# INVESTIGATION ON DEVELOPMENT OF HIGH PERFORMANCE MEDICAL STENTS AS APPLIED WITH MESH STRUCTURES

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**Abstract:** There are concerns about the occurrence of fatigue fractures caused by stress concentrations due to different shape structures and manufacturing methods in conventional stents, and then new stents having high strength and high flexibility are required. Applicable mesh structures for medical stent applications based on the design concepts of high strength and flexibility are designed to solve various problems of conventional stents in this research. The influence of introduced design variables of basic mesh shapes on compression characteristics of meshed stent models are evaluated through finite element analysis using ANSYS Workbench. From analytical results, compressive stiffness of meshed stent models are found to be changed periodically with compressive directions due to the designed basic mesh shapes. Secondly, compressive flexibility of meshed stent models mostly depends on arm's number and shapes of basic mesh shapes. It concluded that the compressive performance of designed meshed stent models in this study can be easily controlled by increase some design variables like angle proportional to the arm length of designed basic mesh shapes and get closed to conventional medical stents with higher strength performances.

**Keywords:** Medical Stents, Mesh Structure, Finite Elements Analysis, Compressive Stiffness

## Introduction

In recent years, stenosis and occlsion have occurred in body lumen such as blood vessels, bile ducts, trachea and other like indispensable for maintenance of human life as in the superficial femoral artery (SFA) occlusion caused by disease. As an effective treatment for such stenosis and occlusion, indwelling of medical stents is performed. The inside of the living body lumen where the stents are placed is a corrosive environment with complicated structures and severe movements. The difficult environment may cause rejection reactions when foreign matter intrudes. Therefore, it is required that medical stent devices applied for the living body lumen have high flexibility, excellent biocompatibility, high strength and durability etc.

However, ready-made conventional medical stents have concerns that the design and manufacturing methods for stent shape structures have caused stress concentrations and then lead to fatigue fractures due to pulsation, or caused neointimal hyperplasia due to strong radial forces generated on the inner wall of the stents [1]~[9]. Therefore, there are needs for medical stents having high strength and high flexibility capable of following severe movements combined with bending, torsion, expansion and contraction in SFA.

Therefore, the purpose of this research is to design applicable mesh structures [10] for medical stent applications to solve the above mentioned problems. Meshed stent models with higher strength and higher flexibility with integral molding are designed and investigated analytically using finite element analysis code ANSYS. The compression characteristics of meshed stent models are examined through finite element analysis and reported in this paper.

## Design of Meshed Stent Model with Mesh Structures

Based on the design concepts of mesh structures with high strength and high flexibility [10], six types of mesh basic shape are designed in this study and applied for meshed stent models as shown in Figure 1. For these mesh basic shape applied stent models shown in Figure 1, the number of basic mesh shape arranged in stent circumferential direction (hereinafter called "N") is changed from 6 to 8, and the angle affecting to arm length (hereinafter called "$\theta$") is changed from 0° to 60°. Three design variables, such as mesh line width (hereinafter called "$w$"), the angle affecting to arm length "$\theta$" and number of basic mesh shape "N" as shown in Figure 2, are introduced for easy understanding. Then meshed stent models are designed for all combinations of N and $\theta$. In addition, hexagonal based meshed stent models [11] are also introduced in this research for comparison. The diameter of stent cylinder model is set at 6.0mm, the strut thickness is set at 0.18mm and $w$ is set at 0.1mm as layout sizes of meshed stent models for analytical approaches. These stent model sizes are same as the medical stents used in SFA.

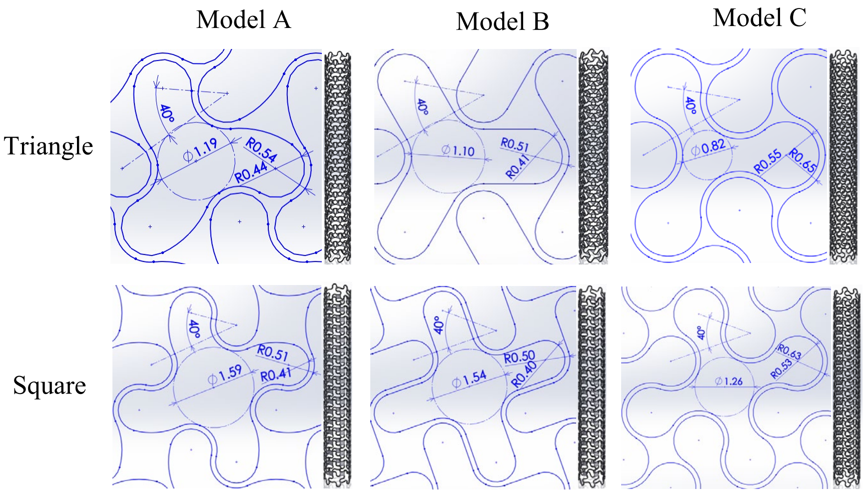



**Figure 1.**Basic mesh shapes with applied meshed stent models (Triangle and Square)

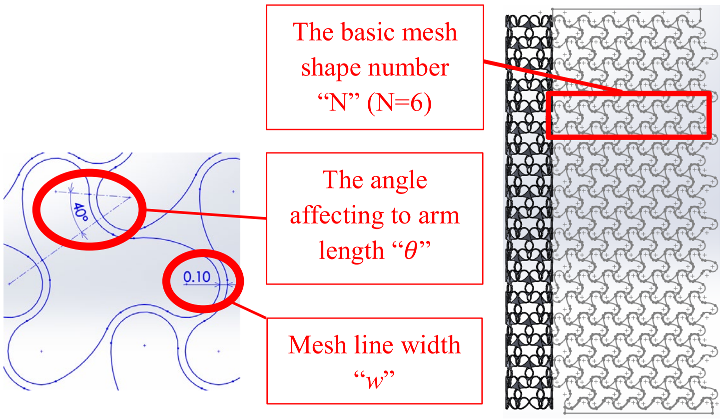



**Figure 2.**Design variables introduced for analytical approach: mesh line width "w", the angle affecting to arm length "$\theta$" and the number of basic mesh shape arranged in the stent circumferential direction "N"

## Evaluation of Compression Characteristics in the Vertical Direction to Cylindrical Axis of Meshed Stent Models

Compression characteristics in the vertical direction to cylindrical axis of meshed stent models were analyzed and evaluated using finite element analysis software ANSYS Workbench. Meshed stent models are sandwiched between flat jigs and applied with compressive load of 10 N in the direction perpendicular to stent cylinder axis as shown in Figure 3. Table 1 shows the material properties and finite element mesh settings for meshed stent modeling. Figure 3 also shows the image of typical finite element mesh of meshed stent model including compressive fixtures.

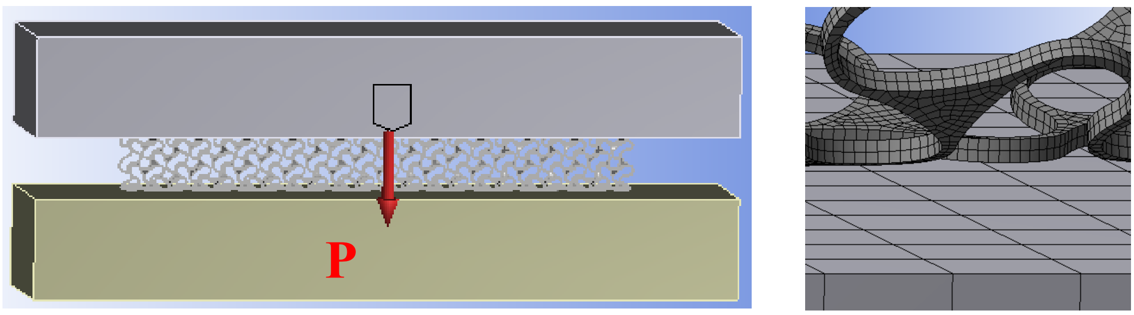



**Figure 3.**Compression of meshed stent model with flat jigs and typical finite element mesh for meshed stent modeling

**Table 1:** Material properties of nickel-titanium, and finite element mesh settings

| | | |
|---|---|---|
| Material properties | Material | Nickel-titanium alloy |
| | Poisson's ratio | 0.3 |
| | Modulus of longitudinal elasticity [GPa] | 75 |
| Finite element mesh setting | Size of elements [mm] | 0.09～0.10 |
| | Number of element in thickness direction | 2～3 |

In this research, compression characteristics of meshed stent models are evaluated by calculation of compressive stiffness. Compressive stiffness can be calculated by equation (1) and represents the supporting ability of the meshed stent to blood vessel. Compressive stiffness $k$ is then calculated by fitting the deformation $\delta$ with compressive load $P$ applied to the meshed stent model as following.

$$k=\frac{P}{\delta} \quad (1)$$

where $k$ : Compressive stiffness [N/mm]
$P$ : Compressive load [N]
$\delta$ : Displacement [mm]

**Compressive stiffness characteristics of meshed stent models using regular triangle, square and hexagon based mesh shapes**

In this section, compressive stiffness of meshed stent models using regular triangle, square and hexagon based mesh shapes are evaluated with fixed $w$ at 0.1 mm and different N and $\theta$. Analyses are carried out to examine the periodicities of meshed stent models due to different basic mesh shapes by rotating the compressive directions round the cylindrical axis from 0° to an angle obtained by dividing 360° by N. Typical compressive stiffness results of different meshed stent models are shown in Figure 4.

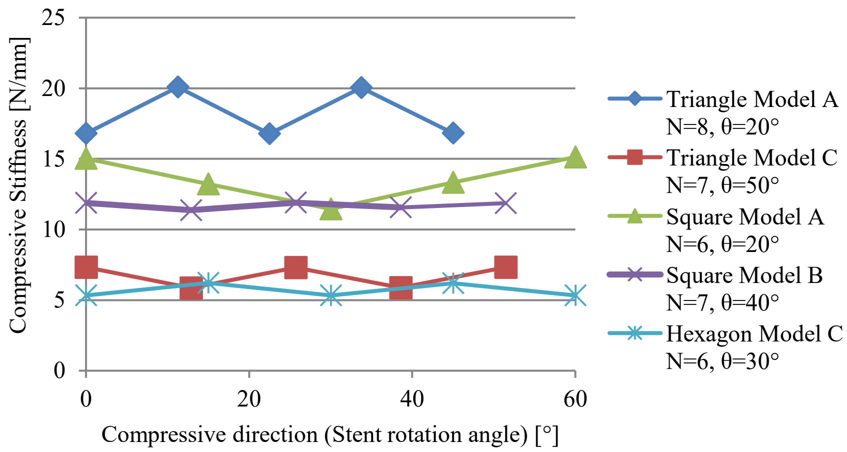



**Figure 4.**Compressive stiffness of meshed stent models with respect to compressive direction

From these results, it can be seen that the compressive stiffness shows periodicity with the change of the compressive direction. It is considered that the major factors for the periodicity are the axisymmetric basic mesh shapes combined with their numbers used for the meshed stent models.

Maximum deviation in compressive stiffness caused by changing the compressive directions for meshed stent models is found as 7.45 N/mm, which is obtained from Square based Model A with N=8 and $\theta$=40° meshed stent model. On the other hand, minimum deviation in compressive stiffness caused by changing the compressive directions for meshed stent models is found as 0.01 N/mm obtained from Square based Model C with N=7 and $\theta$=50° meshed stent model. In the results of this research, it was found that square based models showed most small deviation in compressive stiffness caused by changing the compressive directions, but it was found that the deviation in compressive stiffness is less likely to occur in the hexagon than the triangle and square. For triangle and square based models, there are many models showing deviation more than 3.0 N/mm in compressive stiffness caused by changing the compressive directions, while for hexagon based models showing less than 2.0 N/mm deviations.

In addition, as a tendency of the changes in compressive stiffness of different compressive direction of the meshed stent model, in the case of square based models, it was found that the deviation in compressive stiffness becomes sensitive with the even number of mesh shape N. On the other hand, in the case of triangle based model, the deviation in compressive stiffness was not greatly influenced by the number of mesh shape N. It is conceivable that the arrangement of basic mesh shapes on the side of meshed stent models affects these kinds of tendency.

In the case of square based mesh shapes, when the mesh shape boundary shown in Figure 5 is arranged on the side furthest from the compressive surface lines, the stress caused by compressive force is well dispersed and lead to lower compressive stiffness. On the other hand, when the mesh shape center shown in Figure 5 is arranged on the side furthest from the compressive surface lines, stress concentrations tend to be occurred and lead to higher compressive stiffness. When N is an odd number, the mesh shape center appears on one side furthest from the compression surface lines, and a mesh shape border appears on the other side of meshed stent model. However, when N is an even number, it is clearly distinguished ether the mesh shape center or mesh shape boundary appears on both sides furthest from the compressive surface lines. Therefore, in the case of square based models, when N is an even number, the deviation between highest and lowest value of compressive stiffness caused by changing the compressive directions tends to be large.

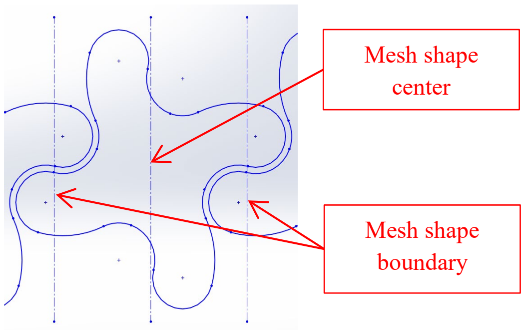



**Figure 5.**"Mesh shape center" and "Mesh shape boundary" in mesh basic shape

From the above discussion, it is necessary to analyze the compressive stiffness of meshed stent models by changing the compressive direction. Then, it is necessary to introduce the average value of compressive stiffness due to the periodicity to evaluate the compression characteristics of meshed stent model. From these results one can see that there is a concern that the blood vessel wall can't be evenly supported using the meshed stent models, and it is necessary to reduce the periodic changes in their compressive stiffness.

**Influence of the angle affecting to arm length $\theta$ on the compressive stiffness of meshed stent models in direction perpendicular to the cylindrical axis**

In this section, effects of the angle affecting arm length to the compressive property of meshed stent models using triangle, square and hexagon based mesh shapes are to be evaluated with basic mesh shape number N setting at 6, 7 and 8, and fixed *w* of 0.1 mm. Analyses are carried out with changing $\theta$ between 0° and 60°. Obtained typical results are shown in Figure 6.

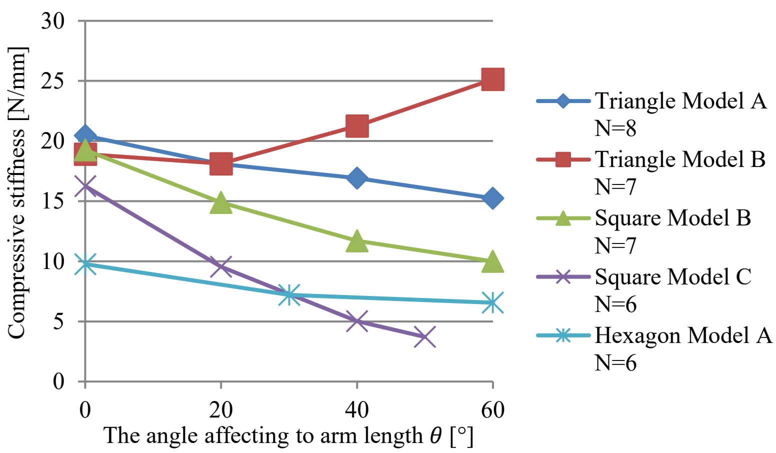
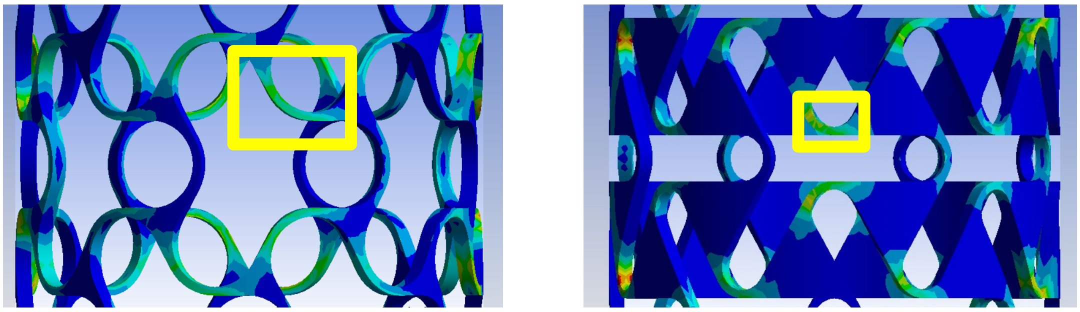



**Figure 6.**Influence of the angle affecting to arm length $\theta$ on the compressive stiffness of meshed stent models

From analytical results, except for triangle Model B, it was found that compressive stiffness is reduced by enlarging $\theta$ of all kind of meshed stent models. In particular, in three kind of Model C, the compressive stiffness can be greatly reduced by increasing the design variable "$\theta$". In the triangle based models, Model C N8 showed the most reduced compressive stiffness with a large deviation of 12.61 N/mm created when the arm angles change from 0 ° to50 °. Even with the square based models, Model C N8 showed the most reduced compressive stiffness with a large deviation of 14.66 N/mm created when the arm angles change from 0° to 50°. On the contrary, the compressive stiffness of Model A is hardly to be reduced, like in triangle based Model A within 2.35 N/mm deviations, and like in square based Model A within 4.19 N/mm when the arm angles change from 0° to 60°. By making $\theta$ larger for Model C than Model A, it is easier to deepen the curvature of the basic mesh shape, and then improve the flexibility of meshed stent model and lead to different responding.

For triangle Model B, as $\theta$ increased, the constant mesh line width portion becomes shorter and then the compressive stiffness of meshed stent model can be considered becoming higher. As shown in Figure 7, in the 20° model, the entire mesh shape is configured with a large constant mesh line width area surrounded in the frame. However, in the 60° model, there are considerably few places where the mesh line width is constant. This is the considered main reason to cause the increase in compressive stiffness of meshed stent model as $\theta$ increased.



$\theta$ = 20° $\theta$ = 60°

**Figure 7.**Equivalent stress diagram accompanying with change in the angle affecting to arm length $\theta$ (Triangle, Model B, N8)

Also in both triangle and square based models, if $\theta$ was the same, the compressive stiffness tended to be smaller in the model with smaller N. On the contrary, with the fixed mesh shape based stent models, the ratio of reduction in compressive stiffness caused by extension of arms is roughly the same regardless of N. For example, in the square based Model C, regardless of N, compressive stiffness decreased by about 40% at 20° model, about 65% at 40° model, about 75% at 60° model compared with 0° model. A similar tendency can also be seen in the ratio of increase for triangle based Model B in which the compressive stiffness increased with $\theta$ increased. Even in the other models, with the fixed mesh shape based stent models, the compressive stiffness decreases almost similarly.

From all the analytical results, it can be seen, as a general trend, the triangle based stent models tend to have lower compressive stiffness than square based models. Furthermore, it can also be found that the compressive stiffness tends to be smaller with the hexagon based models than the triangle based models. The hexagon based stent models have overwhelmingly low compressive stiffness with small value of $\theta$, while with $\theta$ increased, the triangle based or square based Model C would show lower compressive stiffness.

## Evaluation of Compression Characteristics in the Radial Direction of Meshed Stent Models

In this chapter, compression characteristics in the radial direction of meshed stent models are analyzed and evaluated using finite element analysis software ANSYS Workbench. Assuming equally pressure from blood vessel toward to the stent cylindrical center axis is applied on the stent surface, a displacement of 2.0 mm is caused at the surface of the meshed stent model along the pressure direction. Then, from the analyzed reaction force generated on the surface of the meshed stent model, the compressive stiffness of the designed meshed stent model can be calculated. Figure 8 shows the 3D shape of the meshed stent model before/after deformation and the state of finite element mesh for analysis. In addition, the material properties shown in Table 1 are used in analysis, and the setting of finite elements mesh for meshed stent models are shown in Table 2.

In the radial compression analysis, as well as the evaluation of compression analysis in vertical direction to cylindrical axis, compressive stiffness of meshed stent model can be introduced as an evaluation index. Compressive stiffness of meshed stent models by radial compression analysis then can be calculated by equation (2) based on equation (1).

$$k = \frac{P}{\delta} = \frac{Q}{\Delta D} \quad (2)$$

where $k$ : Compressive stiffness [N/mm]
$Q$ : Reaction force generated on the stent surface [N]
$\Delta D$ : Stent diameter deformation amount [mm]

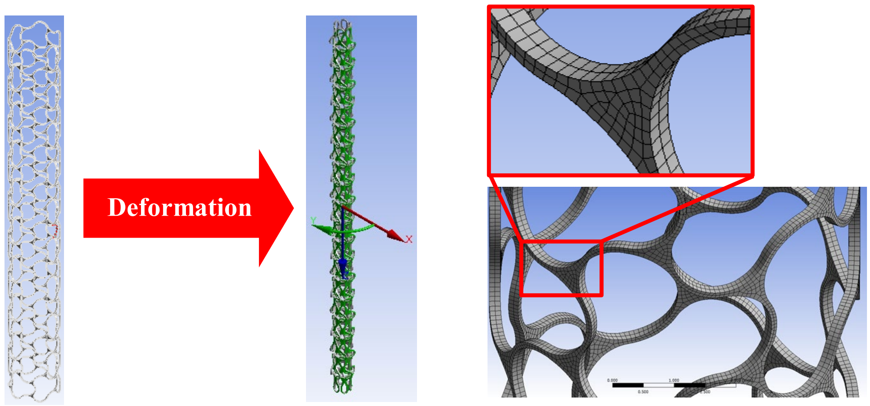



**Figure 8.**Radial compression analysis of meshed stent models with finite element mesh

**Table 2:** Finite element mesh setting for radial compression analysis of meshed stent model

| | |
|---|---|
| Size of elements [mm] | 0.08 |
| Number of element in thickness direction | 2 |

**Influence of the angle affecting to arm length $\theta$ on radial compressive stiffness of meshed stent models**

In this section, the influence of the angle of the arm affecting to arm length "$\theta$" relative to the radial compression characteristics of different meshed stent models with number of mesh shape N at 6, 7, 8, and fixed mesh line width $w$ at 0.1 mm are evaluated. Analyses are carried out with changing $\theta$ from 0° to 60°. Some of typical obtained results are shown in Figure 9.

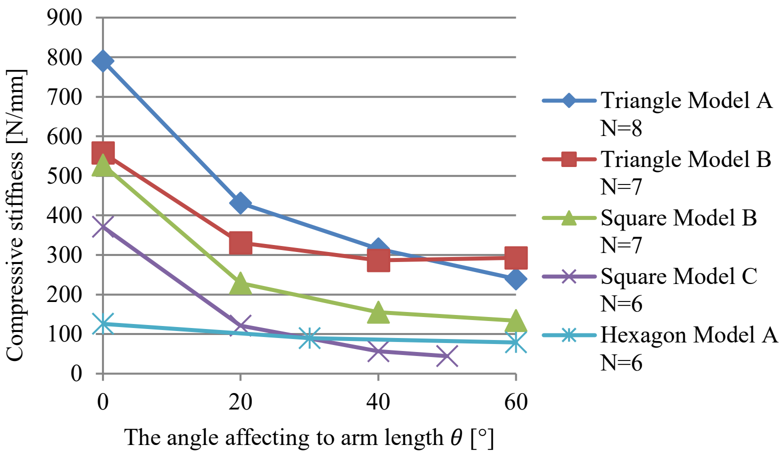



**Figure 9.**Influence of the angle affecting to arm length $\theta$ on the radial compressive stiffness

From the analytical results, it was found that the radial compressive stiffness is reduced by increasing design variable $\theta$ in all meshed stent models. In addition, with same number of mesh shape N, radial compressive stiffness of meshed stent models can be most reduced by increasing $\theta$ of the Model C. In the triangle based models, the decrease in radial compressive stiffness of Model C N8 was the largest of more than 700 N/mm with angle $\theta$ changes from 0° to 50°, which affects the mesh arm length. Even with the square based models, the radial compressive stiffness of Model C N8 decreased largely close to 700 N/mm with same angle changes from 0° to 50°.

Regarding the Model B, it was found that in the case of square based models, the effects of reducing radial compressive stiffness by extending the arm are larger than that of the Model A. While in the case of triangle based models, the reduction effects are reduced. The radial compressive stiffness of triangle and square based Model B at N = 8 and $\theta$ = 50° produced a difference of nearly 200 N/mm. The difference in radial compressive stiffness between triangle and square based other models are shown within 100 N/mm as the largest.

The hexagon based models show smaller radial compressive stiffness than the triangle and triangle based models with smaller "$\theta$", but the effect of reducing the radial compressive stiffness by extending $\theta$ tends to be less. Therefore, when $\theta$ is smaller, the radial compressive stiffness of the hexagon based models may be lower than that of the triangle or square based models.

**Relationship between vertical compression characteristics to cylindrical axis and radial compression characteristics of meshed stent models**

In this section, the relationship between the cylindrical axis vertical compression characteristic and the radial compression characteristic will be examined. Based on the above mentioned analytical results, comparison on square based stent models are shown in Figure 10, in which the horizontal axis shows the vertical compressive stiffness and the vertical axis shows the radial compressive stiffness.

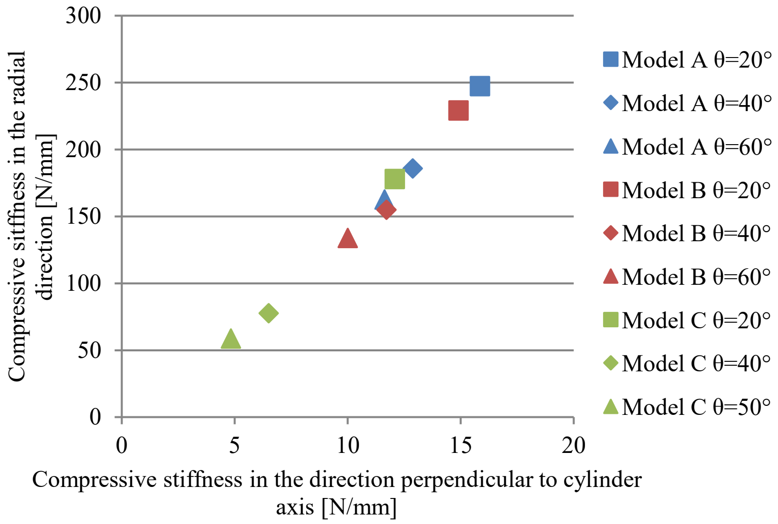



**Figure 10.**Comparison on cylindrical axis vertical compressive stiffness and radial compressive stiffness of square based N8 stent models

From Figure 10 one can see that radial compressive stiffness is higher than that in cylindrical axis vertical direction. In the case of vertical compression to the cylinder axis, meshed stent models are compressed from one direction, whereas in the case of radial compression, meshed stent models are compressed evenly from all directions, and then lead to higher radial compressive stiffness.

In addition, it was found that for both vertical compression to cylindrical axis and radial compression, the compressive stiffness decreases greatly with $\theta$ increased. It means that compression characteristics is very susceptible to the angle affecting to arm length $\theta$ of basic mesh shape. It is most effective way to reduce the compressive stiffness of meshed stent models by increasing design variable $\theta$.

Further, strong correlations between vertical compression to cylindrical axis and radial compression can be found from these results shown in Figure 10, The correlation coefficients for different meshed stent Model A, Model B and Model C were found as 0.99, 0.98 and 0.99. These results shown in Figure 10 are from square based N8 stent models, similar tendencies can be observed for all other meshed stent models including hexagonal based models.

## Conclusion

Based on the design concepts for mesh structures, meshed stent models are designed for SFA treatment stent application. Different design variables such as basic mesh shape type, number of mesh shape N and the angle affecting to arm length on the compression characteristics of meshed stent models are investigated using finite element analysis. From analytical results, the following conclusions are obtained.

(1) Since the compressive stiffness in the direction perpendicular to cylinder axis of meshed stent models vary periodically according to different compressive directions, it is necessary to introduce an average value for the compressive stiffness of meshed stent models.

(2) Combined with basic mesh shape and design variable of the angle affecting to arm length, the length with constant mesh line width might be extremely short even with large value of the angle affecting to arm length, then cause the increased compressive stiffness in the direction perpendicular to cylinder axis.

(3) Strong correlations between vertical compression to cylindrical axis and radial compression are found in the meshed stent models.

(4) Although there are some exceptions, it is possible to reduce the compressive stiffness of meshed stent models by increasing the design variable of the angle affecting to arm length.

(5) Hexagon based stent models have overwhelmingly low compressive stiffness with small angle affecting to arm length $\theta$, but if $\theta$ becomes large, they would have about the same compressive stiffness as triangle or square based stent models.

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