1032 Post Road East
Westport, CT 06880

Protocol: DMRR-001
FINAL REPORT

Reporting Period Covered in this Report: ***15Dec2021 to 16Aug2021***

Date of Final Report: 21Sep2021

Study Information

1.1 Synopsis

Name of Sponsor/Company: DMR Research, PLLC **Sponsor:** Endo Pharmaceuticals Inc.	
Name of Investigational Product: Qwo CCH	
Name of Active Ingredient: Collagenase clostridium histolyticum	
Title of Study: Treatment of 5 subjects to assess the effectiveness of multiple dose, multiple concentrations of clostridium histolyticum-aases, QWO, for the treatment of mild to moderate cellulite in adult females to the buttocks and thighs.	
Lead Principal Investigator: Deanne Mraz Robinson, MD	
Study period: Date first subject enrolled: 29Mar2021 Date last subject completed: 12Aug2021	**Phase of development:** 4

Objectives and Endpoints:

Objectives	Endpoints
Primary	
To assess the effectiveness of multiple dose, multiple concentrations of clostridium histolyticum-aases for the treatment of mild to moderate cellulite in adult females to the buttocks and thighs	The proportion of subjects with improved (+1 or better) score on the Investigator Global Aesthetic Improvement Scale (I-GAIS) for buttock and thigh at Day 90.
Secondary	
To evaluate effectiveness of CCH-aaes in individuals when concomitantly treating the buttock and the thigh in one treatment session	The proportion of subjects with improved (+1 or better) score on I-GAIS for buttock and thighs on Days 22, 43, and 90.
To assess subject satisfaction with CCH treatment of buttock and thigh cellulite in adult females.	Mean change from baseline in Body-Q Appraisal of Cellulite[d] to Day 90.
To generate calculations to determine a matrix of buttock and thigh injections possible from a single 1.84 mg vial	Dilution matrix used in clinical settings.

Status of Enrolled Participants

Total Enrollment	**5**
Total Completed Treatment	**5**
Terminated Study Early	**0**
Completed treatment	**5**
Completed Protocol Follow–up	**5**
Completed **90 day follow up**	**5**
Termination associated with an adverse experience	**0**

Subject Demographics

Subject	Age	Height (in)	Fitzpatrick	Race	Ethnicity
001	38	67	III	White	Not Hispanic
002	39	68	II	White	Not Hispanic
003	39	70	II	White	Not Hispanic
004	41	65	III	White	Not Hispanic
005	50	65	III	White	Not Hispanic

Subject Weight

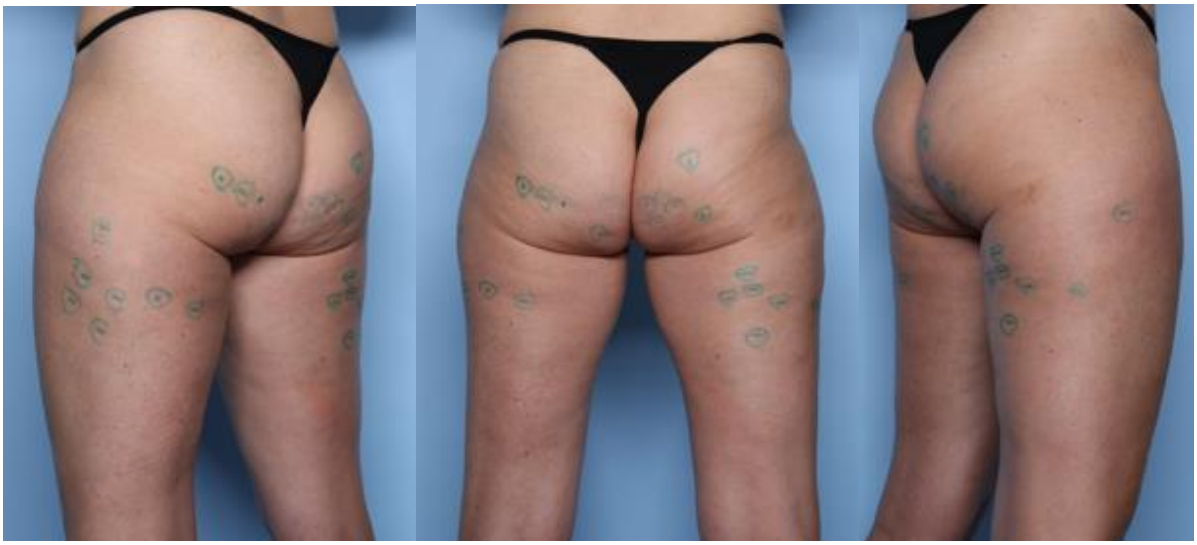
Subject	Weight Day 1	Weight Day 90	BMI Change
001	130	138	**+1.2**
002	144	143	-0.2
003	158.2	164.8	**+1.0**
004	116	117	-0.2
005	125	114	**-1.8**

Summary: Subject 001 and 003 reported changes to their weight due to excessive stress of the COVID-19 pandemic.
Subject 005 reported a significant decrease in weight due to gum surgery, requiring sutures for 8 weeks and the subject unable to ingest solid foods.

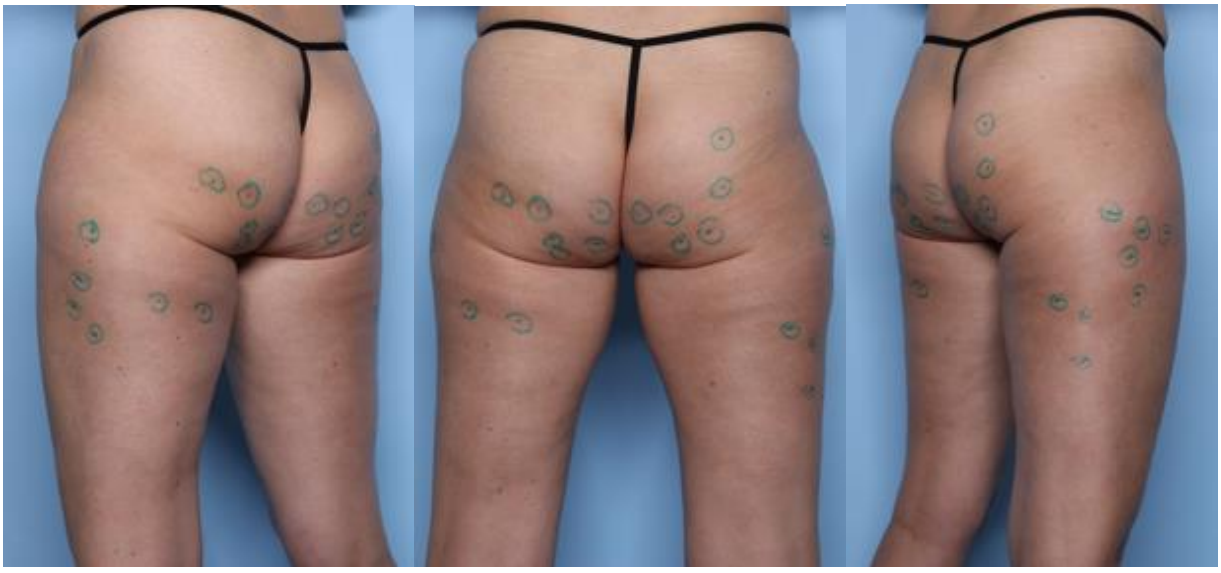
Treatment Visits Day 1, Day 22 & Day 43

Subject 001

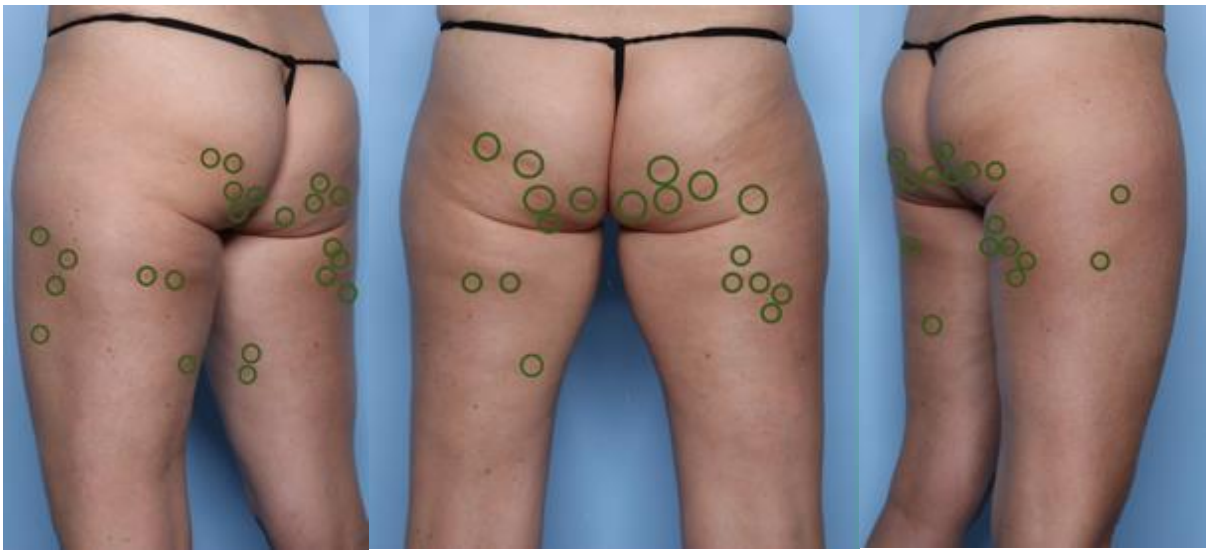
Day 1: 12 buttock dimples
14 thigh dimples
Dilution: 17.6 mL of sterile saline



Day 22: 12 buttock dimples
14 thigh dimples
Dilution: 17.6 mL of sterile saline

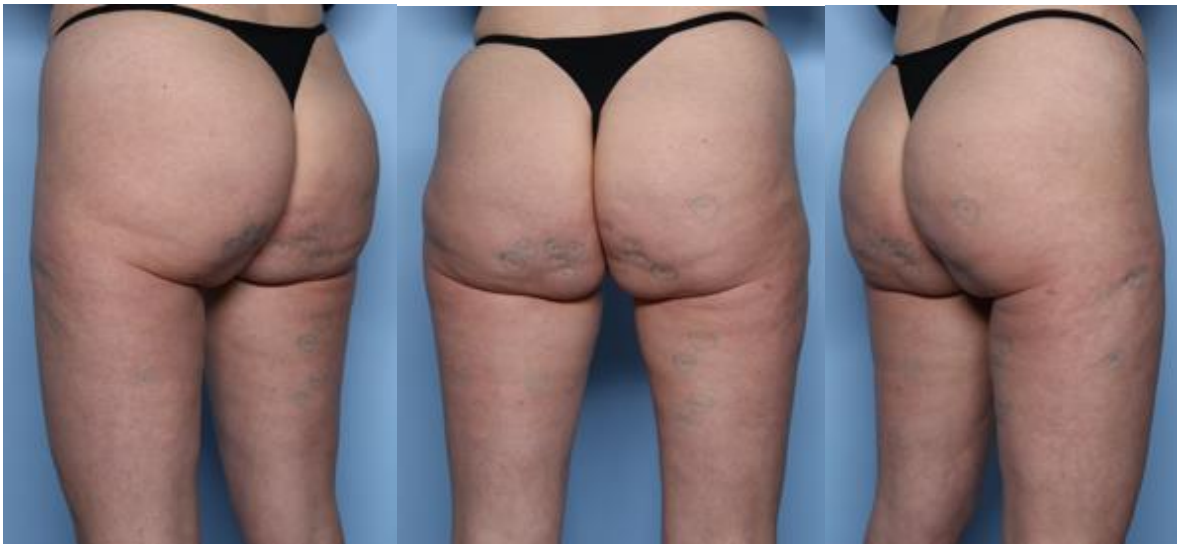


Day 43: 9 buttock dimples
17 thigh dimples
Dilution: 21.2 mL of sterile saline

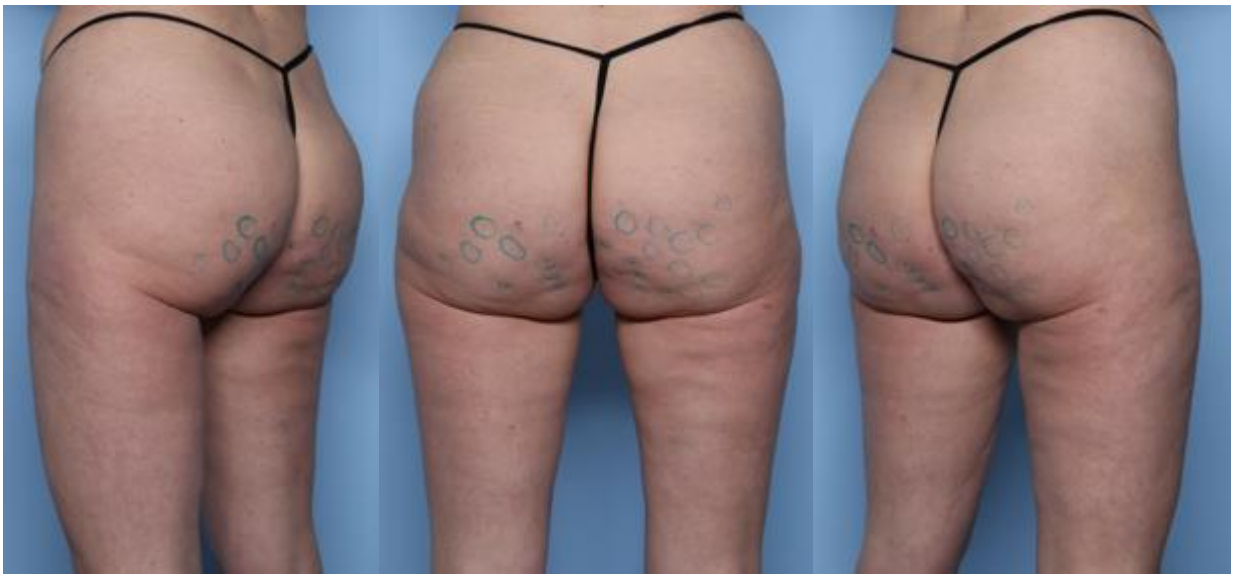


Subject 002

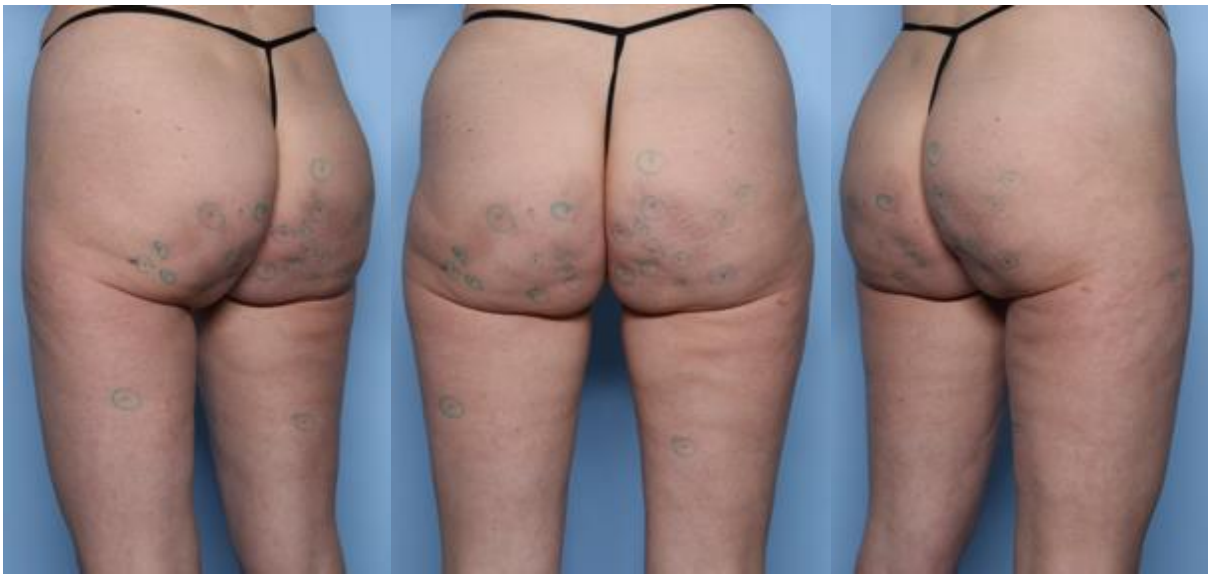
Day 1: 12 buttock dimples
14 thigh dimples
Dilution: 17.6 mL of sterile saline



Day 22: 24 buttock dimples
2 thigh dimples
Dilution: 2.6 mL of sterile saline

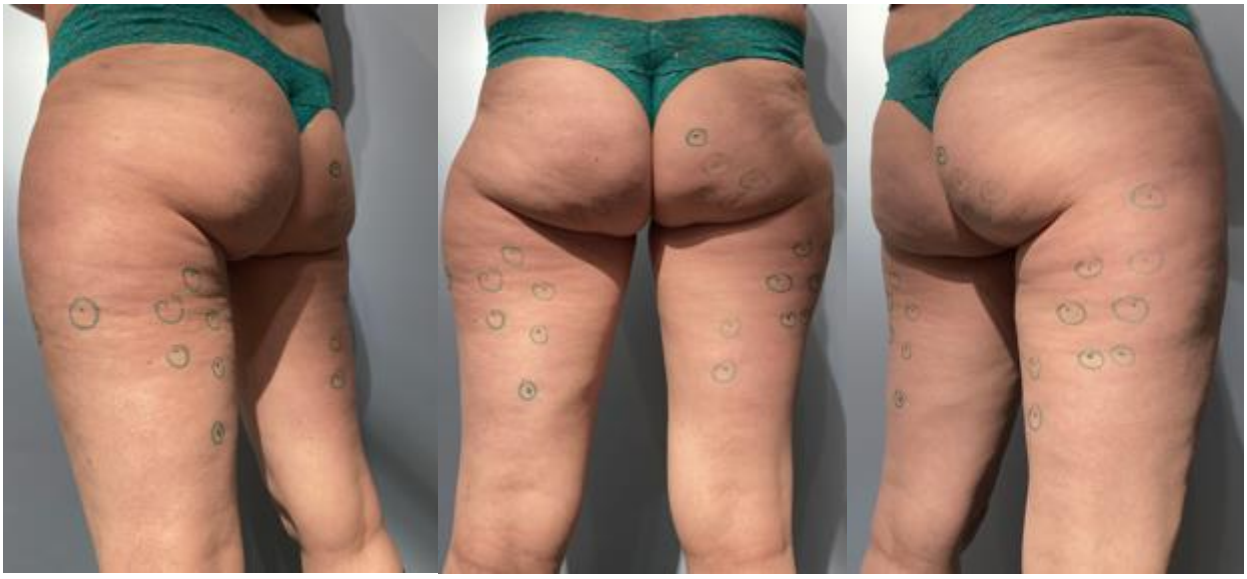


Day 43: 22 buttock dimples
4 thigh dimples
Dilution: 5.2 mL of sterile saline

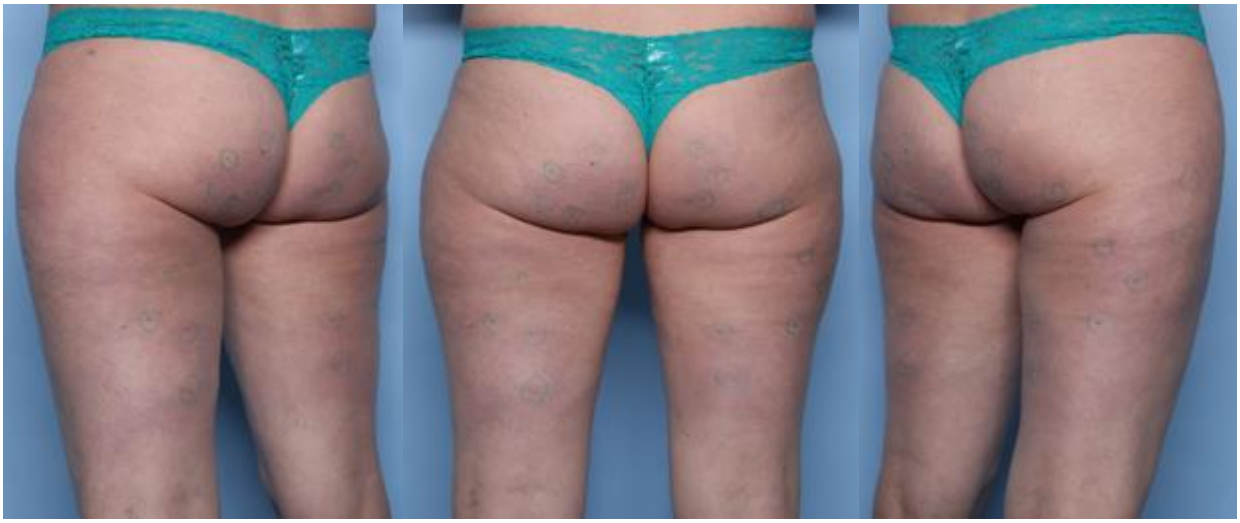


Subject 003

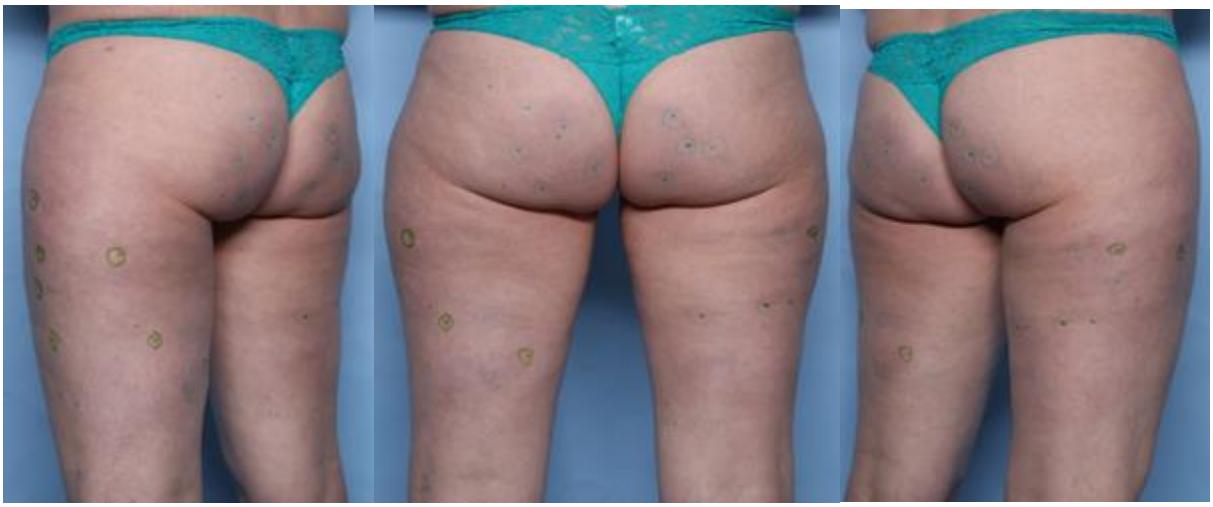
Day 1: 10 buttock dimples
16 thigh dimples
Dilution: 20.0 mL of sterile saline



Day 22: 9 buttock dimples
17 thigh dimples
Dilution: 21.2 mL of sterile saline

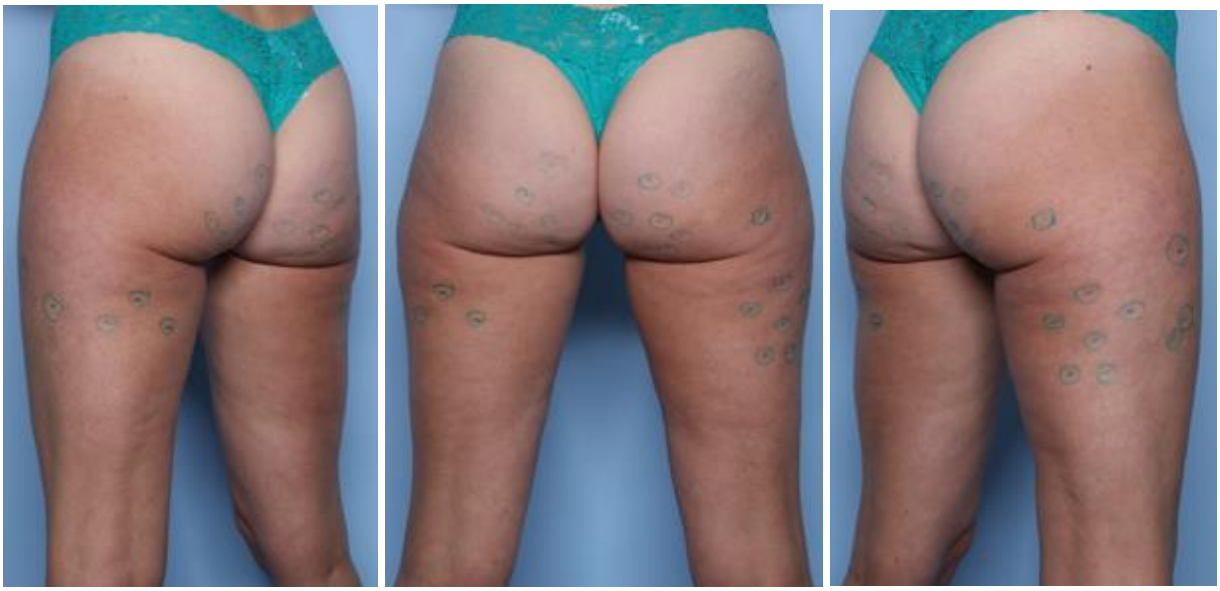


Day 43: 9 buttock dimples
4 thigh dimples
Dilution: 5.2 mL of sterile saline

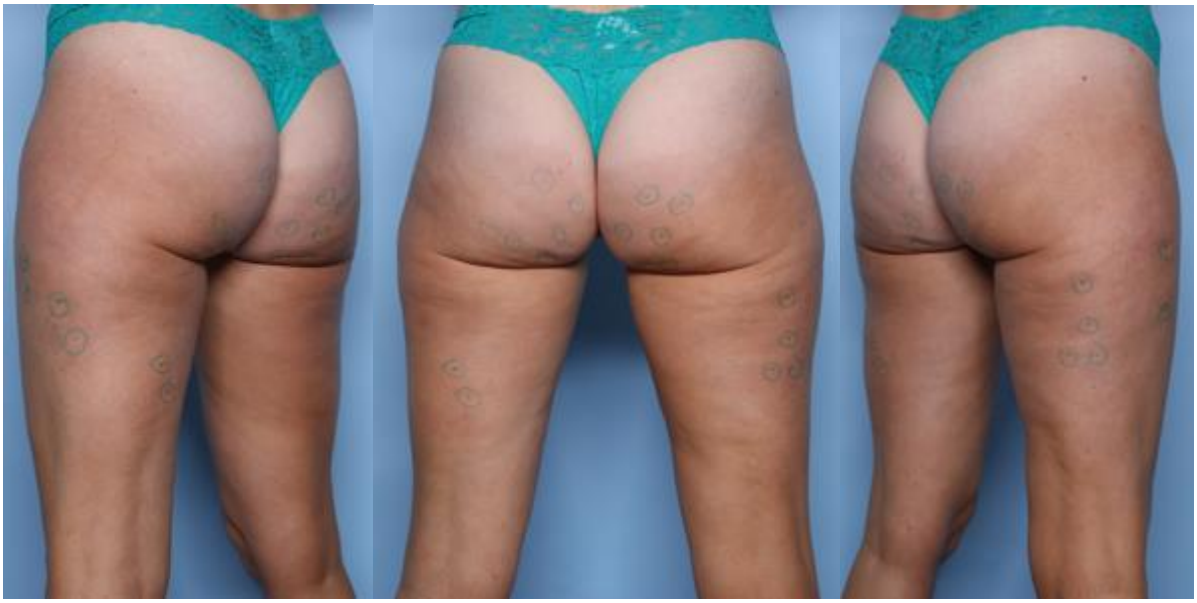


Subject 004

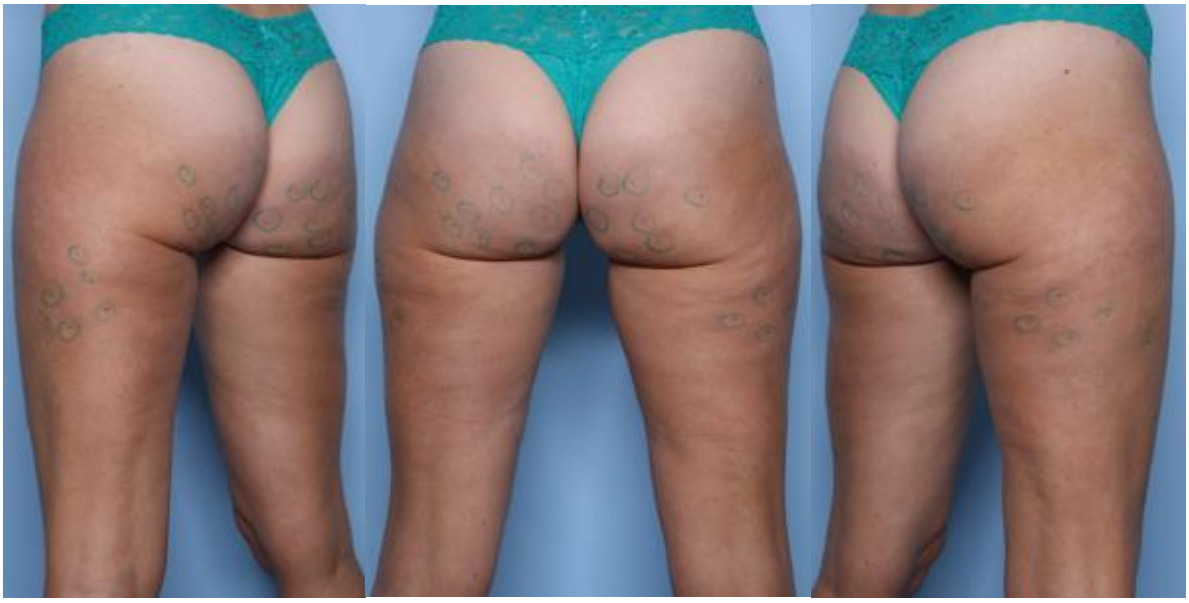
Day 1: 12 buttock dimples
14 thigh dimples
Dilution: 17.6 mL of sterile saline



Day 22: 12 buttock dimples
14 thigh dimples
Dilution: 17.6 mL of sterile saline

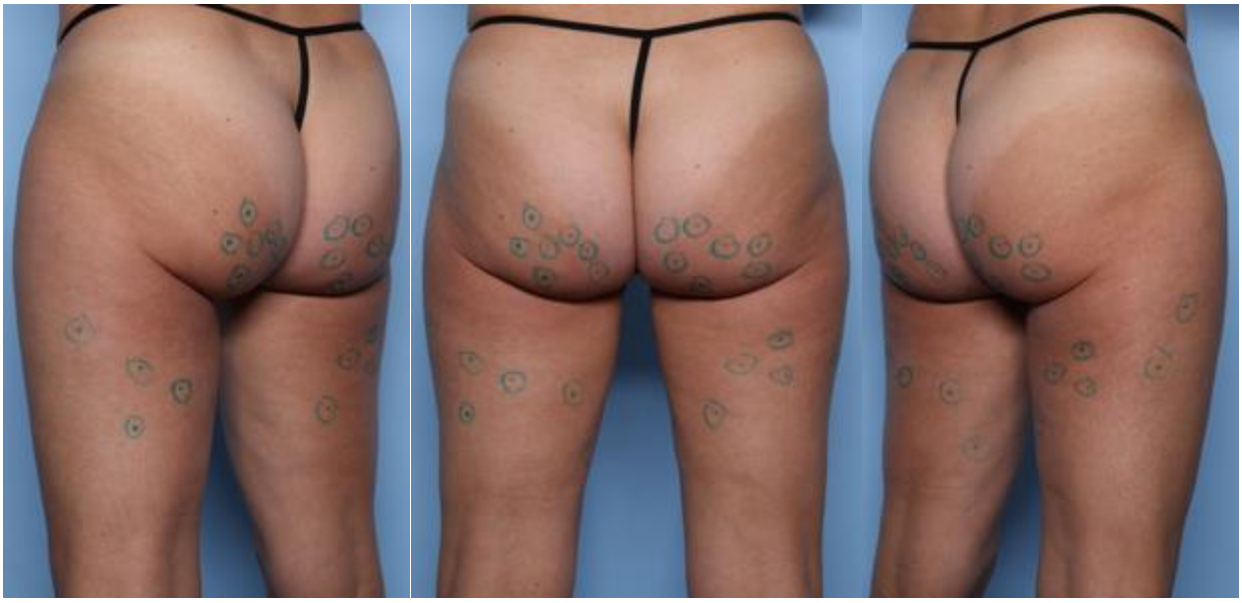


Day 43: 16 buttock dimples
10 thigh dimples
Dilution: 12.8 mL of sterile saline

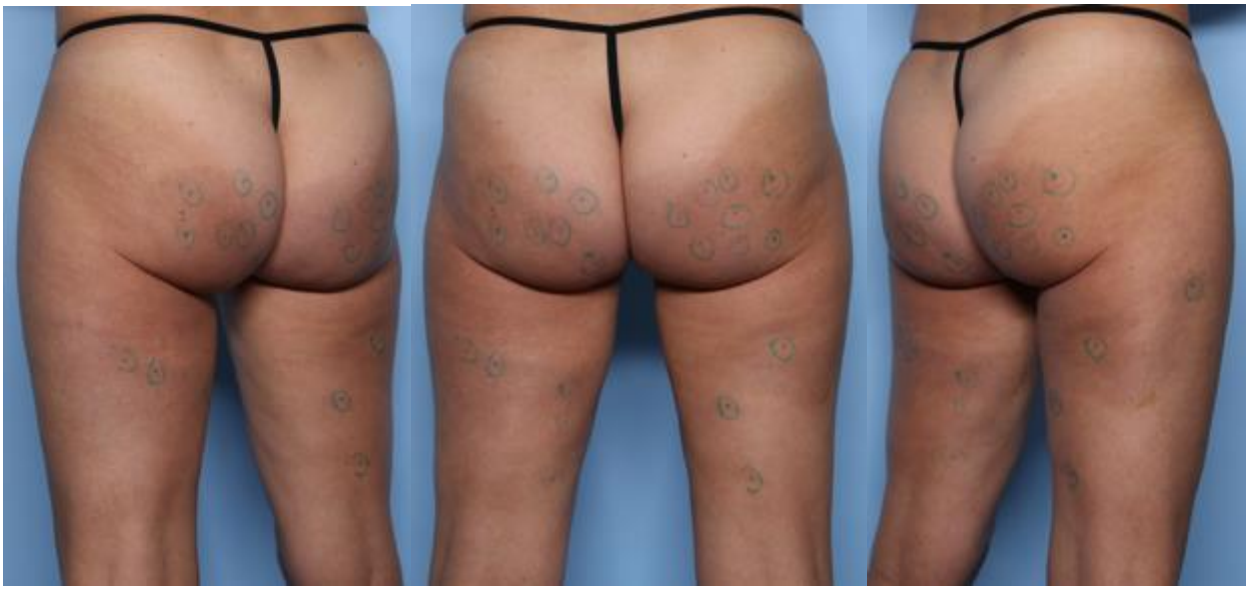


Subject 005

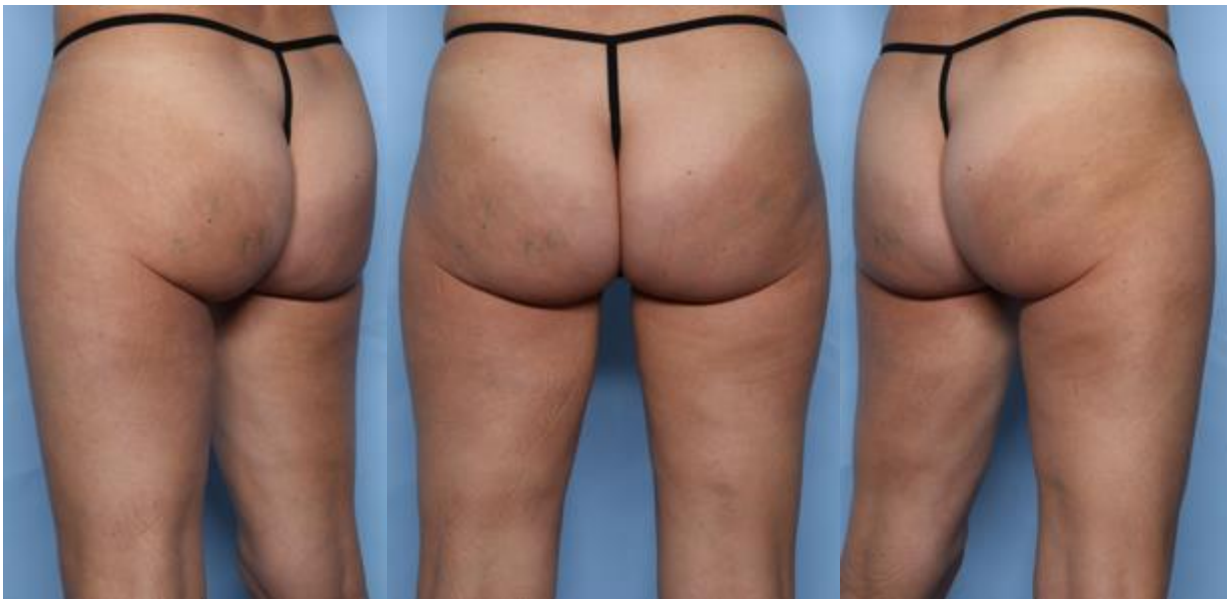
Day 1: 14 buttock dimples
12 thigh dimples
Dilution: 15.2 mL of sterile saline



Day 22: 15 buttock dimples
11 thigh dimples
Dilution: 14.0 mL of sterile saline



Day 43: 10 buttock dimples
2 thigh dimples
Dilution: 20.0 mL of sterile saline



Body-Q Appraisal of Cellulite

The Body-Q Appraisal of Cellulite is a subset of questions from the Body-Q questionnaire developed to measure participant perceptions of weight loss and/or body contouring. The minimum possible score is 11 and the maximum possible score is 44. Individuals with higher scores are less bothered by their cellulite. Copyright Memorial Sloan-Kettering Cancer Center.

Subject	Body-Q Appraisal of Cellulite Day 1 Score	Body-Q Appraisal of Cellulite Day 90 Score	Mean Change
001	11	13	+2
002	11	19	+8
003	22	41	+19
004	17	26	+9
005	16	36	+20

Final Result: All 5 subjects reported feeling less bothered by cellulite from Day 1 to Day 90.

Clinician Reported – Photonumeric Cellulite Severity Scale (CR-PCSS)

Mean change from baseline Clinician-Reported Photonumeric Cellulite Severity Scale (CR-PCSS) is a 5-point photonumeric scale rating cellulite severity from "0" (none) to "4" (severe) from a clinician's perspective.

CR-PCSS Buttocks

Subject	CR-PCSS Buttock Day 1	CR-PCSS Buttock 90 Day
001	2	2
002	3	2
003	2	2
004	2	1
005	3	1

CR-PCSS Thighs

Subject	CR-PCSS Thigh Day 1	CR-PCSS Thigh 90 day
001	2	2
002	2	1
003	2	1
004	2	1
005	3	1

Final Result: Principal Investigator observed a reduction in cellulite severity in 4/5 subjects between day 1 and day 90.

Investigator Global Assessment Scale (I-GAIS)

Rating	Response Option	Description
+3	Very much improved	Optimal cosmetic result from treatment of the treated dimples
+2	Much improved	Marked improvement in the treated area appearance from before treatment, but not completely optimal
+1	Improved	Obvious improvement in the treated area appearance from before treatment, but additional treatment is indicated
0	No change	The treated area appearance is essentially the same as before treatment
−1	Worse	The treated area appearance is worse than before treatment
−2	Much worse	Marked worsening in appearance from the initial condition
−3	Very much worse	Obvious worsening in appearance from the initial condition

Buttock

Subject	Day 22	Day 43	Day 90
001	0	-1	-1
002	0	0	+1
003	0	-1	-1
004	0	+1	+1
005	0	0	+1

Thighs

Subject	Day 22	Day 43	Day 90
001	+1	0	-1
002	+1	+1	+1
003	0	0	+1
004	+1	+1	+1
005	0	0	+1

Final Result: Principal Investigator determined worsening appearance in cellulite for subjects 001 and 003 due to weight gain reported by subjects attributed to COVID-19 stressors. +1 improvement was observed for subjects 002, 004 and 005 between day 1 and day 90.

Adverse Events

The following adverse events were reported by each subject post-treatment sessions, Day 1, Day 22 and Day 43.

Bruising
Moderate to severe bruising was reported after each treatment session, however, diminishing in severity after each subsequent treatment.

- **Con Medications:** Subjects were recommended to use arnica gel topically post procedure.

- **Con Procedures:** Subjects were offered and treated with the pulsed dye laser (PDL) post Day 1 treatment to minimize the severity of bruising. Subject 001 was treated with PDL 72 hours post Day 1 treatment and subject 004 was treated with PDL 24 hours post Day 1 treatment. Subjects treated with the PDL laser reported a significant improvement in the severity of bruising, reporting changes in bruise coloration from purpura to erythema, within 24-48 post treatment.

Edema
Mild to Moderate edema was reported after each treatment session.

- **Con Medications:** Subjects did not report drug administration for edema.

- **Con Procedures:** Subjects were advised to wear compression or tight leggings. Subjects 001 and 003 reported the use of ice to reduce edema after Day 1.

Pruritus
Mild pruritus was reported post treatment after Day 1 and Day 22.

- **Con Medications:** None.

  Con Procedures: None

Hemosiderin Staining
All subjects developed mild to moderate hemosiderin staining post treatment. At day 90/final visit, it was observed that subjects 001, 004 and 005 presented with mild hemosiderin staining. Subjects were advised to avoid prolonged sun exposure and to apply SPF 50+ outdoors.

Tenderness
Subjects reported mild to moderate tenderness post-treatment, with Day 1 being the most severe out of the treatment sessions sand diminishing in severity and each subsequent treatments.
Subjects were advised to take Tylenol or Motrin as needed.