The Byway

a lonely path

by
Margaret M. Waddington MD

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Medical Scope Publishing Corporation, Edmonton, Alberta, Canada

First Edition

ISBN 978-0-9780948-8-1

PRINTED IN CANADA
Printed on acid-free paper

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dedicated to all involved in the fight against cancer

Acknowledgements

Dr. Daniel Kirsch encouraged this endeavor, right from the start: he supplied the Alpha-Stim® 100 Unit that made life bearable when pain and adverse circumstances came my way. He urged me to document events and offered encouragement throughout many years. Most heart-felt thanks to him, and to all those who work at his company to make a fine product.

Anthony P. Pawlak, from Rutgers University, spent many tedious hours doing a detailed statistical analysis of the data. His effort gave legitimacy to the endeavor. We thank him for his effort.

Alison Darrow, meticulous editor and friend, worked tirelessly to complete this project in time for my publisher, Patrick McLaughlin, at Scope Communication in Edmonton Canada, to take the manuscript and turn it into a handsome book.

Many dear friends offered encouragement and ideas and contributed in many untold ways. Thank you for being there, and for your love and kindness, so vital to sustain one in the fight against cancer.

MMW 2007

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Author's Note

Why this story? It is an adventure of taking "the road less traveled" when I was given a diagnosis of cancer, chronic lymphocytic leukemia, eleven years ago.

Aware that "A moment's insight is sometimes worth a life's experience,"[1] I need to report a fortuitous discovery that a novel electromedical treatment stabilized leukemia.

Why not publish in a medical journal, the usual case report? The discovery lacks double blind confirmation and the rigorous clinical requirements science demands today.

Anyone familiar with Nassim Nicholas Taleb's books, *Fooled by Randomness* and *The Black Swan*, will understand my reluctance to be dogmatic, all that certain, or persuasive. Let the evidence speak for itself.

Lastly, it is my wish to express, sincerely, thanks to all friends and colleagues who shared this adventure by giving support, encouragement, and the best advice they could muster. Special thanks to Daniel L. Kirsch, PhD, DAAPM, FAIS, who encouraged me in breaking new ground in electromedicine.

MMW, MD
August 2007

1 Oliver Wendell Holmes, 1809-1894

To Margaret:

Of many gifts of God to man,
The richest one by far
Is friendship — soul to kindred soul:
It lifts both, toward a star.

Louise H. McCoy, 1997


February 26, 1996

Part 1

Onset of Illness

In January 1996, at age 66, I come down with a typical viral illness, with cough and respiratory symptoms. These symptoms drag on for a month, then resolve without use of any medication. The next week, however, I'm totally exhausted. Physically, no illness is apparent, but the severity of the fatigue is such I ask for an appointment with my internist.

Among the lab tests performed is flow cytometry. This test is used to count blood cells, examine their shape and size, and determine whether malignant cells are present. I'm told I have abnormally high numbers of B lymphocytes (a type of white blood cell) and that I have an overall mix of blood cell types that is rare, except in cases of chronic lymphocytic leukemia.

Other findings — the lymphocytes are expressing kappa light chains and surface antigens CD5 and CD 23 — establish this diagnosis firmly and unequivocally. There is no room for doubt. Suddenly I feel as though a ton of bricks has landed on my shoulders. Cancer? Bewildered, I leave the internist's office. What next?

Consultation with an Oncologist

At my internist's insistence, I agree to consult with a board-certified oncologist, a graduate of a prestigious United States medical school renowned for its cancer research facility.

The waiting room is windowless, the walls a pale gray and undecorated. While waiting for an hour for my appointment, I watch cancer patients come and go. Many are thin, emaciated, frail, and sad looking. The receptionist, a gentle person, assures each one: "You look so much better!" I listen and watch, and I am haunted by the memory of Holocaust survivors I encountered after WWII. Is this what chemotherapy does to you? I'm reminded of the inscription at the entrance to Hell:

ABANDON HOPE, ALL YOU WHO ENTER HERE
(Canto 3 of *Inferno* in T*he Divine Comedy* by Dante Alighieri)

The consultation takes an hour and is most thorough. The oncologist's recommendation is to use a drug that I administered as an intern, many years ago. I saw its terrible effects first-hand, and I'm distressed to think that there has been no progress in therapy since then. The final verdict is: "You have a two-year life expectancy unless you accept chemotherapy. Chemotherapy will extend your life, but by no more than eight years."

As I leave the office, I'm overcome by tears. I head out to my farm and walk along the brook until I can compose myself. Overcome and bewildered, I recall Robert Frost's poem *The Road Not Taken*, particularly the last two lines:

I took the one less traveled by
And that made all the difference.[1]

Yes, I'll settle gladly for two years, anything not to go through chemotherapy. Emotions color the decisions we take in life, a lesson taught to me years ago. I love life and hate the ugly side of it! So the decision was simple — or so it seemed at the time.

1 Frost, R. (1949). *Complete Poems of Robert Frost.* Holt, Rinehart and Winston, New York-Chicago-San Francisco Copyright 1962, 17th ed. published 1964. Page 131, *The Road Not Taken.*

Chemotherapy Declined

In consultation with my internist, I freely express my reluctance to have chemotherapy. My age, moderately impaired immune system, and preference to live a full life (for presumably no more than two years) make this decision definitely preferable. Then too, I live by myself, without support other than by friends, and I do not wish to be a burden to others.

My internist agrees to be available for medical problems I may encounter, and a friendship of understanding evolves. He suggests that I abandon plans for travel, flight, hotels, and the like because my immune system is compromised. During the flu season, I should ask others to do my grocery shopping; in addition, avoid movies, church, or other large gatherings of people. He recommends that I look into cancer prevention diets, learn to be cautious in general, and make the most of each day.

The farm is an ideal place to enjoy the moment. I have no livestock to care for, though all the wild animals show up: deer, bear, moose, raccoon, foxes, and a bevy of sundry birds. It is a wonderful place to walk. A gurgling trout brook, fields, and woods. Plenty of work is needed to neaten up the place, for enjoyment and to maintain physical strength.

I'm blessed with support and help from several nearby folk, who seem to understand, without much need for me to explain, that I am on the road less traveled. One lady lost her teenaged son to leukemia and recalls the hardships of the year of chemotherapy, which gave him some temporary relief but took his life within a year.

The Cancer Prevention Diet

The idea is simple: eat right to reduce the risks of cancer. There are several fine books to choose from. Some important aspects are:

- Keep sugar to a minimum, for cancer cells are voracious in their appetite for sugar.
- Avoid smoked and grilled food, which contain carcinogens.
- Avoid meat from animals that are fed hormones or antibiotics.
- Eat protein in moderate amounts (cancer cells love protein).
- Buy organic food when available (the supply is now ample, though costly).
- Get plenty of fresh vegetables and fruit.
- Keep alcohol to a minimum.
- Consume coffee, tea, and chocolate in moderation.
- As a rule, avoid serious dieting and try to keep weight stable.

Take all of this advice with a grain of salt, and discuss your diet with your doctor or a well-trained dietician.

Antioxidants

These substances in foods and beverages are increasingly getting attention as helpful in slowing down leukemia or even in enhancing remissions.[1] The Mayo Clinic is testing a green tea extract called epigallocatechin gallate (EGCG) in patients with chronic lymphocytic leukemia.[2] This extract provides an antioxidant dose equivalent to drinking 20 cups of green tea per day.

Pomegranate juice or fruit in particular is deemed beneficial for its high antioxidant content. These and other dietary supplements are gaining recognition as useful both for improving overall health and for making people with cancer feel better.

1 Shanafelt TD et al. Clinical Effects of Oral Green Tea Extracts in Four Patients With Low Grade B-Cell Malignancies. *Leuk Res* 2006; 30(6):707-12.
2 Rundle, R. Testing the Power of Green Tea: Human Trial Examines Whether Extract Can Kill Stubborn Leukemia Cells. *Wall Street Journal*, March 21, 2006.

Daffodils to the Rescue!

By Fall of 1996, I'm moderately depressed. As fall approaches, I decide that daffodils would be something to look forward to during the long Vermont winter.

Five dear friends agree to help plant 2,000 daffodils on a hillside in sight of the homestead. No sooner have we finished planting than 3,000 more daffodils arrive by mail from the company that supplied the first shipment! I phone them the same day to announce that an error has been made and that I'll return the second shipment post-haste.

"Oh no, do not return the daffodils — plant them or give them to friends. For these, there is no charge."

This second lot is too much of a good thing, or so it seems to me. Help is summoned again. Everyone receives 100 daffodils for their homes, and we plant the rest at the farm.

17 Jan 97

Dear Dr. Margaret -

I found this article in the Family Circle book and thought you might be interested in it.

If you haven't heard of this study on asparagus perhaps you could contact the Rutgers University to find out more. Wouldn't that be wonderful if indeed it did work!!

We think of you often and hope for warm weather and no colds so we can have a good visit.

Your friends,
Elmer & Fran

Elmer and Fran's letter, 17 Jan 97

Dear Dr. Margaret —
I found this article in the Family Circle book and thought you might be interested in it.
If you haven't heard of this study on asparagus perhaps you could contact the Rutgers University to find out more. Wouldn't that be wonderful if indeed it did work!
We think of you often and hope for warm weather and no colds so we can have a good visit.

Your friends, Elmer & Fran

Hope Springs Eternal

Spring is on its way when I receive a letter from my friends Elmer and Fran. Abundant asparagus will be available, so maybe this is worth an experiment?

In past years of medical practice, I usually suggested that my patients try medication for six weeks, barring any adverse side effects. I love asparagus, so why not eat two pounds a day for six weeks? By then, I'll have a follow-up appointment with my internist and a chance to see if the asparagus has any beneficial effect on my white blood cell count, which has been slowly increasing.[1] On March 12, 1997, my count is 13,500. The total lymphocyte count is 8,800. I seem to tolerate the asparagus well enough, but by May 5, 1997, it is obvious that eating asparagus has made no difference. The white blood count is 13,400, and the lymphocyte count has risen to 9,200!

I assure my friends that the asparagus was worth the effort, but that unfortunately I had no luck with it.

Within months, I meet a colleague who knows the scientist at Rutgers who is doing this research. When I tell my colleague about my failed experiment, there is much laughter. "You might have to consume 15 pounds of asparagus per day, and even then, that might be insufficient!" Saponin, the substance named in the article, must be extracted from the asparagus and concentrated. This is after all only a petri dish experiment!

By now, the daffodils are in bloom, and life goes on...

1 A normal white blood cell count ranges from about 4,500 to 11,000 per microliter of blood (the average is roughly 7,000). Chronic lymphocytic leukemia causes a steady, permanent increase in white blood cell count, specifically in the number of lymphocytes.

photo courtesy of Kathrine Sivret

Thoughts for the Day

e-mail from a friend

There is tremendous happiness in making others happy, despite our own situations.
Shared grief is half the sorrow, but happiness, when shared, is doubled.
If you want to feel rich, just count all the things you have that money can't buy.

"Today is a gift, that is why it is called The Present."

Dare to Risk

To laugh is to risk appearing the fool.
To weep is to risk appearing sentimental.
To reach for another is to risk involvement.
To expose your ideas, your dreams before a
crowd is to risk their loss.

To love is to risk being loved in return.
But risks must be taken, because the
greatest hazard in life is to risk nothing.
The people who risk nothing, do nothing,
have nothing, are nothing.

They may avoid suffering and sorrow, but
they cannot learn, feel, change, grow, love, live.
Chained by their attitudes, they are slaves;
they have forfeited their freedom.
Only a person who risks is free.

— Author Unknown

Wildlife Photography

November 1996, I'm invited to participate in a session of wildlife photography taking place at a mountain resort, five miles from the farm. The owner, in extending the invitation, suggests I can stay at the farm and commute to the Inn for the event, and he tells me, "I believe you must long for a change. You've been unable to travel and have a long winter ahead."

I'm delighted, though very much a novice. When asked to show an animal photograph taken during the past year, the other participants show stunning photography. I had only one Monarch Butterfly to show!

No, I had never been to a photography school — so I'm advised to always focus the camera at the animal's eyes. Then we are given an opportunity to photograph a Siberian tiger in snow! The animal has been rescued from a circus, rehabilitated, and is now 20 years old. What a thrill, to have the opportunity to see such a rare animal only five miles from my farm, in VERMONT! It is really an exceptional moment in a life now restricted from travel. The organizers grant me permission to come and go as I please. The bitter cold November wind is chilling to the bone. Standing in snow to do the photography tires me. Within an hour or less, I return to the farm for rest and warmth. I admire the other hardy participants, who can last an eight-hour day. Nevertheless, within a week, I have a treasure trove of wild animal photos. These portraits grace my next book: *Bear With Me*.

THE SIBERIAN TIGER
much feared by all others
in the animal kingdom

In the evening, I resume writing, comfortably settled in my den. This room has a fireplace. There is plenty of wood to keep the place snug and warm.

At Christmas, a friend lights up an outdoor pine tree to cheer up the long winter night. Blissfully, time passes.

The Alpha-Stim® Unit

Summer, always a welcome time, arrives. Flowers, a garden with fresh vegetables, and maintaining the fields — especially driving the tractor to cut around outer edge for space to walk — all seem delightful.

One morning in September 1997, I notice an insect bite and a prominent, rapidly spreading rash on my chest. I phone my internist, who asks me to come in immediately. He will be leaving for a medical conference in a few hours and is concerned that this rash could herald a potentially serious infection. I'm given an antibiotic and instructed to be sure to take the full course.

By the fourth day, liver pain sets in. Wishing to abide by instructions, I finish the supply given to me. By now, the liver pain is intense. Allergic to narcotics, I need help. My physician is still out of town, so I phone a retired neurosurgeon, a special friend, to discuss my options. After further inquiry, he returns my call to say, "We can cut the nerves that supply the liver; or, before taking such a drastic step, you may wish to consult with the physician in charge of sports medicine at our local university. He is a specialist in pain management."

When I see the specialist, he assures me that my liver is greatly enlarged, perhaps because of my untreated chronic lymphocytic leukemia. He recommends a relatively new device: an Alpha-Stim® 100 Unit.[1] This microcurrent stimulator uses electrodes to deliver electrical impulses in a proprietary waveform to control pain. When I put the unit to use, my pain is reduced by 60%–90% within a few minutes. The relief is astounding.

I use the device all day long, though not at night, until December 1997, then for two to three hours every day until early May. By then, my liver is back to normal size, and I'm free of pain. I stop using the unit. The event is judged to be an allergic reaction to the medication, not a result of my leukemia. My liver functions revert to normal.

Relieved, I store the unit away for any future painful event.

1 www.alpha-stim.com

The Eat Right Diet

In June 1998, I receive as a gift a book by Dr. Peter J. D'Adamo: *The Eat Right Diet*. I'm intrigued by this new approach to diet. This book elaborately traces the evolution of blood types and provides evidence that certain diets are best for each blood type. Most interesting to me is the discussion of the cancer–lectin connection. It seems that lectins can be used to agglutinate cancer cells and thus act as a catalyst for the immune system. The author suggests that for blood type A or AB (I have AB blood), one should eat snails (*Helix pomatia*), for they are rich in lectins, and consider them "medicine packaged in a delicious form." Though they are recommended for breast cancer patients, I ask myself: Maybe this could help my impaired immune system, even though I do not have breast cancer but leukemia? On and off, I've had moderate discomfort in my upper right torso, during which my liver is slightly enlarged. My internist has suggested that these symptoms may occur because my impaired immune system has difficulty ridding my body of cancer cells. Perhaps the snails can help.

But how many snails each day? Well, the small cans of snails in the grocery store are judged to be one portion for an adult. I purchase 14 cans — a two-week supply — and eat snails with lunch every day. In two weeks, I'm free of the low-grade, nagging liver pain, and the liver is back to normal size. When I tell my internist about the snails, he looks at me a little strangely. Intrigued, he reads the pertinent chapters in D'Adamo's book. On my next visit, he suggests that maybe six snails a day might be sufficient. I try this variation for two weeks, with less good relief, and decide that 12 snails a day seem just right. Do I get tired of snails? Yes indeed! But stopping the snails always leads to a flare-up of liver swelling, and so before long, I'm back on snails. Friends often ask, "Are you still believing in snails?" Well, yes; they seem to help me to feel better, and they are harmless.

Could my response to the snails be just a placebo effect?

This question leads me to read several books:
The Placebo Response, by Howard Brody, M.D., Ph.D.
The Psychobiology of Mind-Body Healing, by Ernest Lawrence Rossi
The Biology of Belief, by Bruce Lipton Ph.D.

Fascinating reading, and yes, maybe my well-being is enhanced by the placebo effect. All to the good, as far as I'm concerned. Should I really care? Are mind-body healing and the placebo effect not an integral part of medicine? Throughout several centuries, bread rolled into small balls, named pills, enhanced the recovery of many a patient. So I continue with my snail "pills."

During the latter part of 1998, my white blood cell count climbs steadily. I inquire, "Are all these blood tests necessary?" The answer: "The blood tests never will come down; they will just keep getting a little higher as time goes by. This is the nature of leukemia; nevertheless, monitoring the change is important." So lots of data accumulates.

How Do You Pass the Time?

All goes reasonably well until mid-May 1999. I have survived more than three years without chemotherapy, been active, and have been able to lead a nearly normal life, though I notice a tendency to tire far more readily than before the diagnosis of leukemia. By now, I rest one to two hours each afternoon.

During daily walks (at least a mile or more) along the river's edge, I clear brush and pile it in stacks to make homes for wee animals. Vermont winters are long and harsh.

A newly acquired camera becomes my constant companion. I'm told all too often, "Too many pictures!" I turn the surplus photos into cards, as gifts for friends.

To save on printing expenses, I acquire a computer and digital camera, and I develop my own prints. In time, these photos entice a friend to write poems, and 16 small books (the *Vermont* series) are the outcome.

For the first time in my life, I have ample time to read. And read I do. I'm often told, "You don't read books, you just eat them up!" Well, maybe I do. But how to express the thrill of new ideas and adventures found in books written by talented authors?

Then too, I loan my books to friends. Many a heated discussion follows; disagreement or agreement livens things up. On occasion, these debates lead to extended phone calls. All of this activity makes up for my lack of company and relative isolation.

When I am too preoccupied by unwelcome thoughts, I find that a jigsaw puzzle becomes a neat and effective diversion. I've learned that jig saw puzzles halt mental multi-tasking. If you do not focus on the puzzle, you'll never complete the picture. As a means of diverting someone coping with cancer or disappointment, I'll attest that a puzzle is a most helpful occupation, especially in the depths of January or February, when the snow is too deep for snow-shoeing, or ice is underfoot. Once the snow melts, puzzles and games can be stored away.

Then there are my daily chores: cooking and cleaning, and sewing. Correspondence is always in need of attention. Time does not slow down this winter — it seems to go too fast!

By March, the sap is flowing and maple sugaring starts, sweetening the air with its special fragrance. The outdoors is beckoning — a new beginning — and the daffodils are sprouting!

Enlarged Lymph Nodes

In mid-May 1999, I notice fairly abrupt onset of enlarged lymph nodes in both armpits. The nodes reach well over an inch in diameter and are painful to the extent that I learn to sleep with my arms above my head. Soon, however, this solution does not help. It occurs to me that maybe I could use the Alpha-Stim® unit to decrease the pain. Reluctant to experiment without input from the company, I phone them.[1] I inquire, "Is it safe to use the unit for this problem? Where should I apply the electrodes?" I'm told it is quite safe and am instructed where to apply them. Then they request, "Nobody we know of has used the unit for painful lymph nodes. Do please let us know what the outcome is."[2]

Encouraged, I follow their instructions. Lo and behold, I'm virtually pain free shortly after I start using the unit, and within 24 hours, all the lymph nodes shrink dramatically. My internist confirms these observations during my next appointment. He is pleased that I'm pain free and functioning well once again. Unfortunately, the node enlargement tends to recur, usually within two to four weeks. As soon as enlargement or discomfort sets in, I use the unit; it is also quite successful for nodes in the groin.

This pattern persists until May 2001. Suddenly my liver once again becomes enlarged and painful. The diagnosis is toxic hepatitis, an adverse response attributed to the drug Tegretol, which I have been taking for nine years. I stop taking the drug and use the Alpha-Stim® 100 unit 12 hours each day for pain control. By early August 2001, I have made a good recovery: my liver is back to normal. I continue using the unit to treat the lymph nodes, with similar results.

1 Electromedical Products International, Inc., Mineral Wells, TX 1-800-FOR-PAIN
2 In July 2004, I send a testimonial to Dr. Daniel Kirsch at EPI, Inc., describing my experience with the unit.

Early Medical Data

The spreadsheets from 1994 through 12-09-2002 (in PART 2) summarize the lab findings. The drop in lymphocytes is highlighted in orange.

More Intense Use of Unit

PHASE I

In January 2003, I come down with a herpes zoster outbreak, which causes a painful, blistering rash on my right side from midsection to mid-thigh. I start using the Alpha-Stim® 100 unit much more aggressively for pain control, up to 12 hours each day. The blisters, rash, and pain resolve in two weeks, with no after-effects.

In April 2003, I take a turn for the worse. Terrible fatigue sets in, and I sleep 18 hours a day. When I consult with my internist, he presents a bleak outlook: "You have but a few months left." For an hour, he urges me to reconsider chemotherapy. "Perhaps you can have another year to look forward to, were you to have this therapy."

"Give me time to think it over," I reply. Need I admit to sadness and bewilderment?

The farm serves as the place to reconsider my options. I weep on the shoulders of friends and walk and walk along the brook and in the wood till sleep comes from exhaustion. I confer with a colleague when he and his wife return from vacation. "Make the best of the remaining months" is his advice, and I conclude with, "Let me go quietly into the night." I decide again to abstain from drastic intervention.

September 15, 2003

Now, I'm more or less on my own. After two or three days I decide, without telling anyone, to use the Alpha-Stim® unit not just 12 hours each day but instead non-stop, 24 hours a day. By July 7, 2003, I begin to improve. Fatigue lets up, and I have no liver pain of consequence. I decide to continue this routine. When I see my internist in late August, my white blood cell count has dropped from 30,400 to 14,000. Then abruptly, within a span of one or two hours, I develop generalized joint pain and severe shortness of breath. My internist sees me the next morning, starts me on steroids, and orders an echocardiogram, lung scan, and blood tests. He finds that I have pleural and pericardial effusion (fluid around my lungs and heart) and tells me I'm having an acute autoimmune diathesis.[1] I admit to the doctor that I have used the unit 24 hours a day and swear I'll never use it again!

Within less than a week I'm able to stop taking the steroids, and I make a fairly prompt recovery. However, by October 1st my white blood cell count has risen to 54,000. That evening, I receive a phone call from my internist, who tells me, "Margaret, the count is going up rapidly. If I were you, I'd restart the unit but cautiously — please, you have to now find out what setting is adequate without precipitating another adverse episode. Next time, I may not be able to reverse the trouble."

PHASE II

A period of trial and error begins. Blood counts and liver pain are my signposts for using the unit. We become aware that the unit reduces the white blood cell count by killing the cancerous B cells. But when too many are killed, liver pain results, presumably because the load of dead cells overtaxes my liver (which must remove them from the body) and weakens my immune system. My immunoglobulin levels (a measure of my immune function) fluctuate with the white blood cell count to a moderate degree.

1 This reaction, which also occurs in cancer patients during chemotherapy, occurs when dead cancer cells accumulate faster than the body can process and remove them.

The Beaver Pond

In late spring of 2004, neighbors tell me of beavers who are building a lodge and dam across a field, through which a brook meanders, no more than four miles from the farm. They tell me, "You ought to go and watch the beavers, in the late afternoon, and take some photos. The lodge is close to the road. It will do you good; it is so peaceful." I've seen a beaver splash, but I've never seen the beaver that made it. No sooner do they tell me about the beavers than I am off to see them.

Watching the beavers becomes my summer entertainment. Each afternoon by 5 P.M., my car is parked just off the dirt road by the beaver dam. Usually within 20 to 30 minutes, one beaver or the other emerges from their lodge. They often announce their presence with a splash. Methodically, they inspect the lodge, swim along the dam, and then go off to feed on ferns. Within a few weeks I can hear the distinct sound of little voices coming from the lodge, and I see the parents diving down into the water, bringing green loads of food to the lodge. At that point, with the arrival of food, the chorus of faint calls stops.

Soon two little ones emerge from the lodge and follow their parents. In fact, one evening in fall I count five beavers.

Enchanted by the beauty of the pond and the activity of the animals, I take "too many pictures." Friends and neighbors often join to watch the evening events on the pond. An old heron arrives at sunset, ducks come and go, and trout jump up from the water. It is a lively place! Much of the tension I've experienced in the past few years vanishes. I look back on this summer as one of the most treasured summers of my life.

PHASE III

This phase starts on January 27, 2005, after another viral infection. By now I seem to regulate the use of the unit far better, though the white blood cell count has risen somewhat.

On April 27, I realize that the count is rising too fast. Suddenly, I notice that the very slight electrical impulses one may experience from time to time while using the unit are now absent. The unit is deemed to be ineffective, and I purchase a new one. The replacement unit works well; the lymphocyte count drops by 12,000 in ten days — but with a complication. The dead lymphocytes cause a massive collection of fluid in a joint, and the fluid must be removed. When I resume using the unit, I do so cautiously and on a more regular basis.

On January 3, 2006, *normal cell morphology* (shape and size) is reported for the first time: no misshapen cancer cells can be seen under a microscope. My internist raises the question that I may be in a remission (but a spontaneous one?).

In 2004, I send a testimonial[1] to Dr. Daniel Kirsch, inventor of the Alpha-Stim® device. He suggests that I continue with my record keeping and submit data for statistical analysis. In September 2006 the data are submitted to statistical analysis, and are reported in Part II of this book.

Thereafter, the frequency of blood tests is reduced to once every six to eight weeks. Normal morphology keeps showing up.

By now, I use the unit three days each week, for 18 hours on each occasion. I have also added a new treatment to prevent liver pain and joint swelling: Avemar.

Time arrives to write up the adventure.

1 See Part II

Steroids or Avé?

Late spring and summer 2005 are difficult because of several episodes of joint swelling, most serious in my feet. On one occasion, the swelling is so severe that the rheumatologist removes approximately 5 cc of thick yellow fluid from a joint between the toes of my right foot. For fear that this fluid might signal an infection, I receive an antibiotic intramuscularly for four days, until the cultures prove negative for infection. Gout also is ruled out. Steroids are used to relieve the swelling, and the unit reduces the pain. In September, the problem has become chronic. My internist's recommendation: "Steroids, for the rest of your life."

I return home aware that this choice presents little wiggle room. I fill the prescription but, reluctant to take the steroid medication, I drink a cup of hot tea, staring at the vial and stalling for time. Procrastinating further, I go to pick up the mail and find in the mailbox the September 2005 issue of *Alternatives for the Health-Conscious Individual*, a newsletter published by David C. Williams, M.D.[1] The cover article is titled, *A Cancer Therapy Out of the Blue*. Junk mail? Who sent it to me? Well, I'd better read this (another way to procrastinate?).

The eight-page article tells of the work of the Nobel Prizewinner, the late Hungarian biochemist Dr. Albert Szent-Györgyi. He was one of the first to theorize links between free radicals and cancer. Working with a compound Szent-Györgyi had studied, another biochemist developed a powder to boost the immune system and help patients get rid of dead cancer cells. According to the article, the powder is dissolved in cold water and taken as a drink — but is not very tasty! It goes by the name of Avemar® (Avé™ in our country) and has been used for more than ten years in Europe to support immune system function.[2] Well, what have I got to lose? Let's try it. I put off taking the steroid medication, phone the company,[3] and await the shipment. The parcel arrives within 48 hours. I drink down the first glass and have to agree; it does not taste very good.

The next morning, I notice a strange event. For months I've had an intense sugar craving, but now it is gone. Strange? Perhaps, but the sugar craving does not return. Within a week after I start daily use of Avé, I discontinue my "snail pills" with no regrets — I'm tired of that good morsel!

1 www.drdavidwilliams.com
2 www.avemar.com
3 www.americanbiosciences.com

Within ten days, my liver pain lets up completely, all joint swelling clears up, I walk normally again, and I can drive my car without using the cruise control (which I was obliged to do when I wore plastic bags on my swollen feet to replace the shoes I no longer could wear).

My white blood cell count improves, and I'm on my way to a much better stretch of living. In January 2006, the cell morphology is normal. Is this a remission? And if so, is it spontaneous, or has my therapy been working?

Normal cell morphology continues to be reported on and off. By 2007, I'm as active as can be, though I continue to tire readily. I'm using the unit on a regular basis. When I receive the statistical results indicating that I have most likely stabilized the leukemia, the need to write up this adventure strikes home.

From the start, I have saved all laboratory tests and kept a diary. Only when the spreadsheets are added do I recognize the amazing, quite consistent effect of the Alpha-Stim® unit in not only reducing pain drastically (a great help for anyone allergic to narcotics) but also in shrinking lymph nodes swollen by cancer cells and coincidentally reducing the lymphocyte count — a chance discovery.

What are my goals in writing my story?

Maybe a scientist somewhere will consider this discovery worth pursuing in some way.

Maybe a frail elderly person facing chemotherapy might wish to explore, for a week or two, whether this approach might be a useful option. (The unit can be *rented* for this purpose.)

I've survived 11 years, after being told by a specialist I had either two, or no more than eight, years ahead of me. At the last visit to my internist I'm told: No enlarged lymph nodes, liver or spleen and all else checked out normal. Remission? Maybe?

These years have been rich in creativity, happiness and laughter though not without challenge. Taking the byway was the right path for me. It gave me the opportunity to contribute, in a minor way, to my chosen profession, medicine.

The Alpha-Stim® Unit

Medical Data
Statistical Analysis
Testimonial

The Alpha-Stim®

This description of the Alpha-Stim® is courtesy of Electromedical Products International, Inc. (EPI), Mineral Wells, Texas. EPI can be reached by phone at 1-800-FOR-PAIN or on the web at www.alpha-stim.com.

Alpha-Stim® was developed by neurobiologist Dr. Daniel L. Kirsch and engineer Raymond Chan. Dr. Kirsch has been a leading pioneer in the field of electromedicine since 1972. He is board-certified in pain management by the American Academy of Pain Management, a Fellow of the American Institute of Stress, and a Member of Inter-Pain (Germany/Switzerland). He is the Electromedical Department Editor of the journal, *Practical Pain Management* and a Consulting Editor for the *Journal of Neurotherapy*. Dr. Kirsch has served as Clinical Director of the Center for Pain and Stress-Related Disorders at Columbia-Presbyterian Medical Center in New York City and the Sports Medicine Group in Santa Monica, California. He lectures frequently to physicians worldwide on pain and stress management and is an expert consultant to Veterans Affairs Medical Centers and the United States Army.

All life is of an electrochemical nature. There are extensive electrical fields at work throughout the universe and the body. The nervous system, for example, has long been known to work through both electrochemical and purely electrical signals. Results in electromedicine are based on the design of the waveform, the location of the electrodes, the amount of current and time it is used. Alpha-Stim® is a microcomputer incorporating the latest advances in solid state electronics. It is a precision technology which generates a modified square bipolar asymmetric rectangular waveform of 0.5, 1.5, or 100 pulses per second (Hz), at 50 to 600 microamperes (1 µA is one-millionth of an ampere), at a 50% duty cycle. The waveform is balanced to achieve 0 net current in either direction. EPI stands behind its technology with a 5-year warranty.

Alpha-Stim® therapy falls into two general categories. *Microcurrent Electrical Therapy*, or MET, is a term used to describe low level current used for pain control applied through probes, or self-adhesive electrodes. It is distinguished from previous forms of transcutaneous electrical nerve stimulation (TENS) in that MET uses far less current, but delivers the current in much longer pulses. Whereas TENS devices must be constantly worn because they offer virtually no residual effect, MET effects are long-lasting and cumulative. The second category, represented by the application using the ear clip electrodes to treat the brain for anxiety, insomnia and/or depression is known as *Cranial Electrotherapy Stimulation*, or CES. The treatment is simple and can easily be self-administered at any time. People using the Alpha-Stim® usually report a pleasant, relaxed feeling of well-being accompanied by an alert mind.

Alpha-Stim® is often the only means required to relieve anxiety, insomnia, depression and pain. However, it may also be added to other therapy prescribed by your doctor.

Alpha-Stim® will not interfere with most other treatments except that it may reduce the requirements for some medications. It is advisable to reduce pain relievers and mood altering drugs about one-third to one-half upon, or shortly after beginning use of Alpha-Stim® and then continuing to adjust medication levels up or down, as required. Only a licensed physician is qualified to adjust medication dosages so keep your doctor informed of your progress.

While Alpha-Stim® is significantly effective when it is used correctly for 9 out of 10 people who use it, it will not work for everyone. Alpha-Stim® leaves the user alert while inducing a relaxed state. Pain and/or anxiety reduction is usually experienced during a single treatment, but may be seen hours later. Insomnia is usually improved after from 1 treatment to 3 weeks of use. Depression typically takes 3 - 6 weeks of daily treatment to improve, but may take considerably longer. After the condition is under control, use of Alpha-Stim® 2 - 3 times per week is usually sufficient to maintain good results.

Electroencephalographic (EEG) research has confirmed the Alpha-Stim® effect of being more relaxed by showing increased Alpha activity and more alert by showing decreased Delta activity. After treatment, there are usually no physical limitations imposed so most people can resume normal activities immediately. Some people may experience a euphoric feeling, or relaxation that may temporarily impair their mental and/or physical abilities for the performance of potentially hazardous tasks, such as operating a motor vehicle or heavy machinery for up to several hours after treatment.

At present, there are over 150 research studies on using Cranial Electrotherapy Stimulation in humans and more then 30 animal studies. No significant lasting side effects have been reported. Occasional self-limiting headache, discomfort or skin irritation under the electrodes or lightheadedness may occur. If a heavy feeling occurs, continue treatment until at least two minutes after it gives way to a light feeling.

Electromedical Products International, Inc. is an International Standards Organization (ISO) certified establishment. ISO is an International organization working with some 140 countries and the United Nations to maintain standards for all applications of technology for global industry. Requirements for the medical device industry relate to design controls, risk management, environmental controls, special processes (e.g. software validation), traceability, record retention, and regulatory actions (such as vigilance). Alpha-Stim® is FDA authorized for interstate marketing in the USA by, or on the order of a licensed health care practitioner; has the CE Mark for non-prescription sale throughout Europe; and has approval in many other countries including Australia, South Africa, Mexico, Canada, China, South Korea, parts of South America and the Middle East.

Raw Data 08-08-1994 through 12-09-2002 is preliminary data. The Alpha-Stim® unit is used for pain control of swollen lymph nodes. Each decrease in lymphocytes after use of unit is highlighted in orange.

DATE	WBC	TLC	IgA	IgG	IgM	Comments:
08-08-1994	7.9	2.6				
06-09-1995	8.9	4.8				
09-14-1995	11.5	6.6				
02-14-1996	11.2	6.6				abnormal lymphs
02-26-1996	11.4	6.6				flow cytometry, CLL, B cells & Kappa
05-14-1996	12					
08-15-1996	12.5	7.4				
11-08-1996	12	6.6	98	619	31	
12-16-1996	12.1		108	659	36	
01-08-1997	13.1	8				
03-12-1997	13.5	8.8				
05-05-1997	13.4	9.2	94	641	33	
09-03-1997	16.8	12.1	91	632	35	use of Alpha-Stim® unit to control pain from enlaraged liver (drug allergy)
11-04-1997	17.2	12.2	98	692	34	8-12 hours/day 60-80% reduction of pain
01-14-1998	19.9	13.2	102	658	38	
05-14-1998	17.5	10.5	96	647	40	pain free, unit discontinued
07-29-1998	17.8	11.9	94	772	37	
09-28-1998	16.8	12.2	97	741	26	
11-10-1998	18.5	14.4	97	713	30	
01-11-1999	21.2	16.2	93	705	32	
03-08-1999	22.4	14.1	88	664	29	
05-13-1999	23.8	19	81	636	21	start Alpha-Stim® to control pain from enlarged lymph nodes
07-12-1999	21.9	10.07	82	613	24	notice nodes shrinking. Use unit 4-8 hours/day 2 to 4 days/week.
09-13-1999	23.7	12.65	76	555	21	
10-25-1999	22.4	9.85	75	561	20	discontinue unit
12-08-1999	19.8	14.25	75	580	24	restart unit, 2 to 3 days/week

DATE	WBC	TLC	IgA	IgG	IgM	Comments:
02-18-2000	22.1	12.1	80	636	23	do not use unit
04-20-2000	20.8	13.87	70	512	23	"
06-19-2000	24.8	15.82	73	592	24	"
08-21-2000	26.3	19.7	78	623	not done	restart use 2 to 3 days to shrink nodes
09-18-2000	25.2	14.4	71	581	24	"
11-14-2000	23.7	15.6	81	640	25	"
1-15-2001	24.4	10.5	69	550	23	"

KEY FOR ABBREVIATIONS USED IN THE COLUMN TITLES
WBC = White Blook Count
TLC = Total Lymphocyte Count
IgA = Immunoglobulin A
IgG = Immunoglobulin G
IgM = Immunoglobulin M

DATE	WBC	TLC	IgA	IgG	IgM	Comments:
01-15-2001	24.4	10.5	69	550	23	
02-12-2001	24.5	12.3	67	579	not done	
03-04-2001	25.3	13.5	75	572	22	intermittent use of unit
04-05-2001	24.5	9.5	76	562	22	"
05-07-2001	23	14.3	89	568	23	
05-17-2001	24.7	14.9	not done	not done	not done	acute liver swelling. Toxic hepatitis from tegrotol? Drug discontinued
05-21-2001	26.6	19.4	not done	not done	not done	use unit 12 hours/day for control of liver pain
08-11-2001	20.8	11.8	76	543	24	beginning to feel much better
06-25-2001	20	9.2	78	560	26	continue use of unit 12 hours/day
07-16-2001	18.3	11.2	74	574	30	"
08-01-2001	18.4	9.4	76	753	25	stop unit, feel so much better
08-20-2001	15.3	5.8	67	526	25	"
09-10-2001	17.1	4.1	70	589	25	"
10-01-2001	16	5.9	75	601	25	"
10-22-2001	18.2	6	73	586	22	"
11-12-2001	18.2	7.3	72	606	33	stop snails
12-03-2001	17.8	6.7	66	526	20	lymph nodes enlarge all over axilla and groin

DATE	WBC	TLC	IgA	IgG	IgM	Comments:
01-15-2002	21.1	11.2	68	538	24	restart unit over nodes for intermittent pain control
02-11-2002	20.1	9.6	68	533	24	
03-04-2002	20.5	10.1	65	524	21	
03-25-2002	22.6	12.2	63	510	19	restart snails, 12 per day
04-15-2002	23	12.8	69	546	20	
05-06-2002	21	12.6	57	474	16	
05-17-2002	21.4	14.9	62	516	19	
06-07-2002	24.1	13.9	60	495	20	use unit 12 hours/day for 3 weeks - then stop. Liver pain
07-01-2002	22.8	10.7	62	524	20	
07-22-2002	22.5	14.9	60	485	21	
08-19-2002	25.8	16.8	61	524	19	
09-16-2002	25.8	20.6	67	522	21	
10-07-2002	27.1	21	65	491	19	unit used only 4 to 6 hours/day try to reduce liver pain
10-21-2002	26.1	17	58	447	17	unit used 4 to 6 hours/day
11-04-2002	27.6	18.5	63	482	18	"
11-15-2002	25.3	16.4	67	582	19	"
12-09-2002	25.3	13.8	60	486	17	"

Description of Phases

Raw data collected from 08-08-1994 through 12-09-2002 are preliminary. The Alpha-Stim® unit was used during this period for pain control of swollen lymph nodes. The drops in lymphocytes are highlighted in orange.

The assessment of subsequent data is in the form of a statistical analysis, shown in Figures 1–5 and in Tables 1 and 2. These displays represent 3 phases: I, II, and III (described in more detail in Part I of this text), which took place over a period of 1312 days.

The statistical analysis was done by Anthony Pawlak, Graduate School of Education, Department of Educational Psychology Rutgers University, New Brunswick, NJ.

Phase I

January 6, 2003 to September 28, 2003

The unit is used 12 hours/day until May, then for 24 hours/day until August 30, because of clinical deterioration. An episode of autoimmune diathesis follows. The unit is subsequently not used until onset of Phase II.

Phase II

October 1, 2003 to January 18, 2005

With the cell count at 54,000, an internist advises to re-start the unit and use it more cautiously. It is a period of trial and error, experimenting how to get the count lower without triggering another major setback.

Phase III

January 27, 2005 to September 6, 2006

Condition stabilizes until April 27, 2005, when the unit is deemed to be ineffective (recognized by the absence of very slight electrical impulses during the use of the unit). A replacement unit works well until onset of a major joint effusion, attributed to the inability to clear dead cells. From then on, the unit is used randomly, for 18 hours/day, no more than 3 days/week. By January 3, 2006, normal cell morphology is reported for the first time. The possibility that this event represents a spontaneous remission cannot be excluded.

Please consult Part I of this book for additional details about all of these phases.

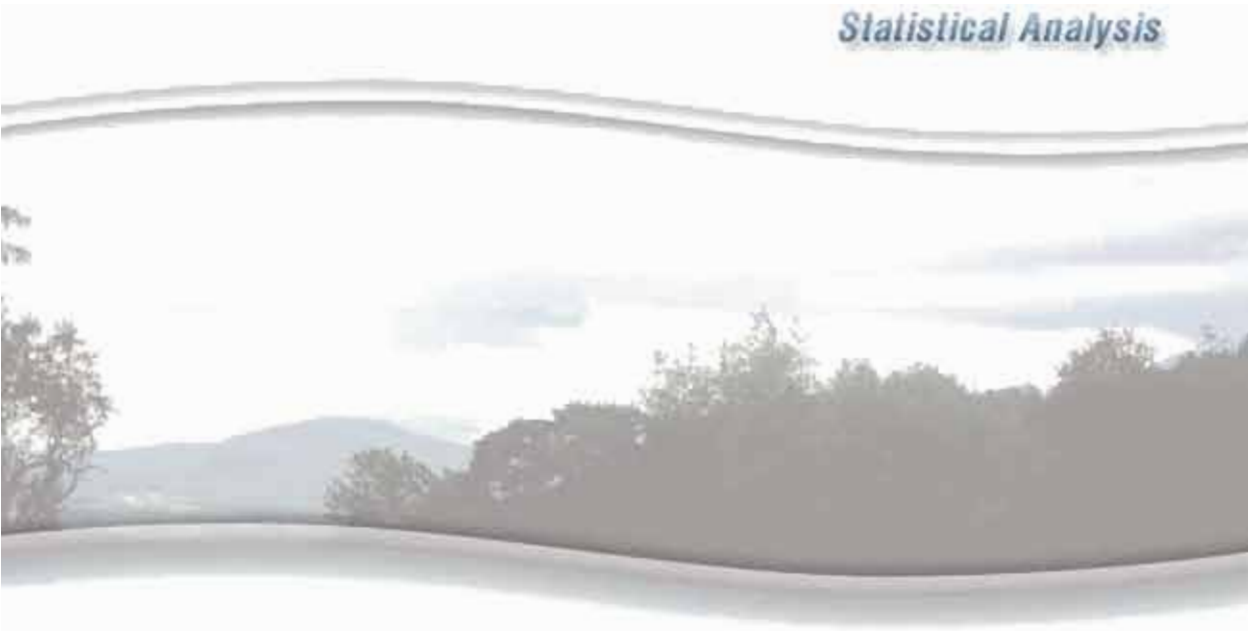
DATE	WBC	TLC	IgA	IgG	IgM	Comments:
PHASE I						
06-Jan-03	26.6	14.3	58	514	< 4	Stop unit because of low IgM level
20-Jan-03	27.4	18.4	64	529	19	Onset of shingles T10-L3, right side only, use unit to control herpetic pain- about 60%. Use no drugs, Recover in 14 days.
10-Feb-03	27.2	15.5	81	565	29	
03-Mar-03	27.9	15.1	57	416	16	
24-Mar-03	29.4	13.9	70	570	23	
21-Apr-03	29.7	21.3	92	511	32	Terribly tired, sleep 18 hours/day.
05-May-03	29.9	19.7	78	508	24	Start unit 12 hours/day over femur bones for 4 weeks.
02-Jun-03	29.9	15.5	61	490	20	Stop unit because of severe liver pain and moderate enlargment.
23-Jun-03	30.9	21.6	90	547	32	Restart unit 12 hours over femur bones, and 12 hours during night to block liver pain at night. Use unit daily 24 hours uninterrupted through 7-07-2003
07-Jul-03	29.7	15.7	99	520	28	Feeling much less tired. No liver pain of consequence.
						Will continue until next lab tests 07-29-2003
29-Jul-03	32.3	18.1				
11-Aug-03	30.4	19.8				
30-Aug-03	14.9	14.9				
28-Sep-03	34.1	173	79	389	19	
PHASE II						
01-Oct-03	54.0	32.4	85	546	24	Alpha-Stim® started
06-Oct-03	42	29.3				
23-Oct-03	30.8	20.0	65	530	19	
03-Nov-03	31.1	19.05				
04-Dec-03	27.6	12.07	54	509	16	
15-Dec-03	20	11.0	53	521	14	Alpha-Stim® stopped

DATE	WBC	TLC	IgA	IgG	IgM	Comments:
05-Jan-04	28.5	18.5	?	?	?	
19-Jan-04	27.6	17.9	37	324	11	
01-Feb-04	28.7	16.3	54	491	17	
26-Feb-04	29.9	18.0	56	555	17	
05-Mar-04	30.5	20.4	57	528	17	
Alpha-Stim® stopped for three weeks						
11-Mar-04	30.2	18.4	57	561	17	
19-Mar-04	28.1	21.3	53	564	17	
26-Mar-04	31.2	21.5	50	492	14	
Alpha-Stim® restarted						*Unit used 4-6 hours/day; electrodes over either rt or lt. ankle
02-Apr-04	28.3	20.9	52	501	14	
09-Apr-04	29.4	18.2	51	513	15	
16-Apr-04	29.1	15.1	59	547	14	
23-Apr-04	28.8	10.9	50	515	14	
30-Apr-04	27.8	12.8	51	503	15	
07-May-04	29.5	20.3	56	545	17	
14-May-04	29.9	23.7		513	15	
21-May-04	29.1	23.7	51	496	17	
28-May-04	32.0	17.0	50	487	15	
03-Jun-04	29.8	20.2	50	501	14	
10-Jun-04	30.6	17.1	51	497	16	
17-Jun-04	29.8	22.9	49	434	14	Alpha-Stim® discontinued; restarted 6/27 till 7/01 for liver pain
24-Jun-04	32.3	28.1	49	483	14	Alpha-Stim® stopped for one week
Alpha-Stim® restarted 6-8 hours/day						
1-Jul-04	30.6	20.8	50	484	14	
22-Jul-04	32.1	18.5	47	442	15	Alpha-Stim® discontinued;
29-Jul-04	34.9	26.5	46	440	14	
02-Sept-04	34.9	26.52	47	482	15	Alpha-Stim® used for 12 hours/day- one week
29-Sept-04	36.5	19.34	50	458	16	Alpha-Stim® not used
11-Oct-04	36.5	30.66	44	468	13	Alpha-Stim® restarted - 8 hours/day for 1 week
29-Dec-04	41.5	26.56	49	51716		

DATE	WBC	TLC	IgA	IgG	IgM	Comments:
1-10-05	40.5	26.73	48	512	15	Morphology ABNORMAL, +4 smudge cells
1-18-05	37.1	28.19	44	413	12	Viral infection (10 days) Unit NOT used
Phase III						
1-27-05	38.6	31.65	43	459	13	Alpha-Stim® restarted for 12 hours for 5 days
2-09-05	38	27.74	46	466	15	2+ smudge cells; abnormal morphology
2-23-05	41.4	32.71	54	498	15	feeling much better-unit not used
3-29-05	36.9	22.87	53	551	15	
4-27-05	37.8	28.72	54	562	16	unit seems NOT effective after 9 years of use - new unit ordered
5-26-05	43.1	36.55	54	554	16	new unit used with sudden onset of lt foot joint effusion (see text)
6-07-05	43.2	28.51	53	511	14	new unit bringing cell count down - but foot very swollen
6-10-05	45.4	41.31	63	551	15	joint aspiration: only lymphocites-cultures negative-steroids started
6-14-05	36.9	32,11	54	562	16	unable to wear shoe, though getting better- unit discontinued because of liver pain
6-22-05	53.6	38.05	52	530	15	unit restarted 6 hours/day for 1 week - improving.
6-29-05 7-06-05	47.9	28.74	52	502	15	sudden swelling in rt foot and all major joints; stay home for 17 days liver function all normal, uric acid normal
7-13-05	44.3	38.54				
7-27-05	42.8	32.37	51	470	15	
8-17-05	44.6	34.78	44	462	12	long term steroids recommended; instead, Avé™ drink started (see text for details)
8-31-05	42.3	27.91				
9-28-05	39.7	32.55	52	505	16	
10-26-05	41.1	20.91	49	458	15	unit not used
11-09-05	42.1	28.98	51	529	15	unit not used
12-09-05	39.9	34.71	49	517	16	unit restarted on 12/26 - 3days, 8-10 hours/day, then off for 3 days

DATE	WBC	TLC	IgA	IgG	IgM	Comments:
1-03-06	39.8	27.06	41	467	<10	Cell morphology NORMAL; 1+ smudge cells
2-08-06	41.2	29.66	33	446	<10	Cell morphology ABNORMAL; 3+ smudge cells
3-15-06	46.2	30.03	41	47	12	Cell morphology NORMAL; NO+ smudge cells
5-08-06	44.7	33.97	26	374	<10	Cell morphology ABNORMAL; 3+ smudge cells. Alpha-Stim® restarted. 3 days for 10 hours, once a week.
6-21-06	42.4	32.64	30	373	<10	Cell morphology ABNORMAL; 3+ smudge cells
7-05-06	43.1	32.03	56	613	205	Cell morphology Abnormal; 3+ smudge cells (Immpower & Immutol worked) Will use Alpha-Stim® 16 hours/day for one week now immune system has improved
7-12-06	39.7	27.11	37	506	<10	Cell morphilogy NORMAL; smudge cells +2; resume Alpha-Stim® in 3 days
7-19-06	43.6	36.19	29	430	<10	7-14 bilateral eye infection- use Vigamox 0.5 solution for 6 days infection clears.
8-09-06	43.1	34.41	40	524	<10	Use Unit 3days/week (18 hr each day) cell morph: NORMAL; smudge c.+2- feel stable and quite well.
9-06-06	45.6	36.51	32	522	<10	Stopped using unit (8/24-9/06) took a break! Unit restarted 9/06!

End of Phase III



Statistical Analysis

by

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Methods

The data were longitudinally collected from a single subject over a period of 1312 days, which began on January 6, 2003 and ended on August 9, 2006. The data were collected as part of the monitoring of the subject by her physician specialist. Five dependent variables of interest were collected: white blood cell count (WBC), total lymphocyte count (TLC), and levels of immunoglobulins A, M, and G (IgA, IgM, and IgG). The entire data collection period was divided up into three phases: Phases 1, 2, and 3. Each phase corresponded to a different treatment protocol that was implemented by the subject. Phase 1, Phase 2, and Phase 3 are described on pages 19, 21, and 24, respectively.

Analyses

Because the data were longitudinal and collected on a single subject, an autoregressive modeling approach was chosen as the most optimal way to analyze the data. Longitudinal data collected on a single subject can contain serial autocorrelation, attributable to the lack of independence of observations over time (Fox, 1997; Neter, Kutner, Nachtsheim, & Wasserman, 1996). Serial autocorrelation is generally conceived as the correlation between regression error values, which are produced by a regression model with some sort of temporal independent variable, and their corresponding counterparts at a given number of time lags (Fox, 1997; SAS Institute Inc., 2004). For instance, correlating a set of regression error terms with a second set of error terms that correspond to the observations at one unit of time immediately previous to the observations associated with the first set of error terms produces a first order autocorrelation coefficient. Without a correction for serial autocorrelation, parameter estimates and/or their standard errors in regression models can be seriously biased (Fox, 1997; Neter et al., 1996; SAS Institute Inc., 2004). Autoregression models can correct for the presence of serial autocorrelation in the error parameter for any given number of temporal lags by incorporating autoregressive lag component(s) in the model (SAS Institute Inc., 2004).

The ultimate goal of this analysis was to determine the autoregressive model for each individual variable per phase. The autoregressive modeling approach enabled the

rate of change during each treatment phase to be determined for each variable, and thus, a key component of each variable's temporal trend could be discerned. For instance, if the autoregression slope for a given variable was statistically not different from zero in a particular phase, then it could be inferred that the mean level of the variable did not appreciably change during that phase. Furthermore, tests were carried out to determine if the autoregressive models for adjacent phases, i.e., Phases 1 and 2, and Phases 2 and 3, were statistically different or similar. This was done through the Chow test for structural break points, which is essentially similar to the F test in ANOVA (SAS Institute Inc., 2004). The length of treatment across all three phases was represented by the number of days since Phase 1 began, with the first day of Phase 1 demarcated as Day 0, the first day of Phase 2 demarcated as Day 268, and the first day of Phase 3 demarcated as Day 752.

An iterative analytical procedure was used to determine the final set of autoregression models for each variable. All analyses were carried out using SAS PROC AUTOREG (SAS Institute Inc., 2004). First, separate autoregression models were fitted for a single dependent variable for each phase, and a backward elimination procedure was used to discover the presence of any statistically significant autoregressive lag components (see SAS Institute Inc. (2007) for more details on the backward elimination procedure). Second, the autoregressive models for each phase were then rerun with the appropriate autocorrelation lag(s), and the residuals from these runs were saved. Third, the saved residuals were standardized and graphically examined for outliers in residual plots in which the standardized residuals were plotted against the corresponding predicted values. Although no universal standard exists per se of a minimum standardized residual value for flagging outliers, many researchers prefer to use a value of |2| (Pedhazur, 1997). For this study, a more conservative value of |2.5| was chosen. Fourth, once any outlier values were identified, they were removed from the analysis, and the analysis cycle began again. The analysis cycles were terminated when no more outliers were identified for any of the autoregressive models across all phases for a given variable.

Once the outliers were removed, a Chow test for significant structural breaks between adjacent autoregressive models was carried out for treatment Phases 1 and 2, and for treatment Phases 2 and 3. In order to minimize the effect of Type I error stemming from doing multiple Chow significance tests, an overall familywise *P* value of 0.05 was chosen for each variable, and a Bonferroni correction was applied, so that the threshold of significance was a *P* value of 0.025. If the Chow tests determined that both sets of adjoining treatment phases did indeed have significantly different autoregressive models, then the models from the last cycle of the previous iterative analyses were retained as the final set of models.

However, if the Chow tests determined that the autoregressive models for at least one set of adjoining treatment phases were not significantly different from each other, then an autoregression model was fitted to both of the adjoining treatment phases in question. The autoregression model for both adjoining treatment phases was then subjected to the iterative analytical procedure described above in order to screen for outliers. The procedure was terminated when no remaining outliers were detected. The Chow test was then done between the autoregression model for the two adjoining treatment phases and the autoregression model for the remaining treatment phase at a significance threshold *P* value of 0.025. If the Chow test determined that both autoregression models were significantly different from each other, then both of the models in the Chow test were retained as the final set of models.

However, if the Chow test determined that the two autoregression models were not significantly different from each other, then a final autoregressive model was fitted across all three treatment phases. The autoregressive model across all three treatment phases was then subjected to the iterative analytical procedure described above in order to screen for outliers. The procedure was terminated once no remaining outliers were identified. The model determined during the last cycle of the iterative procedure was retained as the final model.

In addition to the autoregressive models, a spline regression line was calculated and plotted for each variable. An advantage of spline regression lines is that they

can be relatively robust against outliers but still capture the general trend of the data. The spline regression lines were computed using SAS PROC GPLOT with an interpolation setting of 50 for the spline curve. The interpolation setting can vary from 0 to 99, with a setting of 0 producing a strongly curvilinear line that passes through every single data point, and a setting of 99 producing a perfectly straight line. Thus, a setting of 50 produces a line that is influenced by every single data point, but is still flexible enough to minimize the influence of outliers.

Results

Basic descriptive statistics for each variable across each treatment phase are found in Table 1. Table 2 contains the parameters for the final set of autoregressive models for each variable. The autoregressive parameters are the intercept (the Intercept column) and the slope (the Days of Treatment column) associated with the cumulative length of treatment, and also an autoregressive lag component (the Autoregressive Component column) if the backward elimination procedure determined that there was a statistically significant autoregressive component in the data. The order of lag is designated in the Autoregressive Component column by the term "lag = *o*" where o is the order of lag. The Regression R^2 column contains the proportion of variance explained purely by the structural part of the autoregressive model, i.e., the portion of the model ignoring the autoregressive lag component. The Total R^2 column contains the proportion of variance explained by both the structural part and the autoregressive lag component combined together. Note that if a model has no autoregressive lag component, then the regression R^2 and the total R^2 are equivalent. If a model has a significant autoregressive lag component, then the total R^2 is larger than the regression R^2.

Figures 1-5 graph the data for each separate variable. Each figure is divided into the three treatment phases by vertical reference lines. Any observations that were flagged as outliers are represented by stars rather than solid dots. The autoregression models are represented by the solid straight lines, and they ignore the influence of the outliers. The dashed curved line in each figure is a spline regression line, which does not ignore the outliers, but it does minimize their influence in representing the overall trend of the data across time.

WBC

Figure 1 shows the autoregression lines for WBC. The Chow test for structural breaks showed that the autoregressive models for Phases 1 and 2 were significantly different from each other, $F(2, 42) = 9.57$, $P < 0.001$, and that the autoregressive models for Phases 2 and 3 were significantly different from each other, $F(2, 56) = 14.77$, $P < 0.0001$. According to the autoregressive models summarized in Table 2, in Phase 1 the level of WBC increased, and then during the transition to Phase 2 the level of WBC decreased. During Phase 2, the level of WBC proceeded to increase again. During Phase 3, the slope of the autoregression line was not significantly different from zero, which indicated that the level of WBC stopped increasing at the beginning of Phase 3 and continued to remain steady throughout the duration of the phase.

TLC

Figure 2 shows the autoregression lines for TLC. The Chow test for structural breaks showed that the autoregressive models for Phases 1 and 2 were significantly different from each other, $F(2, 44) = 5.79$, $P < 0.01$, and that the autoregressive models for Phases 2 and 3 were significantly different from each other $F(2, 58) = 8.63$, $P < 0.001$. According to the autoregressive models summarized in Table 2, in both Phases 1 and 3 the slopes of the autoregressive models were not statistically different from zero, while in Phase 2, the slope was positive and statistically greater than zero. This indicated that the mean level of TLC remained steady during both Phases 1 and 3 but increased during the course of Phase 2.

IgA

Figure 3 shows the autoregression lines for IgA. The Chow test for structural breaks showed that the autoregressive models for Phases 1 and 2 were significantly different from each other, $F(2, 37) = 10.37$, $P < 0.001$, and that that the autoregressive models for Phases 2 and 3 were significantly different from each other, $F(2, 51) = 30.28$, $P < 0.0001$. According to the autoregressive models summarized in Table 2, a large increase in the level of IgA occurred during Phase 1, and at the beginning of Phase 2 a large decrease in the level of IgA occurred, and the IgA level continued to decrease during all of Phase 2. At the beginning of Phase 3, the level of IgA increased slightly, but it then continued to decrease during all of Phase 3.

IgG

Figure 4 shows the autoregression line for IgG. The Chow test for structural breaks showed that the autoregressive models for Phases 1 and 2 were not significantly different from each other, $F(2, 39) = 2.54$, $P > 0.05$. Therefore, an autoregression model for the combined data from Phases 1 and 2 was created. The Chow test showed that the autoregressive model for the combined Phases 1 and 2 was not significantly different from the autoregressive model for Phase 3, $F(2, 64) = 1.16$, $P > 0.30$. As a result, a final autoregressive model for all of Phases 1, 2, and 3 was created, and as shown in Table 2, its slope was not significantly different from zero, which indicates that mean level of IgG stayed essentially constant throughout all three phases.

IgM

Figure 5 shows the autoregression lines for IgM. The Chow test for structural breaks showed that the autoregressive models for Phases 1 and 2 were significantly different from each other, $F(2, 38) = 4.27$, $P < 0.025$, and that the autoregressive models for Phases 2 and 3 were significantly different from each other, $F(2, 52) = 13.17$, $P < 0.0001$. As shown in Table 2, the slope of the autoregressive model in Phase 1 was not significantly different from zero, which indicated that the mean level of IgM did not change over the course of Phase 1. Over the course of Phases 2 and 3, the level of IgM decreased steadily, with a slight increase during the transition between Phase 2 and 3.

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Table 1

Descriptive Statistics for the Subject's Immune Variables

VARIABLE	N	MIN	MAX	MEAN	MEDIAN	STD DEV
Phase 1						
WBC	14	14.9	34.1	28.6	29.7	4.4
TLC	14	13.9	21.6	17.2	16.5	2.6
IgA	11	57.	99.	75.4	78.	14.5
IgG	11	389.	570.	505.4	514.	56.7
IgM	11	3.	32.	22.3	23.	8.4
Phase 2						
WBC	36	20.	54.	32.	30.4	5.7
TLC	36	10.9	32.4	20.9	20.3	5.4
IgA	32	37.	85.	52.	50.5	7.8
IgG	33	324.	564.	496.1	501.	48.
IgM	33	11.	24.	15.4	15.	2.3
Phase 3						
WBC	28	36.9	53.6	42.3	42.4	3.6
TLC	28	20.9	41.3	31.5	32.1	4.6
IgA	26	26.	63.	46.4	50.	9.4
IgG	26	373.	613.	496.1	503.5	56.3
IgM	25	9.	16.	13.2	15.	2.9

Note. N = Number of Observations; Min = Minimum Value; Max = Maximum Value; Std Dev = Standard Deviation.

Table 2

Summary of Autoregression Analyses of the Subject's Immune Variables

Variable & Phase	Intercept	Days of Treatment	Autoregressive Component	Reg R^2	Total R^2
WBC					
Phase 1	26.793**** (0.409)	0.023**** (0.003)	—	0.864	0.864
Phase 2	20.125**** (2.806)	0.023*** (0.005)	Lag=1 -0.581*** (0.147)	0.373	0.772
Phase 3	36.959**** (3.148)	0.005 (0.003)	—	0.090	0.090
TLC					
Phase 1	16.234**** (1.314)	0.008 (0.009)	—	0.062	0.062
Phase 2	6.298* (2.846)	0.028**** (0.006)	—	0.443	0.443
Phase 3	30.250**** (5.243)	0.001 (0.005)	—	0.002	0.002
IgA					
Phase 1	65.310**** (2.964)	0.097** (0.024)	Lag=2 0.782** (0.248)	0.666	0.739
Phase 2	66.771**** (2.502)	-0.030**** (0.005)	—	0.585	0.585
Phase 3	86.649**** (7.349)	-0.041**** (0.007)	—	0.578	0.578
IgG					
All Phases	524.264**** (14.383)	-0.030 (0.020)	Lag=1 -0.414*** (0.118)	0.035	0.253
IgM					
Phase 1	18.020** (4.216)	0.04 (0.032)	—	0.147	0.147
Phase 2	18.544**** (1.150)	-0.007** (0.002)	—	0.231	0.231
Phase 3	25.978**** (2.113)	-0.013**** (0.002)	—	0.622	0.622

Note. Reg R2 = Regression R2. Dashes indicate that no statistically significant autoregressive parameter was detected. Values in the parentheses are standard error terms.
**P <0.05. **P <0.01. ***P <0.001. ****P <0.0001.*

Figure 1:
Change over time in subject's white blood cell count

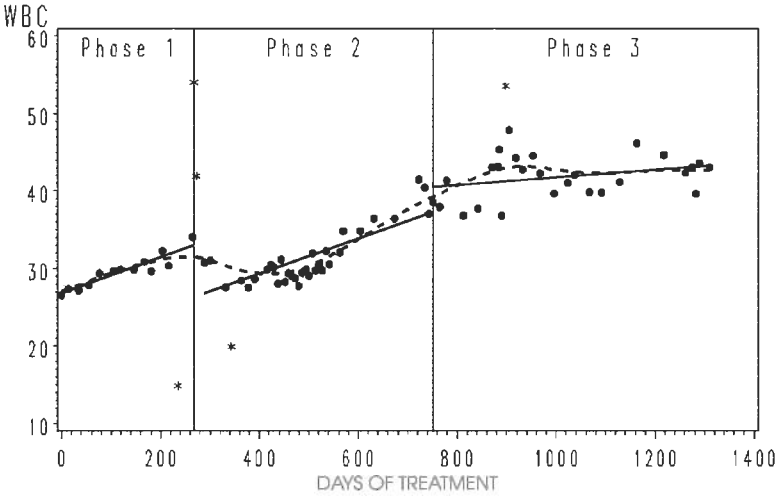


Figure 2:
Change over time in subject's total lymphocyte count

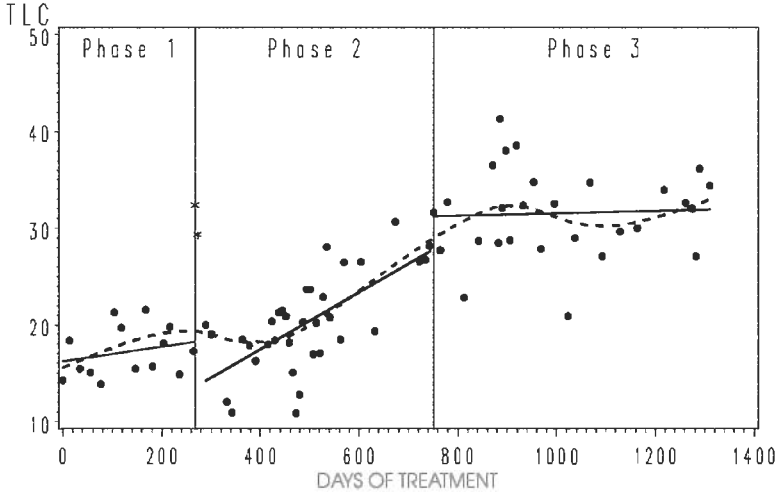


Figure 3:
Change over time
in subject's IgA

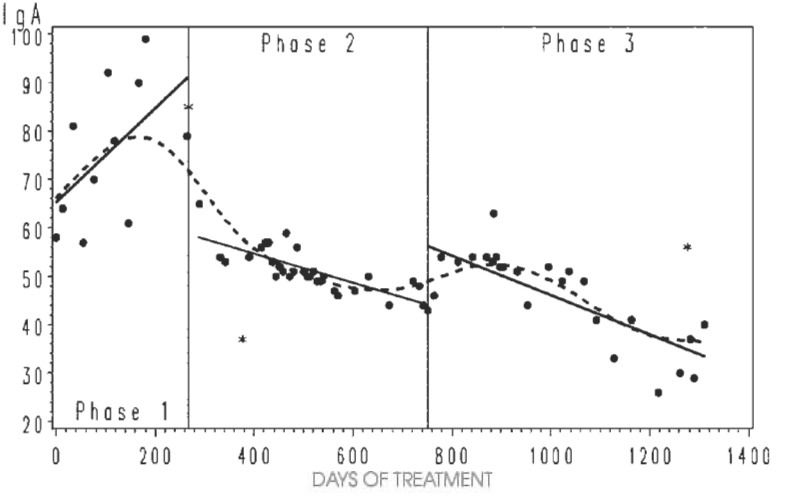


Figure 4:
Change over time
in subject's IgG

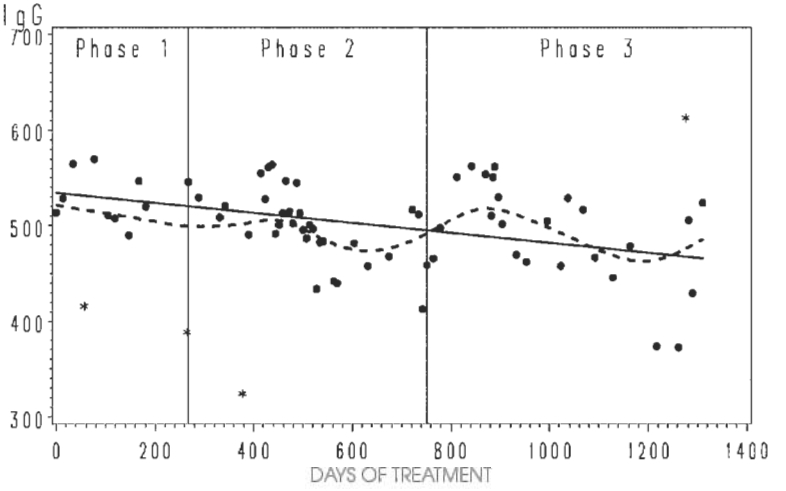
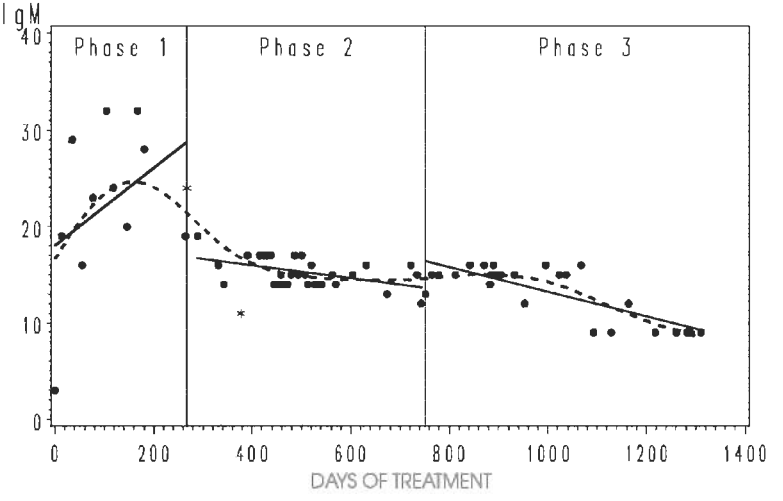


Figure 5:
Change over time
in subject's IgM



Testimonial

In February 1996, at the age of 66, I came down with severe fatigue and was diagnosed with chronic lymphocytic leukemia. The diagnosis was confirmed by flow cytometry; CLL B-cells and kappa cells were found. An oncologist advised chemotherapy, but I declined. I held my own until September 1997, when I received an antibiotic for a rapidly progressive skin rash. I took the full course of medication and developed an enlarged, painful liver, presumably as an adverse response to medication. Because I am allergic to most pain medication, a neurosurgeon referred me to the Sports Medicine Clinic of the University of Vermont, where a pain specialist recommended an Alpha-Stim® 100 unit for pain control. I ordered one and followed the instructions in the Owner's Manual.

The unit gave me 60%-90% pain relief. By December 1997, I was pain-free, and my liver was back to normal size. My liver function tests reverted to normal. I took no medication or herbal concoctions for the liver pain.

In May 1999, I developed firm, enlarged axillary lymph nodes, up to one inch in diameter. They made me so uncomfortable that I slept with my arms raised above my head. In an attempt to decrease the discomfort and pain, I applied the Alpha-Stim® unit for 12 hours. To my relief and amazement, not only did I become pain-free, but the lymph nodes reduced to normal size within no more than 24 hours. Whenever the nodes enlarged, which usually occurred within 2 to 3 weeks, I applied the Alpha-Stim® unit again as needed. My internist confirmed repeatedly that the lymph nodes had shrunk, and he was very pleased.

Until May 2002, my liver function tests remained within normal limits, but then I abruptly developed acute toxic hepatitis attributed to an adverse response to the drug Tegretol. I had been taking this medication for 9 years, since a small brain-stem stroke (confirmed by MRI at the Massachusetts General Hospital). An all-night EEG with blood pressure monitoring demonstrated that I had a nocturnal seizure disorder. I stopped taking Tegretol, and within 6 weeks, my liver was no longer tender and enlarged. During that period, I again used the Alpha-Stim® unit for pain control, with the same degree of pain relief.

In September 2003, I developed a pleural and pericardial effusion and generalized, severe joint pain. My doctor determined that I had an acute autoimmune diathesis, a diagnosis confirmed by echocardiogram, lung scans, and blood tests. Steroids and anti-inflammatory medication resolved this condition. During the acute phase, I did not use the Alpha-Stim® unit.

From the time I started taking Tegretol, I had had routine liver function tests and blood tests. My test results had been normal until the liver toxicity set in. With the onset of leukemia, my blood was also tested for immunoglobulin (IgA, IgG, and IgM) levels. These test results are summarized in Tables 1–5. My internist, on inspecting the blood counts, noted numerous instances when the total white blood cell count and the lymphocyte count dropped after I had used the Alpha-Stim® unit.

Until the data are subjected to statistical analysis, the relevance of this observation will remain unknown. For this reason, I'm submitting this testimonial to you, Dr. Daniel L. Kirsch, the inventor of the Alpha-Stim® unit, for further examination.

I'm familiar with the abstract from the Dr. Clark Research Association: Low-intensity electric current-induced effects on human lymphocytes and leukemia cells, by Narenda P. Singh and Henry Lai, Department of Bioengineering, University of Washington Seattle, WA (http://www.drclark.net/news/lairesearch.htm, accessed 2002). This article prompted my internist to take a second look at the data and ask me to submit my information to you.

Were this information to benefit other patients in some way in their fight against cancer, then I will feel that this attempt to contribute in a minor way is worthwhile. If the analysis demonstrates that my experience results from the well-recognized placebo effect, no harm done.

Thank you for inventing the unit. You are free to publish the data and report as you see fit. At the request of my family, however, I would prefer to use my initials rather than my full name.

ISBN 978-0-9780948-0-1

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