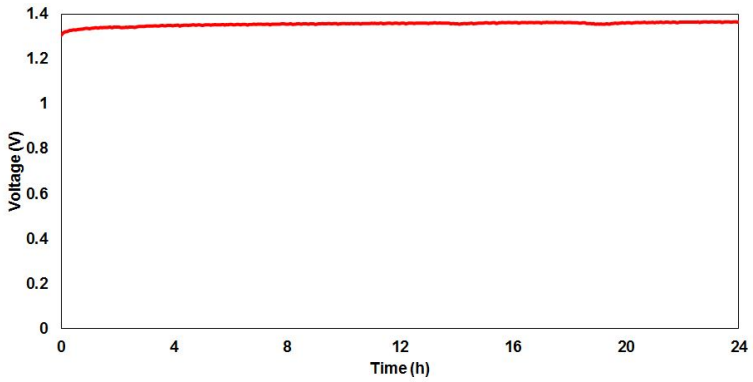


Figure 5.7: Zn-A cell's voltage measured during the test of subject 2.

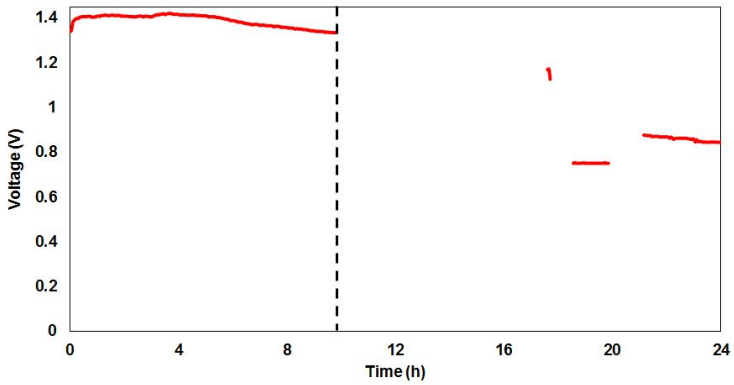


Figure 5.8: Zn-A cell's voltage measured during the test of subject 3. The dashed line indicates the moment when the battery started to fail.

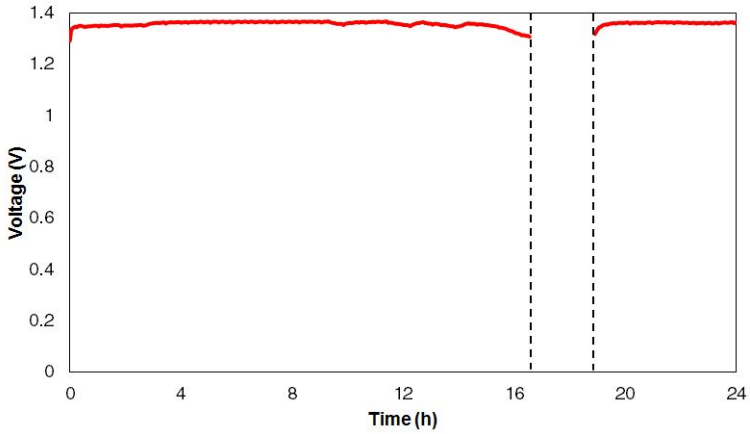
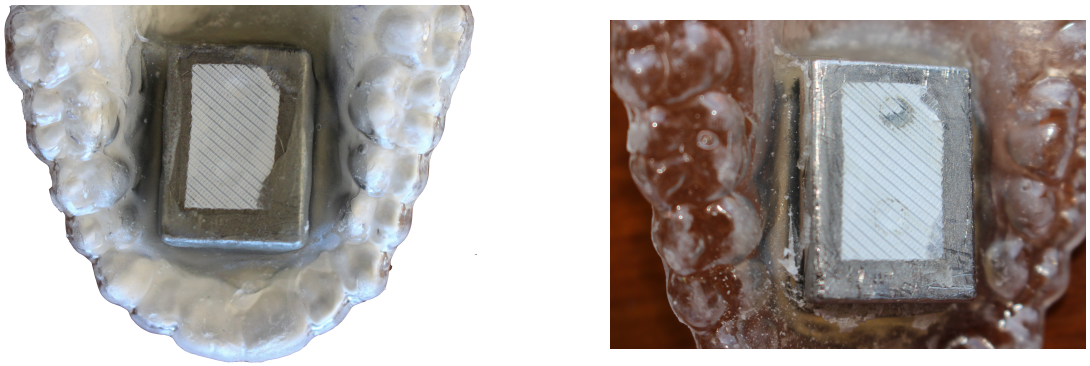


Figure 5.9: Zn-A cell's voltage measured during the test of subject 4.



(a) **(b)**

Figure 5.10: Appliance used by subject 3. **(a)** before the test **(b)** after the test.

5.1.6.3 Discussion

The result from Figure 5.7 shows that the microcontroller was able to measure and store the data during all test, even during sleep. However, the same didn't happen in Figure 5.8 and Figure 5.9. In the first case (Figure 5.8), this might have been caused by the tongue blocking the entrance of air, since the microcontroller failed while the subject was sleeping and/or by the entry of saliva inside the casing, because the membrane used in the test of subject 3 suffered some damages (Figure 5.10b). In the second case, the failure seems to be related only to the lack of oxygen inside the casing.

Regarding the Zn-A cell's voltage being measured, only during the test performed by the subject 3, the cell wasn't able to maintain the flat discharge profile, but as mentioned before the membrane suffered some damaged and the entrance of saliva might have influenced the performance of the cell.

These results (Figures 5.6, 5.7, 5.8, 5.9) showed that the performance of the Zn-A cells varied within different intraoral environments, but the failures observed seem to be somehow related to the sleeping stage.

5.1.7 Test VII

5.1.7.1 Materials and Methods

In the previous tests, we observed that the microcontroller only failed when the subjects were sleeping. As we associate this failure to the fact that the tongue during the night might cover the entrances of air, we decided to create more entrances in the casing in order to increase the air flow to try to overcome this problem. The new casing is shown in Figure 5.11. The discharge circuit and the cycles of activation were the same as the previous one.

Figure 5.11: Stainless steel casing used for test VI

5.1.7.2 Results

The Figure 5.12 shows the Zn-A cell's voltage measured during the test. When reading the flash memory, it was possible to detect a failure of the microcontroller after some hours. During this failure, the subject was sleeping.

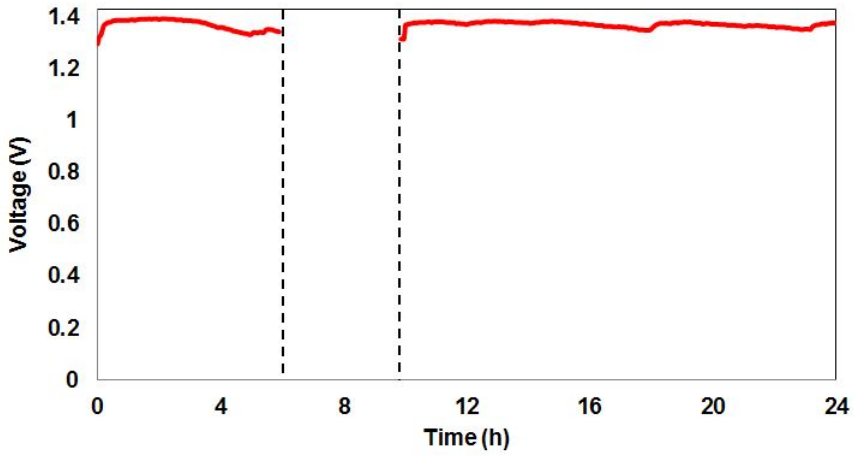


Figure 5.12: Zn-A cell's voltage measured during the test VII. The interval between the dashed line corresponds to the moment when the microcontroller didn't stored values. (Subject 1)

5.1.7.3 Discussion

Considering the result obtained (Figure 5.12), we could verify that the alterations made to the casing were not sufficient to overcome the failure of the battery during the test, which coincides with the moment of the day when the subject is sleeping. The failure might be explained by the fact that the entrances of air are all on the same surface, which is easily in contact with the tongue. Thus, the tongue might be covering the entrances of air during the night, oxygen-starving the cells, which only recover after the subject waking up.

With this test, we could also observe that the performance of the cells didn't improve with more entrances of air.

5.1.8 Test VIII

5.1.8.1 Materials and Methods

Since the addition of more entrances of air was not a good solution to avoid the failure of the battery during the night and assuming the tongue is stopping the air from flowing to the casing, we decide to design a casing with lateral entrances, as shown in Figure 5.13. The discharge circuit and the cycles of activation were the same as the previous one.

Figure 5.13: Stainless steel casing used for test VIII. The holes were made anterior and posteriorly.

5.1.8.2 Results

The Figure 5.14 shows the Zn-A cell's voltage measured during the test. Once again, the failure of the battery during the time when the subject is sleeping was observed.

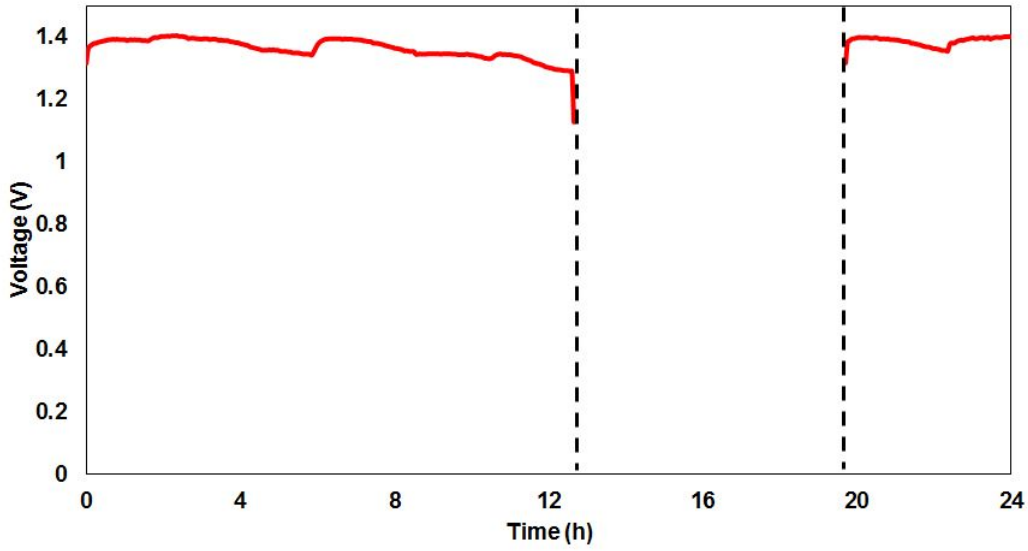


Figure 5.14: Zn-A cell's voltage measured during the test VIII. The interval between the dashed line corresponds to the moment when the microcontroller didn't stored values. (Subject 1)

5.1.8.3 Discussion

The result demonstrated that changing the positions of the entrances of air, didn't overcome the problem detected consecutively. Thus, regardless the position of the air entrances, the air has difficulties in flowing to the inside of the casing during sleep.

Fitzpatrick et al. [72] found that during sleep, healthy subjects, breathe more through the nose than the mouth and sometimes entirely through the nose. This observation might explain why during the night the

air doesn't flow to the casing, along with obstruction caused by the tongue. In [73], the authors measured the upper airway resistance in healthy subjects finding that the resistance when asleep is higher than when awake. These findings can also explain why the battery doesn't fail during the day (awake) because the air flows more easily and can influence the oxygen reaching the cells.

5.2 Simulation Test

Due to lack of time available to perform more tests, we decided to do one last test where the current consumptions of the automatic maxillary expander are considered.

In this case, we analyzed the performance of the battery (3 Zn-A cells), measuring the voltage of the battery, when subjected to currents more similar to the ones it will deal with the real device. The main goal is to observe, at least, if the battery can support those currents, mainly the pulse currents since it is expected that the battery will fail during sleep.

5.2.1 Materials and Methods

As explained, the maxillary expansion with a screw-type maxillary expander is performed by activating the appliance periodically. Considering that, in a rapid maxillary expansion, the rate of expansion is usually 0.5 millimeters per day and that, with the automatic device, we can increase the number of activations per day, we considered a treatment in which the appliance is activated 5 times a day, which results in an expansion of 0.1 mm per activation. Moreover, the maximum speed of the actuator is 0.4 mm/s, so each activation will last 250 milliseconds.

In this test, the circuit we used was the one described in section 4.1.2 and the casing used was the one designed for the previous test (Figure 5.13). As in the previous tests, the test was performed during 24 hours.

Since this test was performed only to observe if the cells can support the currents and recover inside the intraoral environment, instead of programming the microcontroller to activate the pulses every 4.8 hours (that is, 5 activations a day periodically) we decided to program the microcontroller to activate the "motor" every 15 minutes. Thus, if we observe that the battery can power the microcontroller and the micromotor with those cycles of activation and pulse load, for sure it will be able to power the device with longer cycles. Considering that the microcontroller has a current consumption of 0.5 mA when not performing any activation and the applied pulses draw approximately 100 mA during 250 ms, the average load current of this test is about 0.53 mA.

5.2.2 Results

The Figure 5.15 shows the Zn-A cells voltage measured during the test. During a period of time, which corresponded to a period when the subject was sleeping, the battery started to decrease its voltage, reaching a voltage with which the flash memory of the microcontroller can't store data.

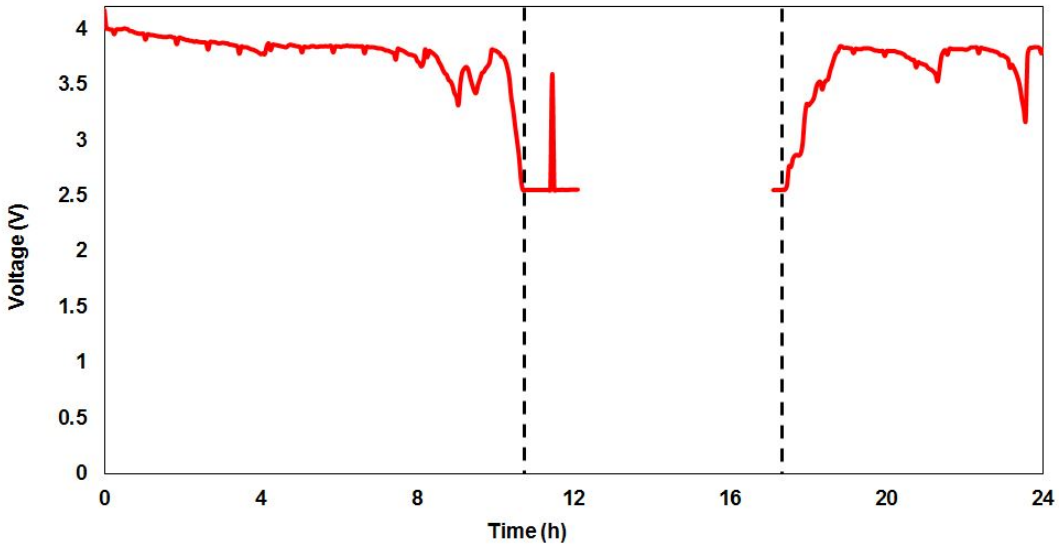


Figure 5.15: Zn-A cell's voltage measured during the simulation test. (Subject 1)

5.2.3 Discussion

In this test, the battery also failed during sleep. This was expected since we couldn't overcome this problem as discussed previously.

Nevertheless, we observed that the battery handles pulses of 100 mA during 250 ms in the intraoral environment without becoming oxygen-starved. Moreover, the battery was able to maintain approximately a constant voltage with cycles of 15 minutes, meaning that between pulses, even with a current of 0.5 mA, the battery can create an oxygen reservoir sufficient to handle those pulses. Comparing the discharge profile with the previous tests it is not as constant but is already a preview that the cells will be able to power the device.

Also, in this test we couldn't program the microcontroller to enter its lowest power modes, as described in section 4.1.2.2, because we needed to use elements that can't function in those modes, but won't be necessarily required when projecting the device. Hence, if the current consumptions of the microcontroller can be decreased, the performance of the cells will improve.

5.3 Overall Discussion

The tests designed for this project were made with the intention of analyzing the performance of the Zn-A cells. We observed that the limiting current of the cells inside the intraoral environment is lower than in the outside. With the first three tests, the cells weren't able to support a background current of 2 mA and pulses of 10 mA during 100 ms, becoming oxygen-starved rapidly, even with intervals of 2 hours between pulses. Nonetheless, after eliminating the background current of the discharge circuit, the cells handled the pulses well, sustaining a constant voltage.

It was already expected that the Zn-A cell's performance *in vivo* was not as good as described by

the manufacturer of the cell, nor *in vitro*, mainly due to the high levels of RH inside the mouth, which decrease the conductivity of the cell. Moreover, the oxygen transfer rate is slower than in the outside, which has a direct influence on the performance of the cell. This was easily observed in the results of Test II (Figure 5.3), where the cell recovered its voltage rapidly when removed from the mouth. These results also explain why the results from the *in vitro* were almost similar to the one performed by the manufacturer, since the cells, when not submerged in the artificial saliva, were exposed to the normal environment with favorable conditions to its good performance.

Throughout the tests (from Test IV to IX), the major and repetitive problem was the failure of the battery when powering the microcontroller and storing information in the flash memory during the sleep stage. Initially, we considered that the place of the entrances of air on the casing was the main source of the problem, but we verified that this might not be the main factor, as the performance of the battery didn't improve when the entrances were changed. The problem might be more related to the subject's ventilation during the different stages of the day.

Moreover, when performing the test in different subjects we verified that the results vary from person to person, which can be related to the different intraoral environment conditions, including the different production of saliva, and also the different ways of breathing during sleep.

Regarding the automatic maxillary expansion appliance, although we couldn't estimate the discharge time of the cells when powering the automatic expander, we were able to confirm that the battery supports the pulse currents needed to power the motor and the overall currents designed for the device under the intraoral environment conditions. Although it was not possible to overcome the problem registered during the sleep stage in different tests, this doesn't invalidate the use of the Zn-A cells to power the device. However, more studies must be performed.

Besides the failure of the battery, other limitation of the project was the limited tests performed, because the appliances were placed with the presence of the dentist, so the tests were only made when the dentist was available. In some cases, the tests were performed with intervals of 2 weeks, decreasing the time available to explore more solutions. Additionally, there were some problems related to the fabrication and delivery of the casing, which also delayed the performance of tests.

Chapter 6

Conclusions and Future Work

6.1 Conclusion

The results obtained during this study support the use of the Zn-A cells in the mouth. Although the performance of the cells is not as good as *in vitro* or in normal environmental conditions, if the device is projected to have pulse currents which can be handled by the cell without becoming oxygen-starved in a single pulse and to have an average current consumptions lower than the limiting current of the cells inside the intraoral environment, the Zn-A cells will be able to power the device with a constant voltage. In the case of the automatic maxillary expansion appliance, this means that the activations of the motor can't have a long duration to avoid the oxygen-starvation of the cells; also, the interval of time between the activations has to be long enough in order to allow the oxygen to enter into the cell to have enough capacity to support the next activation. The last requirement is not a problem because nowadays the appliances are activated at most twice a day and even if we consider 10 activations a day, that is, cycles of activation of 2.4 hours, the cell will have enough time to recover its capacity. Moreover, the microcontroller can be programmed to enter a low power mode between activations with consumptions of 0.5 μA, which will not affect significantly the entrance of oxygen into the cell. Even with higher consumptions ($\approx 0.5mA$) between pulses, during the tests, the cells didn't become oxygen-starved.

The major limitation of these tests was the failure of the cells detected when the subjects were sleeping, which didn't allow us to estimate a capacity for the cell to power the automatic device. Considering this failure, we performed another test where the air holes of the cells powering the microcontroller were covered in order to simulate the situation when there is no more oxygen for the cell than the one existence in its reservoir. The result (Appendix A.2) showed that without performing any activation, the battery was able to power the microcontroller during 3.8 hours with the remaining oxygen inside the cell, which corresponds to a capacity of approximately 1.9 mAh. During the *in vivo* tests, the microcontroller was programmed to continue the activations during the night, thus if the appliance is programmed to enter the sleep mode during the night, without performing any activation of the motor, the failure detected might be avoided. Although a normal person doesn't sleep 3.8 hours, the test was made in the complete absence of air and the microcontroller was not in the lowest power mode available. In theory, the lowest power mode available for the MSP430 is 0.5 μA, as mentioned before, so the oxygen available can be sufficient for the cells to power the microcontroller during that mode. Also, the results showed that the cell recovers after

sleep, thus even if the battery fails, there will be information about the previous activations, which can be used to readjust the next ones.

6.2 Future Work

Regarding future work, an external communication should be considered. Nowadays, there are ways to communicate with devices, in order to transmit and receive data, wireless and low power consumption, such as the Bluetooth low energy (also referred as Bluetooth Smart). If this technology was added to the automatic maxillary expander, not only the activations could be reprogrammed throughout the treatment by the doctor, but also the patient could have some feedback about the treatment. Besides that, our device could be connected to a smartphone or a similar device in order to have access to the real time, in case some failure of the battery occurs. This way is easier to track the failures.

In a more recent future work, the battery should be tested during the night when the microcontroller is in the sleep mode to observe the difference between the results of this study.

The test device should also be redesigned to be smaller than the one used during this project in order to increase the comfort during its utilization. Therefore, the number of subjects willing to perform these tests would increase. Besides that, it would be easier to use the appliance during more days, facilitating the estimation of the Zn-A cells capacity in the intraoral environment.

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Appendix A

Other Results

A.1 Performing Test I outside the intraoral environment

Results from the 2 tests (section 5.1.1) performed in normal environment conditions. The cells were discharged with a background current of 2 mA and pulses of 10 mA during 100 ms every 200 ms. The results are in Figure A.1 and A.2.

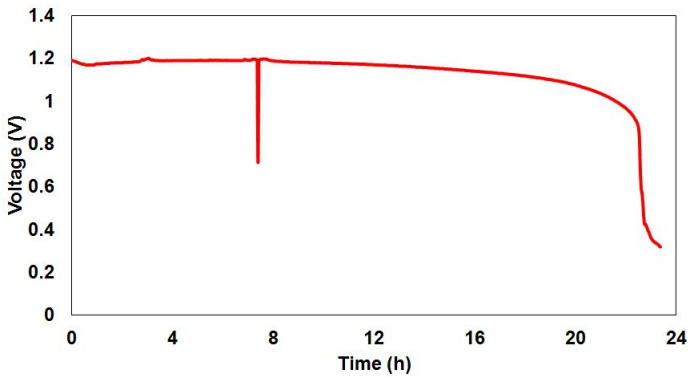


Figure A.1: Experiment 1. Zn-A cell's discharge profile when discharged with a background current of 2 mA and pulses of 10 mA during 100 ms every 200 ms.

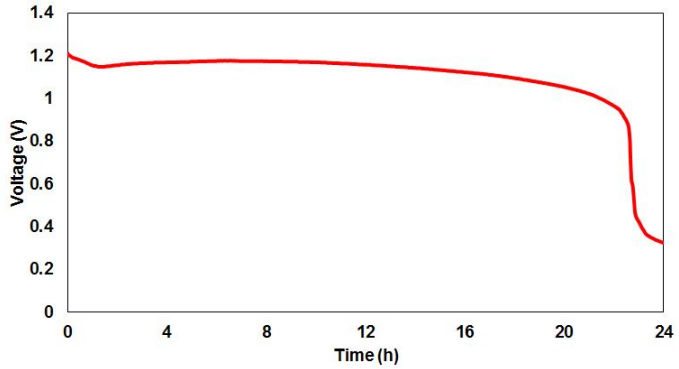


Figure A.2: Experiment 2. Zn-A cell's discharge profile when discharged with a background current of 2 mA and pulses of 10 mA during 100 ms every 200 ms.

A.2 Testing the oxygen reservoir of the Zn-A cell

In this test the air holes of the 3 Zn-A cells forming the battery were covered. The objective was to observe how must time the cells could power the microcontroller. In this case the microcontroller was only programmed to store a random number in the flash memory every 3 minutes in order to obtained a duration of time.

The microcontroller was able to store 77 values, thus the battery powered the microcontroller during approximately 3.8 hours.

Considering that the current consumption of the microcontroller was 0.5 mA, the capacity of the cell with only the oxygen available in its reservoir is about 1.9 mAh.

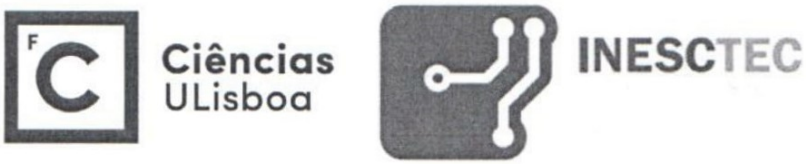
Appendix B

Informed Consent Documents

Before performing the tests, all the participants signed an informed consent. The document was written in Portuguese, since it was the native language of the subjects whom volunteered to participate in this study. We start by explaining the scope of this project, where it is being developed and whom is involved in the study. The goal of the study and what is intended for the subjects to do is detailed, including possible problems associated to it. It is also highlighted that the subject can refuse to participate in the study at any time.

In Figure B.1, B.2, B.3 and B.4 are the signed informed consent.

FORMULÁRIO DE CONSENTIMENTO INFORMADO



INVESTIGAÇÃO NO ÂMBITO DO MESTRADO EM ENGENHARIA BIOMÉDICA E BIOFÍSICA

Autora: Joana Margarida Rodrigues da Silva Dias

Por favor, leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

Este projeto, intitulado "***Towards the development of an automatic maxillary expansion appliance***", está a ser realizado no âmbito de obtenção de grau de mestre em Engenharia Biomédica e Biofísica pela Faculdade de Ciências da Universidade de Lisboa. O projeto está a ser desenvolvido no Instituto de Engenharia de Sistemas e Computadores – Tecnologia e Ciência (INESC TEC) sob a orientação do Dr. Germano Veiga e apoio do Prof. Dr. Francisco do Vale (Faculdade de Medicina da Universidade de Coimbra) e Prof. Dr. Francisco Caramelo (IBILI).

Um dos objetivos deste projeto é testar o funcionamento das pilhas zinco-ar em ambiente intraoral real. Deste modo, é-lhe pedido para colocar um aparelho dentário removível na boca onde estarão inseridas as pilhas de forma a testar então o seu funcionamento. Ser-lhe-á pedido para utilizar o aparelho duas vezes, cada uma com a duração de 1 dia. A colocação do aparelho será realizada por um Médico Dentista especialista em Ortodontia que realizará um molde dos seus dentes previamente.

A preparação e colocação do aparelho nos dentes será realizada no Departamento de Medicina Dentária da Faculdade de Medicina da Universidade de Coimbra.

A utilização do aparelho não irá provocar quaisquer alterações, quer sistémicas quer no aparelho estomatognático, dos participantes. O único efeito aparente estará relacionado com a perturbação da fala, uma vez que o aparelho é um pouco volumoso. Contudo, esse efeito é transitório e não irá impedir-lhe de falar.

A participação neste estudo tem um caráter totalmente voluntário, sem quaisquer custos. Terá total liberdade para recusar a sua participação no estudo a qualquer momento do mesmo.

Assinatura: Joana Margarida Rodrigues da Silva Dias

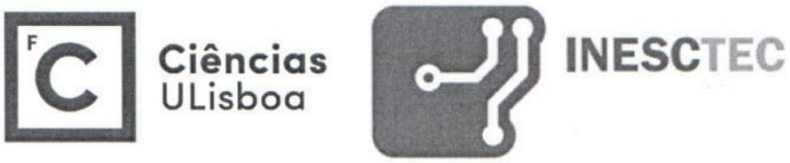
Declaro ter lido e compreendido este documento, bem como as informações verbais que me foram fornecidas pela/s pessoa/s que acima assina/m. Foi-me garantida a possibilidade de, em qualquer altura, recusar participar neste estudo sem qualquer tipo de consequências. Desta forma, aceito participar neste estudo e a utilização dos resultados obtidos para fins científicos.

Nome: JOÃO ÁLVARO SILVA COSTA E SÁ

Assinatura: João Álvaro Silva Costa e Sá **Data:** 08/07/2016

Figure B.1: Signed Informed Consent 1

FORMULÁRIO DE CONSENTIMENTO INFORMADO



INVESTIGAÇÃO NO ÂMBITO DO MESTRADO EM ENGENHARIA BIOMÉDICA E BIOFÍSICA

Autora: Joana Margarida Rodrigues da Silva Dias

Por favor, leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

Este projeto, intitulado "***Towards the development of an automatic maxillary expansion appliance***", está a ser realizado no âmbito de obtenção de grau de mestre em Engenharia Biomédica e Biofísica pela Faculdade de Ciências da Universidade de Lisboa. O projeto está a ser desenvolvido no Instituto de Engenharia de Sistemas e Computadores – Tecnologia e Ciência (INESC TEC) sob a orientação do Dr. Germano Veiga e apoio do Prof. Dr. Francisco do Vale (Faculdade de Medicina da Universidade de Coimbra) e Prof. Dr. Francisco Caramelo (IBILI).

Um dos objetivos deste projeto é testar o funcionamento das pilhas zinco-ar em ambiente intraoral real. Deste modo, é-lhe pedido para colocar um aparelho dentário removível na boca onde estarão inseridas as pilhas de forma a testar então o seu funcionamento. Ser-lhe-á pedido para utilizar o aparelho duas vezes, cada uma com a duração de 1 dia. A colocação do aparelho será realizada por um Médico Dentista especialista em Ortodontia que realizará um molde dos seus dentes previamente.

A preparação e colocação do aparelho nos dentes será realizada no Departamento de Medicina Dentária da Faculdade de Medicina da Universidade de Coimbra.

A utilização do aparelho não irá provocar quaisquer alterações, quer sistémicas quer no aparelho estomatognático, dos participantes. O único efeito aparente estará relacionado com a perturbação da fala, uma vez que o aparelho é um pouco volumoso. Contudo, esse efeito é transitório e não irá impedir-lhe de falar.

A participação neste estudo tem um caráter totalmente voluntário, sem quaisquer custos. Terá total liberdade para recusar a sua participação no estudo a qualquer momento do mesmo.

Assinatura: Joana Margarida Rodrigues da Silva Dias

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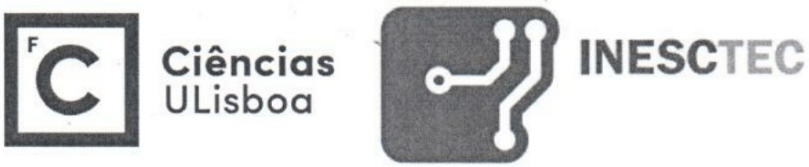
Nome: Joana Margarida Rodrigues da Silva Dias

Assinatura: Joana Dias **Data:** 8 / 7 / 2016

Figure B.2: Signed Informed Consent 2

FORMULÁRIO DE CONSENTIMENTO INFORMADO



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Assinatura: Joana Margarida Rodrigues da Silva Dias

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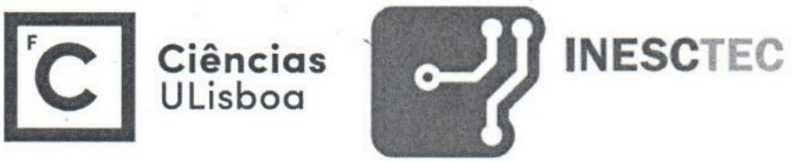
Nome: Mariana da Silva Ferreira Rodrigues

Assinatura: Mariana da Silva Ferreira Rodrigues **Data:** 8 / 7 / 2016

Figure B.3: Signed Informed Consent 3

FORMULÁRIO DE CONSENTIMENTO INFORMADO



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Assinatura: Joana Margarida Rodrigues da Silva Dias

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Nome: Carlo Patrício Pereira Cadete

Assinatura: Carlo Patrício Pereira Cadete **Data:** 8 / 7 / 2016

Figure B.4: Signed Informed Consent 4