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The Power of Prototyping

## **How Collegiate Inventors Competition Finalist Lia Winter Used Early-Stage Prototyping to Improve Orthopedic Surgery Outcomes**



When Lia Winter, CEO of Winter Innovations, tore her hamstring during a high school soccer game, little did she know that this temporary setback would lead to a passion for innovation.

At the time, her immediate concern was returning to the field. Fortunately, Dr. James Bradley, Head Team Orthopedic Surgeon of the Pittsburgh Steelers, was a good friend of the Winter family. At the recommendation of Dr. Bradley, she decided to forgo surgery altogether and undergo a series of platelet-rich plasma injections. The therapy was a success.

“I made a full recovery and was able to play in the last two games of the season,” Winter said in an interview with the National Inventors Hall of Fame® (NIHF). “That experience opened my eyes to the possibilities of medical innovation, and I decided to pursue a degree in biomedical engineering.”

While studying at the University of Pittsburgh, Winter served as an intern at a medical device company where she measured the effectiveness of their suturing needles. As she prepared grafts for mechanical testing, she was surprised to learn that the act of whip stitching is prone to human error, and she identified an opportunity for improvement.

## A New Type of Surgical Needle

When Winter returned to school in the fall for her final year, as part of a senior design project, she was tasked with finding an unmet need in the field of biomedical engineering and health care. Thinking back to her internship, the idea of creating a more effective suturing needle immediately came to mind.

The desire to improve upon surgical outcomes was also a personal one. A year before Winter’s hamstring injury, her mother suffered a torn ACL that required a second surgery after the first one failed due to a grafting and stitching complication.

“It wasn’t just a six-month recovery, it was a few years before she was able to get back to her full activity levels,” Winter said. “The stitching can really have a big impact on someone’s quality of life.”

Winter’s solution to improve surgical stitching was to create a two-part needle — one that would allow the graft to be securely fixed during the stitching process. Not only would this new design increase the speed of the whip stitch procedure, but it would also increase consistency and allow the process to be conducted by a single person.

Because failure rates among primary ACL reconstructions have been reported to be as high as 25%, improving the stitching step of this procedure has the potential to significantly improve patient outcomes.

## Prototyping the EasyWhip Surgical Stitch

Winter’s first goal was to create a working prototype of her two-part stitch idea and get it into the hands of those who would use her device. The time and resources required to produce a functional invention are significant, but prototyping allows inventors to test and refine their ideas before taking additional steps.

The first half of Winter’s senior design class allowed her to focus on early-stage prototyping where she built models of the prep stand (a device that holds the graft in place during the stitching procedure) and her two-part needle.





*An early handmade prototype of Winter's prep stand*

One of the key advantages of early-stage prototyping is its accessibility, and often the materials needed to make these models are readily available household items. Winter's prototypes are an excellent example of this. The prep stand was made of plywood that she cut herself, and she held the wood together with binder clips. The first version of her needle was created using similarly simple materials:

"I stripped the insulation off of a wire, and then put a sewing needle on the end," Winter said. "My simulated suture was a sewing thread."

Constructing her prototypes using accessible, upcycled materials allowed Winter to quickly test her idea and make iterative improvements over time. In fact, since building the first prototype of the EasyWhip™ Surgical Needle during her senior year, she estimates that her invention has undergone 15 revisions — each one improving upon the last.

## Following the Prototyping Process

Thanks to funds generated from pitch competitions around the country, as well as a recent round of investment capital, Winter and her Winter Innovations co-founder, Chief Operations Officer Preston Dishner, have begun producing manufacturing samples to get into the hands of surgeons. According to Dishner, so far the support has been overwhelmingly positive.

"Rather than suggesting changes or tweaks to the design of the product, surgeons have stated that they could see themselves using the product for many of their procedures," Dishner said. "One surgeon remarked that he would have really liked to use EasyWhip that same day for a particular surgery case, and he asked eagerly when it will be available for sale."

These manufactured prototypes will be used to complete all testing required by the Food and Drug Administration for the sale of medical devices. While this process takes place, Winter and Dishner have filed three patent applications as they continue to receive feedback from doctors and medical professionals.





*Winter at the 2019 Collegiate Inventors Competition*

## Making a Difference

Through perseverance and dedication to pursuing her idea for an improved surgical needle, Winter took her senior project and transformed it into a company. While early-stage prototypes of the EasyWhip needle use deceptively simple household materials, these functional models allowed her to demonstrate the feasibility of her invention and continue improving its design through iteration.

Winter's story highlights how important prototyping is to the invention process. Though end users may only experience the final product, what they don't see are the many versions and mockups that came before it. Often unheralded, this early-stage prototyping process is essential to testing the viability of an idea. At the National Inventors Hall of Fame, we have taken this to heart, embracing prototyping throughout our STEM (science, technology, engineering and mathematics) education programming.

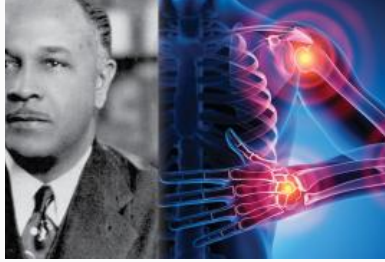
As Winter continues to grow her company and work toward the eventual commercial sale of the EasyWhip, her commitment to creating a better solution for those who must undergo surgery remains steadfast.

"What we're trying to do is improve the outcomes for patients," Winter said. "If fewer surgeries fail, people like my mom don't have to have a second surgery. That's really what all of this is about and why I'm so passionate about it."





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