



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon scanning technology prioritising summary

BodyTite™ radiofrequency-assisted liposuction

November 2010



**Australian
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and Efficacy
Register
of New
Interventional
Procedures -
Surgical**

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PRIORITISING SUMMARY

REGISTER ID S000122

NAME OF TECHNOLOGY BODYTITE™ (RADIOFREQUENCY-ASSISTED LIPOSUCTION)

PURPOSE AND TARGET GROUP MINIMALLY INVASIVE COSMETIC SURGERY FOR LIPOSUCTION AND BODY RECONTOURING

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|--|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input checked="" type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|-----------------------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 162657; 162737 |
| <input type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials underway or completed	Limited use	Widely diffused
Argentina	✓	✓	
Canada	✓	✓	
United States	✓ (possibly)		

IMPACT SUMMARY

Invasix Ltd., an Israeli-based medical device company, has developed BodyTite™, a radiofrequency-assisted liposuction (RFAL) technology. BodyTite is promoted as minimally invasive cosmetic surgery for ‘body recontouring and firming procedures’ via energy applied to subcutaneous adipose tissue and the subdermal skin surface. The technology is currently available through physicians in several countries.

BACKGROUND

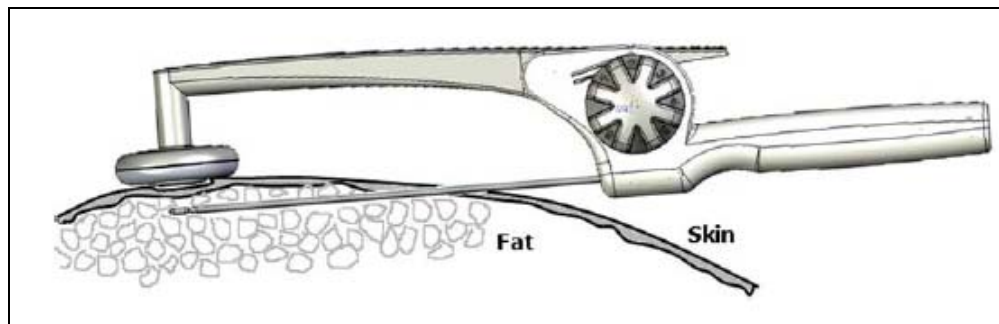
With rising rates of obesity and an increasing focus on body image, liposuction has become the most commonly performed aesthetic procedure in the world (Blugerman et al 2010). For example, in 2007 in the US, 600,000 'lipocontouring' procedures were performed (5% of all elective surgeries) and procedures are expected to double over the next 5 years (Paul and Mulholland 2009).

Liposuction technologies have evolved over time. Dry liposuction improved when tumescent anaesthesia was introduced (subcutaneous infiltration of lidocaine and adrenaline). However, the procedure can be time-consuming, result in insufficient correction of skin laxity, and be associated with systemic and local complications. Newer approaches include power-assisted, ultrasound-assisted, laser-assisted and noninvasive radiofrequency liposuction, but skin laxity has remained a problem (Blugerman et al 2010). Skin laxity (loose sagging skin and localised fat deposits) results from aging (chronological or sun-related) and body changes during pregnancy or weight loss (Brightman et al 2009).

A recent innovation is BodyTite™, a minimally invasive radiofrequency-assisted liposuction (RFAL) technology that generates radiofrequency energy to liquefy subcutaneous fat, coagulate blood vessels, and tighten the skin and adjacent tissues. Typical treatment areas include the abdomen, hips, buttocks, thighs, knees, upper arms and back, along with other areas of fat deposits (BodyTite 2009).

The BodyTite system includes a computer device and a bipolar radiofrequency handpiece with internal and external electrodes (Figure 1). The internal device is inserted via 3 mm incisions and the external electrode closes the radiofrequency current loop by receiving the energy through the skin via a closed-loop system that prevents excessive heating of fat and/or dermis (Blugerman et al 2010).

Figure 1: BodyTite device (Source: Paul and Mulholland 2009)



Energy is delivered to the deeper fat (25 mm to 35 mm in depth) and maintained to allow uniform heating to coagulate the blood vessels and dissolve the fat. The internal probe is then moved to 10 mm to 15 mm below the skin surface where energy is delivered until a skin temperature of 42°C is reached and maintained for 2 minutes. Each procedure covers a skin surface area of 10 cm x 15 cm (Blugerman et al 2010). The hand piece is then

moved to another zone and the procedure is repeated with the internal cannula serving as a suction device to remove liquefied fat, blood and other materials (Paul et al 2010).

Postoperative care varies. In a 2008 case series, surgical incisions were left open but patients were required to wear compression garments continuously for 3 weeks and then at night for an additional 3 weeks (or longer for areas of soft tissue thickening) (Blugerman et al 2010). Postoperative care was not mentioned in the two other included case series (Paul and Mulholland 2009, Paul et al 2010) but the device website makes passing reference to postoperative compression (BodyTite 2010).

CLINICAL NEED AND BURDEN OF DISEASE

According to the Australian Institute of Health and Welfare (AIHW) the number of liposuction procedures performed in 2007-08 was 12,123. This was a 32% increase from the number of procedures performed in the year 2003 (8,232 procedures) and a 66% increase from the number of procedures performed in the year 2000 (4,296 procedures) (AIHW 2010). As liposuction is an elective procedure its clinical need is closely linked with an individual's perception of themselves. The prevalence of obesity may be associated with the increased request for liposuction; however, obesity needs to be treated by a number of means (including diet and exercise) and not by liposuction alone.

The World Health Organization (WHO) predicts that by 2015 approximately 2.3 billion adults will be overweight, and more than 700 million will be obese (World Health Organization 2006). Australia's obesity rate specifically is among the highest in the world (Australian Institute of Health and Welfare 2010). In 1995, 56% of Australian adults were either overweight or obese; by 2007-2008 this percentage had increased by 5 percentage points to 61% (Australian Institute of Health and Welfare 2010).

DIFFUSION

The technology developer, Invasix Inc., was established in 2008. According to the product website, headquarters are in Israel with additional offices in the United States (US), Germany, Canada, Hong Kong and Tokyo, supporting worldwide distribution (BodyTite 2010).

A single use applicator (handpiece) designed to deliver radiofrequency energy to fat layers beneath the skin for simultaneous adipose tissue liquefaction, blood vessel coagulation and skin tightening during a radiofrequency-assisted liposuction procedure, as well as the system designed to generate this energy received Therapeutic Goods Administration (TGA) approval effective 22 June 2009 (Australian Register of Therapeutic Goods [ARTG] number 162657) and 24 June 2009 (ARTG number 162737), respectively (TGA 2010).

Trials have enrolled patients in Argentina and Canada and possibly in the US (although there is no mention of the product on ClinicalTrials.gov). BodyTite has been approved for marketing by Health Canada (Health Canada 2010) and has received CE mark approval for use in Europe, but it is not yet approved by the US Food and Drug Administration (BodyTite 2010).

COMPARATORS

The comparator to the BodyTite system would be conventional liposuction techniques. A number of other liposuction techniques have been developed over time (as discussed in Background); these may also be comparators to the BodyTite system.

SAFETY AND EFFECTIVENESS ISSUES

Three case series studies were eligible for inclusion in this summary. One case series of 20 patients in Canada and/or the US aimed to establish the range of optimal treatment parameters and techniques for RFAL (Paul and Mulholland 2009). The same authors reported on a series of 24 consecutive patients who received RFAL (detail was not adequate to determine overlap with the study above). This study's objective was to examine the extent of thermal-induced subcutaneous tissue contraction due to RFAL (Paul et al 2010). The final study was conducted in Argentina, where 23 patients underwent RFAL in the hands of two surgeons at a private clinic from July to December of 2008 (Blugerman et al 2010).

Study profiles

Paul and Mulholland (2009) reported outcomes in 20 patients undergoing RFAL in 40 lipoplasty zones, primarily hips (16) and abdomen (14). Enrolled were 18 women and two men of average age 44 years (range 17 to 56). Target areas underwent tumescent anaesthesia before BodyTite treatment. Two depth settings were used: deep fat at 30 mm to 45 mm and superficial fat at 10 mm to 25 mm. The main success indicators were safety, ease and speed of treatment; uniform temperature distribution; ability to maintain the desired contraction temperatures; coagulation and liquefaction of adipose tissue; and blood vessel coagulation in the adipose layer.

Paul et al (2010) were particularly interested in the ability of RFAL to contract the subcutaneous collagen matrix and prevent loose skin after liposuction. Consecutive patients (n=24; 22 women and 2 men; mean age 40 years; age range 19-52) underwent RFAL to the hips and abdomen under tumescent anaesthesia. All were healthy with no anaesthetic risks, and all but three (13%) were of body mass index (BMI) <30. The BodyTite system was set to a target temperature of 38°C to 42°C which was maintained for 1 to 3 minutes per spot or 3 to 8 minutes per 10x15 cm zone. To measure linear contraction, distances between incision ports and natural 'fixed' anatomical registration points (moles, umbilicus) were measured before treatment, after treatment, and at 3- and 6-month follow-up visits.

Blugerman et al (2010) prospectively enrolled 23 willing patients with excessive fat and loose skin at the abdominal and thigh regions, and cellulite isolated at the posterior or lateral thigh region. Mean age was 39 years (standard deviation, 12 years) and 87% were women; no patient had undergone previous treatment for fat reduction. Clinical outcomes included weight and circumference, volume aspirated per patient, operative time and degree of skin tightening (i.e. linear contraction).

Safety

In the study by Paul and Mulholland (2009), all patients experienced minimal pain, swelling and bruising (not quantitated). Length of follow-up was not described but the authors identified no complications or long-lasting negative side effects during this time.

No safety outcomes were discussed in the study by Paul et al (2010).

Blugerman et al (2010) reported follow-up extending to 3 months with 70% (16/23) of patients attending (96% of patients attended 6-week follow-up). The authors reported that postoperative pain was minimal in all patients and there were no serious adverse events, re-hospitalisations, burns, deforming scars, haematomas or seromas.

Effectiveness

In the study by Paul and Mulholland (2009) the speed of treatment was 8 to 12 minutes per thermal zone of 10x15 cm (25 mm thickness), a speed comparable to ultrasound-assisted and power-assisted liposuction and superior to laser-assisted liposuction. The authors were pleased with ease of use (no detail was provided). Temperature distribution was uniform compared with other technologies. Biopsies showed defragmentation of fat cells and coagulation of blood vessels in the treated zone, reducing bleeding, and bruising. Collagen denaturation allowed significant contraction and retraction of adipose and dermal tissue.

All patients in the study by Paul et al (2010) showed evidence of linear tightening: 8% to 15% at the end of the surgical procedure and 13% to 47% (mean 31%) by 6 months. The authors hypothesised that skin tightening following thermal lipoplasty is mostly due to subdermal tissue contraction rather than effects on the skin itself.

Finally, the mean volume aspirated per patient in the study by Blugerman et al (2010) was 2404±1290 ml (range, 400-6400 ml), and operative time was 158 ± 44 minutes. Weight and circumference reductions were significant at both 6-week and 3-month follow-up, and by visual estimation the surgeon judged body contour improvement and optimal skin tightening in all patients. Mean linear contraction was 14% at 6 weeks and 24% at 3 months (range 9-42%).

COST IMPACT

No economic studies or cost information were identified in the included literature.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified in the included literature.

OTHER ISSUES

All three available studies were supported by the manufacturer, including supply of devices, partial payment of study-related expenses and financial support of the investigators (payment and stock options). One author common to all three publications (Dr. Malcolm Paul) is chair of the Invasix Ltd. Medical Advisory Board.

SUMMARY OF FINDINGS

From the limited literature available (three very small case series, all industry sponsored), BodyTite may be a safe technology for both liposuction and tightening of subcutaneous tissue. With respect to the latter, its results may be superior to competitive technologies due to a new treatment paradigm that includes liquefying fat, denaturing collagen and coagulating blood vessels. Further studies comparing BodyTite with conventional liposuction techniques in the same patient may be useful in order to compare the degree of skin contracture achievable with each modality.

HEALTHPACT ASSESSMENT

BodyTite may not become available for use in Australia in the near future and further research is required; therefore, it is recommended that no further assessment of this technology be carried out at this time.

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input checked="" type="checkbox"/> Archive |

HEALTHPACT ACTION

NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level IV evidence	3

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

BodyTite

LipoTite

Radiofrequency AND liposuction

HEALTH PACT DECISION

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

PRIORITY RATING

- High** **Medium** **Low**