Smart stent: A new concept for the treatment of central airway obstructions

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Abstract

Stenting has been in practice for the last few decades in the palliative management of both benign and malignant (intrinsic and extrinsic) obstructions of the central airways (i.e. trachea and mainstem bronchi). The symptoms of central airway obstructions are late findings and these symptoms often overlap with those found in asthma and chronic obstructive pulmonary disease. Therefore, its prognosis is poor and the patients with malignancy are often misdiagnosed. Almost all the commercial airway stents are normally preloaded into a significantly small diameter dedicated delivery system and deployed mostly under bronchoscopic guidance. This research work is aimed to use Auxetic (rotating-squares) pattern for the production of a novel Auxetic airway stent to maintain the luminal patency of the central airways in an effective way. This study also endeavoured to manufacture a significantly small diameter Auxetic airway stent. In order to easily deploy the Auxetic stent orally using a balloon catheter, and hence it also prevents the need of an expensive dedicated delivery system.

Keywords: Auxetic; Central airway obstructions; Lung cancer; Airway stents; Palliation; Additive manufacturing

Introduction

Research Motivation

Non-vascular stenting has been in use for the last few decades in the palliation of transient and chronic (benign and malignant) obstructions of natural circulatory pathways that enable the transfer of air, bodily fluids and other substances involved in systemic metabolic and energy exchange. These non-vascular circulatory pathways include the Gastrointestinal (GI), pulmonary, biliary tree and urinary tracts. Obstruction of the central airways, the trachea and mainstem bronchi, can result from a variety of disease processes and is the cause of significant morbidity and mortality. In United States, it is estimated that malignant neoplasms will cause Central Airway Obstruction (CAO) in 80,000 cancer patients a year. It is also evaluated that 20% of these patients will experience significant morbidity due to persistent cough, dyspnea, and obstructive pneumonia, and as many as 35-40% of lung cancer patients die due to complications resulting from locoregional disease [1].

The primary lung cancer is divided into two main types, i.e. (i) Small Cell Lung Cancer (SCLC) and (ii) Non-Small Cell Lung Cancer (NSCLC). NSCLC has further three types which are squamous cell carcinoma, adenocarcinoma and large cell carcinoma. These subtypes are group together because they behave in a similar way and respond to treatment in a different way to small cell lung cancer [2]. In United Kingdom, there are more than 39000 new cases of lung cancer each year and more than 35000 people die from lung cancer, which is more than breast cancer and colorectal cancer combined. Presently, lung cancer is the leading cancer of death in women and about 90% of lung cancers are caused by smoking. Lung cancer deaths in men have decreased by more than a quarter in the UK [3]. An estimated 20-30% of patients with lung cancer will develop complications associated with airway obstructions (atelectasis, pneumonia, dyspnea etc.), and up to 40% of lung cancer deaths may be attributed to locoregional disease [4]. The most common malignant causes of CAO are direct extension into the airway lumen by extrinsic tumours. Of these tumours the most common types are bronchogenic carcinomas (i.e. small cell and non-small cell lung cancers), followed by oesophageal and thyroid carcinomas. Primary tumours of the trachea and bronchi, or intrinsic central airway tumours are relatively rare.

Squamous cell or adenoid cystic carcinoma type of tumours accounts for (70 -80%). Squamous cell carcinomas typically occur later in life and more frequently in men and smokers, while adenoid cystic carcinomas are found in younger patients and are not related to exposure to smoking or to the sex of the patient. Occasionally, but less frequently, metastases from carcinomas of the breasts, kidneys, colon, thyroid and oesophagus may spread to the respiratory system and cause CAO. Clinical manifestations of malignant CAO depend on size, location, and the rate of progression of airway obstruction. If encroachment into the airway is minor, then there will be little impact on airflow and patients will likely be asymptomatic and never brought to clinical attention. The majority of patients that experience symptoms of CAO have advanced disease and a history of underlying malignancy. Thus, symptoms of CAO are late findings and include dyspnea, cough, wheezing, stridor and frequently pneumonia. Because these symptoms overlap with those found in asthma and chronic obstructive pulmonary disease (COPD), patients

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with malignant CAO are commonly misdiagnosed [1].

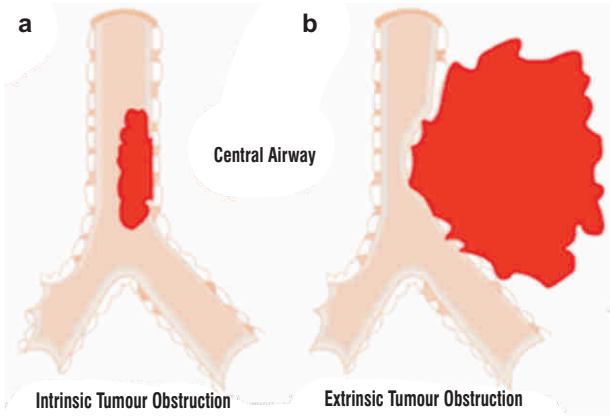

Figure 1:(a) Intrinsic and (b) extrinsic, obstruction of the central airway due to tumour extension [5]

Surgery is the treatment of choice for those patients with early-stage lung cancers; unfortunately, most patients normally develop advanced lung cancer at the time of diagnosis. These patients branded with a poor prognosis may not benefit from surgery with a curative intent; however, palliative treatment is required in such cases with the hope of providing a reasonable quality of life [6]. A number of interventional procedures have been in use to relieve central airway obstructions, which include surgical resection or core-out, Nd-YAG laser ablation, photodynamic therapy, brachytherapy, cryotherapy, electrocautery and pulmonary stenting. These procedures are useful for intrinsic obstructions, and only stenting can provide effective structural support for patients with extrinsic airway compression as well as those with intra-luminal obstructions [7].

The main objective of inserting a tubular stent into central airways (i.e. trachea and mainstem bronchi), is to restore patency of the central airways. Airway stents are useful in airway obstruction, which leads to the onset of debilitating symptoms such as dyspnea regardless of the fact that whether the obstruction is due to a malignant or benign process either intrinsic or extrinsic to the airway. These may also be used to cover fistulae between the central airways and local structures such as the mediastinum or oesophagus [8].

The airway stents were introduced when Montgomery developed a silicone T-tube in 1965 for use in patients with tracheal stenosis. The Montgomery T-tube stent was later modified by Westaby and co-workers in 1982 and they designed the T-Y tube with the intent of providing airway stability in patients with obstruction of the distal trachea and mainstem bronchi. The main drawback in both of these early tubes was that they require a tracheotomy to anchor the horizontal limb of the stent [4]. There are currently two main types of airway stents, i.e. silicone and self-expandable metal stents (SEMS). Almost all the airway stents are normally preloaded (compressed) into a significantly small diameter dedicated delivery system, which can be easily inserted orally and deployed at the targeted site by just pushing the stent outside so that it can restore its actual diameter. SEMs are available in covered (typically with Silastic or polyurethane) and uncovered varieties.

For the treatment of malignant; there are two types of delivery systems for the placement of tracheobronchial stents which are, (i) a flexible device (Telestep) on which the stent is mounted in a compressed and elongated shape, and (ii) a specially designed rigid bronchoscope (Rigidstep). With the Telestep the radiopaque stent is usually deployed under fluoroscopic control through the bronchoscope, and this device can be used for all lesions. With the Rigidstep the deployment procedure is controlled endoscopically by a rigid lens passed down the middle of the bronchoscope with the inside of the stent being visible. Stenotic lesions must have a lumen of greater than 12 mm for the Rigidstep to pass them [5].

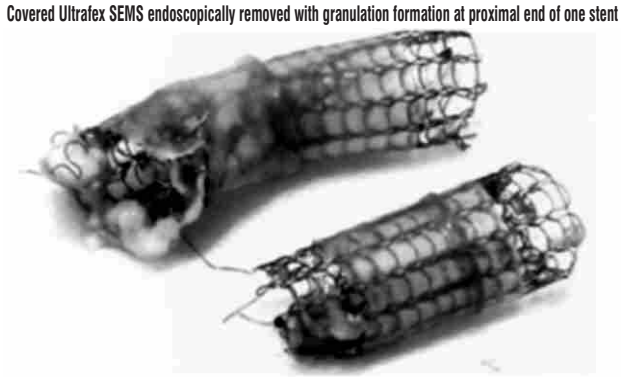

Figure 2: Ultraflex SEMS removed endoscopically [9]

A distinct advantage of metal stents is their larger internal: external diameter ratio as compared with silicone stents. Metal stents are normally placed via flexible bronchoscopy, and silicone stents on the other hand require rigid bronchoscopy for the placement. Silicone stents have an advantage that they are easily removed and are significantly less expensive [4]. SEMS are indicated for unresectable malignant airway disease because, once placed, these are considered permanent and it is very difficult to remove them. These stents also conform better to tortuous airways than rigid silicone stents, as their flexibility allows them to negotiate easily to the changing airway anatomy.

Over a period of time the metal stent is incorporated into the airway wall and its mesh becomes covered with mucosa. Therefore, metal stents may be effective temporarily for the airway obstructions due to intra-luminal tumour or granulation tissue, since both can eventually grow between the wire mesh. Silicone stents are intended to be permanent and can be removed or displaced easily. Silicone stents are used when stenting is intended to be temporary as they can be easily removed when the obstructive airway disease subsides [7]. The complications in airway stents include stent migration more commonly seen with silicone stents, and stent obstruction by recurrent tumour in-growth or granulation tissue formation (typically seen with metal stents [1]. The major complications related to silicone stents are; migration (9.5%), formation of granuloma (7.9%), obstruction secondary to secretions (3.6%) and bacterial overgrowth .

Auxetic Structures

Auxetic structures, has a counter-intuitive behaviour and exhibit the very unusual property of becoming wider transversely when stretched longitudinally, that is they possess negative Poisson's ratio [10]. The Poisson's ratio is defined as the negative ratio of the transverse strain and the axial strain in the direction of loading. All common materials have positive Poisson's ratio, i.e. the materials contract transversely under uniaxial extension, and expand laterally when compressed in one direction. This process of expansion and contraction is reversed in Auxetic structures.

Several Auxetic structures have been fabricated by modifying the microstructure of existing materials in recent years. It was expressed that the Auxetic structures have enhanced and improved properties than the conventional materials. Auxetic materials have increased indentation resistance, enhanced shear modulus, good absorption properties like acoustic absorption, and improved fracture toughness as compared to the conventional materials [11]. In all of the Auxetic materials there is a specific microstructure that is vital to creating a negative Poisson's ratio, deformation mechanism such as rib hinging, bending or stretching and rotating. Their length scale varies from the nanometre for crystal structures to tens of metres for the key-brick structures [12]. There are many types of Auxetic structures which are currently present and vary from each other according to their structural difference, deformation mechanism and scale. A range of Auxetic materials have been discovered, fabricated, synthesized and theoretically predicted [10]. A mechanism to achieve negative Poisson's ratio was previously introduced by [13], which was based on an arrangement involving rigid squares connected together at their vertices by hinges. As each unit cell contains four squares, each square contains four vertices and two vertices correspond to one hinge.

A new mechanism to acquire negative v is based on an arrangement involving rigid squares connected together at their vertices by hinges. As each unit cell contains four squares, each square contains four vertices, and two vertices correspond to one hinge [14].

This research paper aimed at giving a new concept of an Auxetic airway stent as a novel structural support for the treatment of central airway obstructions (i.e. trachea and mainstem bronchi). This new Auxetic airway stent having a negative Poisson's ratio will expand in both circumferential and longitudinal directions. A new manufacturing technique was adopted in this study for the development of Auxetic airway stent. Another focal point of this study is to develop a significantly small diameter stent, in order to easily deploy the Auxetic airway stent using a low cost balloon dilatational catheter, and therefore it also avoids the requirement of an expensive dedicated delivery device.

Materials and Methodology

A polymeric Auxetic airway stent was fabricated in a seamless fashion by introducing rotating-squares geometry into a polymeric tube by using a novel manufacturing technique. Polyurethane was selected as a material because of its good biocompatibility and non-toxicological response and also polyurethane is a material of choice in most of the SEMS as an internal covering. Polyurethane is an attractive choice, since their physicochemical properties can be modified by changing the ratio of soft segment to hard segment and their respective chemistries to conform to the desired application. Therefore, a commercial semi-rigid polyurethane material was acquired to construct an Auxetic airway stent as illustrated in Figure 3.

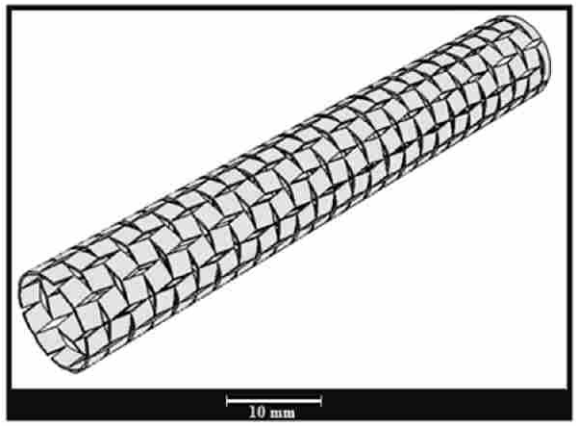

Figure 3: Schematic showing an Auxetic airway stent

Casting using an Antipode-Auxetic tubular template

A novel antipode-Auxetic template which was having recessed rotating-squares and protruded rhombus-shaped parts was used in this method for casting polymer. The antipode-Auxetic template was fabricated by Fused Deposition Modelling (FDM) technique which is an additive manufacturing method (i.e. rapid prototyping method), and which can build prototypes out of thermoplastic polymers. STRATASYS FDM 360mc equipment was used for this purpose which constructed tubular template based on deposition of extruded thermoplastic acrylonitrile-butadiene-styrene (ABS) polymer as shown below in Figure 4.

Figure 4: STRATASYS FDM 360mc machine

Therefore, a three-dimensional (3D) design of the tubular template wascreated by the Autodesk Inventor CAD software. The antipode-Auxetic template was 120mm long with an outer diameter of 15mm and the diamond-shaped parts were 2mm protruded outwardly from the surface of the tubular template. The design file was then transferred as an STL file to the Insight software of the FDM 36mc machine as illustrated below in Figure 5.

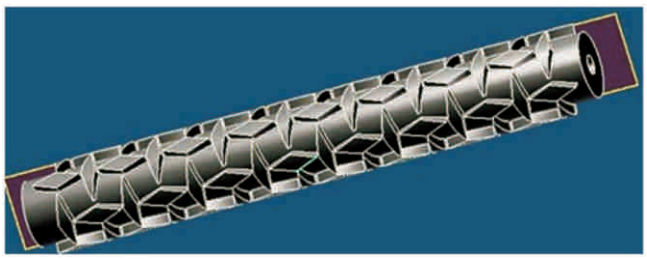

Figure 5: A3D design of Auxetic (reverse) tubular die

FDM 360mc equipment was used for the production of antipode-Auxetic template by using thermoplastic acrylonitrile-butadiene-styrene (ABS) material. The system oven temperature was 90°C, Model temperature was 310°C, and the Support temperature was maintained around 220°C. When the part production was completed by FDM process, the part (in Figure 6) was taken out of the build chamber and the temporary supports were separated away manually by hand.

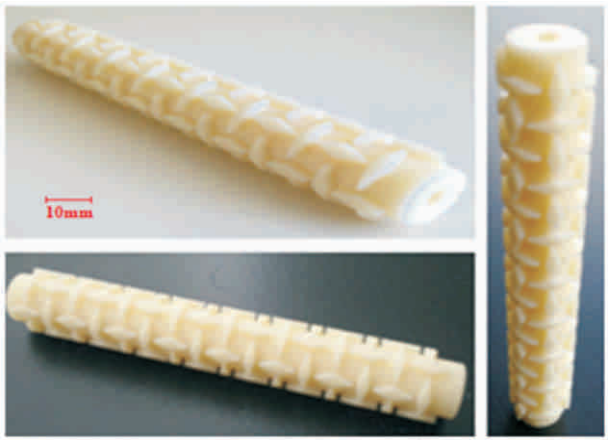

Figure 6: An antipode-Auxetic template made by ABS plastic

For polymer casting into the above developed tubular template, a hollow TEFLON tube was used in a way to tightly enclose the reverse-Auxetic tubular template by pushing out the polymer from the surfaces of the protruded diamond-shaped parts. The internal diameter of the TEFLON (external) tube and the outer diameter of the antipode-Auxetic tubular template were same, in order to achieve friction between the walls of the two tubes as shown in Figure 7. The aluminium foil was used with a clamp to close the TEFLON tube from one side (in Figure 8b).

This method was tried by casting a commercial two part silicone elastomer *Flexil-S* along with cross-linker *Catalyst-S*

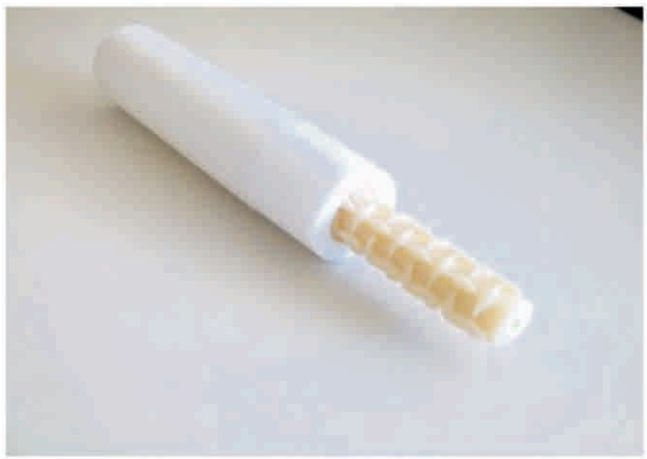

Figure 7:A tubulartemplate is fixed tightly within TEFLON tube

acquired from Jacobson Chemicals Limited. *Flexil-S RTV* material cures at room temperature and was used with the crosslinker *Catalyst-S* which is also a room temperature vulcanized system. The green colour *Catalyst-S* crosslinker (hardening agent) was added into the white colour *Flexil-SRTV* viscous material by the weight ratio of 10:1, i.e. 7 grams of *Catalyst-S* was added into 70 grams of *Flexil-S RTV* material. The viscosities of *Flexil-S* and *Catalyst-S* were 24000cps and 55cps respectively, and the Pot life of *Flexil-S* after mixing with *Catalyst-S* was 75mins. The silicone elastomer material was subsequently dispensed into the TEFLON tube, and the reverse-Auxetic tubular template was gradually inserted manually into the filled TEFLON tube, leading into pressing out of the extra material from the TEFLON tube (in Figure 8a). Once tubular template was completely placed inside the TEFLON tube by pressing out all the extra material and by the removal of the material from the surfaces of the diamond-shaped parts, they were kept for curing for two hours as shown in Figure 8b.

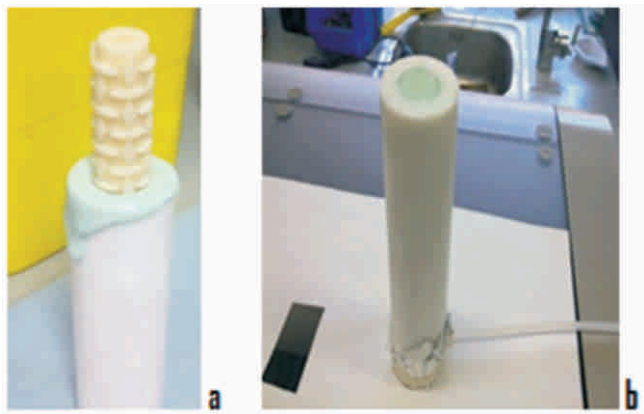

Figure 8: (a) Reverse-Auxetic template being pushed inside a TEFLON tube, and (b)silicone elastomer casted onto an antipode-Auxetic template inside the TEFLON tube

Subsequently, the silicone was completely cured and the aluminium foil was removed. The antipode-Auxetic template

was pushed out from one side of the TEFLON tube carefully. The Auxetic airway stent casted onto a tubular template was then carefully removed, and the material still intact within the hollow diamond-shaped areas of an Auxetic stent was taken away by tweezers (in Figure 9b). The outer diameter of the Auxetic stent was 13mm and the wall thickness was 2mm.

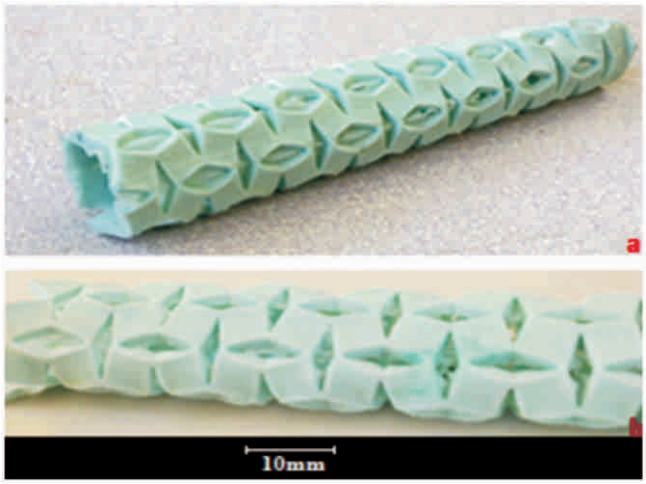

Figure 9:(a) Auxetic stent removed from the templatewith some material intact within the diamond-shaped areas, and (b) material removed by the tweezers

Vacuum Casting

The previous casting method where easily available silicone material was tried for casting into an antipode-Auxetic template was not continued further with polyurethane material, and a new rapid prototyping technique named as vacuum casting was employed in this study. The MK Technology basic model SYSTEM-1 was used for this purpose, which is perfectly dimensioned for classical prototype production. This system comes with a very smart mould lift which helps to adapt the position of the mould exactly to the funnel as shown in Figure 10.

Figure 10: MK Technology basic model SYSTEM-1

A pre-requisite for using a specific polymer in vacuum casting method, is a perfect Master model which can be built conventionally or by new additive manufacturing methods. In the development of Master model every detail of the actual part should be considered, so that the Master model can be duplicated with a desired material by the help of vacuum casting process. A 3D design of the Master model was developed which was an actual Auxetic airway stent by using Autodesk INVENTOR software. The 3D design was 120 mm long with 10mm outer diameter and 0.5mm wall thickness, and was exported to the INSIGHT software of the FDM equipment for part production. The Master model was fabricated by FDM rapid prototyping method using acrylonitrile-butadiene-styrene (ABS) material (in Figure 11).

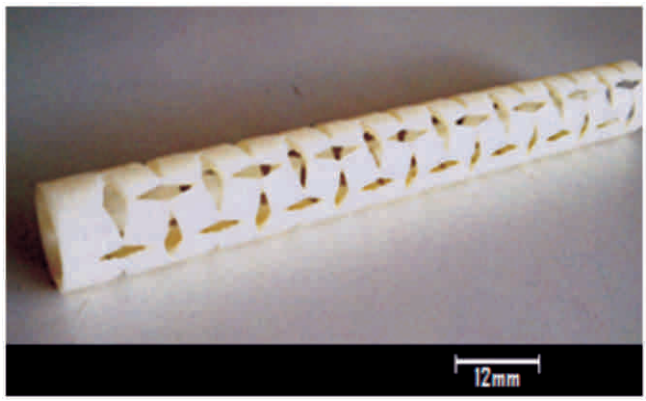

Figure 11: Master model (Auxetic airway stent) made of ABS plastic by FDM process

Initially, for vacuum casting, a silicone mould was required having a Master model suspended inside the mould with gates and risers as illustrated in Figure 12. A solid metal rod was also inserted inside the suspended Mastermodel within the silicone mould.

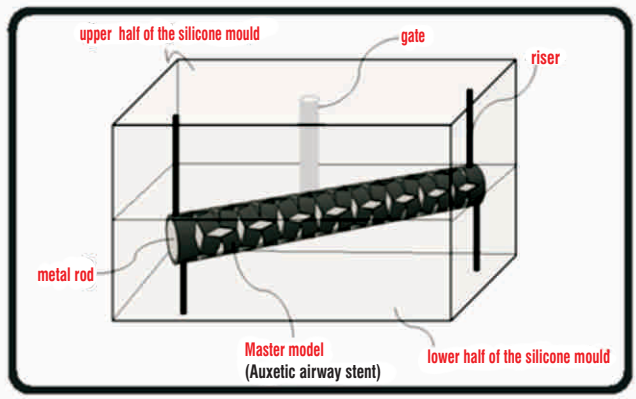

Figure 12: A schematic showing Master model suspended inside the silicone mould

Consequently, a casting frame was developed quickly and inexpensively from melamine coated chip boards glued together. The gates and risers were adjusted and the casting frame must be big enough to allow an all around covering of the Master model with the silicone layer of at least 2 to 3 cm. For the preparation of mould, the silicone was completely pre-degassed since the remaining gas particles within the mould

extend under vacuum and that effect the dimensional stability of the cast. The silicone was carefully poured into the casting frame from one side after degassing. Once the casting frame was completely filled and the Master model was covered by a layer of atleast 2cm of silicone, the casting frame was placed inside the vacuum chamber for further degassing of the silicone. When the silicone was hardened, the compressed air was blown inside the mould through the gate to remove the Master model evenly from the mould without the metal rod, i.e. by leaving inside the metal rod into the casting cavity of the mould.

Subsequently, when the mould was ready for casting, a semi-rigid VC-3300 three part polyurethane resin of 95 shore A hardness was used for casting into a silicone mould under vacuum. The polyurethane casting resin was pre-degassed for about half an hour. The silicone mould was then placed inside vacuum chamber on the mould lift, and the polyurethane was poured into the mould through funnel. After hardening of the casted polyurethane resin within the mould, scalpel and pressurized air was used for effective parting of the mould. The mould was then slightly opened from the side, and the casted Auxetic polyurethane tube with a metal rod was taken out manually by using pliers.

The Auxetic airway stent was finally separated from the metal rod by simply sliding the rod outside. The semi-rigid Auxetic airway stent was exactly replicated by the Master model and was 120mm long with 10mm outer diameter and 0.5mm wall thickness (in Figure 13).

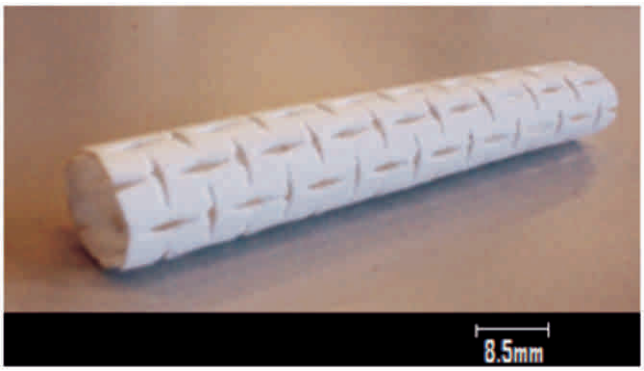

Figure 13:Auxetic airway stent developed seamlessly by using polyurethane material

Auxeticity Test

It was envisaged that the deployment of Auxetic airway stent will be without a dedicated delivery device and bronchoscope. This will be administered orally into the central airways (such as trachea) using a small diameter inexpensive balloon dilatational catheter under fluoroscopic guidance. Therefore, a test was carried out to validate negative Poisson's ratio or Auxeticity in an Auxetic airway stent, i.e. to check whether the stent is expanding both radially and longitudinally when subjected to radial pressures from the balloon catheter. In this experiment, a semi-rigid Auxetic airway stent; 50mm length, 10mm outer diameter and 0.5mm wall thickness, was tested using MEDFLATOR-II inflation device (Smiths Medical Deutschland GmbH) and CRE wireguided balloon catheter (18mm, 19mm and 20mm diametrical range) of 55mm balloon length (supplied by Boston Scientific UK) as shown in Figure 14a. Initially, the Auxetic airway stent was mounted on the balloon and the inflation device with a built-in manometer was filled with water and subsequently attached to the balloon catheter. Small pressure increments from the inflation device were then applied through balloon to the stent, and axial length and the diameter of the stent were recorded at every pressure increment, till the point of stent failure (in Figure 14).

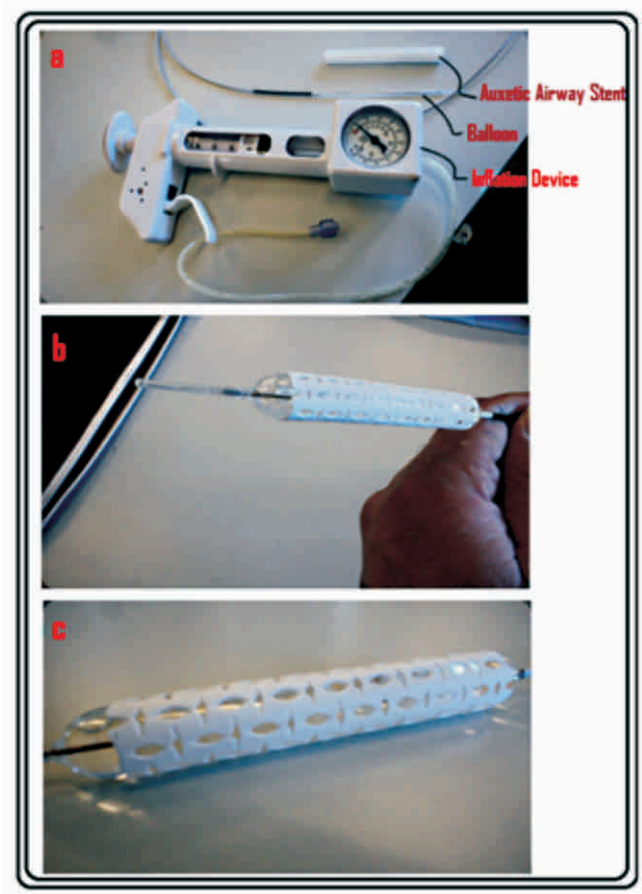

Figure 14: (a) Auxetic airway stent along with balloon catheter and inflation device, (b) Auxetic stent mounted on a balloon catheter and (c) and axial length and diameter of the stent is being checked at different pressures

Results and Discussion

This study employed a new manufacturing route for the production of novel Auxetic airway stent. Polyurethane was used as a material due to its good biocompatibility and non-toxic behaviour. Polyurethane is a good candidate as its physicochemical properties can be adjusted to suit the intended applications, i.e. by changing its hard segment polyurethane can be made either flexible (elastomer) or rigid (plastic) and by tailoring its soft segment polyurethane can be made either biodegradable or stable. The novel concept of an Auxetic oesophageal stent made of polypropylene material was successfully developed and the work has been published . The research work focuses on the seamless manufacturing of

the Auxetic airway stent with a significantly small pre-deployment diameter to facilitate oral insertion.

Initially, a novel antipode-Auxetic tubular template (having recessed rotated squares and protruded diamonds) was used and casting was tried by commercially available silicone elastomer. The antipode-Auxetic template was built by FDM method using ABS plastic material. The silicone casting into tubular template was carried out by using a hollow TEFLON external tube, which tightly enclosed the tubular template and forced the extra polymer on the surfaces of the diamond-shaped parts of the template to come out (as mentioned earlier in Section 2.1).

The silicone casting in an antipode-Auxetic template was found to be complex as the manual extraction of the template from the TEFLON tube was difficult. It was also found difficult when removing the casted polymer from the tubular template, since the Auxetic stent was interlocked between the protruding diamonds of the tubular template. The quality of the final Auxetic airway stent by this technique was poor, because removal of the Auxetic stent from the template was detrimental. It was also found that due to the little gap (possibly in microns) between the lumen of the external TEFLON tube and outer surface of the tubular template, a very thin layer of casted material was present over the surfaces of the diamond-shaped parts of the template which was not pushed out completely. As a result, the diamond-shaped parts of the Auxetic airway stent were not hollow, and the intact material within the confines of the diamond-shaped bits was subsequently removed by the help of tweezers (in earlier Figure 9).

The production of the seamless Auxetic airway stents was subsequently explored by employing vacuum casting (rapid prototyping) technique. A pre-requisite for vacuum casting is a perfect Master model. Therefore, an ABS plastic Master model was fabricated by using new additive FDM manufacturing technique, which incorporated every details of the actual Auxetic airway stent (in Figure 11), ensuring that it can be duplicated with a desired material by the help of vacuum casting process. The vacuum casting technique involved four major process steps ranging from fabrication of the Master model to stent removal from the template. The first two steps were the onetime processes used in this technique, which involved production of the Master model and silicone mould making process. The casting of the seamless Auxetic polyurethane stent lasted 2 hours and 15 minutes, whereas the first two one-off process steps took 7 hours. The vacuum casting method was found to be simple and it produced reproducible results. Additionally, the Master model and silicone mould can be used number of times in vacuum casting method, as it is a one-off investment. Finally, the Auxetic airway stent produced by this technique was an exact replica of the Master model as it was reported earlier by [13] and were good in quality (in earlier Figure 13).

A test was performed in this research by expanding the seamless semi-rigid Auxetic airway stent made of polyurethane material, using a balloon catheter. The test was conducted in order to validate the Auxeticity in an Auxetic airway stent, and for this purpose diametrical change and longitudinal expansion of the stent were estimated at different applied radial pressures (in Table 1).

Table 1: Expansion data of an Auxetic airway stent

Pressure (bar) from Balloon	Stent Diameter(mm)	Stent Length(mm)
0.0	10.0	50.0
0.6	10.5	50.5
1.0	11.5	51.2
1.5	11.8	51.7
2.0	12.7	51.8
2.5	14.7	51.8

From the above Table 1 and in below Figure 15, it was found that the Auxetic airway stent radially expanded from 10.5 to 14.7mm and longitudinally extended from 50.5 to 51.8mm at a range of pressure increments from 0.6 to 2.5bar applied from the balloon. The Auxetic airway stent was finally snapped at a pressure of 2.7bar. Therefore, it was established from this test that the airway stent was Auxetic in nature and the rotation or hinging mechanism of the unit cells of this geometry played a very key role in the overall expansion of the airway stent.

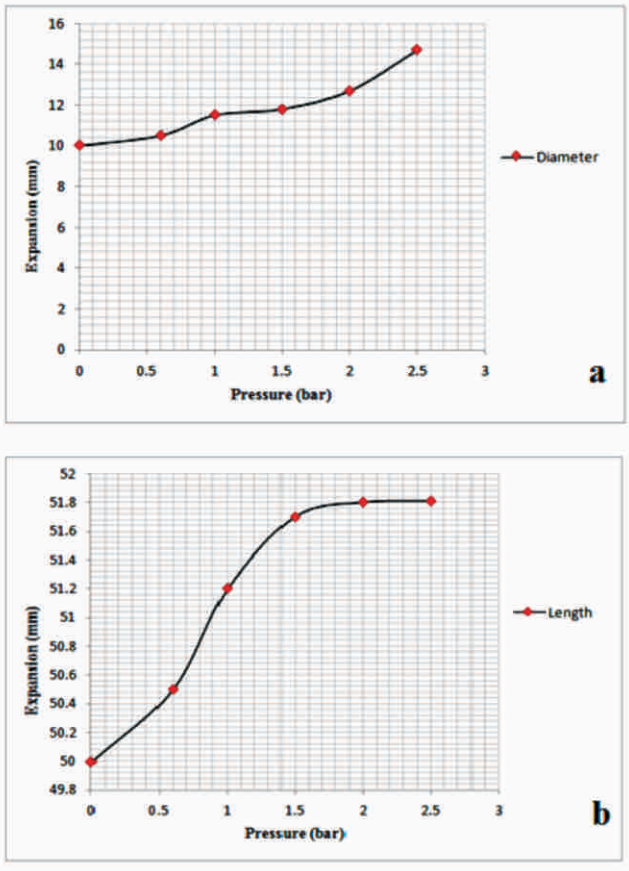

Figure 15: (a) A graph showing diametrical changes of an Auxetic airway stent, and (b) a graph showing the longitudinal extension of the stent

Conclusions

There is a great need to improve the palliative treatment of patients suffering from central airway obstruction by stenting.

This research was carried out with the aim to use the unique Auxetic (rotating-squares) geometry, for the development of novel Auxetic airway stent for treating obstructions of the central airways. A significantly small diameter Auxetic airway stent was developed, in order to easily place the Auxetic airway stent orally using an inexpensive balloon catheter, by avoiding the need of an expensive dedicated delivery device.

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