CASE STUDY: **Effects of Proteolytic Enzymes on Triple-Negative Breast Cancer Post-Mastectomy**

ABSTRACT

Enzyme therapies are becoming more common in disease treatment. Digestive enzymes are used to digest food and metabolic enzymes are involved in every process of the human body and help to build structure and remodel new cells. Therapeutic enzymes (digestive and metabolic) can be used medically either as isolate or adjunctly with other therapies for treatment of various diseases like cancer, cystic fibrosis, dermal ulcers, inflammation, digestive disorders etc. Enzymes as direct pharmaceutical products find numerous applications and the field of cancer research has some good examples of the use of enzyme therapeutics. Therapeutic enzymes are used as oncolytic, anticoagulants, thrombolytics, anti-inflammatories, fibrinolytics, mucolytics, antimicrobials, and at the cellular level have shown to positively impact signaling mechanisms for survival of the host. One such example of a proteolytic enzyme with many health benefits is Bromelain. To elucidate in detail the potential mechanisms of anticancer action, bromelain has been extensively studied in numerous studies. Bromelain anticancer effects were evaluated in both “in vivo” in animal models and “in vitro” as a potential agent against several cancer lines such as gastrointestinal, colorectal, breast, mesothelioma, lung, hepatic, pancreatic, epidermoid, and melanoma. Bromelain has been studied in vitro on several breast cancer cell lines such as MDA-MBA231 breast adenocarcinoma, MCF-7 breast adenocarcinoma, 4T1 breast adenocarcinoma, and GI-101A breast adenocarcinoma where it showed increased cytotoxicity, anti-proliferative, increased apoptosis, increased autophagy, decreased tumor mass, and decreased cell viability. In this case study we apply a high-dose proteolytic blend from Transformation Enzyme Corporation named Professional Protocol™ Protease in powder form to a diagnosed 61-yr-old female with Triple-Negative Breast Cancer left side which opted for left breast lumpectomy with sentinel node dissection, x2 nodes.

INTRODUCTION

According to the World Health Organization In 2020, there were 2.3 million women diagnosed with breast cancer and 685,000 deaths globally. As of the end of 2020, there were 7.8 million women alive who were diagnosed with breast cancer in the past 5 years, making it the world’s most prevalent cancer. Breast cancer occurs in every country of the world in women at any age after puberty but with increasing rates in later life. There are different types of breast cancer, and one type is Triple-Negative Breast Cancer (TNBC). TNBC is a heterogenous group of fundamentally different diseases with different histologic, genomic, and immunogenic profiles which are aggregated under this term because of their lack of estrogen receptor, progesterone receptor, and human epidermal growth factor receptor 2 expression.

A disease with often an aggressive course and a poor prognosis compared to other subtypes of breast cancer, TNBC accounts for approximately 10%–15% of all diagnosed breast cancer cases and represents a high unmet need in the field. In the past, chemotherapy was the only systemic treatment option for this subtype and over the last years several new strategies have been investigated such as immunotherapy, antibody drug conjugates, new chemotherapy agents and targeted therapies. Compared with other subtypes of breast cancer, the survival time of TNBC patients is shorter, and the mortality rate is 40% within the first 5 years after diagnosis. TNBC is highly invasive, and approximately 46% of TNBC patients will have distant metastasis. The median survival time after metastasis is only 13.3 months, and the recurrence rate after surgery is as high as 25%. The metastasis often involves the brain and visceral organs. Distant metastasis mostly occurs in the 3rd year after diagnosis. The average time to relapse in non-TNBC patients is 35-67 months, while that in TNBC patients is only 19-40 months. The mortality rate of TNBC patients within 3 months after recurrence is as high as 75%.

TNBC is complicated by (1) the scarcity of treatment options outside of cytotoxic chemotherapy, more recently immunotherapy in a subset of patients, and (2) limited predictive and prognostic biomarkers to tailor treatment. Although historically TNBC is considered difficult to treat with a poor prognosis, a substantial number of patients (~30%-50%) achieve pathologic complete response (pCR) with neoadjuvant chemotherapy. Combination therapy with an anthracycline and cyclophosphamide followed by a taxane (AC-T) is considered standard of care for patients with stage I-III TNBC and 30%-40% of patients will achieve pCR with this regimen. Though anthracyclines are a pillar of breast cancer chemotherapy, these agents are associated with considerable long-term toxicities including the risk of secondary leukemia and cardiotoxicity. The toxicity associated with anthracyclines has supported the initiative to explore anthracycline-sparing regimens, particularly in TNBC where patients typically present at a younger age. De-escalation, or lowest effective chemotherapy dose, efforts have been successful in hormone-receptor-positive and HER2-positive breast cancer. There is a growing interest in exploring the de-escalation of chemotherapy in TNBC.

In light of de-escalation attempts, for the therapy of inflammatory and malignant disorders, proteolytic enzymes are employed as additives for chemotherapy to reduce side effects of drugs and to improve quality of life. They are used as additives for radiotherapy to reduce inflammation and edema. They are used as additives in surgery to reduce edema and to improve wound healing. They are also used as additives to prevent lymphedema by reducing lymph congestion, detritus, viscosity of the exudate, and stimulation of phagocytosis of associated leukocytes.

CASE STUDY

In this present case study, we have a 61-year-old female with a diagnosis of Triple-Negative Breast Cancer confirmed by biopsy in 12/2022 and referred to as “inflammatory breast cancer with no known cause.” Patient’s family history includes two sisters with breast cancer. The following is the patient’s frame of mind as she was considering her options:

> *“I currently have a mass with necrotic tissue. My personal preference would be to have it removed now. That is being debated. Instead, they are strongly encouraging me to do 5 months of extreme chemotherapy prior to a lumpectomy in order to shrink this mass. It is not too big to be removed now—that is just their preference. I am extremely healthy otherwise! I follow a low inflammatory diet, exercise regularly and practice good sleep, hygiene, etc., along with all the good fundamental principles of functional medicine. My only recent known contributor is extreme family stressors with illness. Otherwise, my only other gut feeling is this*

incidence might have been greatly nudged by a dental procedure. Although this overall picture may present a grave outcome, I am intrigued as to why this inflammation is present to begin with and feel if I don't address that piece head-on, I might not make much leeway with the oncology approach. I'm reaching out to explore some underlying causes of this inflammation (performing gut testing, etc.) and how the use of enzymes might benefit me."

In 1/2023 the patient started working with an herbalist to modify her diet (warm, soft, small foods only, herbal tea, no dairy, no ETOH, no cold foods). She continued with her practice of acupuncture, iodine therapy, and yoga and began a JIn Shin Jyutsu energy balancing routine. Herself a functional medicine practitioner already familiar with testing options, she submitted a stool sample for evaluation by Diagnostic Solutions Laboratory.

"I have a deep understanding that all disease begins in the gut. I have had a series of dysbiosis for years. Having chronic H Pylori has been the most difficult to eradicate adding insult to my coexisting SIBO. I am personally not sure one can exist without the other. If one's constitution is not strong, the weakness creates the vulnerability. The weakened constitution goes back to my gut health, and I believe a large amount of stress for setting me up for a diseased state."

The following are some of the more noteworthy imbalances of bacteria, fungi, and intestinal markers observed in the resulting GI-MAP™ report in 1/2023:

COMMENSAL/KEYSTONE BACTERIA

COMMENSAL BACTERIA	Result	Reference
Bacteroides fragilis	2.87e11 H	1.6e9 - 2.5e11
Bifidobacterium spp.	2.07e10	> 6.7e7
Enterococcus spp.	2.52e4 L	1.9e5 - 2.0e8

FUNGI/YEAST

FUNGI/YEAST	Result		Reference
Candida spp.	7.63e3	High ↑	< 5.00e3

INTESTINAL HEALTH MARKERS

IMMUNE RESPONSE	Result	Reference
Secretory IgA	385 L	510 - 2010 ug/g
Anti-gliadin IgA	339 H	< 175 U/L

H. PYLORI ANTIBIOTIC RESISTANCE GENES

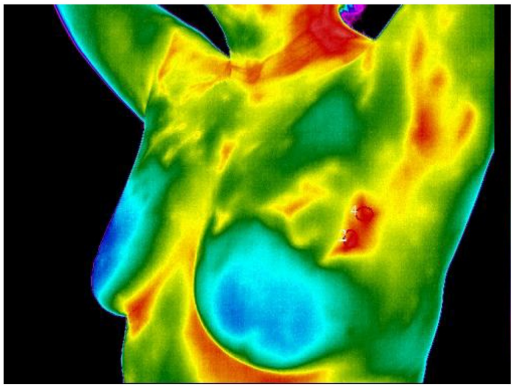
	Result	Reference
Amoxicillin	**Negative**	**Negative**
Genes associated with amoxicillin resistance		
PBP1A S414R	**Absent**	
PBP1A T556S	**Absent**	
PBP1A N562Y	**Absent**	

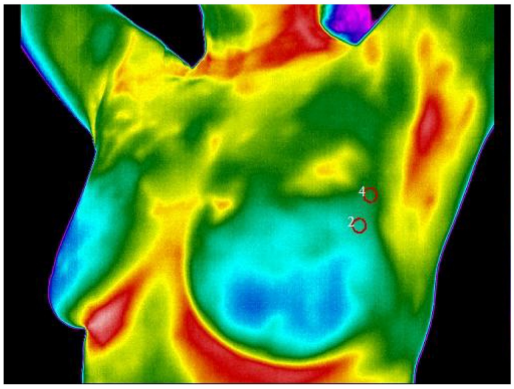
	Result	Reference
Clarithromycin	**Positive**	**Negative**
Genes associated with clarithromycin resistance		
A2142C	**Present**	
A2142G	**Absent**	
A2143G	**Present**	

The patient underwent surgery in 2/2023 when a lumpectomy with dissection of two sentinel nodes on the left breast was performed. She began taking 4-5 capsules of Transformation's Professional Protocol™ Protease 4 x day.

The patient was then willing to comply with a high dose of Transformation's Professional Protocol™ Protease powder as an adjunct therapy for her condition. She began taking 5 gm of powdered Protease 3 x day on an empty stomach in 4/2023, and the dosage was increased to 10 gm in 7/2023. The goal of this protocol was to reduce inflammation, make positive changes to the imaging studies performed, and to improve quality of life.

The following before-and-after images are from Thermograms taken on 11/2022 and 1/2024, respectively. During the accompanying follow-up ultrasound in 1/2024, the doctor remarked, "Your scar looks amazing!"





And upon follow-up functional testing in 1/2024, it was also observed that her previously out-of-range levels of bacteria, fungi, and intestinal markers had returned to normal.

COMMENSAL/KEYSTONE BACTERIA

COMMENSAL BACTERIA	Result	Reference
Bacteroides fragilis	4.50e10	1.6e9 - 2.5e11
Bifidobacterium spp.	3.56e9	> 6.7e7
Enterococcus spp.	1.21e7	1.9e5 - 2.0e8

FUNGI/YEAST

FUNGI/YEAST	Result	Reference
Candida spp.	<dl	< 5.00e3

INTESTINAL HEALTH MARKERS

IMMUNE RESPONSE	Result	Reference
Secretory IgA	1068	510 - 2010 ug/g
Anti-gliadin IgA	121	< 175 U/L

H. PYLORI ANTIBIOTIC RESISTANCE GENES

	Result	Reference
Amoxicillin	**Negative**	**Negative**
Genes associated with amoxicillin resistance		
PBP1A S414R	**Absent**	
PBP1A T556S	**Absent**	
PBP1A N562Y	**Absent**	

	Result	Reference
Clarithromycin	**Negative**	**Negative**
Genes associated with clarithromycin resistance		
A2142C	**Absent**	
A2142G	**Absent**	
A2143G	**Absent**	

CONCLUSION

Compared with other breast cancer subtypes, Triple-Negative Breast Cancer is highly invasive and has a high early recurrence rate. Patients usually relapse within 5 years after surgery, with a very poor overall prognosis. Due to negative expression of ER, PR, and HER2, TNBC is insensitive to endocrine treatment and targeted therapies. Only very limited treatment regimens are available for TNBC, with generally poor efficacy. New therapies are urgently needed. This patient was diagnosed with TNBC in December 2022 and underwent left breast lumpectomy in February 2023. The patient began mega dose of Transformation's Professional Protocol™ Protease powder in April 2023 at 5 grams three times a day with weekly increments of 1 gram until she reached a final dose of 10 grams three times a day in July 2023 and our mega dose protocol ended August 2023. As far as the left breast health, the scarring (cord-like) from the lumpectomy significantly lessened. She began with small and hard residual beads around the nipple from the dye used to explore the surrounding tissue that are down to just one that is barely palpable. The before and after thermogram shown above had a remarkable contrast as well as the GI-MAP™ done pre and post enzyme protocol as shown above. The last ultrasound obtained in January 2024 showed that within the left breast, there is postoperative scarring demonstrated at the 1 to 2 o'clock position at the site of the patient's previously identified left breast mass. There is no residual fluid collection identified. The scar is unremarkable. There is no soft tissue identified. Within the axilla, there are small, scattered lymph nodes appreciated. There is no pathologic adenopathy. Laterally at the 3 o'clock position 4 cm from the nipple there is a tiny intramammary lymph node measuring 4 mm with normal morphology. Ultrasound Impression: Unremarkable evaluation of the right breast. Left breast demonstrates postoperative change. No new findings are appreciated. The scar appears intact without evidence for fluid collection or residual soft tissue density. There is no suspicious adenopathy identified. At the end of this report you can follow the patient's journal throughout her whole ordeal to appreciate what one can experience with such a condition and such a protocol.

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Appendix I - Medical History

In general, good health

Long history of EBV, Herpes I, H-Pylori, dense breasts

1/2023 - Via GI MAP, + for Candida as well as persistent +H Pylori

Past Surgical History:

1981 - Rhinoplasty s/p nasal fracture

1996 - L-Oophorectomy s/p ruptured ovary, 10% of L ovary remains

1997 - L-inguinal hernia repair, mesh graft

2012 - Lumpectomy for L benign cyst suspicious via mammogram

Long history of cysts in thyroid, breasts

Medication Allergies:

Amoxicillin (full body rash)

Food Allergies:

Gluten sensitivity (confirmed on GI MAP)

Medications:

No prescription meds

Supplements:

Vit, B, D, C, each dosed once a day

Digest enzymes: 2-3 digest each meal

Protease enzyme 4 caps every 4 hours, empty stomach

Magnesium powder at HS for constipation and sleep

Cannabis, SL PRN

Head to Toe assessment:

Head: rare headache, -vertigo. Eyes (primarily Left) noted to have changed (blurred, distorted) following fractured tooth #18, left lower. Patient notes, when temporary crown placed, eyes became sensitive to light, flashes were present. Dentist did not feel the association with the dental work had any relationship with change in vision. Oral X-ray did not reveal any issues.

Ophthalmologist confirmed pressures were normal and eyes generally in good health. Patient sought out care from Acupuncturist who was able to correct eyes, 99% in 4-5, one-hour sessions. Speculated possible inflamed cranial nerve was at play.

Ears: tinnitus present in L ear, question onset occurred after first Johnson and Johnson Covid Immunization.

Mouth: multiple crowns. Last crown (#18, large mercury filling cracked. Saw dentist 3 days later. Temporary crown placed.

Eyes: (mostly left) changed. Blurry, etc (see above).

Neck: unremarkable, no pain, good range of motion. No nodes palpated.

Chest: cough present when consuming dairy. Chronic runny nose. NO SOB, dyspnea.

GI: chronic bloat and constipation (improving with enzyme supplementation), negative GERD despite chronic H-Pylori infection. As noted above, most recent GI Map (attached) shows H-Pylori and Yeast, dysbiosis, low SIGA, low elastase. No bloody stools noted. No pain with palpation. Changed diet under guidance of Acupuncturist. Consuming only, soft, small, warm foods/drinks. GI improving, much less bloat.

Urogenital-no history of UTI's, strong bladder control. Pap smear 10/2022 normal.

Integumentary: following last booster (JJ) 4/2022 noted persistent rash between eyebrows and severe chapped (burning) lip, top and bottom, cracks bilateral corner of mouth. Took several months and (very small use of steroidal cream) to clear. Otherwise, skin sl dry but negative for eczema, psoriasis, moles, excessive bruising.

Pain: notes pain left shin/left hip (more at rest) increasingly noted after meals. Ambulates long distances, 4-5 miles without pain, weakness. Much improvement of shin discomfort with change in diet to soft, small, warm foods/drinks only.

Energy: better following 3-week use of Protease enzyme regime. Yoga 3-4x week, walks avg of 4 miles 3-4x week. Tango dance 1x/week.

Sleep: adequate on and off, Gaba helpful and use of cannabis (5mg) proving most helpful.

Mood: generally, very positive and happy. Latest diagnosis confounding given extreme healthy lifestyle: food, sleep, rest, exercise, supplements. However, patient confirms intense stress of many years due to family poor health and many deaths.

Patient history

Patient found lump at upper left lateral region of breast. Thermogram on 12/21/2022 confirmed increased temp to breast region. Seen in GYN office. Mass palpable. US and Biopsy ordered.

Controversy over left axilla involvement. Lymph node in L axillary initially seen on US. After one-week (between initial US and scheduling of biopsy via US) use of castor oil packs and application of Jin Shin Jytusu (hands on treatment) for one week, US at time of biopsy revealed a "changed appearance to a questionable "no" lymph node involvement. At that time of L breast mass biopsy, patient declined axilla biopsy.

It should be noted that Previous Thermogram: 9/2020 very slight increase in heat, 11 o'clock. Small margin but a change non the less, and first seen increase ever, in a series of annual thermograms. Was suggested to repeat Thermogram in 6 months, scheduling interrupted by COVID and unable to locate thermographer. However, maintained annual US. Last US: 1/2022 showed only a cyst at this area (1o'clock). Less than one year later 12/13/2022 a mass was palpable and present with a viable blood supply (angiogenesis).

Therefore on:

12/13/2022 - Biopsy: Left Breast guided ultrasound → biopsy of mass only.

Patient declined axilla biopsy. Patient declined placement of surgical clip.

12/16/2022 - Results: Invasive ductal carcinoma left breast.

12/23/2022 - Met with Surgical oncology: discouraged surgery (lumpectomy) at this point. Suggested 5 months of chemotherapy, followed by surgery and radiation. However, is supportive of lumpectomy if/when patient wants to go in that direction.

12/29/2022 - Met with Oncologist: Options: Standard of Care: Chemotherapy-5 months, followed by lumpectomy/radiation or Immunotherapy or Clinical trial. Made clear If patient opts for surgery first, disqualifies for Immunotherapy and/or Clinical trial.

1/9/2023 - Met with Oncologist again to gain more insight to Clinical Trial

At this point patient declining all

Goal: get to root cause

Current regime:

Acupuncture weekly.

1/21/2023 - Started work with Herbalist as an addendum to acupuncture. Advised to start extreme diet change (warm, soft, small foods only, no dairy, no ETOH, no cold foods). Seeing positive results in symptoms in <48 hours: ex: less shin pain, more energy, overall strength greatly improved. Will start Herbal Tea 1/25/2023

Iodine therapy continues, slowly increased to cap dose of 50mg. Tolerating well.

Proteolytic Enzyme Therapy: 4-5 caps 4x day. Tolerating well, experiencing pain at site of past lumpectomy after two weeks of enzyme use.

JIn Shin Jyutsu 3x day, self- application. Liver and spleen flows.

Diet, following Herbalist diet as stated above.

Blood sugar monitoring. Mean average FBS, 90, glucose throughout the day mean average: 88.

GI Map, DUTCH, CSA Stool test, will send results if desired.

Goal: Increase enzymes, work alongside Dr. Milton Bastidas. Continue with Iodine. Herbal Tea. Acupuncture weekly. Diet change. FAITH. Lumpectomy when time is right.

Surgery:

2/23/2023 - L breast lumpectomy with sentinel node dissection, x2 nodes.

Clinical Study:

4/18/2023 - Spoke with Dr Bastidas and discussed intentions of using Protease enzyme therapy. Goal: 4-6 months high dose Protease.

Appendix II - Patient Log

L breast post-op incision, not so much tender as knobby. I can feel a hard track from the incision to the nipple. (ex: AXILLA then half- moon Incision) then------- hard track to----------> to Left Nipple.

The left nipple also has 3-4 “pellets” surrounding it. They are hard and very tender. This is a post-op issue from the exploration around the entire breast with the injection of radioactive dye.

Bloating after every meal. Bowels sluggish. Weight hard to budge nor matter what I do regarding diet, exercise.

Left eye continues to be blurry and feels like there is something either pressing on it from the top or L side, hard to say where but not right. This occurred right after I broke the tooth last July. Never had this sensation before. Tinnitus L ear. Piercing at times. This was noted after tooth as well but maybe slightly before that. I have lived in this current location just four years and never had tinnitus in a home in lived in for over 37 years. On that note, I know it is new.

Headaches on and off. Not debilitating but bothersome. Mostly early am. I am not one for medications, so I usually just hydrate and keep moving. They do go away. Wonder if they are from the HPylori. I am very careful with gluten and dairy. Think I have some histamine issues too though because my nose runs a lot, mostly after meals. I’ve been eating a lot of congee (rice, ginger, onion, garlic, broth--?? Histamine).

L shin pain. This is new since my diagnosis. I wonder if this related to the stomach meridian. Very much affects the breast as the stomach (and spleen) meridian runs right through the breast.

L hip sore. I can walk miles but at rest it aches. I never had this.

Although family stress has been enormous (many losses, much grief) and I understand this. my moods have been labile. I am feeling very stuck in life and can’t get to the things I really want to do like writing. I am finding I run in circles and never accomplish much. Greatly impacts my self-esteem. This is not at all like me.

4/18/2023 - Started with 5gms, 3x day of powdered Protease. So far, ok. Adjusting to time management. Need to pay attention to taking Protease on an empty stomach, then wait 2 hours to eat and wait two hours to take again. Important to adhere to schedule to get full effect of Protease.

4/20/2023 - In Montreal. Stomach, esophagus area are really upset. Feel a tremendous amount of fullness, to the point I must sit up to sleep. Never had any symptoms of GERD but imagine this feeling is similar. Continue to take 5gms 3x day. I am surprised at this but curious that the Protease is going after something since I have had H Pylori, etc., + SIBO for so long.

4/24/2023 - Home, Overall, totally wiped out. Feel like this might all be die-off?? Hard to get anything done. Just want to sleep. Appetite poor. Discomfort in “stomach and lower esophagus” area still quite bothersome. Trying to drink lots of fluids.

5/5/2023 - Had to stop Protease. Felt so wiped out. Took the weekend off and started cabbage, one head juiced. Not easy to get down but think effective for relieving abdominal discomfort. Almost instant. Still took the weekend off.

5/8/2023 - Restarted right back at 5gms 3x day. Really want to stay with this. Can feel discomfort at my **old former non-cancerous lumpectomy scar (6 o’clock).

Breast scar from current 2/23/2023 surgery is present. It’s knobby and has a hard track going toward the nipple. The nipple also has a few hard, palpable balls. They are tender. I understand this is from the radioactive

dye that was used to explore the breast for pathology. And, in addition because my surgeon made the decision to only make one incision versus two, the draining of this radioactive fluid and the natural swelling and fluid from surgery is somewhat impaired. My axilla also with a very strange sensation as the numbing is still wearing off. The brachial plexus nerve was affected (expected) and is contributing to this feeling. My stomach still has discomfort, but it is def less and if I drink fluids right away, I feel like doing so helps to move the protease through.

5/22/2023 - Doing well. Tolerating the 5gms 3x day. No GI discomfort. Feeling more grounded overall. Left shin pain (origin? Started right around the time I found the mass) is starting to dissipate. Left hip which was really bothering me is getting better too. I can feel some discomfort a few hours after I take the Protease in current breast incision. When I say discomfort, it feels like "activity." Not itchy but a pulling.

6/1/2023 - Feeling pretty good. Still with some fatigue but wondering if stress still contributing to that. Had to reschedule dentist but have an appointment soon. Still feeling a sensation in my current breast scar but it feels like it is softening. Left shin pain gone 99%. My hip is so much better too. I can sleep without it acting out. It is usually at rest that it bothers me. I am still bloated some. Started working with a Nutritionist. Labs drawn. Will forward to Dr. Bastidas.

6/6/2023 - Not sure I will continue with Nutritionist. Does not appear to be aligned with Functional Medicine model. Encouraging severe dieting, < than or equal to 800 Cals/ day and snacks I would never contemplate eating, even short term. Gluten, dairy, artificial sweeteners. However, labs will be beneficial as my oncology team did not draw any of significance. Do not see Oncology until 9/13/2023. My left breast scar is softening to the point I think tract gong to the nipple is halfway gone! I am left with only one of the nipple "pellets" as well. Although that is very sore, it itself is smaller.

6/13/2023 - My husband's job was eliminated. Just a little more stress to juggle but I am so happy that I am not in treatment at Yale (especially since we are losing health insurance). I feel like I made the best decision to do this clinical trial. I am so grateful to Dr. Bastidas and feel like I am really healing on different levels. My overall energy is improving, my skin looks so much clearer, my left hip and L shin are without pain. And my breast incision is continuing to soften. The overall swelling of that breast is decreasing. My axilla is still somewhat numb from the brachial nerve involvement but the whole area is starting to look normal. The nipple itself is less tight, it was casting a slight blue color but that's better too. I am down to one pellet (hard lump) around the nipple area which was disconcerting because they/it was not there pre-op. But down to the last one is awesome! My weight is shifting slowly down. Stopped Nutritionist but eating lighter and having last meal earlier in the afternoon. Bloating improving too. Labs show some imbalances, sent to Dr. Bastidas.

6/28/2023 - Had my first thermogram post-op.

6/29/2023 - Saw Biologic dentist. He did extensive x-rays and testing of acupuncture points. Feels I still have mercury under "that" tooth. The #18 that broke last July, and I feel it very well had everything to do with my abrupt breast changes. Feels root canals are def connected to breast cancer. Started me on four homeopathic. One for grief, one for metals, one for organ support and one for overall support.

6/30/2023 - Woke with horrible headache and body aches. Dentist office feels it is definitely die-off from the homeopathic and advised to back off if necessary. I will try to power through.

7/3/2023 - Up to 10gms/3x day. Tolerating ok! Feeling overall just ok. The scarring just below half-moon incision, (maybe more of a collection of fluid) is really disappearing.

7/6/2023 - Thermogram results: Some heat but totally expected. Looks good. Will repeat in October. No heat seen where scarring is (very minimal now) or where nipple tenderness is. Very relieved. Sent results to Dr. Bastidas. This week has been rough. Just feeling wiped out again and I think it's more the homeopathic and not the protease because I have been on the protease for a bit now.

7/17/2023 - Just starting to feel better, like something shifted. My weight is starting to shift. My L eye is better! Finally. I had terrible back pain all last week despite stretching and yoga. I was tired. My energy is starting to come back. I started charcoal and spirulina to pull out any heavy metals I hype to be eliminating. I was having weird, almost neurologic spasms/jerking in my limbs (subtle)and in what felt like head shakes. That was really concerning but it seems to be quieting. I notice at night my left eye is better. I only watch TV at night and that's when it's regally apparent. It's seeming to be better.

7/20/2023 - Sister with increased growth of soft tissue mass in pelvic cavity secondary to ovarian cancer. In addition, spots seen in liver. Homeopathic started from Biologic dentist seems to really be helping me with grief although this new news is hard. Vacation tomorrow for one week. Tolerating the 10gms 3 times a day as is the current plan. Will regroup with Dr. Bastidas week of Aug 1 after I see biologic dentist and get results from x-rays etc.

7/22/2023-7/29/2023 - Went on vacation and felt well, felt strong walking. Toward the end of the week, I think I acquired food poisoning from an oyster. Took a few days of loose stools. Had to hold the Protease because I could not tolerate anything but back on it a week now. I def feel this in my stomach when I take it. I have a discomfort, but I welcome it because I think the protease is going after something. It is often felt in my esophagus too. I had a lot of bloating in my upper stomach prior to starting this that seems to have gone down!! My stomach has always been an issue with HPYLORI, etc. that I could not get rid of, and the acupuncturist feels my stomach meridian that runs through the breast is not helping things, so I think this is all good.

8/1/2023 - Saw biologic dentist again. I will forward reports to Dr B. He found a ton of heavy metals in me. He really thinks the 2016 root canal and this latest tooth issue (7/2022) is behind my breast issue. When he retested me after a month on his remedies, he found I am about 2/3'rds better with metals but still have a way to go. I am to see him in 8 weeks. I am to continue with the heavy metal homeopathic remedies followed by a chemical cleanse as well. I've had a backache for over a week. On and off. Hoping it's all this cleanse + protease. The lumpy scar that is under my incision feels like it's changed shape, maybe less? I am strong walking and strong in yoga. I am feeling better!

The final part of my four months on Protease really highlighted the significant changes I feel from a digestive standpoint. As a functional medicine practitioner (FDN-P) and a student of Jin Shin Jyutsu ("jutsu") I have a deep understanding that all disease begins in the gut. Breast conditions force us to look at the function of the stomach and spleen meridian. I have had a series of dysbiosis for years. Having chronic H Pylori has been the most difficult to eradicate adding insult to my coexisting SIBO. I am personally not sure one can exist without the other. I also believe the dental procedure I endured played a significant role in the vulnerability of my breast health. I knew what occurred immediately following the fracturing of a large mercury filling on my left side (tooth #18), resulted in significant changes to my left eye in the way of blurriness, which was absolutely new for me. This oddity was all on the same side as the affected left breast that showed itself some 8 weeks later. I never saw that as coincidence but a huge clue to be uncovered. As I've learned in the study of eastern medicine, if one's constitution is not strong, the weakness creates the vulnerability. It's not necessarily the tooth or the manner in which the dental procedure took place but the weakened constitution. That goes back to my gut health and I believe a large amount of stress setting me up for a diseased state. I experienced significantly positive results on the Protease. It was not an easy change. There was much in the way of die-off

but then things started to change. I am no longer bloated! I have normal stools (although still working on this) in the way of no undigested food witnessed with bowel movements. I have actually lost close to ten pounds which was nearly impossible over the last several years despite eating a very healthy diet (GF, dairy free, etc). My mood, despite all the loss I have experienced (3 sisters, my mother, a 39-year-old niece) in the last 10 years, has leveled out. I feel so much more like myself in the way of general happiness, positivity and a "normal" grieving state. An imbalance in stomach and spleen meridians (which I believe the Protease addressed positively) enhances anxiety and worry which might explain why anxiety is rampant today as well as poor gut health and an increase of breast disease in young women. Today I am able to be present with this most recent loss of my last sister on 10/3/2023 and work through it without a insurmountable surge in my emotional health. I believe the Protease improved my emotional constitution as well. In western medicine the two, affected organs (stomach and spleen run through the breast) plus emotional health are unfortunately not often connected. But they can't be separated. By healing my gut with the Protease I believe I am healing my emotional state, in addition the state of my breast.

As far as my breast health, the scarring (cord-like) from the lumpectomy has significantly lessened. I had small hard residual beads around my nipple from the dye used to explore the surrounding tissue that are down to just one that is barely palpable. So far my last thermogram looked good. I will continue to be monitored closely with thermography and US. I will also stay on the Protease in capsule form under my own direction as I truly believe this enzymatic approach brought such significant healing. I will continue to work with the Biologic dentist clearing heavy metals, pesticides and fungi from my system, found upon my work up. I am grateful for Dr Bastidas for suggesting I take that route, simultaneously. I am so grateful Dr Bastidas was willing to work with me and believe doing so got to the root cause of my condition by addressing my pathogens and general dysbiosis. I will repeat a GI MAP and DUTCH test in 1/2024.

Appendix III - Medical Records

SURGICAL PATHOLOGY REPORT

FINAL DIAGNOSIS: BREAST, LEFT, 2 O'CLOCK, BIOPSY:

- INVASIVE DUCTAL CARCINOMA WITH NECROSIS, GRADE 3

- TOTAL SCORE 9 (TUBULE-3, NUCLEAR GRADE-3, MITOTIC FIGURE-3)

- EXTENT 1.2CM ON ONE CORE

- NOTE: By immunohistochemistry GATA 3 and TRPS1 are positive in tumor cells, supporting a breast primary. ER, PR, and HER2 IHC results will be reported in an addendum.

Pathologist:

Uma Krishnamurti, MD

12/14/2022 15:56 - Report Electronically Signed Out

Specimen(s) Received:

BREAST, LEFT, 2:00 , BIOPSY

Clinical History and Impression:

2 sisters with breast cancer

2.6 cm left breast mass, 2:00, 5 cm FN

Interpretation:

Immunohistochemistry was performed on formalin-fixed paraffin embedded tissue on Current Specimen: Part: 1, Block: 1 BR (BREAST, LEFT, 2:00 , BIOPSY).

Invasive carcinoma:

ER: Low-positive (7-10%,1-2 +)

PR: Negative (<1%) (Internal control is positive)

Her2: Negative (1+)

US BREAST BILATERAL LIMITED

Maryam Etesami, MD, and Irene de Oliveira Santo, MD

#E116412906 - MAMMO DIAGNOSTIC TOMO BILATERAL W/LTD US: 12/23/2022

CLINICAL: Newly diagnosed left breast cancer. Last mammo 2014. Digital breast tomosynthesis was performed and used in the interpretation of images. C-View (synthesized 2D) mammography was utilized. Current study was also evaluated with a Computer Aided Detection (CAD) system. Comparison is made to exams dated: 12/5/2022 ultrasound, 11/15/2021 ultrasound, and 11/2/2020 ultrasound - Hammers Healthcare. Real-time ultrasound of the right breast 6 o'clock region and color flow and real-time ultrasound of the left breast 2

o'clock, and axilla regions were performed. Gray scale images of the real-time examination were reviewed. The breasts are heterogeneously dense, which may obscure small masses. There is a benign vascular calcification in both breasts. There is a new high-density mass with an indistinct margin in the left breast at 2 o'clock middle depth 5 cm from the nipple. This correlates as palpated. There is a 2 cm hematoma associated with the mass. Ultrasound demonstrates a new 2.4 cm x 2.8 cm x 1.8 cm oval mass with an indistinct margin at 2 o'clock middle depth 5 cm from the nipple. This oval mass is heterogenous. This correlates with mammography findings. No significant abnormalities were seen sonographically in the right breast or left axilla.

IMPRESSION: KNOWN BIOPSY PROVEN MALIGNANCY - BI-RADS 6, ULTRASOUND KNOWN BIOPSY PROVEN MALIGNANCY - BI-RADS 6. The new 2.4 cm x 2.8 cm x 1.8 cm oval mass in the left breast is consistent with the known carcinoma and is a known biopsy positive for malignancy. No clip was placed during biopsy. The patient will follow-up with her surgeon and oncologist. The exam was reviewed by a staff physician. Your patient's mammograms demonstrate that she has dense breast tissue, which could hide small abnormalities. In compliance with CT Public Act No 09-41 the patient has been sent a letter which informs her that she has dense breast tissue and might benefit from annual supplementary screening tests such as breast ultrasound screening or a breast MRI examination depending on her individual risk factors. The patient may contact you if she has any questions or concerns. Findings and recommendations were discussed with the patient, and a lay letter was provided at time of visit.

BILATERAL BREAST ULTRASOUND

Hammers & Riccio Imaging, PLLC (Gioia Riccio, MD, and Lynwood Hammers, DO, FAOCR)

1/3/2024

Clinical history: Patient had left invasive ductal carcinoma status post lumpectomy in February 2023. Sentinel node dissection was negative. No radiation no chemotherapy. Positive family history of sisters with breast and ovarian carcinoma, niece with colon carcinoma.

Grayscale and color Doppler imaging of both breasts was performed. Imaging was performed to include all 4 quadrants, the retroareolar and axillary regions bilaterally.

Comparison is made to the patient's prior exams.

Within the left breast, there is postoperative scarring demonstrated at the 1 to 2 o'clock position at the site of the patient's previously identified left breast mass. There is no residual fluid collection identified. The scar is unremarkable. There is no soft tissue identified. Within the axilla, there are small scattered lymph nodes appreciated. There is no pathologic adenopathy. Laterally at the 3 o'clock position 4 cm from the nipple there is a tiny intramammary lymph node measuring 4 mm with normal morphology.

Impression: Unremarkable evaluation of the right breast. Left breast demonstrates postoperative change. No new findings are appreciated. The scar appears intact without evidence for fluid collection or residual soft tissue density. There is no suspicious adenopathy identified. Findings were discussed with the patient.

Given the patient's family history, consideration a screening for Lynch syndrome may be helpful.

BI-RADS Category 2

“Your scar looks amazing!” - Dr. Riccio