

Design and Development of an Artificial Intervertebral Disc for Paediatric Synthetic Spine

^{1,3}Nor Amalina Muhayudin, ¹Fiona McEvoy, ¹Anthony Tansey, ¹Yanyi Blake, ²Pat Kiely

¹Mechanical Engineering Department, Institute of Technology Tallaght, Dublin, Dublin 24, Ireland

²Our Lady's Children's Hospital, Crumlin, Dublin12, Ireland

³School of Manufacturing Engineering, University Malaysia Perlis, 02600, Perlis, Malaysia

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 an Artificial Intervertebral Disc (AID) to mimic the behaviour of the paediatric intervertebral disc for use in synthetic spine. The natural intervertebral disc consists of soft nucleus pulposus surrounded by annulus fibrosis and cartilaginous end plate at the top and bottom of the disc. Its main function is to transmit and attenuate compression, torsional, bending load from one vertebral body to the next and to stabilise the intervertebral joints. Early in the research, silicone materials were used to model a simple component disc, but it became apparent that the material responses were inadequate. The synthetic spine was revised to use different materials for each component in the intervertebral disc and thus to more closely simulate the natural disc structures. The composite design applied consisted of soft silicone rubber for the nucleus and more rigid polymer for both the annulus and endplates.

Key words: paediatric spine, artificial intervertebral disc (AID), silicone rubber and synthetic spine

INTRODUCTION

A healthy intervertebral disc comprises of three distinctive components; the nucleus pulposus, the annulus fibrosis and the cartilaginous end plates. The nucleus pulposus is located at the central of the disc and is comprised of collagen fibres embedded in granular gel contained 70-90% water. The annulus fibrosis encloses the nucleus pulposus formed from fibrous tissue in concentric laminated bands [White and Panjabi, 1990]. Hyaline cartilage that separates the two components of the disc from vertebral end plate is called cartilaginous end plate.

The disc is an anisotropic structure, which means the disc allows both elasticity and stiffness. The disc acts as shock absorbers for the spine helping maintain its flexibility. Its main function is to transmit complex compressive, torsional and bending loads from one vertebral to another. Although, the intervertebral disc is subjected to a variety of forces and moments the most prevalent force is compression. According to the study conducted by Yang and King [1984], the intervertebral disc carried approximately 75 to 97 % compressive load in daily activities while the posterior elements of the vertebra carried 3 to 25% of the load, which they referred it as 'facet force'. Stemper *et al* [2010] studied the stiffness and modulus of human thoracic disc segments for both male and female from 17 to 77 years old. They found that, the mechanical response of the spinous decreased with age. The intervertebral disc varied in height and area between the spinal region, age and gender. According to Clark *et al* [2001], a child intervertebral disc is more hydrophilic than adult therefore more flexible.

However, the disc can become damaged or herniated due to trauma or disease. The worst case, surgery may be necessary to replace the disc with an Artificial Intervertebral Disc (AID). Early research in the development of AID replacement began in 1960s (Refer Table 1). The purpose and advantage of AID replacement is to replace the worn out disc, while preserving the motion at the operated spinal level (Refer Table 2).

Since the author's research focuses on scoliosis in children, paediatric synthetic spine will be developed. The difficulties with developing the synthetic spine are that it needs to match the behaviour of a biological spine. However, if a working synthetic spine could be validated, it overcomes many difficulties associated with biological specimens such as handling and biohazard concerns, high cost, limited availability of specimens, and large inter-specimen variability.

This paper aims to develop an AID for paediatric spine to mimic the movement of the human spine suitable for spinal testing and no interest in clinical purpose. The objectives of this study are to determine the best design and materials for the AID and to compare the compressive stiffness and elastic modulus of the AID with literature on human disc.

Table 1: Series of artificial intervertebral disc research [Vuono *et al.*, 1995].

Author	Date	Design
Patil	1982	Springs with metal cups
Edeland	1980-1989	Multiple designs used silicone with and without metal
Main <i>et al</i>	1987	Silicone between metal
Ray and Corbin	1988-1990	Two fillable woven capsule and drug releasing
Steffe	1988	Rubber between metal
Buttner-Janzen <i>et al</i>	1988	Polyethylene between metal
Kostuik <i>et al</i>	1988	Hinged plates with springs
Downey	1989	Elastomer between metal
Lee <i>et al</i>	1989	Fiber reinforced cushion concept
Parsons <i>et al</i> [1992]	1991	Multi-durometer elastomer
Ordway <i>et al</i>	1994	Hydrogel intervertebral disc
Vuon-Hawkins <i>et al</i> [1995]	1995	Multi-durometer composite design
Kotani <i>et al</i> [2002]	2001	Bioactive Three-Dimensional Fabric

Table 2: Artificial intervertebral disc currently available for surgery [Bartel *et al.*, 2008].

Type	Manufacturer	Design
Charite	DePuy Spine [2006]	Two metal endplates at the top and bottom surfaces and a ultra-high molecular polyethylene core in between
ProDisc	Synthes Spine Solutions [Synthes, 2006]	Ball and socket implant consisting of two metal endplates and one plastic inlay
Bryan	Medtronic Sofamor Danek [Medtronic, 2006a]	Titanium and polyurethane device
Prestige	Medtronic Sofamor Danek [Medtronic, 2006b]	Two-piece metal device

MATERIALS AND METHODS

This study started with a simple component disc using silicone rubber but it became apparent that the material responses were not acceptable. The synthetic spine was revised to use different materials for each component in the intervertebral disc and thus to more closely simulate the natural disc structures.

The design for AID was made to compliment the shape of the paediatric vertebra using Creo Parametric 1.0. The outer shape of the disc was designed based on the contours of the vertebra and the shape of the nucleus pulposus was an offset from the contour shape (Refer Figure 1). The end plates with fixed 2 mm height were added at the top and bottom of the disc. The overall height of the AID was 6 mm height with 40% volume of annulus fibrosus this was made based on author’s previous study, which will be discussed further in the discussion.

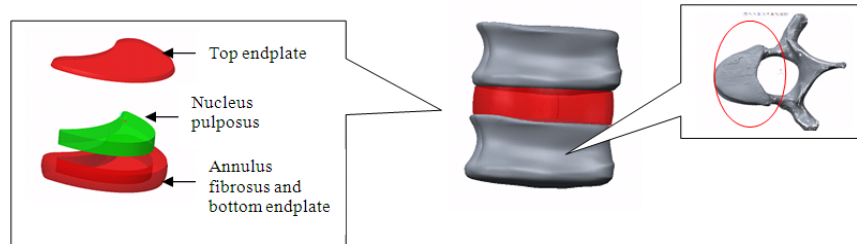


Fig. 1: Design and exploded view of the complete AID.

The materials used for the AID consisted of two types; a single component elastomer called monothane [Jacobson Chemical, 2013] with A-70 hardness and silicone. Monothane being the stiffest material was used to replace both annulus fibrosis and endplates for easy manufacturing. Standard compression and tensile were conducted on monothane to confirm the moulding process and mechanical properties. (Refer Table 3) Since the structure of human nucleus pulposus is gel-like, ranges of silicone with different hardness number were tested. Two different types of silicone rubber with A40 hardness were used (Mold Max and Sorta Clear) and another two silicones (Platsil 00 and lightweight silicone) obtained from a local company, TruLife [Trulife Ireland, 2013] (Refer Table 4).

Table 3: Comparison data between current testing and technical data from supplier of monothane with human data.

Description	Compressive modulus (MPa)	Tensile modulus (MPa)
Human (28-35 years old) [Stemper <i>et al.</i> , 2010]	19.5 ± 4.1	2.9 ± 0.8
Technical data (supplier) [Jacobson Chemical, 2013]	14.91	2.91
Current testing (average)	14.1	3.3

Table 4: Compression Moduli and hardness values for the type of silicone used as nucleus pulposus.

Type of silicone	Compression Modulus (MPa)	Hardness
Mold Max	7.5	A40
Sorta Clear	3.2	A40
Platsil 00	11.4	0030
Lightweight silicone	1.6	N/A

The AID mould was designed with an ‘island’ in the middle which followed the shape of nucleus pulposus and it was constructed in Selective Laser Sintering machine to get an accurate shape. The AID was manufactured in three steps. First step was to mould annulus fibrosis and bottom endplate using monothane in the oven at 135°C for 6-7 hours. Then, the silicone was moulded inside the ‘island’ for nucleus pulposus. The final step was to add the 2 mm top endplate to the moulded part using flexible adhesives from Loctite.

Experimental Set Up:

The components were tested in axial compression on mechanical testing device (Instron’s model 3345, Norwood, MA, USA). The experiment was carried out under load control to 800 N at a rate of 3.3 N/s based on Vuono-Hawkins *et al* [1995] who tested using the same type of materials as this study.

RESULTS AND DISCUSSION

The results were presented in Force-Displacement and Stress-Strain curves. The stiffness was computed from the slope at linear region of the force displacement curve and the modulus was calculated from stress strain curves. (Refer Figure 2 and Table 5). In previous studies, three factors were considered to find the best combination in developing the paediatric disc. These were the disc height of 6 and 8 mm (A), 40% and 50% volume of annulus fibrosus (B) and type of silicone rubber (mold max and sorta clear) for nucleus pulposus (C). Two values were considered for each factor as the low and high setting to design the experiments. Total samples of 24 were tested and the results were analysed using MiniTab 11. By taking significance p-values at values less or equal to 0.01, all factors and two-way interaction (AC and BC factors) showed significant effects. AB and ABC interactions have no or less effect on the results. Although all factors influenced the results, the largest main effect was disc height (Refer Table 6). Biologically, children have shorter height and smaller annulus percentage compared to adult, which was in agreement with the best combinations of factors. The closest combinations with published data were shorter height (6mm), smaller annulus fibrosus volume (40 %) and higher modulus of silicone (7.5 MPa). (Refer Table 7) Since the published data were varied in age, no direct comparison can be made. However, the modulus of this study was within the modulus range of young adult (28± 8 years old). The key element in this study is to design a flexible paediatric AID. Therefore, in this study, the author considered replacing the nucleus pulposus with different types of silicone obtained from TruLife by using the same combination of height (6 mm) and percentage of annulus fibrosus volume (40 %) to find a lower modulus than young adult (28± 8 years old) in order to obtain the flexibility movement required in the synthetic spine.

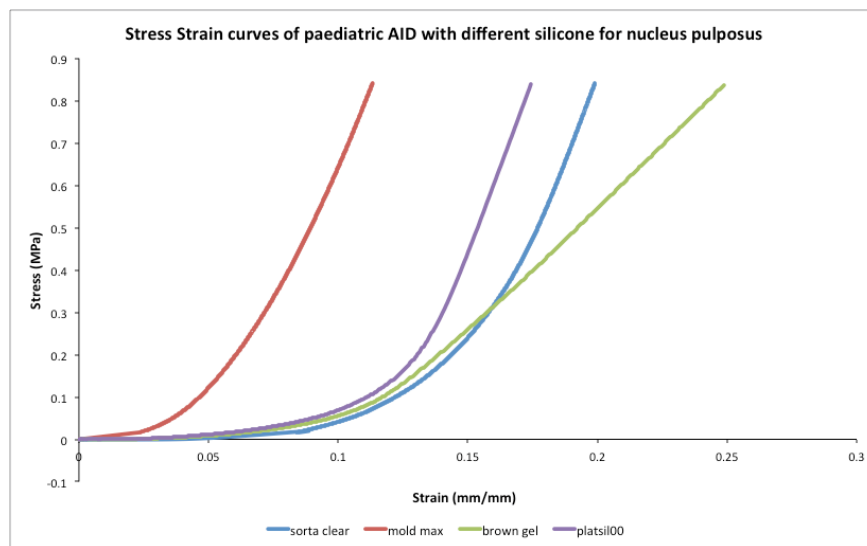


Fig. 1: Stress Strain curves of paediatric artificial intervertebral disc with different silicone as nucleus pulposus.

Table 5: Compression Moduli, Stiffness and Strain values for paediatric AID with different silicones as nucleus pulposus.

Materials	AID Compression Modulus (MPa)	AID Compression Stiffness (N/mm)	AID Compression Strain in between 0.4 to 0.7 MPa stress value (%)
Mold Max	15.63	2016	2.44
Sorta Clear	12.97	1989	2.28
Platsil 00	28.48	2519	1.18
Lightweight silicone	7.1	933	2.28

Table 6: Main Effects and P values of individual and interaction factors.

Factors	Effect	P values
B	1.800	0.000
A	-2.367	0.000
C	-1.267	0.000
A*B	0.000	1.000
B*C	-0.600	0.000
A*C	0.533	0.000
A*B*C	0.267	0.020

Table 7: Comparison data of compression modulus and stiffness of current study with AID and human thoracic disc from literature.

Description	Average Compression modulus (MPa)	Average Compression stiffness (N/mm)
Human [Stemper <i>et al.</i> , 2010]		
28± 8 yrs old	19.5	3300
70± 7 yrs old	10.6	2527
AID [Vuono <i>et al.</i> , 1995]		
Homogenous A70	15.78	1697
57 % Annulus Fibrosus	20.81	1923
Current study		
Mold Max	15.63	2016
Sorta Clear	12.97	1989
Platsil 00	28.48	2519
Lightweight Silicone	7.1	933

From Table 7, an AID with Mold Max as nucleus pulposus was the best comparison if compared with young adult (28± 8 years old) with 20 % differences while, in comparison with older people (70± 7 years old), an AID with Sorta Clear nucleus has the smallest differences. However, this data did not represent data for children. The only children literature found as guidance for thoracic range of motion of children specimen was a comparison of immature and mature sheep spines by Clarke *et al.* [2007]. According to Clarke *et al.* [2007], in immature spines all segments (cervical, thoracic and lumbar) demonstrated a significantly larger range of motion and lower stiffness in comparison to mature spines. Lopez-Valdes *et al.* [2011] used paediatric cadaveric thoracic spine of 7 years olds as specimens to observe the dynamic response between children and adult thoracic spines. The study found that paediatric specimens failed at approximately 11.9 Nm but range of failures of adult specimens was very wide ranging from 23.3 Nm up to 53 Nm. Both of these studies were agreement that paediatric spines were less stiff when compared to adult spines, which indicates a lower modulus when compared to adult. In this case, the lowest modulus is the lightweight silicone AID.

The important element in developing paediatric AID is that the AID will be sufficiently flexible to allow movement in the synthetic spine to mimic children flexibility. Although there appears to be no experimental data of children’s range of motions, recently a finite element model was developed directly from a child’s scan. Jebaseelan *et al.* [2010] developed a complete lumbar section of 8 years old child spine. The study provided range of motion data of children and adult models under the same loading condition. Based on each spinal functional unit of the lumbar section, the average ratio of adult to child’s range of motion under 0.5 Nm loading condition was approximately around 2.2. Although this data was for a child’s lumbar spine, the same results were expected for the thoracic spine. If taking into consideration the ratio of adult to children data, the closest to the ratio of 2.2 were sorta clear and lightweight silicone AID, however since the child was less stiff compared to the adult, lightweight silicone is the most suitable option as the children AID for the synthetic spine. (Refer Table 8).

Table 8: Ratio of human disc young adult to the AID of the current study.

Human Disc [4] (MPa)	Materials	Current Study (MPa)	Ratio
19.5	Mold Max	15.63	1.3
	Sorta Clear	12.97	1.5
	Platsil 00	28.48	0.7
	Lightweight Silicone	7.1	2.7

Conclusion:

The objective of this paper is to design an AID to replicate in paediatric synthetic spine. The essential element is that it can follow the movement of the child spine. The design was simplified for ease of fabrication

and this paper presents four different types of nucleus pulposus with ranges of different hardness. As there is no experimental data of children range of motion to date, the results were compared with a range of motion of children found using finite element model [Jebaseelan *et al*, 2010]. The best selection was the AID with lightweight silicone as the nucleus pulposus as it gave the lowest stiffness value and the ratio of adult to children modulus was the closest with the ratio of adult to children range of motion from the literature. Future works is to determine the range of motion of each functional spinal unit of the paediatric synthetic thoracic spine using MTS Bionix ServoHydraulic spine simulator.

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