



**BUILT BY WOMEN,
WITH WOMEN'S
NEEDS IN MIND.**

How did you take The Smooth Operator® from the research process to production?

That's a long story that I can't do justice here, but here's the short version:

Once the study was complete and it had proven successful, I decided that I wanted to take it to market.

My wife, Claire, stepped up once again and worked closely with the team at Spec and the manufacturing team to make sure that the end result would be designed with women's needs in mind.

The owner of the manufacturing site continued to embrace the need for a female presence and hired a female plant manager, and she in turn is putting together an entirely female team so that, from the ground up, The Smooth Operator ® is being built by women, with women's needs in mind.

Where can we read more about the research behind The Smooth Operator®?

As cellulite is not a disease process, but a cosmetic one, my fellow researchers—Dr. Freeman, Dr. Busuito, and Dr. Plazcek—and I decided to submit to a cosmetic dermatology journal for peer review of our findings. I am happy to announce that on July 28th, 2015, I, as the lead author, received a letter that the research had been accepted and would be published within the next 10 months. I will make the study available upon publication.

Any parting thoughts?

My wish for you—and for all women who would like to reduce their cellulite—is for you to be able to do so safely and effectively. We know that many women have been disappointed in the past by treatments that have made promises and then didn't deliver. This is why, when developing The Smooth Operator ®, we have always striven for the highest level of research. **There is no magic—just good science.**

"One thing was a given: I wanted to manufacture here in America."

That aside, there were two questions to answer initially to make taking this to market possible:

- 1) Were the manufacturers of the materials that I was using able to meet my potential supply needs?
- 2) As I had always made these by hand, was it mass producible?

Once I had successfully answered question number one, I moved on to question two. It took two years to find a design and build firm that was willing to try. Thank you to Rick Schneider and Spec Technologies, Inc. for embracing the challenge and taking this journey with me. You've gone above and beyond!



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KISS CELLULITE GOODBYE



**Featuring Inventor
PAUL J. ROUBAL,
PhD, DPT**





NO MAGIC, JUST GOOD SCIENCE



FEATURING
PAUL J. ROUBAL, PhD, DPT

Paul, let's start out today's interview with an explanation of what an anatomist is?

Sure. An anatomist studies the human body, which in recent years has included the study of the body on a cellular level. Most anatomists teach, research, or do both. Personally, I do teach, but I am more dedicated to research and the treatment of patients.

What inspired you to begin investigating a treatment for cellulite?

In 2007, a patient in her 30's and of athletic build while in for an ACL repair questioned: "I work out, eat right, I'm not heavy, and I've had severe cellulite for 15 years. You have advanced degrees in anatomy, what can be done?"

Over my 38 years of practice, I've had many female patients ask about cellulite, and in conversing with colleagues from different areas of the medical community, I know they share similar stories.

I'm an avid researcher, (check out my profile on Research Gate), and I couldn't shake this woman's question. It was literally keeping me up at night. There had to be a way. I consulted with board-certified plastic surgeons that I know and respect, and according to them, there were no effective treatments available at the time. They also confirmed that this was a common question from female patients.

So, I set about to research and evaluate all of the literature for reasons why women get cellulite and then for ways to reduce it.

How long did you spend on your research?

The background research, which led to the design of the prototype, took about two years to complete. The entire research process took closer to six years, concluding in mid-2013.

What was the goal of your research?

To help. I felt bad, and, to be frank, puzzled that there wasn't a simple solution to this apparently common issue that really bothers some women. Once I felt that I had studied all the credible research available and I understood what the scientific community currently knew about cellulite, it was time to find a solution. My goal was to design a safe and effective way to help reduce the appearance of cellulite. An in-home process that women would find easy to use and was non-invasive.

Was it obvious from your background research what your invention would be?

Yes and no.

It was obvious from the background research what the process needed to be. To ensure successful reduction and not just mask the cellulite, four very clearly defined criteria must be met. It helped with the process of elimination and provided a checklist as I was brainstorming. If something did not have the possibility of meeting all four criteria, I dismissed it automatically.

Again, I drew inspiration from a patient, an elderly patient that I had treated on and off for many years—she had been a dancer. Cleaning out her basement that weekend, she came across a belt massager. We reminisced about the machine and she laughed about how dedicated she had been to using it, but that it didn't deliver as promised. Next, she asked "Why?" and a lightbulb went off!

Based on what I had studied about cellulite and what it would take to reduce it, it was not necessary to reinvent the wheel, just to make modification on an already existing system. It wasn't the machine that needed to be modified, just the attachment—the belt—which I knew from my research needed to be made of different materials in order to create the desired result and deliver as promised. The current belts were made of materials that slide across the skin. I needed to design a belt that would not slide, but adhere to the skin during the oscillation process.

The patient very kindly offered me her oscillating unit, which still

worked and came complete with the original belt. I picked it up from her that Saturday and promptly turned the basement of my house into a workshop.

The next step was to identify the materials necessary and build a prototype. I needed a material that was tacky, and, in thinking about it, I had a material that I had recently started using in my physical therapy practice to break down scar tissue in rehabbing patients. It occurred to me that if I could break down scar tissue with this material with my bare hands, then by attaching it to an oscillating unit—which moves at a far more rapid pace—it should be able to meet the requirements to reduce cellulite.

How did you design the belt?

With great care. The belt that you see today is very different from the original prototype. All materials used to make The Smooth Operator® belt were carefully researched and tested prior to selection. Beyond the function of the belt, many modifications have been made to materials used to aid in the longevity and the comfort of the belt. (My wife was a great sport through the process—every time I made a modification, I would test it on her first.)

The first prototypes I made by hand with the help of my wife and took about three days to complete with the help of the local shoemaker—thanks, Clawson Shoe Repair! By the end, we could make a belt by hand in about an hour.

What were some of the challenges you faced when you went to organize the clinical trial?

I turned part of my clinic into a research center, and in 2011 began advertising for test subjects.

Through the recruitment process, I learned another valuable lesson. I was creating an at-home unit because I thought it to be the most convenient option with regard to the busy schedules that most women carry, with little time for themselves, and where I learned this was a huge plus, the biggest benefit to a home-based unit was privacy. Most women didn't want to bare their cellulite, not even to a medical professional in a clinical setting.

You know, during the course of the study, I continued to have many women approach me about an interest in the product if it ever went to market, but they just couldn't bring themselves to participate in the trial due to feelings of discomfort and embarrassment concerning their cellulite. I made it as

comfortable as I could for the women who did choose to volunteer. I hired and trained an all-female staff; at the beginning of the study each subject was assigned a code name; for further anonymity all photographs taken were just of the body segments treated—no faces; and robes were provided for when they were not being treated.

I also learned that even though we were conducting a scientific study and that maintaining the integrity of the study was of utmost importance to me, to put the volunteers at ease I needed to not have it feel clinical to them. Whereas I originally thought that I would use female students from my clinic that had an interest in research and had worked in labs, I quickly switched gears. Knowing how she was with patients and co-workers, my assistant quickly came to mind and she was happy to join the team. Thanks AJ!

And, a huge thank you to the brave women that did participate for their willingness, trust, enthusiasm, commitment, openness, and continued interest and support. All the way to launch, I have received phone calls and emails following up and inquiring if and when we are going to market—this has helped me push on during the now 8 year process. I am extremely grateful to all of you!

What was the trial like at the beginning?

I started with just one subject to test the protocols and make adjustment before moving forward with a larger group of women. This first subject was very much like the other women that I spoke of: in her 30's, in great shape, maintained an aggressive exercise routine and a balanced diet, and frustrated about her inability—despite great efforts—to reduce her aggressive cellulite. Subject 1 taught us much, and we are grateful to her for taking that bold first step forward and continuing to be one of our biggest champions.

How soon did you know your trial would be a success?

Well, our first 10 test subjects were a variety of women between the ages of 21 and 40, all of different weights, exercise habits, diets, lifestyles, and family lives. We took before and after photos as a means of measuring

our success, at the end of their eight-week treatment program, I can tell you we had a very excited group of women. Ultimately, the trial ran for 18 months and saw 43 test subjects to completion, but we knew our experiment would be a success after that first group.

Were there any unexpected results?

Yes! When I first set up the protocols for the study, I set it up based on the guidelines for anti-aging treatment and had a cut off age for participants at 40 years of age and a requirement that they be still menstruating. This led me to initially turn away a couple of very persistent and eager women—one was 67, and the other was 49 and had had a hysterectomy in her 20's. They kept asking.

I had come to a place where, based on the results of the candidates that had already concluded their participation in the study, I wanted to continue the trial and ramp up the number of participants. That meant that I needed more technicians and that they would need training. Another lightbulb moment! I called these two women and explained that I had a way for them to try the device. I explained to all parties involved that they would not officially be part of the study and not to expect positive results, but if they were willing to go through the 8-week treatment program as if they were in the study to help me train the new technicians, then they could try the device.

Both accepted. After 3 weeks of treatment, both the team and the test subjects approached me to say that they believed the treatment was working in spite of my doubts.

So I took some photos, and not only was there positive change and for both of them, but it was happening at a faster rate than it had for most previous candidates. I reversed my decision, accepted them both as official study participants, and expanded the age range to 70 years of age. I also reopened the discovery stage of my research to look for answers from the scientific community that had come before me in their study of cellulite. These women both continued to see improvement through the end of their commitment to the trial and opened the door for 14 other women who would otherwise have been turned away.

Through the course of the study we not only proved the efficacy of the device for the purpose of reducing the appearance of cellulite, but, we also learned that, because it was adhering to the treatment area, it was also working the muscle, and as a result toning the thigh and gluteal area.

When measured, study participants showed an average change of 2 centimeters difference in the circumference of the treated gluteal area. We were also able to perfect protocol; through conversation, learn from test subjects further about the emotional side of cellulite; and make modifications to the belt to increase quality, maximize comfort, and increase duty life.