Cavitational adipocytolysis with a new micro-gelatinous injectable for subcutaneous adipose tissue volume reduction: *ex-vivo* histological findings

Giovanni Salti MD\(^1\) and Pasquale Motolesse MD\(^2\)

\(^1\)Istituto Medilight – Florence Italy  
\(^2\)Professor FORMEST University of Ferrara Italy

The purpose of this study was to investigate the effects on biopsies of adipose tissue obtained from an abdominoplasty with a new injectable adipocytolytic solution that does not contain phosphatidycholine, combined with external medium frequency ultrasound. Biopsies taken from adipose tissue were infiltrated with injectable device alone and with the injectable combined with a subsequent application of external medium frequency ultrasound. The biopsies were fixed in formalin and embedded in paraffin. Sections were stained with hematoxylin and eosin and then analyzed. Untreated adipose tissue and adipose tissue treated only with intralipo-therapy needle insertion, served as controls. Sections were analyzed using light microscopy. Compared to the adipose tissues that were not treated by infiltration nor by infiltration plus external ultrasound, distinct damages of the cellular structure of the adipocytes could be seen. The destruction was especially visible in the sections treated with the injectable device and external ultrasound (cavitational adipocytolyses). In comparison, the adipose tissue of the controls was mostly intact. In conclusion our results indicate that cavitational adipocytolyses using this injectable solution combined with external medium frequency ultrasound is effective for the lysis of adipocytes.

**KEYWORDS:** Localized adiposity, Adipocytolysis, Aqualyx®, intralipotherapy


**ABSTRACT**

The use of external ultrasound after adipose tissue is infiltrated with saline solution to produce the phenomenon of intra-tissue cavitation was introduced in Italy about 20 years ago. This combination was used to reduce deposits of subcutaneous fat

**INTRODUCTION**

The use of external ultrasound after adipose tissue is infiltrated with saline solution to produce the phenomenon of intra-tissue cavitation was introduced in Italy about 20 years ago. This combination was used to reduce deposits of subcutaneous fat

**CORRESPONDENCE**

Giovanni Salti MD  
Istituto Medilight  
Via Maragliano 29L - 50144 Firenze  
giosal@fol.it

**DISCLOSURES**

Dr. Giovanni Salti has no relevant conflicts of interest to disclose. Dr. Pasquale Motolesse is the creator of the formula of Aqualyx® and he earn royalty from the worldwide distribution.
in body areas where there is an excess of adipose tissue (localized adiposity). The Method, called “Ultrasonic Hydrolipoclasia”\(^{(1)}\) despite opening the way to new possible applications in aesthetic medicine, never proved to be particularly effective. Despite the fact that the initial rational was unclear, the use of Lipostabil introduced more recently\(^{(2,3)}\) opened the way to a new treatment protocol for localized adiposities with certain effectiveness. The great interest and widespread use of localized injections of Lipostabil have stimulated research towards a better understanding of the underlying mechanisms of action of these solutions in the tissues, identifying sodium deoxycholate as the active ingredient, a molecule with a deterging action\(^{(4,5)}\) and excluding the initial hypothesis of a lipolytic action of the phosphatidylcholine\(^{(6)}\). These findings have subsequently led to the formulation of new solutions where only the sodium deoxycholate in aqueous solutions is a high risk for skin necrosis (fig 1 and 2, data not published), given the strong aggressive-

In relation to the mode of action of these injectable solutions, a protocol for the selective infiltration of adipose tissue called intralipotherapy\(^{(7)}\) was proposed, totally different from mesotherapy (intradermotherapy) that is frequently indicated as a method of infiltration. The injectable device (Aqualyx® Marllor International – Italy) (AQL) is a complex microgelatinous solution\(^{(8,9)}\) that does not contain phospholipids; it is formulated to predispose the adipocytes to lysis amplifying the effects of external ultrasound.

**MATERIALS AND METHODS**

Four samples of adipose tissue were obtained from an abdominoplasty in a 35-year-old female subject. All the samples were equal in form and size and composed of adipose tissue, dermis and epidermis (fig.3). Two of the samples were infiltrated with 5 ml of AQL with a 24 Gauge intralipotherapy needle (Lipoinject needle® – Marllor Int. Italy) in

**FIGURE 1.** Skin inflammatory reaction of the upper arm with several ulceration after infiltration of aqueous solution of sodium deoxycholate in unknown concentration (Brazil)

**FIGURE 2.** Cutaneous necrosis of the thigh after infiltration of sodium deoxycholate in aqueous solution in unknown concentration (Poland)
proximity to the free margin of the adipose tissue at a precise depth that will permit taking a precise biopsy.

The third sample was infiltrated with saline solution, while the fourth sample was exposed only to the trauma of the needle.

One of the 2 samples infiltrated with AQL was later subjected to external medium frequency (516-918 kHz - Sonolyx®, Marlloir int. - Italy) ultrasound for 10 minutes with the transducer applied at the cutaneous margin.

From each sample, multiple biopsies were taken 5 mm from the infiltration site.

The tissue removed was conserved in formaldehyde, fixed in paraffin and stained with hematoxylin and eosin and subjected to a blind pathological anatomic evaluation.

RESULTS

The histological aspects observed in the biopsies taken from the four samples are shown in figures 4 A, B, C and D.

The samples examined infiltrate with saline solution and exposed to the trauma needle (fig. 4A, 4B) show normal adipose tissue with preservation of the lobular structure. The sample that was infiltrated only with AQL shows cellular swelling and a “split rail” cellular membrane (fig 4C). The sample that underwent infiltration with AQL and was then exposed to external medium frequency ultrasound, in addition to the aspects that were previously described, showed alteration of the lobular structure with homogenized cytoplasm content and widespread areas of cellular destruction were noted (fig. 4D).

CONCLUSIONS

Cavitational adipocytolysis is a nonsurgical technique that uses ultrasound to induce fat cell death. This study demonstrates the histological changes that occur in adipose tissue when exposed to saline solution, needle trauma, AQL, and ultrasound. The results indicate that ultrasound can further exacerbate these changes, leading to homogenization of the cytoplasm and widespread cellular destruction. This technique offers a potential non-surgical alternative to traditional liposuction.
The protocol developed for reducing the volumetric excess of localized adipose areas that produce alterations of the body contour in relation to modern concepts of aesthetics. The protocol provides for the synergistic association of an injectable specifically formulated solution (AQL) and the application of external ultrasound in order to obtain a more selective adipocytolysis.

The histological evidence from human adipose tissue obtained from an abdominoplasty showed evidence of lytic action of the adipocytes as well as the adipose lobules, resulting from the combination of the two protocols.

Clinical studies awaiting publication, which demonstrate the effectiveness and safety are carried out on an outpatient basis in aesthetic medicine.

REFERENCES


FIGURE 4C. Sample infiltrated with Aqualyx®: adipocytes swelling and “split rain” separation of the cellular membrane lipidic bilayer

FIGURE 4D. Sample infiltrated with Aqualyx® and subsequently exposed to external ultrasound: adipocytes swelling and “split rain” separation of the cellular membrane lipidic bilayer, homogenised cytoplasm content and widespread area of cellular destruction