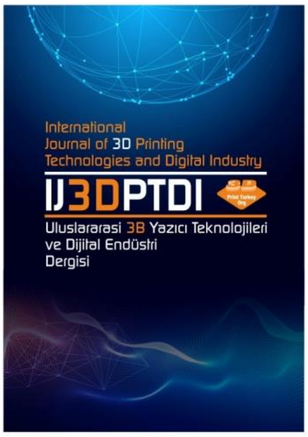

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DESIGNING AND 3D PRINTED PLA BASED IMPLANT USED IN TREATMENT FOR UNILATERAL VOCAL CORD PARALYSIS

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ABSTRACT

This study aims to develop and demonstrate a new method of creating polymeric vocal cord (VC) models via 3D printing to reduce model production time, increase sound efficiency, and lay the groundwork for future models using more realistic geometric and functional biomaterials. For this purpose, it is to produce a poly (lactic acid) (PLA) based VC implant using a 3D printer as a special design according to the patient's vocal structure. In this study, VC 3D PLA implant (VC3DPLAI), VC stretch piece (measured = 35 mm length), fixed to thyroid cartilage VC (cartilage length = 12 mm) and titanium (Ti64) springs pieces are expected to be produced as a patient-specific implant It is composed of three different biomechanical designs. When you compare this implant with other biomaterials, the VC3DPLAI provides personal convenience compared to complex models and allows unlimited time-cost competition.

Keywords: 3D printer, Biomaterials, Implants, Poly (lactic-acid), Thyroplasty, Vocal cord paralysis.

1. INTRODUCTION

Vocal cord (VC) is located in the larynx, right and left. Vocal cord paralysis (VCP) is a voice event that occurs when vocal cord superior (VCS) and vocal cord inferior (VCI) laryngeal nerves do not touch their vocal tracts in the glottic space during phonation [1]–[3]. VCP is generally evaluated in two main groups, one and two sides. In unilateral paralysis, as the affected VC does not reach the midline sufficiently, more space is left between the two cords and the voice becomes quiet. If bilateral paralysis is not enough to open the cords in the middle; although the sound is good, there is not enough air passage, so shortness of breath occurs. Treatment of both conditions is different. The purpose of the one-sided paralysis is to correct voice shortness while the bilateral goal is to correct breath shortness. Medialization technique, which was first applied by Isshiki, is the laryngeal frame surgeon [3]–[7]. In Ishiki's Type-I thyroplasty method, the thyroid cartilage opened a window in the lateral lamina, from which it placed a cylindrical block by medializing the paralytic cavity. In this technique, paralytic side of paralytics textures are brought to the middle line and contacted with the opposite cord [8]–[13]. The medialization laryngoplasty technique applied in vocal cord paralysis is better in terms of sound quality than injected laryngoplasty. Implants applied in Type-I surgery do not change because they are biologically and chemically static with preserved dimensions over time [14], [15]. The permanent vocal mucosa structure in the paraglottic space may cause fibrosis but may be removed more easily than the injection material. Attempts to implant prostheses by laryngoplasty to medialize immobile vocal-preserved and functional prosthesis designs have been increasing day by day [15]–[18]. Many biomaterials are used as VC implant materials such as silicon construction, titanium construction and bioceramic construction materials (Table 1).

Table 1. List of biomaterials are used as VC implant materials

Material	Advantage	Disadvantage
Silicon [19], [20]	Very low financial cost, Inert material, Easy to shape and adapt to the individual situation	To not fix to the thyroid ala
Titanium [21]–[23]	Relatively safe implant material with excellent biocompatibility, Easy to shape and adapt to the individual situation, The design of the implant ensures optimal fixation and stabilization, The implantation is simple and time-saving	Graft rejection and some potential complications
Hydroxyapatite (HA) [23], [26]	Rapid determination of correct size and position, Calcium hydroxyapatite is a FDA approved material, Improved implant stabilization, To minimize tissue reactivity, Locking shims for stabilization	Graft rejection and some potential complications
Lyophilized glutaraldehyde-preserved bovine pericardium (LGPBP) [27], [28]	Easy to insert/remove from the microfenestra, fold, cut, and give shape, Great flexibility	Less memory
Polytetrafluoroethylene (PTFE) [27], [29], [30]	Great memory	Difficult to cut and give shape, Less flexibility
Polyethylene terephthalate [31]–[33] **(PET)**	Great memory	Difficult to cut and give shape, Less flexibility,
Teflon felt (TF) [34], [35]	Great memory	Difficult to fold, cut, give shape, insert/remove from the microfenestra, The requirement for patient cooperation, Less flexibility

This study has discussed the advantage of other PLA-based vocal cord implant models. PLA is a well-known established aliphatic polymer. Its elastic modulus is between 1.5–2.7 GPa and glass transition temperature is around 60°C. Thus, PLA offers great mechanical properties, provides easy blending with many plasticizers to achieve desired rigidity [36]–[38]. In addition, stabilization properties of printed structure are very favorable. Properties of PLA inks for solvent-cast printing of three-dimensional freeform microstructures [39]–[41]. It is semi-crystalline, biocompatible, and has found use in several medical applications like orthopedic implants, drug delivery systems, and bio-fabrication [38], [42]. The semi-crystalline morphology increases mechanical integrity. It is also a hydrophobic polymer, which provides a slow degradation time due to its tendency of noninteraction with water molecules [43]–[46]. Surface modification and tailoring mechanical properties are simpler than its alternatives [47]. Better biocompatibility can be achieved by surface modifications of PLA [48], [49]. Furthermore, surface coatings with inert materials and making cross-linked PLA with other polymers can increase degradation time and that makes PLA a splendid prosthetics material candidate [50]–[53]. In this study, it used with commercially available biomaterials, PLA filaments and VC model which are produced by 3D printer were discussed. How it works, its advantages and disadvantages compared to other similar ones are also discussed.

2. MATERIAL AND METHOD

Except springs all implant parts were printed with the Kupido 3D printer. PLA material is used in this device. This PLA filament was purchased from eSun PLA+ (4043D), of which the average diameter is 1.75 mm ± 0.05 mm. This FDM printing technology, the printing nozzles temperature was set in the range 190° - 205°. Other properties; heated aluminum table; 60°, nozzles size; 0.4 mm, smooth, durable, print speed; 150% mm/sec.

Vocal design consists of three biomechanical designs and methods. Vocal tension piece, fixed to thyroid cartilage and springs that provide flexibility of these two pieces. The technical drawings were made with the Solidworks program. The reason why the thyroid cartilage part is open at both ends is that it creates a cartilage bridge and supports the vocal cord appearance of the vocal back part. The springs are adjusted by pushing and pulling with the cartilage part and provide the desired flexibility in the vocal back part. In this way, the lost sound function will be regained.

The implant prototype is shown in Figure 1 and Figure 3 as a PLA based 3D printed implant model designed and developed for VCP medialization type I surgery. VC3DPLAI model has been our main aim to restore the patient's voice function by adjusting patient's VC tension. Previously used biomaterials, while still providing a static structure to the patient vocal, were only able to serve as fold to the cords and could not produce a permanent and innovative solution to the lost sound aesthetic.

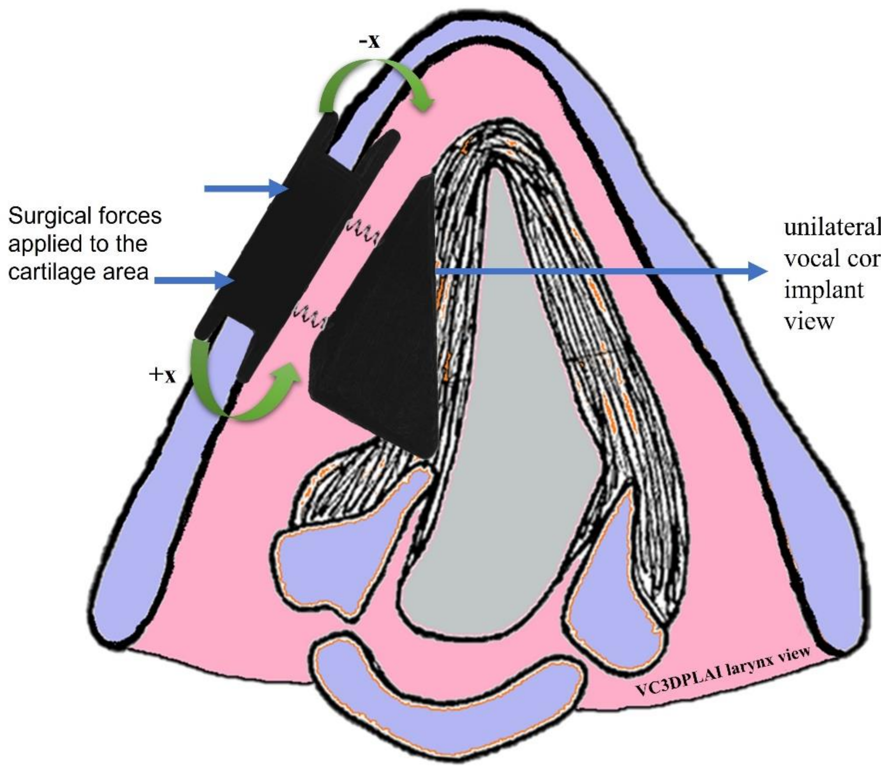

Figure 1. VC3DPLAI Larynx view

VC3DPLAI's technical drawing and 3D printer material are shown in Figure 2 and Figure 4. In the technical study, VC3DPLAI is designed and manufactured according to the person, so the technical drawing data on it is calculated and modeled by taking the average values from the general literature data.

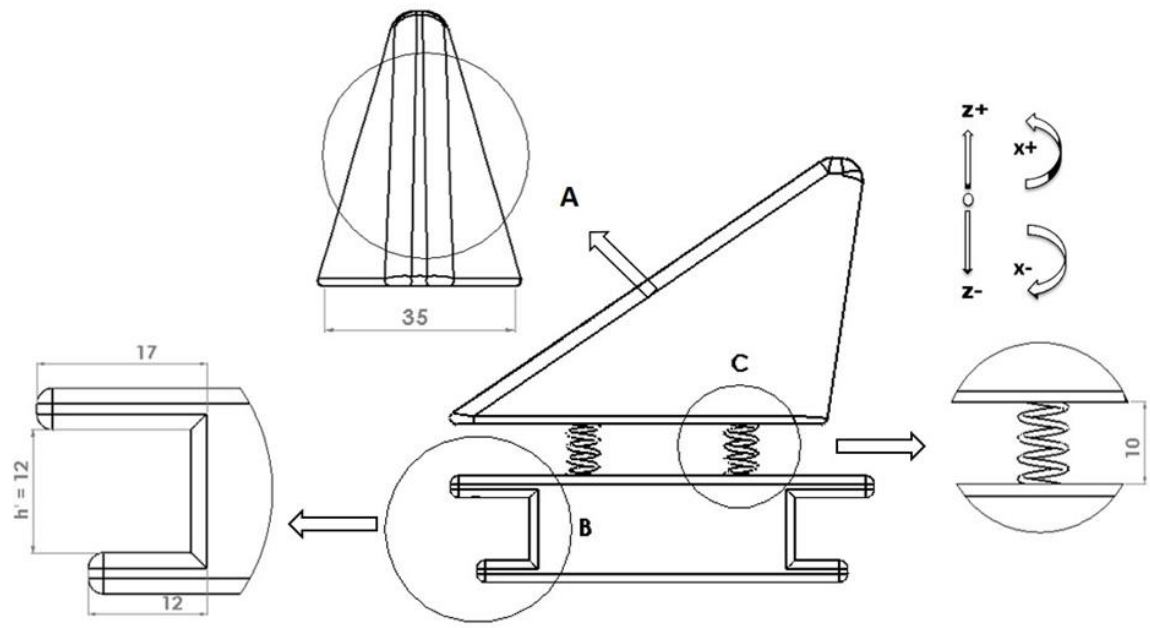

Figure 2. VC prototype technical drawing (This prototype was draw and designed with Solidworks program)

Implant model's work system;

A. VC stretch piece: unilateral VC region designed to create the VC print/back in the tissue region where the VC is formed. This part (with part C springs) provides back and forth stretch in the $^{+}$z and $^{-}$z directions at zero angle. Furthermore; this part makes an angle in the $^{+}$x/$^{-}$x directions (with part C springs). This system with, which brings the vocal to the medial position by making an angle, improves both the quality of the functional change of the degradation of the structure of the mucosa. This piece supporting the VC was measured in T = 35 mm (T; cover inferior medial surface) length. This cord piece has been given a depth (A; cover medial surface) so that the cord can and function without slipping and exuding. This depth varies according to male and female cord structure. The closer the spring distances (spring release, 10 mm) are kept, the farther we can provide the flexibility of the spring.
B. Fixed to thyroid cartilage VC: this part is the lower part of the cartilage that stabilizes the cartilage. Muscle attached to cartilage length is = 12 mm (h').
C. Titanium springs: these springs is Ti64 biomaterial that provides both a stabilized structure and a dynamic function for parts A and B.

3. RESULTS AND DISCUSSION

Voice communication depends on symmetrical vibrations within the VC and is indispensable for various professions such as sales representative, teacher, and doctor. Unexpected dysphonia can force individuals to quit their jobs [54]. VCP is treated by MT 1 surgery. Many implants have been tried for this treatment in the past years. For instance, in the early days, thyroid cartilage was used by itself, and later years many implants such as polytetrafluoroethylene were used. The choice of implant depends mainly on surgical experience. There is no difference between existing implants in terms of surgical success and complications.

Thyroprotip™ titanium model (Strasbourg, France, Figure 3.a) [55] is adjustable implant model with porous structure. This model is the closest implant system to the original desired design. Adjustable bolt is available to increase or decrease sound aesthetics. The cord design, which will bring the paralyzed folded shears to the medial level, is in a pore structure. Injuries can be avoided by injecting antibiotics on the porous structure to prevent complications that may have occurred in wounded or ulcerated surgical injuries. However, system design will have negative implications for future granulomal development on implant model when both porosity and bolt structure are taken into consideration. Tissue formation will transform the whole system into a non-smoothing and convert it into a fully functional model with the fully rigid Montgomery silastic system. In addition, since tissue formation is excessive, it is difficult to remove the implant. TVFMI™ titanium model (Gerhard Friedrich M.D design, Figure 3.b) [56] is a static implant model. Like the clamp system, it compresses the paralyzed fold tissue at the medial level. The contribution of the titanium material to the sound quality is important. Dean and coworkers performed an adjustable laryngeal implant made of titanium developed for the treatment of unilateral VCP. Analysis of subjective responses confirmed marked development in normal laryngeal function, swallowing, and speech. According to their examination, the implant has many advantages containing: exact medialization, ease of secondary adjustment, and conservation of the mucosal wave [57].

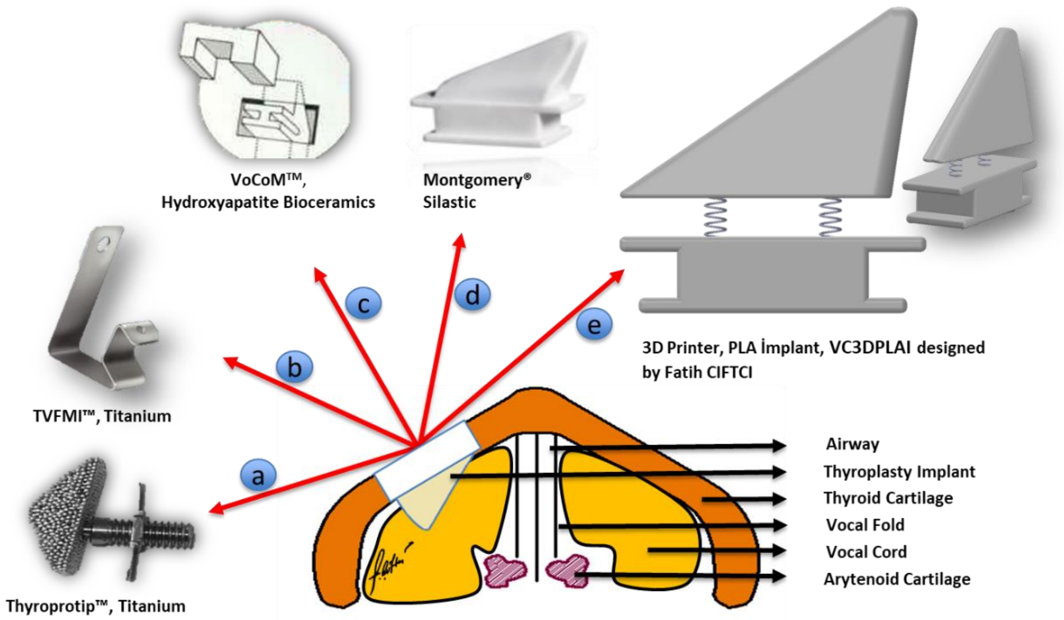

Figure 3. All biomaterial implants used and produced for VC medialization Type 1 surgery, a. Titanium, Thyroprotip™, manufactured by PROTOTIP, Strasbourg, France [55] b. TVFMI™ Titanium Medialization Implant, Gerhard Friedrich M.D. (Graz, Austria) design [58] c. Hydroxyapatite Bioceramics VoCoM™, d. Montgomery® Silastic [59][60] e. 3D Printer manufactured with PLA as prototype, Istanbul, Turkey

VoCOM™ model (Figure 3.c) [61]–[63] is a hydroxyapatite bioceramically based VC implant material. The rigid structure, inert, the same mineral as the bone and the tooth, can be used for bringing the design model to the fore in terms of its chemical properties and its attachment properties. Moreover hydroxyapatite is useful in order to improve implant stabilization. Calcium hydroxylapatite is a kind of bio-ceramic that is approved by FDA in order to use as implant. However, graft rejection and some potential complications are limitations of using hydroxyapatite [62], [64]–[66].

The Montgomery® model (Figure 3.d) [67], [68] is injection molded implanted and used as a silicone material. It only provides a temporary solution to voice functions. There is no quality or enhancement function in the sound quality. Silicone is very cheap, inert material, and easy to shape and adapt to the individual situation. However, it is not fix to the thyroid ala [68].

VC3DPLAI model (Figure 3.e and prototype material Figure 4) we designed offers an alternative to the use and placement of nanocomposite and nanoparticle materials in the treatment of grafts present in vocal cord paralysis and in the treatment phase. This model, which can be adapted to the existing cartilage window, is more suitable for revision surgeries as it will reduce costs. Region B of the model (Figure 4) is designed to hold onto vocal cartilages and to prevent extrusion. The spring in zone 3 is Ti64 material, providing both stabilization and dynamic operation. Areas B and C are coated with hydroxyapatite to activate the surface to provide tissue formation at the fold. Part A is designed to bring the vocal fold to the medial level. The upper and lower points are cylindrical and thought to be non-damaging to tissue. The VC3DPLAI model will be custom designed, according to symphtom phases of fold paralysis, implant model can be designed and producteed as porous structures.

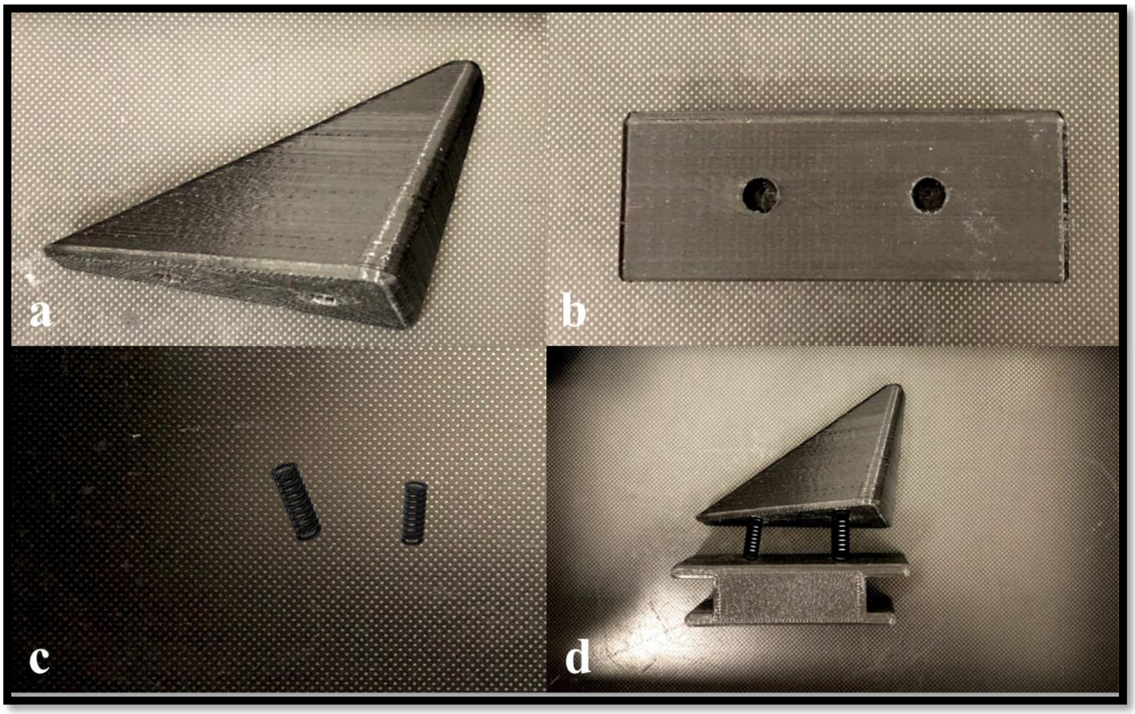

Figure 4. Manufactured VC3DPLAI prototype model materials, a. VC stretch piece b. fixed to thyroid cartilage VC c. titanium springs d. VC implant model

4. CONCLUSION

Recent studies, the VC implants being manufactured are produced as a uniform standard in the static structure. However, these standard dimensions do not correspond individually to the cord or fold structure, which is different anatomical structure for each person. This treatment does not contribute to sound aesthetics. In order to eliminate this problem, in this study, modeling of the unique VC implant using 3D printing technology was compared with other counterparts. Although the prefabricated products that are ready to be used in vocal implants to be manufactured are accepted as the gold standard due to their biocompatibility and superior mechanical properties, they are not able to provide aesthetic image adequately, they are inadequate as a result of implantation with distal angulation and placement and they cannot provide a voice function profile close to the ideal. As a result of that, old implants leave their place to 3D printed implants which can be customizable and ideally designed for each patient. It has been reported by many studies that there are many advantages of the patient specific implants in terms of both function and aesthetics over the prefabricated implants.

In this study, VC3DPLAI was designed and prototyped and custom mode design was discussed. This model, which is expected to be produced as a patient-specific implant by examining the morphologic structure of a UVCP patient, allows for an unlimited amount of time-cost competitiveness, considering personal suitability compared to complex models. The long-term success of the VC3DPLAI implant model, which is to be prepared with a person-specific basis, an important tool for solving prosthetic problems, is not yet known. However, the success of the VC3DPLAI implant is planned to be clarified in the future in line with possible clinical studies and reports. VCP treatments are an important issue for both the application as a surgical technique and the material mechanics and biocompatibility to be developed for this application. Although this approach, which stands as an innovative solution for Ear Nose and Throat surgery, seems scientifically innovative, it should be practically tried and developed by working with otolaryngologists.

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