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ORIGINAL ARTICLE

Selection of the apposite vacuum extractor during operative delivery: A biomechanical study

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Abstract

Background: Operative delivery is a technique used during vaginal or cesarean birth to facilitate the patient's labor course through the assistance of a vacuum extractor. This method is increasingly used compared with forceps. This study aimed to investigate the forced effects of vacuum extractors comprising vacuum cups with different thicknesses on the fetal head and the vacuum extractor during vacuum-assisted delivery and to determine the optimal thickness for reducing the failure rate and minimizing neonatal and maternal morbidity.

Methods: A biomechanical model was developed to examine the impact of vacuum cups with varying thicknesses. This simulation three-dimensional (3D) geometry model was used to evaluate hemispherical-shaped vacuum extractors made of silicone rubber having a similar cup diameter of 70 mm with varying thicknesses (1-5 mm), which were applied to the three models (flat surfaces, hemispherical balls, and fetal head). Under one boundary condition and two different loading conditions, finite element analysis was utilized to simulate the force of vacuum extractors on the fetal head during the process of operative delivery. The main observation indicators were the reaction forces of the constructed model, and von Mises stress on both the vacuum extractors and fetal head.

Results: For the reaction forces on each axis, we found that the sum of the reaction force values on each axis was increased as the thickness of the vacuum extractor was increased, regardless of the surface type. In addition, the reaction force of the fixed-support end was increased with the increased thickness of the vacuum extractor. The von Mises stress distributions of vacuum extractors comprising vacuum cups with different thicknesses, revealed that the thinner the cup, the greater the von Mises stress exerted on the extractor itself regardless of the surface type. The distribution of von Mises stress on the skull structure of the fetal head showed that the thinner the cup, the greater the von Mises stress exerted on the skull structure regardless of the surface type.

Conclusion: A thinner vacuum extractor cup may result in greater injury to the fetus; hence, a thicker vacuum extractor cup is preferably utilized during vacuum-assisted operative delivery. Using a thicker vacuum extractor should yield a higher successful delivery rate and reduce fetal injury.

Keywords: Fetus; Finite element analysis; Operative delivery; Skull; Thickness; Vacuum extractors

1. INTRODUCTION

Operative delivery involves the birth of a child through the assistance of instruments, such as forceps or a vacuum extractor, which can be applied to the fetal head to extract the fetus.[1,2] The rates of operative vaginal delivery vary globally, ranging from 3% to 15%. There are substantial differences in clinical practice, particularly in the choice of instruments, such as a vacuum extractor or forceps. When opting for operative vaginal delivery, practitioners must promptly select the appropriate instrument based on factors such as patient characteristics, labor conditions, fetal head station, occipital position, local protocols, and physician expertize.[3–6] In practice, the use of a vacuum extractor rather than forceps has shown higher utilization and success rates, with the vacuum-to-forceps delivery ratio being approximately 4:1.[7] In addition to their use in operative vaginal delivery, a vacuum extractor or forceps has also been adopted in cesarean section.[8] If used safely, operative delivery can help manage any threat to the mother or fetus, such as maternal

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exhaustion, and a prolonged second stage of labor, as well as any underlying medical conditions. Such conditions include preeclampsia with severe hypertension, myasthenia gravis, cardiovascular aneurysm, or severe valvular heart disease with outflow obstruction, implying not suitable for pushing off, as well as an inappropriate fetal position, vaginal breech delivery, and fetal distress.[9] Contraindications include a not-fully dilated cervix, an unknown position of the fetal head, and an inexperienced operator. Moreover, vacuum extraction should be avoided at the time of face presentation.[2]

Generally, operative delivery failures are associated with various clinical factors, including physician experience, advanced patient age, elevated body mass index, obstructed labor, and a neonatal birth weight exceeding 4000 g.[10,11] Delivery with a vacuum is also associated with significant maternal- and fetal-related complications,[12,13] such as high-degree perineal and vaginal wall lacerations,[14] maternal urinary and anal incontinence, pelvic organ prolapse, and increased risks of postpartum wound or intrauterine infection. In addition, fetal scalp lacerations, cephalohematoma, subgaleal hemorrhage, intracranial hemorrhage, secondary hemorrhage in other organs, shoulder dystocia, clavicular fracture, and even plexus palsy are possible complications.[15–17] Apart from the above-mentioned complications, there is an elevated risk of facial nerve injury, brachial plexus injury, depressed skull fracture, and corneal abrasion in the fetus which can be associated with forceps delivery.[18,19]

In operative delivery with instruments, minimizing possible complications with increased success rates is the priority of obstetricians. Despite prior studies that investigated possible causes of failure in operative vaginal delivery, few have identified any modifiable factors, and even fewer studies have explored a potential approach—the vacuum extractor itself. Previous studies have compared the outcomes of using various rigid and soft cups during delivery, with metal cups demonstrating a higher success rate but resulting in more severe neonatal scalp injuries.[19] Clinically, it is difficult to measure the external forces and effects of vacuum extraction on the fetal head and neck while the fetal head is still located in the vagina during delivery. Several studies have focused on the biomechanical aspects of instrument-assisted deliveries during labor using computer-based simulation.[20–26] A finite element analysis (FEA) model is a biomechanical model widely used to perform numerical simulations for assessing the stress and strain on the fetus and the maternal pelvic floor muscles.[27,28] FEA could be applied to investigate the effect of labor forces on the fetal skull during delivery,[29] as well as the injuries to the pelvic floor tissue during labor.[30] A recent study utilized FEA to investigate the effects of silicone rubber vacuum cups with different sizes on the fetal head during delivery, showing that a larger diameter cup could exert a greater reaction force or stress and strain on the fetal head.[31] Furthermore, a stainless-steel vacuum extractor could exert a more powerful force on the fetal head.[32] Although these studies have examined the use of vacuum extractors during delivery, no study has investigated the biomechanical effects of vacuum cups with varying thicknesses. Hence, this study aims to compare the effects of forces generated by vacuum cups with different thicknesses (1, 2, 3, 4, and 5 mm) on the fetal head by FEA. These findings could provide a reliable reference for both medical device designers and obstetricians to increase the vacuum-assisted vaginal delivery success rate and reduce the incidence of maternal and neonatal complications.

2. METHODS

We created a simplified finite element model, which simulates and represents vacuum-assisted delivery during the second stage of labor in either vaginal delivery or cesarean section. This model integrates the following steps: constructing the simulation geometrical model, setting up both boundary and loading conditions, and defining the material properties of the model. We conducted FEA to determine the optimal thickness for operative delivery using a vacuum. Vacuum extractors were set up based on commonly used hemispherical-shaped vacuum extractors with a cup diameter of 70 mm.[2] Different thicknesses were investigated, including 1, 2, 3, 4, and 5 mm (Fig. 1A), with three-dimensional (3D) models being rendered using the computer graphics software, SolidWorks 2021 (Dassault Systems SolidWorks Corp, Waltham, MA). The extractors were applied to various surface areas, including flat surfaces, hemispherical balls, and fetal head models, to evaluate the effect of the thickness on fetal heads during delivery (Fig. 1B). There were two main compositions, including a 1 mm-thick scalp and a 2 mm-thick skull for the flat surface, hemispherical ball, and fetal head models. A 10 cm was used for the hemispherical ball to simulate a newborn head. The fetal head models were developed based on previous studies to construct geometric computer models of the infant's head.[31–35] The computer models comprised three main parts, scalp, skull, and vacuum extractor, and SolidWorks was used to assemble these parts. Once the models were constructed, they were imported into the ANSYS Workbench software (ANSYS Workbench 18.0; ANSYS Inc, Canonsburg, PA) for FEA.

One boundary condition and two different loading conditions were applied to simulate the force of the vacuum extractors on the fetal head during delivery. The boundary condition set the bottom of the flat surface, the bottom of the hemispherical ball, and the neck area of the fetal head as the fixed-support areas (Fig. 2A, areas labeled in green); with all these areas having an initially set displacement of zero in all directions (X-axis, Y-axis, and Z-axis). The Y-axis was parallel to the displacement direction. Fig. 2B shows two loading conditions during operative in the second stage of labor in this study. One condition simulated the suction of a vacuum extractor on the fetal head. The main area of the applied force was inside the vacuum extractor; when the vacuum suction pressure of the extractor reached 60 cmHg from 0 cmHg in the first 0.5 of a second and the pressure was maintained at 60 cmHg for 1 second. The other condition was a simulation of pulling on the vacuum extractor.[36,37] Displacement control was applied so that the end of the vacuum extractor was displaced 1 mm in the Y-direction starting from 0 mm as the pressure reached 60 cmHg at the first half second.[2] We also defined the contact surface between the fetal head and the vacuum extractor such that the vacuum extractor and the fetal head would not be detached during FEA.

The vacuum extractor material used was silicone rubber, and the material property settings were based on previous studies.[37–39] All materials were assumed to be homogeneous, isotropic, and linear elastic. Hence, Young's modulus and Poisson's ratio of each material were used as the material settings in FEA. All set values are listed in Table 1. Young's modulus, also known as the elastic modulus, is a mechanical property that measures the stiffness of a material. It describes the relationship between stress and strain in a material undergoing tensile or compressive deformation. Poisson's ratio is a dimensionless parameter that describes the relationship between the lateral (transverse) strain and the axial (longitudinal) strain in a material. When a material is stretched or compressed in one direction, it tends to deform in the perpendicular directions as well. Young's modulus and Poisson's ratio are two important mechanical properties of materials: the former measures the stiffness of a material, and the latter describes its deformation behavior.[40] In addition, the mesh of the computer model reached 5% of the stop criteria of the convergence test; thus, the finite element mesh model was appropriate.[41] Fig. 3 shows variations of the mesh models used in this study, and Table 2

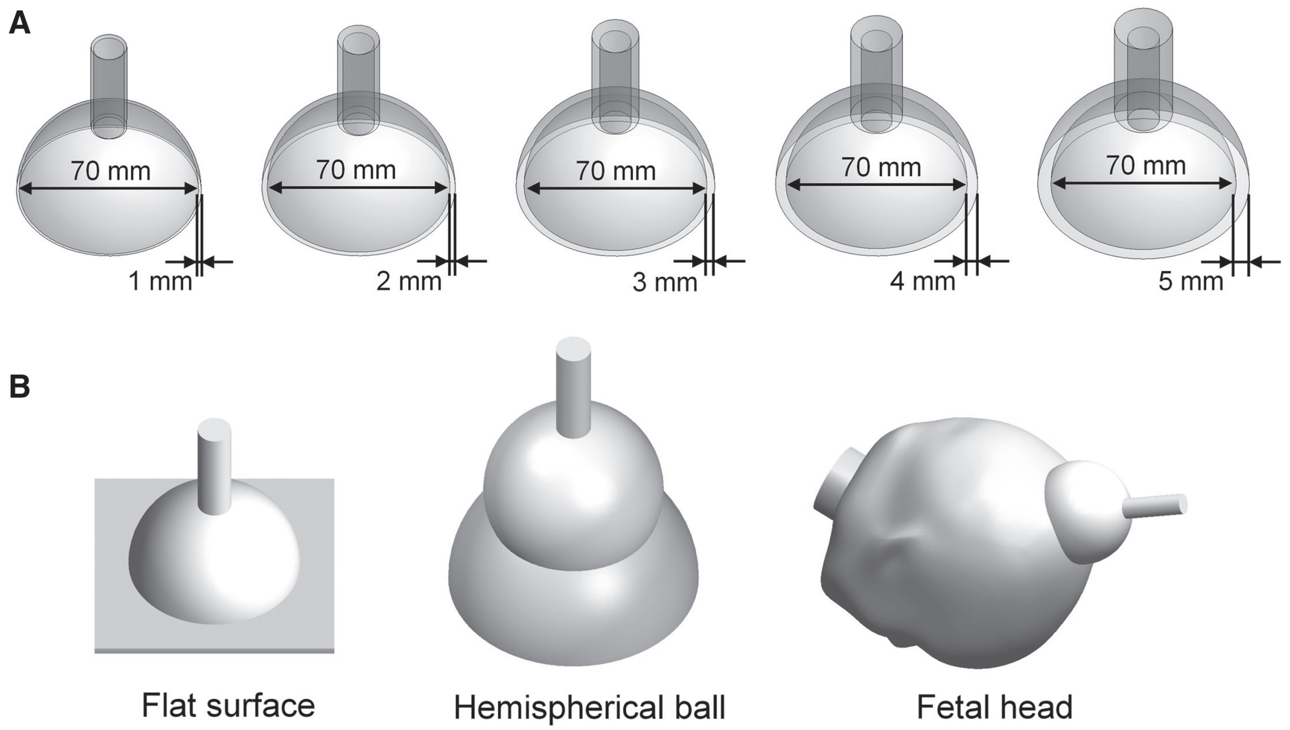

Fig. 1 Construction of the simulation geometry model. A, Vacuum extractors of various thicknesses. Finite element models of five various thicknesses (1, 2, 3, 4, and 5 mm) of vacuum extractors applied to three different surface areas. B, Finite element models of three different applied surface areas. Finite element model of vacuum extractors applied to the flat surface, hemispherical ball, and fetal head models.

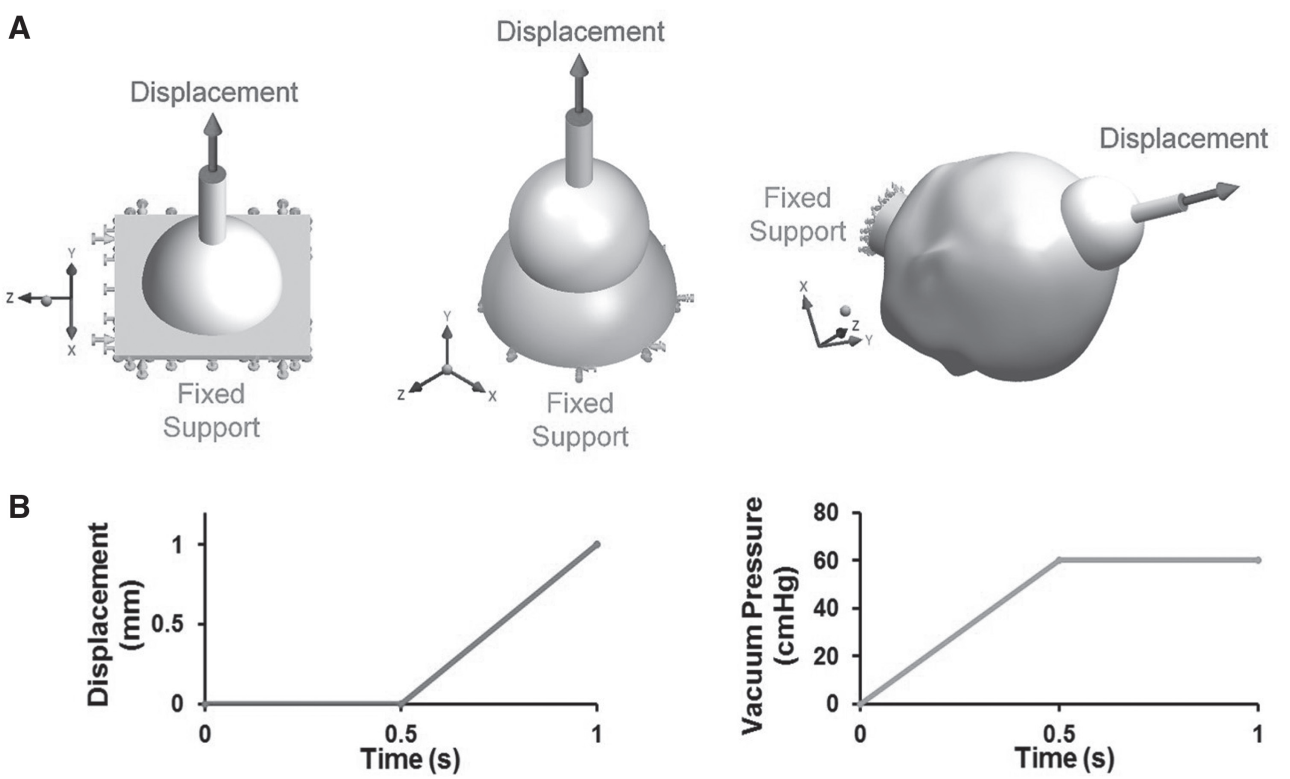

Fig. 2 Loading and boundary conditions of this study. A, The boundary condition set the bottom of three applied models as the fixed-support areas with an initially set displacement of zero in all directions (X-axis, Y-axis, and Z-axis). B, Two loading conditions while operative delivery during the second stage of labor for this study. The figure on the left shows the simulation of the vacuum extractor sucking on the fetal head and the figure on the right shows the simulation of the vacuum extractor being pulled.

Table 1

The material properties settings used in this study

Material	Young's modulus, MPa	Poisson's ratio
Scalp	16.7	0.42
Skull	2500	0.22
Silicone rubber	10.3	0.49

presents the numbers of nodes and elements on the FEA model (nodes and elements were utilized to divide complex structures into smaller, easily calculable parts, allowing for more precise simulation and analysis of stress, deformation, and other physical behaviors; nodes determine the geometry and boundary conditions of the mesh, although elements describe the material properties and physical behavior of the structure, thereby effectively simulating and analyzing various complex engineering problems).[42]

In this study, the main observation indicators of FEA were the reaction forces at the fixed end, von Mises stress on the vacuum extractor, and von Mises stress on the skull structure of the fetal head. The von Mises stress is a theoretical stress used in materials science and engineering to predict the yielding of materials under complex loading conditions. It is an equivalent stress that helps determine when a material will begin to yield under a given set of loads. The von Mises stress is defined based on the principal stresses of the stress tensor. The formula for von Mises stress is

$$\sigma_{\mathrm{von}} = \sqrt{\frac{1}{2}\left[(\sigma_1-\sigma_2)^2+(\sigma_1-\sigma_3)^2+(\sigma_2-\sigma_3)^2\right]},$$

where α_{von} is the von Mises stress. $\alpha1$, $\alpha2$, and $\alpha3$ are the principal stresses of the stress tensor.[43] All indicators were measured to investigate the effect of the thickness of the vacuum extractor on the fetal head during delivery as well as the biomechanics of the vacuum extractor.[31,32,35]

3. RESULTS

In this study, FEA was used to investigate the biomechanical effects of vacuum extractors comprising vacuum cups with different thicknesses on the fetal head by simulating the conditions of the fetus during the second stage of labor in a vaginal delivery (suction pressure up to 60 cmHg with a displacement of 1 mm within 1 second). We examined all the reaction forces and the

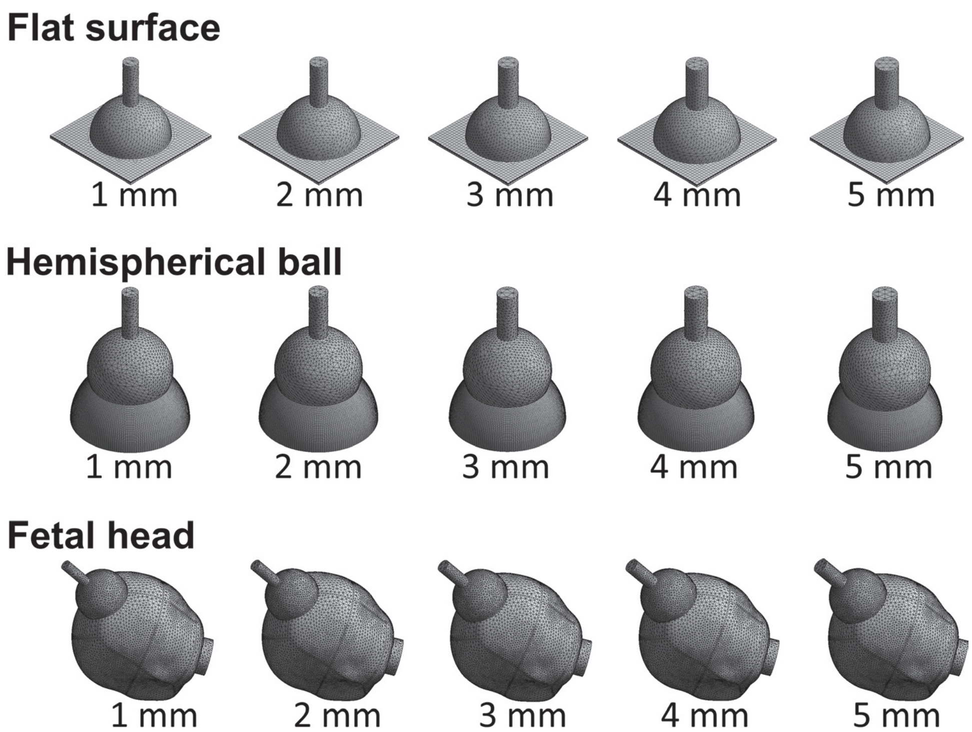

Fig. 3 The various mesh models used in this study. The directions and the values of the reaction forces for the ends of the fixed-support parts of three surface areas in the five simulated scenarios of different thicknesses.

Table 2

The numbers of nodes and elements on FEA model

Different shapes	Thickness	1 mm	2 mm	3 mm	4 mm	5 mm
Flat surface	Node	137 166	137 370	139 042	141 099	142 868
	Element	33 716	33 815	34 727	36 378	37 643
Hemispherical ball	Node	124 607	125 047	125 821	129 860	132 404
	Element	32 091	32 296	32 745	35 616	37 277
Fetal head	Node	153 774	154 108	155 341	160 159	161 859
	Element	79 328	79 494	80 183	83 716	84 834

FEA = finite element analysis.

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interaction forces between the fetal head and the vacuum suction device.

Regarding the reaction forces on each axis, we noticed that the sum of the reaction force values of each axis was increased as the thickness of the vacuum extractor was increased regardless of the surface type. The reaction force of the fixed-support end was also increased with an increased thickness of the vacuum extractor. Table 3 presents all values and distributions of the reaction force on each axis of various vacuum extractor thicknesses and different surface areas.

Results from von Mises stress distributions of the vacuum extractors comprising vacuum cups of different thicknesses revealed that the thinner the cup, the greater the von Mises stress exerted on the extractor itself regardless of the surface type (Fig. 4).

Distribution of the von Mises stress on each skull structure of the fetal head using the vacuum extractor with varying thickness, showed that the thinner the cup, the greater the von Mises stress was exerted on the skull structure of the fetal head regardless of the surface type (Fig. 5).

Table 3

The values of the reaction force and the distributions on each axis of various vacuum extractors comprising vacuum cups with different thicknesses and different surface areas

Different shapes	Thickness	1 mm	2 mm	3 mm	4 mm	5 mm
Flat surface	X-axis	-1.30×10^{-11} N	3.01×10^{-12} N	1.97×10^{-12} N	-3.06×10^{-12} N	2.61×10^{-11} N
	Y-axis	−12.074 N	−17.808 N	−25.041 N	−33.447 N	−43.206 N
	Z-axis	7.63×10^{-11} N	-2.08×10^{-11} N	6.12×10^{-12} N	-1.06×10^{-11} N	2.91×10^{-12} N
	Total	12.074 N	17.808 N	25.041 N	33.447 N	43.206 N
Hemispherical ball	X-axis	-1.41×10^{-11} N	-2.91×10^{-11} N	4.03×10^{-11} N	1.31×10^{-10} N	1.08×10^{-10} N
	Y-axis	−11.895 N	−17.264 N	−23.959 N	−31.4 N	−39.782 N
	Z-axis	1.66×10^{-10} N	-1.67×10^{-10} N	-2.38×10^{-11} N	-1.67×10^{-10} N	1.74×10^{-10} N
	Total	11.895 N	17.264 N	23.959 N	31.4 N	39.782 N
Fetal head	X-axis	1.11×10^{-4} N	1.11×10^{-4} N	1.11×10^{-4} N	1.11×10^{-4} N	1.11×10^{-4} N
	Y-axis	−11.871 N	−17.392 N	−24.261 N	−32.052 N	−40.87 N
	Z-axis	-9.67×10^{-5} N	-9.67×10^{-5} N	-9.67×10^{-5} N	-9.67×10^{-5} N	-9.67×10^{-5} N
	Total	11.871 N	17.392 N	24.261 N	32.052 N	40.87 N

Unit N represents Newton.

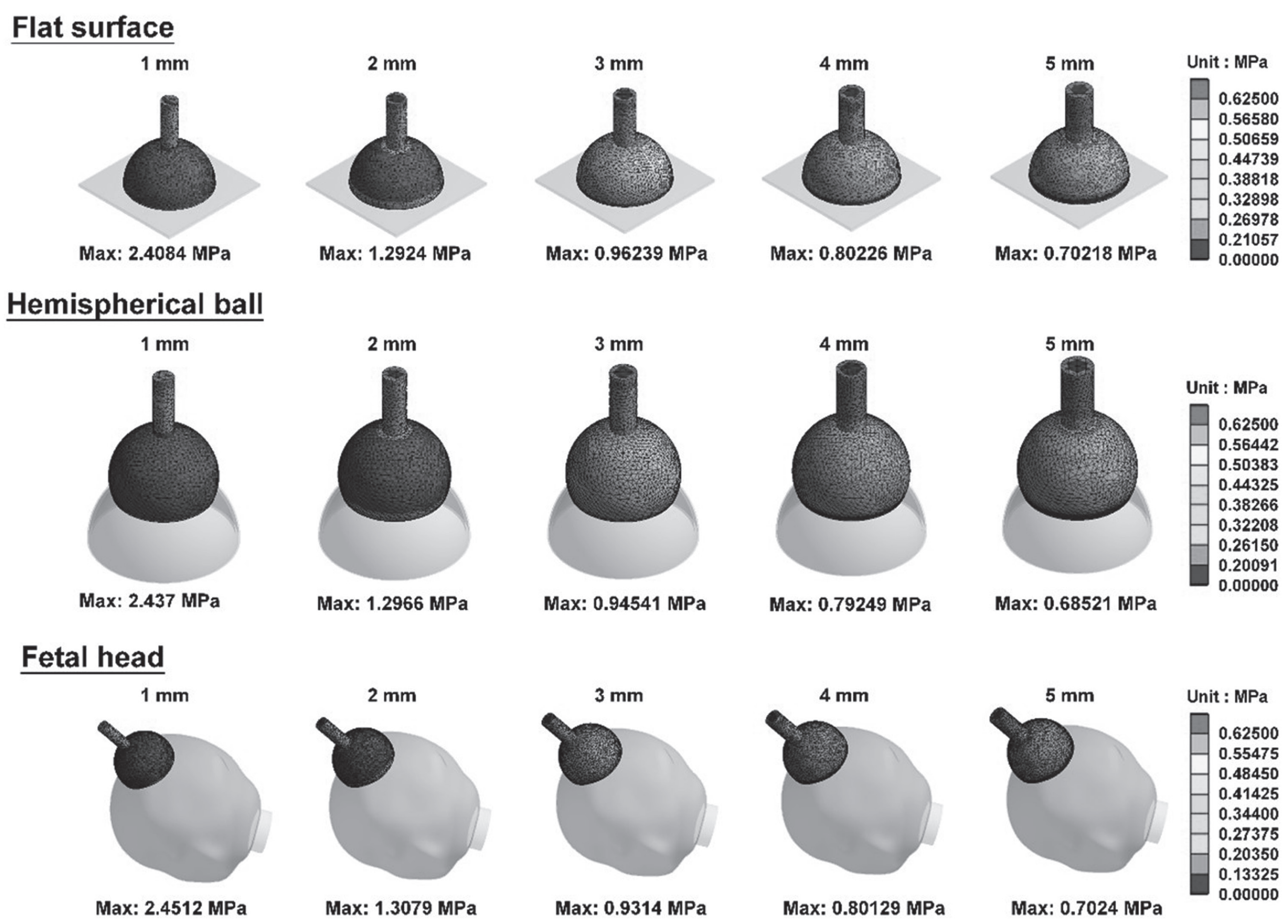

Fig. 4 The von Mises stress distributions of the vacuum extractors when various thicknesses of the vacuum extractors are applied to different surface areas.

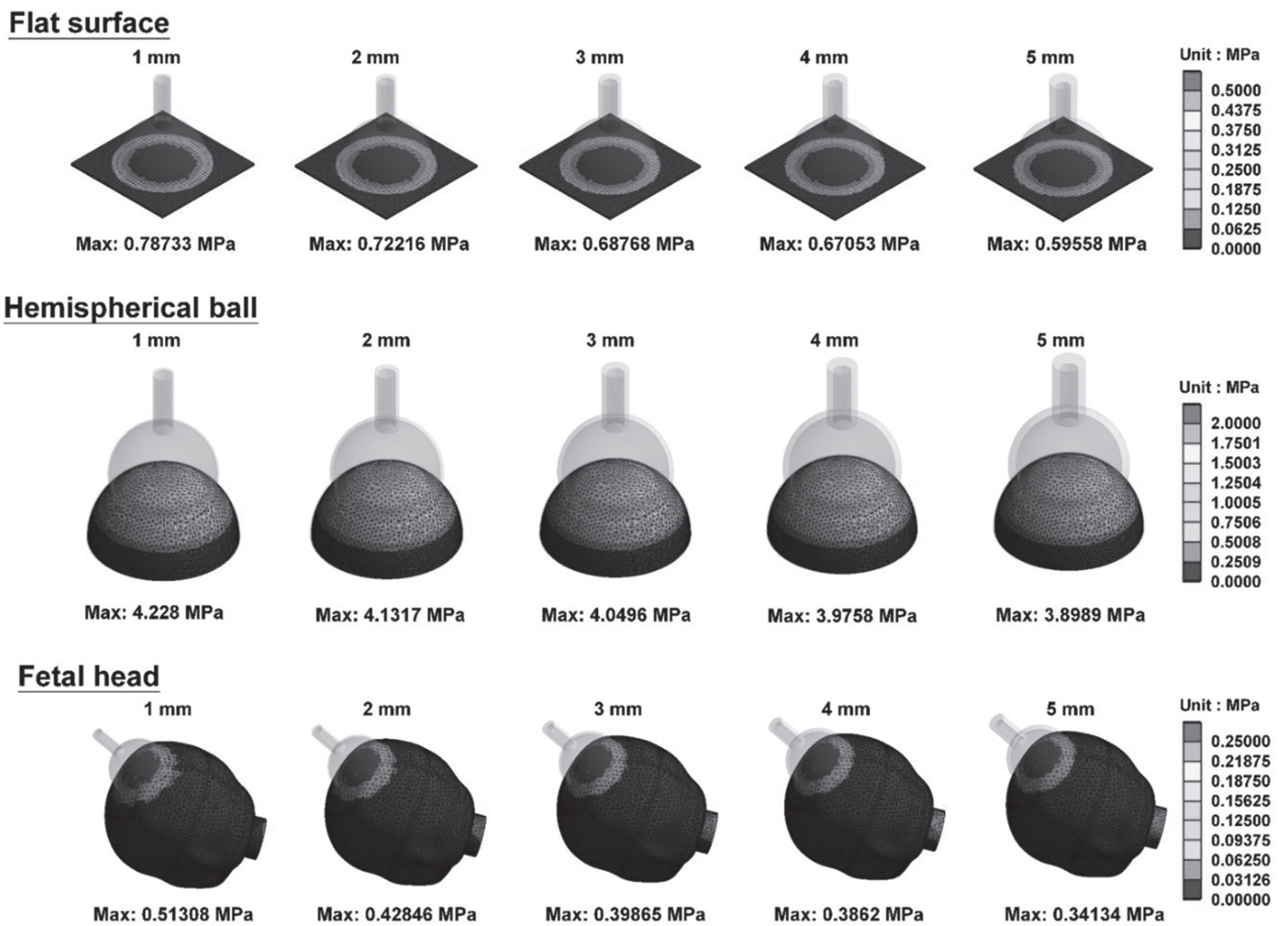

Fig. 5 The distribution of von Mises stress on each skull structure when the vacuum extractor with various thicknesses is applied to different surfaces.

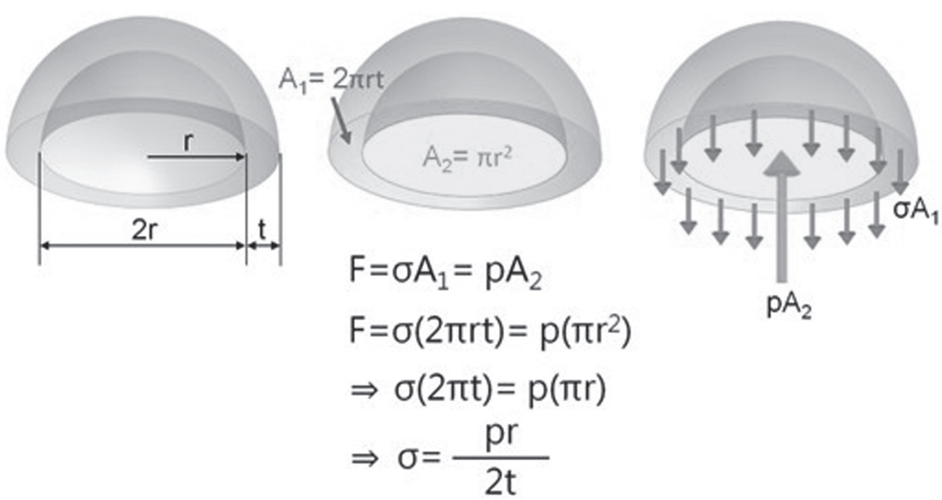

Fig. 6 Mechanics to explain how the vacuum extractor applies force on the skull, where σ is stress on vacuum extractors, *p* is vacuum pressure, *A*1 is the cross-sectional area on the vacuum extractor, *A*2 is the cross-sectional area inside the vacuum extractor, *r* is the radius of the vacuum extractor, and *t* is the wall thickness of the vacuum extractor.

4. DISCUSSION

This study is the first biochemical stimulation-based study using FEA to investigate the effects of vacuum extractors comprising of vacuum cups with varying thicknesses on different surfaces.

Our results indicate that the thicker the vacuum extractor cup, the greater the reaction force regardless of the surface type, which can be explained by the material mechanical stress theory, where force (*f*) is equal to stress (σ) multiplied by the cross-sectional area (*A*).[44] The cross-sectional area of the vacuum extractor in this study was $2\pi rt$ and the radius was constant, where r is the radius of the vacuum extractor, and t is the thickness of the vacuum extractor (Fig. 6). Because the force and cross-sectional area are proportional, the application of force increased as the thickness of the vacuum extractor cup increased. According to the boundary condition, more force is needed to create the same amount of displacement for a thicker cup. In addition, this study used flat surfaces, hemispherical balls, and fetal head models for FEA, and the results showed the same trend. The greater the reaction force, the greater the ability to exert more force on the fetal neck area, thus possibly increasing the risk of newborn neck injuries.

It can be noted that while using a thinner cup, greater stress is exerted on the vacuum extractor to yield the same displacement as stress is inversely proportional to the cross-sectional area. Consequently, there is greater stress on the vacuum extractor itself when a thinner cup is applied compared to a thicker cup.

According to the *Mechanics of Materials* textbook,[44] utilizing the formula $\sigma = pr/2t$ (Fig. 6), where σ being stress and t being the wall thickness of the vacuum extractor, we conclude that when the wall thickness of the vacuum extractor is the same, the stress produced is inversely proportional to the extractor wall thickness. Meaning that, stress on the skull of the fetal head will be greater when using a thinner vacuum extractor cup, thus, possibly leading to damage to displacement or detachment of the extractor and scalp or skull-related damage to the fetal head.

There are some limitations in this study. First, all materials were assumed to be homogeneous, isotropic, and linear elastic based on previous studies.[31,32] Second, vacuum extractor cups with a constant diameter (70 mm) were used to evaluate the impact of varying vacuum cup wall thickness.[31] In clinical situations, based on gestational age, the corresponding size of the fetal head and cups of different sizes may affect the overall results. Third, this study simplified the model of the fetal head to consist of only the scalp and skull. This simplification reduced other confounding factors and facilitated analysis of the effects of varying thicknesses of the vacuum extractor cups. Fourth, ethical issues will make this project unfeasible. Establishing FEA was a more suitable experimental method for investigating the effects of vacuum cup thickness on the fetal head.

In conclusion, our design proposes the mechanism and forces exerted on the fetal head during operative delivery with a vacuum. FEA was applied to investigate the effects of vacuum extractors comprising cups with different thicknesses. Thinner walls may produce a weaker pulling reaction force on the fetal neck but a greater stress on the vacuum extractor causing displacement or detachment, as well as injuries to the fetal heads. Thicker walls may produce a greater pulling reaction force on the fetal neck but less stress on both the extractor and fetal skull. Hence, a thicker vacuum extractor cup is preferably used during operative delivery to increase the success rate and decrease fetal injury.

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