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Uniaxial Biomechanical Properties of 7 Different Vaginally Implanted Meshes for Pelvic Organ Prolapse

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Abstract

Introduction and Hypothesis—Recently, numerous Type I macroporous polypropylene vaginal meshes have been introduced into the market with little known of their differences.

Methods—Seven vaginal meshes were obtained and loaded to failure (N=5/type). Additional cyclic loading determined permanent deformation with submaximal loading.

Results—The load-elongation curves demonstrated a bilinear response with lower stiffness (N/mm), followed by higher stiffness. AscendTM was the stiffest mesh in both regions of the load-elongation curve (0.72 N/mm, 1.66 N/mm) with the lowest transition to higher stiffness (13.4%). PolyformTM had the highest failure load (53.8 N) while UltraproTM had the lowest (7.83 N). NovasilkTM (89.4%) and UltraproTM (87.9%) had the highest relative elongations at mesh failure while AscendTM had the lowest (40.2%). AscendTM had the least relative elongation after 3 protocols of cyclic loading (3.0%, 9.8%, 9.7%).

Conclusion—Current vaginal meshes demonstrate marked variation in biomechanical characteristics which may impact their in vivo behavior.

Keywords

Pelvic Organ Prolapse; Polypropylene Mesh; Prolapse; Mesh; Vaginal Mesh; Vaginal Reconstructive Surgery

Introduction

Pelvic organ prolapse is a common problem with prolapse occurring in up to 50% of parous women.[1] By age 80, 11% of women will have had surgery for either pelvic organ prolapse

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(POP) or stress incontinence, with 1/3 requiring a second operation.[2] It is also expected that urogynecological care will escalate 45% between the years 2000 and 2030.[3] This is a significant and costly health care burden amounting to a direct cost already exceeding \$1 billion in the United States alone.[4]

Synthetic meshes are commonly used as a permanent structural support to repair POP as autologous tissue repair has been associated with failure rates in excess of 30%. [5–8] This is thought to be because native tissue repairs utilize already weakened tissue and consequently fail to address the mechanism that initially caused failure. Thus, it is not surprising that the use of synthetic meshes was reported in 93% of abdominal sacral colpopexies and 58% of vaginal reconstructive procedures.[9]

Despite its widespread acceptance and use, synthetic meshes have had little regulatory oversight. While federal laws have mandated oversight and pre-market approval of medical devices through the 1976 Medical Device Amendments Act, most meshes used in pelvic surgery are not subject to this jurisdiction as they are considered 510 (k) devices, i.e. a device that is based on a similar device that was in use prior to 1976-- in this case, hernia meshes. This is especially alarming now that the FDA released of a public health warning on October 21, 2008 citing a high rate of complications with the use of synthetic meshes following urogynecological implantation. The list of complications includes acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia limiting sexual activity.[15–17] Thus, research on the impact of synthetic meshes on clinical outcomes is sorely needed. This starts with lab-based studies, especially on newer mesh products and designs for which there is little clinical data.

More recently, textile advances have led to the development of lighter weight meshes which will reduce mesh burden and presumably be less stiff, allowing movement of the underlying and adjacent vagina, possibly decreasing erosion into adjacent structures and decreasing exposure in the vagina. The initial polypropylene mesh specific for prolapse repair was Gynemesh PS™ (Gynecare, Somerville, NJ) which was significantly lighter than traditional abdominal hernia repair meshes with a weight of 44g/m². It is currently used in the Gynecare Prolift™ kit. Unfortunately, weight alone is not the only factor that dictates the stiffness of a mesh and its burden on the vagina. Our lab and others have demonstrated that there is substantial variation amongst the various mesh products with similar weights used as midurethral sling surgeries that impact overall stiffness in uniaxial testing conditions.[12–14] Additional factors aside from mesh weight that affect the biomechanical behavior of meshes include the knit or weave pattern, heat sealing of edges, laser cutting, pore size etc.

While we do not currently know the optimal biomechanical properties for urogynecological meshes [10–11], industry appears to be moving in the direction of lighter weight, and presumably less stiff, designs with their newer generation meshes and mesh kits. These include IntePro Lite™ used in Elevate™, Apogee™, and Perigee™ (American Medical Systems (AMS), Minnetonka, Minnesota), Polyform™ used in Uphold™ and Pinnacle™ (Boston Scientific, Natick, MA), Ascend™ (Caldera Medical, Agoura Hills, CA), NovaSilk™ (Coloplast, Minneapolis, MN), and Smartmesh™ used in Minimesh™ and Restorelle™ (Mpathy Medical, Raynham, MA). Some even use additional technology to reduce the resultant mesh burden, such as Ultrapro™ used in Prolift +M™ (Gynecare, Somerville, NJ) which includes interwoven polyglactone 25 fibers which will resorb in the process of mesh incorporation by the host tissue.

We believe that part of the framework for understanding how a mesh behaves in tissue is understanding its basic ex vivo properties. Using a previously published protocol,[14,18] here we describe the uniaxial properties of vaginally implanted pelvic organ prolapse

meshes under a load-to-failure protocol. We also describe the permanent deformation of the meshes after sub-maximal repetitive cyclic loading seen at loads comparable to those seen in the immediate post-op period.[19] Our hypothesis is that newer generation meshes will demonstrate less stiff uni-axial properties than older meshes. We also believe there will be considerable differences in structural properties amongst the meshes used for vaginal repair of pelvic organ prolapse because of their distinct textile manufacturing. It is our goal that this data will provide the baseline information required for future studies of the mesh/tissue complex in vivo eventually leading to the development of improved meshes to reduce their health burden for women.

Materials and Methods

Support

Neither IRB or IACUC approval was required for this research as there were no human or animal subjects. The authors have no conflicts of interest or disclosures to report. This research was funded by a grant from the National Institute of Health, R01 HD061811-03.

Mesh Preparation

Sterile samples were provided by the manufacturers of 7 separate meshes for transvaginal implantation (AMS IntePro Lite™ as Elevate™, Boston Scientific Polyform™, Caldera Ascend™, Coloplast Novasilk™, Gynecare Gynemesh PS™ as Prolift™, Gynecare Ultrapro™ as Prolift +M™, and Mpathy Smartmesh™ as Minimesh™). Samples were removed from sterile packing and cut into 90×15 mm strips along the long axis of planned implantation direction in the vagina. This size was chosen in order to allow for a clamp to clamp distance of 75mm for a constant length to width aspect ratio of 5 to minimize the non-linear effects of clamping on the uni-axial biomechanical properties. With an fixed aspect ratio of 5, this was also the largest specimen that could be tested for some of the transvaginal meshes, and we wanted to maintain a constant area for all meshes. A total of 5 samples were obtained for each mesh (n=5) and separately tested.

Imaging and Porosity

Each mesh was imaged using a light microscope (Olympus, MVX10 MacroView). Images measuring 6.5×5.2 mm (n=4 per mesh) were used to capture the unique pattern and porosity of each mesh (see Figure 1). Porosity was calculated by overlaying a 10 × 12 grid of perpendicular lines on each image. The intersection points of the grid were then determined to either overlay mesh or empty space. The number of points overlaying the mesh and the total number of points were calculated. This provides the ratio of mesh to total volume (M/TV) which is related to the percent of empty space (1-M/TV). This is reported as porosity %.

Uniaxial Testing Protocol

We used a previously described protocol for testing the uniaxial properties of meshes. [12,14] All tests were performed using the Instron™ 4502 (Instron, Norwood, MA, USA) screw driven testing apparatus. All pieces of mesh were attached to custom tissue clamps with a 75 mm piece of mesh between clamps to maintain a constant aspect ratio of 5 for the tested specimen. One clamp was attached to the base of the testing device within a tank of normal saline (0.9% NaCl). The other was attached to the crosshead of the device via a load cell. The mesh was allowed to sit in the 37°C saline bath for 10 minutes prior to testing. A preload of 0.1 N was then applied to remove all slack from the mesh using a constant elongation of 10 mm/min, and the clamp-to-clamp distance was measured. This point was defined as an elongation of zero. A constant elongation rate of 50 mm/min was used to load

the mesh to failure along the longitudinal axis. The load and elongation were recorded throughout the testing period. Relative elongation was calculated by dividing the elongation by the clamp-to-clamp length after preload in order to normalize to the initial mesh length. Load was plotted against relative elongation, and the curves were noted to be bilinear (see Figure 2). There was a period of low stiffness (N/mm) which was defined as the minimum stiffness noted over an interval of 15% elongation. This was followed by a second period of high stiffness (N/mm) defined as the highest stiffness noted over an interval of 30% elongation. The point where these linear segments intersected was defined as the inflection point (%). Data was reported as low stiffness, high stiffness, percent elongation at inflection point as well as load at mesh failure (N) and percent elongation at mesh failure (%). We tested five samples of each type of mesh. Each mesh sample was repeated twice using this protocol and the mean value of each specimen was used for analysis.

Additionally a third piece of mesh from each sample underwent cyclic testing according to a previously described protocol.[12,14] The rationale for this test is that an implanted mesh will experience repetitive sub-failure loads in vivo due to activities which increase intra-abdominal pressure in the postoperative period. The mesh was attached to the Instron™ in the same manner as before with similar dimensions, equilibration time, and preload. After the preload was administered, the longitudinal axis was reset to zero elongation as a frame of reference for permanent mesh deformation. Cyclic loading of sub-maximal loads were applied to the mesh (see Figure 3). These were defined as C1 through C3 with 10 cycles each. Using a constant elongation of 50 mm/min, C1 cycled the load from 0.5 N to 5 N, C2 cycled from 0.5 N to 15 N, and C3 cycled from 0.5 N to 5 N. After each interval (C1-C3) a 0.1 N preload was reapplied and the permanent deformation was assessed as the elongation from the zero point defined after the initial preload. We report the normalized percent elongation relative to the clamp-to-clamp length of the mesh after the initial preload.

Statistics

The chosen sample sizes were based on data from a previous study on Gynecare TVT™ midurethral slings.[12] Five samples per group were needed to detect a minimum of 100% difference in low stiffness, 15% difference in the inflection point, and 75% difference in permanent elongation between Gynecare and other brands with 80% power. A one-way analysis of variance (ANOVA) was used to assess differences between groups for each outcome variable. Post hoc comparisons were performed correcting for multiple comparisons using Sidak for variables that had equal variances and Dunnett T3 for variables with unequal variance.

Results

Our testing demonstrated vast differences among the seven meshes tested. The results are summarized in Tables 1 and 2. As the p-value for the one-way ANOVA for all properties tested was <0.001, multiple statistical comparisons were subsequently performed. Due to the desire to perform all pairwise comparisons, there were a large number of multiple comparisons. The p-values from the multiple comparisons are available in Appendices 1 and 2.

Figure 1 illustrates the gross pattern that is unique for each type of mesh. Light microscopy showed that Mpathy Smartmesh™ was 10.6 to 26.7% more porous than all other meshes (all p-values 0.002). Caldera Ascend™ was the least porous mesh at $51.2 \pm 4.4\%$, although it was not statistically different from Boston Scientific Polyform™ ($p=0.53$). The remaining four meshes were similar in their porosity.

After the uniaxial load-to-failure protocol, all meshes demonstrated a bilinear response to elongation as illustrated by a representative curve in Figure 2. There was a linear period of low stiffness, which was followed by an inflection point after which a linear period of higher stiffness was seen. These parameters are reported as the low stiffness, high stiffness and inflection points. We also report the relative elongation at the inflection point as well as the load at mesh failure and relative elongation at mesh failure in Table 1.

Physiologic stresses most likely correspond to stretch within the low stiffness range. Ascend™ had the largest low stiffness value although it was not significantly different from Gynecare Gynemesh PS™. All other meshes were less stiff than Ascend™ and Gynemesh PS™. Ultrapro™ was by far the least stiff mesh in the low stiffness range. All other meshes ranged from 7.9 to 80.4 times more stiff than Ultrapro™.

Ascend™ was also the most stiff mesh in the high stiffness range of the load-elongation curve, although it was not significantly different from Polyform™. All other meshes demonstrated high stiffness values which were significantly lower than Ascend™. Ultrapro™ was the least stiff mesh in the high stiffness region of the load-elongation curve, and it was significantly less stiff than all other meshes studied. Ultrapro™ had the lowest failure load which was significantly lower than all other meshes (Table 1). The highest load at mesh failure was seen with Polyform™ and it was significantly higher than all other meshes.

We also report permanent deformation of the mesh after a series of cyclic loadings in Table 2. Permanent deformation of the mesh is demonstrated by the right shift of the load-elongation curve with cyclic loading (Figure 3). Meshes were subjected to cyclic loading with a load of 5 N or 1.1 lbs (C1), followed by 15 N or 3.4 lbs (C2), followed by 5 N once again (C3). In general meshes demonstrated greater elongation with 15 N than 5 N. However, after the mesh was permanently deformed with 15 N, additional cyclic loading with 5 N caused minimal additional elongation. The least stiff mesh, Ultrapro™ demonstrated the greatest permanent deformation with cyclic loading. However, due to its relatively low failure load, 2 out of 5 specimens failed during the initial cyclic loading protocol (C1) and were not available to undergo C2 and C3. All other Ultrapro™ samples failed during the C2 cyclic protocol (15 N maximum). Coloplast Novasilk™ demonstrated the second greatest elongation after C1. Due to the failure of Ultrapro™, Novasilk™ had the greatest deformation with C2 and with C3. However, as a result of large standard deviations seen with Novasilk™ this difference was not statistically different from any of the other meshes for either C2 or C3. Ascend™ was found to be the least deformable after all three cyclic protocols. This deformation was significantly less than the prototypical Gynemesh PS™ which had the second lowest permanent deformation for all three protocols. All other meshes demonstrated significantly greater permanent deformations than either Ascend™ or Gynemesh PS™ with cyclic loading for all 3 protocols.

Discussion

Our testing protocol demonstrated that there was significant heterogeneity among the meshes designed for vaginal implantation of repair of pelvic organ prolapse. We were able to show that most meshes were less stiff than the prototypical pelvic mesh, Gynemesh PS™. This finding was not unanticipated, as newer meshes have been engineered to be less stiff than their older counterparts. It is also interesting that Ultrapro™ was the least stiff mesh. It is manufactured by Gynecare who also manufactures the prototypical pelvic mesh, Gynemesh PS™, which is one of the stiffer meshes tested. Even within a single company, newer meshes are less stiff.

We were able to detect significant differences among the meshes for the various biomechanical properties despite performing multiple statistical comparisons. With 7 different meshes, we were required to perform 21 comparisons for each property in order to evaluate all possible pairwise comparisons. With the subsequent adjustment of p-values, this would likely diminish our ability to find differences between the meshes. However, differences were still seen which further reinforces the heterogeneity of these meshes.

The total number of comparisons performed was 156 for all biomechanical properties. There was no statistical difference for 41 of them, and 31 of these involved Novasilk™. This is likely attributable to the comparatively larger standard deviations seen with Novasilk. We feel this is related to the subjective deterioration of the individual fibers and fraying of the Novasilk™ mesh observed when force was applied. While there is no data to substantiate this observation, it was not seen with other meshes. It is unclear if this would have any clinical importance once the mesh was implanted as the fibers would be supported by tissue ingrowth. It is also unclear if this subjective fraying of the fibers would be seen with a larger piece of mesh than the 90×15 mm strip which was used. Possibly a piece of mesh the physiological size which would be implanted would not have this problem.

Our lab has previously published similar data for midurethral slings and abdominal prolapse meshes.[12, 14] Notably, some of the meshes used for abdominal prolapse repair are the same materials used in vaginal prolapse repair although many newer products were tested in this study. Our results are slightly different for the same materials published previously which is due to the change in aspect ratio of the tested mesh. In the previous paper on abdominal prolapse mesh an aspect ratio of 3:1 was employed with mesh pieces 15×5 cm as this was a representative size of mesh for abdominal sacral colpopexy. In the current study we have adjusted the specimen size to maintain a minimum aspect ratio of 5:1 in order to minimize non-linear disturbances in the forces applied. Accounting for the changes in the aspect ratio and specimen area rationalizes the differences in the reported uniaxial properties from the previously published study. Results from the current and previous studies are all valid for comparing meshes within a single study but cannot be compared from one study to another with varying mesh dimensions.

It is important to note that this testing was done ex vivo and in a single dimension. Physiologic stresses are applied in more than a single dimension, and expose these synthetic meshes to a complex loading environment. After implantation meshes are typically incorporated into the host tissue, creating a mesh-tissue complex. This makes understanding the in vivo scenario difficult as each mesh originally exists as a separate structure approximated to tissue with sutures, but later becomes incorporated tissue ingrowth as a mesh-tissue complex. As such, this experimental set-up allows us to draw only preliminary conclusions about the various meshes. We are in the process of validating a ball-burst apparatus to test the 2-dimensional properties of the mesh as the machine used as the textile industry standard is much too large for pelvic meshes. These studies will allow us to better understand the behavior of these meshes under different loading conditions. Additionally, we are currently implanting these meshes into a rodent model with plans for subsequent testing of the mesh-tissue complex in both the uniaxial and biaxial planes which will help us characterize the in vivo properties of the mesh-tissue complex after tissue incorporation. It is likely that the variables of mesh size and aspect ratio, tissue ingrowth, attachment and anchoring technique, and host characteristics will all play an important role in final in vivo characteristics of the mesh-tissue complex.

Further research will need to correlate how these differences in biomechanical performance in the lab affect clinical outcomes. Historical data has shown that products such as Nylon, Marlex, and Gortex meshes experienced higher erosion rates and are now seldom used.

While these meshes had higher stiffness values than those currently being used, the erosion rates of these products is likely also related to other textile qualities such as pore size and braided/woven construction. Nonetheless, we were able to show the continuing trend towards lighter weight, less stiff mesh in newer products with this study. In contrast to this, Deffieux, et al. were unable to show a difference in erosion rates between Gynemesh™ (Gynecare, Somerville, NJ) and the second-generation product Gynemesh PS™ after mesh-augmented transvaginal cystocele repair.[20] We reported properties for Gynemesh PS™ in this study, and while it is one of the stiffer meshes studied, it is lighter and less stiff than its predecessor Gynemesh™. Ultimately, in vivo animal studies and aftermarket human subject trials will be necessary to show how the different properties of the meshes and mesh-tissue complexes affect complications.

In conclusion we have shown that there are marked differences amongst the meshes used for vaginal repair of pelvic organ prolapse. Most newer generation meshes are less stiff than the prototypical pelvic mesh, Gynemesh PS™, in both the high and low stiffness areas of the load elongation curve. The one exception to this is Caldera Ascend™ which was significantly more stiff with an earlier transition to the high stiffness region. Future studies are underway in our lab to study the biaxial properties of these meshes and examine the in vivo properties after mesh implantation. It will then be important to see how this information correlates with clinical outcomes such as mesh erosions and surgical failures.

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AMS IntePro Lite

Boston Scientific
Polysorb

Caldera Ascend

Coloplast
Novosilk Gynecare
Gynemesh PS Gynecare
UltraPro Mpathy
Smartmesh

Figure 1.
Microscopic images with unique pattern and porosity of each mesh

Figure 2.
Representative load-elongation curve after incremental load to failure

Figure 3.
Representative load-elongation curve with submaximal cyclic loading

Table 1

Uni-axial Properties of Vaginally Inserted Pelvic Organ Prolapse Meshes

Mesh	Porosity (%) ^b	Low Stiffness (N/mm) ^c	High Stiffness (N/mm) ^b	Relative Elongation at Inflection Point (%) ^c	Load at Mesh Failure (N) ^b	Relative Elongation at Failure (%) ^c
AMS Intepro Lite™	66.9 ± 0.96	0.071 ± 0.01	0.934 ± 0.04	33.9 ± 1.0	27.2 ± 1.9	67.6 ± 2.1
Boston Scientific Polyform™	56.0 ± 3.2	0.130 ± 0.01	1.42 ± 0.11	39.9 ± 1.5	53.8 ± 4.8	86.5 ± 2.4
Caldera Ascend™	51.3 ± 4.4	0.724 ± 0.20	1.66 ± 0.26	13.4 ± 2.1	41.1 ± 5.3	40.2 ± 2.0
Coloplast NovaSilk™	67.3 ± 3.8	0.072 ± 0.05	0.508 ± 0.09	44.6 ± 7.5	19.6 ± 4.5	89.4 ± 21.4
Gynecare Gynemesh PS™	62.1 ± 3.2	0.286 ± 0.02	1.37 ± 0.09	25.0 ± 0.89	46.3 ± 2.6	66.7 ± 4.6
Gynecare Ultrapro™	66.7 ± 1.5	0.009 ± 0.00	0.236 ± 0.02	46.5 ± 5.2	7.83 ± 0.7	87.9 ± 5.6
Mpathy Smartmesh™	77.9 ± 1.4	0.178 ± 0.03	0.592 ± 0.04	29.2 ± 1.0	22.7 ± 1.8	68.5 ± 2.5
Overall P^a	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

^aOverall P values from one-way analysis of variance^bMultiple comparisons performed using Sidak correction (equal variances)^cMultiple comparisons performed using Dunnett T3 (unequal variances)

Table 2

Permanent Deformation After Cyclic Sub-maximal Loading

Mesh	Relative Elongation After C1 (%) ^b	Relative Elongation After C2 (%) ^b	Relative Elongation After C3 (%) ^b
AMS IntePro Lite™	16.5 ± 0.95	37.0 ± 2.4	38.1 ± 2.3
Boston Scientific Polyform™	10.9 ± 1.2	28.6 ± 1.6	28.8 ± 1.5
Caldera Ascend™	3.00 ± 0.44 ^c	9.84 ± 0.70 ^c	9.72 ± 0.07 ^c
Coloplast NovaSilk™	26.5 ± 9.2	50.8 ± 12.9 ^b	52.8 ± 14.4 ^b
Gynecare Gynemesh PS™	5.66 ± 1.1	17.2 ± 1.8	18.5 ± 3.2
Gynecare Ultrapro™	44.3 ± 3.6 ^d	n/a ^e	n/a ^e
Mpathy Smartmesh™	12.8 ± 2.0	37.4 ± 3.7	38.2 ± 3.5
Overall P^a	<0.001	<0.001	<0.001

^aOverall P values from one-way analysis of variance

^bMultiple comparisons performed using Dunnett T3 (unequal variances)

^cResults not available/ invalid for 2 of 5 tests (n=3)

^d2 of 5 Ultrapro™ meshes failed prior to completion of C1 (n=3)

^eAll Ultrapro™ meshes failed prior to completion of C2

Appendix 1

Multiple Comparison p-values of Uni-axial Properties of Vaginally Inserted Pelvic Organ Prolapse Meshes

Mesh	Porosity (%) ^a	Low Stiffness (N/mm) ^b	High Stiffness (N/mm) ^a	Relative Elongation at Inflection Point (%) ^b	Load at Mesh Failure (N) ^a	Relative Elongation at Failure (%) ^b
IntePro Lite™ vs. Polyform™	0.003	<0.001	<0.001	0.002	<0.001	<0.001
IntePro Lite™ vs. Ascend™	<0.001	0.019	<0.001	<0.001	<0.001	<0.001
IntePro Lite™ vs. NovaSilk™	1.000	1.000	<0.001	0.260	0.039	0.540
IntePro Lite™ vs. Gynemesh PST™	0.632	<0.001	<0.001	<0.001	<0.001	1.000
IntePro Lite™ vs. Ultrapro™	1.000	0.002	<0.001	0.047	<0.001	0.007
IntePro Lite™ vs. Smartmesh™	0.002	0.004	0.002	0.001	0.683	1.000
Polyform™ vs. Ascend™	0.529	0.027	0.076	<0.001	<0.001	<0.001
Polyform™ vs. NovaSilk™	0.001	0.426	<0.001	0.920	<0.001	1.000
Polyform™ vs. Gynemesh PST™	0.189	<0.001	1.000	<0.001	0.038	0.002
Polyform™ vs. Ultrapro™	0.001	<0.001	<0.001	0.351	<0.001	1.000
Polyform™ vs. Smartmesh™	<0.001	0.125	<0.001	<0.001	<0.001	<0.001
Ascend™ vs. NovaSilk™	<0.001	0.016	<0.001	0.005	<0.001	0.060
Ascend™ vs. Gynemesh PST™	0.001	0.078	0.011	0.001	0.431	0.001
Ascend™ vs. Ultrapro™	<0.001	0.014	<0.001	<0.001	<0.001	<0.001
Ascend™ vs. Smartmesh™	<0.001	0.035	<0.001	<0.001	<0.001	<0.001
NovaSilk™ vs. Gynemesh PST™	0.391	0.004	0.000	0.038	<0.001	0.511
NovaSilk™ vs. Ultrapro™	1.000	0.344	0.024	1.000	<0.001	1.000
NovaSilk™ vs. Smartmesh™	0.001	0.068	0.999	0.088	0.980	0.581
Gynemesh PST™ vs. Ultrapro™	0.603	<0.001	<0.001	0.006	<0.001	0.003
Gynemesh PST™ vs. Smartmesh™	<0.001	0.002	<0.001	0.002	<0.001	0.999
Ultrapro™ vs. Smartmesh™	0.001	0.001	0.001	0.014	<0.001	0.007

^aMultiple comparisons performed using Sidak correction (equal variances)

^bMultiple comparisons performed using Dunnett T3 (unequal variances)

Appendix 2

Multiple Comparison p-values of Permanent Deformation After Cyclic Sub-maximal Loading

Mesh	Relative Elongation After C1 (%) ^a	Relative Elongation After C2 (%) ^a	Relative Elongation After C3 (%) ^a
IntePro Lite™ vs. Polyform™	0.001	0.004	0.002
IntePro Lite™ vs. Ascend™	<0.001	<0.001	<0.001
IntePro Lite™ vs. NovaSilk™	0.478	0.684	0.710
IntePro Lite™ vs. Gynemesh PS™	<0.001	<0.001	<0.001
IntePro Lite™ vs. Ultrapro™	0.023	n/a ^b	n/a ^b
IntePro Lite™ vs. Smartmesh™	0.115	1.000	1.000
Polyform™ vs. Ascend™	<0.001	<0.001	<0.001
Polyform™ vs. NovaSilk™	0.160	0.378	0.393
Polyform™ vs. Gynemesh PS™	0.001	<0.001	0.007
Polyform™ vs. Ultrapro™	0.014	n/a ^b	n/a ^b
Polyform™ vs. Smartmesh™	0.739	0.033	0.020
Ascend™ vs. NovaSilk™	0.042	0.134	0.148
Ascend™ vs. Gynemesh PS™	0.037	0.003	0.020
Ascend™ vs. Ultrapro™	0.011	n/a ^b	n/a ^b
Ascend™ vs. Smartmesh™	0.002	<0.001	<0.001
NovaSilk™ vs. Gynemesh PS™	0.063	0.189	0.216
NovaSilk™ vs. Ultrapro™	0.105	n/a ^b	n/a ^b
NovaSilk™ vs. Smartmesh™	0.231	0.712	0.718
Gynemesh PS™ vs. Ultrapro™	0.010	n/a ^b	n/a ^b
Gynemesh PS™ vs. Smartmesh™	0.005	<0.001	<0.001
Ultrapro™ vs. Smartmesh™	0.008	n/a ^b	n/a ^b

^aMultiple comparisons performed using Dunnett T3 (unequal variances)

^bPost hoc comparison not performed due to insufficient cases with Ultrapro™

Notes:

Caldera Ascend™ results were not available/ invalid for 2 of 5 tests (n=3)

Ultrapro™ meshes failed prior to completion of C1 in 2 of 5 tests (n=3)

Ultrapro™ meshes all failed prior to completion of C2 (n=0)