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Novel Silicone Rubber and Polyvinyl Alcohol (PVA) Compound as Nucleus Pulposus Replacement in Intervertebral Disc Herniation Surgery

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ABSTRACT

AIM: To identify a novel material with biomechanical properties identical to the nucleus pulposus in the lumbar vertebrae of goats for use in intervertebral disc herniation surgery.

MATERIAL and METHODS: In this laboratory-based experimental study, the silicone rubber material test group consisted of sample compositions 35PVA65SR, 30PVA70SR, and 40PVA60SR. Axial compression mechanical tests were conducted to assess the biomechanical properties of the resulting material in terms of stress, strain, load, and displacement.

RESULTS: The mechanical compression test results revealed that the stress (MPa) and strain (%) values of the 40PVA60SR material were closest to the control group (p=1.00) with a load of 684 N in each group. The value of material displacement (mm) for 40PVA60SR was also the closest to control (p=1.00) with a loading of 684 N.

CONCLUSION: The new material presents biomechanical properties closest to human nucleus pulposus and is promising in nucleus pulposus replacement therapy. Further clinical research is needed to evaluate other biomechanical properties and the bioavailability of the novel material.

KEYWORDS: Intervertebral disc herniation, Silicone rubber, polyvinyl alcohol (PVA), Compression test, Biomechanics

INTRODUCTION

The most common source of radicular pain and among the most common reasons for spine surgery is intervertebral disc herniation (IDH) (1,9). The two main structures in the intervertebral disc are the annulus fibrosus (AF) and nucleus pulposus (NP) (3,10). In IDH, the NP is displaced outside the intervertebral disc space. Water, type II collagen, chondrocyte-like cells, and proteoglycans make up the NP. This special composite enables the NP to be elastic, flexible under stress forces, and compressible. The AF is made up of concentric layers of collagen type I fibers that form a fibrous tissue with a helical arrangement that surrounds the NP. Sharpey fibers connect this structure to the vertebral body, which is denser in its anterior region (6,22).

Disk herniation and disk degeneration are terms that are often used interchangeably, with IDH being a possible progression from disk degeneration. Proteoglycan loss is commonly associated with disk degeneration (9,26). Genetic, mechanical, and behavioral factors all play a role in the degenerative process. The intervertebral disc (IVD) is a flexible structure that transmits loads through the spine (19,20). Mechanical load contributes to the maintenance of a healthy IVD by sending

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signals to cells that regulate proper matrix homeostasis (19,20) Long-term exposure to hyperloading, on the other hand, is associated with the induction of disk degeneration. IDH occurs through degenerative changes in the annulus, which include desiccation, fissures, disk narrowing, mucinous degeneration, intradiscal gas (vacuum), osteophytes, inflammatory changes, and subchondral sclerosis (22,24). Annulus fissures are prone to weakness, allowing disk material to bulge or migrate outside the annulus margins.

Over the last few years, the surgical management of degenerative disk disease has shifted toward minimizing soft tissue dissection and preserving the spinal motion segment (4,7). A possible alternative to spinal fusion procedures is NP intradiscal or artificial disk replacement. The primary purpose of NP intradiscal replacement is to reconstruct the NP while maintaining the biomechanics of the AF and cartilaginous endplate. NP implants are intended to provide stable motion, increase disc space height, relieve or reduce shear force transmission on the remaining anulus (restoring natural length), and stabilize spinal ligamentous structures (2,3,17,19). The ideal NP implant must possess the same biomechanical properties and bioavailability as human NP. The materials that can be used for artificial disc replacement is a composite of silicone rubber and polyvinyl alcohol (PVA) materials, which have unique material characteristics.

Silicone rubber combines the properties of both inorganic and organic materials and provides many benefits not found in other organic rubbers (15,25). Compared with organic rubber, silicone rubber has higher heat resistance, ozone resistance, weather resistance, chemical stability, and electrical insulation and a lower surface tension. As an elastomer, silicone rubber exhibits high tension and strain (13,14), thus possibly exhibiting the ideal mechanical properties for NP replacement. This study aimed to assess the compressive strength of three silicone rubber mixtures as a substitute for NP in a goat lumbar vertebral model.

MATERIAL and METHODS

Preparation of Silicone Rubber and PVA Material

PVA crosslinked with glutaraldehyde (GA) is obtained by mixing 20% wt PVA in distilled water. This solution is added with H_2SO_4 (aq) solution at as much as 10% wt to initiate crosslinking between PVA and GA. Room-temperature-vulcanizing (RTV) silicone rubber, RTV 585, was prepared with a variety of 5% catalysts. Silicone rubber RTV 585 was mixed with PVA-GA in three compositions: 35PVA65SR (35% PVA and 65% silicone rubber), 30PVA70SR (30% PVA and 70% silicone rubber), and 40PVA60SR (40% PVA and 60% silicone rubber).

Preparation of Goat Lumbar Vertebrae Goat Specimens

This study used the lumbar vertebral body of an adult local goat (*Capra aegagrus*) aged 1.5 to 2 years old and weighing 20–23 kg. The goat lumbar vertebrae used in this study were from lumbar vertebrae 1 to 6. The lumbar spine specimens were intervertebral discs accompanied by superior and inferior vertebral bodies. The muscles and their posterior components were removed. Anterior column units (ACUs) were taken from 12 vertebral lumbar from L1 to L6 on visual inspection. Those with obvious damage or degeneration were excluded. Parallel cuts were made perpendicular to the longitudinal axis of the ACU through the superior and inferior vertebral bodies to ensure that the axial compression load was aligned. Standard digital calipers were used to measure the anatomical dimensions (disk height, superior and inferior vertebral body heights, and disk major and minor diameters) of the lumbar specimens. Each intervention or control group consisted of three ACU vertebral lumbar specimens.

Compression Testing Protocols

The mechanical behavior of the materials was analyzed in compression mode. This study used an Instron mechanical testing machine (Figure 1) (3,5,11). Compression tests were conducted according to the ASTM D395 testing standard. The upper compression plate and lower actuator's initial baseline positions were confirmed and maintained throughout each test condition. Specimens were axially compressed to the maximal load of the machine. This machine had a maximal load of 1,000 N.

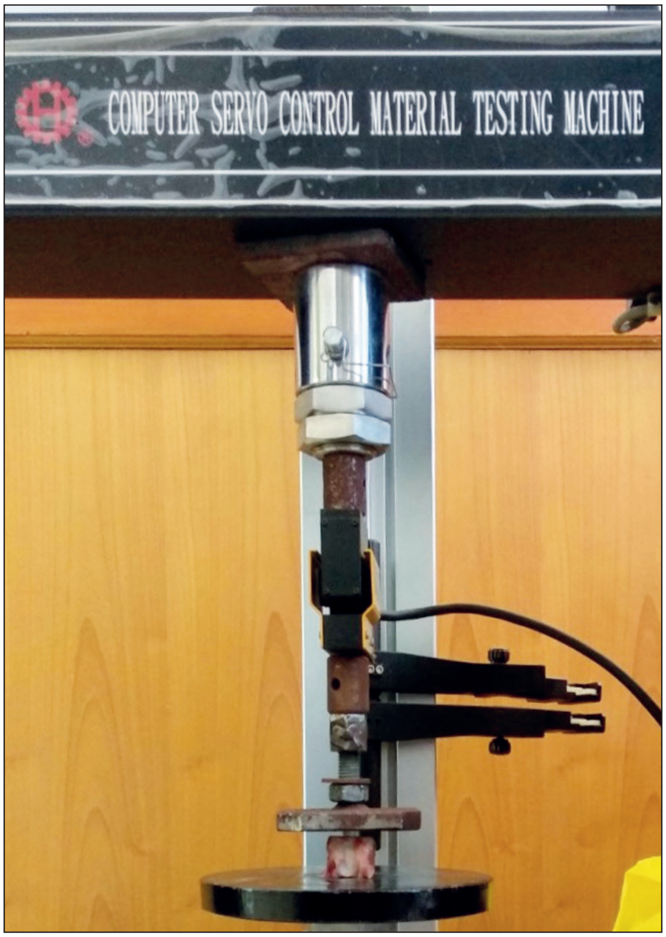

Figure 1: Mechanical testing machine that used in the compression test of the lumbar vertebrae body.

Protocol for Intervertebral Disc Implantation and Testing

Each specimen underwent a series of specimen preparation procedures prior to the axial compressive tests, as shown in Figure 2A-D. First, the intact specimen was drilled through the bone to the IVD with an 8-mm Cloward core drill bit perpendicular to the surface of the superior vertebral body. A cylindrical bone plug was removed from above the disk. Standard surgical instruments were used to remove the central portion of the nucleus in line with the core drill (equal to 8 mm diameter), leaving the residual nucleus and annulus intact. The liquid silicone rubber mixture was then added into the cavity. After the implanted silicone rubber mixture solidified, the bone plug was reinserted into its original hole, and the compression testing protocol was performed (Figure 3).

Statistical Analysis

The load displacement and stress–strain data for each test condition were collected. Multiple group comparisons were performed using one-way analysis of variance (ANOVA) after determining significant intergroup differences by ANOVA. Differences with $p<0.05$ were considered significant, whereas $p=1.00$ indicated the same value as the control groups.

RESULTS

Stress and Strain

Stress and strain values were measured in every group and compared with those of the control group. The mechanical characteristics of the silicone rubber and PVA material were assessed from the stress and strain of the material after being loaded onto a compression test machine. Figure 4 shows representative stress (MPa) and strain (%) graphs for an intervention group and the control group. The stress value is the resistance of the material to the applied force or load (21,23). Strain is defined as the change in shape or size of a material as a result of compressive force on the material (16,18). The stress and strain graphs show the relationship between the stress and strain in every group after applying a load to the material. These graphs showed that the values obtained for the 40PVA60SR group were closest to those of the control group.

The stress and strain values for all groups were compared with the point of loading of 684 N, which is the maximal value for a goat lumbar vertebra when walking (8). The mean stress and strain values for each group were 2.43 ± 0.47 MPa and 12.02% ± 2.78% for the 30PVA70SR group; 1.65 ± 0.75

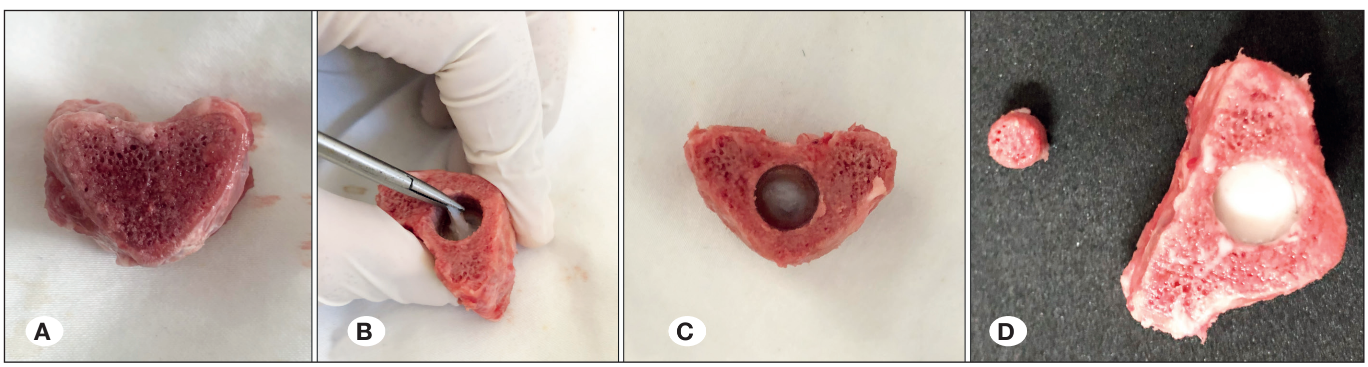

Figure 2: Specimen preparation of the lumbar vertebral body and intervertebral disc. **A)** Anterior column unit (ACU) of the lumbar vertebral body. **B)** Taking the nucleus pulposus. **C)** ACU without nucleus pulposus. **D)** ACU filled with the silicone rubber and PVA material.

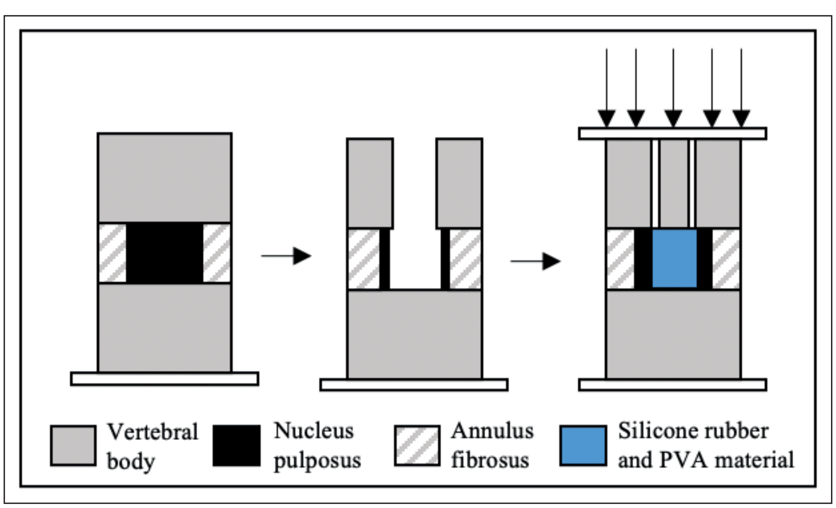

Figure 3: Compressive mechanical testing procedure.

MPa and 11.57% ± 0.45% for the 35PVA65SR group; 2.76 ± 0.34 MPa and 5.74% ± 1.45% for the 40PVA60SR group; and 3.54 ± 1.02 MPa and 3.96% ± 1.93% for the control group. The statistical analysis showed that the stress and strain measurements for 35PVA65SR and 30PVA70SR varied significantly ($p<0.05$) with the control group, whereas those for 40PVA60SR were the closest to the control group ($p=1.00$) (Table I, II).

Load and Displacement

The load and displacement values were compared between the intervention and control groups with the loading 684 N (8). The mean displacement values were 6.01 ± 1.39 mm for the 30PVA70SR group; 5.75 ± 0.27 mm for the 35PVA65SR group; 2.86 ± 0.72 mm for the 40PVA60SR group; and 1.98 ± 0.96 mm for the control group (Figure 5). The statistical analysis showed that the load displacement measurements for 35PVA65SR and 30PVA70SR differed significantly different ($p<0.05$) with the control group, whereas those for 40PVA60SR were the closest to the control group ($p=1.00$) (Table III).

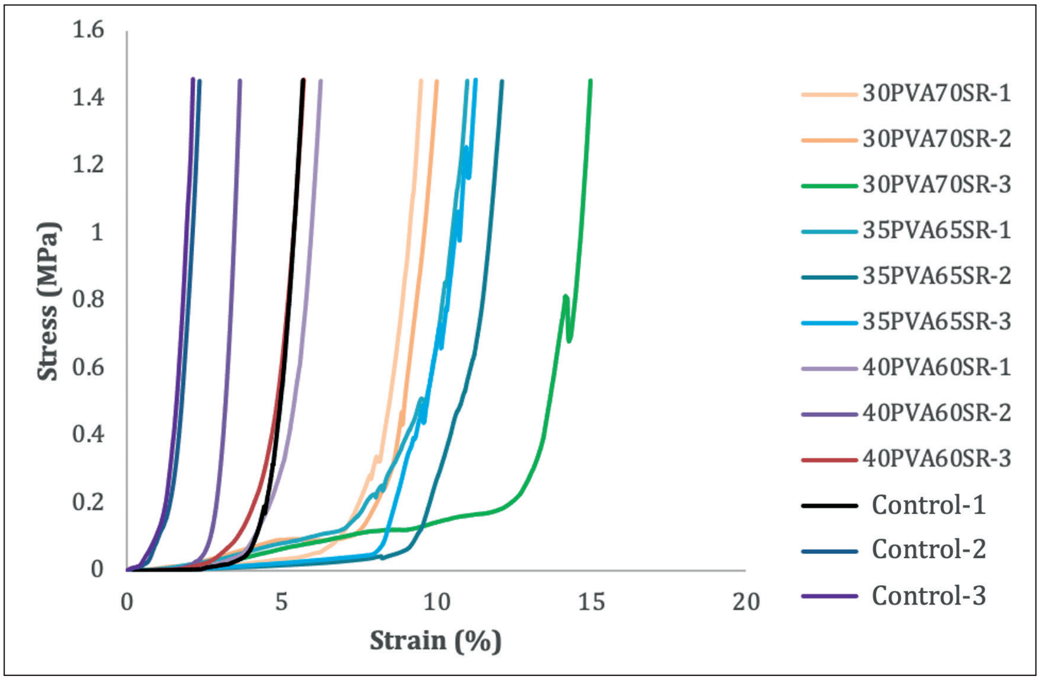

Figure 4: Stress (MPa) and strain (%) graph of the silicone rubber and PVA material group and control.

Table I: Comparison of the Strain (%) in the Silicone RTV 585 and PVA Material Group with Control

(I) Specimen	(J) Specimen	Mean Difference (I-J)	Std. Error	Sig.
Control	35PVA65SR	-7.61*	1.51	0.006
	30PVA70SR	-8.06*	1.51	0.004
	40PVA60SR	-1.78	1.51	1.000
35PVA65SR	Control	7.61*	1.51	0.006
	30PVA70SR	-0.45	1.51	1.000
	40PVA60SR	5.83*	1.51	0.30
30PVA70SR	Control	8.06*	1.51	0.004
	35PVA65SR	0.45	1.51	1.000
	40PVA60SR	6.28*	1.51	0.20
40PVA60SR	Control	1.78	1.51	1.000
	35PVA65SR	-5.83	1.51	0.30
	30PVA70SR	-6.28	1.51	0.20

**The mean difference is significant at the 0.05 level.*

Table II: Comparison of the Stress (MPa) in the Silicone RTV 585 and PVA Material Group with Control

(I) Specimen	(J) Specimen	Mean Difference (I-J)	Std. Error	Sig.
Control	35PVA65SR	1.88	0.57	0.066
	30PVA70SR	1.10	0.57	0.536
	40PVA60SR	0.78	0.57	1.000
35PVA65SR	Control	-1.88	0.57	0.066
	30PVA70SR	-0.78	0.57	1.000
	40PVA60SR	-1.10	0.57	0.541
30PVA70SR	Control	-1.10	0.57	0.536
	35PVA65SR	0.78	0.57	1.000
	40PVA60SR	-0.32	0.57	1.000
40PVA60SR	Control	-0.78	0.57	1.000
	35PVA65SR	1.10	0.57	0.541
	30PVA70SR	0.32	0.57	1.000

**The mean difference is significant at the 0.05 level.*

Table III: Comparison of the Displacement (mm) in the Silicone RTV 585 and PVA Material Group with Control

(I) Specimen	(J) Specimen	Mean Difference (I-J)	Std. Error	Sig.
Control	35PVA65SR	-3.77*	0.76	0.007
	30PVA70SR	-4.02*	0.76	0.004
	40PVA60SR	-0.88	0.76	1.000
35PVA65SR	Control	3.77*	0.76	0.007
	30PVA70SR	-0.25	0.76	1.000
	40PVA60SR	2.88*	0.76	0.32
30PVA70SR	Control	4.02*	0.76	0.004
	35PVA65SR	0.25	0.76	1.000
	40PVA60SR	3.14*	0.76	0.20
40PVA60SR	Control	0.88	0.76	1.000
	35PVA65SR	-2.88*	0.76	0.32
	30PVA70SR	-3.14*	0.76	0.20

**The mean difference is significant at the 0.05 level.*

DISCUSSION

IDH is a condition of NP protrusion from the AF in the intervertebral disc. Biological changes in the intervertebral disc play an important role in the degenerative process leading to IDH (9,22,27). This happens due to reduced water retention in NPs, an increase in the percentage of type I collagen in NPs and the interior of AF, degradation of collagen and the extracellular matrix, as well as an increase in degradation regulatory systems, such as apoptosis, matrix metalloproteinase expression, and the activation of inflammatory pathways (9,27). Furthermore, excessive load on degenerative intervertebral discs also contribute to herniation in NP pathogenesis. Surgical procedures performed to correct IDH microdiscectomy and artificial disk replacement. Thus, the ideal artificial disk replacement material must have similar biomechanical and viscoelastic properties as human NP (11,13).

Silicone rubber has unique characteristics and a higher selling price compared with other elastomers. Silicone rubber is a special elastomer with the properties of a long-lasting and highly resistant elastomer (rubber-like material) composed of silicone (polymer) and other molecules such as carbon, hydrogen, and oxygen (12,15). Silicone elastomers with these properties are classified as RTV silicone rubber (14). The main properties of the silicone elastomer can be modified by replacing most of the methyl groups with phenyl and/or vinyl. The phenyl group increases flexibility at low temperatures (up to −100°C) without compromising high temperature resistance. Vinyl clusters improve compression resistance and ease of vulcanization (11-13).

The first test performed assessed the stress and strain values of each group of silicone rubber and PVA composites by applying the maximum load from the testing machine (Figure 1). Stress and strain are among the assessment parameters used to determine the mechanical characteristics of a material. The values obtained for 40PVA60SR were closest to those of the control group. The results indicate that 40PVA60SR group exhibits similar mechanical strength and strain behavior as the NP in the control group.

The second mechanical test assessed the displacement of the silicone rubber and PVA composite groups and the control group with a load of 684 N. This test assessed the value obtained on the Y axis as a result of the axial loading applied to the specimen. Displacement is an assessment of changes in the length of a material after a stress load. A greater displacement indicates the lower ability of a test material to maintain its shape. The values obtained for 40PVA60SR were lower than those of the other groups and were closest to those of the control group. Thus, 40PVA60SR exhibited the most similar mechanical displacement to the NP in the control group.

Mechanical testing has shown that a material composite of 60% silicone rubber and 40% PVA exhibits a similar mechanical behavior to that of goat NP. This study demonstrated that this material composition increases the hardness of the material. The increased hardness of the silicone rubber and PVA material serves to reduce the deformation that occurs during the compression process (11,13,14,17). Therefore, the material composite of 40% PVA and 60% silicone rubber can be used as an alternative replacement for NP in degenerative intervertebral disc due to NP herniation.

Limitations

Goat vertebrae and disks differ significantly from those of humans, which is one of the study limitations. The vertebral body of a human is larger, wider, and shorter than that of a goat. Furthermore, a human disk is thicker than a goat disk. The slight increase in compression load in the goat specimen causes a large increase in stress value. The limitations of this compression model are that it can only measure axial load and cannot measure other biomechanical properties, such as flexion, extension, rotation, and lateral bending loads.

CONCLUSION

This study identified a novel material with similar biomechanical properties to goat NP and potential for use in NP replacement therapy. The 40PVA60SR exhibited the closest stress, strain, and minimal displacement values to those of the control after physiological loading. Further clinical research is needed to evaluate other biomechanical properties and the bioavailability of this material.

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AUTHORSHIP CONTRIBUTION

Study conception and design: AHB

Data collection: GIP

Analysis and interpretation of results: BU

Draft manuscript preparation: GIP, AR

Critical revision of the article: MAP, EAS

Other (study supervision, fundings, materials, etc...): AHB, EAS, MAP, AR

All authors (GIP, AHB, EAS, MAP, AR, BU) reviewed the results and approved the final version of the manuscript.

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