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Integrating a novel shape memory polymer into surgical meshes decreases placement time in laparoscopic surgery: An *in vitro* and acute *in vivo* study

Michael M. Zimkowski¹, Mark E. Rentschler², Jonathan Schoen³, Bryan A. Rech¹, Nageswara Mandava⁴, and Robin Shandas¹

¹Department of Bioengineering, University of Colorado Denver & Anschutz Medical Campus, 12700 East 19th Avenue, RC2, Aurora, Colorado 80045

²Department of Mechanical Engineering, University of Colorado Boulder, 12700 East 19th Avenue, RC2, Aurora, Colorado 80045

³Department of Surgery, University of Colorado Anschutz Medical Campus, 12700 East 19th Avenue, RC2, Aurora, Colorado 80045

⁴Department of Surgery, Flushing Hospital Medical Center, Flushing, New York

Abstract

About 600,000 hernia repair surgeries are performed each year; recently, the use of laparoscopic minimally invasive techniques has become increasingly popular in these operations. Use of surgical mesh in hernia repair has shown lower recurrence rates compared to other repair methods. However in many procedures, placement of surgical mesh can be challenging and even complicate the procedure, potentially leading to lengthy operating times. Various techniques have been attempted to improve mesh placement, including use of specialized systems to orient the mesh into a specific shape, with limited success and acceptance. In this study, a programmed novel Shape Memory Polymer (SMP) was integrated into commercially available polyester surgical meshes to add automatic unrolling and tissue conforming functionalities, while preserving the intrinsic structural properties of the original surgical mesh. Tensile testing and Dynamic Mechanical Analysis was performed on four different SMP formulas to identify appropriate mechanical properties for surgical mesh integration. *In vitro* testing involved monitoring the time required for a modified surgical mesh to deploy in a 37°C water bath. An acute porcine model was used to test the *in vivo* unrolling of SMP integrated surgical meshes. The SMP-integrated surgical meshes produced an automated, temperature activated, controlled deployment of surgical mesh on the order of several seconds, via laparoscopy in the animal model. Results indicate surgical mesh modified with SMP is capable of laparoscopic deployment *in vivo*, activated by body temperature. This suggests a reduction in surgical operating time and improved mesh placement characteristics is possible with SMP-integrated surgical meshes.

Keywords

shape memory polymer; hernia repair; mesh placement; surgical mesh; laparoscopic surgery

INTRODUCTION

Hernia repair surgery is one of the more common surgical procedures, with more than 600,000 hernia repair operations performed annually in the United States.¹ Hernia repair often involves tissue reinforcement, and these original abdominal wall tissue reinforcement ideas date back to Phelps in 1894, with the introduction of using silver wire coil on the floor of the inguinal canal.² Most recently, as synthetic polymers became more popular as biomaterials, their use as a reinforcement mesh became a natural step since they provide more flexibility than metal predecessors. The three main types of modern synthetic meshes are polypropylene, polyester, and expanded polytetrafluorethylene (ePTFE).² Newer meshes also include absorbable and composite types. Absorbable meshes are designed to break down over time, eventually being replaced with natural tissue. Composite types combine two materials, such as ePTFE and polypropylene.

Minimally invasive laparoscopic surgery has become increasingly popular in recent years and is often used to decrease surgical trauma and recovery time, including in hernia repair procedures.^{1,3} In the United States, 4–5 million laparotomies are performed annually; approximately 20% of these involve incisional hernias (~400,000 to 500,000/year).⁴ Evaluating post-laparoscopic surgery outcomes has confirmed that significantly reduced morbidity and lower recurrence rates can be achieved by reinforcing the tissue with a surgical mesh. A 10-year follow-up showed the cumulative rate of recurrence was 63% for suture only repair and 32% for repairs including mesh.⁴ In patients with small incisional hernias, the recurrence rate was 67% with a suture repair and 17% with a repair including mesh.⁴ Clearly, the use of mesh and laparoscopic techniques has made an important impact in reducing recurrence and surgical complications of hernia repair procedures. However, in some laparoscopic hernia repair procedures, placement of surgical mesh can present a challenge and even complicate the procedure.⁵ The surgical mesh must be rolled and folded into a cannula port, inserted into an abdominal port and released into the abdominal area to be repaired. Once in the abdominal cavity, the surgical mesh must be unrolled, formed to fit the anatomy and attached with sutures, or by a variety of other means. Unrolling and tamping of the surgical mesh can require significant amounts of time, which may increase surgical complications such as recurrence, infection or pain. Various techniques have been attempted to make mesh placement easier, including use of specialized geometry or manufacturing reinforcement rings to push mesh into a specific shape, with limited success.⁶ Perhaps the most well-known example is the Davol Bard® Composix® Kugel® patch, which was voluntarily recalled due to risk of breakage resulting in potentially dangerous complications.⁷ This patch utilized a stiff polymer bent to accommodate the cannula port and which was subsequently released into the abdominal cavity wherein elastic memory snapped the mesh into place. Reports of patient injury began to surface in 2002 and problems ultimately led to a series of FDA recalls from 2005 to 2007.⁷ The failure cause was eventually traced to a weld of the polyethylene terephthalate (PET—commonly called

polyester) ring.⁶ Another example of adding shape memory functionality to a surgical mesh is the Davol Bard® Polysoft®, which utilizes a polyester/PET ring.⁸ Both materials utilize elastic memory to “snap” the hernia mesh into position, an intrinsically dangerous process since the deployment is uncontrolled. The SMPs used in this study have highly tailorable features including thermally triggered deployment, precise control of deployment time, and precise control of mechanical stiffness, which may provide a more useful solution to the problem of self-deploying hernia meshes.

A shape memory polymer (SMP) can be used to obtain controlled deployment. A SMP is a classification of polymers that provide tailorable mechanical functionalities, are capable of active movement into pre-programmed shapes, and can be compressed into a small shape and later unfolded into a functional shape using a trigger, such as temperature.^{9,10} This study focuses on introducing a novel thermally activated SMP, which can be applied to commercially available surgical meshes using an ultra-violet (UV) polymerization process. SMPs have gained increased notice over the past several years as potential biomaterials for minimally invasive surgical devices.^{9,10} SMPs are defined by the ability to recover large deformations from a storage state in response to an environmental stimulus,⁹ and have already been used for orthopedic, cardiovascular and ophthalmic applications, showing good biocompatibility and tissue ingrowth.⁹

The aim of this study was to develop a SMP formula that could be integrated into surgical meshes, and provide the capability of laparoscopic deployment, with unassisted *in vivo* unrolling. Design criteria for the SMP to be integrated into surgical mesh required an ability to activate upon exposure to body temperature, with high strain to failure while imposing minimal change on the native mechanical strength of the mesh. Four SMP formulas were evaluated using the following tests: uniaxial tensile tests; dynamic mechanical analysis (DMA); and measurement of time-to-unroll. Using these tests, two SMP formulas were identified which showed applicable glass transition temperature, and higher strain-to-failure. These two SMP formulas were tested *in vivo* using a porcine model to evaluate efficacy of laparoscopic deployment and unassisted unrolling.

MATERIALS AND METHODS

Creating the modified surgical mesh specimens was accomplished by integrating the novel SMP into a commercially available polyester mesh (PETKM14001, Textile Development Associates). Modified and unmodified surgical meshes were evaluated using DMA, tensile strength, time to unroll, and unrolling behavior in an acute animal model.

Synthesis

Chemicals *tert*-Butyl acrylate (tBA), butyl acrylate (nBA) and poly(ethylene glycol) dimethacrylate (PEGDMA) with average molecular weights of $M_n = 1000$ (PolySciences) and $M_n = 550$, and 2,2-dimethoxy-2-phenylacetophenone (DMPA) photo-initiator were obtained from Sigma-Aldrich, unless otherwise noted. Four polymer solutions were prepared by combining tBA, nBA, and PEGDMA as shown in Table I.

Polymer solution was applied to commercially available surgical meshes using a free radical UV-polymerization process. Similar combinations have been previously described by our group.^{9,11} Surgical meshes were placed in glass molds (75 mm by 25 mm) in a flat configuration, and SMP solution was injected. Glass molds were placed under a 365 nm UV lamp (Model B100AP; Black-Ray) for 10 min for photo-curing.

Dynamic mechanical analysis

Dynamic mechanical analysis (DMA) was performed in tensile loading to determine glass transition temperature (T_g) and storage modulus of all SMP formulations. A graphical representation of the DMA test is shown in Figure 1(a). DMA was performed using a TA Q800 DMA, after cutting a sample of each SMP formula into strips approximately 24 mm $\times$ 4 mm $\times$ 1 mm. The samples were thermally equilibrated at 0°C for 5 min and then heated to 100°C at a rate of 3°C/min. Testing was performed in cyclic strain control at 0.1% strain and at a frequency of 1.0 Hz. A preload force of 0.01N and a force track setting of 125% were used. T_g was defined at the peak of the tan delta curve.

Uniaxial tensile tests

Uniaxial tensile tests were based upon ASTM Test Method D638-03, using Type V specimen geometry. This test procedure was similar to that outlined by Deeken et al. in 2011.¹² Specimens measuring approximately 9.5 mm $\times$ 63.5 mm $\times$ 1 mm were cut using a D638-03 Type-V cast steel die (North East Cutting Die Corporation, Portsmouth, NH, USA). A graphical representation of the uniaxial tensile test is shown in Figure 1(b).

Tensile tests were performed using an Insight 5SL test machine (MTS, Eden Prairie, MN, USA), in an aqueous environmental chamber at 37°C with the specimen immersed in deionized water, using a tension rate of 5 mm/min. SMP formulas alone, unmodified mesh materials and modified mesh materials with integrated SMP were tested.

Time to unroll in water

Developing a useful SMP for deploying a surgical mesh necessitates *in vivo* unrolling within a reasonable time, however the mesh should not unroll readily at typical operating room temperatures. The time required for modified meshes to unroll was evaluated to determine the impact of adding SMP, as a function of temperature, similar to protocols previously described.^{9,13,14} SMP modified mesh specimens approximately 75 mm $\times$ 25 mm were prepared as previously described, and each specimen was heated using hot water (>65°C) to bring the sample into the rubbery region. The sample was rolled tightly by hand and cooled using cold water (<7°C) to bring the sample into the glassy region to retain the rolled configuration. Using soft tipped forceps, each rolled mesh formula was individually deployed into a deionized water bath held at approximately 37°C, to simulate introduction into a wet surgical environment. The elapsed time for unassisted unrolling was recorded by video. A schematic of this process is shown in Figure 2.

Acute animal study

This study was conducted under a test protocol approved by the Institutional Animal Care and Use Committee (IACUC protocol 87,909(05)1D), and the experiment was performed in

a single live female porcine model. The swine was anesthetized and secured in a supine position. Several laparoscopic ports were inserted to perform experiments within the abdominal cavity. At the completion of testing, the animal was euthanized by anesthesia overdose.

Formula C and D were chosen for the acute swine model test due to characteristics identified in tensile and DMA testing. Surgical meshes were placed in glass molds (100 mm × 100 mm) in a flat configuration, and SMP solution was injected, and subsequently cured using ultraviolet energy. After synthesis, modified and unmodified surgical mesh specimens were cut to approximately 70 mm × 70 mm to ensure uniform shape and size. Formula C specimen had a thickness of 0.68 mm, and formula D specimen had a thickness of 1.0 mm. Final specimens were steam sterilized by a standard autoclave system.

The surgical procedure consisted of placing two SMP-modified meshes (formula C and D) against the porcine abdominal wall using standard intraperitoneal laparoscopic approach. Intra-abdominal cavity temperature was monitored before insertion of each mesh using a thermometer (HH506RA, Omega). No peritoneal defect was created in this study. Modified surgical meshes were submerged in sterile water heated to 50°C, rolled to fit into a cannula port and cooled by submerging in sterile water cooled to less than 20°C. The SMP-modified meshes retained the rolled shape, and were inserted into the abdominal cavity of the swine using a 12-mm laparoscopic cannula port. The surgeon (Schoen) positioned the modified mesh on the intestines, and awaited automated unrolling as the temperature of the modified mesh increased to that of the abdominal cavity. Both meshes were secured using 5-mm tacks (Protack, Covidien) at four corners to evaluate feasibility of tack usage with added thickness of SMP. The thicker formula D-modified mesh was punctured twice using a suture grasper (Proxy Biomedical) to evaluate feasibility of penetration properties.

RESULTS

Dynamic mechanical analysis

A sample of each SMP formula was characterized by storage modulus and the tan delta curve. The glass transition temperature (T_g) was determined to be the peak of the tan delta curve. Results are shown in Figure 3.

The storage modulus of formula A ranged from 1528.5–3.6 MPa, formula B ranged from 1298.1–4.1 MPa, formula C ranged from 1176.7–2.7 MPa, and formula D ranged from 970.7–2.3 MPa. The glass transition temperature of formula A was found to be 57°C, formula B was found to be 37°C, formula C was found to be 47°C, and formula D was found to be 44°C.

Uniaxial tensile tests

Uniaxial tensile tests were performed to characterize the tensile strength of SMP alone, unmodified mesh alone, and SMP-modified meshes. Tensile test results are shown in Table II, with sample size denoted “n”.

At high strain the SMP modified mesh behaved more like the control sample, in that SMP began separating from the mesh and mesh fibers engaged similar to that of the tensile test of the unmodified mesh. For this reason, SMP alone was tested to ensure maximization of strain-to-failure. The strain-to-failure of SMP itself is shown in Figure 4.

It was observed that higher strain-to-failure reduced the separation observed between SMP and mesh. Combining lower tensile strength and higher strain-to-failure in SMP-modified meshes suggests the SMP has less impact on the mechanical strength of the mesh itself, allowing deformation to occur in a similar manner to that of unmodified mesh. A Student's *t*-test was used to compare strain-to-failure of the control (mesh alone) and each SMP-modified mesh composite. No statistical difference between strain-to-failure of the control and mesh modified with SMP was observed, as shown in Figure 5.

Time to unroll in water

The time required for each formula to actively unroll the surgical mesh from the rolled configuration to the fully deployed configuration is shown in Figure 6.

Acute animal study

The acute animal study was performed to evaluate the feasibility of an SMP-modified mesh, automated unrolling and the effect of the added SMP on tacking and suturing the mesh. Each SMP-modified mesh was inserted through a 12-mm laparoscopic port, positioned and tacked in place at the discretion of the surgeon (Schoen). While monitoring intra-abdominal cavity temperature over the duration of the procedure, a nominal temperature of 37.5°C was noted. Each modified mesh was submerged in sterile water held at 50°C, which allowed the modified mesh to be rolled into a tight configuration. The rolled mesh was then cooled by submerging in sterile water cooled to less than 20°C. In the rolled configuration, both formulas C and D meshes were easily inserted through the cannula port and manipulated using common laparoscopic tools, similar an unmodified mesh. Upon insertion into the abdominal cavity, the formula C mesh did not unroll automatically, and required considerable manipulation to achieve a flat configuration prior to tacking to the abdominal wall, believed to be a result of the higher T_g . The formula D mesh however, did unroll automatically, and required significantly less manipulation. *In vivo* unrolling of formula C mesh is shown in Figure 7, unrolling of Formula D is shown in Figure 8. A yellow arrow identifies the thermocouple.

DISCUSSION

In several laparoscopic hernia repair procedures, placement of surgical mesh can present a challenge and even complicate the procedure.⁵ The surgical mesh must be rolled and folded into a cannula port, inserted into an abdominal port and released into the abdominal area to be repaired. Once in the abdominal cavity, the surgical mesh must be unrolled, formed to fit the anatomy and attached with sutures, tacks, or other means. The unrolling and fitting process can require significant time, which may increase the risk of surgical complications such as recurrence, infection or pain. We hypothesized that integrating a programmed novel SMP into existing mesh fabrics could produce a more controlled delivery of surgical mesh

via laparoscopy. SMPs can elegantly provide significant advantages over elastic memory because they have highly tailorable features including thermally triggered deployment, precise control of deployment time, and precise control of mechanical stiffness. These advantages can provide a more useful solution to the application of self-deploying hernia meshes. SMPs can recover strains on the order of several hundred percent.¹⁵ This specialized strain recovery capability makes SMPs well suited to surgical mesh applications because current meshes must be rolled tightly for insertion through a cannula port, then formed to fit the anatomy in a flat or curved configuration.

When developing a composite SMP–mesh for a surgical mesh application the desired performance characteristics must be identified. In the case of hernia repair meshes, the integrated SMP is not required to impart significant strength since the native surgical mesh already adequately performs this task, but the SMP must be flexible and allowed to deform with the mesh. Important design criteria for this SMP application include providing high strain to failure, while providing *in vivo* compliance similar to that of an unmodified mesh. In addition, bowel adhesions must be hindered to avoid fistula formation or other complications.

Another important consideration when developing an SMP formula is proper tailoring of T_g . In biomedical SMP applications, it is often advantageous to set the T_g at or slightly above body temperature.¹⁵ For the surgical mesh application, a formula previously described by our group was used as the starting point.⁹ Formula A consisted to 20% PEGDMA-550 and 80% tBA resulting in a T_g of 57°C. This T_g was determined to be too high, because at 37°C, the stiffness of this formula caused an increase in the tensile strength and reduction of strain-to-failure of the SMP–mesh composite compared to the control mesh itself. To lower T_g , nBA was added, creating formula B, which contained 20% PEGDMA-550, 15% nBA, and 65% tBA, resulting in a T_g of 37°C. Formula B showed poor performance with a 65% reduction in strain-to-failure. In creating formula C, the T_g was lowered to 47°C and strain-to-failure was increased 47% over formula B. Formula C consisted of 15% PEGDMA-550, 10% nBA, and 75% tBA. The lower percentage of PEGDMA-550 reduces the effective amount of cross-linking in the copolymer, allowing for the higher strain observed. Formula D was created to further improve strain-to-failure and lower T_g . This was accomplished by further reducing the effective amount of cross-linking in the copolymer by introducing longer PEGDMA chains by using 20% PEGDMA-1000 and 80% tBA. Formula D resulted in a T_g of 44°C.

Based on identified characteristics of T_g , tensile strength, strain-to-failure, and time-to-unroll, formula C and formula D were identified as best candidates for *in vivo* testing. In the case of Formula C PET-SMP-modified mesh, as shown in Figure 7, the modified mesh did not unroll automatically after 2 min. The mesh was ultimately opened and placed using laparoscopic tools, and attached using tacks (ProTack, Covidien). This failure is believed to be a result of the T_g for formula C being placed too far above body temperature. In the case of formula D PET-SMP-modified mesh, as shown in Figure 8, the modified mesh unrolled automatically over a period of 33 s after insertion. The mesh was placed against the porcine abdominal wall using laparoscopic tools and attached using tacks (ProTack, Covidien). The lower T_g of formula D provided a better match for an average abdominal cavity temperature

of 37.5°C, enabling the surgical mesh to automatically unroll, potentially improving mesh positioning and placement.

Bowel adhesion in any hernia repair procedure is a significant concern, and our group believes a partially coated mesh could serve well in prevention of tissue adhesion. Additionally, in some laparoscopic hernia repair procedures such as the totally extra-peritoneal (TEP) approach, the laparoscopic cavity is created between the abdominal wall and the peritoneum. Once the mesh is fixated in place, the peritoneum rests against the mesh, providing a barrier layer between the intestines and the mesh, reducing the risk of adhesion formation. Another laparoscopic approach, trans-abdominal pre-peritoneal (TAPP), does penetrate the peritoneum, creating a “flap” or “window” to the abdominal wall where the mesh is placed. The peritoneal “window” is closed, again creating a barrier layer between the intestines and the mesh, reducing the risk of adhesion formation. We feel the risk of adhesion or fistula formation is no greater than that of the base mesh itself.

The surgical mesh evaluated in this study is not an FDA-approved medical product; therefore, differences may exist between the polyester mesh used and current commercially available medical products. Another limitation of this study includes the manner in which the surgical meshes were integrated with the SMP. The meshes were completely encapsulated in SMP, which eliminates the porous structure of the surgical mesh. This resulted in a thicker mesh than typically desired for hernia repair applications; while the impact on tacking was small, the suture penetration was too laborious for human usage. This thicker, fully covered mesh is not feasible for a long-term *in vivo* biocompatibility due to the significant reduction in tissue ingrowth capacity, a requirement for hernia mesh success. However, it does illustrate that integrating a SMP within surgical mesh is possible. Specialized fabrication modalities or post-polymerization mechanical techniques may be used to ensure the porous structure, required for tissue ingrowth, is conserved with the SMP–mesh composite. Our group has previously performed cytotoxicity studies on the SMP itself, finding the SMP to be very benign.¹³ Additionally, studies are currently underway to investigate *in vivo* biocompatibility of the SMP–mesh composite. Another limitation of this study relates to the sterile packaging of the mesh in preparation for the acute animal study. The mesh became partially unrolled as a result of the steam sterilization method, and subsequently required reheating and cooling using sterile water, to roll the mesh to fit through the cannula port. This problem could be resolved by constraining the mesh in a rolled configuration during sterilization.

A SMP can provide an elegant method of deploying a hernia mesh from a laparoscopic cannula port. The acrylate-based SMP described by our group provides a T_g slightly above body temperature, strain to failure on the order of the commercially available polyester hernia mesh, and provides added functionality of automatic unrolling as the mesh reaches body temperature. This technology has the potential to provide a simple alternative to current products which use cumbersome mechanical techniques to unroll a mesh.

CONCLUSION

SMPs can be synthesized by controlling cross-linking and copolymer composition. A glass transition temperature close to human body temperature can offer several potential uses, including enabling self unrolling of the surgical mesh after laparoscopic delivery. We believe reducing the time required to unroll and tamp the surgical mesh may reduce overall operating time, and therefore reduce the likelihood of surgical complications. Existing surgical meshes could be improved with the application of a SMP, allowing them to automatically deploy as they reach normal body temperature in laparoscopic repair of hernias. Existing surgical meshes already provide adequate mechanical strength, therefore an integrated SMP is not required to provide significant mechanical strength, but significant strain to failure is desired, to allow flexibility and mesh movement *in vivo*. The maximum strain that can be achieved is related to cross-linking density of a copolymer, as shown by formula D. Formula D showed relatively low tensile strength, but provides a significant strain to failure with a T_g of a few degrees above human body temperature. Formula C with a slightly higher T_g showed significantly less unrolling capability, demonstrating proper design of the T_g greatly affects the viability of the copolymer. The next step in the development of this technology is applying SMP in specific geometry or orientation to provide adequate functionality and lightweight profile, while retaining the porous nature necessary for tissue ingrowth.

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FIGURE 1.
(a) DMA diagram (b) uniaxial tensile test diagram.

FIGURE 2.
Time to unroll test procedure.

FIGURE 3.

DMA of formulas tested, (a) storage modulus range: 1528.5–3.6 MPa, $T_g = 57^\circ\text{C}$; (b) storage modulus range: 1298.1–4.1 MPa, $T_g = 37^\circ\text{C}$; (c) storage modulus range: 1176.7–2.7 MPa, $T_g = 47^\circ\text{C}$; (d) Storage modulus range: 970.7–2.3 MPa, $T_g = 44^\circ\text{C}$.

FIGURE 4.
Strain-to-failure of SMP alone; formula C and D show superior T_g and strain-to-failure.

FIGURE 5.

No statistical difference is observed between the SMP-modified mesh and the control.

	T_g (°C)	Time to Unroll (s)
Formula A	57°C	113
Formula B	37°C	3
Formula C	47°C	23
Formula D	44°C	7

FIGURE 6.

Demonstration of unrolling (top panel) and time to unroll (bottom panel) for each of the formulas, in 37°C water bath. As T_g decreases, time to unroll also decreases. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 7.

Significant laparoscopic manipulation was required to facilitate unrolling of the Formula C PET-SMP surgical mesh within 150 s time ($T_g = 47^\circ\text{C}$). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 8.

Significantly less laparoscopic manipulation was required to unroll the Formula D PET-SMP surgical mesh ($T_g = 44^\circ\text{C}$). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

TABLE I

Polymer Networks Tested

	tBA (wt %)	nBA (wt %)	PEGDMA (wt %)
Formula A	80	0	20 ($M_n = 550$)
Formula B	65	15	20 ($M_n = 550$)
Formula C	75	10	15 ($M_n = 550$)
Formula D	80	0	20 ($M_n = 1000$)

TABLE II

Tensile Test Results

		T _g (°C)	Tensile Strength (N)	Strain to Failure (mm)	n
Control	PET mesh alone	–	16.65 ± 3.30	21.92 ± 3.76	14
Formula A	SMP alone	57°	15.96 ± 1.09	28.59 ± 3.78	6
	SMP + Mesh	–	28.10 ± 3.42	17.82 ± 1.25	6
Formula B	SMP alone	37°	3.96 ± 0.25	10.07 ± 0.57	9
	SMP + Mesh	–	19.62 ± 0.36	17.55 ± 1.46	6
Formula C	SMP alone	47°	5.75 ± 0.73	18.85 ± 1.50	10
	SMP + Mesh	–	22.50 ± 2.47	17.38 ± 1.85	6
Formula D	SMP alone	44°	7.15 ± 0.77	31.85 ± 3.69	7
	SMP + Mesh	–	17.45 ± 2.82	17.45 ± 3.35	6