PURDUE UNIVERSITY

CAPSTONE EXPERIENCE 2012

Soytures – Bioabsorbable Soy Sutures

Agricultural & Biological ENGINEERING

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SOYTURES

Problem Statement and Background:

For centuries, dentists and oral surgeons, plastic surgeons, obstetricians, urologists, and even veterinarians have used stitches to close up gashes, cuts, and surgical incisions. Now, many physicians are using sutures that dissolve into the body over time removing the need for subsequent visits. These sutures are bioabsorable.

The current bioabsorbable suture market includes gut sutures, made from processed intestines, and synthetic sutures such as PLA. Soytures have both economic and practical advantages over competing sutures – they are less expensive than PLA sutures and tensile strength can be controlled by changing the recipe.

Soytures provide a new and innovative solution to creating an affordable, strong, and natural medical stitch. This product is an absorbable, soy protein-based suture, which can be utilized for applications ranging from small injuries, requiring external sutures, to large medical procedures.

Experimentation and Testing:

After specifying a range for each variable, 20 randomized product recipes were created using Design Expert statistical software. The response variable, tensile strength, was tested for each suture type and the following relationship was obtained:

$$\text{Tensile Strength} = 25.40 * \text{Soy} + 16.70 * \text{Corn} – 27.57 * \text{Glycerol} + 4.75 \text{ Water}$$

Market Analysis:

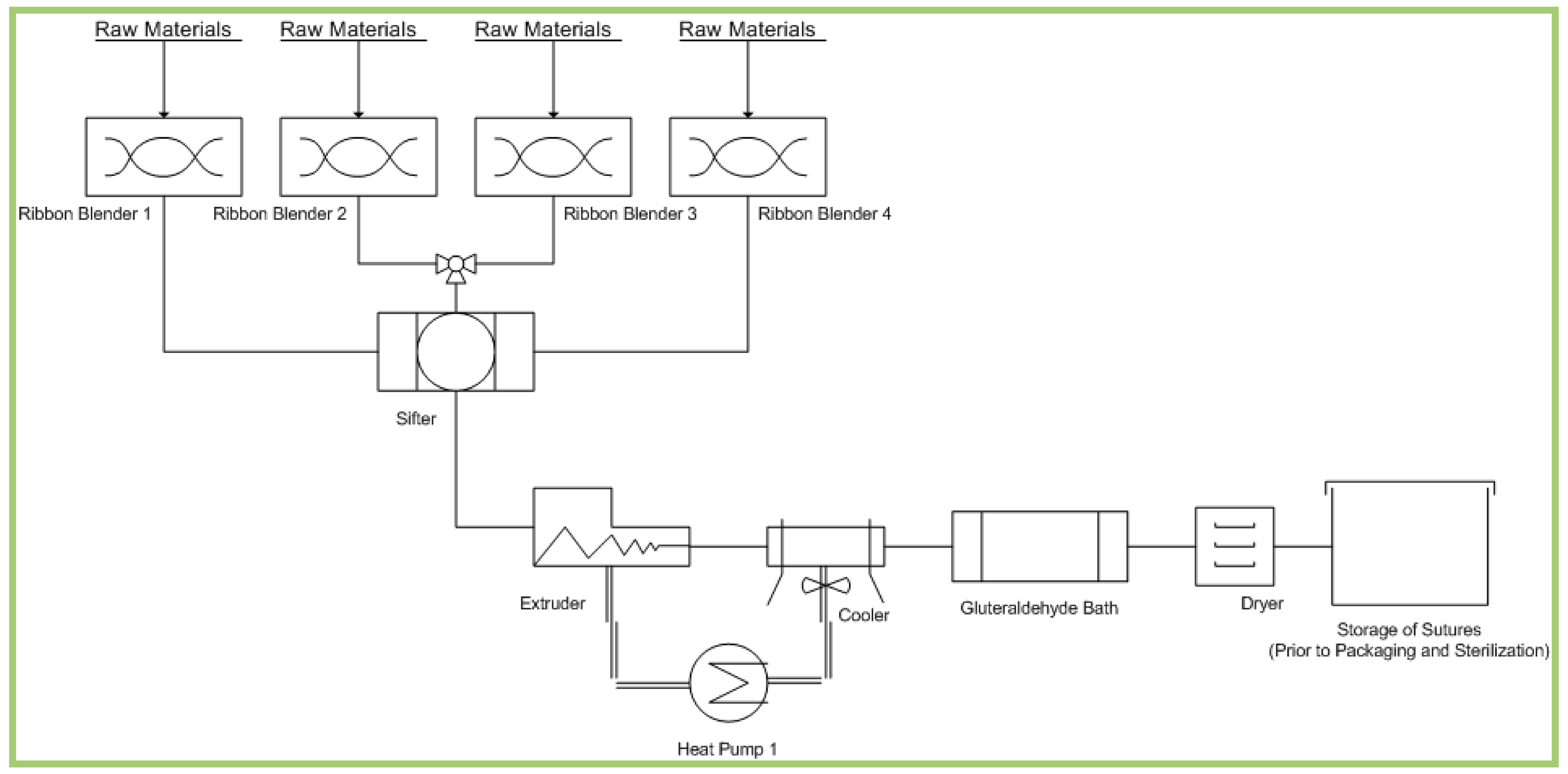
Although sutures are utilized by many members of the population, the choice of suture is rarely made by the consumer. Instead, the doctor performing the procedure selects the suture they believe will best complete the job successfully. Soytures compete functionally with products on the market – so they are likely to be chosen by medical professionals. The target consumers for Soytures are current suture manufacturers. The raw materials for PLA are more than 100 times more expensive than the raw materials for Soytures. Thus, as the fixed costs for production are analogous to the fixed costs for competitors, Soytures gain an economic advantage through its natural ingredient composition.

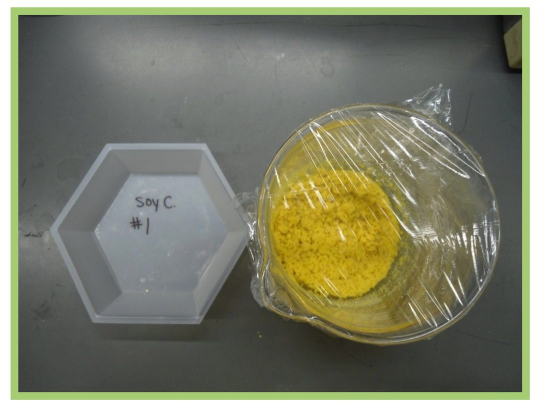
Suture Type	Ingredient	Price /Package	Grams/ Package	Price/ Gram	Product Composition	Cost/ Gram
Polygalactin90 (PLA Suture)	Glycolide	$454.00	50	$9.08	90.00%	
	L-Lactide	$191.00	100	$1.91	10.00%	$8.36
Soytures (Protein Suture)	Soy Protein	$22.99	1814.37	$0.01	31.25%	
	Zein	$57.90	1000	$0.06	13.75%	
	Glycerol	$32.25	112.6	$0.29	12.50%	
	Water	$14.99	464.2	$0.01	42.50%	$0.06

Process Overview:

To create Soytures, 31.25% soy protein isolate, 13.75% zein, 12.5% glycerol, and 42.5% water are mixed to form a homogeneous product. This mixture is then aged for 24 hours at room temperature. The settled mixture is extruded to produce a monofilament which is placed in glutaraldehyde , a cross-linking agent. The monofilament product is then dried and packaged.

Plant Design:





Raw Product

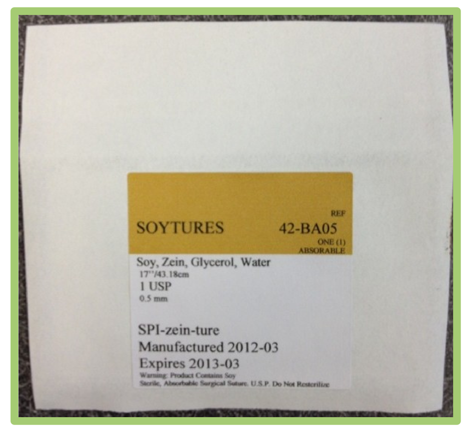
Extruded Product

Glutaraldehyde Bath

Cost Breakdown	Total Amount
Direct Costs	$ 1,355,476.01
Indirect Costs	$ 4,486,250.00
Fixed Capital Investment	$ 5,841,726.01
Working Capital(15%FCI)	$ 876,258.90
Total Capital Investment	$ 6,717,984.92

Economic Summary	
Production Rate (Sutures/Year)	7,600,000
Manufacturing Cost ($/Suture)	$ 0.88
Annual Net Revenue	$ 6,688,000.00
Product Price ($/Suture)	$ 1.50
Annual Net Profit	$ 4,712,000.00

Packaging:



Future Work and Bioabsorbability:

Bioabsorbability can be quantified in many ways. Soytures contain natural proteins that degrade over time. Bioabsorbable products will be utilized by somatic cells, broken down by water in passive hydrolysis, denatured by enzymes, or will degrade naturally. The relationship between mixture components and the bioabsorbability pathways, as well as product characteristics like tissue drag and microbial growth, can be determined as simply as the recipe for tensile strength was found.

Soytures currently use glutaraldehyde as a cross-linking agent; however, glutaraldehyde is associated with low levels of toxicity. Calcification or cytotoxicity of glutaraldehyde has motivated the search for such an alternative that can be used in the healthcare industry. A Korean study found Genipin to be the new alternative natural crosslinking agent for pericardial tissue, considering given its physical, mechanical, biochemical characteristics and low cytotoxicity. Genipin could be further explored to study its effect on immune reaction in the human body and consider it as a replacement for glutaraldehyde in Soytures.

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