A NEW CONCEPT OF DEDICATED DEPLOYMENT DEVICE FOR STENTS HAVING NEGATIVE POISSON'S RATIO

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A NEW CONCEPT OF DEDICATED DEPLOYMENT DEVICE FOR STENTS HAVING NEGATIVE POISSON'S RATIO

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In

Biomedical Sciences and Engineering

By

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I dedicate my thesis to my parents for their affection, love, encouragement and prayers.

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All praise to ALLAH Almighty, the most beneficent, the most merciful, who bestows us with the mind to think and ability to observe, and the power to understand things and to seek knowledge.

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LIST OF ABBREVIATIONS

FEA	Finite Element Analysis
Mm	Millimeter
NPR	Negative Poisson’s Ratio
PU	Polyurethane
3D	3-Dimensional
Atm	Atmosphere (atmospheric pressure)
S.W	Solid Works
Dia	Diameter
U.N	Unit cell

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ABSTRACT

Auxetic stents having negative Poisson’s ratio tend to expand radially as well as longitudinally when unidirectional force is applied. Recently, studies have come up with new designs of auxetic vascular and non-vascular stents which are deployed with commercial balloon catheters. Auxetic stents result in minimal longitudinal elongation when deployed with balloon, hence causing the foreshortening of the stents. This research illustrated a novel deployment device for auxetic stents which will apply force both longitudinally and radially thus causing maximal and effective expansion of auxetic stent. In-silico design of deployment device was made on Pro Engineer Wildfire 5.0. Different parts of device were fabricated by milling and high speed lathe machine. The testing of the device was done using auxetic stents, fabricated by using biocompatible polymer ‘Polyurethane’. To validate the experimental results Finite Element analysis (FEA) of stents was also done. The device functions through an umbrella like mechanism. The length of auxetic stent increases when external hydraulic pressure was applied. Practically, the spokes expanded in response to hydraulic pressure thus expanding the stent radially. The degree of linear expansion in one direction influenced the expansion of auxetic stent in other direction. The device exerted pressure longitudinally on to an auxetic stent and this generated expansion in radial direction as well. Since force is applied and distributed on longitudinal axis which has more number of unit cells and hinges, therefore, more expansion of the auxetic stent is achieved which is not the case when the stent is expanded radially through balloon catheter. Comparative analysis of simulated and practical results demonstrated a good agreement.

INTRODUCTION

Mechanical devices such as stents are placed in lumen of tubular structures to maintain the conspicuousness by providing mechanical support. Stents are generally made of shape settable biocompatible material [1] which are generally of two types; balloon expandable or self-expanding [2]. Balloon expandable stents are delivered within a vasculature, attached on a balloon catheter and expanded radially at the target site to achieve implantation at desired location. Upon expansion the stents achieve plastic deformation and does not recoil thus insuring the safe implantation. Whereas the self-expanding stents are first compressed to reduced size and it is guided to target area through the patient's vascular system, where the stresses stored in stent limbs causes the stent to expand radially hence allowing normal blood flow [3, 4].

Mechanical design of the stent have been demonstrated to have influence on thrombosis and neointimal hyperplasia [5, 6, 7], which eventually pose negative effects on post procedural intervention and rate of restenosis. Many reports recently have raised questions regarding the long term survival of stent and prevention from late thrombosis [8, 9]. The proposed solution to overcome this problem is the use of Auxetic structures. Fabricating stents having auxetic geometry will have better mechanical and physical properties. It has also been proved to minimize site injuries caused due to tissue adhesion.

Auxetic's are type of structures that exhibit negative Poisson's ratio, have proved to be an emerging progress in the field biomedical devices and implants. Negative Poisson's ratio is a mechanical property of materials according to which materials expand in both longitudinal and transverse direction when unidirectional force is applied [10, 11]. Geometries which possess negative Poisson's ratio have capability to become wider when stretched and narrower when compressed. The auxetic structures in biomedical implants demonstrate the improved physical and mechanical properties of the device [12, 13]. Geometries based on auxetic behavior are scale independent, so that the auxetic characteristics with same geometry can be manipulated at any stage. Deformation in auxetic geometry of implants when subjected to uniaxial load is due to the effect of negative Poisson's ratio [14, 15].

Recently, a number of studies have reported new auxetic stents which are deployed using conventional balloon catheters [16, 17, 18]. Balloon catheters are designed to expand radially, which results in minimal longitudinal expansion of stent. The mechanical parameters of balloon stenting have been studied with experimental methods and Finite Element Analysis (FEA), Ju et al performed FEA of balloon expansion of different lengths. He reported two major drawbacks; increased length of balloon results in end flaring (dog boning) and the under length causes the ends of the stent to bend thus preventing the complete expansion of stent [22] (Figure 1.1).

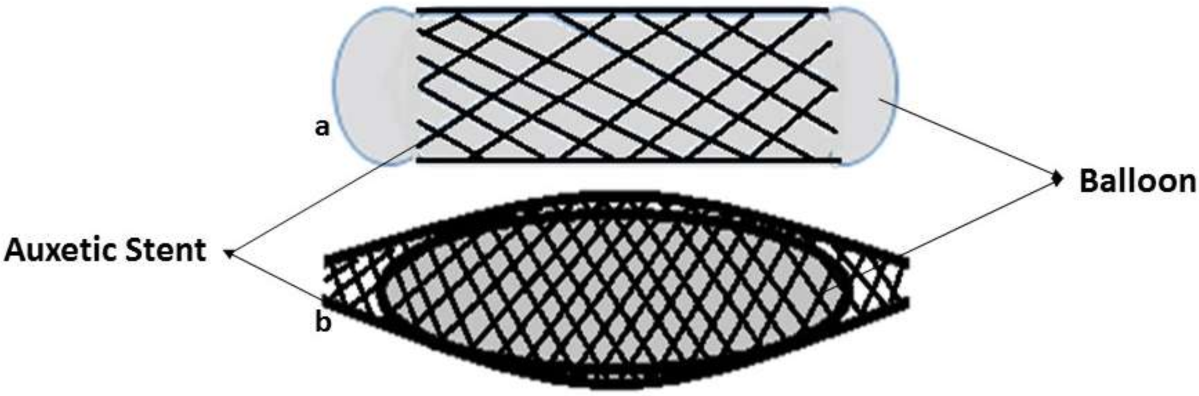


Figure 1.1: Complications of using balloon catheter (a) dog boning of balloon, (b) bending of stent ends.

This research presents the design and development of a novel deployment device for auxetic stents. A device comprising of umbrella shaped mechanism is developed for the effective deployment of auxetic stents. The device is designed in such a fashion that it applies longitudinal forces on the stent and by virtue of having negative Poisson’s ratio of the stent, the stent then expands both radially and longitudinally, and therefore generates maximal and effective expansion due to having more number of unit cells/ hinges in longitudinal axis.

LITERATURE REVIEW

2.1 Background of stenting

Biomedical implants such as stents are widely being used in the treatment of vascular and non- vascular diseases. Stents are placed in lumen of tubular structures to maintain the conspicuousness by providing mechanical support. They are considered as one of the most valuable medical device in the market. The clinical outcome of implanting a stent highly depend on the mechanical characteristic of stent.

The stent can be seen as a lattice in which a single unit cell is repeated in horizontal and vertical direction to form a medical device (Figure 2.1). The properties of a single unit cell in lattice materials have been proved to have same macroscopic properties of macrostructure of a stent [23,24]. Thus choice of a unit cell would be the starting point having desirable properties.

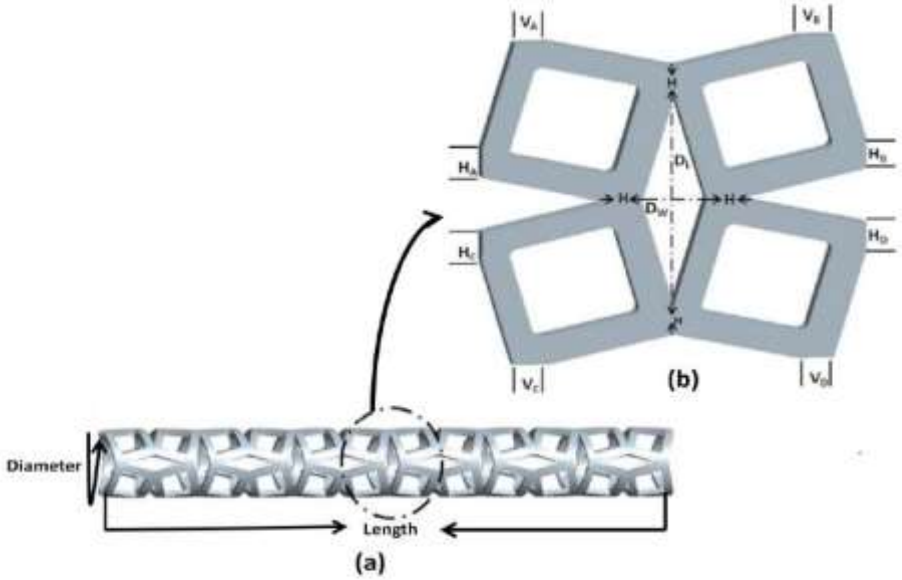


Figure 2.1: (a) 3D model of auxetic stent (b) Single unit cell of auxetic stent.

In general, while introducing the stent the access to the vascular system is made at a peripheral site. A variety of tools are used in endovascular surgery, but some essentials are sheaths, guidewires, catheters, imaging devices, and contrast agents [25]. After attaining vascular access, sheaths are used to provide a port to the artery, providing a relatively straight lumen for inserting additional devices as well as a valve preventing excessive bleeding through the access site. Guidewires are then inserted to provide a “rail" for catheters to follow. Guidewires are easier to maneuver through complex and tortuous anatomy than catheters and can straighten tortuous vessels. Guidance for guidewire positioning is provided by a medical imaging device, most typically flouroscopy. Catheters are then advanced over the guidewires to the target site, also visualized by flouroscopy.

2.2 Deployment mechanism used for stents

Various means are applied in order to achieve accurate placement of vascular or non vascular stent within a physical lumen and to make sure that the stent is placed rightly within the body. Commercially available stents falls within two types: self-expanding and balloon expandable stents [26].

In balloon expandable mechanism of deploying the stent the stent is attached at the outer surface of an uninflated balloon, which is then deployed inside the body vessel and when it reaches its desire location, the balloon is inflated thus expanding the stent attached to it (Figure 2.2). Once the stent is deployed in the targeted vessel the balloon is removed by deflation. The advantage of balloon expandable stent is such that it can be expanded according to the diameter of the vessel into which it is being introduced. However such stents, are vulnerable to compression due to external forces after implantation which can lead to collapsing of recoiling of the stent.

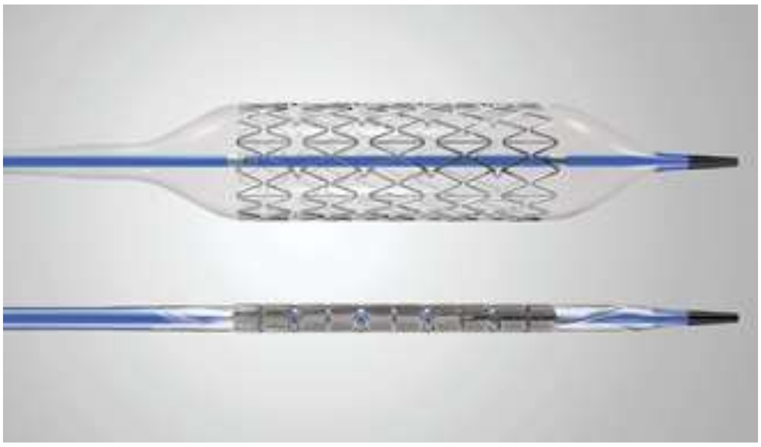


Figure 2.2: Balloon expandable stent mounted on balloon catheter.

Self-expanding stents are type of stents which are generally in in expanded form, when in relaxed state. The insertion procedure is similar to balloon-expandable stents, except a mechanism releasing the self-expanding stent is used instead of a balloon to get the device to expand to its final diameter. These type of stents are deployed in a collapsed form into the body lumen and are triggered to release a particular mechanism so that it may expand to its relaxed, expanded position (figure 2.3). The advantage of such stents over balloon expandable stents is that they are less susceptible to recoil but they can be expanded only to a limited diameter. There is high risk of stent migration if the size of stent is smaller than the targeted vessel and chances of trauma of vessel wall increases if oversized stents are used.

Figure 2.3 self-expandable stent.

2.3 Complications of Stenting

Stenting is now a days commonly being used for many vascular and non-vascular diseases. In addition to its benefits many complication are also being faced such as neointimal hyperplasia, thrombosis and vessel injury (figure 2.4). These complications are commonly being linked with mechanical and structural design of the stent [5]. The clotting of blood in response to reaction with foreign materials and surfaces is thrombosis, whereas the tissue growth into the deployed stent is referred to as neointimal hyperplasia. In this type of complication of stenting the epithelial and smooth cells migrate which can be result of changes in structural and fluid shear forces [27, 28]. Injury of vessel is an acute type of complication depending on the mechanism of implantation of the stent.

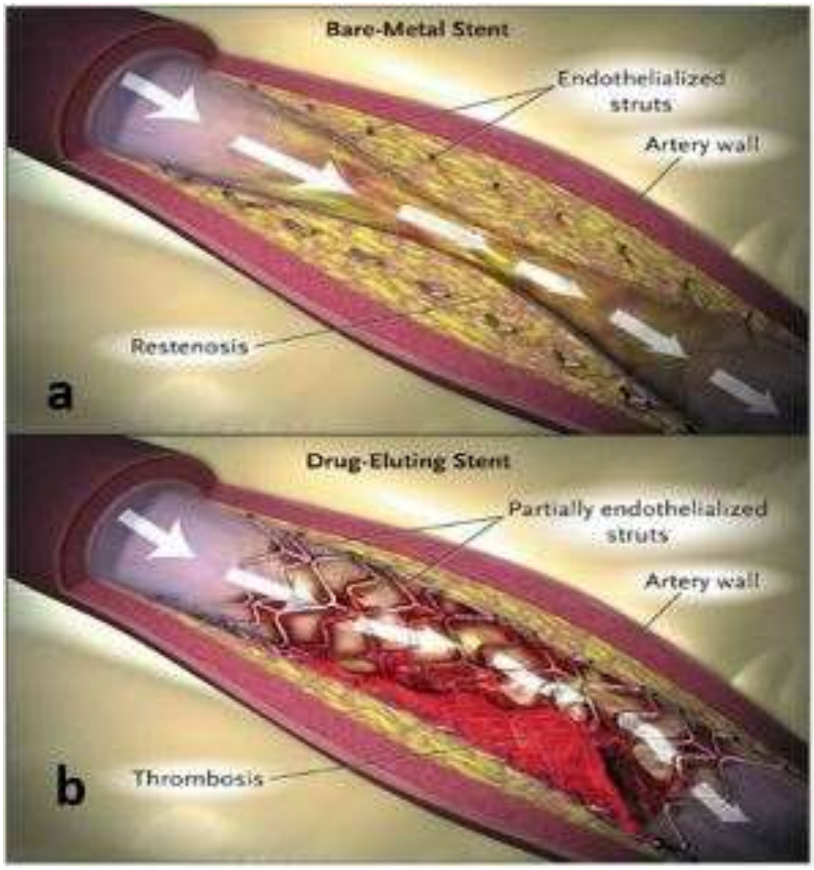


Figure 2.4: Complications of stenting, (a) restenosis (b) thrombosis.

Many methods have been employed to reduce the complications due to stent implantation. Such as thrombosis can be reduced with medication and neointimal hyperplasia can be managed with the use of drug eluting stents. However, recently many questions have been raised regarding the long term survival and late thrombosis events of drug-eluting stents [8, 9]. Mechanical design of stent has been proved to have ample impact on neointimal hyperplasia and thrombosis. Recent studies have exposed that the mechanical design of the stent has a reflective impact on late lumen loss [6, 7]. Platelet activation and thrombogenesis are also considered to have linked with the design of stent. The proposed solution to overcome this problem is the use of Auxetic structures. Fabricating stents having auxetic geometry will have better mechanical and physical properties. It has also been proved to minimize site injuries caused due to tissue adhesion.

2.4 Introduction to Auxetic

One of the fundamental mechanical property of material under deformation is its Poisson’s ratio. Poisson’s ratio is a property which tells us the thinning capability of the material when it is stretched. Normally all the materials have positive Poisson’s ratio. The probability that it can be negative has been identified over 150 years ago [29]. Simeon Dennis Poisson’s was the one to invent Poisson’s ratio in 1785, as it is named after him. He was a mathematician born in France. Poisson’s ratio is defined as the ratio of strain of transverse contraction to strain of longitudinal extension w.r.t the direction of applied force. The deformation due to tensile forces is taken as positive whereas compressive deformation is taken as negative. Poisson’s ratio definition has a minus sign, so common materials usually have positive poison’s ratio. Almost all normal materials have +ve Poisson’s ratio, ranging from 0.3 to about 0.5 [15]. Auxetic materials are such having negative Poisson's ratio which are described below in detail (figure 2.5).

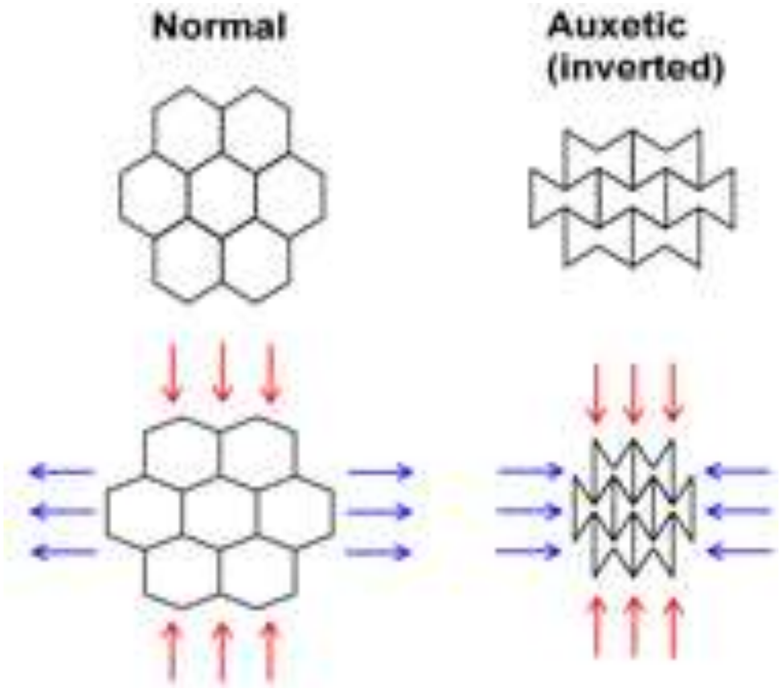


Figure 2.5: Illustrating the behavior of normal and auxetic geometries.

The materials having negative Poisson's ratio endure that the material is expanded laterally when stretched and becomes thin when compressed. Viewing Poisson's ratio of material as a change in volume when deformation is applied the negative sign indicates simply an increase in volume upon extension. Such materials exhibiting this novel behavior are generally termed as 'Auxetic Materials'.

The first book published describing negative Poisson's ratio was in 1944 by love [29]. According to the author he was the first to record the fact. The next document regarding auxetic materials was established by Gibson in 1982 [23]. He analyzed the auxeticity of 2 dimensional silicone rubber which was deformed by ribs flexure. After 5 years the concept of negative Poissons's ratio was first published in science magazine by lakes in 1987 although he did not used the term 'auxetic'[31,32]. The terminology ‘auxetic’ was first used in 1991 which was derived from the word ‘auxetikos meaning that which tends to increase’. This terminology was first used by Evans et al. This concept was than further developed which lead to the fabrication of modern day auxetic materials [33, 34].

Alderson in 1999 claimed to introduce auxetic material having novel elastic property of negative Poisson’s ratio. Claiming that the material when stretched becomes thicker and when compressed it becomes thinner. Such property was seemingly opposing to response of materials commonly. He also reviewed the advances in design, modeling, testing, manufacturing, and the possible applications of auxetic polymer, cellular solids, composites in devices used in aerospace engineering. Yang et al. in 2004 reviewed the molecular designs of auxetic materials concerning nanobiotechnology [35].

Many naturally occurring auxetic materials have also be found such as cat skin, cow teat skin and some bones. In manufacturing synthetic replacement bio implants it is mostly desirable to consider auxetic behavior in order to make sure an adequate match of mechanical properties of real and artificial materials [32]. Presently, fibrous biomedical implants includes surgical implants, cartilage, suture muscle or anchors, the additional advantage of using such materials is that it encourages bone in-growth [15].

2.5 Biomedical applications of Auxetic materials

The increasing trend to incorporate artificial devices like bone and joint replacements, dental prostheses, implanted sensors (e.g. for blood glucose), stents, heart pacemakers and heart valves into the human body has sharply focused attention onto the compatibility of the materials from which such devices are made with human physiology . Therefore, it is a major current challenge in biomaterials to develop implants that are truly permanent and to design and manufacture such materials to make them maximally compatible with living tissue. Using auxetic fibers in developing biomedical implants leads to many benefits as it ensures an adequate match in mechanical properties, it improves anchoring property of implant and provides greater strength to load bearing components. Evidence has proved that the load bearing cancellous bone with a cellular microstructure is also auxetic in nature. So there is a greater probability that other examples of auxetic biomaterials exists naturally, and by developing bio implants with negative Poisson's ratio optimized results in a specific application can be achieved. In manufacturing artificial replacements biomaterials it is necessary to consider auxetic functionality so that proper match between in mechanical properties of the real and synthetic material can be attained. Auxetic prostheses for the repair of cardiac valve have been proposed and it has been found 3 times more difficult to indent as compared to conventional material even at low loads [36].

From the perspective of traditional mechanics the existence of auxetic material has been remained controversial, manmade materials having auxetic behavior have been produced recently. Anisotropic fibrous composites and solids such as metallic foams or polymers with re-entrant microstructure are example of synthetic auxetic materials. Biomedical application of auxetic materials includes artificial skin, drug release unit, ligaments, and biomedical bandages vascular and non-vascular stents. Auxetics have also been found to provide increased fracture toughness and energy absorption (figure 2.6).

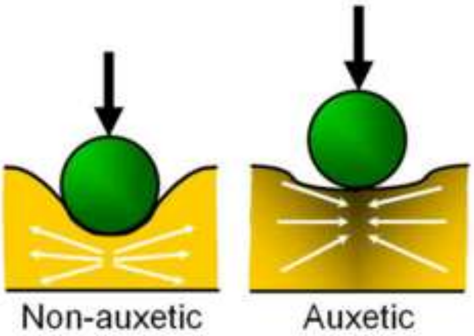


Figure 2.6: Showing increased energy absorption capability of auxetic materials.

Models based on Auxetic geometries are scale independent, so the auxetic characteristics in the same geometry can be manipulated at any stage [14]. Deformation in auxetic geometry when subjected to loads is due to negative Poisson's ratio. The auxetic behavior can be achieved at any level either macro, micro or nano. The popularity of auxetic materials in commercial applications have been increased due to better shear stiffness, indentation resistant and strain fracture toughness [18, 37].

Number of auxetic materials have been theoretically proposed, fabricated and manufactured.

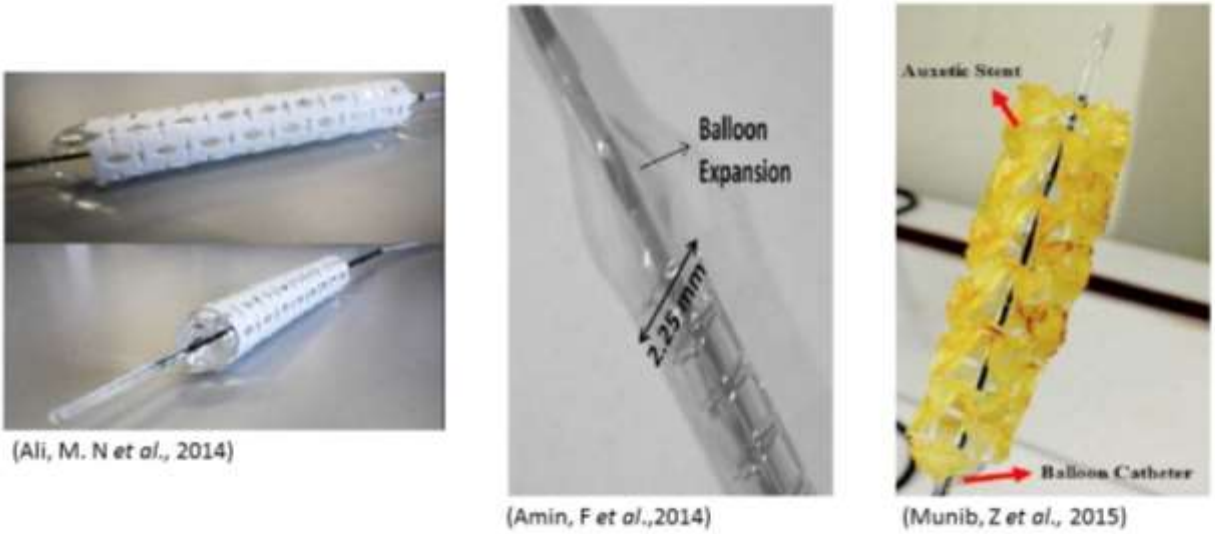
The geometries of these structures may be based on triangles, polygons, squares, rectangles which are connected through edges and hinges. We focused mainly on two auxetic geometries which were proposed by Grima, rotating squares and rotating triangles [19,20,21].

One of this mechanism based on rotating squares was proved practically by Ali el al, consists of solid squares which are connected by hinges at their vertices such that four squares connects to form a diamond [18,20]. Another two dimensional model is based on rotating triangles which are connected to each other by simple hinges. Under stress of loaded form this model deforms through a mechanism in which equilateral triangles behaves like semi rigid or rigid units and they rotate relative to each other

[21]. Such structures have been proposed to produce the effect of negative Poisson's ratio i.e. auxetic behavior in polymers and nanostructured foams depending on the type of application.

Many studies in past have come up with new auxetic stents and presently conventional balloon catheters are used for their expansion as they are cost effective and easily available [16, 17,18] (figure 2.7). Deployment mechanism of balloon catheter is based on radial expansion due to which less number of hinges/unit cells are expanded minimizing the expansion longitudinally, hence causing foreshortening of stents. Moreover, due to sub-optimal expansion, stent radially recoils which leads to repeated dilations to obtain plastic deformation.

Figure 2.7: Auxetic stents recently reported.



(Ali, M. N *et al.*, 2014)

(Amin, F *et al.*,2014)

(Munib, Z *et al.*, 2015)

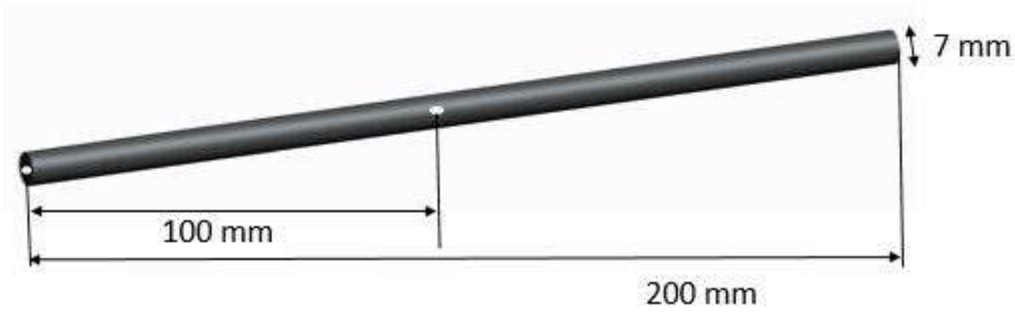
MATERIALS AND METHODS

3.1 In-silico Design:

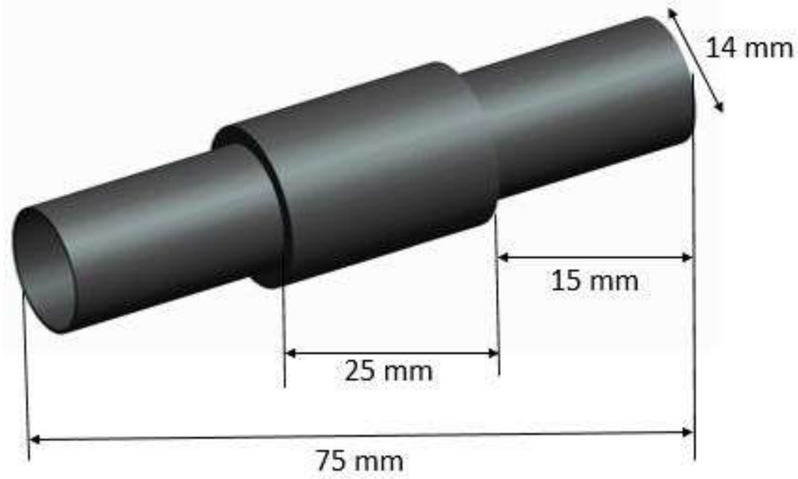
The in-silico macro model design of the deployment device was made on Pro-Engineer wildfire 5.0. The stent expansion device consists of multiple parts which were assembled to obtain the final device. The overall device consisted of 18 parts; the spokes were connected to each other with pin joints having slider parts on both sides which slide over the main rod (Figure 3.1 and 3.2). The hollow cylinder is fixed with the main rod. The circular bars were arranged and held together so as to operate through umbrella mechanism. Thus this arrangement contributes to overall extension of the structure in both x and y direction when external hydraulic pressure is applied.

Figure 3.1: Illustrating different parts of the device, (a) Cylindrical part fixed with main rod having pin joints with spokes, (b) Cylindrical moving parts which slides over both the sides of

main rod having pin joint with spokes, (c) Hollow cylinder fixed with main rod, (d) spokes attached to sliding parts, (e) spokes attached to fixed cylindrical part, (f) main rod.



(a)



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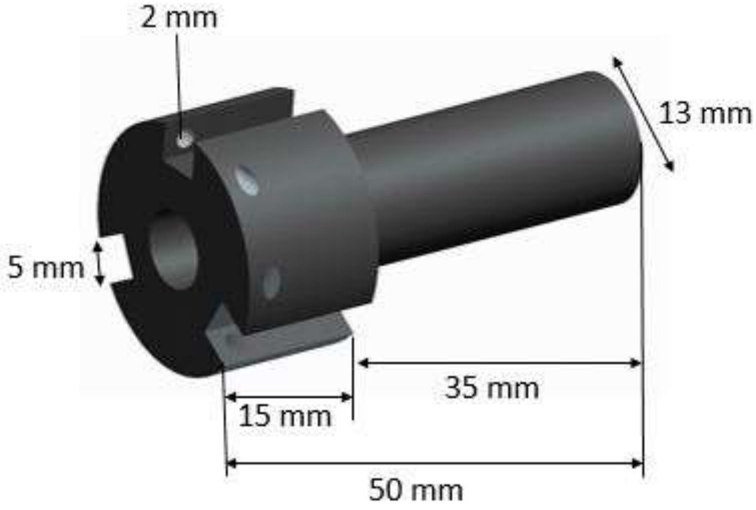
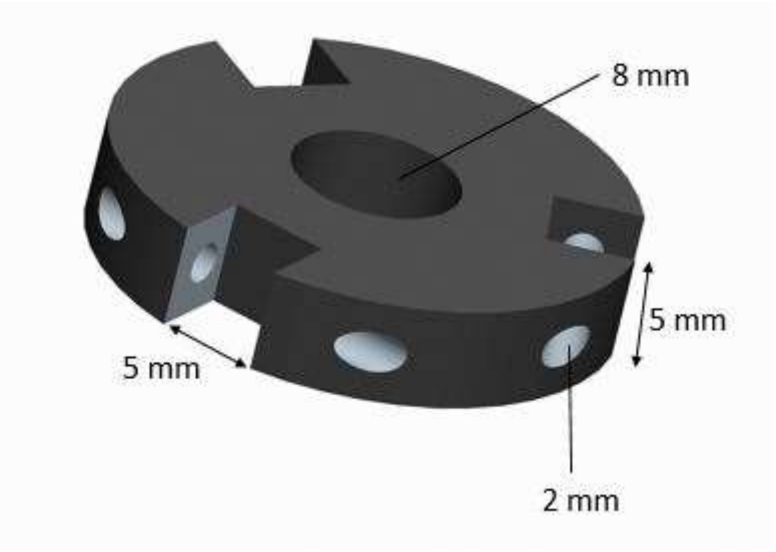


(c)



(d)

(e)

(f)

Figure 3.2: In-silico design and Measurements of (a) main rod (b) hollow cylinder (c) sliding part

(d) Fix part (e) and (f) rods.

The complete device consisted of 18 parts as shown in the figure, the main rod having a water inlet at one side and an outlet exactly at the middle of the rod. The main rod and cylindrical moving parts were attached in such a way that they slide over main rod .Two similar cylindrical fixed parts were fixed to the ends of main rod. Spokes (e) as shown in the figure were attached to cylindrical fixed parts on both ends of main rod, 120˚ apart from each other through a pin joint (Figure 3.3). Spokes (e) were connected through pin joint to both sliding parts at 120˚. Hollow cylinder (c) was fixed with main rod forming a compartment for pressure to build. Figure 3.4 shows complete assembled un-expanded device with water inlet and outlet. Figure 3.5 shows expanded device with elongation along x and y direction.

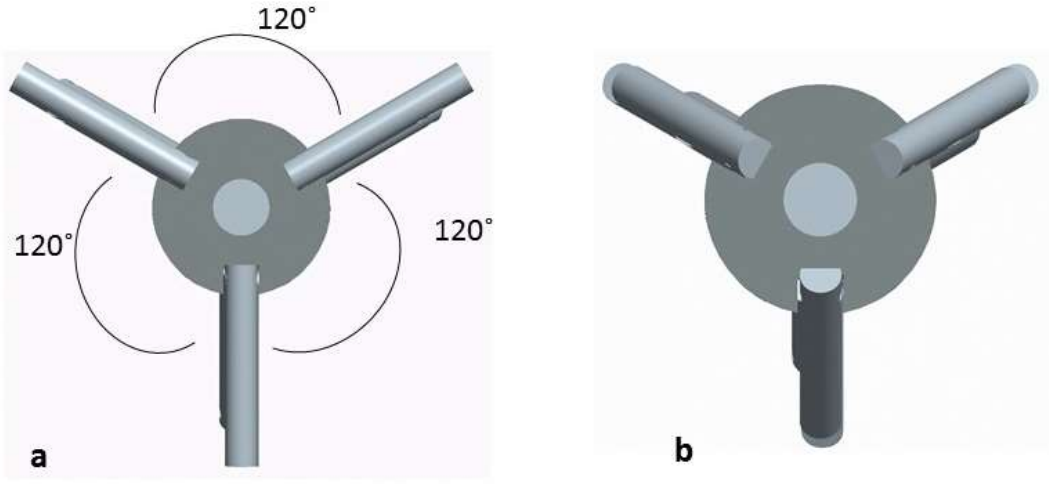


Figure 3.3.Top view of the device showing the arrangement of the spokes in (a) expanded and (b) unexpanded form.

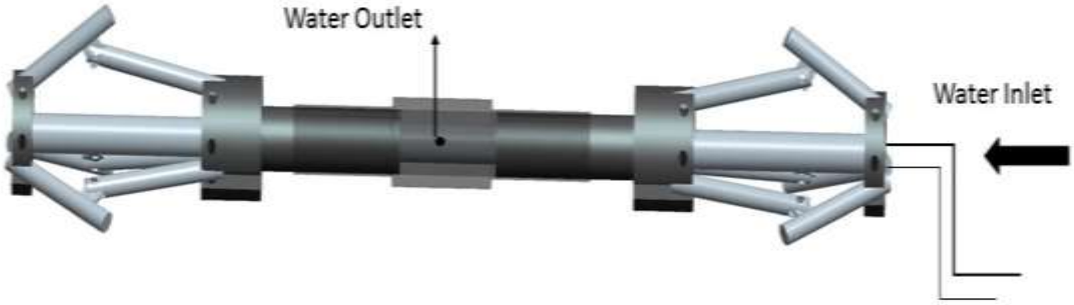


Figure 3.4: 3D front view showing water inlet and outlet.

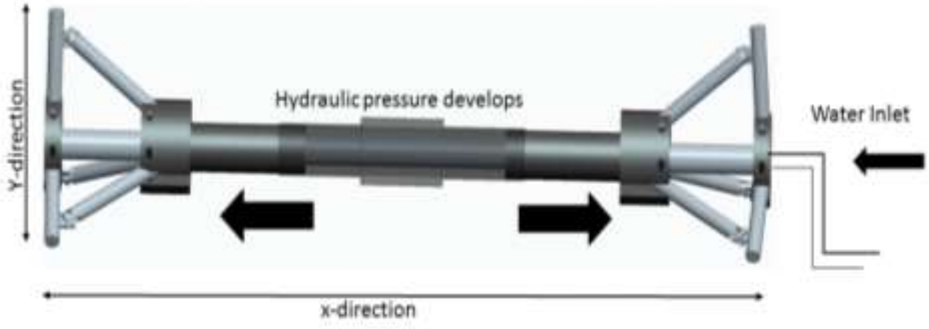


Figure 3.5: Front view of device showing the relative directions of expansion in x and y direction when pressure is exerted.

3.2 Fabrication of the Device:

The material of choice for fabrication of macro model of expansion device was metal. Brass and high grade aluminum metal was used for fabrication. The parts were fabricated using high speed lathe and milling machine at Manufacturing Resource Centre, NUST (MRC) (Figure 3.6).

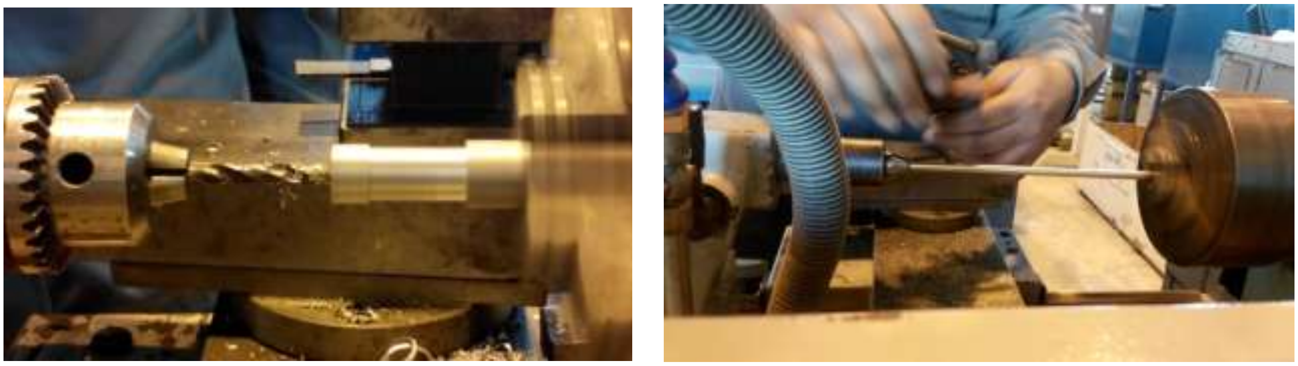


Figure 3.6: Fabrication of different parts on High speed lathe machine.

3.3 Device Assembly:

To seal the device O-rings and Teflon tape were used. Four O-rings were connected two at the inner surface of sliding part providing sealing between the main rod and cylindrical moving parts. And two were attached at the outer surface of sliding part, sealing the cylindrical moving parts and part hollow cylinder as shown in the figure 3.7.

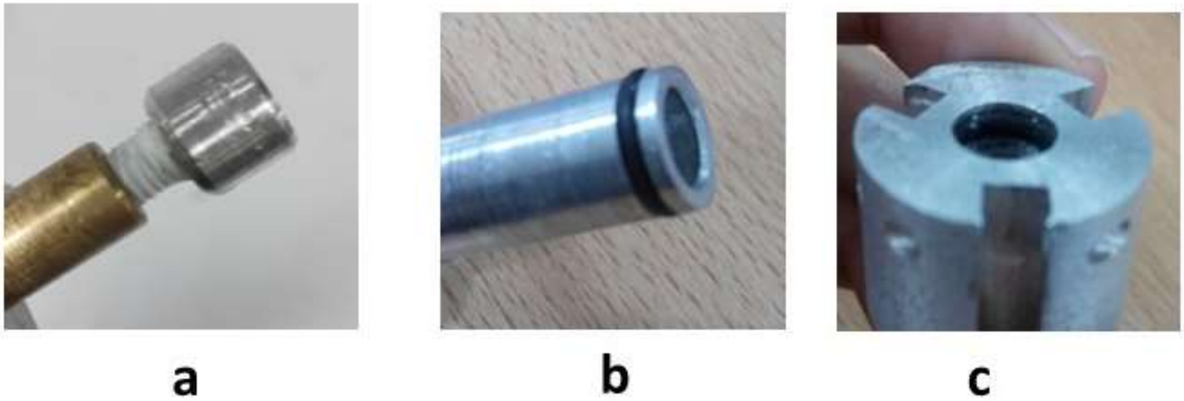


Figure 3.7: Showing the sealing mechanism, (a) Teflon tape attached to prevent water leakage, (b) O-rings attached to outer surface, (c) O-rings attached to inner surface.

Pins were used to connect the spokes to each other and to the parts attached to main rod. Figure 3.8 shows complete unexpanded device.

Figure 3.8: Assembled deployment device.

3.4 Testing of the device:

To test the deployment device two different geometries of auxetic stents were fabricated [19]. The designs were first made using software Pro-Engineer wildfire 5.0.The design was cut on the sheet of polyurethane and then folded to form tubular stent.

Polyurethane was selected due to its elastic properties so that the expansion achieved by deployment device could easily be recorded.

First geometry selected for device testing ‘rotating square’ model [20]. The parameters which control the behavior of rotating square design are the two angles which are formed at the vertices of joining squares and the constants of hinging and stretching. Along with these parameters the direction of application of force also plays a major role in overall expansion of the design (Figure 3.9).

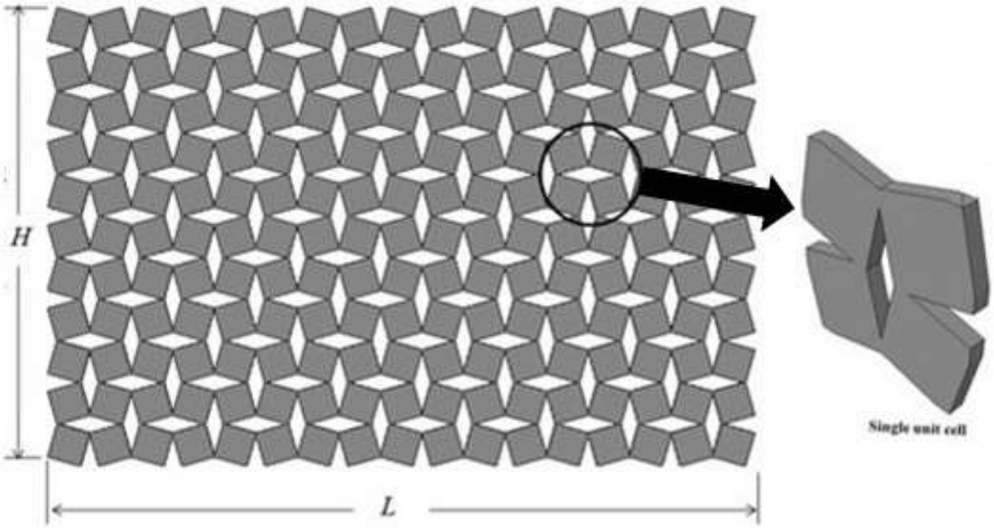


Figure 3.9: Rotating Square Auxetic geometry with pattern of unit cells in horizontal and vertical direction with height (H) and length (L).A single unit cell is shown at right.

The second design selected was ‘rotating triangle’ geometry [21]. The unit cells were arranged in such a pattern that they repeat multiple times in horizontal and vertical direction. Flexible hinges are the connections between the adjoining unit cells (Figure 3.10).

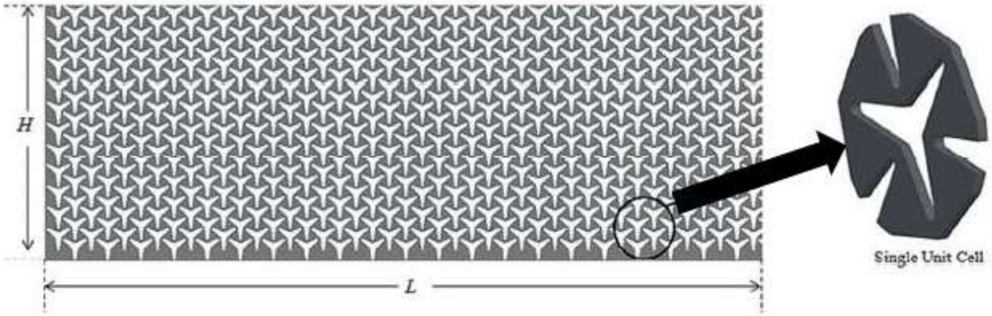


Figure 3.10: Rotating triangle Auxetic geometry with pattern of unit cells in horizontal and vertical direction with height (H) and length (L).A single unit cell shown at right side

3.5 Casting of Auxetic stent

The polyurethane used for the fabrication of sheets was PMC-744 (Smooth-On INC.PA, USA). It consists of two parts A and B which were mixed in 2:1 respectively and then poured into the mold to form sheet of 2mm thickness.

Rotating squares and rotating triangle auxetic geometries were cut on polyurethane films using CO2 laser cutting machine. The sheets were then folded to form a circular stent with the help of adhesives (Figure 3.11 and 3.12). The auxetic stent was then mounted on the device to test its expansion mechanism. The expansion of length and diameter were recorded with respect to pressure values ranging from 1 to 4 atm.

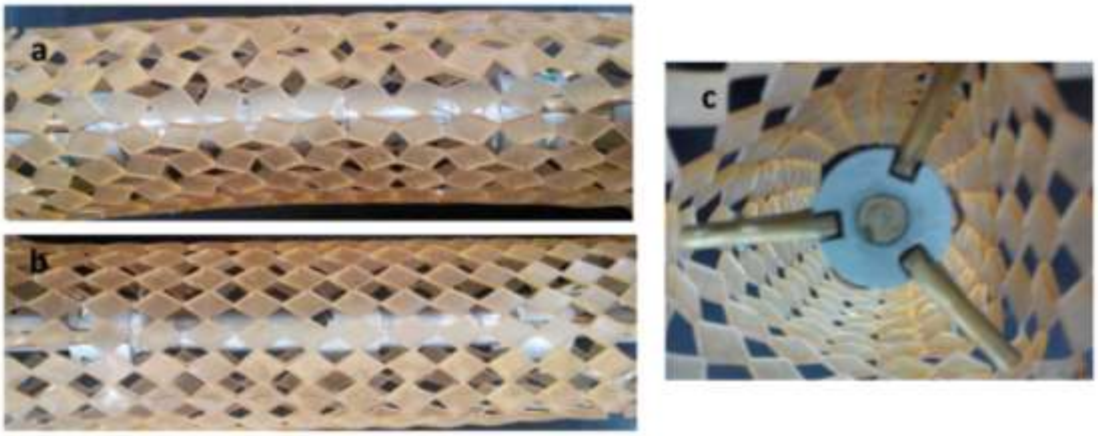


Figure 3.11: Front view showing rotating square Auxetic stent mounted on device, (a) un-expanded view, (b) expanded view, (c) top view of deployment device.

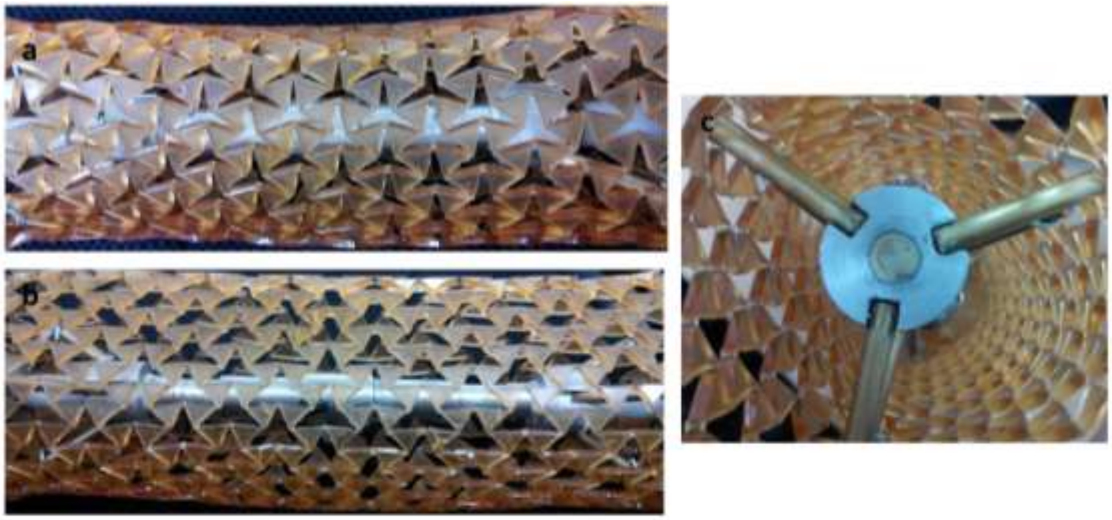


Figure 3.12: Front view showing rotating triangle Auxetic stent mounted on device, (a) un-expanded view, (b) expanded view, (c) top view of deployment device.

3.6 Balloon Expansion test

To compare the deployment device results with conventional method, both the stents of same dimensions were expanded using conventional balloon catheter method (figure 3.13). The change in length and diameter were recorded and then compared with experimental results of deployment device.

Figure 3.13: (a) Rotating square geometry auxetic stent mounted on balloon, (b) Rotating triangle geometry auxetic stent mounted on balloon.

3.7 Simulation Analysis

To further validate the results FEA of auxetic stents was performed using software Solid works® Premium 2011.The FEA model was built with the same dimensional details as the physical Auxetic stents tested. To simplify the model symmetry was assumed along the length and therefore, only one unit-cell (comprising of eight rotating-squares) was incorporated into the FEA model (figure 3.14). The material chosen for FEA was polyurethane whose properties were similar to polymer that was used for experimental testing of deployment device. The mesh size was 61792 elements and the time taken to complete the meshing was 21 sec (Figure 3.15 and 3.16). The pressure values were kept as variable and displacement along x and y axis was calculated.

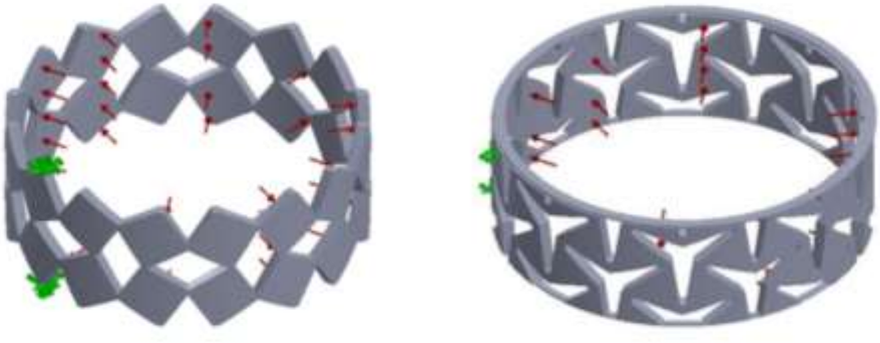


Figure3.14: Showing fixtures and Pressure directions.

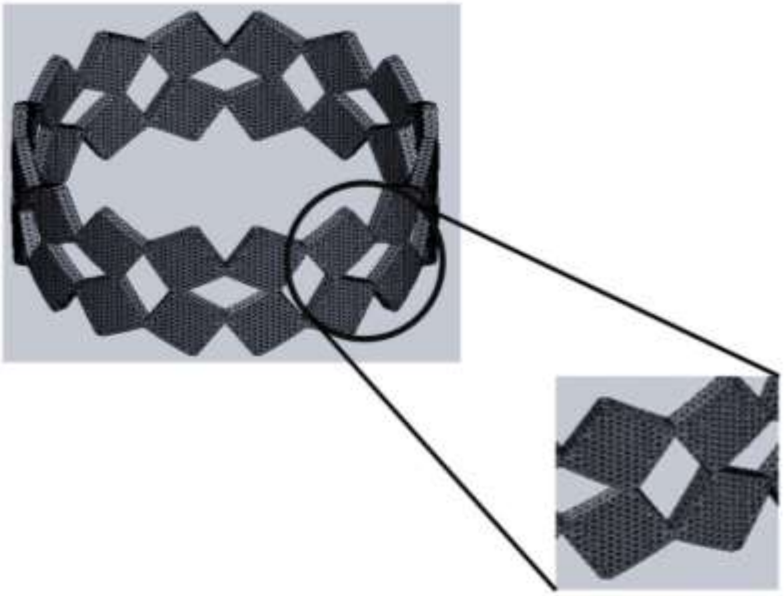


Figure3.15: Meshed unit cell of rotating square geometry

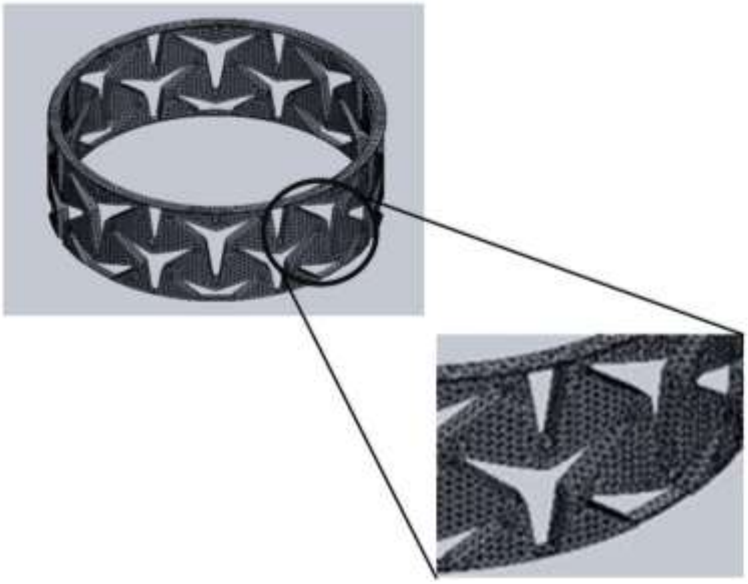


Figure 3.16: Meshed unit cell of rotating triangle geometry.

RESULTS AND DICUSSION

4.1 In-silico Analysis

This analysis was performed using the same software in which device design was made i.e. Pro Engineer. The movement of deployment device from unexpanded to expanded form results in change in angles and length of the device. The angles ‘a’, ’b’ and ‘c’ are formed as a result of connection of spokes (Figure 4.1) changes as the device starts expanding. Angles ‘a’ and ‘c’ decreases whereas ‘b’ increases as the device is expanded .The measurements of change in angles recorded from in-silico analysis are shown in figure 4.2.The expansion of spokes results in elongation of device along y-direction. When pressure is applied the cylindrical parts move outwards causing elongating along x direction (Figure 4.3). The spokes attached to these parts exert pressure on to the spokes attached to fixed cylindrical parts and they expand in y direction in a similar fashion as spokes of an umbrella (figure 4.4).

The extent of elongation in y direction obtained by flexing solely depends on the length of the spokes attached fixed cylindrical part. The greater the length of these rods the greater extension is achieved. Whereas the elongation along x direction can also be altered by altering the length of main rod .Thus the length of the rods is the main factor controlling the expansion of the whole mechanism and can be customized according to the requirement and size of stent.

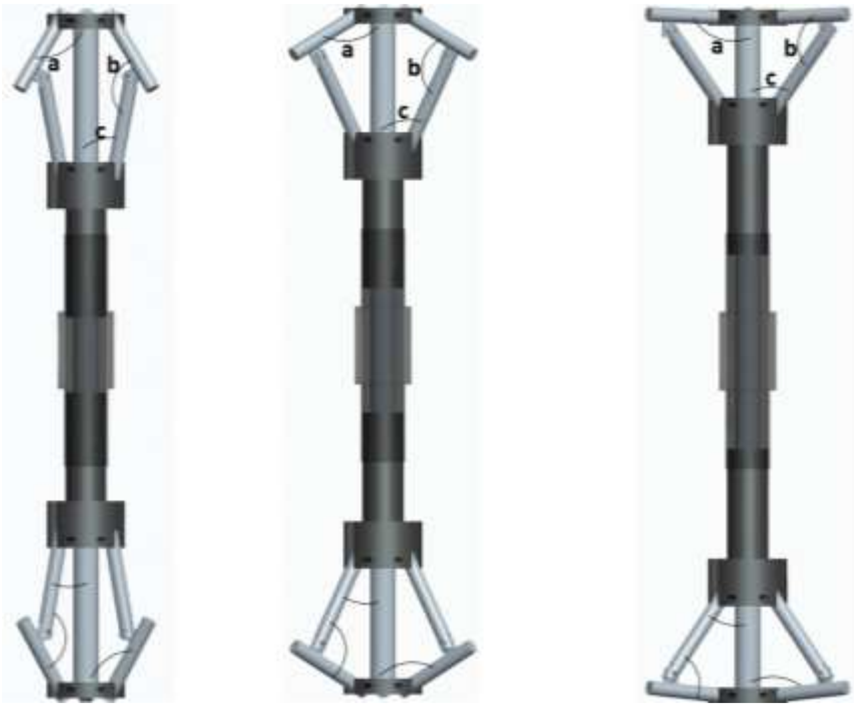
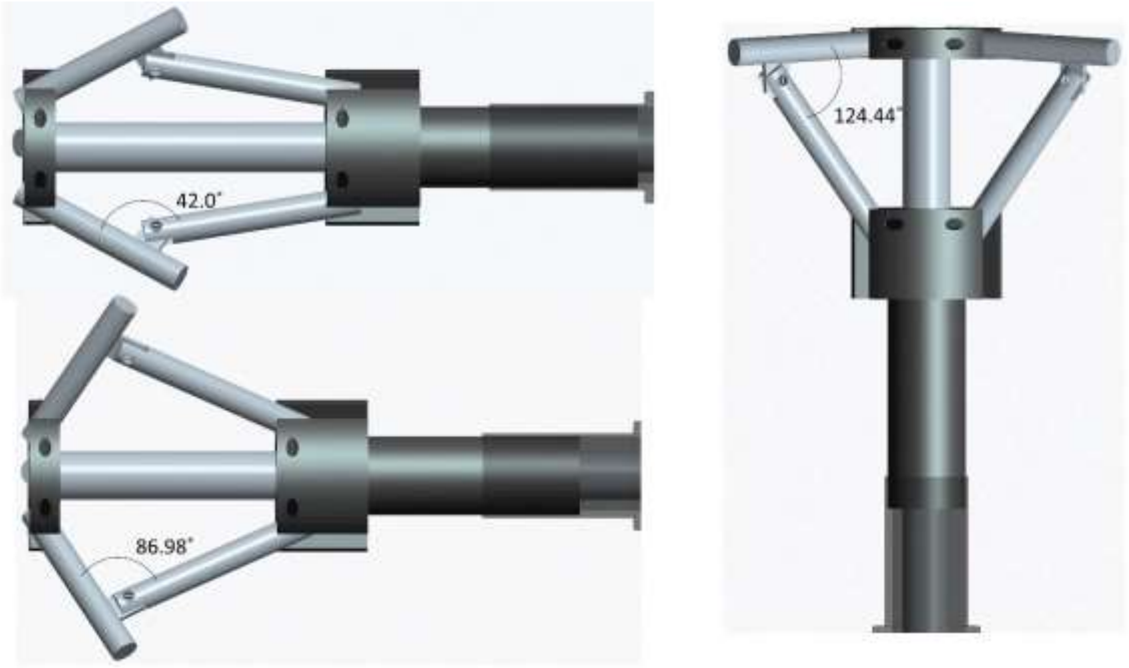


Figure 4.1: Top view of device showing the change of angle's between the spokes as the device is shifted from unexpanded to expanded form.

(a)



(b)

(c)

Figure 4.2: a, b and c showing the extent of change in angle as the device is shifted from unexpanded to expanded form.

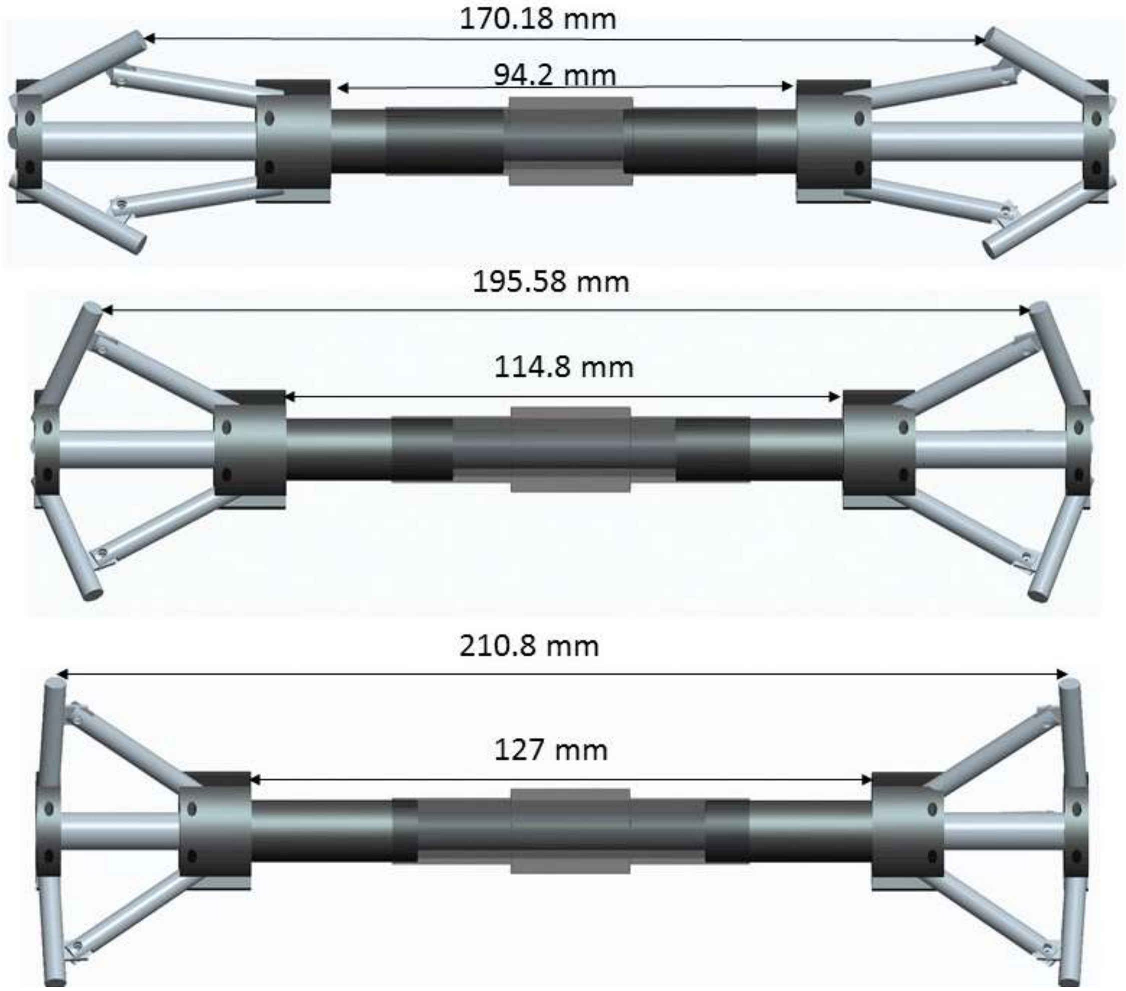


Figure 4.3: Front view showing the change in length from spoke to spoke on expansion of device which results in elongation along x-direction.

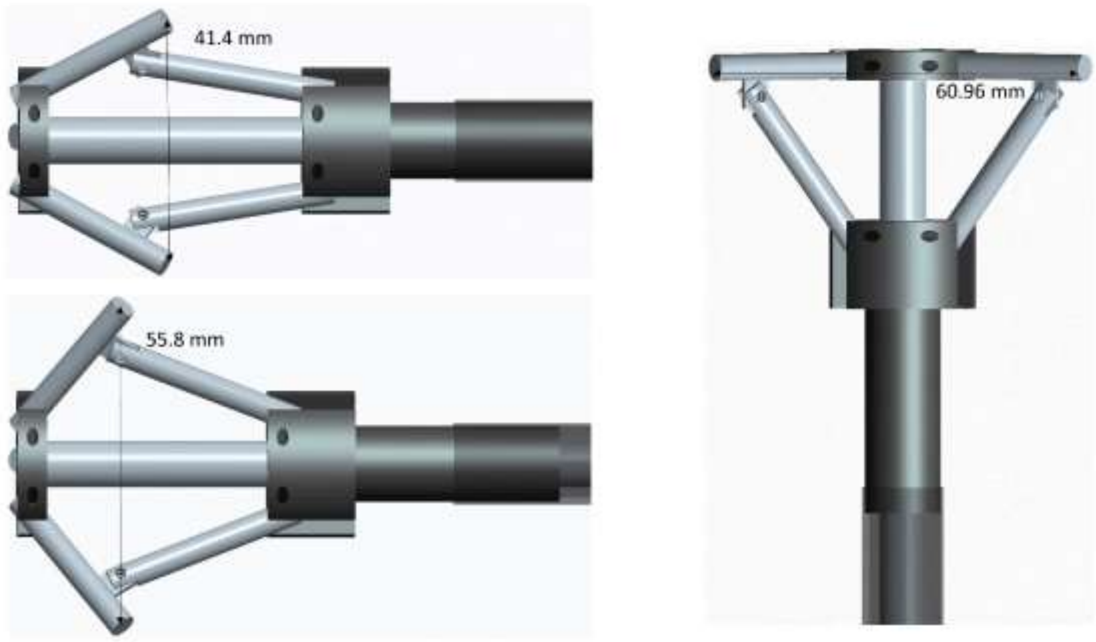


Figure 4.4: Showing change in length between spokes resulting elongation along y-direction.

4.2 Experimental results

Inflation device was used to apply pressure to deployment device as shown in figure. The auxetic stent was mounted on the device in unexpanded form. Hydraulic pressure was applied and expansion along diameter and length were recorded. Three trials were performed using the same stent and then average elongation was calculated. The expansion achieved by inflating auxetic stent (rotating square geometry) is illustrated in table 4.1. The results were plotted in graph shown in Figure 4.5 and 4.6 which clearly shows a linear behavior in expansion both longitudinally as well as radially.

Pressure	**Mean Dia (mm)**	**Mean Length (mm)**	**Unit Cell. L (mm)**	**Unit Cell. dia(mm)**
0	53.17	173	21.89	18.44
1	54.36	175	22.29	18.9
1.8	55.4	185	23	19.5
2	56.44	187	23.85	20.23
3	57.23	195	24.13	20.75
3.1	58.13	200	24.35	21.16
4	60.85	205	25.58	21.58

Table 4.1:Illustrating radiall and longitudinal expansion achieved by testing of device on rotating square geometry auxetic stent.

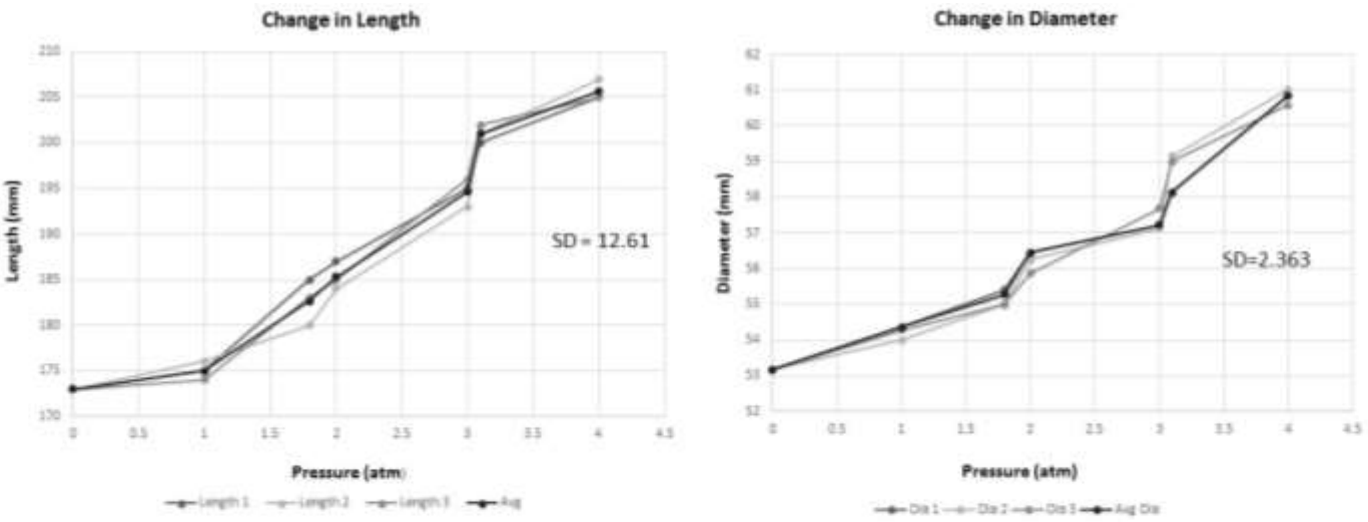


Figure 4.5: Length and Diametrical elongation of rotating square geometry stent.

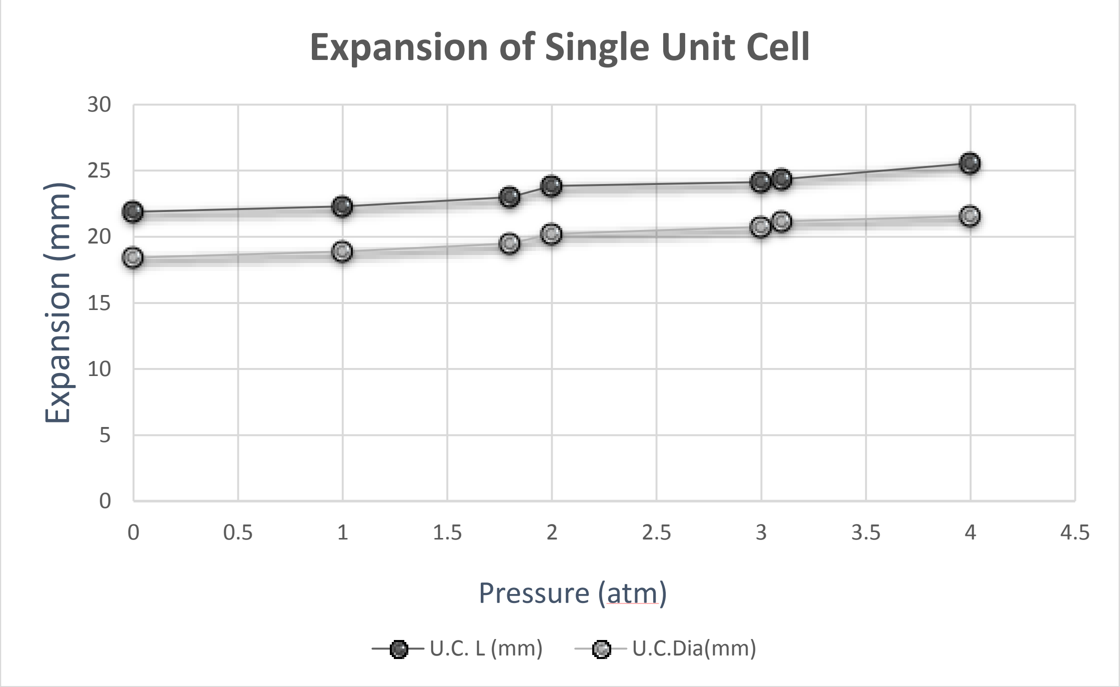


Figure 4.6: Expansion of single unit cell at different pressure values of rotating square geometry.

Similarly the auxetic stent with rotating triangle geometry was also tested using deployment device. The pressure values were kept same i.e. 0-4. Radial and longitudinal expansion was recorded as shown in table 4.2. From the graph plotted in figure 4.7 it is clear that linear expansion was achieved both radially and longitudinally.

Pressure	**Mean Length (mm)**	**Mean Dia (mm)**	**Unit cell length (mm)**	**Unit Cell dia (mm)**
0	175	52.94	20.49	18.04
1	177	53.38	20.63	18.97
2	180	54.58	21.45	20.29
3	187	56.87	22.3	20.4
3.5	200	58.02	23.77	21.66
4	207	60.47	24.12	20.23

Table 4.2:Illustrating radiall and longitudinal expansion achieved by testing of device on rotating traingle geometry auxetic stent.

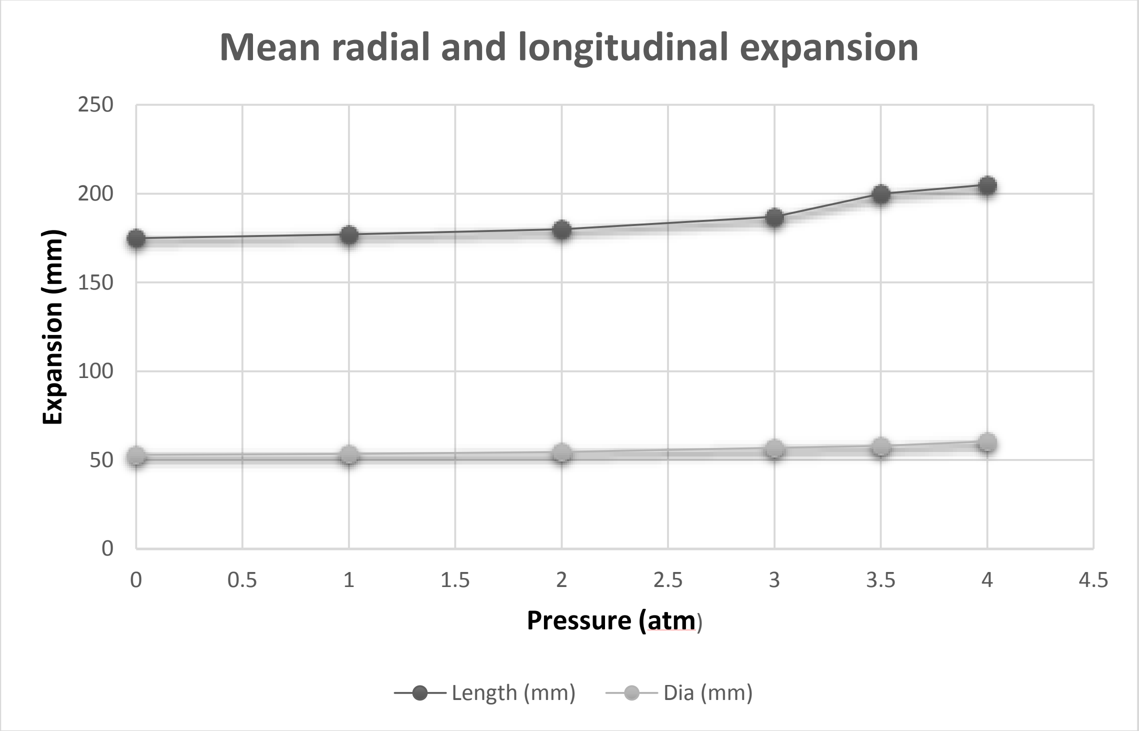


Figure 4.7: Mean radial and longitudinal expansion of rotating triangles geometry auxetic stent.

4.3 Comparative Analysis

To compare the results obtained by testing the deployment device expansion with conventional balloon was also performed. Table 4.3 shows the comparative analysis of the results obtained by expanding rotating square geometry by both the mechanisms. Initial length of stent was 175mm and on complete expansion from device length increment 205mm was recorded whereas using the balloon, length was increased only by 5 mm i.e. from 175mm to 180mm. Diametrical expansion was more or less the same from both the mechanisms. As according to results there was significant longitudinal elongation achieved by device expansion.

Table 4.4 illustrates the results obtained by expanding rotating triangle geometry by both the expansion mechanisms. Similar results were obtained as by rotating square auxetic stent. A significant elongation both radially and longitudinally was observed by expanding the stent using our device, whereas minimal longitudinal elongation was achieved through balloon expansion.

	Device		**Balloon**	
	Length (mm)	Diameter **(mm)**	**Length (mm)**	**Diameter (mm)**
Unexpanded	175	53.17	175	53.17
Expanded	**205**	**60.96**	**180**	**60.17**

Table 4.3: Comparative analysis of rotating square geometry experimental results with balloon expansion results.

	Device		**Balloon**	
	Length (mm)	**Diameter (mm)**	**Length (mm)**	**Diameter (mm)**
Unexpanded	**175**	**52.94**	**175**	**52.94**
Expanded	**207**	**60.47**	**190**	**60.51**

Table 4.4: Comparative analysis of rotating triangle geometry experimental results with balloon expansion results.

4.4 Simulation Analysis

In this analysis the data obtained by experimental testing of the device was compared to data of FEA of auxetic stent. Figure 4.8 and 4.9 illustrates the simulation results. From the displacement values along x and y directions, strain was calculated. Table 4.5 and table 4.6 shows the comparative analysis of physical and FEA results of rotating square geometry and rotating triangle geometry respectively. The strain values of both physical experimental testing of both geometries and the FEA testing were calculated and plotted as shown in figure 4.10 and 4.11. From comparative data plotted it can be established that satisfactory agreement was achieved between the experimental stent expansion and FEA model, even the material used for FEA model and fabrication of auxetic stent was different.

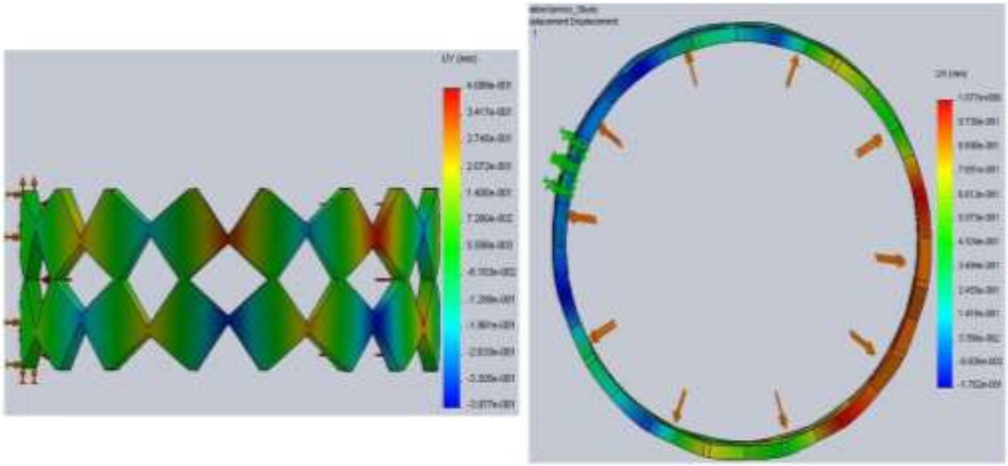


Figure 4.8: Simulation results, displacement along x and y axis of rotating square geometry.

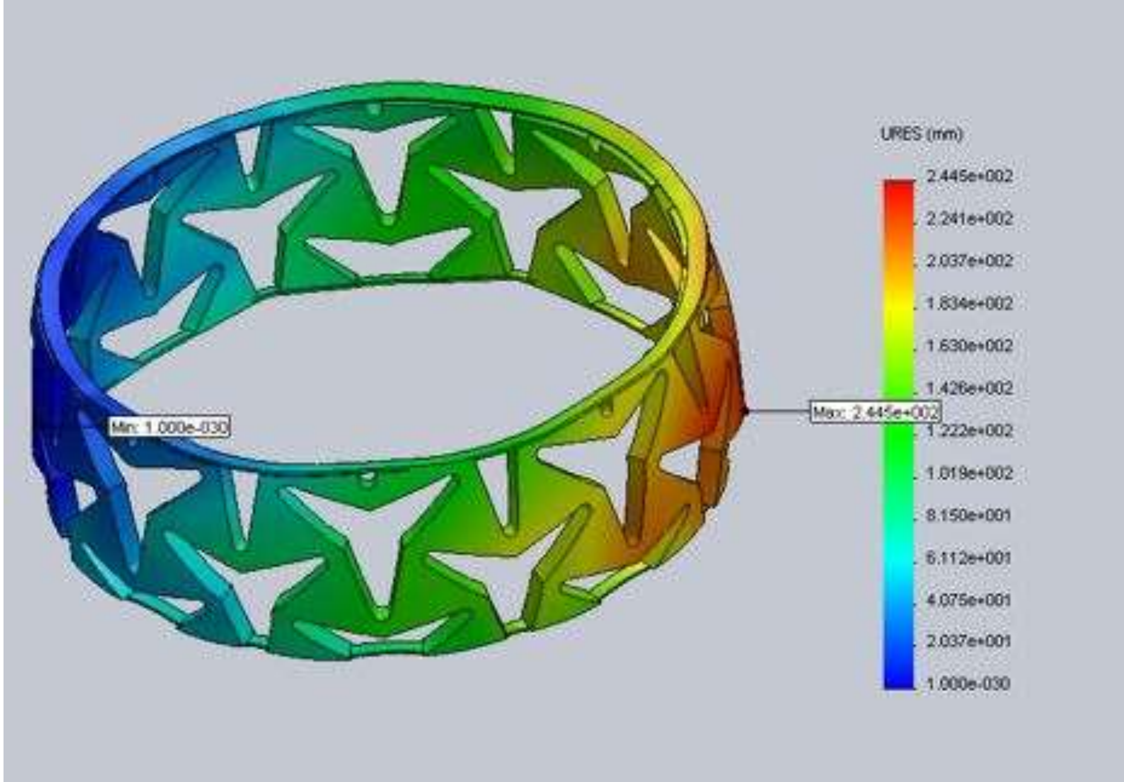


Figure 4.9: Simulation results, resultant displacement of rotating triangle geometry.

Pressure	S.W.strain x-axis	S.W.strain y-axis	Strain diameter	Strain Length
1	0.04	0.03	0.02	0.046
2	0.085	0.071	0.061	0.089
3	0.094	0.106	0.076	0.112
4	0.127	0.141	0.116	0.168

Table 4.5: Simulation results Vs experimental results of rotating square geometry.

Pressure	S.W.strain x-axis	S.W.strain y-axis	Strain diameter	Strain Length
1	0.108	0.0452	0.04	0.0315
2	0.216	0.0905	0.181	0.072
3	0.324	0.135	0.264	0.115
4	0.432	0.175	0.35	0.206

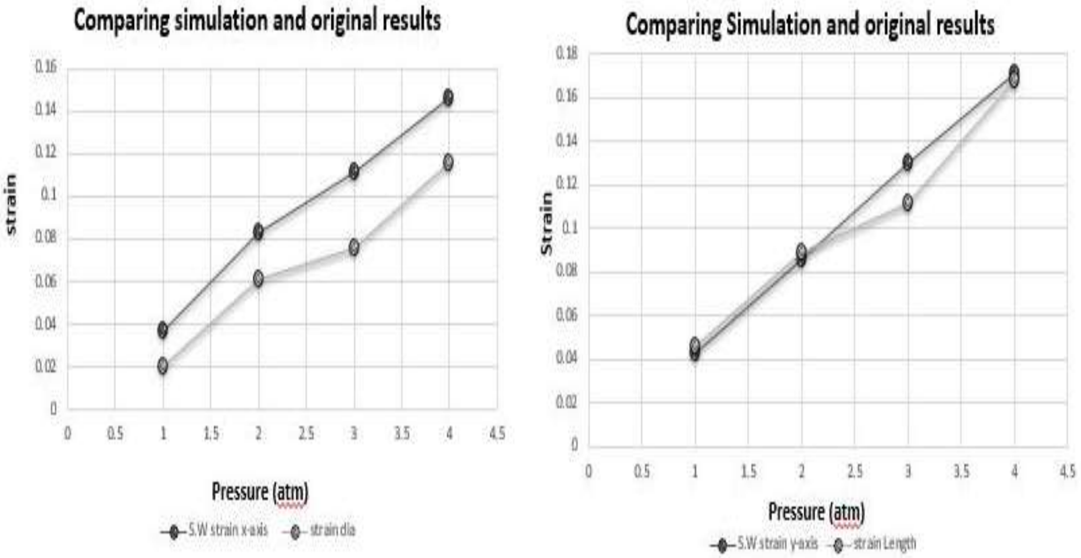


Figure 4.10: Comparing simulation along x-axis and y-axis with experimentally obtained results of rotating square geometry.

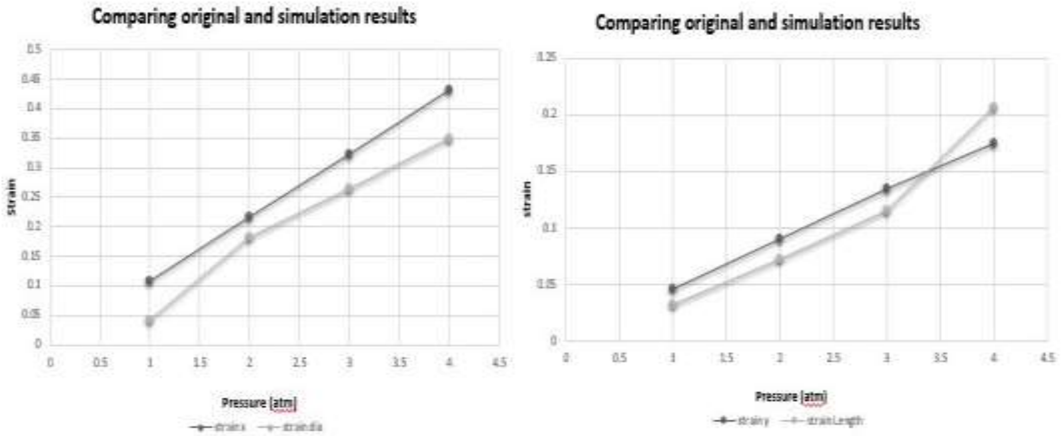


Figure 4.11: Comparing simulation along x-axis and y-axis with experimentally obtained results of rotating triangle geometry.

CONCLUSION

The device can be used for the expansion of auxetic stents having negative Poisson' ratio, as according to results uniform expansion is achieved both radially and longitudinally. As the device exerts pressure longitudinally due to which force is applied on more unit cells/hinges which results in overall expansion .Comparative analysis of experimental and FEA results shows coherence of expansion along 'x' and 'y' direction.

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APPENDIX

- **Patents (Filed):**

1. Umar Ansari, Murtaza Najabat Ali, **Faiza Bukhari**, Hafsah Akhtar, “A novel Deployment Device For Stents Having Negative Poisson’s Ratio.
2. Murtaza Najabat Ali, Umar Ansari, Hafsah Akhtar, **Faiza Bukhari**, “A New Stent with Novel Auxetic Structural Configuration.

- **Research Papers (Submitted):**

1. **Faiza Bukhari**, Murtaza Najabat Ali, Umar Ansari, Hafsah Akhtar, Hassaan Aslam (2015), “A Dedicated Deployment Device for the Effective Expansion of Stents having Negative Poisson's Ratio”, Journal Of Applied Biomaterials And Functional Materials. (JABFM-D-15-00078)
2. Hafsah Akhtar, MurtazaNajabat Ali , Umar Ansari, **Faiza Bukhari**, Fatima Darakhshan (2015), “Designing and Development of Novel Auxetic Geometry for non-vascular Oesophageal Stent Application”, Journal of Medical Devices. (MED-15-1215)
3. Hafsah Akhtar, MurtazaNajabat Ali, Umar Ansari, **Faiza Bukhari**, Maryam Masood (2015), “5-Florouracil loaded poly(caprolactone)-poly(vinyl alcohol) and poly(lactic acid)-poly(vinyl alcohol) hybrid films: Potential polymeric chemotherapeutic formulation”, Journal of Materials Sciences.
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Novel Auxetic Geometry.", Advances in Polymer Technology-Wiley. (ADV-07-15-169)

- **Review Articles (Submitted):**

1. **Faiza Bukhari**, Umar Ansari, Murtaza Najabat Ali, Hafsah Akhtar (2015), "An appraisal of the efficacy of different training techniques involved in phlebotomy and venous access applications", Applied Clinical Informatics. (ACI-2015-05-R-0066)

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4. Hafsah Akhtar, **Faiza Bukhari**, Misbah Nazir, Adeeb Shehzad, Nabeel Anwar (2015), "Therapeutic Efficacy of Neurostimulation for Depression: Techniques, Current Modalities and Future Challenges", Neuroscience Bulletin. (NSB-2015-06-125)