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The Single-Incision Sling to Treat Female Stress Urinary Incontinence: A Dynamic Computational Study of Outcomes and Risk Factors

Dynamic behaviors of the single-incision sling (SIS) to correct urethral hypermobility are investigated via dynamic biomechanical analysis using a computational model of the female pelvis, developed from a female subject's high-resolution magnetic resonance (MR) images. The urethral hypermobility is simulated by weakening the levator ani muscle in the pelvic model. Four positions along the posterior urethra (proximal, midproximal, middle, and mid-distal) were considered for sling implantation. The α -angle, urethral excursion angle, and sling-urethra interaction force generated during Valsalva maneuver were quantitatively characterized to evaluate the effect of the sling implantation position on treatment outcomes and potential complications. Results show concern for overcorrection with a sling implanted at the bladder neck, based on a relatively larger sling-urethra interaction force of 1.77 N at the proximal implantation position (compared with 0.25 N at mid-distal implantation position). A sling implanted at the mid-distal urethral location provided sufficient correction (urethral excursion angle of 23.8 deg after mid-distal sling implantation versus 24.4 deg in the intact case) with minimal risk of over-tightening and represents the optimal choice for sling surgery. This study represents the first effort utilizing a comprehensive pelvic model to investigate the performance of an implanted sling to correct urethral hypermobility. The computational modeling approach presented in the study can also be used to advance presurgery planning, sling product design, and to enhance our understanding of various surgical risk factors which are difficult to obtain in clinical practice. [DOI: 10.1115/1.4030978]

Keywords: stress urinary incontinence, sling, finite-element method, modeling

Introduction

Stress urinary incontinence (SUI), the involuntary urinary leakage associated with increases in intra-abdominal pressure (IAP), affects about 25–50% women in the U.S. with an annual treatment cost exceeding \$12 billion [1]. The total number of women who will undergo SUI surgery will increase 47.2% from 210,700 in 2010 to 310,050 in 2050 [2]. In recent decades, midurethral sling has become the standard treatment for women with SUI when conservative treatments have failed. The typical outcome of a successful sling surgery corrects urethral hypermobility [3], which is often associated with SUI patients due to insufficient pelvic floor support to the urethra and can be clinically assessed by the Q-tip test [4]. By providing additional support to the urethra, the implanted sling helps restore the continence mechanism. Most

recently, the SIS [5], with only one single incision of the anterior vaginal wall made for the sling passage, was touted with high expectation. However, the actual clinical performance has not been encouraging with many differing conclusions reported regarding its effectiveness and safety [6–9]. Urinary retention is a serious postoperative complication of failed sling surgeries and may attribute to excessive sling-urethra interaction force, which overtightens the sling and obstructs the urethra blocking normal urethral opening required for voiding [10]. Postoperative pain may also be associated with excessive sling tension as too much force may cause implant shrinkage, which has been reported as a major cause of severe pain after pelvic floor repair surgeries [11]. Currently, there is no agreement regarding which type of sling is the best in terms of effective surgical outcome with the lowest complication rate. Many studies advocate that the midurethral sling technique should be put under more scrutiny with larger controlled clinical trials. A better understanding of the dynamic process required to stabilize the urethra under stress using the midurethral sling would be useful to advance sling design and proper placement.

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In spite of a large amount of existing clinical trial data, the outcomes are often subjective with no ability to objectively study the dynamic process that a sling–tissue interaction represents in a real world setting. Medical imaging techniques, such as perineal ultrasonography [12] or MR imaging [13], have been employed to study this topic. However, only two-dimensional images can be provided and more importantly, the critical biomechanical information, such as interaction behaviors, between the sling and surrounding tissues is still missing, which limits the quantitative analysis of some key aspects of the sling performance. Computational models, based on realistic female pelvic anatomy, offer a useful tool for quantitative biomechanical analysis to female pelvic floor dysfunctions [14]. Models have been employed to study pelvic organ prolapse [15–17], childbirth-related trauma [18,19], and ligament impairment [20]. However, these models often missed some necessary anatomical structures that maintain the integrity of the natural pelvic anatomy, and efforts have been rarely made to study the interventional treatments. In this study, a comprehensive pelvic model was developed with 44 anatomical structures in the female pelvis incorporated to study the midurethral sling performance on a subject-specific basis. A SIS was incorporated in the pelvic model at four different locations along the posterior urethra, and dynamic biomechanical analysis was performed. The interaction behaviors of the midurethral sling in the female pelvis were investigated by examining the dynamics of the bladder neck, urethra, and sling under increased IAP. Analyses of biomechanical parameters (α -angle [21], Q-tip excursion angle [4], and sling–urethra interaction forces) obtained from computer simulation results were performed to investigate the effect of implant positions on the treatment outcome (urethral hypermobility) as well as potential risk factors (retention and pain). The computational modeling and dynamic biomechanical analyses provide insights into underlying mechanics for SUI treatments that are difficult to obtain from clinical trials or static imaging tools alone.

Materials and Methods

Female Pelvic Model. The computational model of the female pelvis and the mechanical properties of tissues involved in the pelvic model are adopted from a previous study based on subject-specific MR images of a 21-year-old asymptomatic female (nulliparous, nonsmoker, and body mass index (BMI) = 22) [22] (Fig. 1). Slight geometric modifications were made to accommodate the sling to the established model. Very briefly, axial MR images were acquired in the supine position at rest using a 3.0 T MR scanner (Trio Tim, Siemens, Erlangen, Germany) (slice thickness 3 mm; matrix 320×160 ; field of view 430 mm; and pixel size 1.344 mm). Segmentation was performed on axial MR images for

each anatomical pelvic structure with the guidance of one urologist using MIMICS 11.0 (Materialise Group, Leuven, Belgium). The closed surfaces were then imported into MAYA 8.5 (Autodesk Inc., San Rafael, CA) and RHINOCEROS 4.0 (McNeel North America, Seattle, WA) for artifact smoothing and intersecting surface correction and converted into solid geometries. All solid geometries were discretized into a finite-element mesh with 126,378 tetrahedral elements using ABAQUS 6.12 (SIMULIA, Providence, RI). The final 3D pelvic model contains 44 anatomical parts including pelvic muscles, ligaments, bones, fat, bladder, urethra, uterus, vagina, colon, rectum, and anus. ABAQUS general contact function and tie constraints were employed to realize the interactions and connections between soft tissues.

The general contact algorithm in ABAQUS was applied to mimic the natural interaction between parts that are in contact but anatomically independent (e.g., the interaction between the bladder and the uterus). Tie constraints that bind two shared surfaces were used to couple motions of parts which are biologically connected and to model the connecting effects of fasciae (e.g., the tendinous arch of levator ani muscle). Connector elements, with the ability to model connective tissues, such as ligaments [17], were employed in this study to model the ligaments surrounding the urethra (e.g., the pubourethral ligament). Although soft tissues show viscoelastic behavior [23,24], a previous study found quasi-linear material property of urological soft tissues when the stress level is under 70% of the maximal stress value [25]. As such, soft tissues involved in the pelvic model were modeled as linear elastic solids using material properties from Young's moduli of the bladder, urethra, uterus, rectum, muscle, ligament, and vaginal tissue (0.05, 0.03, 0.05, 0.1, 2.4, 1.2, and 7.4×10^{-3} MPa) [25]. The bony pelvis was modeled as one rigid and fixed structure considering its negligible deformation under normal pelvic functions due to its much higher stiffness compared with soft tissues [26]. Two uniformly distributed pressures were applied on the front and top surface of the pelvic model to induce IAP (Fig. 1(d)). A specifically designed bodyfill part, which fills the abdominal cavity, was created for the pressure transmission (Fig. 1(d)). The bottom of the model was constrained from all displacements. The IAP was calculated as the averaged contact pressure (ABAQUS variable *CPRESS*) between the urine and inner bladder wall. ABAQUS EXPLICIT solver was used for the finite element method (FEM) implementation. The IAP was calculated as the averaged contact pressure between the inner bladder wall and the urine. The IAP achieved at maximal Valsalva was assumed as 100 cm H₂O, which is within the physiological range as SUI patients exhibited an IAP at maximum straining of 99.3 ± 51.8 cm H₂O (7–193 cm H₂O) [27].

For the validation purpose, dynamic MR images were acquired in the midsagittal plane approximately every 1.5 s while the

Fig. 1 (a) and (b) show the pelvic muscles and bones in the front and back views (muscles shown include: m. piriformis, m. coccygeus, m. iliococcygeus, m. pubococcygeus, m. obturator internus, and m. puborectalis), organs and fatty tissues are removed for better visualization. (c) The main pelvic organs in the oblique view (from top to bottom: rectum, uterus and bladder). (d) The model and the boundary conditions in the midsagittal view. The solid part in the abdomen represents the bodyfill part.

subject performed several Valsalva maneuvers. High consistency was achieved between the simulated pelvic floor deformation and the dynamic MR imaging observation.

SIS Model. The simulated SIS was modeled based on realistic specifications of MiniArc™ (American Medical Systems, Minnetonka, MN). The sling was modeled as a strip (length $\times$ width $\times$ thickness: 2.8 in. $\times$ 0.42 in. $\times$ 0.025 in.), as shown in Fig. 2(a). The sling was meshed into 4600 eight-node hexahedral elements, as shown in Fig. 2(b). The experimental uniaxial stress-strain data, provided by American Medical Systems, is shown in Fig. 2(c). A second-order polynomial hyperelastic model [28] was used as the constitutive model of the sling. The test data were imported into the ABAQUS hyperelastic material model, and the least-square fit was performed automatically by the solver to obtain the optimal parameters ($C_{10} = -0.160$, $C_{01} = 0.389$, $C_{20} = 6.014$, $C_{11} = -9.059$, and $C_{02} = 3.808$). As the sling was modeled with its ideal shape in the undeformed state, before the Valsalva simulation, a separate preparation simulation was performed to move it to the planned implantation positions in a shape that is conforming to the surfaces of posterior urethral wall and anterior vaginal wall (Fig. 3). After the preparation simulation, the sling was deformed to the planned implantation position and shape and then imported to the Valsalva simulation model as the initial status. The sling motion was controlled by three reference points: one at the middle bottom position of the sling (mid-bottom point) and two at each end (end points), as shown in Fig. 2(b).

Step 1: The sling was first placed below the bladder neck (Fig. 4(a)) between the anterior and posterior urethral walls without touching the anterior vaginal wall. All interactions with the sling were excluded except for the vaginal wall. A uniform posterior displacement boundary condition was assigned to the center nodes of the sling in order to move the sling off from posterior urethral wall and push the sling against the anterior vaginal wall. The sling surface was adjusted to the anterior vaginal wall due to their interaction. At the end of this step, the sling was completely out from touch with the urethra and tightly pressed against the vagina (Fig. 4(b)).

Fig. 2 (a) Dimensions of the MiniArc™ SIS (in inches), (b) finite-element meshes of the sling with three control points, and (c) curve fitting results for the MiniArc™ SIS with second polynomial hyperelastic material model

Fig. 3 Sling implantation positions at rest status. The first column shows the midsagittal view of the pelvic bone (bottom left), bladder (top), urethra (bottom right), urine (inside the bladder), and sling (behind the urethra). The second column shows the sling shape and positions from the posterior view. The alpha-angle is defined as the angle between the urethral axis (right dashed line) and the vertical line (left dashed line), as shown in the first row (test A1). The urethral axis is defined as the line between two reference points (indicated by the cross-marks) along the posterior urethral wall, same for all tests.

Step 2: The interaction of the sling with the urethral wall and the pelvic bones was activated in this step. A displacement boundary condition was assigned to the mid-bottom point to drag the entire sling down along the posterior urethra to the desired implantation position. The amount of displacement was directly calculated based on the vector distance from its initial position to the desired position on the posterior urethral wall. Another displacement boundary condition was assigned to each end point to advance the sling arms into the obturator foramen in each side. The displacements were obtained from several preliminary tests so that the sling was advanced into the obturator internus muscle and the obturator membrane below the inferior pubic ramus, while the maximum principal strain was kept under 10% for the entire sling except a few regions around the reference nodes. At the end of this step, the sling reached its desired position, but a certain amount of oscillations existed because of the motions in the previous steps (Fig. 4(c)).

Step 3: The sling ends were then fixated in space and the sling was kept at rest to attenuate the oscillations. When the equilibrium state was achieved, the deformed sling was in its desired implantation state (Fig. 4(d)) and exported as an orphan mesh (ABAQUS [29] orphan mesh), which preserved the deformed shape and also released the tension caused during the previous boundary conditions as the sling should be implanted in a tension-free manner. The orphan mesh sling was then re-imported into the pelvic model for Valsalva maneuver simulation.

The friction coefficient of the sling with surrounding tissues (bladder, urethra, vagina, and pelvic bones) was 0.2 as suggested by the American Medical Systems. To simulate the fixing effect of the obturator internus muscle on the sling, the portion of the nodes on the sling arms that were in contact with the obturator internus muscles was constrained with encastre boundary conditions (ABAQUS [29] encastre), which prohibited all translation and rotation displacements.

Fig. 4 Illustration of the preparations of the sling for test A4. Three columns show the relative positions of the sling to pelvic organs in the midsagittal, posterolateral, and anterolateral views. Bladder (shown in column 2) and uterus/vagina (shown in column 3) were hidden in some views for visualization purpose. Different rows represent the results at different steps: (a) initial, (b) after step 1, (c) after step 2, and (d) after step 3.

Plan of Simulation. Table 1 lists all six tests performed in this study. Test C0 serves as the intact control test in which no urethral support structures were weakened. Test C1 serves as the SUI control test in which the levator ani muscle, the most important urethral support structure, was weakened by reducing its stiffness by 95% to simulate the insufficient urethral support in SUI patient. In neither control test was the sling implanted. Ideally, after implantation, a SIS would be placed at the junction between the lower and middle urethra and present a flat to a gentle C shape at rest. Poorly placed slings may shift upward or downward along the posterior urethral wall. To compare the effect of different sling implantation positions on the treatment outcome, four tests were performed (tests 01–04, sling tests). In each test, the levator ani muscle was weakened and the sling was implanted at a different

location along the posterior urethral wall using the method described previously. The center of the sling was placed at positions from the bladder neck by 10% (test A1, proximal), 30% (test A2, midproximal), 50% (test A3, middle), and 70% (test A4, mid-distal) relative to the urethral length (Fig. 3).

Quantitative Analysis of Sling Performance. SUI is often characterized by urethral hypermobility. Transperineal ultrasound reveals that the α -angle, a measure of urethral mobility and defined as the angle between the vertical axis and the urethral axis, was significantly different on straining ($P < 0.05$) between the study (SUI) and control groups [21]. In this study, we employed the α -angle as a key biomechanical parameter to evaluate the sling surgery treatment outcome, as the successful sling surgery would significantly decrease the urethral hypermobility ($P < 0.001$) [3]. To measure the α -angle in ABAQUS, two reference points along the posterior urethra were selected to define the urethral axis (Fig. 3). The static α -angle was calculated using the initial coordinates of these two points. A history output request was set to monitor the displacements of these two points so the change of the α -angle during the simulation could be calculated. The urethral excursion angle, defined as the change of the α -angles at rest and at maximal Valsalva (denoted by $\Delta\alpha$), was used as an alternative measure to examine the urethral mobility, as $\Delta\alpha$ is mathematically equal to the Q-tip excursion angle that is frequently used in clinical Q-tip tests to assess urethral hypermobility [4,30]. The sling–urethra interaction force was used to assess potential postoperative overcorrection, considering that too much interaction force (overtightened sling) might cause urethral retention, which is a common complication of failure sling surgery [10]. A history output request was set to monitor the total contact force for the sling–bladder interaction pair. The history output requests were executed once every 1 ms throughout the entire Valsalva simulation.

Results

Table 1 summarizes the simulation results obtained from all six tests. The α -angle at the rest state is 15.9 deg for all tests, as they shared the same geometric model of the pelvis. An α -angle of 40.3 deg was achieved in the intact control test and an α -angle of 52.5 deg was achieved in the SUI control test at maximal Valsalva. α -angles of 39.7 deg (mid-distal, test A4), 36.0 deg (middle, test A3), 29.8 deg (midproximal, test A2), and 26.5 deg (proximal, test A1) were achieved in the four sling tests.

The increase of IAP with the simulation time for all tests is presented in Fig. 5(a). The corresponding urethral excursion angles ($\Delta\alpha$) were calculated for each test and plotted against the IAPs in Fig. 5(b). A urethral excursion angle of 24.4 deg was achieved from the intact control test (test C0) and a urethral excursion angle of 36.6 deg was achieved from the SUI control test (test C1). Urethral excursion angles of 23.8 deg (mid-distal, test A4), 20.1 deg (middle, test A3), 13.9 deg (midproximal, test A2), and 10.6 deg

Table 1 Plan of simulations and results

			α -angle (deg)			
Test #	Impaired structure	Sling implantation position	Rest	Maximal Valsalva	Difference, $\Delta\alpha$	Sling–urethra interaction force, F (N)
Control tests						
C1	None	No sling	15.9	40.3	24.4	
C2	LAM	No sling	15.9	52.5	36.6	
Sling tests						
A1	LAM	Proximal	15.9	26.5	10.6	1.77
A2	LAM	Midproximal	15.9	29.8	13.9	1.37
A3	LAM	Mid	15.9	36.0	20.1	0.96
A4	LAM	Mid-distal	15.9	39.7	23.8	0.25

Note: LAM, levator ani muscle.

Fig. 5 (a) Plot of the increase of IAP with time for sling and control tests, (b) plot of urethral excursions angle against IAP for sling tests and control tests, and (c) plot of interaction forces against IAP for sling tests

(proximal, test A1) were achieved in sling tests, respectively. The sling intervention demonstrated its efficiency in bringing down all large urethral excursion angles achieved in the sling tests to lower levels (reduced by 35.0% in test A4, 45.1% in test A3, 62.0% in test A2, and 71.0% in test A1).

Figure 3 shows that all implanted slings present a shape of a flat line in the midsagittal view at rest. Figure 6 shows the deformed bladder, urethra, and sling at maximal Valsalva in both control tests and four sling tests. Note that slings implanted at proximal and midproximal urethra locations resembled a “C”-shape due to the applied pressure, while slings implanted at middle and proximal urethra locations still maintained the shape of a flat line.

Figure 5(c) shows the development of the sling–urethra interaction forces over the increase of IAPs. It can be seen that the interaction force increases as the IAP increases in all the tests. Also note that the magnitude of the interaction force increases as the implantation location of the sling approaches the urethrovesical junction. The interaction forces of 0.25 N (mid-distal, test A4), 0.96 N (middle, test A3), 1.37 N (midproximal, test A2), and

1.77 N (proximal, test A1) were achieved in the sling tests at maximal Valsalva, respectively.

Discussion

Over the last two decades, numerous slings have been invented and made available for SUI surgery. The mechanical properties of these slings varied significantly [31] but there is no unequivocal agreement regarding the best material [32]. A number of poor quality slings have been implanted into women with SUI and caused severe complications in the past years. A reliable and convenient method to test the sling products is lacking. A computational model and dynamic biomechanical analysis approach will bridge this gap by providing three-dimensional dynamic responses of the organs and tissues in the pelvis in response to sling implantation.

In this study, a computational model of the female pelvis, which consists of 44 anatomical structures of the female pelvis and represents the most comprehensive model of the female pelvis in SUI research, to the best of our knowledge, was developed and utilized to investigate the performance of midurethral sling surgery in correcting urethral hypermobility.

The pelvic floor deformation in response to increased IAP during the Valsalva maneuver was predicted by the computer simulation. Urethral mobility was quantitatively characterized by α -angles and urethral excursion angles (the change in α -angle from rest to maximal Valsalva) and compared across different scenarios (control tests and sling tests). In addition, the interaction behavior of the SIS with urethra was studied. The potential complication of overcorrection or muscle pain was assessed by comparing the sling–urethra interaction forces for four sling implantation locations.

The α -angles predicted by the computational model in the control tests are in agreement with perineal sonography findings [21] (for intact subjects, 15.9 deg versus 15.0 deg $\pm$ 6.7 deg at rest and 40.3 deg versus 31.3 deg $\pm$ 11.7 deg at maximal Valsalva; and for SUI patients, 52.5 deg versus 51.0 deg $\pm$ 14.0 deg at maximal Valsalva). The predicted α -angles in the sling tests are in agreement with postsling surgery Q-tip tests [3] (26.5 deg for test A1 with the proximal sling implanted, 29.8 deg for test A2 with the midproximal sling, 36.0 deg for test A3 with the middle sling, and 39.7 deg for test A4 with the mid-distal sling versus 30.19 deg $\pm$ 9.37 deg at maximal Valsalva). The urethral excursion angles characterized in the two control tests ($\Delta\alpha$ = 24.4 deg intact control and $\Delta\alpha$ = 36.6 deg SUI control) are qualitatively in agreement with reported Q-tip test using $\Delta\alpha$ = 30 deg as the criteria for urethral hypermobility [30]. After sling implantation, the urethral excursion angle was lowered down from 36.6 deg to 10.6 deg (test A1), 13.9 deg (test A2), 20.1 deg (test A3), and 23.8 deg (test A4). The simulated sling intervention showed successful corrections of urethral hypermobility.

Fig. 6 Shapes of sling in the midsagittal view at maximal Valsalva. The two reference points used to define the urethral axis are marked by crosses.

Studies show that the SIS with a shorter arm length causes less pain to patients in the short term than trans-obturator tape (TOT) or tension-free vaginal tape (TVT) slings [33]. Although urinary bladder nociceptors respond to the stimuli that cause pains, it remains unclear how they are distributed exactly. Nevertheless, our clinical experience shows that many patients, but not all, have pain relief after removing a sling that is too tight obstructing the urethra. The sling–urethra interaction forces, indicating the force which the implanted sling exerts on the urethra during a pressure event, may properly characterize the tightness of the sling against the urethra. This study represents the first effort, to the best of our knowledge, to investigate the interaction forces during pressure events. Specifically, our computation results show that the interaction force was much higher (1.77 N in test A1 compared with 0.25 N in test A4) when the sling was placed in a more proximal position, which may indicate that a sling implanted at a more proximal position will more likely lead to pain and urinary retention in treated SUI patients.

Inappropriate sling implantation positions may lead to overtightened slings and cause severe complications, such as retention and postoperative pain. The maximal sling–urethra interaction force developed postoperatively in response to increased IAP can be used to better understand and predict those complications. Unfortunately, the sling–urethra interaction force information is difficult to obtain in practice due to the lack of appropriate measurement tools. Based on the force–IAP relationship observed from this study, the maximal sling–urethra interaction force can be estimated from IAP measurements using the computational modeling and biomechanical analysis approach. This provides a way to predict the surgery outcome (through the correction of urethral hypermobility) and the potential risks the patient may be exposed to (through the sling–urethral interaction forces at maximal Valsalva).

Biomechanical analysis results indicate that the proximal urethra sling may provide the best performance in correcting the urethral hypermobility, as the $\Delta\alpha$ (10.8 deg, test A1) was the lowest among all four sling tests. The appearance of the proximal urethra sling in the midsagittal view (Fig. 6, test A1, flat line at rest and C-shaped at maximal Valsalva) also fell into the group that may represent the best outcome reported in Ref. [12]. However, this $\Delta\alpha$ value was even less than the intact $\Delta\alpha$ (24.4 deg, test C1), indicating an overtightened sling that might obstruct the urethra. This was also demonstrated by the largest sling–urethra interaction force (Table 1). Our results also showed, on the other hand, that a sling implanted at the mid-distal position generated a $\Delta\alpha$ value of 23.8 deg (test A4), which is closest to the intact $\Delta\alpha$. The interaction force in this case was also the lowest. As such, a sling implanted in the midurethral location will provide sufficient correction with minimal risk of overtightening and represent the optimal choice for sling surgery. This finding is consistent with the optimal outcome achieved when the sling is placed at the junction of the middle and distal thirds [12].

These simulation results are consistent with clinical findings and suggest that the computational model could help us gain a thorough understanding of the mechanics of various physiological phenomena inside the female pelvis. The computational model could be used to optimize preoperative surgery planning, or to resolve SUI for patients with postoperative failure, or to evaluate obstruction and pain with individual imaging applied to this computational model.

Conclusions

A computational model of the female pelvis with an implanted SIS was developed in this study to examine the effect of different implantation positions on the treatment outcome and potential complication factors. Four different locations along the posterior urethral wall were examined. Dynamic biomechanical analysis results showed that the mid-distal position for sling implantation offered the best overall performance for restoring urethral support

while keeping the sling–urethral interaction force low. This study represents the first effort in utilizing a comprehensive pelvic model to investigate the performance of midurethral surgery in correcting urethral hypermobility. The computational modeling and biomechanical analysis approach presented in the study can also be used to advance presurgery planning, sling product design, and our understanding of various pathophysiological phenomena which are difficult to obtain with currently available technology.

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