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Nor Amalina Muhayudin

Universiti Malaysia Perlis, 02600, Arau Perlis, Malaysia

Khairul Salleh Basaruddin

Universiti Malaysia Perlis, 02600, Arau Perlis, Malaysia

Fiona McEvoy

Technological University Dublin, fiona.mcevoy@tudublin.ie

See next page for additional authors

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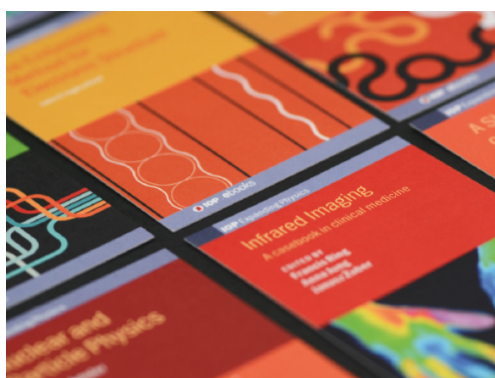
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Design and Development of Artificial Spinal Ligaments for Paediatric Synthetic Spine

Nor Amalina Muhayudin^{1,2*}, Khairul Salleh Basaruddin², Fiona McEvoy³, Anthony Tansey³

¹ School of Manufacturing Engineering, Universiti Malaysia Perlis, 02600, Arau Perlis, Malaysia

² School of Mechatronic Engineering, Universiti Malaysia Perlis, 02600, Arau Perlis, Malaysia

³ Mechanical Engineering Department, Institute of Technology Tallaght, Dublin, D 24, Ireland

*amalmuhayudin85@gmail.com

Abstract. A synthetic spine is a model fabricated from artificial materials consisting of the vertebrae, intervertebral discs and ligaments for spinal testing. The synthetic spine overcomes many difficulties associated with biological specimens such as handling, biohazard concerns, high costs, and limited availability of specimens, quality and large inter-specimen variability. This paper presents the design and development of spinal ligaments to mimic the stiffness of the paediatric ligaments for use in the synthetic spine. Spinal ligaments are uniaxial structures in the spine that carry tensile loads along the direction of the fibres. Early in the research, silicone materials were used to cover the whole spinal unit, but it became apparent that the material responses were inadequate. The synthetic spine was revised to use fibreglass tape to more closely simulate the natural spinal structures. The composite design applied in this paper consisted of soft silicone rubber and fibreglass tape to obtain the natural stiffness that normally occurred in the spinal ligaments.

1. Introduction

Spinal ligaments are naturally designed so that when it was subjected to different forces and moments it will only resist tensile forces along the directions of the fibres. The main functions of the ligaments are to hold the vertebrae together, stabilise the spine and protect the spinal cord including the disc by allowing limited physiologic motion. There are two primary ligament systems in the spine, the intra-segmental and inter-segmental systems. The intra-segmental system attached individual vertebra together, which includes the ligamentum flavum (LF), interspinous (ISL) and intertransverse (TL) ligaments. The inter-segmental system that holds the vertebrae together includes the anterior (ALL) and posterior (PLL) longitudinal ligaments, and the supraspinous (SSL) ligaments. The spinal ligaments are primarily collagenous except for the ligamentum flavum, which is primarily comprised of elastin. Facet capsular ligaments (CL) attach the articular processes of the vertebra and encapsulate the facet joint.

Adams et al. using a stepwise reduction method to characterise the resistance of flexion by posterior ligaments on 27 human cadaveric lumbar spines [1]. The specimens were tested with all ligaments intact, and then each ligament was dissected accordingly, starting with ISL/SSL, followed by LF and finally CL. The study suggested that CL provided about 40% of the joint resistance in full flexion, while others had only a small role to play. Interestingly the intervertebral disc contributed 30% resistance [1]. The findings were in agreement with Gillespie et al. on porcine spine [2]. Heuer et al. investigated the function of anatomical components using eight human lumbar spinal segments under multiple loadings [3]. Similar to Adams et al. and Gillespie et al., the ligaments were intact for the first test and then tested after dissection



of different components [1–3]. The results were in agreement with them where the dissection of posterior ligaments increased flexion movement and ALL contributed the most in resisting extension [1–3].

The main challenge in investigating the effects of individual ligament is to keep the ligaments intact during testing as once one ligament began to detach, it was impossible to reattach it back. Most of the studies to date used Finite Element Analysis (FEA) models as it provided more control of all the ligaments. Among FEA studies were Zander et al. , Lee et al. and Brodin et al., who investigated the effects of individual ligaments on spinal movements [4–6]. Zander et al. conducted nonlinear studies using L3-L4 to investigate the influence of ligament stiffness on rotation and forces in ligaments [4]. They found ALL was completely unloaded during flexion and was the only ligament loaded during extension. This was in agreement with Heuer et al [3,4]. Lee et al. conducted a material sensitivity study on L2-L3 under sagittal plane loading and took into consideration the variation in humans by using probabilistic method [5]. The model was then compared against experimental data with and without posterior elements. The results differed from experiments under high extension loadings when the posterior elements were dissected. They also found the ALL significantly affected the extension spinal movements [5].

Recently, Lapierre et al. in collaboration with Sawbones to develop synthetic spinal ligaments using polyester fibres and a polyurethane matrix for their lumbar analogue model [7]. Based on their preliminary test, all the posterior spinal ligaments including ISL, SSL, and TL were fabricated mainly for aesthetic appeal since these ligaments do not have a large effect on the spinal motions as compared with ALL and PLL.

This paper aims to develop spinal ligaments for paediatric synthetic spine to mimic the movement of the human spine suitable for spinal testing and no interest in clinical purpose. The objectives of this paper are to determine the design and materials for the paediatric spinal ligaments and to replicate the stiffness that normally occurred in human spinal ligaments. Since most of the studies found that ALL significantly affected the spinal movements, this paper focused on developing ALL and PLL individually as an improvement from the authors previous developed synthetic spine [8].

2. Materials and Methods

The difficulties in developing the spinal ligaments lay in finding appropriate materials to mimic the behaviour of the ligaments and attaching the fibres within the material. The materials selected for spinal ligaments consisted of fibre tape and two different types of silicone rubber (MoldMax 40 and SortaClear 40). A pre-made fibre tape was embedded within the silicone materials. The fibreglass tape was used because it is extremely strong and lightweight. Fibreglass is a fibre reinforced polymer made of a plastic matrix reinforced by fine fibres of glass. The weave pattern of the fibre tape was measured based on the 45 degree bias direction of a woven fabrics as shown in Figure 1. The fibre tape provided the stiffness when embedded within the silicone rubber material and controlled the non-linear force displacement properties of the ligaments.

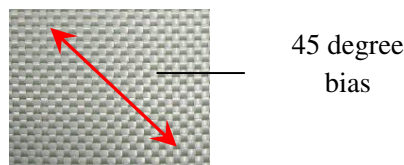


Figure 1. The 45 degree bias direction of the fibre tape

The mould forming the spinal ligaments was designed to embed the fibre into the middle of the silicone rubber (Sorta Clear 40). Two clamping holders were fixed each end to ensure the fibre tape did not deform during the remaining curing process (24 hours at room temperature) as shown in Figure 2. It was essential to ensure that the fibre tape remained within the silicone rubber because the elastic zone (EZ) stiffness of the synthetic ligaments is controlled by the volume fraction of the fibre while the neutral zone (NZ) stiffness is based on the silicone rubber material itself. Tensile tests were performed on all five specimens until failure at 0.0423 mm/sec at a constant rate with 4 N preload based on the experimental set up used by Lapirre et al. on synthetic spinal ligaments for adult lumbar model [7].



Figure 2. The fibre tape was clamped at both ends of the mould.

Synthetic ligaments fabricated in this present study used a combination of two different type of materials; fibre tape and silicone rubber in order to replicate the mechanical properties of human spinal ligaments. The synthetic ligaments can be considered as a composite material; therefore, the rule of mixtures could be applied to predict the synthetic ligament stiffness. In order to apply the rule of mixtures, these assumptions had to be taken into considerations; fibres were uniformly distributed throughout the matrix (silicone rubber), perfect bonding between fibres and matrix, matrix is free of voids, applied loads are either parallel or normal to the fibre direction, no residual stress and fibre and matrix materials behave linearly like elastic materials.

The first step to verify the synthetic ligament was to ensure that the completed synthetic ligament was a mixture of both materials as shown in Figure 3. An Equation 1 was used.

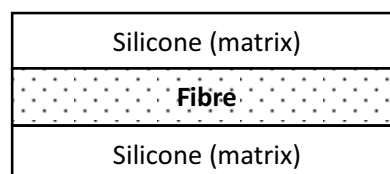


Figure 3. The schematic diagram of synthetic ligament.

$$\rho_c A_c = \rho_f A_f + \rho_m A_m \quad (1)$$

Where A_c , A_f and A_m are composite, fibre and matrix cross-sections and ρ_c , ρ_f and ρ_m are composite, fibre and matrix density. Assuming that the strains of all elements along one direction are equal therefore based on the parallel combination of rule of mixtures; the total density of the composite material is given using Equation 2.

$$\rho_c = \rho_f V_f + \rho_m V_m \text{ with parallel combination, } \rho_c = \rho_f V_f + \rho_m (1 - V_f) \quad (2)$$

The percentage difference of the expected and the achieved composite material was only 0.1%, thus suggesting that the composite material fabricated in this present study followed the static equilibrium principle. The next step was to predict the upper and lower limit of the elastic modulus of the synthetic ligaments. The general rule of mixtures used to predict various properties of composite materials made up of continuous and unidirectional fibres. In this present study, the upper limit of the modulus corresponded to the loading parallel to fibres could be simplified as Equation 3. The lower limit of the modulus corresponded with the transverse loading and was simplified in Equation 4.

$$E_u = E_f V_f + E_m V_m \quad (3)$$

$$E_L = \frac{E_f E_m}{E_f V_m + E_m V_f} \quad (4)$$

Where E_f and E_m were the elastic modulus of fibre and matrix and V_f and V_m were the volume of fibre and matrix.

3. Results and Discussion

The elastic modulus of the fibre tape was measured from stress-strain curves from the tensile tests of five specimens, (Refer to Figure 4). The results for fibre tape were consistent for all five specimens with an average elastic modulus of 1.87 GPa. The elastic modulus was calculated at the slope of linear region.

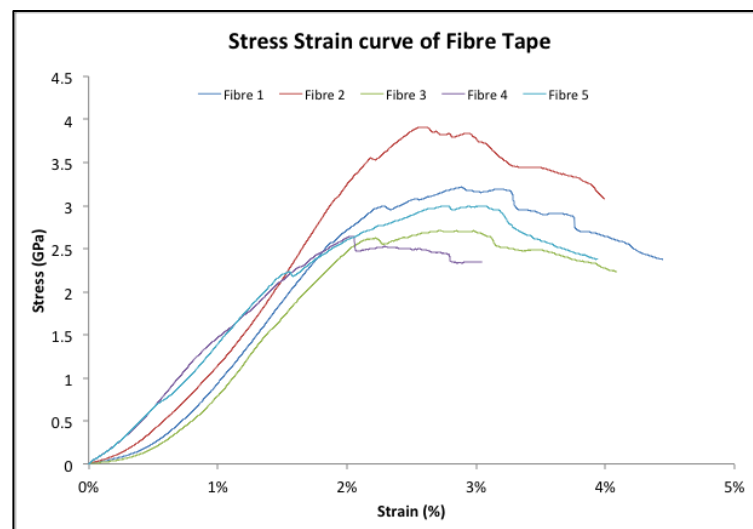


Figure 4. Stress strain curve of fibre tape.

The elastic modulus of the Sorta Clear 40 (matrix) used in this present study was calculated from Mechanical Data Sheet (MDS) which approximately around 0.62 MPa. Based on these two moduli, the lower and upper limit moduli for the synthetic ligaments could be predicted. By using Equation 3 and 4, the upper limit (E_u) the lower limit (E_L) of the synthetic ligament were 112.78 MPa and 0.66 MPa. Two variables were measured to compare with human spinal ligaments they were the NZ stiffness and EZ stiffness. Figure 5 showed the typical load displacement curve obtained from synthetic ligament.

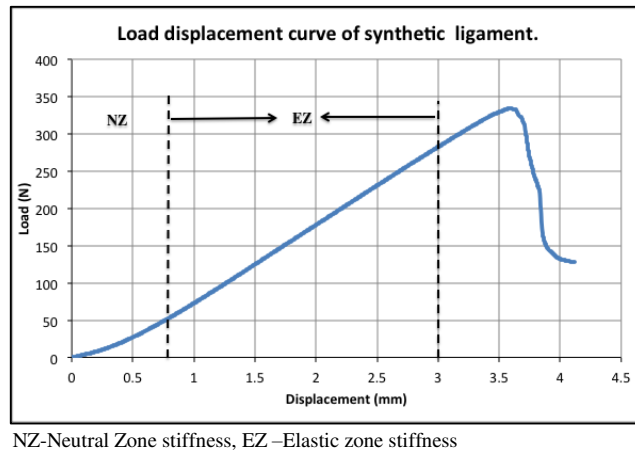


Figure 5. Typical load displacement curve of synthetic spinal ligament.

The average measured NZ was 37.8 N/mm and the EZ stiffness was 109.6 MPa. A comparison between the findings of present study and literatures are summarised in Table 1 [9–12]. The synthetic ligament in this present study has been simplified to one composite material for both ALL and PLL. The synthetic ligament was dissected to two parts to represent ALL (2/3) and PLL (1/3) and since it followed the static equilibrium principle, both parts carried similar mechanical loads. As presented in Table 1, the stiffness for both ALL and PLL of human adult spinal ligament had a large range of data. Since no data was found for paediatric spinal ligaments, the NZ stiffness and EZ stiffness of synthetic ligament measured in this study were compared with adult data and were within the ranges provided. The paediatric spinal ligament was expected to follow the pattern of intervertebral disc where the stiffness of paediatric ligament was lower than adult ligaments because both are soft tissues. The value of both stiffness were closer to the lower limit of the adult ligaments provided by literature, it was assumed that the synthetic ligament had more flexibility compared to adult ligament [9-12]. The average elastic modulus measured for synthetic ligament was approximately 22.5 MPa, which was within the upper and lower limit of the modulus calculated using rule of mixture. Based on the above argument, the synthetic ligament fabricated in the present study was used as spinal ligaments in the synthetic paediatric spine.

Table 1. Comparison of NZ and EZ stiffness of ALL and PLL between the present study and literature [9-12]

Ligament	NZ stiffness (N/mm)	EZ stiffness (N/mm)
ALL	19.64 - 78.64 (literature)	17.3-632.36 (literature)
	37.8 (present study)	109.6 (present study)
PLL	9.52 - 296.57 (literature)	8.5-573.33 (literature)
	37.8 (present study)	109.6 (present study)

4. Conclusion

The objective of this paper is to design synthetic spinal ligaments to replicate the stiffness in paediatric synthetic spine. This study focused only on ALL and PLL since the rest of spinal ligaments do not have an

essential effect to the spinal movements. The design of synthetic spinal ligaments presented in this paper was simplified for ease of fabrication. Since there is no experimental data of paediatric spinal ligaments and range of motion to date, the results then were compared with experimental and FEA spinal ligaments of adult data. The results indicated that the stiffness of fabricated synthetic spinal ligaments in this study was closer to the lower limit of the adult range and it was assumed that it may provide more flexibility. Future works is to determine if the synthetic spinal ligament provided the expected movement on the spinal unit by testing the range of motion of the paediatric synthetic spine using MTS Bionix ServoHydraulic spine simulator.

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