DRAFT

The UK Market for Tissue Sealing Agents

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Introduction

Sealing and haemostasis of tissue plains is relevant in every branch of surgery currently practiced in UK. Since early times various agents and preparations have been used to achieve this goal. The present, described material, is a fibrin "glue" with clinical profile replicating the body's natural wound healing process, specifically prepared for surgical applications, namely . Additionally, this report relates to the potential for sales and marketing of within the Plastic Surgery community of the UK.

Key centres of practice for Plastic Surgeons in the UK have already been identified, together with a listing of the majority of consultants, refined to a proposed short list of key opinion leaders / champions.

There are 58 key NHS centres, as defined by The British Association of Plastic Surgeons (BAPS) and around 260 consultants specialising in the field, giving a ratio of around 1 consultant to every 225,000 of population. As usual with most surgical specialities, this ratio compares unfavourably with European partners and very poorly with USA, where the ratio is around 1 in 50,000.

In the private sector, the picture is more favourable with around 100 hospitals offering Plastic Surgery. This is mostly Aesthetic work and reflects the growth in popularity of various procedures for purely cosmetic reasons. It is estimated that the total value of the Cosmetic market in the UK is $360m and growing at a rate of around 40% a year ( ). It is fair to say however that the majority of this growth is driven by non-surgical cosmetic procedures such as Botulinum Toxin (Botox), or Collagen injections. As non surgical procedures are not relevant to the use of , they will not be considered here, suffice to say that the general perceptions of looking younger, feeling healthier, coupled with media attention and growth in disposable income is fuelling a healthy Aesthetic surgery market in the UK.

Within the NHS, Plastic Surgery for aesthetic reasons is a low priority. Due to its nature, most procedures cannot be considered life threatening and the majority of purely aesthetic work is not available. This throws up some concerns, in the certain procedures which may be considered purely aesthetic, tattoo removal, breast hypertrophy, bat ears or nasal deformity, for example, carry an elements of social, psychological or physical gain which will obviously benefit the well-being of the patient and are considered for NHS treatment. Given the desires to reduce waiting lists and the inevitable prioritisation of treatments is meaning that procedures for purely aesthetic reasons are low priority and reducing. Another downside of this is that aesthetic surgery in the private sector needs to be carried out by suitably qualified surgeons. To ensure they have the necessary skills to perform aesthetic procedures, there needs to be sufficient training within the NHS, for surgeons, before they become consultants, to ensure standards are maintained. A strong debate rages at the moment between the accreditation of many Plastic Surgeons operating in the private sector. BAPS has a key priority to ensure that all practicing surgeons have the appropriate accreditation and training. To this end, they support the availability of certain aesthetic procedures within the NHS.

For the purposes of this report, only key surgical procedures will be considered, those where Tisseel will have use. For further rationalisation, the following areas will be considered:

Reconstructive Surgery – mostly NHS procedures and including, Breast procedures, Eyebrow / Eyelid, External Ear and Nasal. Limb reconstruction, particularly following trauma and injury will also be considered as a whole, since the use of is applicable.

Aesthetic – mostly in the private sector and including Breast Augmentation / Reduction, Face / Neck, Brow / Eye and Abdominal, The Tummy Tuck. Liposuction, which accounts for 30% of aesthetic procedures in UK (British Association of Aesthetic Plastic Surgeons, BAAPS audit for 2006, extrapolated by ADI Medical), will not be considered, since the use of during the procedure is not relevant.

Burns – NHS procedures and usually involving skin grafting.

Additionally to this an area of abdominal hernia repair (Epigastric or Ventral) will also be considered.

For the sake of simplicity, procedures are characterised in terms of their numbers performed in NHS, or Private settings in 2005 and 2006, where reliable data exists and an extrapolation to 2007 and beyond. Estimates as judged by ADI Medical are applied where appropriate.

The average value of each procedure is assumed to be the use of

Extrapolation, comparison with other markets and informed view is taken into account in arriving at final numbers. Additionally rounding is used to give meaningful, yet accurate data. Values are given in US Dollars, though in the main these are derived from Sterling and converted at a rate of 1.61.

Reconstructive Plastic Surgery

Despite the recent upsurge in aesthetic plastic surgery procedures and the desire by many to undergo surgical procedures for social and feel good reasons, the mainstay of UK Plastic Surgery is reconstruction in various body areas, through the NHS. Numbers of procedures can be determined accurately, since reliable data exists from the Department of Health, through clinical audit.

Traditional surgical techniques within the field of Plastic Surgery have involved the use of sutures extensively, since the whole field is largely concerned with reshaping and resealing tissue planes, whilst minimising blood loss. Suturing with traditional materials leads to scarring, whilst this is irrelevant internally, the presence of a scar on external skin surfaces largely defeats the object of reconstruction, since aesthetic appearance, post operatively is paramount. The availability in the field of materials that can seal and glue tissue surfaces, whilst controlling blood loss and achieving

similar strength to that of traditional sutures will be an enormous benefit to the field of Plastic Surgery. Hence the availability of Tisseel to Plastic Surgeons will have key benefit to practice, whilst not adding greatly to overall procedural costs.

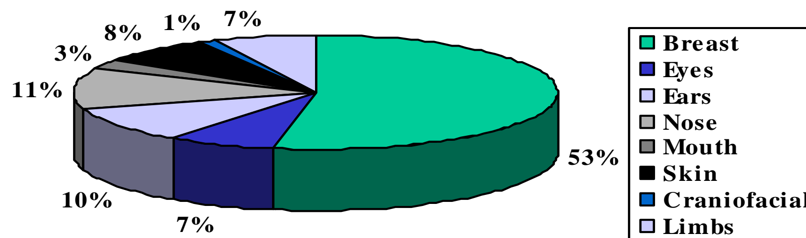
Procedural numbers are as follows:

Body Area				
Breast	25,100	26,650	28,000	29,100
Eyes	3,400	3,670	3,920	4,100
Ears	4,750	5,100	5,450	5,750
Nose	5,230	5,650	6,050	6,400
Mouth (Cleft Palate)	1,200	1,300	1,400	1,475
Skin – general flap procedures	3,900	4,000	4,100	4,200
Craniofacial	600	570	550	550
Limbs	4,400	4,000	3,680	3,500
Total	**44,680**	**50,940**	**53,150**	**55,075**

Source:

In most cases, there is a steady increase in procedure numbers, of between 5-7%. Reductions are seen in craniofacial surgery and limb reconstruction. Both of these are possibly attributable to steady declines in post RTA trauma as a result of seat belt compliance and likely road safety improvements resulting from government speed and drink drive campaigns and the widespread use of speed cameras!!

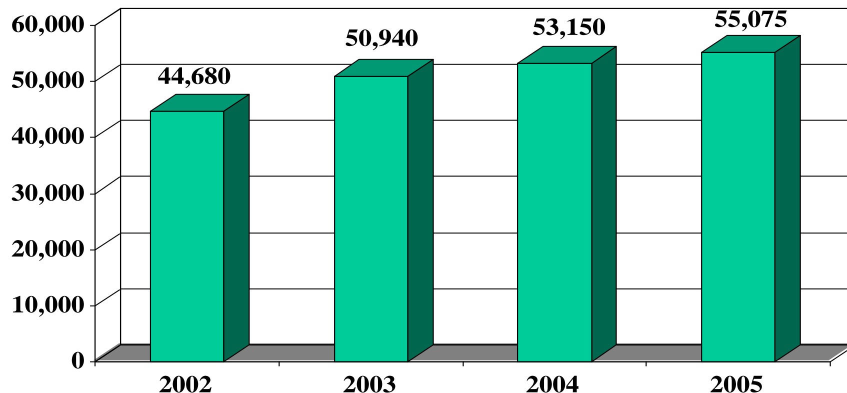
Reconstructive Plastic Surgery, UK, Procedures by Body Area, 2004



Breast procedures, particularly mastectomy is still rising, although better and earlier diagnosis of cancer will result in continued reduction in rates over the coming years.

The overall increases seen are probably a fair reflection of government policy in reducing waiting times and increasing surgical throughput.

Reconstructive Surgery, UK Procedure Totals 2002 - 2005



Developing form the 2004 figures and assuming could be used in all of these procedures, the market in Reconstructive surgery will be:

53,150 x $210 = $11,161,500

Aesthetic Plastic Surgery

There are differing views on the growth rates currently inherent in the UK aesthetic market for plastic surgery. There is no doubt that a substantial increase is underway in the non-surgical sector. suggests this growing by 20-25% a year and this sector in the USA saw a 43% increase in 2003 (American Society of Plastic Surgeons). Growth rates in the surgical sector are far less dramatic however. Additionally to this, accurate data is not available. Three sources have been used to identify the numbers of aesthetic procedures performed and a view taken to rationalise these into predictable and accurate data for the true market:

– Probably an over estimate for surgical procedures, their methodology is largely gained from private hospital interviews and estimates based on that.

. – More likely accurate however only 60% of UK Plastic Surgeons are members and only 70% of those responded to audit, therefore this number will be low. Additionally they see little procedure growth, whereas this is not the case from within the private healthcare community.

– Although it is very dangerous to compare accurate US audit figures in this field, a view can be taken. A very general principal is that UK Medical Device markets are around 8% of those in USA (Commercial Opportunities in Medical Devices, Smi Publishing 2002). Given that much more aesthetic plastic surgery is undertaken in USA than in Europe, or UK, an estimate for comparison is given at 2% of USA total.

The total numbers and growth rates for these three sources, given the provisos and calculations above, provide UK estimates of:

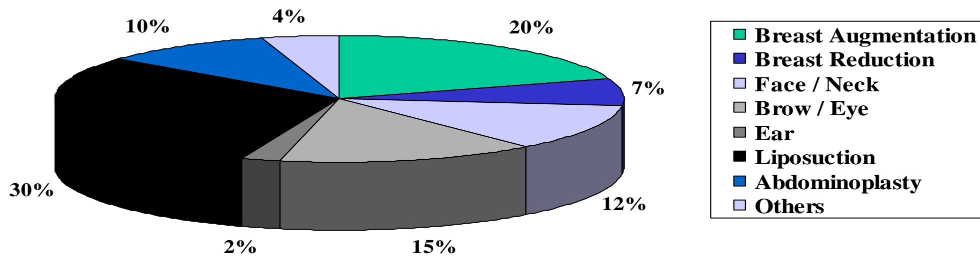
Assessing the various parameters within the market, ADI believes the true number for 2007 to be approximately 24,765 procedures, with a growth rate of around 6%.

The breakdown by procedure can be estimated as follows:

Procedure				
Breast Augmentation	4,700	4,900	5,200	5,500
Breast Reduction	1,600	1,700	1,800	1,920
Face / Neck	2,800	2,940	3,120	3,340
Brow / Eye	3,500	3,675	3,900	4,200
Ear	475	500	530	570
Liposuction	7,150	7,500	7,950	8,500
Abdominoplasty (Tummy Tuck)	2,300	2,450	2,600	2,780
Others	1,000	1,100	1,150	1,230
Total	**23,525**	**24,765**	**26,250**	**28,040**

Sources:

Aesthetic Plastic Surgery, UK Procedures 2004



NB Liposuction shown for comparison only

Aesthetic Plastic Surgery, UK Procedure Rates,
2002 - 2005

As previously mentioned, Liposuction is extracted from this list, since it is not a pre-requisite procedure to benefit from the use of intraoperatively. Final numbers for 2007 therefore are:

18,300 procedures, potentially utilising x $210 = $3,843,000

Growth rates assumed are between 5-7%, which is considered realistic for what in effect is major surgery, albeit for aesthetic reasons.

The average UK costs of some common examples of these types of procedures are as follows:

Breast Enlargement $6,440

Breast Reduction	$7,245
Eyelid Reshaping	$4,830
Face / Brow lift	$7,245
Nose Reshaping	$5,152
Tummy Tuck	$7,245
And the most common,	
Liposuction	$4,830

Source: BUPA average cost listing, 2004

Given the size and growth within the market, it is unsurprising that there is ever more competition emerging between aesthetic surgery providers. BUPA, Nuffield and BMI Healthcare are the main providers, there are however many independent hospitals and centres providing aesthetic surgery, many of these have been established and are owned by groups of Plastic Surgeons. Examples of these are:

London Centre for Aesthetic Surgery, The McIndoe centre, The National centre for Cosmetic Surgery and The Institute of Cosmetic and Reconstructive Plastic Surgery.

Given the costs detailed above, it is clearly a potentially lucrative field for providers and likely to grow over the coming years. Larger disposable incomes in the middle classes are aiding the drive to allow individuals to contemplate these surgeries, whereas even 10 years ago they would be beyond the reach of most.

One concern for market growth is a drive to other countries offering reduced price aesthetic surgery as part of tourism packages. The so-called cosmetic vacation is gaining popularity, where vacation is combined with aesthetic surgery for an all-inclusive package. Popular destinations at present are: Cyprus, South Africa, parts of Spain and Czech Republic. It is unclear how this will develop in terms of numbers however it is a clever marketing ploy.

These data are mostly derived from sources within Plastic Surgery. It should be recognised that other surgical disciplines are involved in aesthetic procedures. ENT surgeons will offer ear and nose surgery, whilst General surgeons may well perform Abdominoplasty and maybe Liposuction. Since Aesthetic surgery does not have a great press all the time and is often considered elitist or vain, the BAAPS and BAPS organisations are very keen to have a full register of all surgeons performing aesthetic procedures in the private sector. The genuine aim of this is to safeguard standards and ensure there well defined training programmes. Nevertheless, given the lucrative nature of private aesthetic surgery it is as well to be aware that there will be rogue operators and from time to time press fuelled animosity to the whole field.

Burns

The subject of burns is often an emotive one, since a burns accident will be painful, debilitating, often life threatening and can take many years of painful surgery to restore a similar look. Of course some are worse than others and overall the incidence of major burns is rare. Coupled with this, accident prevention measures, particularly

domestic fire campaigns are having an effect in reducing incidence. There are only 7 recognised centres in England, which should be considered burns units, although they also have full programmes of other plastic surgery procedures. In addition to this, there are 2 in Scotland, 1 in Wales and 1 in N.Ireland.

The relevant procedures where is likely to be used are the types of skin grafting. Techniques and availability of better devices for harvesting has improved the quality and success of many skin graft procedures, with better outcomes consistently reported. would be used in the de novo cases of grafting, conceivably, both on donor and recipient site.

Incidence of skin grafts has been very stable over the last few years, with small reductions seen in 2007. The Dept of Health numbers for UK are:

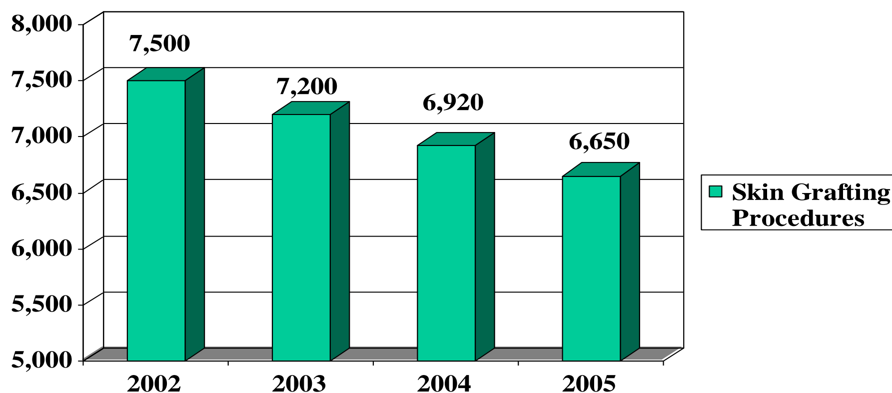
2002	7,500
2003	7,200

This represents around a 4% reduction and can be considered to continue that trend through 2004 and 2005, giving total potential of:

2004	6,920
2005	6,650

With burns however there is usually a major incident somewhere through a 5 or so year period, which although will not drastically increase numbers will however cause much public and press focus on the subject, recent examples are:

UK Rates for Skin Grafting, 2002 - 2005



Bradford
Piper Alpha

Kings Cross
Paddington

The unfortunate potential for terrorist attack and it's consequences should also be taken into account, although an assessment of true impact on numbers is impossible at this time.

The market value for [redacted] in Burn grafting applications therefore is:

6,920 Procedures x $210 = $1,453,200

Abdominal Hernia Repair

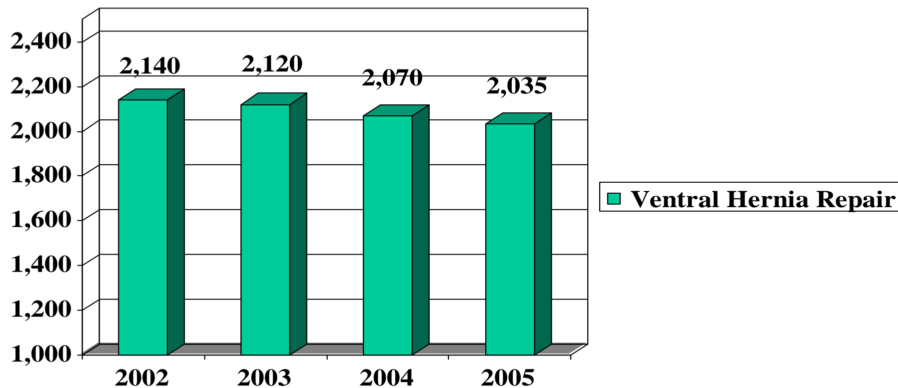
As a final assessment of market worth for [redacted] in Plastic Surgery applications an analysis was done for its use in the above. Although not a plastic surgery procedure, it was felt to have key benefit in the newer surgical techniques for hernia repair, particularly the so-called suture-less, or tension free repairs.

Also particularly relevant was the Ventral or Epigastric hernia, the highest level on the body. The numbers for total abdominal wall hernia repair are also almost identical from year to year. In most cases these will be carried out in the NHS, although private healthcare insurance will cover for these, unlike aesthetic surgery, therefore a small percentage will be performed in a private setting. With this in mind the estimate for Ventral hernia procedures in UK is:

Year	Procedures
2002	2,140
2003	2,120
2004	2,070
2005	2,035

Source [redacted]

UK Rates of Ventral Hernia Repair, 2002 - 2005



This gives a market total of:

2,070 x $210 = $434,700

Summary

Since [redacted] has been available in UK for some time, its use in Plastic Surgery is known. Some surgeons have used it and other tissue sealing agents in these applications. Since in most cases these have been off label/licence use, there has never been any concerted effort to rationalise the potential of the product in plastic surgery and thus develop a marketing strategy to target this application.

Four areas of potential use were examined here:

Reconstructive Plastic Surgery (mostly within NHS, elective, emergency and trauma surgical procedures for varieties of defect)

Aesthetic Plastic Surgery (Vast majority within private, self pay settings for elective, look better procedures

Burns (NHS, mostly emergency skin grafting procedures following traumatic burning)

Ventral / Epigastric Hernia Repair (NHS and private elective procedures).

Summarising volume and values for these gives a total market for these sectors as follows:

	[redacted]	[redacted]
Reconstructive	53,150	11,161,500
Aesthetic	18,300	3,843,000
Burns / Skin Grafting	6,920	1,453,200
Ventral Hernia Repair	2,070	434,700
Total	**80,440**	**16,892,400**