XYBERCYL LABORATORIES

NEW MESH MATERIAL

THE FIRST

PERMANENT SYNTHETIC BIOLOGICAL

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Joel Gorman, M.D.

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Introduction – New Mesh Material

By Jack Graudenz, Director

"A Layman's Perspective"

***XyberCyl* Laboratories** has developed the first **permanent synthetic biological** method for treating ventral hernias. In development over the past ten years, ***XyberCyl's* New Mesh Material** has undergone steady development and is now on the verge of a breakthrough in solving the worldwide conundrum of ventral hernia disease.

At XyberCyl Laboratories, we have taken an "out-of-the-box" approach to problem solving bringing about the development of XyberCyl's patented **New Mesh Material**.

To paraphrase, if I may, the road to mesh failure/complications is paved with good intentions. However, the historical approach has been to develop a mesh solution and attempt to make it work. XyberCyl's approach has been to take something that works (based upon over 2,000 surgeries) and make it into a **New Mesh Material.**

Since the 1980's, surgical mesh in its various iterations has been the abdominal repair support method of choice. Unfortunately, and without exception, surgical meshes are recognized as foreign bodies – resulting in a series of undesirable consequences. These can include scarification, mesh shrinkage or even failure, chronic pain, chronic infection, adhesions – and, most importantly, inhibit natural healing.

The high degree of "failure" and its associated risk (>17% average failure rate for inguinal hernias; >35% for ventral hernias) is a compelling statistic. While "advances" in surgical mesh have been forthcoming on a regular basis (whether textile, solid, or biologic), the net results and issues remain the same, albeit in different degrees and with alternate reasons for failure.

The single most important issue in surgical mesh treatment of defects has been Foreign Body Reaction ("FBR"). It is true that attempts have been made to address this issue, in some instances with limited success. However, some surgical mesh solutions are actually dependent upon FBR for the solution to initially succeed. FBR is needed for strength (scar tissue) in the knitted non-absorbables – but it causes grave complications; less FBR only means less strength with clinical failures, and, in any case, less complications are only debatably achieved. FBR is also required to absorb the absorbable meshes (synthetic or animal) which are designed to later disappear to avoid FBR. Thus, they also are non-starters on that basis (and also on the basis that disappearing means recurrences). For historical completeness, we can explain that solid sheets having at most micro-pores did achieve a great reduction in FBR while maintaining strength – but at the expense of incorporation or tissue integration, where it failed, leading to detachment and often infection.

The idea of a "biological" is to cure the hernia (avoid recurrence) without complications. Or, to produce natural tissue healing (which the previous biologicals did by dissolving in a FBR that would replace them by scar tissue or natural tissue, in theory) without complications (agreed by all to be due to FBR). Thus, there is the obvious contradiction that all biologicals until now (animal and

synthetic) are dependent on FBR to avoid FBR! Much like the previous contradiction of the knitted synthetics, to avoid FBR by utilizing less material – causing mesh failure.

XyberCyl's **New Mesh Material** on the other hand is injection-molded resulting in a monofilament construction not unlike a crisscross of surgical threads (which we can all agree are invisible to a human body and do not induce FBR). Thus, it behaves like a "biologic" yet remains permanently in place to ensure full and complete natural healing. And, consequently, XyberCyl's **New Mesh Material** meets all published criteria for the optimum surgical mesh solution.

Two pre-clinical studies were undertaken pitting the **New Mesh Material** against two leading surgical mesh products. The results were quite compelling, providing substantive support to XyberCyl's **New Mesh Material** as the answer to the serious challenges facing the surgical community with respect to ventral hernia defect repair, as well as other applications.

The first porcine pre-clinical trial was an Open Study, where **New Mesh Material** and Prolene mesh were each implanted in animals in an onlay manner. For each mesh, two of the same type of mesh were implanted in different porcine subjects (i.e. selected animals with **New Mesh Material** and others with Prolene mesh). A control area was designated between each of the onlayed meshes in the animal (thus, FBR and natural healing related to a specific mesh could be directly compared in each animal with an untreated control area).

In the Open Study, the results were quite dramatic and profound. The table below summarizes the results of the Open Study.

Open Study		
Parameter	New Mesh Material	Prolene
Natural Healing	Robust	Inhibited
Inflammatory Response	No	Yes
Thickness of Healing Response	2.1 cm	0.8 cm
Healing Compared to Control	Equivalent	Significantly Less
Palapable Stiffening	No	Yes

In every category of comparison, the results with **New Mesh Material** were significantly and measurably better when compared to Prolene mesh. Detailed histologic studies further confirmed the observed results listed in the table above, underscoring the superiority of **New Mesh Material** in this study with respect to natural healing, total lack of FBR, healing response, and lack of scarified tissue.

The second porcine pre-clinical trial was a Laparoscopic Study, where **New Mesh Material** and Ventralight ST mesh were each implanted in animals laparoscopically. This study was carried out by the world-renowned surgical Dr. Salvatore Morales-Conde in Seville, Spain. In each of several animals in the study, either **New Mesh Material** or Ventralight ST mesh were implanted.

In the Laparoscopic Study as well, the results were quite dramatic and profound. The table below summarizes the results of the Laparoscopic Study.

Laparoscopic Study		
Parameter	New Mesh Material	Ventralight ST
Natural Healing	Yes	Suppressed
Integration - Surrounding Tissue	Yes	No
Shrinkage	0%	17%
Wrinkling/Folding	None	Prominent
Adhesions	None	None

In every category of comparison, the results with **New Mesh Material** were significantly and measurably better when compared to Ventralight ST mesh (with the exception of one category where the two meshes were equivalent). Detailed histologic studies further confirmed the observed results listed in the table above, underscoring the superiority of **New Mesh Material** in this study, in particular with regards to the total lack of shrinkage, wrinkling/folding, and adhesions. Furthermore, the absence of FBR with **New Mesh Material** was confirmed by its superiority in natural healing and integration within the surrounding tissue.

To summarize, the pre-clinical studies confirm that, as opposed to all current areal implants that cause a FBR that leads directly to encapsulation by scar tissue formation in the permanent synthetic knitted meshes (and never really resolves with chronic inflammation), or in the absorbable meshes that cause long lasting FBR that supposedly dissolves the mesh but certainly weakens it with increased recurrences, **New Mesh Material**:

- Causes no significant FBR
- Results in no encapsulation and no scar tissue
- Becomes fully incorporated within prolific physiological and well-integrated natural tissue

Moreover, the FBR of all previous meshes causes their contracture or shrinkage that results in hernia recurrence. The FBR also causes the mesh to stiffen as a hard plate that often is the source of chronic pain, discomfort and physical limitation. Therefore, as opposed to the shrinking and stiffening of the leading commercial meshes that was indeed found in these studies, **New Mesh Material** showed a remarkable lack of shrinkage and stiffening in these studies.

An introduction to ***XyberCyl's* New Mesh Material** is presented here in three parts.

Part I provides an overview of the New Mesh Material.

Part II reviews the pre-clinical proof-of-concept studies.

Part III presents supportive clinical proof-of-concept evidence.

Part I Overview – The New Mesh Material

Injection molded **New Mesh Material** introduces a new biological approach for the permanent cure of ventral hernias. By *avoiding suppression* of natural tissue self-healing, **New Mesh Material** establishes a new paradigm for durable ventral hernia repair: "**mesh incorporation into natural healing tissue without foreign body reaction**". Besides providing a durable natural tissue cure, this paradigm reduces adverse sequelae (chronic pain, mesh shrinkage with hernia recurrence, adhesions with obstruction and fistulae) and prevents chronic infections.

New Mesh Material is produced by injection molding smooth thread-like components separated by uniquely large open spaces. Precisely due to this new construction **New Mesh Material** is able to catalyze robust natural tissue healing. First, **New Mesh Material** stabilizes the closed ventral hernia defect, thus preventing repetitive bulging and re-herniation that otherwise mechanically disrupt innate natural healing. The **Mesh Material** then goes beyond mechanical stabilization, and its smooth injection molded construction uniquely avoids foreign body reaction, while its patented open spaces uniquely avoid physical barriers. Foreign body reaction and physical barriers are both potent suppressors of natural tissue. Thus, avoidance of mechanical, biological and physical natural tissue suppression is the hallmark of the **New Mesh Material** biological paradigm.

Robust healing then ensues unleashed, and the non-reactive **New Mesh Material** itself remains as soft and flexible as when implanted, while prolific natural tissue growing through and around it acquires functional characteristics similar to native abdominal wall.

Validating *pre-clinical* evidence for the new biological paradigm of **incorporation into natural healing tissue without foreign body reaction** is presented in **Part 2**. A purified formulation of low-density polyethylene was the component used for **New Mesh Material** in these studies.

Part 3 will then present *clinical* evidence supporting the **Mesh Material**'s new biological paradigm.

Part II *Pre-Clinical* Proof-of-Concept Studies

Introduction

The primary purpose of the proof-of-concept studies is to validate the main assertions that following implantation onto the abdominal wall **New Mesh Material** causes *essentially no foreign body reaction and yet is fully incorporated into natural tissue*. Secondary purposes include showing that by six weeks post-implantation **New Mesh Material** has set the stage for *permanent cure*, and that the **Material** possesses *mechanical strength* for withstanding physiologic stresses until such permanent cure may be substantially completed. A final purpose of both the Open and Laparoscopic studies is to support the contention that the **New Material**'s behavior is *unique*, by comparing it to the behavior of two commercially available reference items, Prolene in the Open study and Ventralight ST in the Laparoscopic study. Macroscopic and histologic observations constitute the validating evidence in these studies.

Methods

Open and Laparoscopic Models in Swine

In the Open Model **New Mesh Material** was implanted onto the *anterior* surface of the midline abdominal wall, and in the Laparoscopic Model it was implanted onto the *posterior* surface of the abdominal wall. Specifically, anterior implantation in the Open Model consisted of on-laying 15cm X 15cm **New Mesh Material** in two animals onto rectus muscle exposed bilaterally by constructing turnover flaps of the anterior rectus sheathes. See Figures 1 and 2 below.

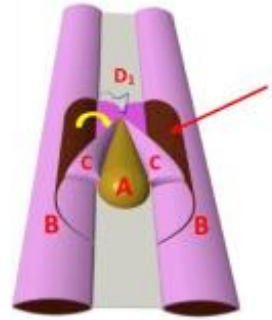


Figure 1

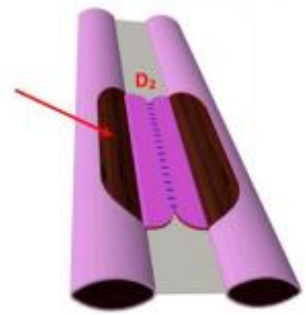


Figure 2

Fig.1. (A) Hernia bulging through midline defect; (B) Incision of anterior rectus sheathes to produce flaps bilaterally; (C) Flaps of anterior rectus sheathes peeled off of muscle and turned over towards midline (yellow arrow); (D_1) initiation of suture of turned over flaps. Fig.2. (D_2) completion of suturing of turned over flaps to seal midline defect. (RED ARROWS indicate exposed rectus muscle fibers that provide acute fascial injury that activates natural tissue healing.)

Prolene 15cm X 15cm was implanted identically in two animals as a reference for comparison. In each animal an equivalent segment of exposed rectus muscle was left un-implanted as a negative control. The preparations are shown in Photos 1 and 2 below.

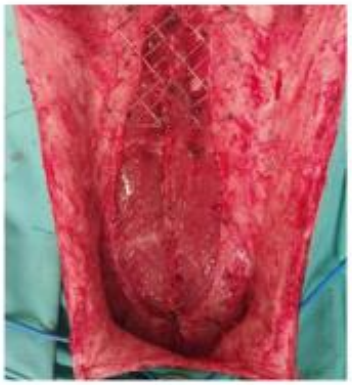


Photo 1 New Mesh Material [IMG 20191111 WA0002]
***New Mesh Material* contouring similar to Prolene in Photo 2**

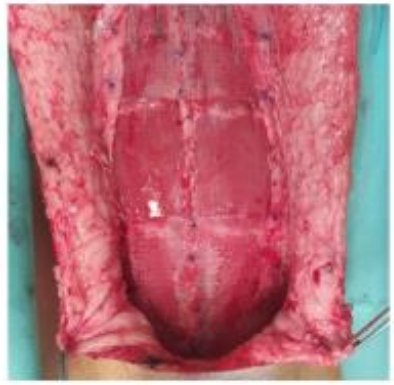


Photo 2 Prolene [IMG 20191111 WA0007]
Well contoured Prolene implant in Open Study

A mirror image of this anterior preparation was produced laparoscopically in six swine by posterior rectus sheath turnover flaps, known as the LIRA procedure of Morales-Conde. These six animals comprised the Laparoscopic Model, in which 8cm X 8cm **New Mesh Material** and Ventralight ST reference mesh were implanted onto the bilaterally exposed rectus muscles. This Laparoscopic Model is represented in Photos 3 and 4 below.

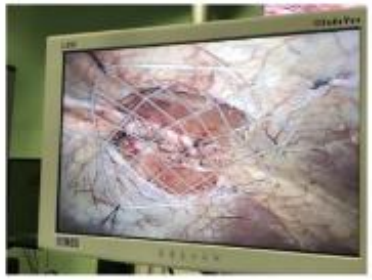


Photo 3 [IMG 4473] On-laid 8 x 8 cm ***New Mesh Material*** **in Laparoscopic** Study

Photo 4 [IMG 4479] On-laid 8 x 8 cm Ventralight ST **in Laparascopic** Study

During mesh deployment especially in the Laparoscopic Model a clear difference in visualization for fixation to underlying tissue became apparent, as seen in a photograph of Ventralight ST blinded fixation (Photo 5) and of exposed New Mesh Material fixation (Photo 6).

Photo 5 [IMG 4479]

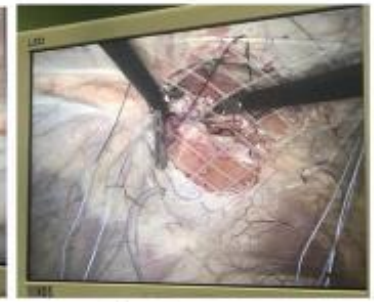


Photo 6 [IMG 4469]

In both the Open and Laparoscopic Models, the animals were observed for six weeks, at which time they were sacrificed humanely, and the sites containing **New Mesh Material**, the Prolene and Ventralight ST reference materials, and un-implanted controls were described grossly, excised and sent for histological examination.

Results

Spontaneous self-healing natural tissue in un-implanted controls

The phenomenon of innate robust natural tissue was confirmed grossly in the un-implanted control sites in the Open Model (Photos 7 and 8) and in the Laparoscopic Model (Photo 9).

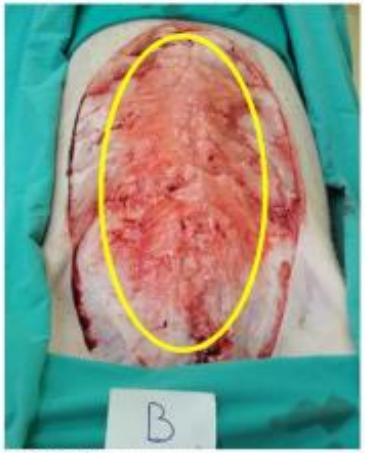


Photo 7 [IMG 20191230 WA0010]

Photo 8 [IMG 20191224 WA0015]

Functioning fibrotic structure of natural tissue of Crescent-shaped anterior surface profile of natural anterior abdominal wall in Open Study. (Yellow healing tissue in the Open Study. ellipse emphasizes prolific extent)

Photo 9 [5964]

Natural healing in exemplary control site in Laparoscopic Study (freshly excised)

The thickness at six weeks of the natural healing tissue at the control sites was 2.0cm and 0.8cm in the Open and Laparoscopic Models, respectively. Histologically, natural tissue consisted of a homogenous layer of slender fibrocytes containing no significant evidence of acute or chronic inflammation or scar tissue in both the Open (Figure 3 below) and Laparoscopic Models (Figure 4 below).

Figure 3

Open Study natural tissue

Figure 4

Lower blue color represents 10mm thick homogenous natural tissue in Laparoscopic Study

Implanted New Mesh Material does not inhibit spontaneous natural tissue and incorporates without foreign body reaction

Implanted **New Mesh Material** did not alter the generation of innate natural tissue observed in the controls in the Open and Laparoscopic Models. This is illustrated in Photo 10 from the Open Model where gross cross-section examination through the **New Mesh Material** implant site revealed natural tissue identical to that of the un-implanted control sites (Photo 11).

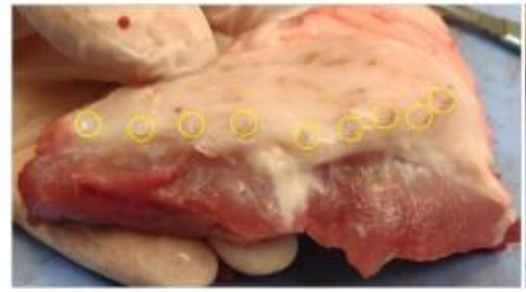


Photo 10 New Mesh Material [IMG 20191224 WA0018]

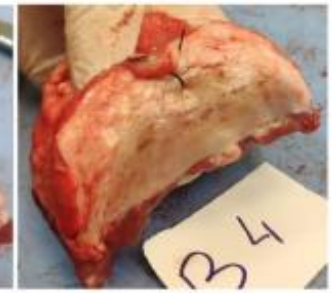


Photo 11 Control
[IMG 20191224 WA0035]

Circles surround cross-sectioned New Mesh Material struts; with thick layer of natural healing similar to control (Photo 11).

Implanted **New Mesh Material** did not cause a noticeable foreign body reaction with acute or chronic inflammation in the 2cm thick natural tissue (Figure 5). Natural tissue freely surrounded and fully incorporated the **New Mesh Material** structure (Photo 10). Notably, the thick layer of natural tissue containing the **New Mesh Material** (as seen in Photo 7 above) was completely soft and non-palpable through the abdominal skin just prior to sacrifice (Photo 12).

Figure 5

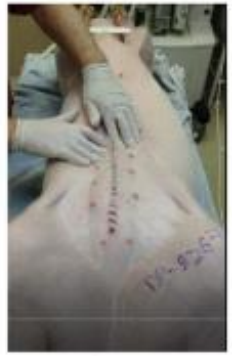


Photo 12

Photo 13

In the Laparoscopic Model, gross examination revealed natural tissue growing freely into the wide-open spaces between the struts of the flat and non-contracted **New Mesh Material**. (Photo 13) Microscopic examination of such natural tissue revealed non-inflammatory fibrocytic homogeneity without foreign body reaction (Figure 6, lower blue tissue) that was indistinguishable from natural tissue at the un-implanted control sites (Figure. 7).

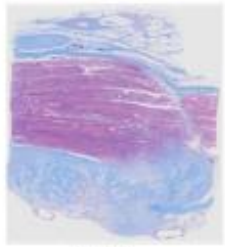


Figure 6

Figure 7

Mesh shrinkage results from the foreign body scar tissue reaction to a mesh. The median 0% shrinkage measured for **New Mesh Material** in the Laparoscopic Study is thus further evidence of its non-reactiveness or biocompatibility (Photo 14).

Photo 14

Photo 15

Adhesion formation can also be considered a secondary result of foreign body reaction specific to intra-abdominal surgery. The complete absence of adhesions to **New Mesh Material** in the Laparoscopic Study (Photo 15) therefore further supports the assertion that the **Material** does not cause a significant foreign body response.

Implanted New Mesh Material sets the stage for permanent healing of hernia defects

Although neither of the current experiments tested **New Mesh Material** in the repair of an actual abdominal wall hernia defect, there were important indications that its use would support that purpose. The natural tissue that formed at **New Mesh Material** implant sites showed a striking tendency to blend anatomically into the surrounding normal tissues. In the Open Model, such anatomic integration occurred specifically to the surrounding fascia (Figure 8) which appeared to be identical to blending observer in un-implanted controls (Figure 9).

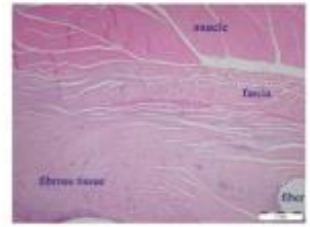


Figure 8

H & E; Blending of fascia with natural healing tissue in *New Mesh Material* specimen similar to blending in Figure 9 of non-implanted control (PV 89-20)

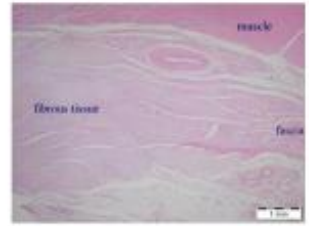


Figure 9

H & E; Note fascial blending of fascia with natural healing fibrotic tissue in control specimen (PV 82-20)

In the Laparoscopic Model such well-integrated melding was observed to adjacent *muscle fibers* in New Mesh Material specimens (Figure 10) similar to controls (Figure 11).

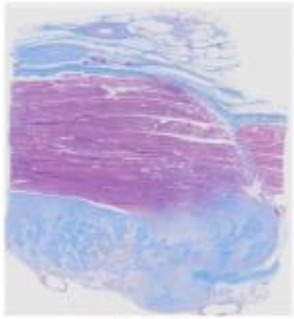


Figure 10

New Mesh Material-implanted specimen: blending between light-blue natural healing tissue (8 mm thick) and purple muscle fibers. Note two strut cross sections.

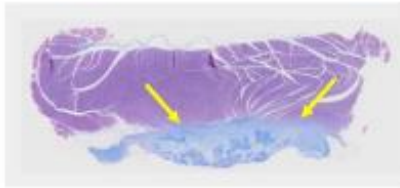


Figure 11

MT-stained; natural healing in non-implanted control site appears as light-blue tissue in lower half of photo micrograph. Note blending to muscle at yellow arrows.

Such distinct anatomical integration would seem to bode well for permanent healing after **New Mesh Material** reinforcement of hernia defects closed by turnover flaps. In addition, the extraordinary amount of robust healing seen at six weeks after **New Mesh Material** implantation in the Open Model (see Photo 7 above) would suggest the **Material**'s excellent potential for catalyzing permanent cure of ventral hernias in open clinical surgery.

Evidence for New Mesh Material's adequate mechanical strength

New Mesh Material underwent six weeks of implantation onto the physiologically active abdominal wall of 50kg swine. The mechanical performance of the **New Mesh Material** equaled that of the reference meshes, Prolene and Ventralight ST, in that structural failure at the mesh edges or centrally was not seen in any mesh. In addition, preliminary bench top studies showed the mechanical strength of **New Mesh Material** to be well above the accepted 16N. From a mechanical standpoint, implanted **New Mesh Material** is strong enough for the crucial reinforcement of closed ventral hernias, and for gradually assuming a mechanical role secondary to maturing natural tissue.

Evidence that the New Mesh Material's biologic behavior is unique

That **New Mesh Material** embodies a paradigm that is indeed new, and that the **Material**'s corollary behavior is indeed unique requires comparisons to other mesh prostheses. With this aim, **New Mesh Material** was compared to Prolene in the Open Study and to Ventralight ST in the Laparoscopic Study.

As opposed to the **New Material**'s biocompatibility in the Open Study described above, Prolene in the Open Study showed histological evidence of encapsulation with acute and chronic foreign body reactivity (Figure 12), and wrinkling with a physical barrier effect limiting the small amount of associated tissue healing present (Figure 13).

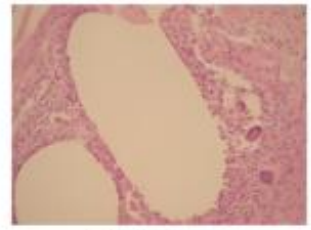


Figure 12

Prolene: Florid giant cell foreign body reaction around the vacuoles left by the material, rich in lymphocytes and macrophages

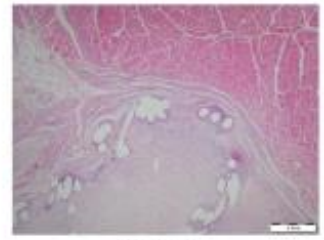


Figure 13

Note folding of plane of Prolene fibers blocking penetration of fibrotic tissue (PV 76-20)

This was reflected grossly as palpable stiffening of the Prolene-implanted abdominal wall (Photo 16) that contrasted with the soft and compliant wall associated with **New Mesh Material** incorporation into robust natural tissue, as shown in Photo 17.

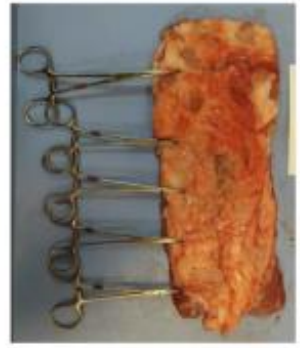


Photo 16 (IMG 20191230 WA0028)

Indurated and thin tissue response to Prolene in open study. Note pock-marked bare areas of exposed muscle fibers.

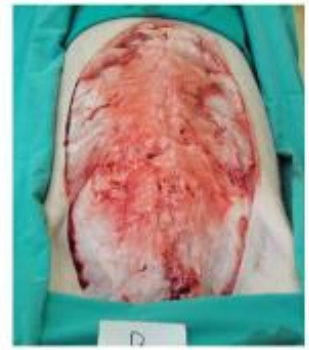


Photo 17 (IMG 20191230 WA0010)

New Mesh Material functioning fibrotic structure of natural tissue of anterior abdominal wall in Open Study.

The Laparoscopic Study extended the range of parameters compared. More complete macroscopic comparison was possible, showing distinct wrinkling and folding of Ventralight ST as opposed to the almost perfectly flat disposition of **New Mesh Material** after six weeks implantation.

Photo 18 (5944)
Explanted Ventralight ST

Photo 19 (6288)
Formalin-preserved Ventralight ST specimens

Photo 20
Folded and wrinkled Ventralight ST

Photo 21 (5975)

Example of freshly harvested specimen of *New Mesh Material* implant with natural tissue

Photo 22 (6284)

Formalin-preserved *New Mesh Material* specimens demonstrating typical flat disposition. This shows that folding and wrinkling are not artifacts of formalin preservation.

Photo 23 (5910)

Another fresh *New Mesh Material* specimen demonstrating typical flat disposition of device at harvesting

Histological comparison was no less contrasting, with Ventralight ST showing foreign body reactivity associated with total inhibition of natural healing tissue (Figure 14) as opposed to the unhindered natural tissue of New Mesh Material described above.

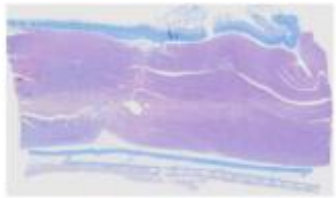


Figure 14

Note line of Ventralight ST sectioned fibers at bottom.

Ventralight ST's foreign body reaction further manifested itself in significantly greater shrinkage (median 17%) compared to that of **New Mesh Material** (median 0%). Moreover, Ventralight ST's perfect resistance to adhesions in the Laparoscopic study (Photo 24) conceals a profound difference from **New Mesh Material**'s equivalent adhesion resistance (Photo 25). Ventralight ST apparently has two distinct functional layers, a proprietary hydrogel coating (Sepramesh Technology) facing the abdominal cavity and a knitted mesh abutting the wall tissue. The latter retains the propensity for encapsulation by foreign body reaction along with total inhibition of natural tissue, while the former imparts excellent adhesion resistance at six weeks. In comparison, the single structural layer of **New Mesh Material** shows both, total *avoidance* of foreign body reaction and *no* inhibition of natural tissue along with an equally excellent resistance to adhesions – without any additional coating.

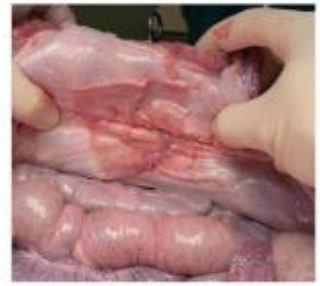


Photo 24 (5998)

Ventralight ST

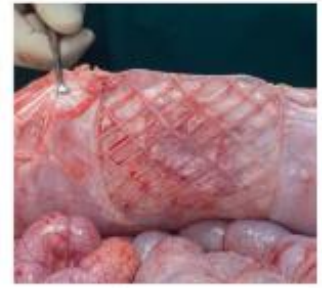


Photo 25 (5857)

XyberCyl New Mesh Material

In summary, the biological behavior of **New Mesh Material** both on the anterior and posterior sides of the abdominal wall has now been substantially proven in pre-clinical studies to uniquely fulfill the new paradigm of **incorporation without foreign body reaction** compared to two leading commercial meshes.

Part III Supportive *Clinical* Proof-of-Concept Evidence

In essence, **New Mesh Material** is simply a prefabricated embodiment of the well-known ***handwoven nylon darn surgical techniques***. Clear similarities between them exist, including the thread-like mechanical tissue support separated by wide-open spaces. As these are the essential characteristics underpinning the new biological paradigm embodied in **New Mesh Material**, it is logical to search the handwoven surgical experience for evidence supporting the clinical use of the **New Material**.

In brief, thousands of nylon darn hernia repairs, both inguinal[1] and ventral[2] have confirmed abundantly that an open on-laid array of widely separated smooth synthetic fibers (#0 and #1 nylon loop sutures) crisscrossing large segments of the abdominal wall, is substantially never associated with subjective or objective stiffening of the abdominal wall and chronic infection, and only very rarely with chronic pain. Furthermore, evidence from physical examination, radiological studies and recurrent re-operation have on occasion brought to light remarkable anecdotal evidence for rapidly growing prolific and permanent natural healing tissue that fully surrounds and incorporates the previously placed nylon darn sutures. Photos 26 and 27 illustrate the intraoperative array of fibers upon their clinical surgical implantation.

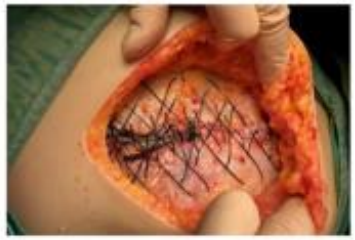


Photo 26

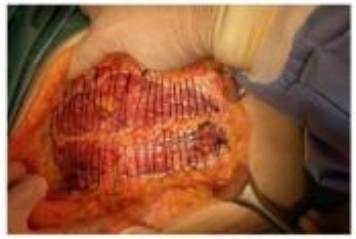


Photo 27

The quite obvious physical similarity between the handwoven clinical placement (in the photos above) and the placement of prefabricated **New Mesh Material** (Photo 28) in the pre-clinical studies described hereabove, is the basis for the assumption that the future clinical implantation of the latter should recapitulate the clinical experience of the former. It is hoped, and moreover imperative that **New Mesh Material**'s unique biological paradigm that has now been validated in pre-clinical studies should be borne out in the near future in direct clinical studies. For this purpose, the FDA approved long-term implantable material, silicone, is soon to be tested in large animal studies as the new advantageous constituent of **New Mesh Material**.

Photo 28

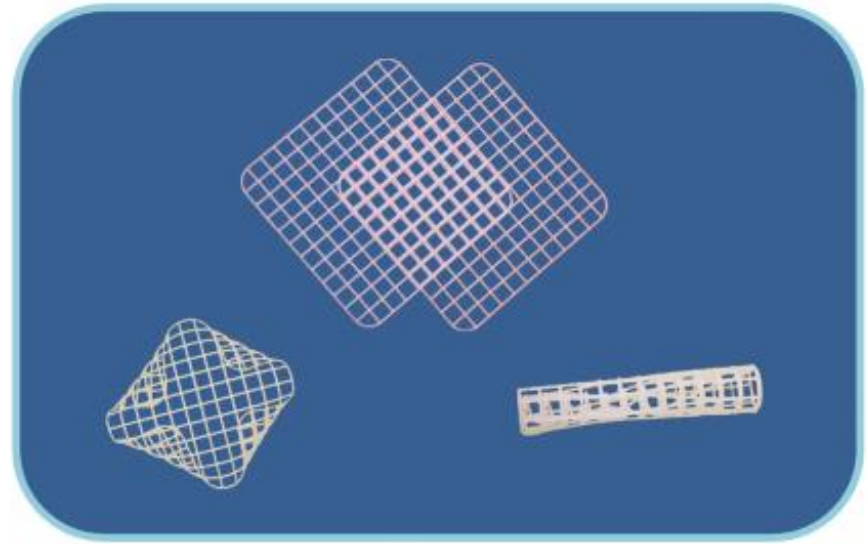
[1] Bendavid R, Abrahamson J, Arregui ME, Filament JB, Phillips EH, editors. Abdominal Wall Hernias: Principles and Management. Springer-Verlag New York, Inc.; 2001. Chap. 50, The Darn Repair; Jack Abrahamson

[2] Zinner MJ, Shwartz SI, Ellis H, editors. Maingot's Abdominal Operations. 10th Ed. Connecticut: Appleton and Lange; 1997. Chap. Hernias; by Jack Abrahamson

CONCLUDING STATEMENT

By avoiding mechanical, biological and physical suppression of self-healing, **New Mesh Material** establishes a new biological paradigm for ventral hernia repair, "full mesh incorporation into robust natural tissue without foreign body reaction". Thus, **New Mesh Material** provides a durable natural tissue cure while greatly reducing complications including chronic infection. This new concept of biological healing has now been validated experimentally in two large animal studies, both open and laparoscopic. Moreover, abundant clinical precedence for the applicability of the **Material**'s concept in humans has also been presented.

Two statements spanning 166 years of surgical literature are relevant to the now considerably tested performance of **New Mesh Material**. In 1857 Theodore Bilroth made the famous statement, "If we could artificially produce tissue of the density and toughness of fascia and tendon, the secret of the radical cure of the hernia repair would be discovered."[3] In 2023 Ellis and Miller declared, "The ideal mesh for abdominal wall reconstruction is inert, resists degradation, allows for host ingrowth, able to clear infection and escapes patient detection."[4] Now with the use of long-term implantable silicone as the constituent material, **New Mesh Material** as a validated concept is in an exceptional position to materialize Bilroth's secret and fulfill Ellis and Miller's ideal.



[3] J.E. Skandalakis, G.L. Colborn, L.J. Skandalakis, D.A. McClusky, Historic aspects of groin hernia repair R.J. Fitzgibbons, A.G. Greenburg (Eds.), Nyhus and Condon's hernia (5th ed), Lippincott, Williams & Wilkins, Philadelphia (2002), p. 39

[4] Ryan Ellis MD, Benjamin T. Miller MD, Mesh Selection in Abdominal Wall Reconstruction: An Update on Biomaterials, Surgical Clinics of North America, Volume 103, Issue 5, October 2023, Pages 1019-1028

For more information, please contact:

Jack Graudenz

+972-52-233-5060

jack@xybercyl.com

Please visit our website at

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