True Shape

Al solution to accurately classify lipedema and mitigate negative implications from misdiagnosis

Naleef Fareed, PhD MBA & Vincenza Cifarelli, PhD

Today

- Mary, a 25 year old, visits her primary care doctor and is <u>concerned about her weight and figure</u>. After having put her through a <u>weight loss regiment that</u> <u>was not successful</u>, she is recommended to a endocrinologist.
- The endocrinologist <u>prescribes drugs that were also</u> not successful.
- She visits a bariatric physician and is recommended to go through <u>expensive and life changing bariatric</u> <u>surgery.</u>
- One year later, her <u>problem persists</u>. She experiences continued pain, cardiac complications from the surgery, along with with depression and stress.

The future

- Mary's primary care/specialist doctor recommends Mary to obtain sonograms and collects additional biological data. She inputs these key values about Mary in the <u>True Shape prediction model and receives</u> a high score for Mary.
- Mary is recommended <u>treatment that is appropriate</u> <u>for her condition</u> and is provided with <u>life style</u> <u>modification options that help her manage her</u> condition.
- Now that Mary is aware of her condition, she is able to manage it effectively – not purchasing risky treatments, avoiding being misdiagnosed, and asking the correct questions.

9%-11% of women worldwide have misdiagnosed obesity

Women with lipedema







Buck et al. 2016

Lipedema is a disorder characterized by abnormal deposition of subcutaneous adipose tissue leading to disproportional volume increase of lower extremities

Lipedema has distinct clinical features and health implications

Clinical Presentation:

- Abnormal deposition of subcutaneous adipose tissue
- Bilateral and symmetrical manifestation
- Occurrence almost exclusively in women and starts in puberty
- Fat is nodular, painful and tenderness on pressure
- Easy bruising
- Fat is resistant to diet and exercise
- It leads to considerable disability and daily function impairment

Lipedema can be differentiated from obesity and/or lymphedema based on subjective criteria

	Lipedema	Lymphedema	Obesity
Increase in fat	+++	(+/+++)	+++
Disproportion	+++	+	(+)
Edema	+/+++	+/+++	(+)
Tenderness to pressure	+++	_	_
Easy bruising	+++	_	_

Lipedema fat is resistant to diet and exercise

Lipedema misdiagnosed as obesity is costly and causes unnecessary pain and suffering for the patients

Current management:

- Liposuction
- Decongestive therapy including compression garments, manual lymphatic drainage, movement therapy, dietary recommendation

Estimated prevalence

- Hard to determine as the condition is not accurately diagnosed
- Approximately 40% prevalence of obesity among women 20 and over (~40,000,00 in the U.S.)
 - Of these women, four million may have lipedema and are incorrectly diagnosed as being obese

The value proposition

We propose to build an AI based predictive model that translates objective imaging and biological data to identify and correctly treat Lipedema

The value calculation

- The cost of not detecting lipedema:
 - Expensive but non-effective diet and exercise training
 - Estimated cost wastes per patient per month: (\$40 +)
 - Non-effective surgeries such as bariatric surgery:
 - Estimated cost per patient: \$20,000 (\$300 per month)
 - Patient's long-term health risks and insurance costs

The value calculation

- Total cost of not detecting lipedema:
 - \$400 monthly cost of late detection
- Total cost of detecting lipedema:
 - \$1000 per year
- On average now, a patient with lipedema is detected after 18 months
 - **>** \$7200

Our value

- Our technology will detect lipedema for patients during month 6 with 80% recall and precision, which means we will save:
 - -0.8* (\$400*(18-12)) 0.2* \$1000 = \$3640
- So the ROI for payer of using this technology is:
 - Charge \$50K 1st year
 - ROI for 100 patients = 73%

Business Model/Strategy

- Algorithms will be intellectual property
- Build network of relationships with providers (physician practices), provider organizations (medical centers), and payers (Aetna, Highmark)
- Provide a portal version to generate risk prediction scores
- Additional services will include:
 - Retraining model on organization-specific data
 - Testing and UX design improvements
 - Training to use the tool

Market Analysis

- Currently, there are no other applications being used in the market
- Main competitor is physician predisposition to diagnose patient as being obese and making recommendations for bariatric surgery
- There are models for obesity, but most of these are mainly logistical regressions based on strict assumptions
- Our model has the potential to be extended to sub-conditions related to lipedema upon successful validation of the first model

Risk Assessment

	Risk Factor	Risk Mitigation
	Model is not a good classifier	We will implement AI/ML best practices to ensure multiple validation methods are used and access data from multiple sources to develop a robust classifier
/	Model is too complicated to use	We will engage in UX testing and training to ensure that the application's use is adopted over time
	Provider buy-in	We will provide demonstrations and get buy-in from payers and patients to ensure provider use

CUSTOMER VALIDATION

"True Shape provides an innovative and personalized approach to correctly identify and treat heterogeneity in obesity."

Jordan Powell, Illinois Primary Health Care Association

Health_®

"Very interested in partnership with True Shape"