



# CONSULTING ROOM

*Your Aesthetic Partner*



## FEATURE ARTICLE

**Is Fat-Freezing Walking on Thin Ice?**



## IS FAT-FREEZING WALKING ON THIN ICE?

Consulting Room Editor, Lorna Jackson & Aesthetic Surgeon Mr. Niroshan Sivathasan investigate...

**M**arket research reporter, Research and Markets<sup>1</sup> has forecast that the global market for non-invasive fat reduction devices is set to grow at a compound annual growth rate (CAGR) of 26.6% during the period 2016-2020. Whilst increasing demand for non-surgical interventions is one factor, this phenomenal growth forecast is said to be due to advances in non-invasive fat reduction technologies and devices, such as transdermal-focused ultrasound, low-level lasers, high-intensity focused ultrasound, monopolar RF, and thermal lipolysis (such as cryolipolysis).

Of course, as a group, they offer a huge range of diverse technologies with differing, proven levels of efficacy for achievable fat reduction; which may be the only factor you consider when deciding on which technology is superior.

When something new comes to the marketplace, such as cryolipolysis, there is much hype and enthusiasm

for the latest armoury to add to the fight against the 'bulge'. But, it's only once some time has elapsed that we can truly evaluate just how efficacious something is in the long-term, how it compares to competing modalities, and if there lurks the potential for more complex side effects than became apparent in the early days of use.

With this in mind, it's time to see if the concept of cryolipolysis is starting to walk on thin ice.

### The Birth of Fat-Freezing

Cryolipolysis – also referred to, and marketed as, fat-freezing, cryo lipo, cryolysis, cryogenic lipolysis, ice body sculpting, ice liposuction and cryogenic liposuction – aims to target and destroy fat cells through the application of extreme cold which induces the process of apoptosis (programmed cell death). As such, it is a non-invasive modality for the removal of subcutaneous fat.

It has been around in the aesthetic marketplace for over seven years now, when Zeltiq Aesthetics first introduced the CoolSculpting® device and the concept of 'cryolipolysis', over which the company claims to maintain the global trade mark.

The fat-freezing sector has continued to grow, as treatment options have expanded, and more competing devices have been commercialised, resulting in a significant downstream expansion in the number and types of businesses offering the service.

Allergan, the maker of Botox®, which recently completed the acquisition of Zeltiq Aesthetics, was quoted in Bloomberg<sup>2</sup> discussing the decision to add this technology to its existing aesthetic portfolio. *"Body contouring in our view is where facial injectables were 10 years ago,"* said Allergan Chief Commercial Officer Bill Meury. *"It has excellent future growth prospects".* If Allergan is getting on board, by snapping up the market leader, then

maybe the lure of fat-freezing has not melted away just yet.

Devices marketed in the UK vary in their make-up, from those solely equipped with cryo technology, to devices which combine freezing with other modalities such as radiofrequency, ultrasound cavitation or acoustic waves for adjunctive body contouring.

Although not an exhaustive list, devices include: CoolSculpting® (Zeltiq Aesthetics), Cooltech® (Cocoon Medical), CTN (Cryotech Nordic), LipoGlaze™ (Amabelle UK), 3D-lipo (3D brand), PROSHOCK ICE™ (Promoitalia), LipoContrast® (CLINIPRO), CRISTAL® (Deleo), Z Lipo (Zimmer), Lokkima and Nice Lipo (3D Nice Lipo). It is worth noting that not all systems are CE-marked medical devices, an example being LipoGlaze which only has cosmetic certification.

It's also true to say that it is very easy to source imported and OEM branded cryolipolysis devices from the Far East. These have indeed flooded the lower end of the marketplace, including beauty salons and mobile business models, where lower capital costs and entry price points for consumers are ubiquitous.

To find out more about opinions on the front line, Consulting Room carried out a small survey of UK based practitioners to find out about experiences and concerns with cryolipolysis technologies. Participation was low, with only 8 respondents. 5 reported using or having used the 3D-lipo device and 3 the CoolSculpting system. Reports of in-clinic complications, or being referred patients with complications from other providers, was quite low, but tended to include patients unhappy with poor or non-existent results, sensory changes (numbness and/or late-onset pain), skin discolouration, bruising and thermal burns. There was one report of paradoxical adipose hyperplasia. Half of respondents had not seen any complications, whilst the highest

reported complications at joint 38% were intangible change (essentially being completely ineffective) and delayed-onset pain.

## Safety and Efficacy

The targeted cooling of subcutaneous adipocytes, or fat cells, induces lipolysis, or the breaking down of the fat cells, without directly damaging any of the surrounding tissue, such as the skin.

Adipocytes are more vulnerable to energy extraction, so once cooled, they undergo apoptosis, which is controlled and theoretically predictable in its temporal course, unlike with necrosis. When apoptosis occurs, the fat cells' walls break down causing lipids from the cells to be released, and this occurs over a period of two to four months. These lipids are transported by the lymphatic system to be processed and eliminated by the body. The resulting fat loss is gradual and typically observed as

natural, circumferential reduction, and since the process is very steady, it is considered safe as there is no danger of overloading the lymphatic system.

Kenneth Klein, MD et al. noted in a paper published in 2009 that non-invasive cryolipolysis for subcutaneous fat reduction does not affect serum lipid levels or liver function tests<sup>3</sup>. This was determined after bilaterally treating forty patients with love handles using the CoolSculpting device, and doing follow-up tests at various time points, up to 12 weeks. He followed this up with another paper in May 2017 which concluded that multiple, same day cryolipolysis treatments (of the lower abdomen and both flanks), for the reduction of subcutaneous fat are safe and do not affect serum lipid levels or liver function tests<sup>4</sup>.

Consumers are attracted by the 'cool' sounding idea of being able to 'zap', or 'freeze away', unwanted fat without the

need for diet, exercise, and downtime. The idea of banishing 'pinchable' fat bulges, such as pot bellies, love handles, bra bulges, muffin tops and saddle bags has caused demand to soar. With this growth in demand, we have seen a proliferation in providers and devices, all whilst little regulation stands in the way of who should and should not be performing treatments; as well as little, to no, clinical data or technical accountability for many of the commercialised devices in Britain and mainland Europe.

Like all relationships which begin on a happy footing, it may be said that the aesthetic sector is starting to feel the 'seven-year itch' in its marriage with cryolipolysis, as more and more reported and circumstantial problems, come to light – both technology- and technician- related.

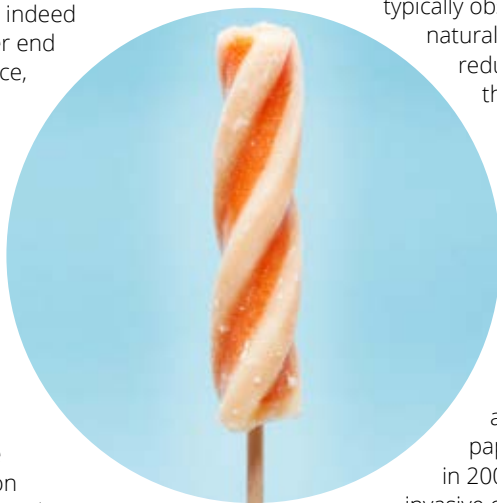
## Reported Problems

As well as official reporting, there are also in-practice experiences, and cases based on anecdotal accounts or opinions, plus consumer feedback and reviews on their experiences. These should not be ignored, and may go on to stimulate further evidence-based research.

Clinical studies on cryolipolysis have established its safety, efficacy, and tolerability for fat reduction in a variety of areas including all around the torso (abdomen, back, chest, and flanks), submentum, arms, and thighs. In most cases, such studies have led to continued U.S. approval labelling for the Zeltiq device. Long-term study data is now available to show follow-up on treated patients up to nine years' post-treatment, and these demonstrate longevity of the cryolipolysis results<sup>5</sup>.

Most risks highlighted in relation to cryolipolysis are deemed mild and transient, or as otherwise expected with many comparable cosmetic treatments, and include redness, swelling, discomfort, tenderness, bruising and altered sensation.

Yet, it's not until a considerable period of evaluation and in-the-field experience, gathered over several years post-commercialisation, that the true extent of potential complications for a treatment may be properly assessed; and this is where we are now for fat-freezing. The evidence



base is growing, understanding is growing, and real-world statistics of potential complications from this modality is becoming apparent.

As is often the case when a brand or device is the market leader, it is Zeltiq's CoolSculpting device which can be attributed with the most published clinical data. This includes the good, the bad, and the ugly; including complication reports. This is partly due to FDA-mandated official reporting requirements and the documentation of complications, for U.S.-approval of the device. That is not to say, however, that many of the reported problems could not, and are not being seen with other, similar devices; just that a lack of reporting for medical devices in Europe means that most go either undocumented with regulators, or not directly attributed in case study papers in journals.

Early post-market surveillance<sup>6</sup> of the CoolSculpting device in the USA showed reports of 'severe pain' during treatment. Of more than 60,000 cryolipolysis treatments between June 2009 and December 2010, there were 23 reports of 'severe pain' associated with Zeltiq's system (0.05%). Hyperpigmentation associated with first- or second-degree burns was another rare adverse event that arose, with 4 reported cases (less than 0.01%).

According to Dr. Nazanin Saedi of the University of California, Irvine, consequential to these reports, there have been changes to the user manual, as well as revisions in user training, user interface, and procedure monitoring, which make the likelihood of burn injury or subsequent hyperpigmentation more unlikely, even in the event of misuse. She noted in 2011, that there had been no further reports of burn injury or hyperpigmentation during the last 30,000 procedure cycles with the device. Reports of pain, which is, of course, subjective, still persist,

and there is ongoing discussion on appropriate pain medication for this.

All new-to-market devices are likely to encounter 'teething problems', hence the role of post-market follow-up for ironing out these wrinkles, whether by device evolution, software changes or amendments to protocols and training programmes. Yet, some complications only materialise with long-term use.



A simple internet search can also reveal much about anecdotal reports from consumers, and practitioners, in relation to a treatment. A search for cryolipolysis revealed consumer reviews posted on the *RealSelf* website detailing accounts of burn scars<sup>7</sup>, pigmented marks and other problems, such as uneven or over-treated results, occurring post-cryolipolysis.

Here are some of the evidence-based reports<sup>8</sup> on complications associated with cryolipolysis apparatus and treatment, including, but not limited to the CoolSculpting device.

## Delayed Onset Pain

Anecdotally, patients are likely expected to experience neurogenic pain for anywhere from a fortnight to a month after treatment.

Delayed post-treatment pain is not an uncommon adverse effect after cryolipolysis as reported by American dermatologists Terrence Keaney, MD and Tina Alster, MD in 2015 in *Dermatologic Surgery*<sup>9</sup>.

They performed a retrospective review of 125 patients who received 554 cryolipolysis procedures over a 1-year period. Their data gathering showed that young women, with a mean age of 39, undergoing abdominal cryolipolysis were at greatest risk of experiencing delayed post-treatment pain, irrespective of the number of treatment cycles.

The pain was said to be self-limiting, lasting between 3 and 11 days and resolved completely without long-term consequences. The authors advised that patients should be counselled on the possibility of the occurrence of delayed-onset pain.

Pain descriptions vary but typically include deep burning, stabbing, and being tender or overly sensitive to the touch<sup>10</sup>.

The most likely practical consequence of the occurrence of this side effect is for the patient to fail to complete the originally planned treatment programme of multiple sessions, due to fear and a desire for pain-avoidance. This was the case in an adverse event report lodged with the FDA<sup>11</sup>. This could result in both inadequate results after having limited treatment sessions and may garner requests for refunds and reports of it being a 'waste of money'.

## Uneven Results

This is quite a common complication, particularly where bilateral areas are treated, as it's much easier to see where there has been greater response in one side than the other. Patients should be told about this as a matter of course. Re-treatment is usually enough to achieve satisfaction and a happy patient, as noted by Eric Swanson, MD<sup>12</sup>. He was commenting on a 2013 paper by plastic surgeon, Grant Stevens, MD<sup>13</sup> which reviewed the treatment of 528 patients from January 2010 to December 2012. Of this cohort, 4 patients were initially dissatisfied, but this resolved with additional cryolipolysis and resulted in contented patients.

Of course, an asymmetry or under treatment is relatively simple to correct, but excessive fat removal in the treatment area, resulting in an unwanted indentation, or ledging, is also a noted complication by physicians. In some cases, the contour deformity may be improved through corrective procedures<sup>14</sup>.

In one online blog post, entitled '*How CoolSculpting ruined my body*'<sup>15</sup>, the female blogger states; "*After a few months, the frozen fat was released from my body, and rather than having smooth, perfect thighs, the attachments had left indents - paddle shaped indents,*

*like a sideways oval, on my outer thighs and squiggle like indents on my inner thighs. I was horrified. I was told that it was incredibly rare and happens to 1 in 200 patients...I was told it 'worked too well' and that 'it isn't that bad, you can hardly tell!'"*

She goes on to explain that she is now booked in with a surgeon to have her inner and outer thighs smoothed, using liposuction, to remove the indents. Ironically, she says; *"I never wanted liposuction, the whole point of CoolSculpting is to avoid major surgery, but found myself getting a consultation to see if fixing it were possible"*.

## Paradoxical Adipose Hyperplasia (PAH)

Paradoxical adipose hyperplasia (PAH) is a phenomenon involving unintended, unpredictable stimulation of subcutaneous fat to grow, which is then visible as tissue enlargement. In this case, this fatty growth tends to start two or three months after treatment with cryolipolysis, becoming more visible after four or five months when the expected reduction in surrounding fat has occurred; the growth is painless but the area is firmer to the touch and noticeably expanded.

A recent case was highlighted to Consulting Room of a UK-based cosmetic clinic which is now facing a legal claim from a man who received a cryolipolysis treatment and subsequently experienced PAH. The claimant was not made aware of this possible adverse complication during the consent process.

This begs the question:

how many clinics are transparently stating PAH in their cryolipolysis information for patients consenting to treatment? Also, how much of a problem is the occurrence of this adverse effect?

Drs Rox Anderson and Mathew Avram noted in an informal paper written in 2012<sup>16</sup>, when Zeltiq

first recognised that paradoxical growth was a possible outcome, that there are a number of hypotheses proposed for the pathogenesis of it. These include: (1) hypertrophy of a subset of pre-existing mature adipocytes that survive cryolipolysis (fat is capable of hypertrophy in response to metabolic and hormonal changes, without necessarily creating new cells); (2) recruitment of the abundant, existing pre-adipocyte and/or adipose tissue stem cell population, induced by cytokines associated with the healing phase after cryolipolysis (e.g. by IGF-1 and other signals); (3) stimulated uptake and differentiation of circulating stem cells into fat; (4) induced changes in local expression of receptors associated with adipocyte metabolism; and (5) induction of both adipocyte and fibrous tissue hypertrophy in response to hypoxia. They concluded that many stimuli are known to increase fat tissue including glucocorticoids, loss of sympathetic innervation, and hypoxia. It may be in rare cases that a combination of these stimuli occurs.

So even though the exact aetiology of paradoxical hyperplasia remains unknown, Zeltiq's post-market data analysis suggests several risk factors, and had confirmed reports of 11 separate occurrences, (4 female and 7 male) at the time of this 2012 paper, (rising to 33 cases by 2014, 15 men and 18 women). For instance, male patients have a 2 – 3 times higher risk than female; patients of Hispanic descent are also among the higher risk group, implying that a patients' genetic make-up may be a contributing factor. Certain clinical practices, such as the use of

higher vacuum employed

by the CoolMax applicator, have been shown to be associated with the increase of PAH cases. The enlargement of tissue tends to stabilise by approximately four or five months after treatment, with no continued growth, however regression is not

spontaneous and further cryolipolysis treatments do not appear to resolve it - it is recommended

that this is best done through surgical means (i.e. excision or suction lipectomy). They noted that paradoxical hyperplasia has been observed with different applicator types, in different anatomical areas (abdomen as well as flanks), and also that there were no common patient characteristics, such as past medical histories, that could be identified at that time.

***“Careful patient selection avoiding men with visceral abdominal adipose and firm, non-distensible, fibrous fat may be important to minimize the risk of PAH.”***

There are only a handful of published case studies of PAH following cryolipolysis treatment on PubMed. All the documented reports are of men, in their 40s and 50s. Three were treated on their abdomen, and one in the pectoral area. The problems did not resolve by themselves and were mostly treated using liposuction. In those reported cases where the practitioners went on to test the tissue that was extracted via liposuction, it was found to be mostly fat cells and some scar tissue formation.

Although the cases published on PubMed involved only males, in reality, Zeltiq states that it has a 55-45 split between female and male patients who manifested paradoxical hyperplasia post-treatment. Yet, when compared with the general CoolSculpting treatment population of 85-15 split in favour of females, then male patients do have a 'corrected' higher risk of experiencing paradoxical hyperplasia.

Zeltiq also stated that it tracks the incidence rate on a quarterly basis. They reported at the time of asking that, as of the end of September 2015, the paradoxical hyperplasia incidence rate was about 0.025% (or 1 case



per 4,000 cycles). This rate had been stable for the preceding 7 quarters (since Q1 2014).

Patients who are considering undergoing this procedure should be counselled on the possibility of its occurrence, as well as the surgical options available should it occur.

In the last year, the number of clinical papers discussing and reviewing the complication of PAH, and documenting case studies has risen. A report by Seaman S.A. et al<sup>17</sup> felt that the precise pathogenesis of PAH was poorly understood, so they aimed to characterise the pathological changes in the adipose tissue of PAH on a cellular level.

They stated, "...tissue with PAH had fewer viable cells, significantly decreased quantities of interstitial cells ( $p = 0.04$ ), and fewer vessels per adipose tissue area when compared to the control tissue. Adipocytes from the PAH tissue were on average slightly smaller than the control adipocytes. Adipocytes of PAH tissue had irregularly contoured edges when compared to the smooth, round edges of the control tissue."

Controversially, they used their findings to point out anomalies in the data originally provided by Zeltiq.

"These findings from a neutral third party are contrary to prior reports from the inventors of this technique regarding effects of cryolipolysis on both the microvasculature and interstitial cells in adipose tissue. Our use of different assays to compare cryolipolysis-treated PAH tissue with untreated adipose tissue in the same patient showed adipose tissue that developed PAH was hypocellular and hypovascular. Contrary to prior reports from the inventors, cryolipolysis may cause vessel loss, which could lead to ischemia and/or hypoxia that further contributes to adipocyte death"; they concluded.

Terrence Keaney, MD also highlighted the increased risk to men considering

cryolipolysis.

*"Recent studies have suggested that PAH can be more common than expected and have a predilection for males, as a disproportionate number of the cases reported in the literature have occurred in men, despite the fact that fewer men are likely to be treated with cryolipolysis. Sexual dimorphism in adipose anatomy may provide insight into the increased susceptibility of men to PAH. Careful patient selection avoiding men with visceral abdominal adipose and firm, non-distensible, fibrous fat may be important to minimize the risk of PAH";* he stated in a clinical paper published in the Journal of Cosmetic Dermatology in December 2016<sup>18</sup>.

Consulting Room Advisor and aesthetic surgeon, Mr. (Dr.) Niroshan Sivathasan, has encountered a worrying manifestation in his own practice. Two males who had previously had Coolsculpting for pseudo-gynaecomastia undertaken elsewhere, presented with localised soft-tissue growth; however, after liposuction to the area was undertaken, the fat grew back, and in one case, the growth was aggressive subsequent to and despite the gold-standard surgical debulking.

Mr. Sivathasan postulates that a survival mechanism, possibly involving heat shock proteins, may be getting triggered. Interestingly, in keeping with the PubMed-listed reports, these patients were in their 40s and 50s.

## Nerve Damage

There are multiple reports of patients experiencing a loss of sensation or feeling in the treated area, for a period of a few weeks. One American physician shared<sup>19</sup> a rare case of treating an abdomen with the large CoolSculpting handpiece resulting in a lack of feeling for his patient for almost six months.

Last summer, Sang Jun Lee et al.,

noted in a clinical paper that although clinical studies about cryolipolysis had shown various potential side effects including temporary erythema, bruising and transient numbness, they believe they were the first to report on motor nerve malfunction after cryolipolysis<sup>20</sup>.

They submitted a case study of a 24-year-old female who had received cryolipolysis on her abdomen and arms. After 10 days, she complained of weakness in her arms and an inability to lift heavy objects. Although this continued for 6 months, it was said to resolve and the patient fully recovered without intervention. The authors believe this to be a rare complication of cryolipolysis, particularly relevant to treatment of the arms.

## Frostbite, Burns and Skin Necrosis

A case study of frostbite following cryolipolysis treatment in a beauty salon, which resulted in substantial necrosis of the flank was reported in the Journal of Wound Care<sup>21</sup> by surgical trainee W. L. Choong and Plastic Surgery Specialty Registrars Mr. M. J. Hallam and Mr. H. S. Wohlgenut who practice in plastic surgery departments in hospitals in Scotland.

The patient did not seek medical attention until one week after treatment. On examination, two distinct areas of significant frostbite in the left flank with surrounding erythema were revealed. The authors note that surgical intervention is recommended to be avoided in cases of frostbite, thus conservative treatment resulted in recovery of the affected area.

As well as discussing the medical aspects of the case, this is believed to be the first time that such a report has included commentary from the authors directly targeted at provoking discussion and highlighting the necessity for increased regulation in the United Kingdom. The authors believe emphasis must be placed on increasing patient awareness on the potential hazards of seeking cosmetic treatment from unregulated providers.

Of course, complications like this don't just happen 'in the wrong hands'. For example, Mr. Sivathasan has been



asked by a colleague for advice on managing a small area of cryolipolysis-induced frostbite on the abdomen of a patient who had recently had an abdominoplasty. Mr. Sivathanan believes that the blood supply to the surgically manipulated skin involved in the tummy tuck, would have been evolving and stabilising, and that such a patient should not have had cryolipolysis.

In another case which was reported earlier this year by Iad Nseir, MD et al, in *Aesthetic Surgery Journal*<sup>22</sup>, a 42-year-old female who had no significant medical history sustained lateral thigh skin necrosis post-cryolipolysis which was undertaken by a dermatologist. The report states that the treatment of the lesions required a surgical procedure, referred to as a necrosectomy, with complete wound healing achieved in two weeks, and a satisfying aesthetic result after six months.

## DIY Disasters

As with most things in life, there will always be someone who looks for the short-cut, the work-around, or the cheap, (and often dirty) solution. This is no different with fat-freezing, as more and more discussions, examples and attempts at do-it-yourself cryolipolysis are surfacing online.

Most accounts are anecdotal, and to be found on obscure websites and chat forums, including an entire wiki<sup>23</sup> on DIY-cryolipolysis; but the prevalence of home-made devices and solutions is certainly on the rise. You don't have to go far to find demonstration videos showing the basic 'bag of ice cubes' idea, all the way up to technical specifications for the more engineering-minded inventors who want to 'build' a machine! I urge you to spend a moment reading about one man's *FrankenSculptor*<sup>24</sup> creation; and if you can do it without your chin hitting the floor then you did better than me!

Two doctors and a nurse from two burns centres in Nashville and Alabama, in the USA, have reported in the *Journal of Wound Care*<sup>25</sup> on a case presentation of full-thickness wounds resulting from DIY cryolipolysis. It goes without saying that you simply can't make this up and people will indeed try anything if they think they can

replicate a treatment at home!

This case study discussed a 55-year-old woman who suffered from frostbite while attempting a do-it-yourself version of cryolipolysis using dry ice, (solid carbon dioxide), in lieu of a professional medical device. They report that dry ice has a sublimation point of  $-78^{\circ}\text{C}$ , meaning that at its very warmest, dry ice is around 80 degrees below the freezing point of water, which is far colder than the recommended temperatures for cryolipolysis treatments, which generally stay around  $-7^{\circ}\text{C}$ .

She presented herself at a regional burns unit and her past medical history showed depression, anxiety, migraines and fibromyalgia. Her reckless act resulted in 4% total body surface area full- and partial-thickness wounds to her abdomen one week after the initial injury.

Their account states; *"She had recently attended a consultation for a breast reduction, but did not qualify because her body mass index (BMI) was too high. She subsequently turned to the internet for advice on targeted fat reduction, believing that with enough fat loss she would then qualify for the desired surgery. She reported attempting to use dry ice to induce cryolipolysis after watching YouTube videos describing how to do it from home. She stated she wrapped the dry ice in a paper bag and Saran Wrap (cling film) and laid on top of it, rotating it among the four quadrants of her abdomen at 15 minute intervals. After the last application, she reported her skin felt 'frozen' and 'numb,' and that once it began to thaw she began to experience excruciating pain. Redness and swelling immediately developed. Due to the unbearable pain, she took an eszopiclone tablet and ibuprofen and went to sleep. She stated that when she woke the next day, her wound had blistered, and she began daily wound care using triple antibiotic ointment and gauze. She presented to a general surgeon several days later who*



*advised her to schedule an appointment with a burn centre."*

The authors note that the more superficial wounds healed with porcine xenograft and a silver-impregnated dressing, whilst the superior, deeper wound was excised and primarily closed with a fleur-de-lis panniculectomy.

They highlight that this case illustrates how online information of dubious quality can put the uneducated patient at risk of injury. *"...there is a dark side to the flood of information offered by the internet. 'Crowd-sourced' platforms...allow users to publish information of dubious quality with little editorial oversight, and hapless patients often lack the expertise to distinguish helpful suggestions from potentially disastrous advice"*; they quote.

They urge fellow healthcare professionals to be aware of the questionable resources available online, and to help patients become more discerning consumers of online information, and conclude that strategies to prevent such injury should be developed on a national scale.

But, I would argue that people will always try ill-advised things, despite the best intentions of educators and public safeguarding exercises, especially where their mental health is already compromised. It is true, as highlighted by the authors of this case study, that there is a prevalence of YouTube videos and blogs which extol home fat-freezing solutions including wrapping refreezable ice packs in beach sarongs or using a hip flask filled with antifreeze.

Policing this is next to impossible, so further traumatic cases, if anyone attempts such solutions, are inevitable, and consumer stupidity cannot be legislated against.



## Treatment Considerations

It's not all doom and gloom, and like many things in aesthetics, it comes down to adequate training, experience, skill and good patient selection.

As noted by Dr. Terrence Keaney, particularly attention must be paid when consulting men for cryolipolysis treatments.

***“...device companies, such as Zeltiq, need to be much more upfront about potential complications...”***

It is felt by some that there is still much to learn about the effects of differing treatment protocols on both efficacy and safety, and minimising of potential risks. Questions posed include further investigation into the rate of cooling achieved by different devices, and how this affects the known risk factors. Some, like the CoolTech device, reduce the temperature slowly at the start of the treatment, and increase it again slowly, towards the end of the treatment.

Similarly, the degree of cooling needs to be further investigated. The CoolSculpting device controls cooling down to -7°C, while CoolTech claims to

oscillate from 3°C to -8°C, and 3D-lipo and PROSHOCK ICE are the warmest, reaching -5°C. Others, like LipoContrast use a thermal contrast lipolysis method which subjects the fat cells to a sequence of hot-cold-hot exposure.

All these differences spark the need for further scientific investigation and comparison studies, which to date are lacking.

*“Whilst there is no doubt that cryolipolysis produces excellent results, in my opinion, from the data that I have seen in conjunction with basic scientific principles, ultrasound-based fat cavitation is the safest and most consistent modality for non-surgical fat destruction”;* said Mr. Sivathanan. *“The body-shaping market has seen double-digit annual growth over recent years, but for energy-based modalities, the combination of satisfaction and economics only works in patients with localised pockets of fat or those for whom downtime post-surgery is impossible.”*

Mr. Sivathanan also cautioned that, *“device companies, such as Zeltiq, need to be much more upfront about potential complications, such as temporary dysaesthesias from the indiscriminate freezing of tissues, and that ‘moobs’ should not be treated with cryolipolysis until more is understood about the particularly aggressive nature of the reflex fat development.”*

## Industry Concerns

You don't have to go very far to find stories in the press with headlines such as *“burnt and left in agony by a fat-busting therapist who had only trained*

*as a hairdresser”*<sup>26</sup>, *“fat freezing disaster leaves young mum with second degree burns”*<sup>27</sup>; or *“Luton woman scarred for life after fat freezing treatment for cellulite”*<sup>28</sup>.

Lawyers are also making money from this marketplace, with Penningtons Manches LLP openly publicising a case<sup>29</sup> that they took on against a Berkshire clinic, whereby a woman experienced severe burns across her abdomen following a fat freezing treatment (device unreported). Despite having had an uneventful previous treatment session, the solicitors believed that on this occasion the treatment was not carried out with sufficient care.

All these reports highlight the terrible consequences that can happen if staff are poorly trained in delivering cryolipolysis treatments, have little anatomical or medical knowledge, use inferior devices or do not take adequate care and precautions; yet regulation of the delivery of this treatment lags severely behind.

The cost of treatment is often a significant driver for consumers. This has led to a market for cheap, price-led deals using voucher schemes, such as Groupon and Wowcher. This can only be maintained as a business model through the use of cheaper devices – both in terms of the capital outlay required to buy the device, and ongoing consumable costs.

The CoolSculpting device, currently the only cryolipolysis device with American FDA approval for the non-surgical removal of fat, does not come cheap; think small terraced house in mid-

Wales, and has the most expensive consumables compared to competitor devices<sup>30</sup>. This means that before a treatment can even commence, it has cost the practitioner around £100 to £250 which must be paid back to Zeltiq.

*"It is expensive," said one cosmetic clinician, "...every 6 months there is a new expensive 'cup'. They charge a fortune for 'cards', it's mega revenue for nothing. It works, but other fat freezing seems to be just as good, with no consumables expenses."*



It's true that most other cryolipolysis devices on the marketplace do not carry such high consumable costs. Yet, with generic cryolysis devices being touted at prices as low as £50 per area on GumTree<sup>31</sup>, it's no surprise that many medically-led cosmetic clinics are up in arms and wondering how they can compete.

With no real regulation in place, the only thing in place to 'police' the marketplace is insurers; unless someone chooses to offer treatment without insurance cover! We spoke to leading insurers for the aesthetic sector, Hamilton Fraser to find out more about who they insure and the claims statistics for the treatment.

A spokesperson said; *"Our claims experience is very low for this treatment, and since 2008 we have had a total of*

*4, with nothing paid out on any of them. In the past 2 years, we have only had 2 claims reported to us. Our acceptance criteria allow doctors, dentists and nurses, who must be registered with their relevant governing body and beauticians (NVQ Level 3 or higher); all must have the relevant training. I think by being quite restrictive with who we insure, it does eliminate bad practice. Admittedly we do not drill down on the machinery they will be using, unless a claim comes in, as the onus is on the practitioner to ensure they are treating the patient within the parameters of their qualifications and their regulatory bodies. Previously, we used to rate this in the same way as laser lipolysis, however we have reduced our rates due to the lack of claims."*

When asked in the Consulting Room survey what issues there are in relation to the use of cryolipolysis treatments, 75% cited that consumers think it's a quick fix for weight loss. As noted from other responses, this is quite often leading to patient dissatisfaction with the results they achieve, (dependent on the device), and many seek a refund.

5 out of 8 respondents felt that the influx of cheap, copycat or inadequate devices was a real concern, alongside inappropriate people performing the treatment.

*"Clinics who have decent equipment are extremely frustrated about imitation, inferior machines, which at best do nothing (but give fat freezing a bad rep), and at worse harm people. A lot of these inferior machines claim to do the same as CoolSculpting, and even use our pictures in their adverts. It drives me mad!";* said one cosmetic doctor.

Half also blamed a lack of regulation, the proliferation of treatment in non-medically led environments, a lack of medical understanding of the impact of the modality on skin tissues, and an inability to deal with complications when they arise, for the many issues which are now arising.

Another cosmetic doctor told her story; *"A place where I was visiting and renting a room on a sessional basis offers 3D-Lipo with the cryo option...The directors of the 'clinic'...would book patients in via Groupon, boldly advertise the treatment, and do it all by themselves. I was never asked to assess these patients...that a completely non-medical, non-clinical, salesperson can get the machine, get insurance, and advertise it makes me sick. Cold injury, as a form of thermal injury needs to be better studied before it is unleashed 'over the counter.'"*

We have been banging our heads against the wall, for many years now, to highlight the problems of an unregulated aesthetic marketplace. The exponential growth of the sector and the revenue and profit potentials mean that whilst consumer demand is high, and regulation is practically non-existent, there is very lucrative business to be had offering fat-freezing treatments.

But, as well as understanding the technology, which is complex enough for healthcare professionals, an appreciation of the potential for complications is of paramount importance, both for patient safety and proper patient selection. Determining in whose hands this should be permitted is open for debate, but, we will probably have to see a rise in reported harm before regulators determine whose hands are wrong.

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