

# An Auxetic structure configured as oesophageal stent with potential to be used for palliative treatment of oesophageal cancer; development and in vitro mechanical analysis

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**Abstract** Oesophageal cancer is the ninth leading cause of malignant cancer death and its prognosis remains poor. Dysphagia which is an inability to swallow is a presenting symptom of oesophageal cancer and is indicative of incurability. The goal of this study was to design and manufacture an Auxetic structure film and to configure this film as an Auxetic stent for the palliative treatment of oesophageal cancer, and for the prevention of dysphagia. Polypropylene was used as a material for its flexibility and non-toxicity. The Auxetic (rotating-square geometry) structure was made by laser cutting the polypropylene film. This flat structure was welded together to form a tubular form (stent), by an adjustable temperature control soldering iron station: following this, an annealing process was also carried out to ease any material stresses. Poisson's ratio was estimated and elastic and plastic deformation of the Auxetic structure was evaluated. The elastic and plastic deformation behaviours of the Auxetic polypropylene film were evaluated by applying repetitive uniaxial tensile loads. Observation of the structure showed that it was initially elastically deformed, thereafter plastic deformation occurred. This research discusses a novel way of fabricating an Auxetic structure (rotating-squares connected together through hinges) on Polypropylene films, by estimating the Poisson's ratio and evaluating the plastic deformation relevant to the expansion behaviour of an Auxetic stent within the oesophageal lumen.

## 1 Introduction

### 1.1 Problem area

Two types of oesophageal cancer are squamous cell carcinoma and adenocarcinoma. Squamous cell carcinoma can occur anywhere along the length of the oesophagus because it covers the entire oesophagus, and adenocarcinoma begins in glandular tissue, which normally does not cover the oesophagus. Before an adenocarcinoma can develop, glandular cells must replace an area of squamous cells, as in the case of Barrett's oesophagus. This occurs mainly in the lower oesophagus, which is the site of most adenocarcinomas [1]. Dysphagia is the difficulty in swallowing and occurs mainly due to adenocarcinoma of the lower third of the oesophagus and cardia. These tumours are thought to arise in areas of Barrett's oesophagus, which itself is secondary to gastroesophageal reflux disease (GERD). Unfortunately, despite recent advances, the prognosis remains poor and many of these patients have incurable disease at the time of presentation. Malignant obstruction of the oesophagus may also arise as a result of extrinsic compression from adjacent lymph nodes or tumours arising in the mediastinal organs [2].

The treatment of oesophageal cancer will depend on selecting the best risk/benefit ratio, modified by the patient's preferences and available professional expertise [3]. Staging is performed based on the tumour-node-metastases (TNM) classification of the American Joint Committee on Cancer and the International Union against Cancer, and is used to correlate stage and disease prognosis [3]. Patients with early disease (stages 0, I, and IIA) are usually treated with surgery alone [4]. Endoscopic resection or ablation may be curative in stages 0 and I. In advanced oesophageal cancer (stages IIB and III), surgery,

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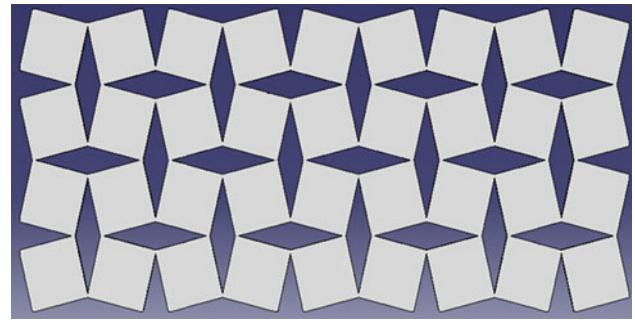
radiation, and chemotherapy in combination are associated with modest prolongation of survival, but with high morbidity and low cure rates [5]. In patients with metastatic disease (stage IV), radiation and chemotherapy may provide palliation and a variety of endoscopic methods such as stenting can provide palliation of malignant dysphagia [6]. The main goal of palliative treatment is to improve the quality of life for the limited span of life left to the patient [7]. Oesophageal stents are advantageous over other types of palliative treatments particularly for the relief of dysphagia on a more permanent basis [8].

The oesophageal stent acts mechanically by pushing aside the tumour mass; thereby reinstating a limited oral diet, hence obviating the need for hospitalization which makes it a well-established palliative method [9]. The original stents were plastic and were placed either at laparotomy or endoscopically [10]. Both have a significant procedure related complication rate, including perforation, haemorrhage, pressure necrosis, and aspiration [11]. The major reason for this serious complication rate is the size and rigidity of the deployment system, which requires balloon dilatation up to 22.5 mm. The internal diameter of these stents is relatively small, so patients must be maintained on a modified diet or risk stent blockage [12, 13]. Insertion of a self-expandable metal stent (SEMS) has become a well-established technique over the past 10 years. The major advantage of stent insertion is that it offers rapid improvement in dysphagia, and SEMS have a relatively low procedure-related complication rate [14].

Immediate complications associated with SEMS placement included problems with stent deployment or expansion [15], stent misplacement, perforation, and chest pain [16]. Late complications included stent migration (because the covered stent restricts the anchorage of stent mesh with the tissue), occlusion of the stent due to tumour in-growth and out-growth (mainly due to uncovered stent), or food impaction [17]. Potentially life-threatening complications may include immediate respiratory compromise, aspiration, fistula formation, and procedure-related death [18].

## 1.2 Auxetic structure

From the daily life experience, when the material is stretched, the material not only becomes longer in the direction of stretch but also becomes thinner in cross-section [19]. The behaviour of the material in this case under deformation is governed by one of the fundamental mechanical properties of material, i.e. the Poisson's ratio ( $\nu$ ). The Poisson's ratio of a material is the ratio of the lateral contractile strain to the longitudinal tensile strain for a material undergoing tension in the longitudinal direction, i.e. it shows that how much a material becomes thinner when it is stretched [20]. Therefore, most of the materials



**Fig. 1** The geometry of the Auxetic “rotating-square” structure

have a positive  $\nu$ . The Auxetic structures have enhanced and improved properties than the conventional materials. Auxetic materials have increased indentation resistance, good absorption properties (acoustic absorption), and higher fracture toughness as compared to the conventional materials [21, 22].

In the biomedical field Auxetic micro-porous and cellular materials have potential, like a dilator for opening the cavity of an artery or similar vessel has been described for use in coronary angioplasty and related procedures. The artery is opened up by lateral expansion of a flexible Auxetic polymer hollow rod or sheath under tension [23]. The potential to create filters by polymeric Auxetic structures with an enhanced pore size and with shape tuneability, can offer potential ways of overcoming the problems of filter systems with conventional materials, like reduction in filtration efficiency and the development of a pressure drop across the filter because it becomes blocked [24].

A new mechanism to achieve negative  $\nu$  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 [25].

This research work was inspired by the Auxetic (rotating-squares) geometry theoretically predicted by J.N. Grima [25], who theoretically emulated the natural cellular framework of zeolites. The Auxetic (rotating-squares) geometry has never been used for this application before. Therefore, the main focus of this research work was to design and manufacture an Auxetic (rotating-squares) film in a novel way and to configure this film as an Auxetic stent for the palliative treatment of oesophageal cancer, and to acquire mechanical data relevant to the novel expansion behaviour of an Auxetic stent (Fig. 1).

## 2 Material and methodology

Thick polypropylene films of 0.5 and 3 mm thickness were used and were supplied by Pyramid Co. (Manchester, UK).

Polypropylene material was selected because it is simple to acquire this material because of its good commercial application and it is easy to handle because of its good thermo-mechanical properties, it is made of relatively inert and flexible material, its good biocompatibility and anti-inflammatory response [26]. Polypropylene is a crystalline thermoplastic polyolefin (family of polymers made from olefin monomers) resin and is generally considered biologically resistant to microorganisms [27].

2.1 Fabrication procedure of Auxetic structure

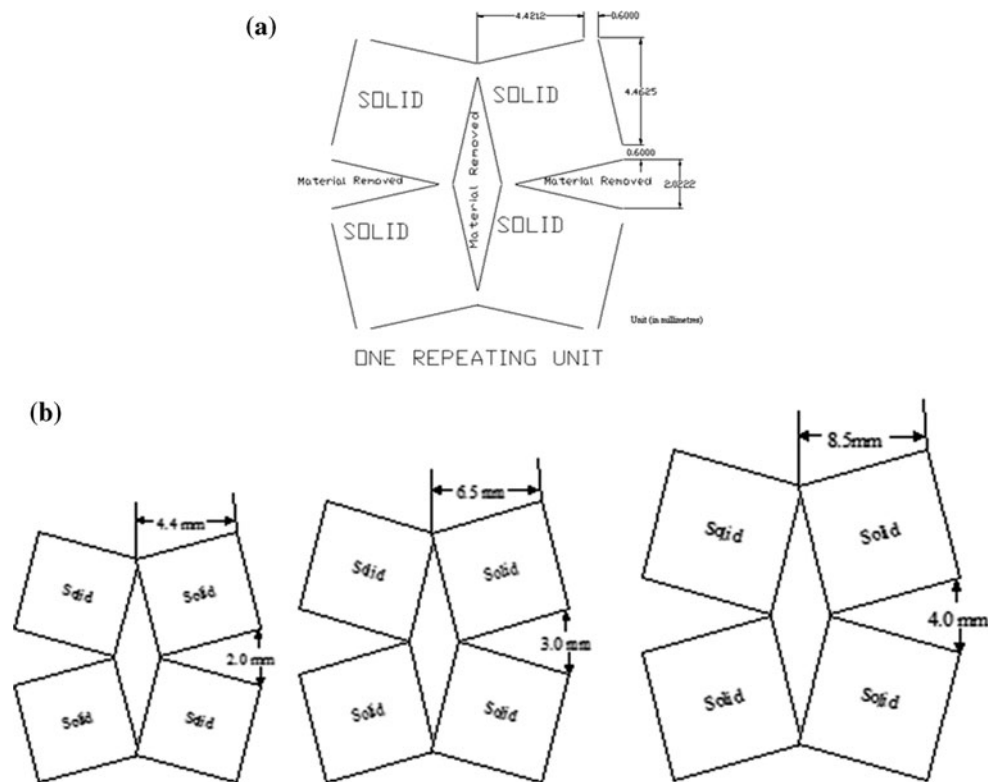
A thermo-mechanical method was adopted consisting in cutting 0.5 mm thick A4 size polypropylene films, in an arrangement involving rigid squares (i.e., rotating-square geometry) connected together at their vertices through hinges by using computerized numerical control (CNC) guided laser cutting machine. A rotating-square geometry was designed by using AutoCAD engineering software. The main reason we used the laser cutting technique is that the design dimensions and specifications were in millimetres, and dimensions of one unit cell shown below in Fig. 2a. That is, an accurate and precise cutting was required to attain Auxeticity in the material. The laser cutting of polypropylene films was outsourced to Advanced Plastic Technology Co. (Milton Keynes, UK). The company used Euro-laser (M-1600) CNC laser cutting machine

for the cutting of 0.5 and 0.8 mm thick A4 size polypropylene samples with CO<sub>2</sub> laser beam of 0.3 mm width with 1.5 W power.

Initially, the Advanced Plastic Technology Co. (Milton Keynes, UK) supplied three different sample sizes of laser cut Auxetic polypropylene (rotating-square geometry) films for the selection as depicted in Fig. 2b. Due to the polypropylene low melting point, we experienced some melt-related problems when starting to laser cut the first two samples with smaller rotating-square unit cells. Therefore, among the three different sample sizes the third sample with big unit cells better tolerated the laser cutting technique, and there was no sign of melt problem and broken hinges between the unit cells and the unit cells were functional.

The scanning electron microscopy (SEM) was carried out for the topographical characterisation of the three different samples surfaces. First of all, three stubs were prepared with three different sample sizes, and then sputter coating was done on each of them with gold in order to make them conductive at 1.5 kV and 5 mA with 2 min coating time (30 s bursts were used to prevent excessive heat). Finally the data obtained from the micrographs was useful in selecting the appropriate size of the rotating-square unit cells, and the last sample size was finally selected due to less heat affected zone and broken hinges.

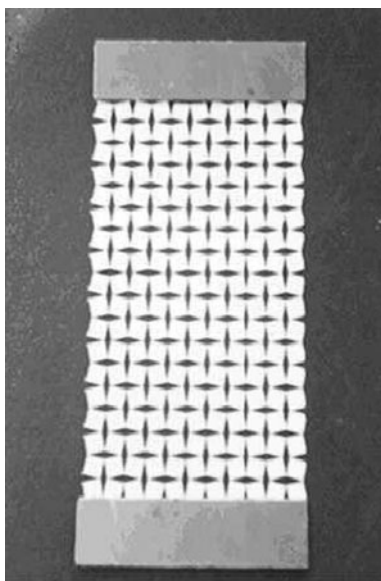
**Fig. 2** **a** Dimensions of single repeating unit cell of rotating-square geometry, and **b** the unit cell dimensions of three sample sizes



## 2.2 Mechanical properties characterisation

Mechanical properties characterisation of the Auxetic A4 size polypropylene films was carried out using the Instron tensile testing equipment to measure the axial and transverse strains for Poisson's ratio estimation under uniaxial tension, and to measure the percentage of longitudinal strain with corresponding value of applied load to analyse the elastic and plastic deformation behaviour under uniaxial tensile load. Initially, the 0.5 mm thick Auxetic polypropylene samples were prepared by cutting A4 size polypropylene films 100 mm wide and 20 cm in length. Mild (low carbon) steel strips 100 mm long and 25 mm wide were made, and prepared for the adhesive to get a good surface interface with polypropylene film, by abrading the surface of mild steel strips using 500 grid wet and dry abrasive paper. Then the adhesive was applied on the mild steel strips, and the proximal and distal ends of the polypropylene films (100 mm in length, and 25 mm wide) were enclosed within the two mild steel strips as shown below in Fig. 3. Both of the enclosed ends of the polypropylene films were clamped for half an hour using micro-clamps to obtain good adhesion of the mild steel strips.

For the characterisation of the Auxetic polypropylene films, the Instron test equipment was first calibrated and then the Auxetic polypropylene sample was clamped within the jaws of Instron machine. Digital Linear variable differential transformer (LVDT) meter was also installed to measure the longitudinal displacement of the sample. Initially, original length and width of the sample was measured, and different uniaxial tensile loads were applied. Then the deformed length and width values were recorded to compute the Poisson's ratio.



**Fig. 3** Auxetic polypropylene samples joined with mild steel strips

In order to identify the values for strain and applied load for the evaluation of elastic and plastic deformation of the Auxetic sample. A small tensile load like 500 g was applied at 5 mm/min cross-head speed to a maximum 2.5% strain repeatedly to the mounted sample between the jaws of Instron machine, and the graph was recorded. The load was then increased to 1 and 2 kg respectively, and the graph was attained. Then finally 3 kg load was applied and the sample did not reach the maximum load and it was collapsed at 2.8 kg to a maximum strain of 10.5% at an extension of 17 mm. Another 0.5 mm thick Auxetic sample was clamped into the machine and the same process was repeated. The second sample was collapsed at 3.2 kg load; the graph was recorded simultaneously throughout the procedure.

## 2.3 Fabrication of Auxetic oesophageal stent

The Auxetic oesophageal polypropylene stent was made by giving a tubular shape to the Auxetic polypropylene 0.5 mm thick film. In order to obtain the above-cited shape, the polypropylene film was wrapped around the 26 mm thick wooden tubular shaped rod. Then, the wooden rod with wrapped Auxetic polypropylene film was clamped as shown below in Fig. 4a, the adjustable temperature controlled soldering iron was used to weld the ends of the Auxetic polypropylene film and was set at 170°C temperature.

Note that during the experiments, it was always considered the melting temperature of polypropylene (160°C). Then, after having welded both ends symmetrically an oesophageal Auxetic stent was made as shown in Fig. 4c, which was 12.5 cm long, internal diameter was 26 mm, and the outer diameter was 27 mm.

Finally, an annealing process was used to ease or remove the stresses on the Auxetic stent due to the welding of two joints of the polypropylene film. The Auxetic stent was deployed on a metal pipe and it was wrapped first with aluminium foil to avoid any damages on the surface of the stent. Then aluminium wire was spiralled around the covered stent to secure the stent and aluminium foil on the metal pipe. Then the pipe with covered Auxetic stent was placed in the oven at 70°C temperature for heating. The Auxetic stent was heated on the constant temperature for 17 h, which was the temperature at which the Auxetic polypropylene stent was soft enough for internal stresses to ease.

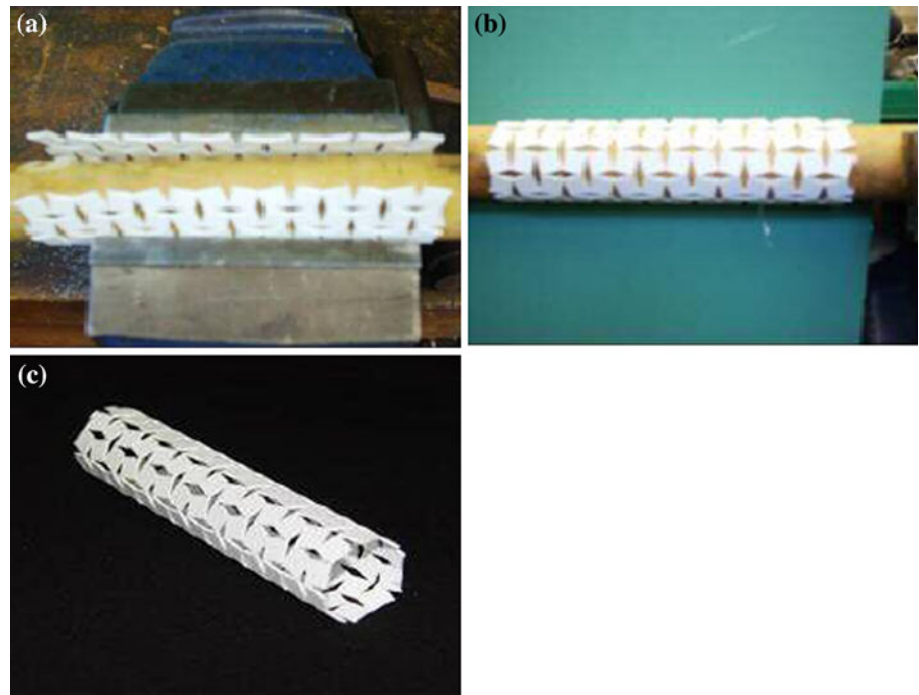
## 3 Results

### 3.1 SEM

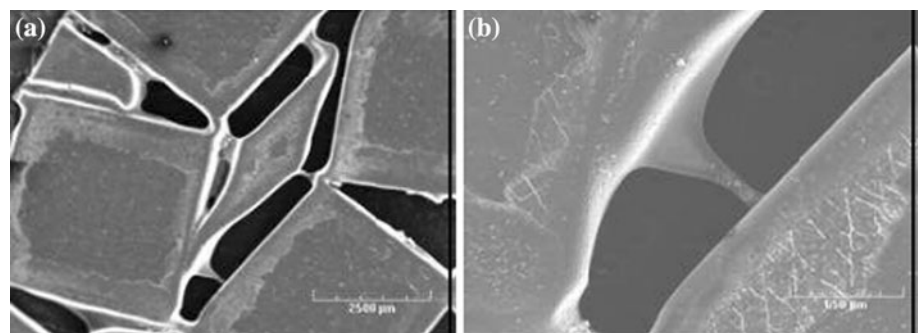
The SEM was used for the surface morphology test of three different sample sizes. This was performed in order to



**Fig. 4** **a** Clamped wooden rod wrapped with Auxetic film, **b** Auxetic oesophageal stent after welding, and **c** Auxetic oesophageal stress-free stent after annealing



**Fig. 5** SEM micrographs of first sample Auxetic PP film, **a** with 11× magnification and **b** 40× magnification



select the appropriate size of the rotating-square unit cells geometry. Initially, the first (smaller unit cell) sample stub was chosen for scanning and it was scanned first with 2,500  $\mu\text{m}$  scale marker size (11× magnification), and then was scanned with 650  $\mu\text{m}$  scale marker size (40× magnification) as shown in Fig. 5.

From the above micrographs, we observed that, with smaller unit cells sample, when the laser beam produced fusion or when it melted the material, the covering gas ( $\text{O}_2$ ) could not remove properly the molten material out of the small cut kerf. As a result, the latter, the unit cells and their corresponding hinges were overlapped and broken apart. We also found that there was a thick molten material accumulated out of the small cut kerf on the boundary of each square.

The second sample micrographs (slightly bigger unit cells from the first sample) showed that the material was still not properly removed from the cut kerf by the covering

gas. However, there was a significant problem of broken hinges and unit cells as shown in Fig. 6.

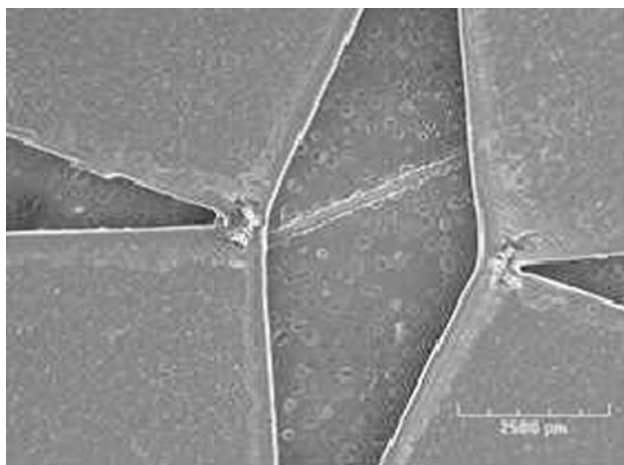
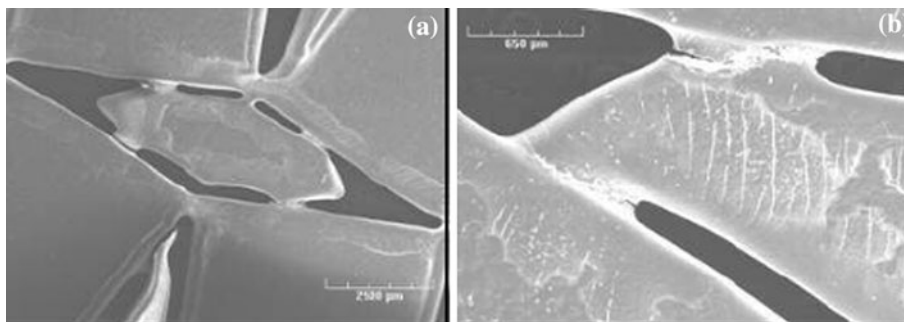
The last sample (with bigger unit cells geometry) was considered to correspond the most to our requirements and was selected for the fabrication of the oesophageal stent as shown in the micrographs in Fig. 7.

The material was accurately removed by the covering gas from the cut kerf in the last sample. There were no signs of broken hinges or unit cells and the geometry was fairly neat.

### 3.2 Calculation of Poisson's ratio

The original length and width of one Auxetic polypropylene film when clamped into the jaws of the Instron testing machine was  $l_0 = 161.8$  mm, and  $w_0 = 98$  mm respectively. First experiment was conducted to calculate Poisson's ratio by applying different uniaxial loads to one Auxetic

**Fig. 6** SEM micrograph of second sample with **a** 11× magnification and **b** 40× magnification

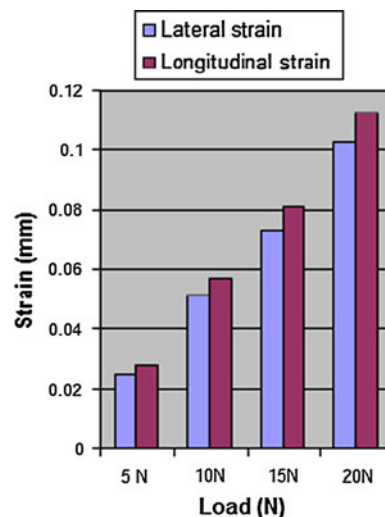


**Fig. 7** SEM micrograph of last sample

polypropylene film, and Poisson's ratio was calculated as  $\nu = -0.89 \pm 0.01$  on  $x$ -axis (i.e. longitudinal direction) at different load values as shown below in Table 1; Fig. 8.

### 3.3 Examination of deformation behaviour

The second experiment was carried out to estimate the plastic deformation and examine the deformation behaviour of the structure. The stress–strain curves from the Instron machine plotter during loading and relaxing formed a closed loop (hysteresis). The graph depicts a straight line during loading going upward and a curved line during unloading moving downward, coming back to the origin (zero) from where the straight line started as shown in Fig. 9a.



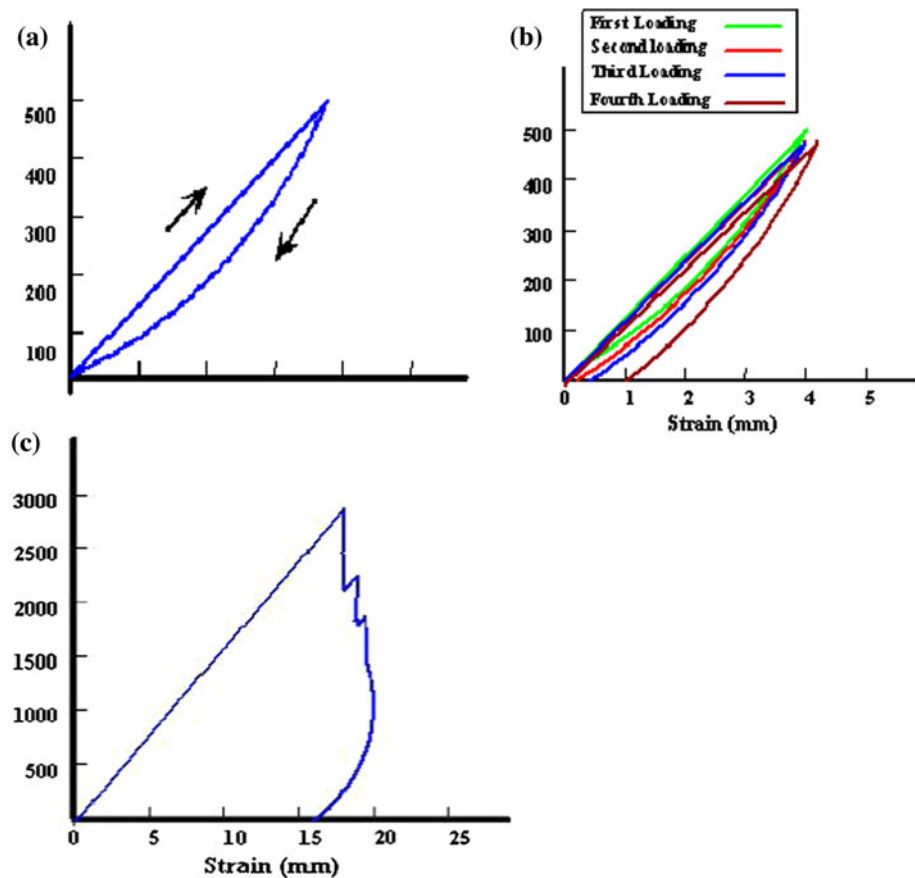
**Fig. 8** Strain values in  $x$ -axis (longitudinal) and  $y$ -axis (lateral) at different loads

The hysteresis graph in Fig. 9b, clearly shows that under repetitive 500 g of tensile load the sample was initially behaving ideally and showing elastic deformation (see Fig. 9a). However, after having experienced the same load four times repeatedly, the curved line started to come back away from its origin (i.e., zero), which indicates that the stretch-induced repetitive tensile load prevent the sample from coming back to its original position. As a result, this lead to a plastic deformation. The graph in Fig. 9b showed evidence that under 500 g tensile load to a maximum 2.5% strain at 4 mm extension, the curved line (forming the closed loop) started to come back away from zero (origin), and the sample (rotating-square geometry) was slightly

**Table 1** Estimation of Poisson's ratio of 0.5 mm thick polypropylene film

Load (N)	Deformed length (l mm)	Deformed width (w mm)	Lateral strain $\varepsilon_y = w - w_0/w_0$ (mm)	Longitudinal strain $\varepsilon_x = l - l_0/l_0$ (mm)	Poisson's ratio on $x$ -axis $\nu_{xy} = -\varepsilon_y/\varepsilon_x$
5	166.4	100.5	0.0255	0.0284	-0.89
10	171	103	0.0510	0.0568	-0.89
15	175	105.2	0.073	0.081	-0.90
20	180	108.1	0.103	0.112	-0.91

**Fig. 9** **a** Typical stress–strain graph while loading and unloading, **b** a graph showing plastic deformation as the curve is coming back away from its origin while unloading, and **c** the sample is collapsed at 2.8 kg load

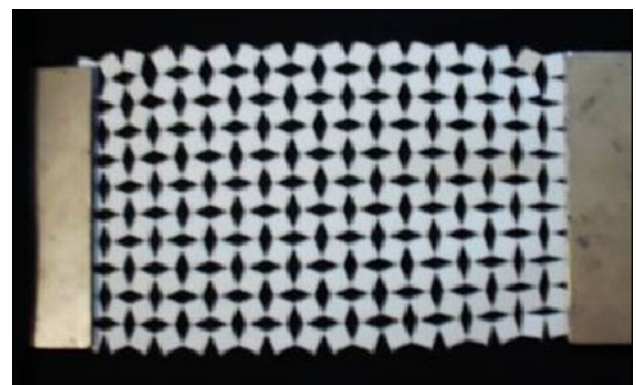


opened even without any load owing to the plastic deformation. Also from the graph it is quite obvious that after fourth loading repetition, the sample was not returning back completely and was having 1 mm extension to a maximum 0.62% strain. Similarly, the same procedure was carried out by applying 1 and 2 kg load repeatedly. Observation from the graph allowed us to say that for a 1 kg load, the sample expanded for about 6 mm to a maximum of 3.7% strain. It has to be noted that after few repetitions it kept almost 2 mm extension to a maximum 1.23% strain and was depicting a plastic deformation. The graph with 2 kg applied load showed that the sample was opened and plastically deformed. Finally, the sample (rotating-squares structure) broke at 2.8 kg tensile load in Fig. 9c to a maximum 10.5% strain and at 16.5 mm extension.

It is quite clear below in Fig. 10 that after applying repeatedly a load on the sample, the latter is opened and plastically deformed. The diamond shaped cuts between the rotating-squares are wide opened after loading.

#### 3.4 Auxetic oesophageal stent (prototype)

The Auxetic polypropylene 0.5 mm thick film was wrapped around the 26 mm wooden rod in order to give it a

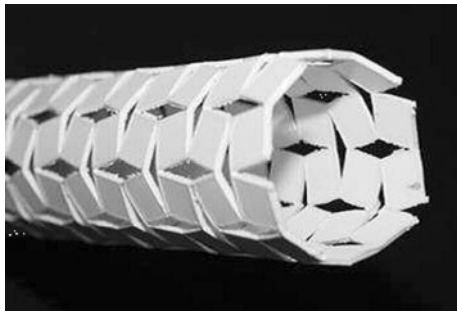


**Fig. 10** Auxetic PP sample plastically deformed

tubular shape and to weld the two film joints symmetrically. Annealing process was also carried out at 70°C to ease the stresses of the stent as shown in Fig. 11.

#### 4 Discussion

The goal of this study was twofold: (i) designing and manufacturing an Auxetic structure film in a novel way and (ii) configuring this film as an Auxetic stent for the palliative



**Fig. 11** Auxetic oesophageal stent

treatment of oesophageal cancer, and for the prevention of dysphagia. The oesophagus is an expandable normally closed muscular tube which has two major functions, that is the transport of the food bolus from mouth to stomach and the prevention of retrograde flow of gastrointestinal contents. Among many symptoms in the vast majority of patients suffering from oesophageal cancer, dysphagia is the most crucial symptom. Dysphagia is the inability to swallow food or liquid bolus through the oesophagus to the stomach. Initially, dysphagia begins with solids and may progress to the point that swallowing liquids or even saliva becomes difficult. Dysphagia does not take place until the oesophageal lumen is significantly compromised, and this indicates the presence of a relatively large and aggressive tumour. Polypropylene was selected as a material after doing a literature review because of its biocompatibility or anti-inflammatory response, and its wide application in the medical arena. A 0.5 mm thick Auxetic polypropylene film was fabricated using the laser cutting process. This geometry has already been discussed theoretically by [25], it has to be noted that these authors did not use the laser ablation technique for creating Auxetic (rotating-squares) geometry. In this study, Poisson's ratio was calculated, as it is the ratio of the lateral contractile strain to the longitudinal tensile strain for a material undergoing tension in the longitudinal direction. Results regarding the original Auxetic polypropylene film length and width ( $l_0 = 161.8$  mm and  $w_0 = 98$  mm) showed that, in accordance with the literature [25], the Poisson's ratio on  $x$ -axis was negative ( $\nu_{xy} = -0.89 \pm 0.01$ ). This provides evidence of an Auxeticity of the laser ablated polypropylene film (rotating-square geometry). The plastic deformation behaviour of an Auxetic polypropylene film was evaluated, relevant to the expansion of an Auxetic stent plastically inside the oesophageal lumen. Initially, it was observed by applying different tensile loads that the Auxetic polypropylene sample was behaving elastically. Thereafter, it started deforming plastically after applying the tensile loads repeatedly by keeping some strain values.

For 500 g uniaxial tensile load, the sample attained a 4 mm extension for a maximum of 2.5% strain and came back to zero when the load was released. However, still

with the same applied load (i.e., 500 g), the sample was coming back but away from zero (origin). Furthermore, after the fourth repetition of loading, it was recorded that the sample was keeping 1 mm of strain value instead of coming back to zero (origin). This indicates that it was plastically deformed and even the diamond shaped cuts within the geometry of the sample, were opened.

Similarly, when a 1 kg load was applied the sample extended to 6 mm for a maximum of 3.7% strain elastically. However, after few repetitions of loading, it started deforming plastically and after the fourth repetition it kept a strain value of 2 mm. The same behaviour of the Auxetic polypropylene sample was observed with 2 kg uniaxial applied load repeatedly, the sample started behaving plastically and it was keeping 2.3 mm strain value after fourth repetition of loading. The diamond-shaped cuts within the rotating-square geometry were wide opened and were giving evidence of a plastic deformation. Eventually, the maximum load value and its corresponding strain value were calculated at which the Auxetic (rotating-squares geometry) structure was collapsed. These values were 2.8 kg uniaxial tensile load to a maximum 10.5% strain at an extension of 16.5 mm. These maximum load and strain values are also useful for the future application of the Auxetic stent into the oesophagus. During the Auxetic polypropylene sample deformation under uniaxial tensile loading, it was also found that the sample was making dome-shaped doubly curved surface (synclastic) unlike other conventional materials which make saddle-shaped surface (anticlastic). This is also predicted to be advantageous in terms of Auxetic stent expansion inside the oesophageal lumen wall evenly from each side. Finally, an Auxetic stent was fabricated by wrapping a 0.5 mm thick Auxetic polypropylene film around the 26 mm diameter wooden rod, and having welded symmetrically by joining both ends of the Auxetic film together. Annealing process was also carried out to ease the stresses which were induced by joining the two ends of the Auxetic polypropylene film by welding. It is found that after annealing process the Auxetic stent attained a good tubular shape and even the stresses on the welded area also disappeared. Due to the unique deformation mechanism and the geometry (rotating-squares) of the Auxetic polypropylene stent, it is believed that the stent will get bigger and fatter when stretched longitudinally and get the anchorage with the surrounding tumour tissue inside the oesophagus. Also, the rotating-squares mesh along the length of the Auxetic stent will be helpful to get a good grip with tumour tissue by embedding inside the tissue.

The deformation behaviour of the Auxetic polypropylene film assessment was performed in order to evaluate whether a structure plastic deformation occurred; as it is predicted that only plastic deformation is required in the



palliative treatment application of the Auxetic stent. Also, the large lumen diameter of the Auxetic oesophageal stent is beneficial for the patients suffering from severe dysphagia, because it will prevent the obstruction (re-stenosis) and food impaction.

## 5 Conclusion

There is a great need to improve the palliative treatment of the oesophageal cancer patients suffering from dysphagia by oesophageal stenting. All the plastic and self-expandable metallic stents available for the palliation have some early or delayed complications involved. This research was carried out with the aim to use the unique Auxetic structure in the shape of oesophageal stent, and to evaluate its efficacy in terms of palliation. The Auxetic polypropylene material was fabricated by a unique method and was used to manufacture an oesophageal stent because of the enhanced mechanical and other properties of the material. It is predicted that because of the improved properties and unique deformation mechanism, an Auxetic stent will not require balloon pre and post dilation at the time of deployment. Hence, Auxetic stent will itself behave like a balloon and will dilate the oesophagus by its novel expansion behaviour in both ways, i.e. transversely and longitudinally. The large lumen diameter of the Auxetic stent is useful in solving problems like food impaction, and obstruction (stenosis). Secondly, because of the good mesh on the outer surface of the Auxetic stent, the chance of complications like migration/misplacement might become less.

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