

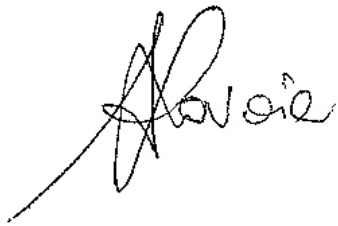
NONINVASIVE BODY CONTOURING BY SHOCK WAVES AND
CRYOLIPOLYSIS: A CLINICAL STUDY

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A handwritten signature in black ink, appearing to read 'A. Savoia', with a long, sweeping underline that extends to the left.

Introduction

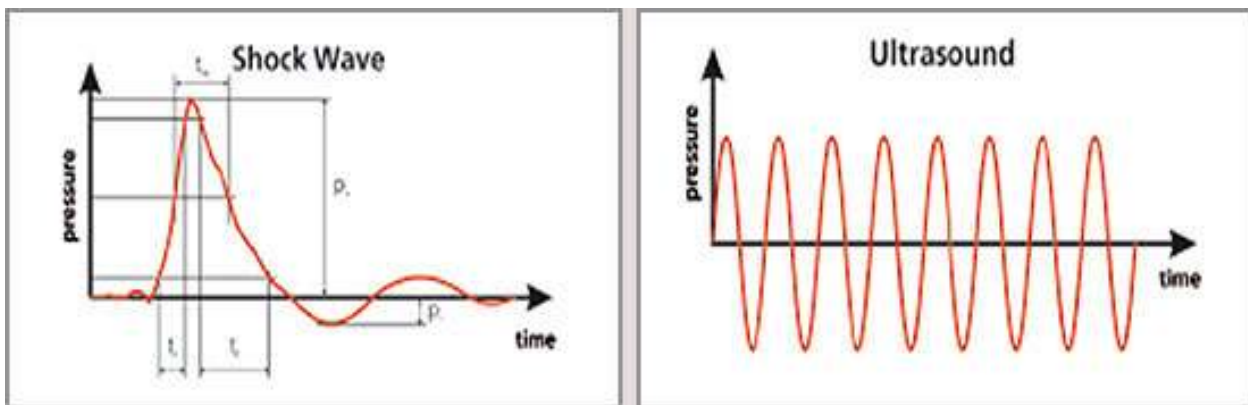
Body contouring by liposuction for the removal of excess weight is the most frequently performed cosmetic surgery in the United States [1]. Because of the numerous drawbacks of the surgical procedure (hospitalization, anaesthesia, clinical complications, long post-operative recovery), there is a greater demand in body aesthetic medicine for non-invasive procedures [2-4]. Non-invasive alternatives to liposuction up to date include lifestyle changes in diet and exercise; alternatively mesotherapy, multiple injections of bile salt solutions, creams and lasers are currently used, but none of these procedures is approved by the U.S. Food and Drug Administration [4,5]. In particular, novel applications using ultrasound without surgical interventions have been investigated to deliver an energy signature through the skin for the disruption of adipose tissue [6,7].

Shock Wave is a soft and painless method, able to efficiently contrast the beauty flaws of cellulite thanks to particular acoustic waves characterized by elevated widths and pressures[8].

Shock waves have been used in the medical field since 1980 in the treatment of lithiasic pathologies (renal calculi break-up) with the aim of being able to destruct the targeted structures without damaging surrounding tissues. Towards the mid 80's, new studies have opened ulterior horizons on the effective therapeutic potentiality of shock waves, in particular in the orthopedic field, both for the cure of soft tissues as well as for the cure of osseous tissues. Research is always greater in the last years in the dermatological field, where shock waves seem to have a great therapeutic efficiency in many pathologies such as chronic wounds, burns and diabetic ulcers. In aesthetic medicine, shock waves are used to efficiently fight the fibrous cellulite beauty flaw.

Shock waves induce the formation of “**wavefronts**” that travel at the speed of sound in the media in which they have been produced and “**Cavitation**” phenomenon.

“Wavefronts” overlap, and once they reach the tissues characterized by connective alterations, aim of the treatment (fibres), they produce an elevated pressure force which determines the formation and then the implosion of water bubbles, which release very strong micro-flows, **splitting the sclerotic fibrous tissue**. “Cavitation” phenomenon occurs when the shock wave in contact with a fluid, produces the generation of multiple pressure differences that give origin to the formation of bubbles of gas.



Instead, cryolipolysis is a non-surgical alternative to liposuction, an absolutely non invasive manner to improve the aspect, model the silhouette and reduce excess fat, thanks to the aid of cold. Born in the USA, cryolipolysis has quickly become a must to efficiently reduce localized fat. The prefix “Cryo” is derived from the Greek word kryos, meaning frost, which is the “cold” used to eliminate excess fat. Fat, in fact, is much more sensitive to cold compared to other anatomic structures in the area treated, such as skin, dermis, vessels, nerves and muscles going towards Apoptosis [10]. The adipose tissue is placed in contact with iced plates by using a pressure applicator that thermically “kills” fat without damaging the skin. The dead cells are then metabolically disposed of, exactly as it occurs for the fat found in food. The positive sides of cryotherpay and of shock waves have led to a greater number of these operations compared to ones of plastic surgery[11,12,13,14].

Indeed, an ideal non-invasive procedure of delivering energy to the fat would reduce peri-procedural morbidity such as infection, scarring, anaesthesia-related complications, and other risks associated with surgical procedures.

We describe here the pivotal clinical trial of a new non-invasive device for body contouring, ***Proshockice*** (PromoItalia Group S.p.A., Pozzuoli, Italy), for the reduction of localized fat and cellulite, that uses an innovative and patented combined technology denominated “Ice-shock-lipolysisTM” to reduce subcutaneous fat volume and fibrous cellulite in areas that would normally be treated by liposuction, thanks to the combination of acoustic waves and criolipolysis (Ice-lipolysisTM technology).

The data produced demonstrates that the *Proshockice* device provides a safe and effective non-invasive technology for the body contouring and cellulite treatment.

Materials and Methods

Apparatus

The apparatus used, *Proshockice* (PromoItalia Group S.p.A, Naples, Italy), emits Shock waves at a frequency variable from 1 to 16 Hz, at a power variable from 200 up to 500 Kg/cm² . The temperature for criolipolysis is variable from +5 up to -5 °C and vacuum pressure is variable from 0.2 Bar up to 0 Bar. It is also equipped with two probes: “Freezing ProbeTM” to work in an aimed way on localized fat and for vasoconstriction, useful for vascular gymnastics with vacuum effect, and the “Shock ProbeTM” to work on the fibrous component of fat and cellulite.

In order for the transducer (which emits the shock waves) to transfer the waves, a conductive gel must be used.

Patients

50 patients have been participated in this study (42 females and 8 males), aged between 25 and 63 years old, all with localized fat and cellulite. For the study, the population of patients has been divided based on the areas treated: abdomen, ankles, buttocks and outer thighs. Prior to assessment and treatment, all patients received explanations about the procedure and read and signed an informed consent. All patients underwent a screening visit including physical examination and blood tests. Exclusion criteria for this study were: osteoporosis, phlebitis and thrombophlebitis, patients carrying metallic fragments, articular prosthesis, intrauterine devices or pace-maker, pregnant women, patients with a reduced nervous sensibility or with neurological pathologies, patients affected by obliterating arteriopathies and patients affected by important inflammatory processes or neoplastic diseases.

It is very important to assure that during the period of treatments the patients have assumed at least two litres of water a day, and have followed a moderated hyperproteic diet; moreover, none of the patients underwent other slimming or aesthetical procedures (endermologie, mesotherapy, radiofrequency, ultrasound low frequency etc.) during the study.

Treatment and evaluation protocol

Each treatment has been carried out according to a default protocol and the duration set depending on the width of the area to treat, varied from a minimum of 20 minutes to a maximum time of 60 minutes. The treatment has been practised by placing two transducers on the skin contemporaneously. In particular, the ***use of the Freezing Probe*** is recommended for treating fatty tissue; 30 minutes of Ice-lipolysis with slow movements on the area in the sliding mode with a temperature range between 0 and -5°C; the ***use of the Shock Probe*** in association with the conductive gel to realize 10-15 minutes of Shocktherapy.

For edematous cellulite, the *use of the Freezing Probe* is recommended to realize 5 minutes of Ice-lypolysis (no apoptosis but vascular gymnastics) and the use of the *Shock Probe* to realize 5 minutes of Shocktherapy. Repeat the alternating of Icelypolysis and Shocktherapy for four times (20 minutes per side).

Finally, for fibrous cellulite, the use of *the Shock Probe is recommended* to realize 10 minutes of Shocktherapy to vehiculate a lipolytic product, the *use of the Freezing Probe* to realize 10 minutes of Ice-lypolysis and Use the Shock Probe to realize 10 minutes of Shocktherapy to work on the fibrous component. Repeat the alternation of Icelypolysis and Shocktherapy for 30 minutes per side. Max total time: 1 hour.

We have attended at least 15 days between a session and the following, in order to guarantee a total time of hepatic recovery, even in case of the eventual presence of pathologies in sub-clinical phases. The evaluation period lasted 10 consecutive weeks at the frequency of 1 session every 15 days for a mean total of 5 sessions. Prior to the start of the treatment program and at the end of the treatment, each subject's age, height and weight were recorded along with a perimetric measurement of the area to be treated and photos of the subject. In detail, for the perimetric measurements the conditions were: the patients with standing up feet apart at always the same distance; marking the height from the floor up to the area of concern; measuring just below the marking, making sure the measuring tape is parallel to the floor. The conditions for the photos (digital camera C5050 from Olympus) were: the subject standing up feet apart at always same distance; camera distance from subject always the same; camera height, angle and focal always the same; light always the same with 4 flash lights in slave mode (2 behind the subject and 2 on either side of the camera); 4 photos taken at each evaluation period (1 photo of front, 1 photo of back, 1 photo of right and left side).

Subjective evaluations: An auto-evaluation questionnaire has been given to all patients, with a scale from 0 to 5, where a subjective evaluation concerning the skin's compactness, the volumetric reduction of fat, comfort, and satisfaction compared to the outcome of the treatment, was requested.

Instrumental evaluations: Ultrasound survey's have been carried out before and after the treatment with the intent of evaluating the reduction of the hypodermic layer and the integrity of the surrounding structures.

Laboratory evaluations: The haematic levels of cholesterol have been constantly verified with specific reference to the VLDL (fraction of cholesterol in which metabolization products of triglycerides contained in adypocytes pass), in particular, the drawing has been performed 24 hours before the beginning of the first session, immediately after, after 96 hours and after 7 days. An evaluation of the markers with hepatic functions (GOT, GPT, GT range) has been carried out, before the beginning of the treatment and 15 days after the last session.

Statistical analysis

The differences were evaluated by Wilcoxon tests for paired continuous variables. The software used for statistical analysis was SPSS (SPSS, Chicago 17.0). P value <0.05 was considered statistically significant.

Results

The characteristics of the patients and measurement data are summarized in Table 1. Fifty patients were enrolled and all completed the study. Areas treated included the abdomen (16 patients), the thighs (20 patients), the buttocks (10 patients) and the ankles (4 patients). Except for the patients treated in the abdominal area, all the other patients had bilateral treatments at each session length. All patients were able to resume normal activities upon completion of the session. The median fat thickness reduction at

the end of the treatment was 6.2 cm for the abdomen, 6.3 cm for the thighs, 5 cm for the buttocks and 2.2 cm for the ankles. Final reduction of fat thickness was significant when compared to the measurement prior to the treatment ($Z=-5.384$, $P<0.0001$). The greatest reductions were observed in the thighs and in the abdomen, while the ankles showed the lowest reduction. There was no statistical difference in fat thickness reduction between men and women. In subjects treated for fibrous cellulite, besides the reduction in centimetres, a modification of the cutaneous aspect with an attenuation of the “orange peel” skin effect has been observed. Interestingly, patient weight remained constant over the treatment in all patients, strongly suggesting that the fat thickness reduction was due to the treatment. Improvements in body contour were visibly appreciable in all patients at the end of the treatment, as supported also by the data from the subjective evaluations, that showed always a clear satisfaction in all the patients treated with a score of 4 or 5. In figure 1a and 1b an example of body contouring is depicted, while in figure 2 a and 2 b representative ultrasound image pair, showing fat thickness before and after treatment of the abdomen is shown. Cholesterol levels were mildly increased after the treatments, but remained within normal limits (data not shown). Consistently, evaluation of the markers with hepatic functions (GOT, GPT, GT range) demonstrated no alterations in the hepatic functions. Finally, no severe adverse events were reported during and after the completion of the procedures; in particular no paresthesias, haematomas, ecchymoses, or oedema were noted or reported.



Figure 1.a



Figure 1.b

Figure 2.a

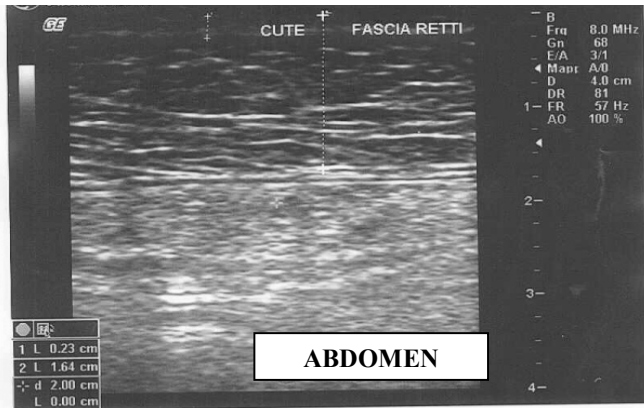
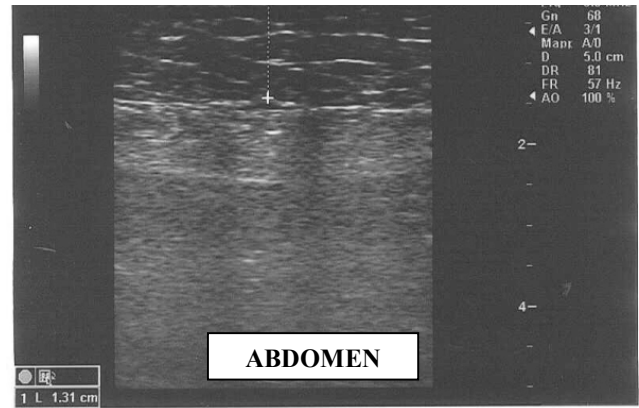


Figure 2.b



Discussion

Our clinical study shows that *Proshockice* is safe and effective in body contouring. Shock wave and criolipolysis are applied externally and transmitted through the skin to the subcutaneous fat, where they are adsorbed. In particular, this procedure significantly reduced the circumference of the treated areas. This reduction was caused by a reduction in fat thickness, as assessed by ultrasound measurement. Interestingly, the reduction in fat thickness could not be ascribed to weight loss, since no statistically significant weight reduction was observed in any of the patients treated. One of the most important aspects that distinguishes liposuction by *Ice-shock-lipolysis* from other methods of liposuction is the much less numerous drawbacks respect to the surgical procedures. Indeed, the procedure described was well tolerated. The great majority of the patients treated reported that they experienced minimal or no discomfort during or after the procedure. Physical examination and laboratory assessment throughout the study period showed no clinically significant changes. In particular, no paresthesias, haematomas, ecchymoses, or oedema were noted, neither hyper-pigmentation or hypo-pigmentation was reported. Moreover, cholesterol levels were mildly increased after the treatments, but remained within normal limits and assessment of hepatic function revealed no changes in markers of liver functions (GOT,

GPT, GT range), thus suggesting that fat released from treated areas was cleared by the natural fat metabolism pathways.

We conclude that the action of *Proshockice* apparatus is a safe, effective, and well-tolerated non-invasive procedure for body contouring. In particular, we believe that this could be an ideal non-invasive alternative to conventional liposuction for patients who would require only small or moderate amounts of adipose tissue removal or are not suitable for surgical approaches to body contouring. Further studies are required to assess whether serial treatments would produce incremental fat reduction and whether greater fat reduction could be achieved through various treatment combinations, in conjunction with weight loss strategies or other aesthetic technologies to treat obesity related fat depots.

Table 1. Characteristics of the patients enrolled in the study

| <i>N</i> ^o | <i>Sex</i> | <i>Age</i> | <i>Peso (kg)</i> | <i>Height (cm)</i> | <i>Treatment site</i> | <i>Perimetric measurements (cm)</i> | <i>Subjective evaluation</i> | |
|-----------------------|------------|------------|------------------|--------------------|-----------------------|--------------------------------------|------------------------------|---|
| 1 | F | 41 | 68 | 163 | abdomen | 92/86 | reduction 6 | 4 |
| 2 | F | 42 | 65 | 160 | abdomen | 84/79 | reduction 5 | 5 |
| 3 | F | 48 | 70 | 168 | abdomen | 88/82 | reduction 6 | 4 |
| 4 | M | 47 | 89 | 178 | abdomen | 106/98 | reduction 8 | 5 |
| 5 | F | 51 | 58 | 155 | abdomen | 84/80 | reduction 4 | 4 |
| 6 | M | 36 | 80 | 174 | abdomen | 96/89 | reduction 7 | 5 |
| 7 | M | 44 | 84 | 180 | abdomen | 92/84 | reduction 8 | 5 |
| 8 | F | 36 | 81 | 169 | abdomen | 94/89 | reduction 5 | 4 |
| 9 | M | 21 | 76 | 177 | abdomen | 92/87 | reduction 5 | 4 |
| 10 | M | 45 | 88 | 183 | abdomen | 108/98 | reduction 10 | 5 |
| 11 | M | 45 | 67 | 166 | abdomen | 88/81 | reduction 7 | 5 |
| 12 | M | 43 | 79 | 173 | abdomen | 100/92 | reduction 8 | 5 |
| 13 | M | 43 | 72 | 166 | abdomen | 102/93 | reduction 9 | 5 |
| 14 | M | 55 | 76 | 170 | abdomen | 99/91 | reduction 8 | 5 |
| 15 | F | 62 | 65 | 156 | abdomen | 90/84 | reduction 6 | 5 |
| 16 | F | 43 | 75 | 170 | abdomen | 90/83 | reduction 7 | 5 |
| 17 | F | 40 | 74 | 167 | thighs | 96/88 | reduction 8 | 5 |
| 18 | F | 36 | 68 | 164 | thighs | 94/88 | reduction 6 | 5 |
| 19 | F | 42 | 74 | 180 | thighs | 88/84 | reduction 4 | 4 |
| 20 | F | 38 | 81 | 169 | thighs | 102/96 | reduction 6 | 5 |
| 21 | F | 47 | 77 | 171 | thighs | 100/96 | reduction 4 | 4 |
| 22 | F | 43 | 60 | 162 | thighs | 92/86 | reduction 6 | 5 |
| 23 | F | 35 | 75 | 172 | thighs | 95/90 | reduction 5 | 4 |
| 24 | F | 45 | 66 | 161 | thighs | 95/88 | reduction 7 | 5 |
| 25 | F | 39 | 74 | 165 | thighs | 100/92 | reduction 8 | 4 |
| 26 | F | 57 | 65 | 158 | thighs | 99/90 | reduction 9 | 5 |
| 27 | F | 34 | 54 | 160 | thighs | 90/84 | reduction 6 | 5 |
| 28 | F | 37 | 60 | 159 | thighs | 91/84 | reduction 7 | 5 |
| 29 | F | 45 | 64 | 159 | thighs | 34/32 | reduction 2 | 4 |
| 30 | F | 29 | 59 | 164 | thighs | 36/33 | reduction 3 | 5 |
| 31 | F | 37 | 70 | 162 | thighs | 40/36 | reduction 4 | 5 |
| 32 | M | 49 | 71 | 167 | thighs | 37/34 | reduction 3 | 5 |
| 33 | M | 44 | 70 | 172 | thighs | 33/31 | reduction 2 | 4 |
| 34 | M | 38 | 78 | 170 | thighs | 36/33 | reduction 3 | 4 |
| 35 | F | 50 | 55 | 154 | thighs | 34/32 | reduction 2 | 5 |
| 36 | F | 32 | 63 | 164 | thighs | 36/33 | reduction 3 | 5 |
| 37 | F | 37 | 70 | 162 | buttocks | 88/82 | reduction 6 | 5 |

| | | | | | | | | |
|----|---|----|----|-----|----------|-------|-------------|---|
| 38 | F | 41 | 64 | 166 | buttocks | 90/85 | reduction 5 | 4 |
| 39 | F | 38 | 69 | 163 | buttocks | 86/81 | reduction 5 | 5 |
| 40 | F | 38 | 62 | 157 | buttocks | 83/79 | reduction 4 | 4 |
| 41 | F | 52 | 68 | 161 | buttocks | 88/81 | reduction 7 | 5 |
| 42 | F | 36 | 60 | 156 | buttocks | 82/79 | reduction 3 | 4 |
| 43 | F | 33 | 60 | 160 | ankles | 28/27 | reduction 1 | 4 |
| 44 | F | 27 | 58 | 154 | ankles | 27/25 | reduction 2 | 5 |
| 45 | M | 47 | 82 | 179 | ankles | 30/26 | reduction 4 | 5 |
| 46 | F | 31 | 65 | 161 | ankles | 29/27 | reduction 2 | 4 |
| 47 | F | 33 | 70 | 166 | buttocks | 98/88 | reduction 3 | 4 |
| 48 | F | 44 | 63 | 159 | buttocks | 96/83 | reduction 3 | 5 |
| 49 | F | 51 | 67 | 160 | buttocks | 98/84 | reduction 4 | 5 |
| 50 | F | 46 | 71 | 160 | buttocks | 92/77 | reduction 5 | 5 |

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Figure Legends

Figure 1a and 1 b Outer thighs (A) before treatment and (B) after treatment.

Figure 2a and 2b Fat thickness assessment by ultrasound before (A) treatment and after (B) treatment, shows thinning of the subcutaneous fat layer from 16.4 mm to 13.1 mm. This patient was treated on the abdomen.

CURRICULUM VITAE

Antonella Savoia

Born in Naples on the 16/09/1975 and therein residing at via Salvator Rosa 284 Tel.: 333/2896965

TRAINING COURSE

- **2000** She obtains an academic degree by the Medicine and Surgery college of the Second University of Naples with a score of 110/110 with honours with an experimental thesis entitled **“Effects of the slow release of somatostatin similar on the shrinkage of GH secreting hypophysis adenome.”**
- Winner of the competition reserved to the students of the Second University of Naples for the assignment of the “Erasmus” scholarship for the academic year 1999/2000 by the University la Mediterran e of Marseille with practical internship in the Endocrinology department of the hospital TIMONE and laboratory activity by the Institute of “Endocrinological and Metabolic biochemical” directed by Prof. Carayon.
- She is qualified to practice the medical profession in the second session of the year 2001 with a score of 90/90.
- Biennial course (2003-2004) of internistic and interventistic ultrasound by the hospital “D. Cotugno” of Naples issued by the S.I.U.M.B. and A.N.E.I. and Theoretical-Practical Updating and Formation course in Hepato-Gastroenterological Ultrasound.
- 2005 Registration to the CTU of the Court of Naples.
- Training medical assistant from 2002 to 2007 by the Endocrinology department of the S.U.N. directed by Prof. A. Bellastella with a training course completed by hospital structures:
 - Diabetologic and nutritional disease services of the hospital San Gennaro of Naples directed by Prof. Renato Carleo (in 2004, 2005, 2006)
 - Endocrino-surgery services of the hospital Pascale (2004-2006).
- 2005 Course of “BLS/D performer” and following certificate issued by the IRC (Italian Resuscitation Council).
- 2006 While obtaining her master, she attends the Endocrinology Department of the hospital Cardarelli of Naples directed by Dr. R. Volpe, participating to the ambulatory care activity.
- Collaborates with Prof. Annamaria De Bellis in the Immunoendocrinology department of the second university of Naples.

- 2007 She has majored in Endocrinology and metabolic diseases with a score of 50/50 with honours.
- From 2002 to this day she works with Aesthetic medicine collaborating with an aesthetic centre where she practices the newest fashionable techniques in the medical-aesthetic field: (fillers and bio-revitalization techniques, mesotherapy and carboxitherapy, low frequency ultrasounds, intradermal radiofrequency). She is also occupied with dietology.
- From 2008 to this day, she is a scientific representative of the Research and Development Center of Promoitalia Group Spa, world-wide leading company in the medical-aesthetic field, where she sees to validations, clinical studies, risk analyses, patents, elaboration of scientific articles and publications on International magazines.
- 2009 She has invented the patent requested by the Promoitalia entitled “technique for the creation of an autologous capsule induced by radiofrequency for containing filling solutions”, deposited on the 10/04/09 with n. NA200900017.

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