THE UNIVERSITY
of EDINBURGH

Medical Doctorate Thesis
Appendices

Evaluation of massive weight loss body contouring

Nada Al-Hadithy
20th February 2015
Supervisor: Ken Stewart
Matriculation Number 1164772

THE UNIVERSITY *of* EDINBURGH

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Aesthetic (Cosmetic) Surgery and other related procedures Evidence Based Framework for Decision Making

Procedures that NHS Leeds considers medically necessary despite their aesthetic (cosmetic) aspects as well as cosmetic procedures that NHS Leeds considers are medically unnecessary

Appendix A: Surgery Following Significant Weight Loss (panniculectomy, arm and thigh reductions, mastopexy)

Introduction

This framework applies for all patients who achieve significant weight loss either through weight management programmes or through surgical treatment. Removal of redundant skin folds resulting from weight loss after surgery will not be routinely funded. Such requests will be considered as exceptional cases and wil need to meet the criteria outlined below.

Surgery will not be funded unless there has been at least 25% weight loss either following surgery or a planned weight loss programme where the BMI is 30 or less for 12 months

Panniculectomy

NHS Leeds considers panniculectomy medically necessary where, in addition to the criterion in the introduction above:

- the panniculus hangs below the level of the pubis; or
- the medical records document that the panniculus causes chronic intertrigo (dermatitis occurring on opposed surfaces of the skin, skin irritation, infection or chafing) that consistently recurs over 3 months while receiving appropriate medical therapy, or remains refractory to appropriate medical therapy over a period of 3 months.

NHS Leeds considers panniculectomy cosmetic when these criteria are not met.

NHS Leeds considers panniculectomy experimental and investigational for minimising the risk of hernia formation or recurrence. There is no adequate evidence that pannus contributes to hernia formation.

NHS Leeds considers repair of a true incisional or ventral hernia medically necessary.

NHS Leeds considers repair of diastasis recti, defined as a thinning out of the anterior abdominal wall fascia cosmetic since evidence suggests this does not represent a "true" hernia and is of no clinical significance.

Otherwise NHS Leeds considers abdominoplasty or suction lipectomy to be cosmetic.

Arm and thigh reductions

NHS Leeds considers arm and thigh reductions medically necessary where, in addition to the criterion in the introduction earlier:

- the flaps cause significant documented problems with activities of daily life (e.g. ambulatory restrictions); or
- the flaps cause a chronic and persistent skin condition (e.g. intertriginous dermatitis, panniculitis, cellulitis or skin ulcerations) that is refractory to at least six months of medical treatment. In addition to good hygiene practices, treatment should include topical antifungals, topical and/or systemic corticosteroids and/or local or systemic antibiotics; or
- the flaps cause disabling psychological distress.

Mastopexy

NHS Leeds considers mastopexy medically necessary for female patients where, in addition to the criterion in the introduction earlier:

- the breasts cause significant documented problems with activities of daily life (e.g. ambulatory restrictions); or
- the breasts cause a chronic and persistent skin condition (e.g. intertriginous dermatitis, panniculitis, cellulitis or skin ulcerations) that is refractory to at least six months of medical treatment. In addition to good hygiene practices, treatment should include topical antifungals, topical and/or systemic corticosteroids and/or local or systemic antibiotics; or
- the breasts cause disabling psychological distress.

Disabling psychological distress will need to be demonstrated and supported by documentary evidence of significant morbidity, but referral to psyschiatry is not necessary before the request is considered by the panel.

Problems with activities of daily life will need to be demonstrated and supported by documentary evidence of significant morbidity which has necessitated medical intervention.

Background

In order to distinguish a ventral hernia repair from a purely cosmetic abdominoplasty, NHS Leeds requires documentation of the size of the hernia, whether the ventral hernia is reducible, whether the hernia is accompanied by pain or other symptoms, the extent of diastasis (separation) of rectus abdominus muscles, whether there is a defect (as opposed to mere thinning) of the abdominal fascia, and GP notes indicating of the presence and size of the fascial defect.

Abdominoplasty is a surgical procedure to remove excess skin and fat from the middle and lower abdomen and to tighten the muscles of the abdominal wall. The procedure can improve cosmesis by reducing the protrusion of the abdomen. However, abdominoplasty is considered by NHS Leeds to be cosmetic because it is not associated with functional improvements.

The above framework is based on the following references:

1. Core GB, Mizgala CL, Bowen JC 3rd, Vasconez LO. Endoscopic abdominoplasty with repair of diastasis recti and abdominal wall hernia. Clin Plast Surg. 1995;22(4):707-722.
2. Lockwood T. Rectus muscle diastasis in males: Primary indication for endoscopically assisted abdominoplasty. Plast Reconstr Surg. 1998;101(6):1685-1691.
3. Bridenstine JB. Use of ultra-high frequency electrosurgery (radiosurgery) for cosmetic surgical procedures. Dermatol Surg. 1998;24(3):397-400.
4. Matarasso A, Matarasso SL. When does your liposuction patient require an abdominoplasty? Dermatol Surg. 1997;23(12):1151-1160.
5. Nahas FX, Augusto SM, Ghelfond C. Should diastasis recti be corrected? Aesthetic Plast Surg. 1997;21(4):285-289.
6. O'Brien JJ, Glasgow A, Lydon P. Endoscopic balloon-assisted abdominoplasty. Plast Reconstr Surg. 1997;99(5):1462-1463.
7. No authors listed. Guiding principles for liposuction. The American Society for Dermatologic Surgery, February 1997. Dermatol Surg. 1997;23(12):1127-1129.
8. Coleman WP 3rd, Lawrence N. Liposuction. Dermatol Surg. 1997;23(12):1125
9. No authors listed. Update from the Ultrasonic Liposuction Task Force of the American Society for Dermatologic Surgery. Dermatol Surg. 1997;23(3):211-214.
10. Apfelberg DB. Results of multicenter study of laser-assisted liposuction. Clin Plast Surg. 1996;23(4):713-719.
11. Ramirez OM. Abdominoplasty and abdominal wall rehabilitation: A comprehensive approach. Plast Reconstr Surg. 2000;105(1):425-435.

Lothian NHS Board

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Ms Nada Al-Hadithy
Royal Hospital for Sick Children
9 Sciennes Rd
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Date 01 June 2010
Our Ref
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Extension 89061
Direct Line 0131 536 9061
Email lyndsay.baird@nhslothian.scot.nhs.uk

Dear Ms Al-Hadithy

Study Title: **Skin Laxity Post Bariatric Surgery: A Prospective Study into Psychological, Physiological and Aesthetic Results.**
REC reference number: **10/S1102/2**
Protocol number: **V.1**

Thank you for your letter of 29 March 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance

arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*
Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*	
Covering Letter		06 January 2010	
REC application	V.2.5	15 January 2010	
Investigator CV			
Summary/Synopsis	V.1	06 January 2010	NOT required
Questionnaire	Validated	06 January 2010	
C.V			
C.V			
C.V			none available
Letter from Sponsor		14 January 2010	
Protocol		30 March 2010	✓
Participant Information Sheet	2	30 March 2010	✓
Participant Consent Form			
GP/Consultant Information Sheets	1	30 March 2010	
Questionnaire: EDQ	9.0		
Questionnaire: Rosenberg Self Esteem Scale			
Questionnaire: The Derriford Appearance Scale (DAS 59)			
Response to Request for Further Information		29 March 2010	
Letter of invitation to participant	2	30 March 2010	
GP letter	2	1st June 2010	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports

- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/S1102/2	**Please quote this number on all correspondence**

Yours sincerely

Professor Peter Hayes
Chair

Email: lyndsay.baird@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Mr Ken Stewart, NHS Scotland*

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

NHS
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Director:
Professor David E Newby

CPP/MJ /approval

5 July 2010

Miss Nada Al-Hadithy
NHS Scotland
St John's Hospital
Livingston
EH54 6PP

Dear Miss Al-Hadithy,

Lothian R&D Project No: **2010/SJ/PS/01**

Title of Research: Ptosis Post Bariatric Surgery: A Prospective Study into Psychological, Physiological and Aesthetic Results

REC No: 10/S1102/2

CTA No: N/A

Eudract: N/A

PIS: version 2, March 2010

Consent: no version number or date

Protocol No: no version number or date

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

CPhillips

Dr Christine P Phillps
Deputy R&D Director

enc Research Governance Certificate ☐ (to be signed and returned)
Tissue Policy (if applicable) ☐

cc Jayne Blanshard, CRF

Mr Ken Stewart, Consultant Plastic and Reconstructive Surgeon, NHS Scotland, 9 Sciennes Road, Edinburgh EH9 1LF

Patient Covering Letter
Version 3
September 2010

Miss Nada Al-Hadithy
Specialist Trainee in Plastic Surgery
Plastic and Reconstructive Surgery Department
St John's Hospital
Howden
Livingston
EH54 6PP

n.alhadithy@doctors.org.uk

Re: A Study into Factors Influencing Skin Laxity and the Possible Need for Plastic Surgery Following Bariatric Surgery

Dear

We are currently undertaking a study with patients who are having weight loss (bariatric) surgery. We are interested to find out if there is a relationship between how you view yourself and your body following bariatric surgery and our objective assessment.

This may help us determine which patients will need plastic surgery following their bariatric surgery and if there is an optimal rate of weight loss to combat the effects of massive weight loss on skin laxity.

We would like to invite you to take part in the study. Before you decide it is important to understand why the research is being done and what it will involve. We have tried to explain the study in the information sheets included with this letter. Please take time to read them carefully. If you would like more information about this project, please don't hesitate to contact me using the email address or postal address above.

You can also discuss the study with your GP if you wish. If you would prefer to discuss any aspects of this trial with a surgeon who is independent of this study, Mr Patrick Addison, Consultant Plastic Surgeon at St John's Hospital, Livingston, (address as above) is willing to answer any questions you might have. You can also contact him through his secretary on 01506 523 117.

In addition, Mrs Helen McPhee, Plastic Surgery Clinical Nurse Practitioner is available at on 01506 523 000 on **bleep 3983**.

Please take time to decide whether or not you wish to take part. If you would like to help us and join the study, please can tell your surgeon/the bariatric team who will give you a form to sign.

Yours sincerely,

Miss Nada Al-Hadithy MBBS, BSc, MRCS
St John's Hospital, Howden.

September 2010
Letter to GP
Version 2

Miss Nada Al-Hadithy
Specialist Trainee in Plastic Surgery
Plastic Surgery Department
St John's Hospital
Howden
Livingston
EH54 6PP

n.alhadithy@doctors.org.uk

Dear General Practitioner,

Re: Patient Name:
DOB:

Enrolment into an Observational Study of Ptosis Post Bariatric Surgery: A Prospective Study into Psychological, Physiological and Aesthetic Results.

Your patient has consented to participate in the above study.

We are currently undertaking an observational study of patients who are having bariatric surgery. The aims of this study are as follows:

1. To describe ptosis, weight loss and psychological change following bariatric surgery and investigate associations with type of procedure, pre-operative assessment of anxiety and depression, self –esteem and appearance scale.
2. To investigate if there is an ideal rate of weight loss to minimise patients' psychological deterioration and demand for plastic surgery after bariatric surgery.
3. To describe proportions of patients who have had bariatric surgery that request plastic surgery and determine how this matches guidelines set out between different health care authorities for NHS funded plastic surgery.
4. To act as a pilot study for a larger multi centre trial to develop a predictive assessment tool for which patients are more likely to request plastic surgery following bariatric surgery.

Your patient has been given a patient information sheet highlighting the study protocol. The participant will be followed up prior to bariatric surgery and at set points after the operation. They will be reviewed at their routine bariatric clinic appointments by an accredited clinical research nurse from the Wellcome Trust Clinical Research Facility.

At the beginning of the study there will be a baseline questionnaire to complete and bloods will be taken for storage for potential future genetic screening. At each set point post bariatric surgery there will be several questionnaires to complete and, anthropometric measurements and 3D photographs to be taken.

The study protocol is summarised in the below table:

Intervention	Time							
	Pre Op	SURGERY	4 weeks	8 weeks	3 months	6 months	1 year	2 years
Pt counselled & PIS given	+							
Recruitment & Consent Form	+							
Bloods for EDTA	+							
Routine Bloods inc Zinc & Vit D	+					+		+
EDQ	+							+
3 D Photograph	+		+	+	+	+	+	+
Anthropometric Measurements	+		+	+	+	+	+	+
BAROS			+	+	+	+	+	+
HADS	+		+	+	+	+	+	+
The Derriford Appearance Scale (DAS 24)	+		+	+	+	+	+	+
WHO BREF	+		+	+	+	+	+	+
SF36								

The principal investigator is Miss Nada Al-Hadithy, Specialist Trainee in Plastic surgery. You can contact her via email: n.alhadithy@doctors.org.uk.

The supervisor is Mr Ken Stewart, Clinical Lead and Consultant in Plastic Surgery. He can be contacted via his secretary on 01506 523 115.

Mr Patrick Addison, Consultant Plastic Surgeon at St John's Hospital, Livingston, is an independent point of contact, outwith the study available to answer any additional questions. You can contact him through his secretary on 01506 523 117.

In addition, Mrs Helen McPhee, Plastic Surgery Clinical Nurse Practitioner is available at on 01506 523 000 on **bleep 3983**.

This study has been approved by the Regional Ethic Committee and has been fully supported by the Bariatric Services in Lothian.

If you have any questions please do not hesitate to contact me.
Many thanks

Yours sincerely

Nada Al-Hadithy

CONSENT FORM

Title of Project: **A Study into Factors Influencing Skin Laxity and the Possible Need for Plastic Surgery Following Bariatric Surgery**

Name of Researcher: **Principal: Miss Nada Al-Hadithy, ST2 Plastic Surgery**
Chief: Mr Ken Stewart, Consultant Plastic Surgeon

	Please Initial
1. I confirm that I have read and understand the information sheet dated (version) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	□
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	□
3. I understand that sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	□
4. I agree to my GP being informed on my participation in the study	□
5. I agree to take part in the above study.	□

Name of Patient **Date** **Signature**

6. I agree to have my blood collected for saving for future genetic screening	□

Name of Patient **Date** **Signature**

7. I agree to have photographs taken of my full body from neck to knees, front and back, naked.	□

Name of Patient **Date** **Signature**

Name of Person taking consent **Date** **Signature**

When completed 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes.

Information Sheet for Participants
Research Project

A Study into Factors Influencing Skin Laxity and the Possible Need for Plastic Surgery Following Bariatric Surgery

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with other if you like.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This is a 3 year study but anyone taking part will be involved for a follow up period of 2 years. We will aim to recruit 100 patients.

PART 1

What is the purpose of the study?

You are about to have weight loss surgery. The results can have huge health benefits including treatment of diabetes, relief from arthritis pain in the knee and hips, lowering blood pressure and reduction in the risks of heart attack and stroke.

Unfortunately in a large number of patients there will be the unwanted side effect of excess loose skin. We are performing a study to determine if there is an optimal rate of weight loss to minimise this excess skin. We will also be looking at whether the patient's psychological profile before surgery correlates to his/her psychological profile after bariatric-surgery, and how this may change with weight loss.

Why have I been invited?

You have been invited because you are due to have bariatric surgery within the next few months. We intend to invite a total of 100 patients to participate in the study.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will give to you. After you had some time to think about it, we will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of the care you receive.

What happens if I agree to take part in the study?

This study is completely voluntary and whether you choose to take part or not, will in no way affect your care under the bariatric team.

If you do decide to take part, you will be very well looked after by our clinical research nurse. Refusing to take part will not affect your treatment in any way.

If you do decide to take part, you will be given baseline health and psychological questionnaires to fill out and have measurements of your body weight, height and arm, thigh, torso and a special photograph to track the changes in your body volume, surface area and skin laxity.

You will be followed up for 1-2 years and will be seen 5-6 times during this. These appointments will be at the same time of your routine pre operative assessment and follow up as per your normal surgical protocol.

The clinical research nurse will be based in OPD 4 at the RIE during your routine Friday afternoon clinic appointments where the body measurements will be taken and you will have the opportunity to go through any queries with her.

In addition, you will be able to contact Miss Nada Al-Hadithy via her email on n.alhadithy@doctors.org.uk with any queries.

What will I have to do?

If you decide to take part in this research, your doctor/member of the bariatric team/ clinical research nurse will give you a consent form, which you will have to sign to say that you agree to take part. Of course, you can ask him/her more questions about the research if you wish. You will be given a copy of your consent form, which you should store safely. You will also be given a separate consent form to sign for the medical photography and 3D photographs to be taken.

Before your surgery you will be asked to fill out a baseline health and diet questionnaire (EDQ) and 3 questionnaires relating to your how you feel about your body and your mood (Rosenberg, WHOQOL BREF and Derriford). The questionnaires will take approximately 2 hours to complete.

We will ask you to fill these questionnaires out at home and bring them into your appointment completed. If there are any areas of the questionnaire which you do not feel sure about, you can always ask one of the researchers when you come in for your appointment.

Before your surgery, you will have body measurements and photographs taken. **The photographs will be taken from neck to knees, front and back, whilst you are fully undressed (except your pants)**.

They will be taken by a medical photographer with a special camera in the Medical Photography Department, RIE at the same time of your routine outpatient appointment. They will be taken in a room with ensured privacy. The photographs will be taken from every angle of your body, in order to build an accurate, to-scale 3D image of your body from neck to knees. In order to do this, you will need to stand on a rotating disc, to capture your body from the necessary angles. There will be a chaperone with you whilst

the photographs are taken. The photographs will be stored on the NHS Lothian Medical Imaging Software, which strictly abides to NHS confidentiality rules. These 3D images may be of benefit to you for future reconstruction if you are eligible for and want plastic surgery.

Before your surgery you will have blood taken for:

1. Storage for possible future genetic analysis. If this were to go ahead you would be contacted again for consent at that time.
2. Hormone levels
3. Nutrition screening: including levels of zinc and vitamin D.

The blood for genetic analysis will be purified and the serum will be stored in the Clinical Research Facility, Royal Infirmary Hospital. These samples will be kept until the completion of analysis of the research data. This will be approximately 3 years from when they are taken. If a pattern is found which may have a genetic predisposition, we will contact you at this time, to ask for your consent to do genetic screening of your sample. Further ethical approval will need to be sought if this is the case. If no patterns are found, the sample will be destroyed at this time.

After your surgery, at 1 month, 2 months, 3 months, 6 months, 1 year and 2 years you will have the same body measurements and photographs taken. You will be sent the same questionnaires on the function of your daily life, your mood and how you feel about your body. We will ask you to fill these questionnaires out at home and bring them into your appointment completed. If there are any areas of the questionnaire which you do not feel sure about, you can always ask one of the researchers when you come in for your appointment.

Below is a table of the time frame of events as part of this study protocol. The time is measured relative to when you have your bariatric surgery.

Intervention	**Time**							
	Pre OP		**1 month**	**2 months**	**3 months**	**6 months**	**1 year**	**2 years**
Candidate counselled re study & PIS given	**+**	**OPERATION**						
Recruitment & Consent Form Signed	**+**							
Bloods for Serum Save & Hormones	**+**							
Routine Bloods inc Zinc & Vit D	**+**					**+**		**+**
EDQ: Baseline Questionnaire	**+**							**+**
3 D Photograph	**+**		**+**	**+**	**+**	**+**	**+**	**+**
Anthropometric Measurements	**+**		**+**	**+**	**+**	**+**	**+**	**+**
BAROS	**+**		**+**	**+**	**+**	**+**	**+**	**+**
HAD	**+**		**+**	**+**	**+**	**+**	**+**	**+**
The Derriford Appearance Scale (DAS 24)	**+**		**+**	**+**	**+**	**+**	**+**	**+**
WHO QOL BREF	**+**		**+**	**+**	**+**	**+**	**+**	**+**
SF36	**+**		**+**	**+**	**+**	**+**	**+**	**+**

Key
PIS = Patient Information Sheet
Inc = Including
Vit D = Vitamin D

What are the disadvantages and possible risks of taking part?

There should be no additional harmful effects caused by participation in this study in addition to those already explained to you by your consultant for those people undergoing bariatric surgery. The disadvantages are the time and commitment if will take for completion of this research. The recurring questionnaires will take about 1 hour to complete. In addition, each appointment for photographs and body measurements will take about 1 hour. However, please do note that that these appointments will be part of your normal routine follow up post bariatric surgery and the photographs and measurements will be carried out whilst you are waiting to the see the Bariatric Nurse Specialist or Dietician etc. There are no experimental aspects of this study. It is an observational study, where we are trying to learn about how the skin behaves with massive weight loss and how you feel about yourself following bariatric surgery. Therefore there are no active 'treatments' from this study itself (of course you will still receive all the bariatric treatment planned with your bariatric surgeon).

What are the benefits of taking part?

We cannot promise the study will help you but the information we get from this study will help improve the treatment of people who need bariatric surgery in the future. We do not know what the best rate of weight loss is; if there are predisposing conditions which lead to excessive skin laxity or which patients will be more likely to need plastic surgery following bariatric surgery, and that's why we are undertaking this research. The information we get from this study will help us to plan treatment for future patients in need of bariatric surgery and plastic surgery. Although participation in this study does not guarantee reconstructive surgery, the 3D photographs taken may be used to help plan your reconstructive surgery in the future, should you request it and be eligible for it. In addition some patients do find that having an opportunity to discuss their experiences and emotions following life changing events (such as bariatric surgery) helpful. We hope you will find this the case.

What will happen after the study?

We would like to ask your permission to keep your contact details, so that we could approach you about any possible future long term studies on how are feeling and functioning following your bariatric surgery.

We would like to ask your permission to take a blood sample and save it for possible genetic screening to determine if there are certain gene types associated with skin laxity.

What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART2

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, we will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, nothing will change in your normal care. If you decide to continue in the study you will be asked to sign a duplicate consent form. Also on receiving new information we might consider it to be in your best interest to withdraw you from the study. We will explain the reasons for this.

What will happen if I don't want to carry on with the study?

You will be able to withdraw from the study at any time and without giving a reason. This will not affect your normal care in any way.

What if there is a problem?

If you have a concern about any aspect of this study, you can contact Mr Ken Stewart, the Consultant Plastic Surgeon running the study on 01506 523 115.

Alternatively you can contact the independent advisor, Mr Patrick Addison via his secretary, on 01506 523 117. Who will be happy to do his best to answer any questions you may have. In addition, Mrs Helen McPhee, Plastic Surgery Clinical Nurse Practitioner is available at on 01506 523 000 on **bleep 3983**.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

If you are harmed due to someone's negligence, then compensation is the responsibility of Lothian NHS Trust for the clinical care you receive. If you are harmed by taking part in this research project by an unforeseen accident (non-negligent harm) then there are no special compensation arrangements in place. However, this is thought o be very unlikely. In such cases you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this research be kept confidential?

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the Plastic and Reconstructive Surgery Department, St John's Hospital, Livingston and Dimensional Imaging 3D to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All data and information gathered during the study will be entirely confidential and nothing will be published which might identify you. All data will be stored on encrypted computers. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. We will keep your name, address and phone number so that we can contact you to make or change appointments should this be necessary. This information will only be available to the researcher involved in the study and will be kept in a locked filing cabinet.

If we decide to use your contact details for another trial assessing your post bariatric surgery outcome, for example, after 3 years or more after your surgery we will have to apply for separate approval from the Lothian Research Ethics Committee.

Will there be payment for participation?

No. There will be no payment for involvement in the study, however your expenses related to the study can be reimbursed. For example, if you needed to make an additional trip to the RIE for a reason relating to the study we will be able to reimburse your travel expenses.

Involvement of your GP

In the consent form we will ask your permission to inform your GP that you are participating in this study.

What will happen to the results of the research study?

On completion of the study, we will send a report on the outcome of the research in lay terms to all participants in the study.

We also intend to publish the results of this study in a series of international medical journal. However, it can often take up to two years after completion of the study for the research to be published. If you would like a copy of the published results you can contact us and we will send you a copy of the publications. You will not be identified in any report or publication.

Who is organising and funding the research?

All research in the NHS is looked at by an independent group of people, called
A Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Lothian Research Ethics Committee.

Contact for further Information

Miss Nada Al-Hadithy
Principal Investigator
Specialist Trainee in Plastic Surgery
St John's Hospital, Livingston, Howden, EH54 6PP
n.alhadithy@doctors.org.uk

The local independent advisor of this research is:
Mr Patrick Addison
Consultant Plastic and Reconstructive Surgeon
St John's Hospital
Livingston
Howden
EH54 6PP
You can contact him through his secretary on 01506 523 117.

Thank you very much for reading this information

Miss Nada Al-Hadithy, MBBS, BSc, MRCS
Specialist Trainee Plastic Surgery
Lothian NHS Trust

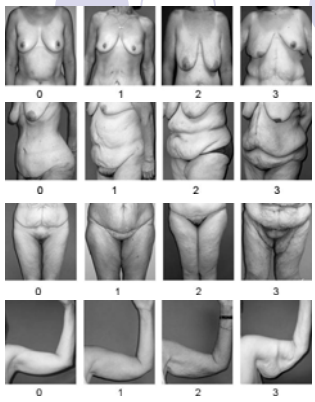
Study in Changes Following Weight Loss

Nada Al-Hadithy
Ken Stewart
Plastic & Reconstructive Surgery

You Are Trying to Lose Weight

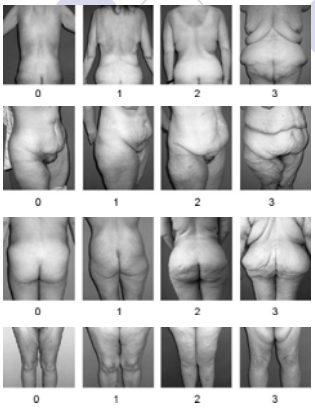
- Weight loss will have huge health benefits
  - Heart
  - Brain
  - Knees
  - Blood sugar
  - LIFE

But



With the massive weight loss, skin often does not shrink well

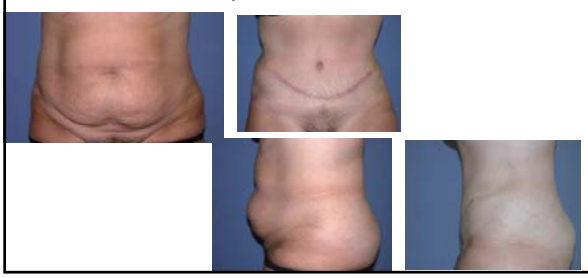
Pittsburgh Classification of Contour Deformities, Rubin et al, 2005



That's where plastics comes in…

So?

Body contouring post-bariatric surgery is the biggest growth areas in plastic surgery in the USA at present.



WARNING

THIS STUDY DOES NOT GUARANTEE PLASTIC SURGERY

So then you ask…Why Me?

- Study to determine if there is an optimal rate of weight loss to minimise droopiness of the skin
- Determine how patients feel about themselves at different milestones in weight loss
- Understand the change in body shape with weight loss

What Will You Have To Do?

- Attend Research Clinic
- Complete Questionnaires
- Anthropometric Measurements
- 2 Sets of Clinical Photographs

- All of the above either once or twice depending on you.

Questionnaires

- Fill out 5 questionnaires posted to you at home
- Come to our research clinic
- Bring the completed questionnaires with you

Anthropometric Measurements

- Measurements of:
  - BMI
  - Arms
  - Thighs
  - Torso
  - Breasts
  - Waist
  - Hips
  - Skin folds
- Chaperone present
- Taken by trained researcher

Clinical Photographs

- Clinical Photography Department RIE

3D Photographs

- System used by the American Army for reconstruction
- Dimensional Imaging - World Leading 3D 4D Surface Imaging.flv

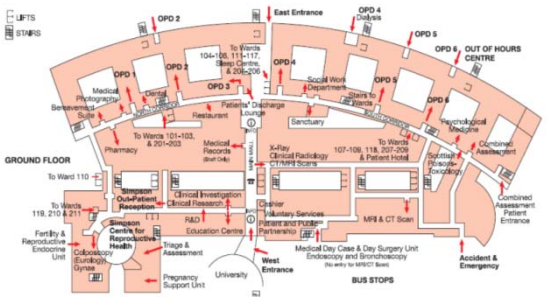
Anything Else?

- Appointment: lasts approximately 2 hours
- You can withdraw from the study at any time
- No questions asked
- Travel expenses will be reimbursed
- This study has ethics committee approval
- Supported by NHS Lothian

Where?

- The Clinical Photography Department of the Royal Infirmary Edinburgh

Where?



When?

- Clinics will be arranged
- within the next 6 - 8 weeks
- Thursday
- If you wish to join we will call you with details

Data Storage

- All photographs will be stored on encrypted NHS computers in the WABA software package.
- Anonymised case report forms will be kept in a locked filing cabinet in OPD 4 at the RIE.
- All computers and memory sticks used for data collection and analysis will be encrypted.

What next?

- You decide if you want to join
- Please give me your names
- I will give you a Patient Information Sheet
- We will contact you to further discuss

EDQ

Version 9.0

INSTRUCTIONS: Please fill in the circle that best describes you for each item.

A. DEMOGRAPHIC INFORMATION

1. Sex: ○ Female ○ Male

2. Current Age: _____ years

   Date of Birth:

   ☐☐ / ☐☐ / ☐☐☐☐

3. Race (fill in only one):
   - ○ White
   - ○ African American
   - ○ Native American
   - ○ Hispanic
   - ○ Asian
   - ○ Other (please specify) _____

4. Marital Status (fill in only one):
   - ○ Never married
   - ○ Married (first marriage)
   - ○ Divorced or widowed and presently remarried
   - ○ Monogamous relationship, living with partner (but not married)
   - ○ Monogamous relationship, not living with partner
   - ○ Divorced and not presently married
   - ○ Widowed and not presently remarried

5. What is your primary role? (fill in only one)
   - ○ Wage earner, full-time
   - ○ Wage earner, part-time
   - ○ Student, full-time
   - ○ Student, part-time
   - ○ Homemaker
   - ○ Unemployed
   - ○ Other (specify) _____

B. WEIGHT HISTORY

1. Current Weight: ☐☐☐ lbs.

2. Current Height: ☐ ft. ☐☐ in.

3. I would like to weigh: ☐☐☐ lbs.

4. **Highest Weight** (non-pregnancy) since age 18:

   Weight ☐☐☐ lbs. **at** **Age** ☐☐ yrs.

5. **Lowest Weight** since age 18:

   Weight ☐☐☐ lbs. **at** **Age** ☐☐ yrs.

6. **Highest Weight between ages 12 and 18:**

   Weight ☐☐☐ lbs. **at** **Height** ☐ ft. ☐☐ in. **at age**
   - ○ 12
   - ○ 13
   - ○ 14
   - ○ 15
   - ○ 16
   - ○ 17

7. **Lowest Weight between ages 12 and 18:**

   Weight ☐☐☐ lbs. **at** **Height** ☐ ft. ☐☐ in. **at age**
   - ○ 12
   - ○ 13
   - ○ 14
   - ○ 15
   - ○ 16
   - ○ 17

8. At your current weight, do you feel that you are:
   - ○ Extremely thin
   - ○ Moderately thin
   - ○ Slightly thin
   - ○ Normal weight
   - ○ Slightly overweight
   - ○ Moderately overweight
   - ○ Extremely overweight

9. How much do you fear gaining weight?
   - ○ Not at all
   - ○ Slightly
   - ○ Moderately
   - ○ Very much
   - ○ Extremely

Continue on Next Page

10. How dissatisfied are you with the way your body is proportioned?

- ○ Not at all dissatisfied
- ○ Slightly dissatisfied
- ○ Moderately dissatisfied
- ○ Very dissatisfied
- ○ Extremely dissatisfied

11. How important is your weight and shape in affecting how you feel about yourself as a person?

- ○ Not at all important
- ○ Slightly important
- ○ Moderately important
- ○ Very important
- ○ Extremely important

12. How fat do you currently feel?

- ○ Not at all fat
- ○ Slightly fat
- ○ Fat
- ○ Very fat
- ○ Extremely fat

13. **Please indicate on the scales below how you feel about different areas of your body.**
(Fill in the circle of best response for each body part.)

	(a) Face	(b) Arms	(c) Shoulders	(d) Breasts	(e) Stomach	(f) Waist	(g) Hips	(h) Buttocks	(i) Thighs
Extremely positive	○	○	○	○	○	○	○	○	○
Moderately positive	○	○	○	○	○	○	○	○	○
Slightly positive	○	○	○	○	○	○	○	○	○
Neutral	○	○	○	○	○	○	○	○	○
Slightly negative	○	○	○	○	○	○	○	○	○
Moderately negative	○	○	○	○	○	○	○	○	○
Extremely negative	○	○	○	○	○	○	○	○	○

14. On the average, how often do you weigh yourself?

- ○ Never
- ○ Less than monthly
- ○ Monthly
- ○ Several times/month
- ○ Weekly
- ○ Several times/week
- ○ Daily
- ○ 2 or 3 times/day
- ○ 4 or 5 times/day
- ○ More than 5 times/day

C. DIETING BEHAVIOR

1. On the average, how many main meals do you eat each day?

☐☐

2. On the average, how many snacks do you eat each day?

☐☐

3. On the average, how many days a week do you eat the following meals?

Breakfast: ☐ days a week Lunch: ☐ days a week Dinner: ☐ days a week

4. Do you try to avoid certain foods in order to influence your shape or weight?

- ○ Yes (If Yes, what?) _____
- ○ No

5. Have you ever been on a diet, restricted your food intake, and/or reduced the amounts or types of food eaten to control your weight?

- ○ Yes
- ○ No (If No, go to section D, "BINGE EATING BEHAVIOR.")

6. At what age did you first begin to diet, restrict your food intake, and/or reduce the amount or types of food eaten to control your weight?

☐☐ years old

7. At what age did you first begin to diet, restrict your food intake, and/or reduce the amount or types of food eaten to lose weight?

☐☐ years old

Continue on Next Page

8. Over the last year, how often have you begun a diet that lasted for more than 3 days?

   ☐☐☐ times

9. Over the last year, how often have you begun a diet that lasted for 3 days or less?

   ☐☐☐ times

10. Indicate your preferred ways of dieting (fill in all that apply).

- ○ Skip meals
- ○ Completely fast for 24 hours or more
- ○ Restrict carbohydrates
- ○ Restrict sweets/sugar
- ○ Reduce fats
- ○ Reduce portion size
- ○ Exercise more
- ○ Reduce calories
- ○ Other: _____

11. In which of the following treatments or types of treatment for eating or weight problems have you participated?

(a) Supervised Diets:	Yes	No	If Yes, ages used	Weight at Start	Weight at End
Weight Watchers ®	○	○			
Jenny Craig ®	○	○			
Nutrasystems ®	○	○			
Optifast ®	○	○			
Procal ®	○	○			
Nutramed ®	○	○			
Liquid protein diet	○	○			
Others: _____	○	○			

(b) Medication for Obesity:	Yes	No	If Yes, ages used	Weight at Start	Weight at End
Phentermine	○	○			
Fenfluramine	○	○			
Xenical (Orlistat ®)	○	○			
Sibutramine (Meridia ®)	○	○			
Topiramate (Topomax ®)	○	○			
Wellbutrin (Buproprion ®)	○	○			
Over-the-counter diet pills (specify): _____	○	○			
Other medication treatment (specify): _____	○	○			
Human Chorionic Gonadotropin (HCG)	○	○			
Others: _____	○	○			

(c) Psychotherapy for Eating Problems, Weight Loss, or Weight Gain:	Yes	No	If Yes, ages used	Weight at Start	Weight at End
Behavior Modification	○	○			
Individual Psychotherapy	○	○			
Group Psychotherapy	○	○			
Hypnosis	○	○			
Others: _____	○	○			

(d) Psychotherapy for Eating Disorder:	Yes	No	If Yes, ages used	Weight at Start	Weight at End
Individual Cognitive Behavioral	○	○			
Group Cognitive Behavioral	○	○			
Interpersonal Psychotherapy	○	○			
Nutritional Counseling	○	○			
Others: _____	○	○			

Continue on Next Page

(e) Medication for Eating Problems/Weight Problems:	Yes	No	If Yes, ages used	If Yes, maximum dosage
Fluoxetine (Prozac ®)	○	○		
Desipramine (Norpramin ®)	○	○		
Paroxetine HCl (Paxil ®)	○	○		
Sertraline HCl (Zoloft ®)	○	○		
Citalopram (Celexa ®)	○	○		
Fluvoxamine (Luvox ®)	○	○		
Naltrexone (Trexan ®)	○	○		
Escitalopram (Lexapro ®)	○	○		
Quetiapine (Seroquel ®)	○	○		
Olanzapine (Zyprexa ®)	○	○		
Risperidone (Risperidol ®)	○	○		
Others: _____	○	○		

(f) Self-help groups:	Yes	No	If Yes, ages used
Bulimia Anonymous	○	○	
Overeaters Anonymous	○	○	
Anorexics Anonymous	○	○	
Others: _____	○	○	

(g) Surgical Procedures:	Yes	No	If Yes, at what age	Weight at Start	Weight at End
Liposuction	○	○			
Gastric bypass	○	○			
Gastric banding	○	○			
Other intestinal surgery (specify): _____	○	○			
Gastric balloon/"bubble"	○	○			
Others: _____	○	○			

12. Please record your major diets which resulted in a <u>weight loss of 10 pounds or more</u>.

	Age at time of diet	Weight at start of diet	# lbs. lost	Type of diet
(1)				
(2)				
(3)				
(4)				
(5)				
(6)				
(7)				
(8)				
(9)				
(10)				

13. Have you ever had any significant physical or emotional symptoms while attempting to lose weight or after losing weight?

○ Yes ○ No

If Yes, describe your symptoms, how long they lasted, if they made you stop your weight loss program, and if they made you seek professional help.

Problem	Year	Duration (weeks)	Stopped weight loss program? **Yes**	**No**	Type of professional help, if any
			○	○	
			○	○	
			○	○	
			○	○	
			○	○	

Continue on Next Page

D. BINGE EATING BEHAVIOR

1. Have you ever had an episode of binge eating characterized by:

   (a) eating, in a discrete period of time (e.g., within any two hour period), an amount of food that is definetely larger than most people eat in a similar period of time?
   ○ Yes ○ No

   (b) a sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating)?
   ○ Yes ○ No

   If No to either a) or b), go to section E, "WEIGHT CONTROL BEHAVIOR."

2. Please indicate on the scales below how characteristic the following symptoms are or were of your binge eating.

	Never	Rarely	Sometimes	Often	Always
(a) feeling that I can't stop eating or control what or how much I eat	○	○	○	○	○
(b) eating much more rapidly than usual	○	○	○	○	○
(c) eating until I feel uncomfortably full	○	○	○	○	○
(d) eating large amounts of food when not feeling physically hungry	○	○	○	○	○
(e) eating alone because I am embarrassed by how much I am eating	○	○	○	○	○
(f) feeling disgusted with myself, depressed, or very guilty after overeating	○	○	○	○	○
(g) feeling very distressed about binge eating	○	○	○	○	○

3. How old were you when you began binge eating?

   ☐☐ years old

4. When did binge eating start to occur on a regular basis, on average at least 2 times each week?

   ☐☐ years old

5. What was your height and weight at that time?

   Weight ☐☐☐ lbs. **at** **Height** ☐ ft. ☐☐ in.

6. What is the total duration of time you had a problem with binge eating (whether or not you are binge eating now)?

   Days ☐☐ **Months** ☐☐ **Years** ☐☐

E. WEIGHT CONTROL BEHAVIOR

1. Have you ever self-induced vomiting after eating in order to get rid of the food eaten?
   ○ Yes ○ No (If No, go to question 8.)

2. How old were you when you induced vomiting for the first time?

   ☐☐ years old

3. How old were you when you first induced vomiting on a regular basis (on average at least two times each week)?

   ☐☐ years old

4. How long did you self-induce vomiting?

   Days ☐☐ **Months** ☐☐ **Years** ☐☐

Continue on Next Page

5. Have you ever taken syrup of Ipecac ® to control your weight?

   ○ Yes ○ No

6. How old were you when you took Ipecac ® for the first time?

   ☐☐ years old

7. How long did you use Ipecac ® to control your weight?

   Days ☐☐ **Months** ☐☐ **Years** ☐☐

---

8. Have you ever used laxatives to control your weight or "get rid of food?"

   ○ Yes ○ No (If No, go to question 13.)

9. How old were you when you first took laxatives for weight control?

   ☐☐ years old

10. How old were you when you first took laxatives for weight control (on a regular basis on average at least two times each week)?

    ☐☐ years old

11. How long did you use laxatives for weight control?

    Days ☐☐ **Months** ☐☐ **Years** ☐☐

12. What type and amounts of laxatives have you used? (Indicate all types that apply and the maximum number used per day.)

			Maximum Number per Day							
	Yes	No	1	2	3	4	5	6-10	11-20	>20
Ex-Lax ®	○	○	○	○	○	○	○	○	○	○
Correctol ®	○	○	○	○	○	○	○	○	○	○
Metamucil ®	○	○	○	○	○	○	○	○	○	○
Colace ®	○	○	○	○	○	○	○	○	○	○
Dulcolax ®	○	○	○	○	○	○	○	○	○	○
Phillips Milk of Magnesia ®	○	○	○	○	○	○	○	○	○	○
Senokot ®	○	○	○	○	○	○	○	○	○	○
Perdiem ®	○	○	○	○	○	○	○	○	○	○
Fleet ®	○	○	○	○	○	○	○	○	○	○
Other (specify): _____	○	○	○	○	○	○	○	○	○	○

---

13. Have you ever used diuretics (water pills) to control your weight?

    ○ Yes ○ No (If No, go to question 18.)

14. How old were you when you first took diuretics for weight control?

    ☐☐ years old

15. How old were you when you first took diuretics for weight control (on a regular basis, on average at least two times each week)?

    ☐☐ years old

16. How long did you use diuretics for weight control?

    Days ☐☐ **Months** ☐☐ **Years** ☐☐

17. What type and amount of diuretics have you used? (Indicate all that apply and the maximum number used per day.)

(a) Over-the-counter Diuretics:			Maximum Number per Day										
	Yes	No	1	2	3	4	5	6	7	8	9	10	>10
Aqua-Ban ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Diurex ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Midol ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Pamprin ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Others (specify): _____	○	○	○	○	○	○	○	○	○	○	○	○	○

Continue on Next Page

(b) Prescription Diuretics:	Yes	No	Maximum Number per Day 1	2	3	4	5	6	7	8	9	10	>10
	○	○	○	○	○	○	○	○	○	○	○	○	○
	○	○	○	○	○	○	○	○	○	○	○	○	○

18. Have you ever used diet pills to control your weight?

○ Yes ○ No (If No, please go to question 22.)

19. How old were you when you first used diet pills for weight control?

☐☐ years old

20. How long did you use diet pills to control your weight?

Days ☐☐ **Months** ☐☐ **Years** ☐☐

21. What types and amounts of diet pills have you used **within the last month**? (Indicate all that apply and the maximum number per day.)

(a) Over-the-counter:	Yes	No	Maximum Number per Day 1	2	3	4	5	6	7	8	9	10	>10
Dexatrim ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Dietac ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Acutrim ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Protrim ®	○	○	○	○	○	○	○	○	○	○	○	○	○
Ma Huang	○	○	○	○	○	○	○	○	○	○	○	○	○
Ephedrine	○	○	○	○	○	○	○	○	○	○	○	○	○
Chromium	○	○	○	○	○	○	○	○	○	○	○	○	○
Guarana seed	○	○	○	○	○	○	○	○	○	○	○	○	○
Garcinia Cambogia	○	○	○	○	○	○	○	○	○	○	○	○	○
Caffeine	○	○	○	○	○	○	○	○	○	○	○	○	○
Other (specify): _____	○	○	○	○	○	○	○	○	○	○	○	○	○

(b) Prescription:	Yes	No	Maximum Number per Day 1	2	3	4	5	6	7	8	9	10	>10
	○	○	○	○	○	○	○	○	○	○	○	○	○
	○	○	○	○	○	○	○	○	○	○	○	○	○

22. During the entire LAST MONTH, what is the average frequency that you have engaged in the following behaviors? (Please fill in one circle for each behavior.)

	Never	Once a Month or Less	Several Times a Month	Once a Week	Twice a Week	Three to Six Times a Week	Once a Day	More Than Once a Day
Binge eating (as defined on pg. 5, D.1.)	○	○	○	○	○	○	○	○
Vomiting	○	○	○	○	○	○	○	○
Laxative use to control weight	○	○	○	○	○	○	○	○
Use of diet pills	○	○	○	○	○	○	○	○
Use of diuretics	○	○	○	○	○	○	○	○
Use of enemas	○	○	○	○	○	○	○	○
Use of Ipecac ® syrup	○	○	○	○	○	○	○	○
Exercise to control weight	○	○	○	○	○	○	○	○
Fasting (skipping meals for entire day)	○	○	○	○	○	○	○	○
Skipping meals	○	○	○	○	○	○	○	○
Eating very small meals	○	○	○	○	○	○	○	○
Eating meals low in calories and/or fat grams	○	○	○	○	○	○	○	○
Chewing and spitting out food	○	○	○	○	○	○	○	○
Rumination (vomit food into mouth, chew, and re-swallow	○	○	○	○	○	○	○	○
Saunas to control weight	○	○	○	○	○	○	○	○
Herbal products ("fat burners")	○	○	○	○	○	○	○	○

Continue on Next Page

23. During **any one month period**, what is the HIGHEST frequency that you have engaged in the following behaviors? (Please fill in one circle for each behavior.)

	Never	Once a Month or Less	Several Times a Month	Once a Week	Twice a Week	Three to Six Times a Week	Once a Day	More Than Once a Day
Binge eating (as defined on pg. 5, D.1.)	○	○	○	○	○	○	○	○
Vomiting	○	○	○	○	○	○	○	○
Laxative use to control weight	○	○	○	○	○	○	○	○
Use of diet pills	○	○	○	○	○	○	○	○
Use of diuretics	○	○	○	○	○	○	○	○
Use of enemas	○	○	○	○	○	○	○	○
Use of Ipecac ® syrup	○	○	○	○	○	○	○	○
Exercise to control weight	○	○	○	○	○	○	○	○
Fasting (skipping meals for entire day)	○	○	○	○	○	○	○	○
Skipping meals	○	○	○	○	○	○	○	○
Eating very small meals	○	○	○	○	○	○	○	○
Eating meals low in calories and/or fat grams	○	○	○	○	○	○	○	○
Chewing and spitting out food	○	○	○	○	○	○	○	○
Rumination (vomit food into mouth, chew, and re-swallow	○	○	○	○	○	○	○	○
Saunas to control weight	○	○	○	○	○	○	○	○
Herbal products ("fat burners")	○	○	○	○	○	○	○	○

F. EXERCISE

1. How frequently do you exercise?

○ Not at all
○ Once per month or less
○ Several times per month
○ Once per week
○ Several times per week
○ Once per day
○ Several times a day

2. If you exercise, how long do you usually exercise each time?

○ Less than 15 minutes
○ 15 - 30 minutes
○ 31 - 60 minutes
○ 61 - 120 minutes
○ More than 120 minutes

3. If you exercise, please indicate the types of exercise you do (fill in all that apply).

○ Biking
○ Running
○ Swimming
○ Weighttraining
○ Aerobics
○ Calisthenics
○ Walking
○ In-lineskating
○ Stairmaster
○ Treadmill
○ Stationary bike
○ Other: _____

G. MENSTRUAL HISTORY

1. Age of onset of menses: ☐☐ years

2. Have you ever had periods of time when you stopped menstruating for three months or more (which were unrelated to pregnancy)?

○ Yes ○ No If Yes, number of times: ☐☐

3. Did weight loss ever cause irregularities of your cycle?

○ Yes ○ No If Yes, describe:

_____

_____

4. Have you menstruated during the last three months?

○ Yes ○ No

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5. Are you on birth control pills? ○ Yes ○ No

6. Are you on hormone replacement? ○ Yes ○ No

7. Are you post menopausal? ○ Yes ○ No

8. Please indicate when during your cycle you feel most vulnerable to binge eating. Please fill in the single best response.

○ I do not binge eat during menstruation
○ 11 - 14 days prior to menstruation
○ 7 - 10 days prior to menstruation
○ 3 - 6 days prior to menstruation
○ 1 - 2 days prior to menstruation
○ After menstruation onset
○ No particular time

9. Do you crave particular foods (have a desire or urge to consume a specific food item or drink) for the <u>few days prior to</u> menstruation?

○ Yes ○ No If Yes, what foods do you crave?

_____

_____

10. Do you crave particular foods (have a desire or urge to consume a specific food item or drink) <u>during</u> your menstruation?

○ Yes ○ No If Yes, what foods do you crave?

_____

_____

11. Marriage and pregnancy:

	Yes	No	Does Not Apply
(a) Did problems with weight and/or binge eating begin before you were married?	○	○	○
(b) Did problems with weight and/or binge eating begin after you were married?	○	○	○
(c) Did problems with weight and/or binge eating begin before your first pregnancy?	○	○	○
(d) Did problems with weight and/or binge eating begin after your first pregnancy?	○	○	○

12. Do you have children?

○ Yes ○ No (If No, skip to section H, "HISTORY OF ABUSE.")

(a) For your FIRST child, what was your...

...weight at the start of your pregnancy? ☐☐☐

...weight at delivery? ☐☐☐

...lowest weight in the first year after delivery? ☐☐☐

(b) For your SECOND child, what was your...

...weight at the start of your pregnancy? ☐☐☐

...weight at delivery? ☐☐☐

...lowest weight in the first year after delivery? ☐☐☐

(c) For your THIRD child, what was your...

...weight at the start of your pregnancy? ☐☐☐

...weight at delivery? ☐☐☐

...lowest weight in the first year after delivery? ☐☐☐

(d) For your FOURTH child, what was your...

...weight at the start of your pregnancy? ☐☐☐

...weight at delivery? ☐☐☐

...lowest weight in the first year after delivery? ☐☐☐

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H. HISTORY OF ABUSE

1. Before you were 18, did any of the following happen to you?

Yes	No	
○	○	Someone constantly criticized you and blamed you for minor things.
○	○	Someone physically beat you (hit you, slapped you, threw something at you, pushed you).
○	○	Someone threatened to hurt or kill you, or do something sexual to you.
○	○	Someone threatened to abandon or leave you.
○	○	You watched one parent physically beat (hit, slap) the other parent.
○	○	Someone from your family forced you to have sexual relations (unwanted touching, fondling, sexual kissing, sexual intercourse).
○	○	Someone outside your family forced you to have sexual relations (unwanted touching, fondling, sexual kissing, sexual intercourse).

2. After you were 18, did any of the following happen to you?

Yes	No	
○	○	Someone constantly criticized you and blamed you for minor things.
○	○	Someone physically beat you (hit you, slapped you, threw something at you, pushed you).
○	○	Someone threatened to hurt or kill you, or do something sexual to you.
○	○	Someone threatened to abandon or leave you.
○	○	You watched one parent physically beat (hit, slap) the other parent.
○	○	Someone from your family forced you to have sexual relations (unwanted touching, fondling, sexual kissing, sexual intercourse).
○	○	Someone outside your family forced you to have sexual relations (unwanted touching, fondling, sexual kissing, sexual intercourse).

I. PSYCHIATRIC HISTORY

1. Have you ever been hospitalized for psychiatric problems?

○ Yes (If Yes, please complete the section below.)
○ No

HOSPITAL NAME & ADDRESS (CITY, STATE)	WHAT YEAR	DIAGNOSIS (IF KNOWN) OR PROBLEMS YOU WERE HAVING	TREATMENT YOU RECEIVED	WAS THIS HELPFUL? Yes	No
				○	○
				○	○
				○	○
				○	○
				○	○

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2. Have you ever been treated out of the hospital for psychiatric problems?

   ○ Yes (If Yes, please complete the section below.)

   ○ No

YEAR(S) WHEN TREATED	DOCTOR OR THERAPIST'S NAME & ADDRESS (CITY, STATE)	DIAGNOSIS (IF KNOWN) OR PROBLEMS YOU WERE HAVING	TREATMENT YOU RECEIVED	WAS THIS HELPFUL? Yes	No
				○	○
				○	○
				○	○
				○	○
				○	○

3. Complete the following information for any of the following types of medications you are now taking or have ever taken:

		Took Previously	On Currently	Current Dosage	If taking currently, for what problem?
(a) ANTIDEPRESSANTS					
Prozac ®	(Fluoxetine)	○	○		
Zoloft ®	(Sertraline)	○	○		
Paxil ®	(Paroxetine)	○	○		
Luvox ®	(Fluvoxamine)	○	○		
Celexa ®	(Citalopram)	○	○		
Effexor ®	(Venlafaxine)	○	○		
Wellbutrin ®	(Bupropion)	○	○		
Elavil ®	(Amitriptyline)	○	○		
Tofranil ®	(Imipramine)	○	○		
Sinequan ®	(Doxepin)	○	○		
Norpramin ®	(Desipramine)	○	○		
Vivactil ®	(Protriptyline)	○	○		
Desyrel ®	(Trazodone)	○	○		
Parnate ®	(Tranylcypromine)	○	○		
Nardil ®	(Phenelzine)	○	○		
Anafranil ®	(Clomipramine)	○	○		
Remeron ®	(Mirtazapine)	○	○		
Serzone ®	(Nefazodone)	○	○		
St. John's Wort		○	○		
Lexapro ®	(Escitalopram)	○	○		
(b) MAJOR TRANQUILIZERS					
Clozaril ®	(Clozapine)	○	○		
Zyprexa ®	(Olanzepine)	○	○		
Risperdal ®	(Risperidone)	○	○		
Haldol ®	(Haloperidol)	○	○		
Navane ®	(Thiothixene)	○	○		
Trilafon ®	(Perphenazine)	○	○		
Thorazine ®	(Chlorpromazine)	○	○		
Stelazine ®	(Trifluoperazine)	○	○		
Prolixin ®	(Fluphenazine)	○	○		
Orap ®	(Pimozide)	○	○		
Moban ®	(Molindone)	○	○		
Loxitane ®	(Loxapine)	○	○		
Seroquil ®	(Quetiapine)	○	○		
Mellaril ®	(Thioridazine)	○	○		
Geodon ®	(Ziprasidone)	○	○		
Abilify ®	(Aripiprozole)	○	○		

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		Took Previously	On Currently	Current Dosage	If taking currently, for what problem?
(c) MINOR TRANQUILIZERS					
Valium ®	(Diazepam)	○	○		
Librium ®	(Chlordiazepoxide)	○	○		
Serax ®	(Oxazepam)	○	○		
Halcion ®	(Triazolam)	○	○		
Tranxene ®	(Clorazepate)	○	○		
Ambien ®	(Zolpidem)	○	○		
Klonopin ®	(Clonazepam)	○	○		
Ativan ®	(Lorazepam)	○	○		
BuSpar ®	(Buspirone)	○	○		
Dalmane ®	(Flurazepam)	○	○		
Xanax ®	(Alprazolam)	○	○		
Sonata ®	(Zaleplon)	○	○		
(d) MOOD STABILIZERS					
Lithobid ®	Lithium ®	○	○		
Depakote ®	Sodium Valproate ®	○	○		
Tegretol ®	(Carbamazepine)	○	○		
Topomax ®	(Topiramate)	○	○		
Lamictal ®	(Lamotrigine)	○	○		
OTHER:		○	○		
OTHER:		○	○		
OTHER:		○	○		
OTHER:		○	○		

J. MEDICAL HISTORY

1. Please list all medical hospitalizations:

WHEN? YEAR(S)	WHERE? (Hospital Name & City)	PROBLEM	DIAGNOSIS	TREATMENT YOU RECEIVED

2. Please list all other medical treatment you've received. (Include any significant problem, but do not include flu, colds, routine exams.)

WHEN? YEAR(S)	WHERE? (Doctor's Name & Address)	PROBLEM	DIAGNOSIS	TREATMENT YOU RECEIVED

Continue on Next Page

K. CHEMICAL USE HISTORY

1. In the last six months, how often have you taken these drugs?

	Not At All	Less Than Monthly	About Once a Month	Several Times a Month	About Once a Week	Several Times a Week	Daily	Several Times a Day
ALCOHOL	○	○	○	○	○	○	○	○
STIMULANTS (Amphetamines, Uppers, Crank, Speed)	○	○	○	○	○	○	○	○
DIET PILLS	○	○	○	○	○	○	○	○
SEDATIVES (Barbiturates, Sleeping Pills, Valium ®, Librium ®, Downers)	○	○	○	○	○	○	○	○
MARIJUANA/HASHISH	○	○	○	○	○	○	○	○
HALLUCINOGENS (LSD, Mescaline, Mushrooms, Extasy)	○	○	○	○	○	○	○	○
OPIATES (Heroin, Morphine, Opium)	○	○	○	○	○	○	○	○
COCAINE/CRACK	○	○	○	○	○	○	○	○
PCP (Angel Dust, Phencyclidine)	○	○	○	○	○	○	○	○
INHALANTS (Glue, Gasoline, etc.)	○	○	○	○	○	○	○	○
CAFFEINE PILLS (No Doz ®, Vivarin ®, etc.)	○	○	○	○	○	○	○	○
OTHER: _____	○	○	○	○	○	○	○	○
_____	○	○	○	○	○	○	○	○

2. What is the most you have used any of these drugs during a one-month period (month of heaviest use)?

(Example: If you used sleeping pills about once a month many years ago, but not at all now, you would fill in the circle under "About Once a Month" on the line "Sedatives - Barbiturates...")

	Not At All	Less Than Monthly	About Once a Month	Several Times a Month	About Once a Week	Several Times a Week	Daily	Several Times a Day
ALCOHOL	○	○	○	○	○	○	○	○
STIMULANTS (Amphetamines, Uppers, Crank, Speed)	○	○	○	○	○	○	○	○
DIET PILLS	○	○	○	○	○	○	○	○
SEDATIVES (Barbiturates, Sleeping Pills, Valium ®, Librium ®, Downers)	○	○	○	○	○	○	○	○
MARIJUANA/HASHISH	○	○	○	○	○	○	○	○
HALLUCINOGENS (LSD, Mescaline, Mushrooms, Extasy)	○	○	○	○	○	○	○	○
OPIATES (Heroin, Morphine, Opium)	○	○	○	○	○	○	○	○
COCAINE/CRACK	○	○	○	○	○	○	○	○
PCP (Angel Dust, Phencyclidine)	○	○	○	○	○	○	○	○
INHALANTS (Glue, Gasoline, etc.)	○	○	○	○	○	○	○	○
CAFFEINE PILLS (No Doz ®, Vivarin ®, etc.)	○	○	○	○	○	○	○	○
OTHER: _____	○	○	○	○	○	○	○	○
_____	○	○	○	○	○	○	○	○

3. Assuming all the drugs mentioned above were readily available, which would you prefer? _____

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Have you ever had any of the following problems because of your alcohol or drug use? (if Yes, please specify.)

4. Drinking and driving when unsafe?
   - ○ Yes.....When?
   - ○ No
   - ○ More than 6 months ago
   - ○ During the past 6 months
   - ○ Both

5. Medical problems?
   - ○ Yes.....When?
   - ○ No
   - ○ More than 6 months ago
   - ○ During the past 6 months
   - ○ Both

6. Problems at work or school?
   - ○ Yes.....When?
   - ○ No
   - ○ More than 6 months ago
   - ○ During the past 6 months
   - ○ Both

7. An arrest?
   - ○ Yes.....When?
   - ○ No
   - ○ More than 6 months ago
   - ○ During the past 6 months
   - ○ Both

8. Family trouble?
   - ○ Yes.....When?
   - ○ No
   - ○ More than 6 months ago
   - ○ During the past 6 months
   - ○ Both

---

9. Have you ever smoked cigarettes?
   - ○ Yes
   - ○ No (If No, go to question 10.)

   What was the most you ever smoked?
   - ○ Only occasionally
   - ○ Less than one pack per day
   - ○ About one pack per day
   - ○ One to two packs per day
   - ○ About two packs per day
   - ○ More than two packs per day

   If you are smoking now, how much do you smoke?
   - ○ Only occasionally
   - ○ Less than one pack per day
   - ○ About one pack per day
   - ○ One to two packs per day
   - ○ About two packs per day
   - ○ More than two packs per day

---

10. Do you drink coffee?
    - ○ Yes
    - ○ No (If No, go to question 11.)

    On the average, how many cups of caffeinated coffee do you drink per day?
    - ○ Less than 1
    - ○ 1 cup per day
    - ○ 2 cups
    - ○ 3 cups
    - ○ 4 cups
    - ○ 5 cups
    - ○ 6 - 10 cups
    - ○ More than 10 cups

    On the average, how many cups of decaffeinated coffee do you drink per day?
    - ○ Less than 1
    - ○ 1 cup per day
    - ○ 2 cups
    - ○ 3 cups
    - ○ 4 cups
    - ○ 5 cups
    - ○ 6 - 10 cups
    - ○ More than 10 cups

---

11. Do you drink tea?
    - ○ Yes
    - ○ No (If No, go to question 12.)

    On the average, how many cups of caffeinated tea do you drink per day?
    - ○ Less than 1
    - ○ 1 cup per day
    - ○ 2 cups
    - ○ 3 cups
    - ○ 4 cups
    - ○ 5 cups
    - ○ 6 - 10 cups
    - ○ More than 10 cups

    On the average, how many cups of decaffeinated tea do you drink per day?
    - ○ Less than 1
    - ○ 1 cup per day
    - ○ 2 cups
    - ○ 3 cups
    - ○ 4 cups
    - ○ 5 cups
    - ○ 6 - 10 cups
    - ○ More than 10 cups

---

12. Do you drink cola or soft drinks?
    - ○ Yes
    - ○ No (If No, go to next section.)

    On the average, how many cans/glasses of caffeinated cola or soft drinks do you drink per day?
    - ○ Less than 1
    - ○ 1 can per day
    - ○ 2 cans
    - ○ 3 cans
    - ○ 4 cans
    - ○ 5 cans
    - ○ 6 - 10 cans
    - ○ More than 10 cans

    On the average, how many cans/glasses of decaffeinated cola or soft drinks do you drink per day?
    - ○ Less than 1
    - ○ 1 can per day
    - ○ 2 cans
    - ○ 3 cans
    - ○ 4 cans
    - ○ 5 cans
    - ○ 6 - 10 cans
    - ○ More than 10 cans

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L. FAMILY MEMBERS

1.

	NAME	AGE IF LIVING	CAUSE OF DEATH	AGE AT DEATH
FATHER				
MOTHER				
BROTHERS & SISTERS				
SPOUSE				
CHILD 1				
CHILD 2				
CHILD 3				
CHILD 4				

2. Are you a twin? ○ Yes ○ No

(If Yes, is your twin identical? ____Yes ____No)

3. Were you adopted? ○ Yes ○ No

(If Yes, at what age were you adopted? _____)

M. FAMILY MEDICAL AND PSYCHIATRIC HISTORY

1. Fill in the circle in the column of any of your *blood relatives* who has, or has had, the following conditions or problems:

** Include half brothers/half sisters*

CONDITIONS	MOTHER	FATHER	*BROTHERS	*SISTERS	UNCLES	AUNTS	GRANDPARENTS	CHILDREN
Alcoholism or Drug Abuse	○	○	○	○	○	○	○	○
Anorexia Nervosa	○	○	○	○	○	○	○	○
Anxiety	○	○	○	○	○	○	○	○
Arthritis/Rheumatism	○	○	○	○	○	○	○	○
Asthma, Hay Fever, or Allergies	○	○	○	○	○	○	○	○
Binge-Eating	○	○	○	○	○	○	○	○
Birth Defects	○	○	○	○	○	○	○	○
Bleeding Problems	○	○	○	○	○	○	○	○
Bulimia Nervosa	○	○	○	○	○	○	○	○
Cataracts	○	○	○	○	○	○	○	○
Cancer or Leukemia	○	○	○	○	○	○	○	○
Colitis	○	○	○	○	○	○	○	○
Deafness	○	○	○	○	○	○	○	○
Depression	○	○	○	○	○	○	○	○
Diabetes	○	○	○	○	○	○	○	○
Drug Abuse	○	○	○	○	○	○	○	○
Epilepsy (seizures, fits)	○	○	○	○	○	○	○	○
Eczema	○	○	○	○	○	○	○	○
Gall Bladder Malfunction	○	○	○	○	○	○	○	○
Gambling	○	○	○	○	○	○	○	○
Glaucoma	○	○	○	○	○	○	○	○
Gout	○	○	○	○	○	○	○	○
Heart Attack	○	○	○	○	○	○	○	○
Heart Disease	○	○	○	○	○	○	○	○
Hyperlipidemia (excessive fat in blood)	○	○	○	○	○	○	○	○

CONDITIONS	MOTHER	FATHER	*BROTHERS	*SISTERS	UNCLES	AUNTS	GRANDPARENTS	CHILDREN
Hypertension (high blood pressure)	○	○	○	○	○	○	○	○
Jail or Prison	○	○	○	○	○	○	○	○
Kidney Disease	○	○	○	○	○	○	○	○
Liver Cirrhosis	○	○	○	○	○	○	○	○
Manic Depression (Bipolar)	○	○	○	○	○	○	○	○
Mental Retardation	○	○	○	○	○	○	○	○
Migraine or Sick Headaches	○	○	○	○	○	○	○	○
Nerve Diseases (Parkinson's, MS, etc.)	○	○	○	○	○	○	○	○
Obesity (overweight)	○	○	○	○	○	○	○	○
Psychiatric Hospitalization	○	○	○	○	○	○	○	○
Thyroid Disease/Goiter	○	○	○	○	○	○	○	○
Pernicious Anemia	○	○	○	○	○	○	○	○
Psychosis	○	○	○	○	○	○	○	○
Rheumatic Fever	○	○	○	○	○	○	○	○
Schizophrenia	○	○	○	○	○	○	○	○
Sickle Cell Disease	○	○	○	○	○	○	○	○
Stroke	○	○	○	○	○	○	○	○
Suicide Attempt	○	○	○	○	○	○	○	○
Suicide (completed)	○	○	○	○	○	○	○	○
Syphilis	○	○	○	○	○	○	○	○
Tuberculosis (TB)	○	○	○	○	○	○	○	○
Other Glandular Diseases	○	○	○	○	○	○	○	○
Ulcers	○	○	○	○	○	○	○	○
Yellow Jaundice	○	○	○	○	○	○	○	○
Other: _____	○	○	○	○	○	○	○	○

Continue on Next Page

2. If any of your *blood relatives* have not had ANY of the above conditions or problems, please indicate here:
   - ○ Mother ○ Brothers ○ Uncles ○ Grandparents
   - ○ Father ○ Sisters ○ Aunts ○ Children

N. MEDICATION HISTORY

1. What medications are you now taking?

MEDICATION NAME	DOSAGE	HOW LONG HAVE YOU BEEN TAKING THIS MEDICATION?

2. What drugs, medications, or shots are you allergic to?

MEDICATION/DRUG/SHOT NAME	REACTION

O. SOCIAL HISTORY

1. Highest level achieved in school (choose one):
   - ○ 8th grade or less
   - ○ Some high school
   - ○ High school graduate
   - ○ Trade or technical school
   - ○ Some college
   - ○ College graduate
   - ○ Graduate study
   - ○ Graduate degree
   - ○ Post-graduate degree

   Specify highest degree attained:
   - ○ M.D./D.O.
   - ○ Ph.D./Psy.D./Ed.D.
   - ○ Pharm.D.
   - ○ M.A. or M.S.
   - ○ B.A. or B.S.
   - ○ B.S.N.
   - ○ Other: _____

2. Are you now employed? ○ Yes ○ No If No, when were you last employed? _____

3. Current occupation or last work if now unemployed: _____

4. Were you ever in the armed services? ○ Yes ○ No

   Years of service (from when to when?) _____ Highest rank achieved _____

5. Have you ever been arrested? ○ Yes ○ No

Age(s) when arrested:	Reason(s) for arrest:	Did you spend time in jail?
_____	_____	_____
_____	_____	_____

Continue on Next Page

P. MEDICAL CHECKLIST

Fill in the circle of any of the following that you have experienced during the last four weeks. You should indicate items which are very noticeable to you and not those things which, even if present, are minor.

GENERAL:
- ○ Severe loss of appetite
- ○ Severe weakness
- ○ Fever
- ○ Chills
- ○ Heavy sweats
- ○ Heavy night sweats - bed linens wet
- ○ Fatigue
- ○ Sudden change in sleep

SKIN:
- ○ Itching
- ○ Easy bruising that represents a change in the way you normally bruise
- ○ Sores
- ○ Marked dryness
- ○ Hair fragile - comes out in comb
- ○ Hair has become fine and silky
- ○ Hair has become coarse and brittle

HEAD:
- ○ Struck on head - knocked out
- ○ Frequent dizziness that makes you stop your normal activity and lasts at least 5 minutes
- ○ Headaches that are different from those you normally have
- ○ Headaches that awaken you
- ○ Headaches with vomiting

EYES:
- ○ Pain in your eyes
- ○ Need new glasses
- ○ Seeing double
- ○ Loss of part of your vision
- ○ Seeing flashing lights or forms
- ○ Seeing halos around lights

EARS:
- ○ Pain in your ears
- ○ Ringing in your ears
- ○ Change in hearing
- ○ Room spins around you

NOSE:
- ○ Bleeding
- ○ Pain
- ○ Cannot breathe well
- ○ Unusual smells

MOUTH:
- ○ Toothache

  Soreness or bleeding of:
  - ○ Lips
  - ○ Tongue
  - ○ Gums
- ○ Unusual tastes
- ○ Hoarseness

NECK:
- ○ Pain
- ○ Cannot move well
- ○ Lumps
- ○ Difficulty swallowing
- ○ Pain on swallowing

NODES:
- ○ Swollen or tender lymph nodes (Kernals)

BREASTS:
- ○ Pain
- ○ New lumps
- ○ Discharge from nipples

LUNGS:
- ○ Pain in chest
- ○ Pain when you take a deep breath
- ○ New cough
- ○ Coughing up blood
- ○ Green, white, or yellow phlegm
- ○ Wheezing
- ○ Short of breath (sudden)
- ○ Wake up at night - can't catch breath
- ○ Unable to climb stairs

HEART:
- ○ Pain behind breastbone
- ○ Pain behind left nipple
- ○ Pain on left side of neck or jaw
- ○ Heart racing
- ○ Heart thumps and misses beats
- ○ Short of breath when walking
- ○ Need 2 or more pillows to sleep
- ○ Legs and ankles swelling (not with menstrual period)
- ○ Blue lips/fingers/toes when indoors and warm

GASTRO-INTESTINAL:
- ○ Have lost all desire to eat
- ○ Food makes me ill
- ○ Cannot swallow normally
- ○ Pain on swallowing
- ○ Food comes halfway up again
- ○ Sudden persistent heartburn
- ○ Pain or discomfort after eating
- ○ Bloating
- ○ Sharp, stabbing pains in side or shoulder after eating

Continue on Next Page

GENITO-URINARY:

- ○ Stabbing pain in back by lower ribs
- ○ Urinating much more frequently
- ○ Sudden awakening at night to urinate
- ○ Passing much more urine
- ○ Not making much urine
- ○ Unable to start to urinate
- ○ Must go to urinate quickly or afraid of losing urine
- ○ Pain on urination
- ○ Wetting yourself
- ○ Blood in urine
- ○ Pus in urine

NEUROLOGICAL:

- ○ Fainting
- ○ Fits
- ○ Weakness in arms or legs
- ○ Change in speech
- ○ Loss of coordination
- ○ Sudden periods or onset of confusion
- ○ Sudden changes in personality (suddenly not the same person)
- ○ Loss of ability to concentrate
- ○ Seeing things
- ○ Loss of touch
- ○ Tingling in arms or legs
- ○ Unable to chew properly
- ○ Memory loss
- ○ Tremulous or shaky

MALE:

- ○ Pain in testicles
- ○ Swelling of testicles
- ○ Swelling of scrotum

FEMALE:

- ○ Sudden change in periods
- ○ Between periods bleeding

LIST ANY OTHERS NOT MENTIONED ABOVE:

_____

_____

_____

DAS24 4 pages

Hospital Anxiety and Depression Scale (HADS)

Name: _____ Date: _____

FOLD HERE

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

FOLD HERE

A	D		A	D
		I feel tense or 'wound up'		
3		Most of the time		3
2		A lot of the time		2
1		From time to time, occasionally		1
0		Not at all		0
		I still enjoy the things I used to enjoy		
	0	Definitely as much		
	1	Not quite so much		
	2	Only a little		
	3	Hardly at all		
		I get a sort of frightened feeling as if something awful is about to happen		
3		Very definitely and quite badly		3
2		Yes, but not too badly		2
1		A little, but it doesn't worry me		1
0		Not at all		0
		I can laugh and see the funny side of things		
	0	As much as I always could		
	1	Not quite so much now		
	2	Definitely not so much now		
	3	Not at all		
		Worrying thoughts go through my mind		
3		A great deal of the time		
2		A lot of the time		
1		Not too often		
0		Very little		
		I feel cheerful		
	3	Never		
	2	Not often		
	1	Sometimes		
	0	Most of the time		
		I can sit at ease and feel relaxed		
0		Definitely		
1		Usually		
2		Not often		
3		Not at all		
		I feel as if I am slowed down		
		Nearly all the time		3
		Very often		2
		Sometimes		1
		Not at all		0
		I get a sort of frightened feeling like 'butterflies' in the stomach		
		Not at all	0	
		Occasionally	1	
		Quite often	2	
		Very often	3	
		I have lost interest in my appearance		
		Definitely		3
		I don't take as much care as I should		2
		I may not take quite as much care		1
		I take just as much care as ever		0
		I feel restless as if I have to be on the move		
		Very much indeed	3	
		Quite a lot	2	
		Not very much	1	
		Not at all	0	
		I look forward with enjoyment to things		
		As much as I ever did		0
		Rather less than I used to		1
		Definitely less than I used to		2
		Hardly at all		3
		I get sudden feelings of panic		
		Very often indeed	3	
		Quite often	2	
		Not very often	1	
		Not at all	0	
		I can enjoy a good book or radio or television programme		
		Often		0
		Sometimes		1
		Not often		2
		Very seldom		3

Now check that you have answered all the questions

	A	D
TOTAL		

Name: **Study number:**

Date when completing form:

SF-36 Health Survey

INSTRUCTIONS: This survey asks your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

When complete, please return the questionnaire in the envelope provided.

---

1. In general, would you say your health is:

(circle one)

Excellent	……..	1
Very good	…….	2
Good	…….	3
Fair	…….	4
Poor	…….	5

2. Compared to one year ago, how would you rate your health in general now?

(circle one)

Much better now than one year ago	…….	1
Somewhat better than one year ago	…….	2
About the same as one year ago	…….	3
Somewhat worse than one year ago	…….	4
Much worse now than one year ago	…….	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

Activities	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling or stooping	1	2	3
Walking more than a mile	1	2	3
Walking half a mile	1	2	3
Walking one hundred yards	1	2	3
Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	Yes	No
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort	1	2

5.During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	Yes	No
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(circle one)

Not at all	……	1
Slightly	……	2
Moderately	……	3
Quite a bit	……	4
Extremely	……	5

7. How much bodily pain have you had during the past 4 weeks?

(circle one)

None	…….	1
Very mild	…….	2
Mild	…….	3
Moderate	…….	4
Severe	…….	5
Very severe	…….	6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all	……..	1
A little bit	……..	2
Moderately	……..	3
Quite a bit	……..	4
Extremely	……..	5

9. These questions are about how you feel and how things have been with you during the past 4 weeks.
For each question please give the one answer that comes closest to the way you have been feeling.
How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and low?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

(circle one)

All of the time ……. 1
Most of the time ……. 2
Some of the time ……. 3
A little of the time ……. 4
None of the time ……. 5

11. How TRUE or FALSE is each of the following statements to you?

(circle one number on each line)

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get ill more easily than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5

Bariatric Analysis and Reporting Outcome System

BAROS

Weight Loss % of Excess Wt. or % of Excess BMI (POINTS)	Medical Conditions (POINTS)	Moorehead-Ardelt QUALITY OF LIFE QUESTIONNAIRE II
Weight Gain (-1)	Aggravated (-1)	MOOREHEAD - ARDELT QUALITY OF LIFE QUESTIONNAIRE SELF ESTEEM, AND ACTIVITY LEVELS *Please make a check in the box provided to show your answer.* 1. Usually I Feel... (Very Badly About Myself — Very Good About Myself) 2. I Enjoy Physical Activities... (Not At All — Very Much) 3. I Have Satisfactory Social Contacts... (None — Very Many) 4. I Am Able to Work... (Not At All — Very Much) 5. The Pleasure I get Out Of Sex Is... (Not At All — Very Much) 6. The Way I Approach Food Is... (I Live to Eat — I Eat to Live)
0 – 24 (0)	Unchanged (0)	
25 – 49 (1)	Improved (1)	
50 – 74 (2)	One major resolved Others improved (2)	
75 – 100 (3)	All major resolved Others improved (3)	
SUB TOTAL	SUB TOTAL	SUB TOTAL

COMPLICATIONS:
Minor: Deduct 0.2 point
Major: Deduct 1 point

REOPERATION:
Deduct 1 point

TOTAL SCORE

OUTCOMES GROUP SCORING

Failure	≤ 1
Fair	> 1 to 3 points
Good	> 3 to 5 points
Very Good	> 5 to 7 points
Excellent	> 7 to 9 points

SEMI STRUCTURED INTERVIEW

1) Qualitative data was collected by a plastic surgery registrar (NAH) trained in psychotherapy. The semi-structured interview was conducted in a quiet clinic room at St John's Hospital in Livingston or the RIE. The interviewer was blinded to the psychometric scores.

    a) Career Progression

        i) Have you noticed a change in your career either in terms of financial remuneration or career progression/ change in status/responsibilities since your procedure?

    b) Relationships

        i) What are the attitudes of your family and peers to you during this weight loss process?

        ii) Do you have any sexual intimate relationships?

        iii) Are you experiencing any change in this relationship since your procedure?

    c) Healthy Lifestyle Choices

        i) What is your attitude to exercise?

        ii) (In smokers/ ex-smokers) What is your attitude to smoking?

        iii) How do you feel about the possibility of sustaining long term weight loss?

    d) Identity

        i) How do you feel about your body image?

    e) Lifestyle and everyday living

        i) How has your life health changed since your procedure?

    f) Which factors from the psychological scores were most relevant to you?

    g) Are you experiencing anything which has not been captured in the psychological scores that you think is important?

Wednesday, 13 October 2010

Protocol for 3D Photographs for Patients

The patients will be standing with their neck, iliac crests and Achilles tendon measured from the wall at the certain points.
The patients will stand with their hands on the lateral aspect of the hips
The patients will have their 3D photograph taken from the anterior view only. However, it is imperative that the breast is captured to the full extent laterally.

The photographs should be taken to capture the patients from their neck to the knees. Please set up the tripod on which the cameras are held, to be at this level.

There will be no other angles of 3D photographs.

The patients will still have 2D photographs taken from the anterior and posterior aspect.

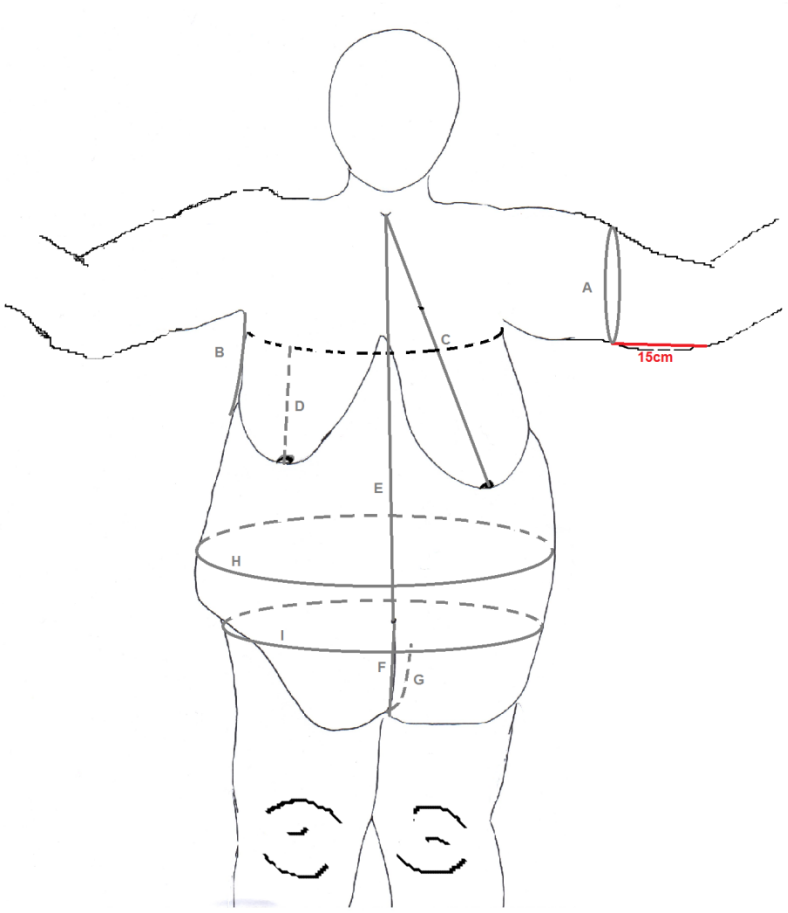
Appendix A

All surface linear measurements to be taken as follows:

Same metric plastic tape measure used with accuracy to 1mm. It was laid on the patient without any tension and with no compression of tissue. When measurements are taken on the underside of ptotic skin folds, the tape measure is held in place at the origin draped over the skin fold, as it is reflected back to enable measurement.
Each measurement was taken 3 times to ensure accuracy.
Patient undressed except for pants, standing straight with no shoes on

Position on Diagram	Measurement	Description
A	Arm circumference	With the patient abducting arms to 90 degrees. Circumferential measurement taken 15cm proximal from bony prominence of olecranon.
B	Apex of axilla to lateral folds	Linear measurement from apex of axilla to crease of final lateral fold in mid axillary line.
C	Suprasternal notch to left and right nipples	Linear measurement from superior border of the manubrium to each nipple (not the areola).
D	Nipple to inferior mammary folds	Linear measurement along the breast meridian taken to infra mammary fold.
E	Suprasternal notch to umbilicus	Linear measurement from superior border of manubrium to superior border of umbilicis
F	Umbilicus to pannus (a)	Linear measurement from inferior border of umbilicus to inferior border of pannus
G	Pannus to pubic symphysis (b)	Linear measurement from inferior border of pannus, under the skin fold to the pubic symphysis.
	Umbilicus pubic symphysis (a+b)	Linear measurement from inferior border of umbilicus to bony prominence of pubic symphysis. Where a large pannus was present, the tape was draped over the surface and wrapped under the fold before reaching the pubic symphysis. This measurement was taken to ensure that measurements were reliable and reproducible.
H	Waist circumference:	Circumferential measurement taken at the narrowest point of the abdomen.
I	Hip circumference:	Circumferential measurement taken in line with the anterior superior iliac spines.

Note:
Grey lines represent measurements taken.
The dotted lines represent the posterior aspect of the marking.


A
B
C
D
E
H
I
F
G
15cm

BAPRAS Survey

1. Please select your NHS practice location by city and hospital.
2. How many massive weight loss (MWL) body contouring procedures do you perform on average per year in your NHS practice?
    - ≤5
    - 6-10
    - 11-20
    - ≥20
3. What percentage of your MWL body contouring patients have a peri-operative BMI of:
    - <27
    - 27-30
    - 31-39
    - ≥ 40
4. Are you part of a bariatric surgery MDT ?
    - Yes
    - No
    - No – but I would like to be
5. What difficulties does your unit have regarding surgery for the MWL patient ?
    - No difficulties
    - Additional training needed
    - Funding not available
    - No bariatric MDT
    - Surgeons not interested in this work
    - Trust not supportive
    - Other (please specify)
6. Do you consider MWL body contouring to be aesthetic or functional surgery?
    - Aesthetic
    - Functional
    - Both
7. Do you think body contouring surgery should be funded by the NHS?
    - Yes
    - No
    - Do not know
8. Which of the following should be funded by the NHS in MWL patients?
    - Face lift
    - Neck left
    - Brachioplasty
    - Mastopexy
    - Reduction mammoplasty
    - Interim apronectomy/panniculectomy
    - Abdominoplasty
    - Lower body lift
    - Mons lift
    - Buttock lift
    - Thigh lift
    - Liposuction
9. Should NHS funding for MWL body contouring be conditional on healthy lifestyle choices?
    - Yes
    - No
    - Don’t know
10. Would you find clear national guidelines on patient selection criteria for MWL body contouring helpful?
    - Yes
    - No
    - Don’t know

11. What should national guidelines include?
    - Age
    - BMI (current)
    - Career progression

Dieting behaviour (current)
Exercise status
Functional morbidity
Indication of patient's perception of severity of disfigurement
Length of weight stability
Length of pannus
Lipodystrophy
Past medical history
Percentage excess weight loss
Psychological morbidity
Relationship status
Skin conditions as a result of excess skin
Smoking status
Support from friends and relatives
Active delusional or schizophrenic illness
Birth of a child
Body dysmorphic disorder
Death of a close family member in last 12 months
Eating disorder
History of self-harm in last 2 years
Major depressive illness
Obsessive compulsive disorder
Substance abuse problem
None
Other (please specify)

BAPRAS
British Association of Plastic Reconstructive and Aesthetic Surgeons

RCS
ADVANCING SURGICAL STANDARDS

2014

Commissioning guide:

Massive Weight Loss Body Contouring

Sponsoring Organisation: British Association of Plastic, Reconstructive and Aesthetic Surgeons
Date of evidence search: March 2013
Date of publication: March 2014
Date of Review: March 2017

NICE accredited
www.nice.org.uk/accreditation

NICE has accredited the process used by Surgical Speciality Associations and Royal College of Surgeons to produce its Commissioning guidance. Accreditation is valid for 5 years from September 2012. More information on accreditation can be viewed at www.nice.org.uk/accreditation

CONTENTS

Executive Summary

This document is about guidance for commissioning reconstructive procedures, post massive weight loss and is based on the best available evidence.

General criteria for body contouring surgery

- Age over 16 years
- Starting BMI above 40kg/m^2 or above 35kg/m^2 with co-morbidities AND current BMI of less than or equal to 28.0kg/m^2 AND weight stability of 12 months AND significant functional disturbance (both physical and psychological)

Exceptions to general criteria

- Starting BMI above 40kg/m^2 or above 35kg/m^2 with co-morbidities and 75% excess body weight – should be eligible for apronectomy only - if they are unable to slim down to a BMI of 28 or less. A BMI of up to 40kg/m^2 can be considered here.
- Weight stability of 12 months and significant functional disturbance applies here too.

Key Recommendations

- Request for central funding for body contouring surgery
- Development of registry of operations and complications (+/- quality of life measures) to which patient data are mandatorily submitted
- National use of referral document for GPs for body contouring surgery (Appendix 1)

This guidance will be reviewed in 2017.

Glossary

Term	Definition
Body mass index (BMI)	A measure for human body shape based on an individual's weight and height. BMI = body weight in kilograms / height in meters squared
Excess body weight	Calculation of change of BMI relative to a maximum normal BMI of 25kg/m^2
Massive weight loss	Loss of 50% or more excess body weight
SF-36v2®	QualityMetric's SF-36v2® health survey asks 36 questions to measure functional health and wellbeing from the patient's point of view. It is a practical, reliable and valid measure of physical and mental health that can be completed in five to ten minutes. For more information visit: http://www.qualitymetric.com/WhatWeDo/SFHealthSurveys/SF36v2HealthSurvey/tabid/185/Default.aspx

Significant functional disturbance	This includes infections, disability, time in hospital, smell, excoriation, severe intertrigo, evidence of significant interference with activities of daily life, ulceration and psychological disturbance (e.g. depression)
Weight stability	Weight stability described in this document allows for a maximum of 5kg increase or a 5kg decrease in weight.

Introduction

Body contouring surgery is reconstructive surgery following massive weight loss.

In 2010, 65.1% of all adults aged 16 years and over were overweight or obese. Morbid obesity rates (body mass index (BMI) ≥40kg/m^2) increased from 1.2% in 1995 to 2.7% in 2003, and fluctuated between 2.2% and 2.7% between 2008 and 2010.

Weight loss surgery or bariatric surgery is commissioned nationally across England. In adults with a BMI of more than 40kg/m^2 (or more than 35kg/m^2 with co-morbidities) in whom surgical intervention is considered appropriate, bariatric surgery is recommended as a treatment option in the National Institute for Health and Clinical Excellence (NICE) guidelines.[1]

As a result of the drive to tackle obesity, there are increasing numbers of patients with massive weight loss and skin redundancy. This has led to post-weight loss deformities of loose, ptotic skin envelopes and residual adiposities with resultant contour irregularities.[2] The resultant redundant skin presents new quality of life concerns in a range of areas such as mobility, decreased activity, body image dissatisfaction[3] and depression.[4] The excess skin causing physical discomfort, psychosocial problems, lost work days/productivity and concern about quality of life[5] in general has led to an increasing uptake of body contouring surgery,[6] to manage the complex problems[7] that span multiple parts of the body after massive weight loss.

NICE guidelines state that surgery for obesity should only be undertaken by a multidisciplinary team that can provide expertise including psychological support before and after surgery as well as information on or access to plastic surgery where indicated.[1] According to the 2004 review of bariatric surgical services in Scotland:[8]

- Plastic surgery is an integral part of an overall bariatric surgical service.
- Criteria for patients undergoing plastic surgery must be clearly defined.
- The number of patients being referred for this type of surgery is small at present but is likely to increase in the foreseeable future. This will have implications for waiting lists.

Variation of provision

In England there is no standardised guidance for provision of body contouring following massive weight loss. In a recent study carried out by Mukherjee *et al*, out of the 67 respondents of 147 of the primary care trusts in England, only 54 had referral guidelines for plastic surgery and 23 excluded all post-bariatric surgery body contouring procedures.[9] According to a study carried out by Butler, 95.1% of plastic surgery units in the country

offer some form of reconstructive surgery following massive weight loss, with a large variation of what is available between each unit, and 4.9% of units do not offer any surgery owing to lack of primary care trust funding.[10,11] Butler found that 56% of units do not offer psychology or psychiatry screening, for 14% this information was unknown and only 24% of all the plastic surgery units in the UK offer it routinely.

A recent study [12] showed that 37.7% of patients who were approved in Scotland for post-bariatric body contouring would not have fulfilled the Leeds criteria,[13] which set out the funding request policy for low volume services or treatments that are not routinely commissioned. This is another example of the postcode lottery that exists for the commissioning of plastic surgery services.[14, 15]

Access to body contouring surgery

According to a cohort study published in 2013, of 34 patients who had not yet applied for plastic surgery, 13 had been told by their general practitioners (GPs) that they would not qualify for plastic surgery on the National Health Service despite losing more than 75% of their excess body weight.[12]

Why is this surgery a priority?

Research demonstrates significant improvements in patients' physical function, emotional wellbeing, body image satisfaction, identity shifts, sexual vitality, greater wellbeing and quality of life once they have undergone body contouring surgery following massive weight loss.[16-18] Highton *et al* found that 92% of 86 surgeon members of the British Obesity and Metabolic Surgery Society felt that patients face functional problems relating to skin redundancy after massive weight loss and a high percentage of patients complain about this problem.[19]

One series of 122 patients (2000–2005) were reviewed for patient satisfaction and quality of life.[20] Another retrospective case series (12 years) involving 151 central body lifts revealed both patient and physician satisfaction.[21] Neither of these studies had comment on the methods or instruments used for quality of life measures. Klassen *et al* demonstrated an improvement in quality adjusted life years following massive weight loss body contouring.[22]

Al-Hadithy et al demonstrated that the QualityMetric SF-36® health survey parameters for physical function, bodily pain, general health, vitality and overall physical health are significantly better in bariplastic surgery patients than in those who only had bariatric surgery. Previous studies have shown that physical dimensions of the SF-36® improve after bariatric surgery[23] and other studies have demonstrated that body image and quality of life improves following abdominoplasty in non-bariatric[24] and bariatric patients.[25, 26] Early data demonstrate a greater change in physical health and functional outcome over psychological outcome for the patients who had received body contouring surgery. Following plastic surgery in the bariatric population patients had more active lifestyles, improved self-confidence and greater career progression.[27, 28]

1 High value care pathway for body contouring surgery

Referral pathway

Referral to plastic surgery should be encouraged through the primary care sector if the patient fulfils the criteria, using the referral tool (Appendix 1).

Psychological assessment should be included as part of the patient pathway, to be undertaken by a clinician with experience in treating obese patients. If patients have been referred through a bariatric multidisciplinary team, then the psychological assessment is unlikely to need repeating but if no previous psychological assessment has been performed, this will need to be arranged prior to referral to plastic surgery.

General criteria for body contouring surgery

- Age over 16 years
- Starting BMI above 40kg/m^2 or above 35kg/m^2 with co-morbidities AND current BMI of less than or equal to 28.0kg/m^2 AND weight stability of 12 months AND significant functional disturbance (both physical and psychological)

Body contouring surgery creates large wounds. The current evidence favours this surgery when patients have 'fully deflated'. Performing BCS at higher BMI's is associated with higher risk of complications.[29-44] After reviewing British Obesity & Metabolic Surgery Society (BOMSS) input the group decided to increase the BMI from 27 to 28 for reconstructive body contouring surgery. This BMI level is considered safe for surgery.

Exceptions to general criteria

- Starting BMI above 40kg/m^2 or above 35kg/m^2 with co-morbidities and 75% excess body weight – should be eligible for apronectomy **only** – if they are unable to slim down to a BMI of 28 or less. A BMI of up to 40kg/m^2 can be considered here.
- Weight stability of 12 months and significant functional disturbance applies here too.

Exclusion criteria

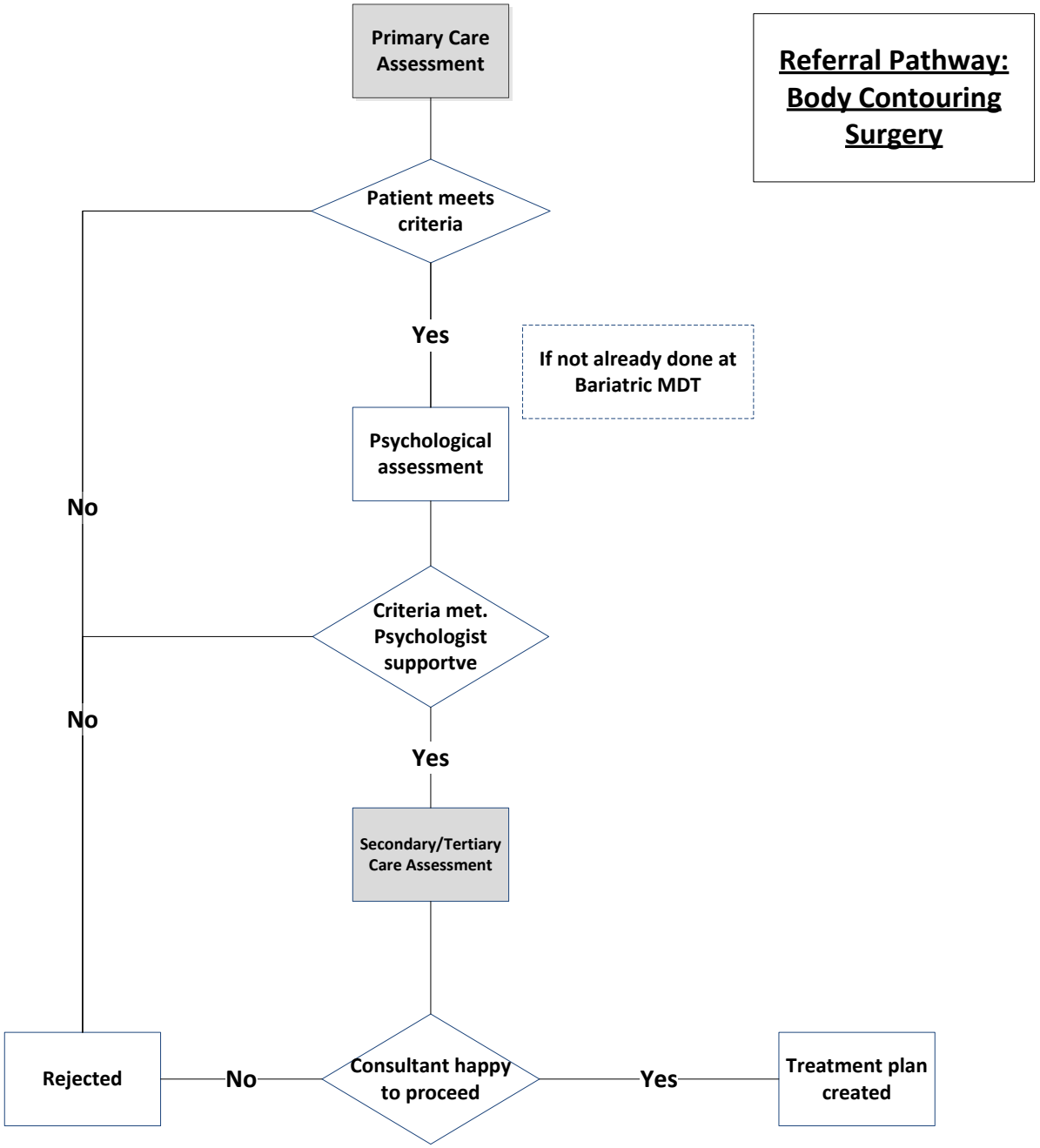
- Current smoker
- Active psychiatric or psychological condition that would benefit from diagnosis and treatment prior to referral for body contouring surgery or that would contraindicate surgery including:[25]
  - patients who have had an episode of self-harm within the last two years;
  - patients with a previous diagnosis of body dysmorphic disorder;
  - patients with a disproportionate view of the problem following consultation with a consultant Plastic Surgeon;
  - patients who currently have on going alcohol or drug misuse problems.

NB: General health, social and lifestyle issues should also be taken into account before offering body contouring surgery to patients

If a patient meets the criteria for body contouring surgery, the GP may begin the pathway to surgery. If a patient is very deserving of surgery, but does not meet all the criteria, they can still be considered via the exceptional circumstances route. This will involve the completion of an IFR (individual funding request) form by the GP, and if approved the pathway may proceed to psychological and consultant plastic surgical assessment.

Where should surgery be undertaken?

Body contouring surgery should be undertaken at a centre where there is a bariatric multidisciplinary team or integrated links to a bariatric multidisciplinary team.



2 Procedures explorer for body contouring surgery

Users can access further procedure information based on the data available in the quality dashboard to see how individual providers are performing against the indicators. This will enable CCGs to start a conversation with providers who appear to be 'outliers' from the indicators of quality that have been selected.

The Procedures Explorer Tool is available via the Royal College of Surgeons website.

3 Quality dashboard for body contouring surgery

The quality dashboard provides an overview of activity commissioned by CCGs from the relevant pathways, and indicators of the quality of care provided by surgical units.

The quality dashboard is available via the Royal College of Surgeons website.

4 Levers for implementation

4.1 Audit and peer review measures

The following measures and standards are those expected at primary and secondary care. Evidence should be able to be made available to commissioners if requested.

Measure	Standard
BMI	Provider demonstrates adherence to BMI eligibility criteria
Multidisciplinary team (MDT) status	Provider has MDT in place or can demonstrate integrated links to MDT
Body contouring database	Provider can demonstrate collection of data

4.2 Quality specification/CQUIN (Commissioning for Quality and Innovation)

Measure	Description	Data specification (if required)
Referral	Referral for bariatric surgery patients as well as for patients who have lost weight through diet and exercise	Hospital data
Readmission rates for complications	Provider demonstrates a readmission rate of <10%	Data available from Hospital Episode Statistics
Psychological evaluation in patient pathway	Provider demonstrates access for patients to psychological evaluation, to be undertaken by a clinician with experience in treating obese patients	
Aspirational: patient reported outcomes measures	Provider can demonstrate collection of patient satisfaction and patient reported outcomes measures, for example by completing pages 3-5 of the referral tool at last plastic surgery clinic appointment	

5 Directory

5.1 Patient information for body contouring surgery

Name	Publisher	Link
Body reshaping – patient information guide	BAPRAS	http://www.bapras.org.uk/guide.asp?id=252

5.2 Clinician information for body contouring surgery

Name	Publisher	Link
Up-dated adult exceptional aesthetic referral protocol (June 2011)	NHS Scotland	http://www.sehd.scot.nhs.uk/mels/CEL2011_27.pdf
G43 Obesity: NICE guideline	NICE	http://guidance.nice.org.uk/CG43/NICEGuidance/

5.3 NHS Evidence case studies for body contouring surgery

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6 Benefits and risks of implementing this guide

Consideration	Benefit	Risk
Patient outcome	Ensure access to effective conservative, medical and surgical therapy. Reduce long-term follow-up for the chronic complications of skin redundancy (psychology, dermatology, clinical nurse specialist, physiotherapy).	Unrecognised deterioration on conservative therapy
Patient safety	Surgery will be undertaken in a specialist centre with appropriate support for the massive weight loss patient.	
Patient experience	Improve access to patient information, support groups and equitable access to body contouring service.	
Equity of access	Improve access to effective procedures.	
Resource impact	Reduce unnecessary referral and intervention. If referral pathway and tool use, streamline referral process, reduce consultant clinic time wastage and ensure audit	Resource required to establish MDT

of outcomes.

7 Further information

7.1 Research recommendations

- Research should be undertaken into the true cost of body contouring surgery. Cost varies across the UK and proper research is required to understand the average fee. 7.2 Other recommendations

- Request for central funding for body contouring surgery
- Development of registry of operations and complications (+/- quality of life measures) to which patient data are mandatorily submitted
- National use of referral document for GPs for body contouring surgery (Appendix 1)
- Wide dissemination of useful information on body contouring surgery to primary care and public (cf patient information leaflet)
- Patient support groups to be notified of this guidance
- Professional organisations (BAPRAS media company) can assist in disseminating the guidance information.
- GP surgeries need access to the guidance
- Appendix 1 data to be centrally collated at BAPRAS for use in further research.
- A review of the current evidence to be carried out in 5 years, and guidance adjusted according to new evidence.

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7.4 Guide development group for Body contouring surgery

A commissioning guide development group was established to review and advise on the content of the commissioning guide. This group met once, with additional interaction taking place via email.

Name	Job Title/Role	Affiliation
Mark Soldin, Chair	Consultant Plastic Surgeon	BAPRAS
Fiona Hogg	Consultant Plastic Surgeon	BAPRAS
Jane Deville-Almond	Patient Representative	Chair, British Obesity Society
Ken Clare	Patient Representative	Chair, Weight Loss Surgery Info
Elaine Sassoon	Consultant Plastic Surgeon	BAPRAS
Isabel Teo	Plastics Registrar	BAPRAS
Nada Al-Hadithy	Plastics Registrar	BAPRAS
Maleeha Mughal	Plastics Registrar	BAPRAS
Jo Gilmartin	Lecturer in Health and Psychology	Leeds University
Kiranmayi Penumaka	GP	Halesowen Central Medical Practice
Nick Wilson-Jones	Consultant Plastic Surgeon	BAPRAS
Richard Welbourn	Consultant General Surgeon; President, British Obesity and Metabolic Surgery Society	British Obesity and Metabolic Surgery Society
Steve Lloyd	Chair	Hardwick CCG

7.5 Funding statement

The development of this commissioning guidance has been funded by the following sources:

- DH Right Care funded the costs of the guide development group, literature searches and contributed towards administrative costs.
- The Royal College of Surgeons of England and the British Association of Plastic, Reconstructive and

Aesthethic Surgeons provided staff to support the guideline development.

7.6 Conflict of Interest Statement

Individuals involved in the development and formal peer review of commissioning guides are asked to complete a conflict of interest declaration. It is noted that declaring a conflict of interest does not imply that the individual has been influenced by his or her secondary interest. It is intended to make interests (financial or otherwise) more transparent and to allow others to have knowledge of the interest.

The following interested were declared by the group:

Name	Job title/role	Declared interest
Miss Fiona Hogg	Consultant Plastic Surgeon	• Received fees from Ethicon to attend education events on massive weight loss body contouring surgery
Dr Jo Gilmartin	Lecturer in health and psychology	• Received pump priming funds for undertaking quality of life research which contributed to the commissioning guide
Mr Mark Soldin	Consultant Plastic Surgeon	• Received pump priming funds for undertaking quality of life research which contributed to the commissioning guide • Runs a private clinic in South West London
Miss Nada Al-Hadithy	Plastic Registrar	• Received funding from the William Rainey Foundation to undertake Doctor of Medicine (MD) study
Mr Richard Welbourn	Consultant General surgeon	• Occasional mentorship fees for surgeons visiting the unit paid to employer – none received in 2013 • Sponsorship for attending conferences from Ethicon Endo-Surgery within the last year, previous sponsorship from Allergan and Covidien for attending conferences / courses and writing fees for published articles (in newsletters)

Appendix 1

The British Association of Plastic, Reconstructive and Aesthetic Surgery Post Bariatric Outcome Tool

What is the British Association of Plastic, Reconstructive and Aesthetic Surgery (BAPRAS) Post Bariatric Outcome Tool? (PBOT)

The underlying construct being measured is adjustment (psychological and functional) to problems of massive weight loss and massive weight loss body contouring (MWLBC). From a psychological perspective, this will manifest differently for each individual respondent. However, we believe that the basic structure of adjustment is common across most people. Adjustment comprises negative emotions of fear, social anxiety, shame and negative affect along with behavioural response of avoidance and withdrawal that frequently disrupts lifestyle. We believe that we have captured this in the patient reported outcome measure (PROM) with contextually relevant questions specific to this unique cohort of patients.

Description of the BAPRAS PBOT

The BAPRAS PBOS is a 77 item scale designed to fulfil thee purposes:

1. To streamline the referral process and ensure those patients being referred meet the national guidelines.
2. To measure distress and dysfunction due to problems of the side effects of massive weight loss.
3. To quantify patient reported outcomes following massive weight loss body contouring.

Referral Tool Component

The first 2 pages are to be completed by the referring doctor with the patient. In the UK, this is usually the general practitioner (GP). Page 1 facilitates the collection of demographic and clinical information relevant to patients considering massive weight loss body contouring. Page 2 collates known problems with excess skin, functional and psychological morbidity, past medical history and drug history.

PROM Component

The third to fifth pages are to be completed by the patient. This consists of questions for further demographic data collection and post-operative complication history which will aid screening of appropriate patients for surgery; and identify: adjustment to massive weight loss; functional impairment and perception of disfigurement.

There are two diagrams. One is a visual prompt so that the patient can highlight areas of concern on his/her body. The other is a visual analogue scale of how he/she perceives his/her size. The second visual analogue scale should be compared with the clinical photographs of the patient to identify how closely the patient's perception of his/her body image reflects objective assessment of the clinical photograph by the MDT panel.

The final part of the questionnaire is a blank space for patients to include any additional information they feel is important.

Administering the Score

The PBOT should be completed before referral to the plastic surgery unit, and will be reviewed with clinical photographs by the massive weight loss body contouring multi-disciplinary team (MDT). It can also be used at 3 months, 6 months and/or 1 year+ post massive weight loss body contouring in order to measure outcomes in this group of patients.

Scoring

Of the 77 items on the questionnaire, there are 41 items to score for the two components.

Score Component	Questions to Score	Minimum	Maximum
Referral Tool (Pages 1-2)	14 (of 30)	-26	16
PROM Component (Pages 3-5)	27 (of 47)	20	132

Referral Component Rules

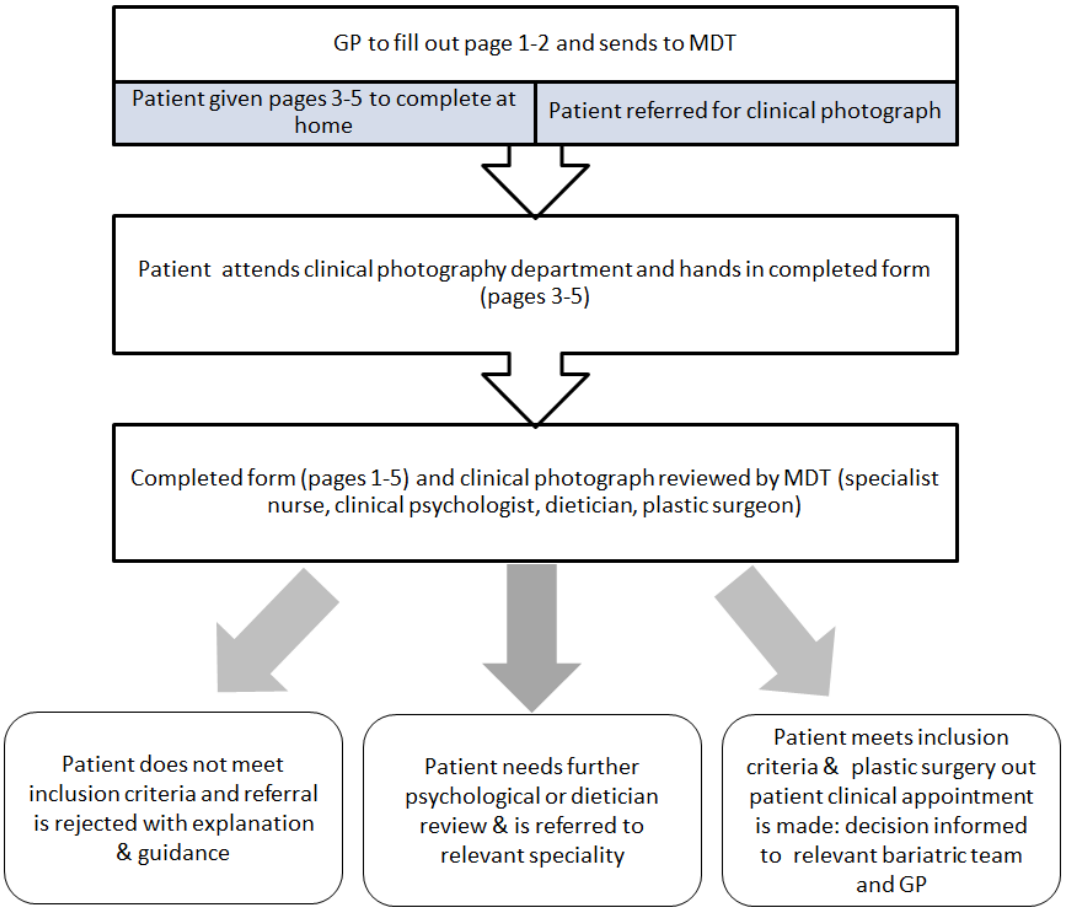
The referral component part of the PBOT directly reflects the inclusion criteria from the BAPRAS National Body Contouring Commissioning Guidelines.

When marking the referral tool component, to qualify for next stage of screening process for massive weight loss body contouring they must score > 8: points in the referral tool. Of these 8 points, 3 must come from the first 3 questions, i.e., the patients must score at least 1 for questions 1-3.

ANY psychiatric history should warrant referral to clinical psychologist for further enquiry.
ANY patients who have a discrepancy of more than 2 points between their self-assessment on the visual analogue scale of size and shape and the objective assessment of the panel should warrant referral to the clinical psychologist.

PROM Score Rules

The PROM component of the PBOT is a means of identifying which patients are adjusting to their new body habitus and which patients are having difficulty with coming to terms with their new shape. It is also a method of collecting data on satisfaction with the care they received, outcomes and contour. It will not alter which patients will meet the inclusion criteria for provision of massive weight loss body contouring on the NHS but should help collect data on this new cohort of patients to provide the best evidence based care in the future.


GP to fill out page 1-2 and sends to MDT
Patient given pages 3-5 to complete at home
Patient referred for clinical photograph
Patient attends clinical photography department and hands in completed form (pages 3-5)
Completed form (pages 1-5) and clinical photograph reviewed by MDT (specialist nurse, clinical psychologist, dietician, plastic surgeon)
Patient does not meet inclusion criteria and referral is rejected with explanation & guidance
Patient needs further psychological or dietician review & is referred to relevant speciality
Patient meets inclusion criteria & plastic surgery out patient clinical appointment is made: decision informed to relevant bariatric team and GP

Appendix 2: Referral Tool

Pages 1-2: For the referrer to complete			
Patient name:			Date of referral:
Date of birth: NHS number:			Name of referrer:
Address:			Address:
Phone number:			Phone number:
Funding secured:	Yes ☐	No ☐	Email:

Maximum ever weight (kg):	Weight lost (kg):	Current weight (kg):	Current height (m):

Length of time maintained at current weight:	Weight fluctuation of ≥5kg in the last 6 months? Yes ☐ No ☐

Plastic surgery procedure desired:	1. 2.

Method of weight loss: please select any applicable from below:					
Diet	☐	Exercise	☐	Surgery	☐

Type of Bariatric Surgery			Not Applicable (please move on) ☐		
		Date & Details	Surgical Approach Please select one from below:		Date
Gastric Balloon	☐				
Gastric band	☐		Laparoscopic	☐	
Gastric sleeve	☐		Lap converted to open	☐	
Roux en Y	☐		Open	☐	
Duodenal Switch	☐				
Complications or additional information					

As a **result of the excess skin** the patient suffers with (please tick all that apply):						
Skin condition	Dermatitis ☐	Hidradenitis ☐	Intertrigo ☐	Infection ☐	Lymphoedema ☐	Ulceration ☐
Evidence of Functional impairment	Yes ☐ Give details:					No ☐
Evidence of Psychological impairment	Yes ☐ Give details:					No ☐

Past Medical History: Please write:		
Please tick if there is any history of the following:		Date of diagnosis & details
Active delusional or schizophrenic illness	☐	
Body dysmorphic disorder	☐	
Eating disorder	☐	
History of self-harm in last 2 years	☐	
Major depressive illness	☐	
Obsessive compulsive disorder	☐	
Substance abuse problem	☐	

Psychiatric History: (Please write)	
Drug History: Please write:	Any history of recreational drug use? Please give information
Allergies:	

Any additional information:

Page 3-6: For the patient to complete		
Patient Name:	Date of Completion:	Date of Birth:

Describe and date the surgery you have had for weight loss and body contouring:
Describe any complications you may have experienced from the surgery above:

Have you had any weight fluctuation in the last 6 months? (Tick the box which applies to you)	None ☐	0-5kg ☐	>5-10kg ☐	>10-20kg ☐	>20kg ☐

For the above surgery please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I am satisfied with the medical care I received					
I am satisfied with the outcome of my most recent surgery					
I am satisfied with my scar					
I am satisfied with my contour					

Have you **ever** smoked?	What was the most you **ever** smoked?		**If you are smoking now**, how much do you smoke?	
☐ Yes ☐ No (move onto the next question)	Very rarely	☐	Very rarely	☐
	Socially (≤2 cigarettes per week)	☐	Only socially (≤2 cigarettes per week)	☐
	< 5 cigarettes per day	☐	< 5 cigarettes per day	☐
	5-10 cigarettes per day	☐	5-10 cigarettes per day	☐
	11-20 cigarettes per day	☐	11-20 cigarettes per day	☐
	21-40 cigarettes per day	☐	21-40 cigarettes per day	☐
	>40 cigarettes per day	☐	>40 cigarettes per day	☐
If you have quit, when did you quit:				

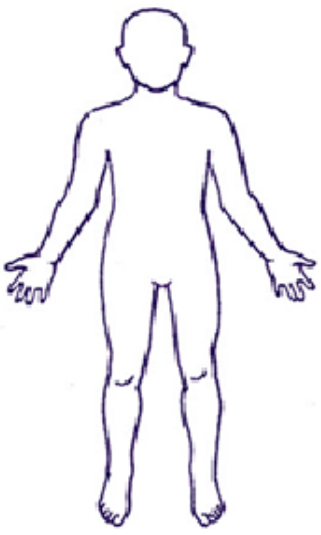
Marital status (please check one):	Please tick	Current occupation (please write): _____		Please describe what you eat on a daily basis:
Single	☐	Full time employment	☐	
Married	☐	Self employed	☐	
Divorced	☐	Part time employment	☐	
Separated	☐	Student	☐	
Widowed	☐	Unemployed	☐	

Living with significant other	☐	Other:_____		
Have you had a pregnancy in the last 12 months?	No ☐	Yes ☐	Please give details	
Have you experienced the death of a close family member in last 12 months?	No ☐	Yes ☐	Please give details	
Have you experienced a relationship breakdown in the last 12 months?	No ☐	Yes ☐	Please give details	

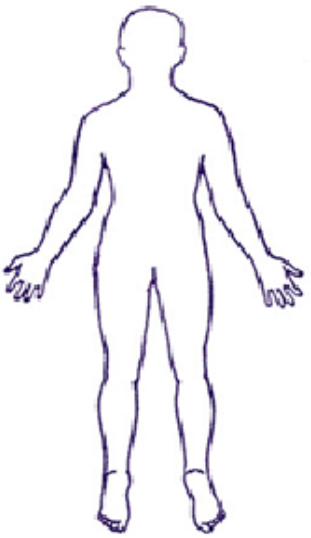
How frequently do you exercise?		If you exercise, how long do you exercise each time?		Where do you do most of your exercise?	
Not at all	☐	Less than 15 minutes	☐	Inside	☐
Once per month or less	☐	15 - 30 minutes	☐		
Several times per month	☐	31 - 60 minutes	☐	Outside	☐
Once per week	☐	61 - 120 minutes	☐		
Several times per week	☐	More than 120 minutes	☐		
Once per day	☐				
Several times a day	☐				

If you exercise, please indicate the types of exercise you do (fill in all that apply).									
Cycling	☐	Stationary bike	☐	Swimming	☐	Stairmaster	☐	Zumba	☐
Running	☐	Treadmill	☐	In-line skating	☐	Weight training	☐	Aerobics	☐
Walking	☐	Cross trainer	☐	Dancing	☐	Yoga	☐	Pilates	☐
Other (please write):									

Is there a part of your appearance that you are concerned with? Use the diagram to record where and write why you are concerned:



Front



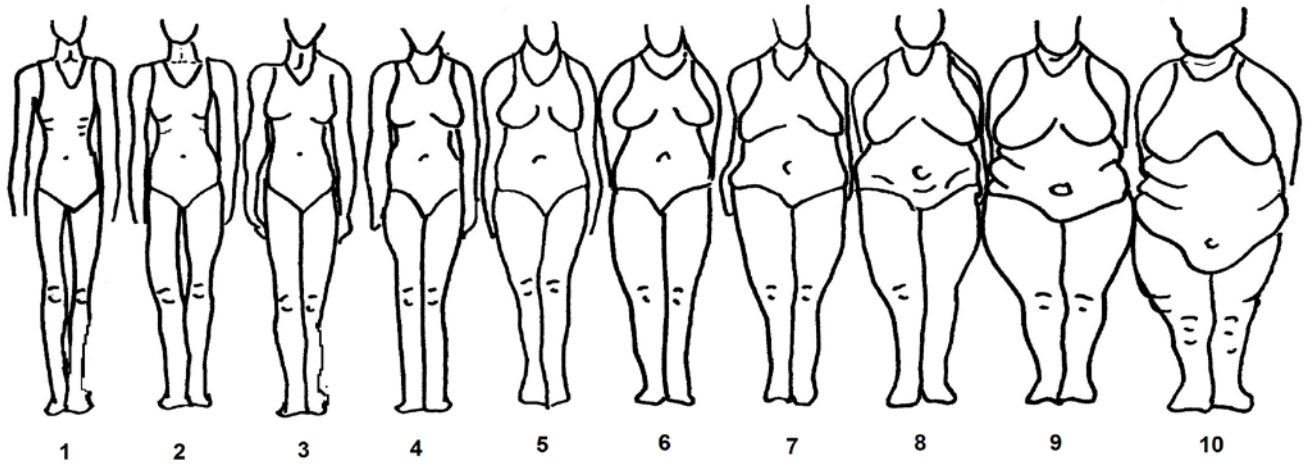
Back

Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
I find it difficult to move around					
I avoid going out of the house					
I get distressed when I see myself in the mirror					
I have problems finding clothes that fit					
I am unable to exercise as much as I would like					
I feel uncomfortable getting undressed in front of my partner					
There is an adverse outcome on my sex life					
I have physical pain					
I am limited in what I can do during the course of a typical day					
I am unable to interact with my family as I would like					
I find it difficult to socialise					
There is an adverse outcome on my professional life					
I am unhappy with my physical appearance					
I do not undress in front of other people (changing rooms)					
I am unable to independently perform some activities of personal hygiene (e.g. bathing, brushing my hair or wiping myself after the toilet)					

Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	☐
I can climb 1 flight of stairs without resting	☐
I can climb half a flight of stairs without resting	☐
I require a wheelchair	☐
I am housebound	☐

Activities of daily living	Please circle the choice that best suits you now			
In general my health is	Excellent	Good	Fair	Poor
I am able to work	Not at all	A little	Often	Very much
I am able to do the things I want to do	Not at all	A little	Often	Very much
I have satisfactory social contacts	Very many	Satisfactory	A few	None
I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all

Please select from the following scale, which image you think best represents your body size and shape.



Please write down any additional information you think is important:

Thank you for completing this form.
Please ensure it gets sent to the massive weight loss body contouring team at:

Referral Tool Mark Scheme

1. (Weight Lost/ (original weight-ideal weight)) x 100= percentage excess weight lost. (Where ideal weight = 25 x height $(m)^2$)	Mark	Tick which applies
≤49%	0	
50-100%	1	
>100%	2	

2. Current BMI = mass in kg/(height in m)2	Mark	Tick which applies
>30	-1	
>27-30	0	
26-27	1	
≤25	2	

3. Length of time maintained at current weight.	Mark	Tick which applies
<12 months	0	
>12 – 18 months	1	
>18 months	2	

4. Weight fluctuation ≥5kg in the last 12 months	Mark	Tick which applies
Yes	-2	
No	0	

5. Skin conditions	Points
Allocate one point for each condition (maximum 6)	

6. Evidence of functional impairment	Mark	Tick which applies
Yes	1	
No	0	

7. Evidence of psychological impairment	Mark	Tick which applies
Yes	1	
No	0	

8. Psychiatric History:	Mark	Tick which applies
Active delusional or schizophrenic illness	-1	
Body dysmorphic disorder	-1	
Eating disorder	-1	

History of self-harm in last 2 years	-1	
Major depressive illness	-1	
Obsessive compulsive disorder	-1	
Substance abuse problem	-1	

9. Any history of recreational drug use	Mark	Tick which applies
No	0	
Yes	-1	
10. Smoking History:	Mark	Tick which applies
Never smoked	1	
Quit smoking	0	
Smokes rarely	-1	
Smokes socially	-1	
Smokes <5 cigarettes per day	-2	
5-10 cigarettes per day	-3	
11-20 cigarettes per day	-4	
21-40 cigarettes per day	-5	
>40 cigarettes per day	-10	

Question	Mark	Tick which applies
11. Have you had a pregnancy in the last 12 months?		
No	0	
Yes	-1	
12. Have you experienced the death of a close family member in last 12 months?		
No	0	
Yes	-1	
13. Have you experienced a relationship breakdown in the last 12 months?		
No	0	
Yes	-1	

14 Patient's clinical photograph matches patient's self-selection of body image on scale	Mark	Tick which applies
Yes	1	
No	-2	
More than 2 points difference between patient assessment and objective assessment score by MDT panel should prompt a referral to psychologist		

Referral Tool total score _____

PROM Mark Scheme

In order to score, please circle the answers the patients used in their questionnaire.

At the end add up the total score.

1. Have you had any weight fluctuation in the last 12 months?	None	0-5kg	>5-10kg	>10-20kg	>20kg
	1	-1	-2	-3	-4
Please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
2. I am satisfied with the medical care I received	5	4	3	2	1
3. I am satisfied with the outcome of my most recent surgery	5	4	3	2	1
4. I am satisfied with my scar	5	4	3	2	1
5. I am satisfied with my contour	5	4	3	2	1

6. How frequently do you exercise?		If you exercise, how long do you exercise each time?	
Not at all	0	Less than 15 minutes	0.25
Once per month or less	1	15 - 30 minutes	0.50
Several times per month	2	31 - 60 minutes	1
Once per week	3	61 - 120 minutes	1.5
Several times per week	4	More than 120 minutes	2
Once per day	5		
Several times a day	6		

Score = frequency x exercise time =

Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
7. I find it difficult to move around	5	4	3	2	1
8. I avoid going out of the house	5	4	3	2	1
9. I get distressed when I see myself in the mirror	5	4	3	2	1
10. I have problems finding clothes that fit	5	4	3	2	1
11. I am unable to exercise as much as I would like	5	4	3	2	1
12. I feel uncomfortable getting undressed in front of my partner	5	4	3	2	1
13. There is an adverse outcome on my sex life	5	4	3	2	1
14. I have physical pain	5	4	3	2	1
15. I am limited in what I can do during the course of a typical day	5	4	3	2	1

16. I am unable to interact with my family as I would like	5	4	3	2	1
17. I find it difficult to socialise	5	4	3	2	1
18. There is an adverse outcome on my professional life	5	4	3	2	1
19. I am unhappy with my physical appearance	5	4	3	2	1
20. I do not undress in front of other people (changing rooms)	5	4	3	2	1
21. I am unable to independently perform some activities of personal hygiene (e.g. bathing, brushing my hair or wiping myself after the toilet)	5	4	3	2	1

22. Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	4
I can climb 1 flight of stairs without resting	3
I can climb half a flight of stairs without resting	2
I require a wheelchair	1
I am housebound	0

Activities of daily living	Please circle the choice that best suits you now			
23. In general my health is	Excellent	Good	Fair	Poor
	4	3	2	1
24. I am able to work	Not at all	A little	Often	Very much
	1	2	3	4
25. I am able to do the things I want to do	Not at all	A little	Often	Very much
	1	2	3	4
26. I have satisfactory social contacts	Very many	Satisfactory	A few	None
	4	3	2	1
27. I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all
	4	3	2	1

PROM total score_____

Dear Massive Weight Loss Body Contouring Commissioning Group,

I hope you are all well.
Thank you to Richard and Jo for getting back to me with extremely valuable feedback on the reporting tool.

In order to provide the best possible tool, I would be hugely grateful if you could have a look at the attached document and see if you think it would be useful.
As a GP - would this be something you would want to fill out?
As a registrar - would this be something you could ask the patients about?
As a consultant- would this streamline your clinics and ensure you select the best patients for surgery?
As a psychologist - would this tool provide you with useful baseline information?
As a patient - would this tool seem comprehensible and fair to you?

There are millions of other considerations - but a few of your very valuable thoughts will bolster this part of the commissioning guidelines and hopefully make the patient journey easier for all involved.

I would be super grateful for any thoughts, comments or ideas.
Thanks again
With warmest regards
Nada

Dear Darzi Fellow,

Re: Referral tool to aid referral to plastic surgery multi-disciplinary team (MDT) for body contouring following massive weight loss.

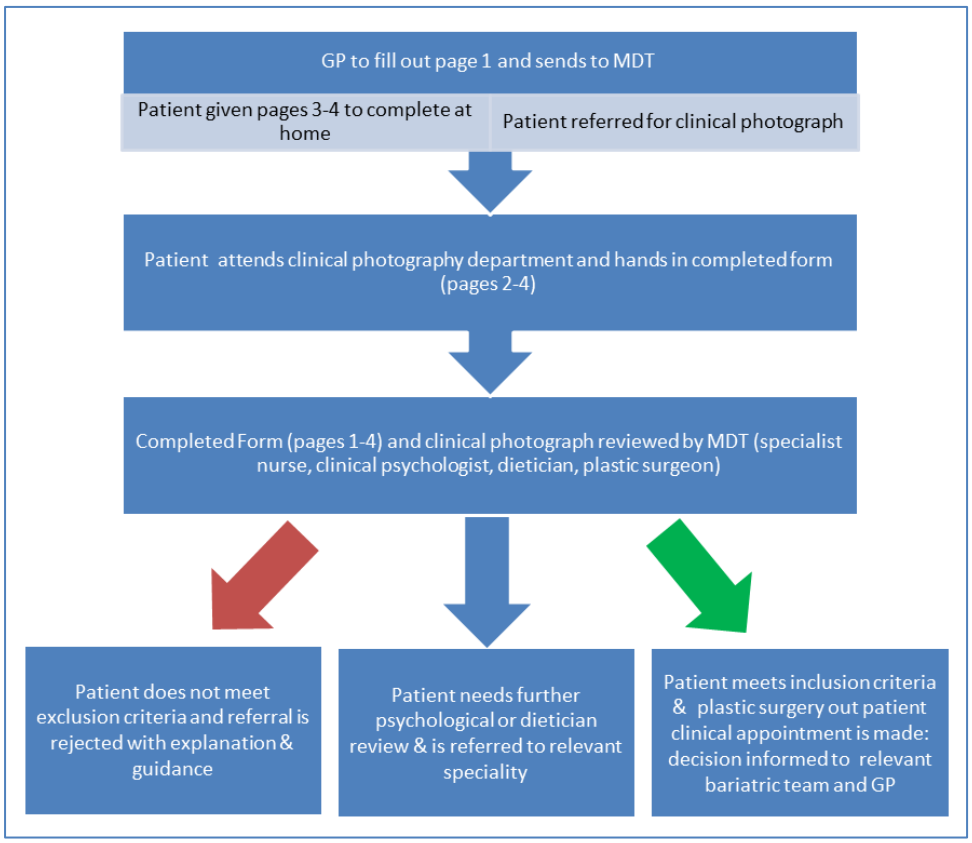
Thank you for reviewing the attached tool.

As part of the plastic surgery commissioning guidelines, the British Association of Plastic Surgeons is proposing the development of a referral tool to be used nationally.

This referral tool is for all patients wishing to undergo reconstructive surgery following massive weight loss following either bariatric surgery or natural weight loss methods.

The referral tool has been devised for 2 main reasons:
1. To ensure that appropriate patients are referred for assessment and thereby streamlining the patient journey
2. To enable collation of data on these patients to evaluate health care outcomes and report back to healthcare commissioners.

The first page is to be completed by the referring doctor (the GP) and the other pages are to be given to the patient to complete at home. The patient will then be referred for a clinical photograph and will hand in his/her completed form whilst in the department. The clinical photograph and all pages of the document will be reviewed by the massive weight loss body contouring MDT to determine if they meet the inclusion criteria. Please see attached a flow chart of the proposed patient journey.



Thank you very much for your extremely valuable feedback on the reporting tool.
Your thoughts, comments and criticisms are hugely appreciated.

With best wishes
Nada Al-Hadithy

Page 1: For the Referrer to complete:					
Patient Name: Date of birth: Height: Referral Source: Address: Phone Number: Email:	Original weight: Original BMI:			Current weight: Current BMI:	
	Weight lost:				
	Percentage excess weight loss:				
	Length of time maintained current weight:				
	Method of weight loss: please select from below:				
	Diet	Bariatric Surgery			
		Gastric band ☐	Gastric sleeve ☐	Roux en Y ☐	Duodenal Switch ☐
	Operation:	Open ☐	Closed ☐	Date of surgery	
	Complications:				
	Additional information:				
Funding Secured?	Plastic surgery procedure desired: 1. 2.				
Yes ☐ No ☐					

Past Medical History: Please write:	As a result of the excess skin:		
	Skin condition	Intertrigo ☐	Hidradenitis ☐
		Infection ☐	Dermatitis ☐
		Lymphoedema ☐	Ulceration ☐
	Evidence of Functional morbidity	Yes ☐	No ☐
	Evidence of Psychological morbidity	Yes ☐	No ☐

Psychiatric History: Please write:	Please tick if there is any history of the following:	
	Active delusional or schizophrenic illness	☐
	Body dysmorphic disorder	☐
	Eating disorder	☐
	History of self-harm in last 2 years	☐
	Major depressive illness	☐
	Obsessive compulsive disorder	☐
	Substance abuse problem	☐
	If any of the others are ticked, please give dates of diagnosis and last acute episode.	

Drug History:	Any history of recreational drug use? Please give information
Allergies:	

Page 2-4: For the patient to complete		
Date of Completion:	Patient Name	Date of Birth

Have you ever smoked?	`What was the most you ever smoked		If you are smoking now, how much do you smoke	
☐ Yes ☐ No (move onto the next question)	Only occasionally	☐	Only occasionally	☐
	Less than one pack per day	☐	Less than one pack per day	☐
	About one pack per day	☐	About one pack per day	☐
	One to two packs per day	☐	One to two packs per day	☐
	About two packs per day	☐	About two packs per day	☐
	More than two packs per day	☐	More than two packs per day	☐
If you have quit, when did you quit:				

Marital status (please check one):	Please tick	Occupation:	
Single	☐	Full time employment	☐
Married	☐	Self employed	☐
Divorced	☐	Part time employment	☐
Separated	☐	Student	☐
Widowed	☐	Unemployed	☐
Living with Significant Other	☐	Other:	

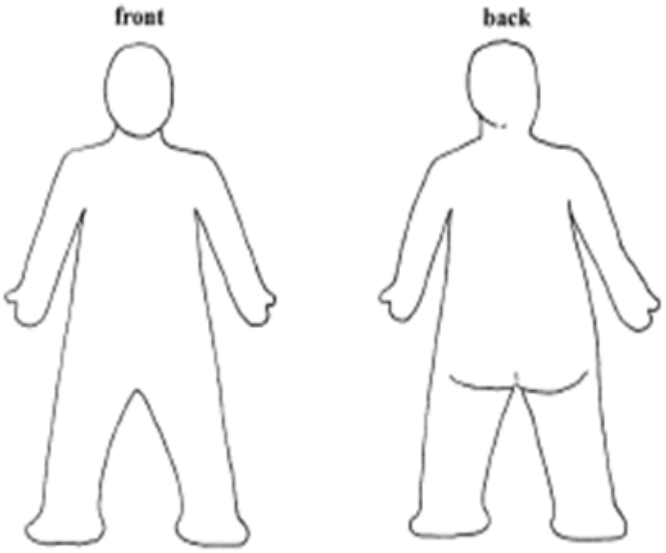
Have you had a pregnancy in the last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced the death of a close family member in last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced a relationship breakdown in the last 12 months?	No ☐	Yes ☐	Please give details

Please describe what you eat on a daily basis:			
On the average, how many main meals do you eat each day?		Indicate your preferred ways of dieting (select all that apply)	
		Skip meals	☐
On the average, how many snacks do you eat each day?		Completely fast for 24 hours +	☐
		Restrict carbohydrates	☐
		Restrict sweets/sugar	☐
How many of the following meals do you eat a week?		Reduce fats	☐
Breakfast	Days	Reduce portion size	☐
Lunch	Days	Exercise more	☐
Dinner	Days	Reduce calories	☐
		Take diet supplements	☐

How frequently do you exercise?		If you exercise, how long do you exercise each time?	
Not at all	☐	Less than 15 minutes	☐
Once per month or less	☐	15 - 30 minutes	☐
Several times per month	☐	31 - 60 minutes	☐
Once per week	☐	61 - 120 minutes	☐

Several times per week	☐	More than 120 minutes	☐
Once per day	☐		
Several times a day	☐		
If you exercise, please indicate the types of exercise you do (fill in all that apply).			
Cycling	☐	Stationary bike	☐
Running	☐	Walking	☐
Swimming	☐	In-line skating	☐
Weight training	☐	Stairmaster	☐
Aerobics	☐	Treadmill	☐
Dancing		Other: _____	

Is there a part of your appearance that you are concerned with?
Use the diagram to record where and why you are concerned:



Please tick the box which best applies to you	Not at all		Neutral		Extremely
Because of this body area:	1	2	3	4	5
I get distressed when I see myself in the mirror					
I find it difficult to mobilise					
I have problems finding clothes that fit					
I am able to exercise as much as I would like to.					
I avoid going out of the house					
I feel uncomfortable getting undressed in front of my partner					
I have physical pain					
I am limited in what I can do					
I get distressed when going to social events					

Activities of daily living	Please circle the choice that best suits you			
In general my health is	Excellent	Good	Fair	Poor
I am able to work	Not at all	A little	Often	Very much
I have satisfactory social contacts	Very many	Satisfactory	A few	None

I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all

Please select from the following scale, which image you think best represents your body size and shape. If you feel you are in between 2 images, mark in between.

Consent for clinical photography for MDT

Page 1: For the Referrer to complete:					
Patient Name: Date of birth: NHS Number: Height: Referral Source: Address: Phone Number: Email:	Original weight: Original BMI:			Current weight: Current BMI:	
	Weight lost:				
	Percentage excess weight loss:				
	Length of time maintained current weight:				
	Method of weight loss: please select from below:				
	Diet ☐	Bariatric Surgery			
		Gastric band ☐	Gastric sleeve ☐	Roux en Y ☐	Duodenal Switch ☐
	Operation	Laparoscopic ☐	Lap converted to open ☐	Open ☐	Date:
	Complications:				
	Additional information:				
Funding Secured?		Plastic surgery procedure desired: 1. 2.			
Yes ☐	No ☐				

Past Medical History: Please write:	As a result of the excess skin:		
	Skin condition	Intertrigo ☐	Hidradenitis ☐
		Infection ☐	Dermatitis ☐
		Lymphoedema ☐	Ulceration ☐
	Evidence of Functional morbidity	Yes ☐	No ☐
	Evidence of Psychological morbidity	Yes ☐	No ☐

Psychiatric History: Please write:	Please tick if there is any history of the following:		Date of Diagnosis & Details
	Active delusional or schizophrenic illness	☐	
	Body dysmorphic disorder	☐	
	Eating disorder	☐	
	History of self-harm in last 2 years	☐	
	Major depressive illness	☐	
	Obsessive compulsive disorder	☐	
	Substance abuse problem	☐	

Drug History: Please write:	Any history of recreational drug use? Please give information
Allergies:	

Patient Name: Name of referrer:

Page 2-4: For the patient to complete in the clinical photography department		
Patient Name:	Date of Completion:	Date of Birth:

Have you ever smoked?	`What was the most you ever smoked		If you are smoking now, how much do you smoke	
☐ Yes ☐ No (move onto the next question)	Only occasionally	☐	Only occasionally	☐
	Less than one pack per day	☐	Less than one pack per day	☐
	About one pack per day	☐	About one pack per day	☐
	One to two packs per day	☐	One to two packs per day	☐
	About two packs per day	☐	About two packs per day	☐
	More than two packs per day	☐	More than two packs per day	☐
If you have quit, when did you quit:				

Marital status (please check one):	Please tick	Current Occupation:	
Single	☐	Full time employment	☐
Married	☐	Self employed	☐
Divorced	☐	Part time employment	☐
Separated	☐	Student	☐
Widowed	☐	Unemployed	☐
Living with Significant Other	☐	Other:	

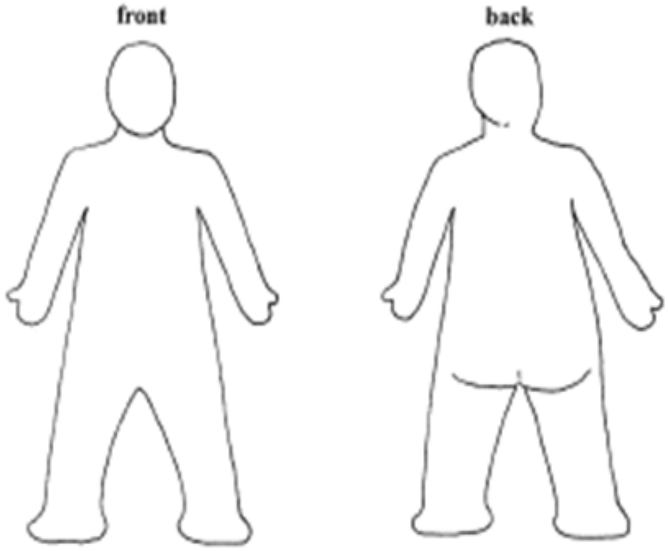
Have you had a pregnancy in the last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced the death of a close family member in last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced a relationship breakdown in the last 12 months?	No ☐	Yes ☐	Please give details
Please describe what you eat on a daily basis:			

How frequently do you exercise?		If you exercise, how long do you exercise each time?	
Not at all	☐	Less than 15 minutes	☐
Once per month or less	☐	15 - 30 minutes	☐
Several times per month	☐	31 - 60 minutes	☐
Once per week	☐	61 - 120 minutes	☐
Several times per week	☐	More than 120 minutes	☐
Once per day	☐		
Several times a day	☐		
If you exercise, please indicate the types of exercise you do (fill in all that apply).			
Cycling	☐	Stationary bike	☐
Running	☐	Walking	☐
Swimming	☐	In-line skating	☐
Weight training	☐	Stairmaster	☐
Aerobics	☐	Treadmill	☐
Dancing		Other: _____	

Patient Name: Name of referrer:

Please select from the following, the item that applies best to you:	
Can climb 3 flights of stairs without resting	☐
Can climb 1 flight of stairs without resting	☐
Can climb half a flight of stairs without resting	☐
Requires wheelchair	☐
Housebound	☐

Is there a part of your appearance that you are concerned with?
Use the diagram to record where and why you are concerned:

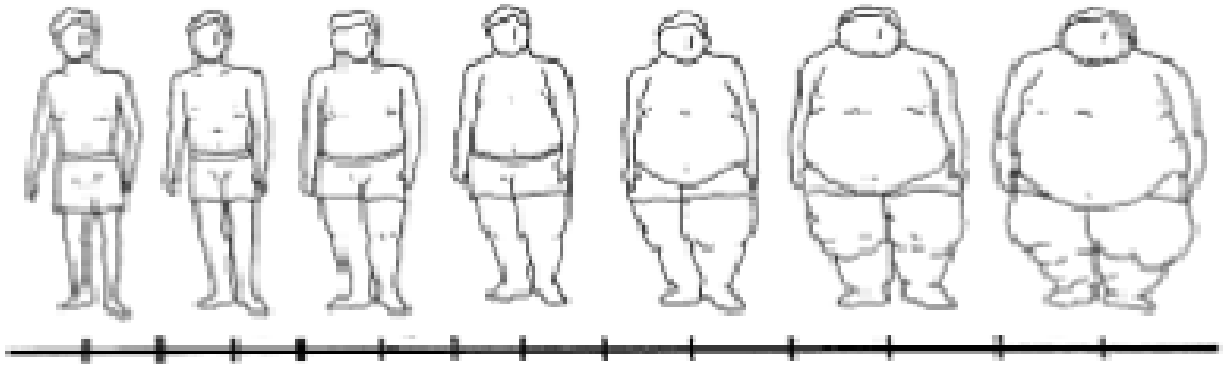


Please tick the box which best applies to you: Because of this body area:	Not at all		Neutral		Extremely
	1	2	3	4	5
I avoid going out of the house					
I get distressed when I see myself in the mirror					
I find it difficult to mobilise					
I have problems finding clothes that fit					
I am unable to exercise as much as I would like to					
I feel uncomfortable getting undressed in front of my partner					
I have physical pain					
I am limited in what I can do					
I get distressed when going to social events					

Activities of daily living	Please circle the choice that best suits you			
In general my health is	Excellent	Good	Fair	Poor
I am able to work	Not at all	A little	Often	Very much
I have satisfactory social contacts	Very many	Satisfactory	A few	None
I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all

Patient Name: Name of referrer:

Please select from the following scale, which image you think best represents your body size and shape. If you feel you are in between 2 images, mark in between.



Please write down any additional information you think is important:

Consent for clinical photography for MDT

Patient Name:

Name of referrer:

Pages 1-2: For the referrer to complete			
Patient name:			Date of referral:
Date of birth: NHS number:			Name of referrer:
Address:			Address:
Phone number:			Phone number:
Funding secured:	Yes ☐	No ☐	Email:

Maximum ever weight (kg):	Weight lost (kg):	Current weight (kg):	Current height (m):

Length of time maintained at current weight:	Weight fluctuation of ≥5kg in the last 6 months? Yes ☐ No ☐

Plastic surgery procedure desired:	1. 2.

Method of weight loss: please select any applicable from below:		
Diet ☐	Exercise ☐	Surgery ☐

Type of Bariatric Surgery			Not Applicable (please move on) ☐		
		Date & Details	Surgical Approach Please select one from below:		Date
Gastric Balloon	☐				
Gastric band	☐		Laparoscopic	☐	
Gastric sleeve	☐		Lap converted to open	☐	
Roux en Y	☐		Open	☐	
Duodenal Switch	☐				
Complications or additional information					

As a **result of the excess skin** the patient suffers with (please tick all that apply):						
Skin condition	Dermatitis ☐	Hidradenitis ☐	Intertrigo ☐	Infection ☐	Lymphoedema ☐	Ulceration ☐
Evidence of Functional impairment	Yes ☐ Give details:					No ☐
Evidence of Psychological impairment	Yes ☐ Give details:					No ☐

Patient Name/ Sticker:

Past Medical History: Please write:		
Please tick if there is any history of the following:		Date of diagnosis & details
Active delusional or schizophrenic illness	☐	
Body dysmorphic disorder	☐	
Eating disorder	☐	
History of self-harm in last 2 years	☐	
Major depressive illness	☐	
Obsessive compulsive disorder	☐	
Substance abuse problem	☐	

Psychiatric History: (Please write)	
Drug History: Please write:	Any history of recreational drug use? Please give information
Allergies:	

Any additional information:

Patient Name/ Sticker:

Page 3-5: For the patient to complete		
Patient Name:	Date of Completion:	Date of Birth:

Describe and date the surgery you have had for weight loss and body contouring:
Describe any complications you may have experienced from the surgery above:

Have you had any weight fluctuation in the last 6 months? (Tick the box which applies to you)	None ☐	0-5kg ☐	>5-10kg ☐	>10-20kg ☐	>20kg ☐

For the above surgery please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I am satisfied with the medical care I received					
I am satisfied with the outcome of my most recent surgery					
I am satisfied with my scar					
I am satisfied with my contour					

Have you **ever** smoked?	What was the most you **ever** smoked?		**If you are smoking now**, how much do you smoke?	
☐ Yes ☐ No (move onto the next question)	Very rarely	☐	Very rarely	☐
	Socially (≤2 cigarettes per week)	☐	Only socially (≤2 cigarettes per week)	☐
	< 5 cigarettes per day	☐	< 5 cigarettes per day	☐
	5-10 cigarettes per day	☐	5-10 cigarettes per day	☐
	11-20 cigarettes per day	☐	11-20 cigarettes per day	☐
	21-40 cigarettes per day	☐	21-40 cigarettes per day	☐
	>40 cigarettes per day	☐	>40 cigarettes per day	☐
If you have quit, when did you quit:				

Marital status (please check one):	Please tick	Current occupation (please write): _____		Please describe what you eat on a daily basis:
Single	☐	Full time employment	☐	
Married	☐	Self employed	☐	
Divorced	☐	Part time employment	☐	
Separated	☐	Student	☐	
Widowed	☐	Unemployed	☐	
Living with significant other	☐	Other:_____		

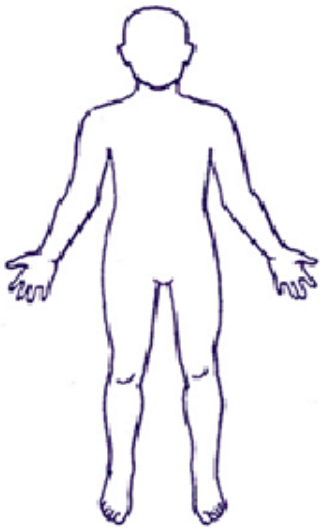
Have you had a pregnancy in the last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced the death of a close family member in last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced a relationship breakdown in the last 12 months?	No ☐	Yes ☐	Please give details

Patient Name/ Sticker:

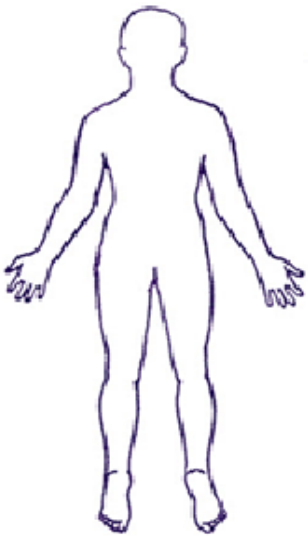
How frequently do you exercise?		If you exercise, how long do you exercise each time?		Where do you do most of your exercise?	
Not at all	☐	Less than 15 minutes	☐	Inside	☐
Once per month or less	☐	15 - 30 minutes	☐		
Several times per month	☐	31 - 60 minutes	☐	Outside	☐
Once per week	☐	61 - 120 minutes	☐		
Several times per week	☐	More than 120 minutes	☐		
Once per day	☐				
Several times a day	☐				

If you exercise, please indicate the types of exercise you do (fill in all that apply).									
Cycling	☐	Stationary bike	☐	Swimming	☐	Stairmaster	☐	Zumba	☐
Running	☐	Treadmill	☐	In-line skating	☐	Weight training	☐	Aerobics	☐
Walking	☐	Cross trainer	☐	Dancing	☐	Yoga	☐	Pilates	☐
Other (please write):									

Is there a part of your appearance that you are concerned with? Use the diagram to record where and write why you are concerned:



Front



Back

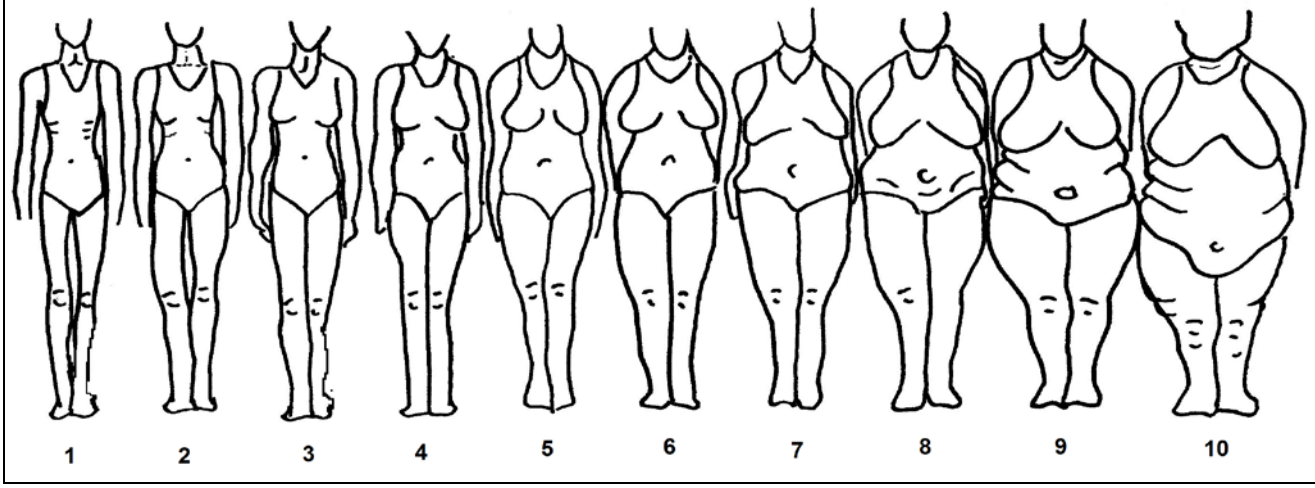
Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
I find it difficult to move around					
I avoid going out of the house					
I get distressed when I see myself in the mirror					
I have problems finding clothes that fit					
I am unable to exercise as much as I would like					
I feel uncomfortable getting undressed in front of my partner					
There is an adverse outcome on my sex life					
I have physical pain					
I am limited in what I can do during the course of a typical day					
I am unable to interact with my family as I would like					
I find it difficult to socialise					
There is an adverse outcome on my professional life					
I am unhappy with my physical appearance					
I do not undress in front of other people (changing rooms)					
I am unable to independently perform some activities of personal hygiene (eg bathing, brushing my hair or wiping myself after the toilet)					

Patient Name/ Sticker:

Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	☐
I can climb 1 flight of stairs without resting	☐
I can climb half a flight of stairs without resting	☐
I require a wheelchair	☐
I am housebound	☐

Activities of daily living	Please circle the choice that best suits you now			
In general my health is	Excellent	Good	Fair	Poor
I am able to work	Not at all	A little	Often	Very much
I am able to do the things I want to do	Not at all	A little	Often	Very much
I have satisfactory social contacts	Very many	Satisfactory	A few	None
I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all

Please select from the following scale, which image you think best represents your body size and shape.



Please write down any additional information you think is important:

Thank you for completing this form.
Please ensure it gets sent to the massive weight loss body contouring team at:

Patient Name/ Sticker:

The Post Bariatric Outcome Tool

What is the Post Bariatric Outcome Tool? (PBOT)

The underlying construct being measured is adjustment (psychological and functional) to massive weight loss and massive weight loss body contouring (MWLBC). From a psychological perspective, this will manifest differently for each individual respondent. However, we believe that the basic structure of adjustment is common across most people. Adjustment comprises negative emotions of fear, social anxiety, shame and negative affect along with behavioural response of avoidance and withdrawal that frequently disrupts lifestyle. We believe that we have captured this in the patient reported outcome measure (PROM) with contextually relevant questions specific to this unique cohort of patients.

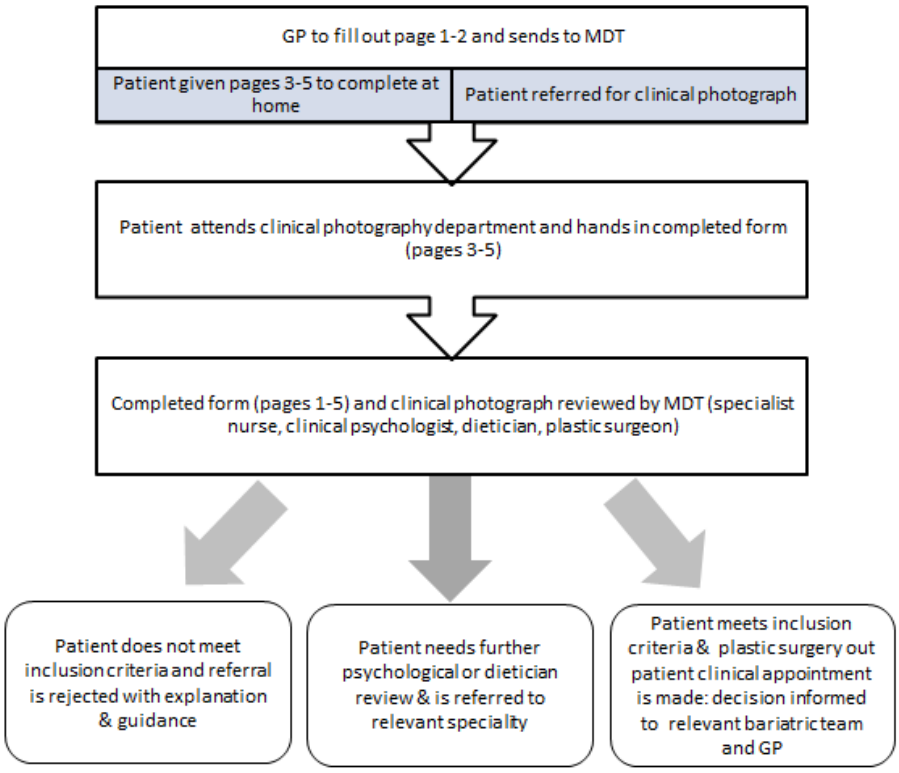
Description of the PBOT

The PBOT is a 77 item scale designed to fulfil three purposes:

1. To streamline the referral process and ensure those patients being referred meet the national guidelines.
2. To measure distress and dysfunction due to problems of the side effects of massive weight loss.
3. To quantify patient reported outcomes following massive weight loss body contouring.

The first two pages are to be completed by the referring doctor with the patient. In the UK, this is usually the general practitioner (GP). Page 1 facilitates the collection of demographic and clinical information relevant to patients considering massive weight loss body contouring. Page 2 collates known problems with excess skin, functional and psychological morbidity, past medical history and drug history.

The third to fifth pages are to be completed by the patient. This consists of questions for further demographic data collection and post-operative complication history which will aid screening of appropriate patients for surgery; and identify: adjustment to massive weight loss; functional impairment and perception of disfigurement.



There are two diagrams. One is a visual prompt so that the patient can highlight areas of concern on his/her body. The other is a visual analogue scale of how he/she perceives his/her size and shape. The second visual analogue scale should be compared with the clinical photographs of the patient to identify how closely the patient's perception of his/her body image reflects objective assessment of the clinical photograph by the multi disciplinary team (MDT) panel. There are two versions of the PBOT, one with female figures and another with male figures. The appropriate scale should be given to the patient depending on his/her sex.

The final part of the questionnaire is a blank space for patients to include any additional information they feel is important.

Administering the Score

The scale deals with sensitive and personal information. It therefore should only be administered by professionals who are aware of the ethical implications of dealing with such data and are working within the ethical guidelines of appropriate governing bodies.

The PBOT should be completed before referral to the plastic surgery unit, and will be reviewed with clinical photographs by the massive weight loss body contouring multi disciplinary team (MDT). It can also be used at 3 months, 6 months and/or 1 year+ post massive weight loss body contouring in order to measure outcomes in this group of patients.

Scoring

Of the 77 items on the questionnaire, there are 41 items to score for the two components.

Score Component	Questions to Score	Minimum	Maximum
Referral Tool (Pages 1-2)	14 (of 30)	-26	16
PROM Component (Pages 3-5)	27 (of 47)	20	132

Rules

When marking the referral tool component, to qualify for next stage of screening process for massive weight loss body contouring they must score > 8: points in the referral tool. Of these 8 points, 3 must come from the first 3 questions, ie, the patients must score at least 1 for questions 1-3.

ANY psychiatric history should warrant referral to clinical psychologist for further enquiry.
ANY patients who have a discrepancy of more than 2 points between their self-assessment on the visual analogue scale of size and the objective assessment of the panel should warrant referral to the clinical psychologist.

Referral Tool Mark Scheme

Use the PBOT marking aid – which has all the questions for the referral tool component numbered in red.

1. Percentage excess weight lost = (weight Lost/ (maximum ever weight-ideal weight)) x 100 (Where ideal weight = 25 x height $(m)^2$)	Mark	Tick which applies
≤49%	0	
50-100%	1	
>100%	2	

2. Current BMI = current weight in kg/(height in m)2	Mark	Tick which applies
>30	-1	
>27-30	0	
26-27	1	
≤25	2	

3. Length of time maintained at current weight.	Mark	Tick which applies
<12 months	0	
>12 – 18 months	1	
>18 months	2	

4. Weight fluctuation ≥5kg in the last 6 months	Mark	Tick which applies
Yes	-2	
No	0	

5. Skin conditions	Points
Allocate one point for each condition (maximum 6)	

6. Evidence of functional impairment	Mark	Tick which applies
Yes	1	
No	0	

7. Evidence of psychological impairment	Mark	Tick which applies
Yes	1	
No	0	

8. Psychiatric History:	Mark	Tick which applies
Active delusional or schizophrenic illness	-1	
Body dysmorphic disorder	-1	
Eating disorder	-1	
History of self-harm in last 2 years	-1	
Major depressive illness	-1	
Obsessive compulsive disorder	-1	
Substance abuse problem	-1	

9. Any history of recreational drug use	Mark	Tick which applies
No	0	

Yes	-1	

10. Smoking History:	Mark	Tick which applies
Never smoked	1	
Quit smoking	0	
Smokes rarely	-1	
Smokes socially	-1	
Smokes <5 cigarettes per day	-2	
5-10 cigarettes per day	-3	
11-20 cigarettes per day	-4	
21-40 cigarettes per day	-5	
>40 cigarettes per day	-10	

Question	Mark	Tick which applies
11. Have you had a pregnancy in the last 12 months?		
No	0	
Yes	-1	
12. Have you experienced the death of a close family member in last 12 months?		
No	0	
Yes	-1	
13. Have you experienced a relationship breakdown in the last 12 months?		
No	0	
Yes	-1	

14 Patient's clinical photograph matches patient's self-selection of body image on scale	Mark	Tick which applies
Yes	1	
No	-2	
More than 2 points difference between patient assessment and objective assessment score by MDT panel should prompt a referral to psychologist		

Referral Tool total score _____

PROM Mark Scheme

Use the PBOT marking aid to help score. All the questions for the PROM component have been coded in letters in purple.

A. Have you had any weight fluctuation in the last 6 months?	None	0-5kg	>5-10kg	>10-20kg	>20kg
	1	-1	-2	-3	-4
Please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
B. I am satisfied with the medical care I received	5	4	3	2	1
C. I am satisfied with the outcome of my most recent surgery	5	4	3	2	1
D. I am satisfied with my scar	5	4	3	2	1
E. I am satisfied with my contour	5	4	3	2	1

How frequently do you exercise?		If you exercise, how long do you exercise each time?	
Not at all	0	Less than 15 minutes	0.25
Once per month or less	1	15 - 30 minutes	0.50
Several times per month	2	31 - 60 minutes	1
Once per week	3	61 - 120 minutes	1.5
Several times per week	4	More than 120 minutes	2
Once per day	5		
Several times a day	6		

F. Score = frequency x exercise time =

Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
G. I find it difficult to move around	5	4	3	2	1
H. I avoid going out of the house	5	4	3	2	1
I. I get distressed when I see myself in the mirror	5	4	3	2	1
J. I have problems finding clothes that fit	5	4	3	2	1
K. I am unable to exercise as much as I would like	5	4	3	2	1
L. I feel uncomfortable getting undressed in front of my partner	5	4	3	2	1
M. There is an adverse outcome on my sex life	5	4	3	2	1
N. I have physical pain	5	4	3	2	1
O. I am limited in what I can do during the course of a typical day	5	4	3	2	1
P. I am unable to interact with my family as I would like	5	4	3	2	1
Q. I find it difficult to socialise	5	4	3	2	1
R. There is an adverse outcome on my professional life	5	4	3	2	1
S. I am unhappy with my physical appearance	5	4	3	2	1
T. I do not undress in front of other people (changing rooms)	5	4	3	2	1
U. I am unable to independently perform some activities of personal hygiene (eg bathing, brushing my hair or wiping myself after the toilet)	5	4	3	2	1

V. Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	4
I can climb 1 flight of stairs without resting	3
I can climb half a flight of stairs without resting	2

I require a wheelchair	1
I am housebound	0

Activities of daily living	Please circle the choice that best suits you now			
W. In general my health is	Excellent	Good	Fair	Poor
	4	3	2	1
X. I am able to work	Not at all	A little	Often	Very much
	1	2	3	4
Y. I am able to do the things I want to do	Not at all	A little	Often	Very much
	1	2	3	4
Z. I have satisfactory social contacts	Very many	Satisfactory	A few	None
	4	3	2	1
Σ. I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all
	4	3	2	1

PROM total score_____

Pages 1-2: For the referrer to complete			
Patient name:			Date of referral:
Date of birth: NHS number:			Name of referrer:
Address:			Address:
Phone number:			Phone number:
Funding secured:	Yes ☐	No ☐	Email:

1. & 2.			
Maximum ever weight (kg):	Weight lost (kg):	Current weight (kg):	Current height (m):

3. Length of time maintained at current weight in months:	4. Weight fluctuation of ≥5kg in the last 6 months? Yes ☐ No ☐

Plastic surgery procedure desired:	1. 2.

Method of weight loss: please select any applicable from below:		
Diet ☐	Exercise ☐	Surgery ☐

Type of Bariatric Surgery			Not Applicable (please move on) ☐		
		Date & Details	Surgical Approach Please select one from below:		Date
Gastric Balloon	☐				
Gastric band	☐		Laparoscopic	☐	
Gastric sleeve	☐		Lap converted to open	☐	
Roux en Y	☐		Open	☐	
Duodenal Switch	☐				
Complications or additional information					

As a **result of the excess skin** the patient suffers with (please tick all that apply):						
5. Skin condition	Dermatitis ☐	Hidradenitis ☐	Intertrigo ☐	Infection ☐	Lymphoedema ☐	Ulceration ☐
6. Evidence of Functional impairment	Yes ☐ Give details:					No ☐
7. Evidence of Psychological impairment	Yes ☐ Give details:					No ☐

Patient Name/ Sticker:

Past Medical History: Please write:		
8. Please tick if there is any history of the following:		Date of diagnosis & details
Active delusional or schizophrenic illness	☐	
Body dysmorphic disorder	☐	
Eating disorder	☐	
History of self-harm in last 2 years	☐	
Major depressive illness	☐	
Obsessive compulsive disorder	☐	
Substance abuse problem	☐	

Psychiatric History: (Please write)	
Drug History: Please write:	**9.** Any history of recreational drug use? Please give information
Allergies:	

Any additional information:

Patient Name/ Sticker:

Page 3-5: For the patient to complete		
Patient Name:	Date of Completion:	Date of Birth:

Describe and date the surgery you have had for weight loss and body contouring:
Describe any complications you may have experienced from the surgery above:

A. Have you had any weight fluctuation in the last 6 months? (Tick the box which applies to you)	None ☐	0-5kg ☐	>5-10kg ☐	>10-20kg ☐	>20kg ☐

For the above surgery please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
B. I am satisfied with the medical care I received					
C. I am satisfied with the outcome of my most recent surgery					
D. I am satisfied with my scar					
E. I am satisfied with my contour					

10. Have you **ever** smoked?	What was the most you **ever** smoked?		**If you are smoking now**, how much do you smoke?	
☐ Yes ☐ No (move onto the next question)	Very rarely	☐	Very rarely	☐
	Socially (≤2 cigarettes per week)	☐	Only socially (≤2 cigarettes per week)	☐
	< 5 cigarettes per day	☐	< 5 cigarettes per day	☐
	5-10 cigarettes per day	☐	5-10 cigarettes per day	☐
	11-20 cigarettes per day	☐	11-20 cigarettes per day	☐
	21-40 cigarettes per day	☐	21-40 cigarettes per day	☐
	>40 cigarettes per day	☐	>40 cigarettes per day	☐
If you have quit, when did you quit:				

Marital status (please check one):	Please tick	Current occupation (please write): _____		Please describe what you eat on a daily basis:
Single	☐	Full time employment	☐	
Married	☐	Self employed	☐	
Divorced	☐	Part time employment	☐	
Separated	☐	Student	☐	
Widowed	☐	Unemployed	☐	
Living with significant other	☐	Other:_____		

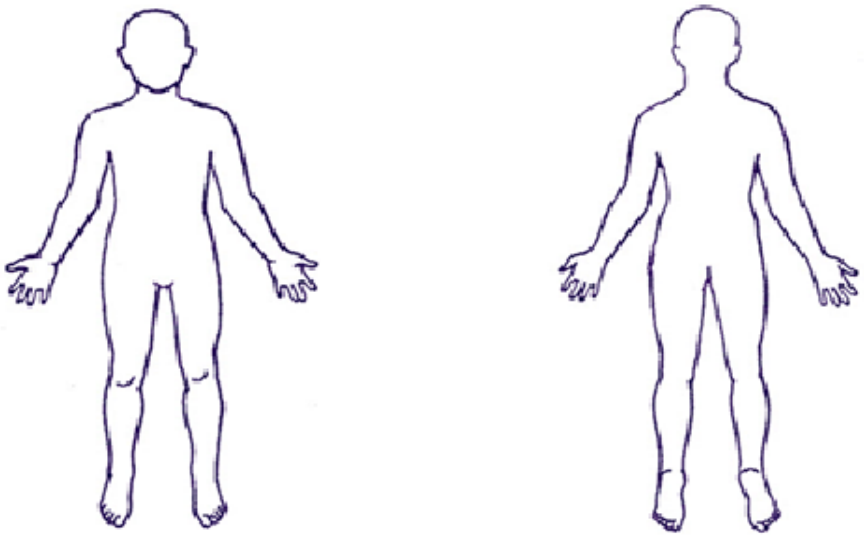
	No	Yes	Please give details
11. Have you had a pregnancy in the last 12 months?	☐	☐	
12. Have you experienced the death of a close family member in last 12 months?	☐	☐	
13. Have you experienced a relationship breakdown in the last 12 months?	☐	☐	

Patient Name/ Sticker:

F.					
How frequently do you exercise?		If you exercise, how long do you exercise each time?		Where do you do most of your exercise?	
Not at all	☐	Less than 15 minutes	☐	Inside	☐
Once per month or less	☐	15 - 30 minutes	☐		
Several times per month	☐	31 - 60 minutes	☐	Outside	☐
Once per week	☐	61 - 120 minutes	☐		
Several times per week	☐	More than 120 minutes	☐		
Once per day	☐				
Several times a day	☐				

If you exercise, please indicate the types of exercise you do (fill in all that apply).									
Cycling	☐	Stationary bike	☐	Swimming	☐	Stairmaster	☐	Zumba	☐
Running	☐	Treadmill	☐	In-line skating	☐	Weight training	☐	Aerobics	☐
Walking	☐	Cross trainer	☐	Dancing	☐	Yoga	☐	Pilates	☐
Other (please write):									

Is there a part of your appearance that you are concerned with? Use the diagram to record where and write why you are concerned:



Front Back

Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
G. I find it difficult to move around					
H. I avoid going out of the house					
I. I get distressed when I see myself in the mirror					
J. I have problems finding clothes that fit					
K. I am unable to exercise as much as I would like					
L. I feel uncomfortable getting undressed in front of my partner					
M. There is an adverse outcome on my sex life					
N. I have physical pain					
O. I am limited in what I can do during the course of a typical day					
P. I am unable to interact with my family as I would like					
Q. I find it difficult to socialise					
R. There is an adverse outcome on my professional life					
S. I am unhappy with my physical appearance					
T. I do not undress in front of other people (changing rooms)					
U. I am unable to independently perform some activities of personal hygiene (eg bathing, brushing my hair or wiping myself after the					

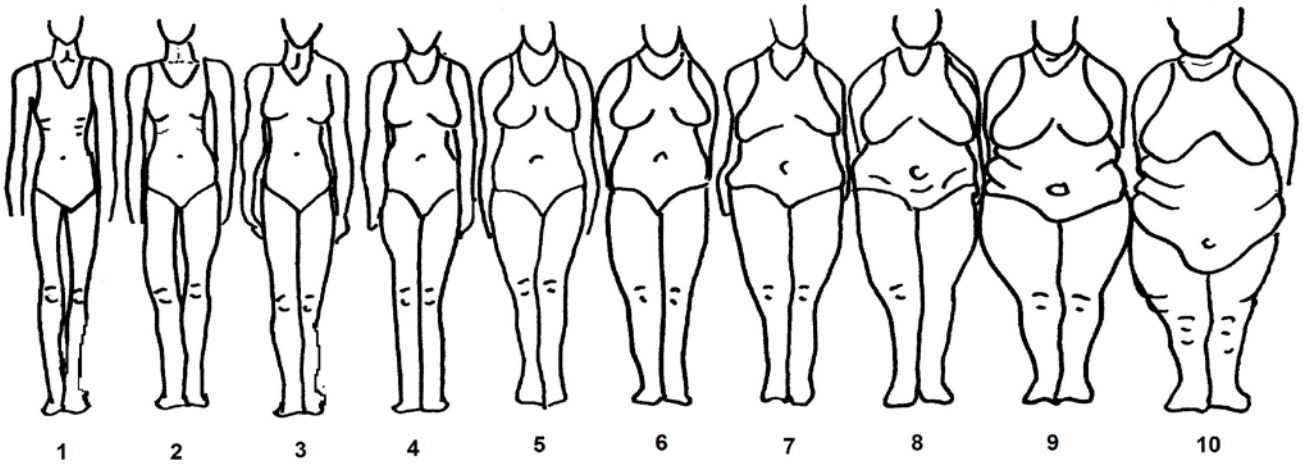
Patient Name/ Sticker:

toilet)					

V. Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	☐
I can climb 1 flight of stairs without resting	☐
I can climb half a flight of stairs without resting	☐
I require a wheelchair	☐
I am housebound	☐

Activities of daily living	Please circle the choice that best suits you now			
W. In general my health is	Excellent	Good	Fair	Poor
X. I am able to work	Not at all	A little	Often	Very much
Y. I am able to do the things I want to do	Not at all	A little	Often	Very much
Z. I have satisfactory social contacts	Very many	Satisfactory	A few	None
Σ. I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all

14. Please select from the following scale, which image you think best represents your body size and shape.



Please write down any additional information you think is important:

Thank you for completing this form.
Please ensure it gets sent to the massive weight loss body contouring team at:

Patient Name/ Sticker:

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Abstract: The past 20 years has seen a doubling in the worldwide prevalence of morbid obesity (usually defined as a body mass index BMI, >40kg/m2) . Scotland has one of the worst obesity records amongst developed countries . In 2010, 65.1% of all adults aged 16 and over were overweight or obese. Morbid obesity rates (BMI 40kg/m2 or more) increased from 1.2% in 1995 to 2.7% in 2003, and fluctuated between 2.2% and 2.7% between 2008 and 2010 (Figure 1).
Morbid obesity is associated with twice the mortality compared with the general population. The National Audit Office (NAO) estimated that in 1998 over 30,000 deaths a year in England were attributable to obesity, approximately 6% of all deaths in that year . Obesity is associated and with other conditions such as hypertension, type 2 diabetes, cardiovascular disease, osteoarthritis and cancer, as well as increased rates of psychiatric illness. ,

Cover Letter (signed by all authors)
Click here to download high resolution image

Miss Nada Al-Hadithy

nadaucl@yahoo.com

8th August 2012

Dear JPRAS,

Re: Functional and Psychosocial Improvement following Body Contouring Procedures in Bariatric Patients – The Evidence

Thank you for considering the attached paper for publication in JPRAS.

The current "Guide for Authors" has been read, thereby indicating compliance with those instructions and acceptance of the conditions posed. The authors have seen and agreed to the submitted version of the paper, and bear responsibility for it; all who have been acknowledged as contributors or as providers of personal communications have agreed to our inclusion; the material is original; and it has been neither published elsewhere nor submitted for publication simultaneously.

If accepted, the paper will not be published elsewhere in the same or similar form, in English or in any other language, without written consent of the copyright holder.

Thank you

Yours sincerely

Nada Al-Hadithy

Joanna Mennie

Tiarnan Magos

Ken Stewart

Desire for Post Bariatric Body Contouring in South East Scotland

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Introduction

The past 20 years has seen a doubling in the worldwide prevalence of morbid obesity (usually defined as a body mass index BMI, >40kg/m2)[1]. Scotland has one of the worst obesity records amongst developed countries[2]. In 2010, 65.1% of all adults aged 16 and over were overweight or obese. Morbid obesity rates (BMI 40kg/m^2 or more) increased from 1.2% in 1995 to 2.7% in 2003, and fluctuated between 2.2% and 2.7% between 2008 and 2010 (Figure 1).

Morbid obesity is associated with twice the mortality compared with the general population. The National Audit Office (NAO)[3] estimated that in 1998 over 30,000 deaths a year in England were attributable to obesity, approximately 6% of all deaths in that year[4]. Obesity is associated and with other conditions such as hypertension, type 2 diabetes, cardiovascular disease, osteoarthritis and cancer, as well as increased rates of psychiatric illness.[5, 6]

Background

The estimated cost to the NHS in Scotland of obesity and related illnesses in 2007/8 was in excess of £175 million[7]. Interestingly, only 2% of this total is due to treating obesity itself, 98% is consumed by the treatment of obesity co-morbidities such as high blood pressure, diabetes and heart disease. The study

concludes that obesity carries important cost consequences that rank second only to smoking as a cause of burden upon the NHS. With these economic and health costs, tackling obesity is a key priority for the public health sector in Scotland[8,9,10,11].

The three main treatment options for morbid obesity are lifestyle change, pharmacotherapy and surgery. Lifestyle changes of calorie restriction and increase physical activity can achieve moderate weight loss in the short term. However, up to 66% of patients regain weight within 24 months and long-term results are poor[12,13,14]. Those patients on pharmacotherapy[15] lose a modest amount of weight and still have significant chance of regaining the lost weight once they come off the medication. The aetiology of morbid obesity is complex, involving the interaction of psychosocial, genetic, endocrine and metabolic factors, making conservative treatment difficult and prone to failure.[16]

Surgery is more invasive than the other options, but at present appears to be the only means of achieving considerable and sustained weight loss in people with morbid obesity. There are several different procedures that can be used in bariatric surgery. Malabsorptive (ie bypass procedures) and mixed malabsorptive/restrictive procedures have been shown to be more effective in terms of weight loss and controlling diabetes than restrictive procedures (eg gastric banding)[17, 18]

The Swedish Obese Subjects non-randomised controlled trial compared surgical and conventional interventions, and showed a clear benefit on mortality for surgery at 10 years, with an average weight loss of 16% in the surgical arm compared with 1.6% in the non-surgical arm.[19,20,21] A systematic review of 22,094 bariatric patients demonstrated major improvements in prevalence or control of obesity-related conditions including diabetes, hypertension, obstructive sleep apnoea and hyperlipidaemia[22].

Therefore weight loss surgery or bariatric surgery is increasingly being offered in both National Health Service (NHS) funded and in private UK medical practice. In adults with a BMI of more than 50 kg/m^2 in whom surgical intervention is considered appropriate, bariatric surgery is recommended as a first-line option (instead of lifestyle interventions or drug treatment) in the NICE guidelines.[23]

As a result of this drive to tackle obesity, there are increasing numbers of patients with massive weight loss and skin redundancy. Unfortunately with the massive weight loss in a short time skin often does not shrink well. This has led to post weight loss deformities of loose, ptotic skin envelopes and residual adiposities with resultant contour irregularities[24]. In Scotland there are clear guidelines for the provision of plastic surgery following bariatric surgery[25]. Two body contouring procedures are offered if the following inclusion criteria are met:

- Severe, intractable intertrigo beneath the skin fold and massive weight loss (BMI≤27).
- Significant weight loss following treatment for morbid obesity resulting in functional problems (BMI<27).
- Lipodystrophy
- Adjunct to reconstructive procedures

This can include abdominoplasty or apronectomy; liposuction, thighplasty or brachioplasty and will only be offered following clinical psychological assessment and demonstration of maintenance of a stable weight, BMI ≤27, for more 1 year. However, the exclusion criteria for bari-plastic surgery can include:

1) Patient has had a major life event in the previous 12 months particularly:
    a) marital / relationship breakdown
    b) birth of a child
    c) death of a close family member.
2) Patient currently has:
    a) a major depressive illness
    b) an active delusional or schizophrenic illness
    c) an eating disorder
    d) obsessive-compulsive disorder
    e) substance abuse problem.

3) Patient has had an episode of self-harm within the last two years.

4) Patient has been previously diagnosed with body dysmorphic disorder.

5) Patient clearly has a disproportionate view of problem following your examination.

In England there are no standardised guidelines for provision of body contouring post massive weight loss. In a recent study carried out by Mukherkee et al, of the 67 respondents of 147 of the Primary Care Trusts in England only 54 have referral guidelines for plastic surgery and 23 exclude all post bariatric surgery body contouring procedures[26]. South Staffordshire Primary care trust (PCT) states that "Patients must be informed that the PCT will not fund cosmetic procedures to remove any excess skin folds that may result from rapid weight loss"[27]. Whereas Leeds PCT has laid our specific criteria[28].

According the a study carried out by Butler[29], 95.1% of plastic surgery units in the country offer some form of reconstructive surgery following massive weight loss, with a large variation of what is available between each unit, and 4.9% of units do not offer any surgery due to lack of PCT funding. Referral via the exceptional aesthetic pathway can sometimes been seen as a caveat to these rules. However, as NHS East Lancashire PCT determines, exceptionality is essentially an equity issue that is best expressed by the question: 'On what grounds can the PCT justify funding this patient when others from the same patient group are not being funded?" The burden of proof lies on the patient and his champion.

The disparity in plastic surgery service provisions for patients who have experienced massive weight loss, exist both in terms of type and availability. NICE guidelines state that surgery for obesity should only be undertaken by a multidisciplinary team that can provide expertise including psychological support before and after surgery and providing information on or access to plastic surgery where indicated.[30] However, Highton et al found that only 66% of bariatric surgeons routinely counsel patients about excess skin following massive weight loss before they undergo bariatric surgery[31] and Butler found that 56% of units do not offer psychology or psychiatry screening, 14% is unknown and only 24% of all the plastic surgery units in the UK offer it routinely[30].

There is currently no national consensus as to whether a publicly funded health system should be providing these patients with treatment, as it regarded as aesthetic surgery. “Aesthetic surgery is not routinely offered by the NHS and can only be provided on an exceptional case basis.” However, some would argue that body contouring after bariatric surgical weight loss resides at a perplexing intersection between aesthetic and functional surgery[32].

A UK government commissioned working group[33] determined that a national, stakeholder-led “Successor Network” should be created to outline and establish strategic actions with outcome objectives and measures for procedures at a national level. Strategic action (B) is to provide appropriate, timely and informed patient care by specialists, with the patient as an active partner in their health care. Action (D) is to develop and implement clinical pathway outcome objectives and measures. Currently this is missing in the post bariatric body contouring service in the UK and the onus of responsibility lies on plastic surgeons to collect and present the data demonstrating that there is much to gain by offering patients reconstructive surgery after massive weight loss. This would support the Action on Plastic Surgery Local Recommendation 2: to facilitate the roles of; lead plastic surgeon, senior plastic surgery nurse and lead therapist working within plastic surgery, who would act as “Local Champions” for the delivery of plastic surgery services.

Consequently Soldin et al demonstrated significant improvements in patients’ physical and emotional well-being once they have undergone body contouring surgery following massive weight loss[34]. Highton et al found that 92% of 86 surgeon members of the British Obesity and Metabolic Surgery society felt that patients face functional problems relating to skin redundancy after massive weight loss, and a high percentage of patients complain about this problem. There is a gradual shift from deeming post bariatric surgery body contouring as an aesthetic procedure to seeing it as a necessary step in providing complete care for the bariatric patient as part of their surgical package.

Since December 2011, BAPRAS[35] has been pushing for national guidelines on reconstructive surgery following bariatric weight loss procedures. National guidelines on post-bariatric body contouring surgery

are needed to improve the comprehensive treatment of these patients. The clinical and cost effectiveness of bariatric surgery has been well established. However the same has not been achieved in the body contouring cohort[36]. At the current time, we have not verified that surgical correction of these post-weight loss deformities can positively impact either quality of life or psychosocial function[33]. Further studies focussing on the outcome of body contouring after massive weight loss could support the development of national guidelines on post bariatric surgery body contouring and these becoming an integral part of the bariatric surgery pathway. Current research in this arena is very limited and there is a dearth of evidence as to how best to achieve these goals.

Aims

This study aims to determine

1. the demand for plastic surgery in patients who have had bariatric surgery
2. the areas of anatomy that provoke the most concern and requests for surgery
3. the correlation to desire for plastic surgery and type of bariatric procedure received
4. determine whether those patient approved for post bariatric surgery body contouring in Scotland, would have been approved according to guidelines in Leeds PCT

Methods

Regional Ethical Committee approval was obtained for the study protocol. Written informed consent was obtained from all subjects.

A cross sectional study was carried out of 150 consecutive patients in the Royal Infirmary of Edinburgh bariatric surgery services. 11 were on the weight management programme and were yet to receive

bariatric surgery. 139 had undergone bariatric surgery. Each of the patients were weighed and consented to participate in a 10 minute interview. Weight was measured using manual scales. Participants were asked to remove shoes and any bulky clothing. A single measurement was recorded to the nearest 100g.

The interview was conducted in a quiet clinic room at St John's Hospital in Livingston, by a plastic surgery registrar trained in psychotherapy.

Interview Questions

1. Date of birth
2. Bariatric surgery type received
3. Time following bariatric procedure
4. Complications following bariatric procedure
5. Initial weight prior to bariatric surgery
6. Current weight
7. Current medical problems (for which on medication or under follow up with a health care practitioner)
8. Desire for plastic surgery
9. Area of face/body which causes concern

The weight loss was calculated from the patients' account of their original weight and the original weight as documented in the clinical notes. If there was a discrepancy in the two, the weight as per the clinical notes was used as the baseline weight. History type and date of bariatric surgery as well as any complications was cross checked with patients' notes.

Antrhopometric measurements of pannus length were taken by the same practitioner.

Results

Data was analisd with IBM SPSS 20. Analisis was carried out at University College London Statistical Support Service, Centre for Paediatric Epidemiology and Biostatistics.

150 patients were interviewed. 102 (68%) wanted plastic surgery, 36 (24%) did not want plastic surgery and 12 (8%) were not sure.

Description of study population

Of the 139 patients who had undergone bariatric surgery: 102 were positive in desiring plastic surgery, mean age 48.3 (interquartile range 44 – 54) and had lost a mean of 55.12 kg (interquartile range 38.6-72.5kg). 36 were negative for desiring plastic surgery, mean age 52 (interquartile range 47-59) and had lost a mean of 25.12kg (4-50.8kg). There were 12 patients who were not sure yet, mean age 39 years (interquartile range 34-52) old and had lost a mean of 16.4kg (interquartile 5 – 38.3 kg). (Figure 2)

Patients of different types of bariatric surgery reported their weight loss. A Kruscal Wallis test indicated a significant effect of type of bariatric surgery on weight loss such that weight loss was higher after a laparoscopic gastric bypass surgery (Median = 57.15kg; range = 138.8) than the rest of the surgery methods, $p = 0.038$. (Figure 3)

Correlation between bariatric surgery type and desire for plastic surgery

Of the 139 patients of the study who had bariatric surgery, 102 were positive in desiring plastic surgery whereas 36 negative. There was one post-operative patient who was not sure yet. Trying to identify the effect of bariatric surgery on their decision we excluded from the analisis patients who were under the Weight management programme because they may get bariatric surgery in the near future and the patient that was not sure yet.

As can be seen in the figure 4, 34.3% of those who desired to have plastic surgery had laparoscopic gastric bypass whilst 2.9% open gastric bypass, giving a total 37.3% of those who desired to have plastic surgery

had gastric bypass. 37.3% had gastric sleeve whilst 25.5% gastric band. Patients who didn't want a plastic surgery were split 31.3%, 31.3% and 37.5% respectively. There is no significant difference in terms of type of bariatric surgery and desire for plastic surgery p=0.421 (significance level a=5%). Time frames post bariatric surgery were compared to desire for plastic surgery. Those patients who had been more than 6 months post bariatric surgery were more likely to want plastic surgery than those patient who were under 6 months post bariatric surgery p = 0.002.

Area that provoked the most concern

Of the 102 patients who desired plastic surgery the abdomen was the area that provoked the most concern, the chest came second and the arms and thighs and buttocks last. (Figure 5)

Comparison between fulfilment of Leeds Criteria in receiving surgery

Of the 102 patients, who wanted plastic surgery, 53 had been approved for plastic surgery and were on the waiting list, 15 had been rejected for plastic surgery and 34 had not yet applied.

The 53 who had been approved for plastic surgery had a mean age of 47.4 (interquartile range 44 – 52) and had lost a mean of 65.12 kg (interquartile range 42.6-74.6kg). This amounted to between 54-100% of their excess weight.

The 15 who had been rejected for plastic surgery were a mean age of 48.9 (interquartile range 44 – 54) and had lost a mean of 42.25kg (interquartile range 33.5-49.2kg). This amounted to 28-58% of their excess weight. The 15 that had been rejected for plastic surgery were for the following reasons: BMI >27 = 9, psychologically unsuitable n=2, medically un fit n=2, smoker n=2. In all cases, the patient was given the option of addressing the cause for rejection and being reviewed at a later date.

Of the 34 patients that had not yet applied for plastic surgery 13 had been told by their GPs that they would not qualify for plastic surgery on the NHS, despite loosing more than 75% of their excess body weight. The other 21 patients had not yet reached their target weight.

The 53 patient who had been approved for plastic surgery, were compared to the Leeds criteria as below:

The Leeds Criteria

1. There has been at least 25% weight loss either following surgery or a planned weight loss programme where the BMI is 30 or less for 12 months and
2. Panniculus hangs below the level of the pubis
3. The medical records document that the panniculus causes chronic intertrigo (dermatitis occurring on opposed surfaces of the skin, skin irritation, infection or chafing) that consistently recurs over 3 months while receiving appropriate medical therapy, or remains refractory to appropriate medical therapy over a period of 3 months.

All patient who had been approved for plastic surgery fulfilled criteria 1 and 3. However, only 33 of the patients had a panniculus below the level of the pubis.

Discussion

The demand for body contouring post massive weight loss is on the rise and currently there is no evidence to demonstrate if patients who remove the redundant skin gain physical and psychological benefits. Weight loss, age and sex alone are not determinants of desire for plastic surgery.

This study demonstrates that although there is a statistically significant correlation between weight loss and type of bariatric surgery, it does not follow that those patients with the most weight loss desire plastic surgery above others. There is no obvious effect of age or gender on desire for plastic surgery. The

abdomen was the area that provoked the most concern, followed by the chest/breast, then limbs. This study identified that of the patient who had bariatric surgery, 73.4% desired plastic surgery to manage their post massive weight loss skin redundancy. This was vastly different to Sarwer, who recorded one quarter of patients who have bariatric surgery request body contouring[37, 38] but very similar to Kitzinger et al who reported 75% female and 68% male patients reporting a desire for body contouring surgery[39]. Clearly further work needs to be done to identify the differences

The psychological implications of redundant skin are believed to play a central role in the decision to seek body contouring surgery. A recent study in a non-bariatric patient population suggested that abdominoplasty could have a positive impact on sexuality[40], however there is a dearth of evidence for psychological and functional outcomes in the bariatric population. At present, it is unknown whether persons who have undergone bariatric surgery and who elect to undergo subsequent body contouring surgery experience the anticipated physical and psychosocial benefits. Clearly, studies of these issues are needed

Sarwer et al hypothesized that patients who lost the most weight would express the greatest desire for post bariatric body contouring surgery. Similar to our study, this was not proven. In his study of 207 patients, with data for 160 participants; mastopexy/male gynaecomastia mastectomy was the most frequently performed procedure and remained in demand after 9 years; the second most contoured area was the abdomen. This may be different from our cohort of patients as there were more females than males and our patient group was older than his population. Patients with greater BMIs wanted post bariatric body contouring, however with time, their desire decreased. Predictors of desire for post bariatric surgery body contouring remained elusive[41].

There is clearly a need for further studies to identify the psychological and functional consequences of bariatric surgery and what are the true and perceived needs for post bariatric surgery body contouring in the NHS. At the current time, we have not verified that surgical correction of these post-weight loss deformities can positively impact either quality of life or psychosocial function. There are no validated

patient report outcome measures for this cohort of patient and the use of valid and reliable measures of physical and psychosocial status should provide important information on the experiences of this growing population of patients.

In addition, there was a disparity between those patients who were approved in Scotland for post bariatric body comparing to those who would have fulfilled the Leeds criteria. 20 patients offered plastic surgery did not have a panniculus which hung below the umbilicus. This amounts to 37.7% of the cases carried out in Scotland being above the threshold for surgery in Leeds. This is another example of the postcode lottery that exists for plastic surgery services commissioning[42, 43].

Interestingly, of those 34 patients who had not yet applied for plastic surgical review, 13 had been informed by their GP that they would not qualify. In Scotland, there is clear guidance on the referral pathway for post bariatric body contouring[25], however, as gate keepers commissioning health services, GPs have the unenviable responsibility of keeping up to date with the changing landscape of healthcare services[44]. Some would argue that this further represents a postcode lottery[45], as individual GP knowledge on local provisions can be an aide or an impediment to accessing care.

Since December 2011, BAPRAS[46] has been pushing for national guidelines on reconstructive surgery following bariatric weight loss procedures. Further studies focussing on the outcome of body contouring after massive weight loss could support the development of national guidelines on post bariatric surgery body contouring. Our health care system demands evidence to perpetuate treatment availability and guide clinical decision making. Plastic surgeons should champion the needs of the post bariatric patient requiring body contouring procedures, by collecting further data to identify outcomes in this patient group, improve equality in the NHS and in so doing provide best practice.

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Figure 1

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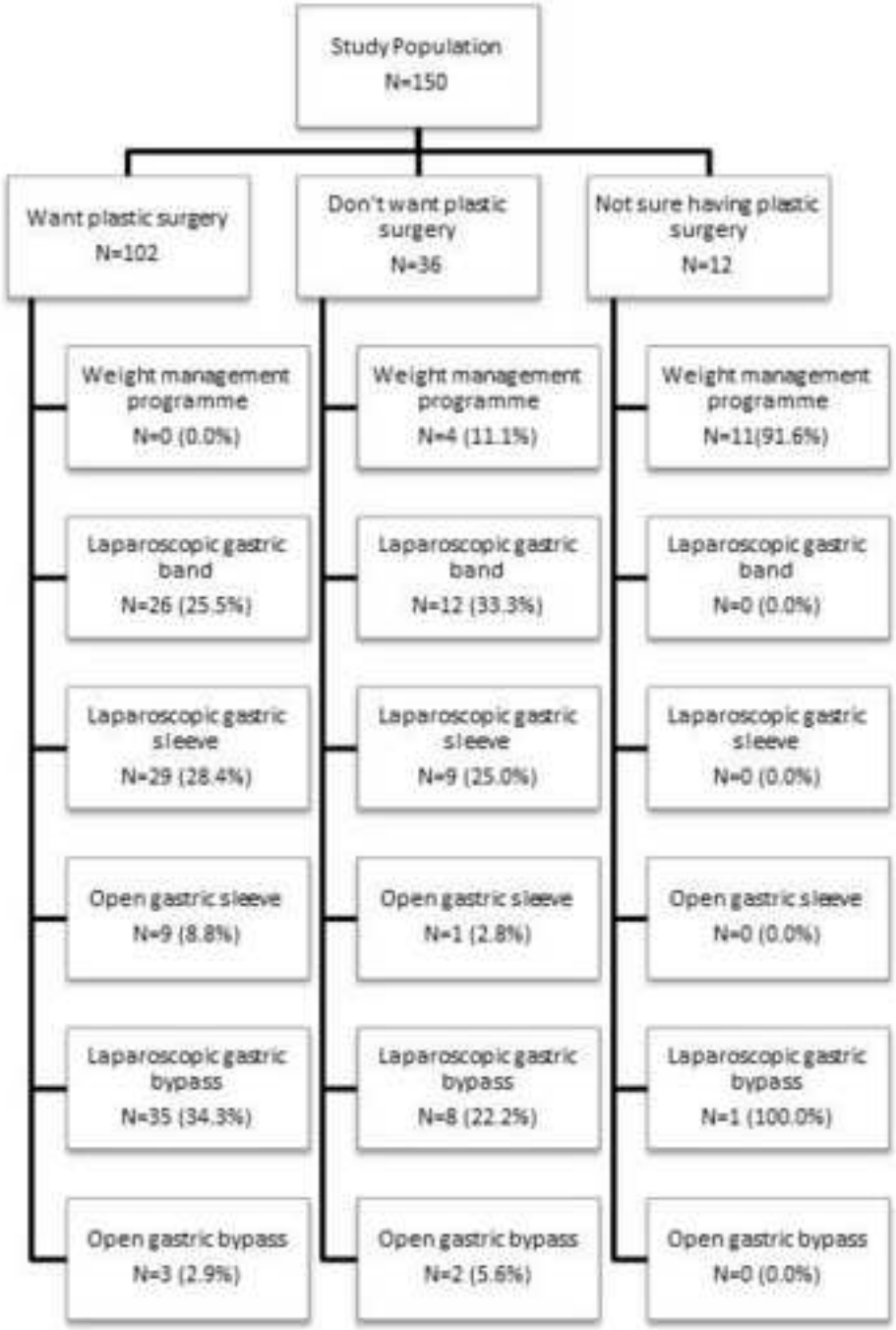

Figure 2

Figure 2

		Does want plastic surgery (n=102)	Does not want plastic surgery (n=36)	Not sure about plastic surgery (n=12)
Average Age (interquartile range)		48.3 (44-54)	52 (47-59)	39 (34-52)
Sex	M	38 (37.3%)	16 (44.4%)	3 (25.0%)
	F	64 (62.7%)	20 (55.6%)	9 (75.0%)
Type of bariatric surgery	Weight management programme (none)	0 (0.0%)	4 (11.1%)	11 (91.6%)
	Gastric band	26 (25.5%)	12 (33.3%)	0 (0.0%)
	Sleeve gastrectomy	38 (37.3%)	10 (27.8%)	0 (0.0%)
	Gastric bypass	38 (37.3%)	10 (27.8%)	1 (8.3%)
Type of bariatric procedure	Open	12 (11.8%)	3 (8.3%)	0 (0.0%)
	Closed	90 (88.2%)	29 (80.6%)	1 (8.3%)
Mean weight loss (kg) (interquartile range (kg))		55.1 (38.6-72.5)	25.1 (4.0-50.8)	16.4 (5.0 – 38.3)
Number of medical problems		2.45	3.86	4.25

Figure 3

	Weight loss kg						
Type of bariatric surgery	**N**	**Mean**	**Median**	**(SD)**	**Minimum**	**Maximum**	**p-value**
Laparoscopic gastric band	26	44.68	39.24	(34.06)	7.40	151.00	**0.038**
Laparoscopic gastric sleeve	29	56.12	47.00	(26.61)	19.00	126.80	
Open gastric sleeve	9	51.75	48.10	(16.39)	38.10	91.90	
Laparoscopic gastric bypass	35	62.13	57.15	(27.16)	16.40	155.20	
Open gastric bypass	3	64.03	46.10	(31.15)	46.00	100.00	
Total	102	55.11	50.00	(28.65)	7.40	155.20	

Figure 4

FIGURE 4

ASSOCIATION OF TYPE OF BARIATRIC SURGERY AND DESIRE FOR PLASTIC SURGERY, EDINBURGH (2011)

	Desire for plastic surgery				
	Yes		No		
Type of bariatric surgery	**N**	**(%)**	**N**	**(%)**	**p-value***
Open gastric bypass	3	(2.9)	2	(6.3)	0.452
Laparoscopic gastric bypass	35	(34.3)	8	(25.0)	
Open gastric sleeve	9	(8.8)	1	(3.1)	
Laparoscopic gastric sleeve	29	(28.4)	9	(28.1)	
Laparoscopic gastric band	26	(25.5)	12	(37.5)	

*Chi-square test

Figure 5

Figure 5

Area of concern	Number of patients
Abdomen	48
Chest	29
Arms	12
Thighs	9
Buttocks	4

Figure Legends

Figure 1: Flow diagram of study population

Figure 2: Background information of study population

Figure 3: Table of weight loss in kilograms for each type of bariatric surgery

Figure 4: Table demonstrating association of type of bariatric surgery and desire for plastic surgery

Figure 5: Table of body part causing concern

Plastic and Reconstructive Surgery

Does the degree of ptosis predict the degree of psychological morbidity in bariatric patients undergoing reconstruction?

--Manuscript Draft--

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Abstract:	see manuscript for abstract
Response to Reviewers:	12th February 2014 Dear Prof Rohrich, Editor-in-Chief, RE: PRS-D-13-02391R1, entitled "Does the degree of ptosis predict the degree of psychological morbidity in bariatric patients undergoing reconstruction?" Thank you for reviewing my revision submitted to PRS. I am extremely grateful for the opportunity to submit my work to your journal. I have made the necessary alterations to the paper, to reflect the reviewer's comments and hope it can now be further considered. Please see my itemized response below. Many thanks for your kind help and time, With best wishes Nada Al-Hadithy Response to Reviewer Comments: Reviewer #3: The authors did a number of changes as a result of the reviewers comments and the paper is more readable. Still, in my opinion it will be difficult to digest this paper especially if presented in a journal with a surgical orientation. Especially the figures 4-10 are difficult to understand and I am not sure if the readers of the journal will benefit from this type of presentation of the data. I would suggest to consider presenting the data in a simpler format (a table maybe). Thank you for your comment. I have deleted figures 5-10. However, have kept the box and whisker plots for comparison of Derriford to anthropometric measures (figure 4). I hope to convince you that this will be of use to the reader. I have moved the explanation of the box and whisker plots to the beginning of the paragraph so that the

	reader can understand what the diagram is showing. I think it's a very elegant way of presenting the data, to demonstrate how anthropometric outcomes have statistically significant effect on outcome measures (in the case of figure 4 - the Derriford 24). Where, once the line in the middle of the box has crossed above the red line, a threshold has been crossed, which renders the finding statistically significant and provides a positive DAS-24 score. In terms of converting this data to a table, I don't think it would be any easier to understand and now that the rest of the box and whisker plots have been removed I hope that the reader will find figure 4 less befuddling. I hope this helps and am extremely grateful for your review. Many thanks for your thoughts and comments With best wishes Nada Al-Hadithy

Does the degree of ptosis predict the degree of psychological morbidity in bariatric patients undergoing reconstruction?

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Abstract

Background: There is proven therapeutic benefit in bariatric surgery for obese patients. Consequently the National Institute of Health, USA and the National Institute of Clinical Excellence, UK has provided referral guidelines for bariatric surgery. Successful bariatric surgery will result in massive weight loss and ptotic skin, which can cause significant functional and psychological problems. As bariatric surgery increases so will the demand for plastic surgery. Currently there is no evidence based indication for massive weight loss body contouring and therefore there is no standardized provision.

Methods: A prospective multicentre, observational study of outcomes in 75 patients undergoing bariatric and plastic surgery procedures at 2 clinical sites was performed to determine whether the degree of ptosis can be determined by the type (malabsorptive or restrictive) of bariatric surgery and if the extent of disfigurement has an impact on psychological morbidity.

Results: Massive weight loss body contouring (MWLBC) is not purely aesthetic surgery but leads to functional and psychosocial benefits. This study has given preliminary data on which anthropometric measurements and their thresholds lead to the greatest benefit from MWBLC. From this study, the fourth quartiles of the following anthropometric measurements: xiphisternum to pubic symphysis (≥91cm), umbilicus to pubic symphysis (≥38cm) and hip circumference (≥143cm) were statistically significant in crossing the psychometric tolerances from within the normal range to pathological psychology.

Conclusion: This study demonstrated that there is a statistically significant quantifiable correlation between type of bariatric surgery, degree of ptosis and psychological morbidity in patients who have undergone bariatric surgery. This pilot study could provide the basis for evidence based guidelines for plastic surgery referral.

Introduction

There is proven therapeutic benefit in bariatric surgery for obese patients[1]. Successful restrictive bariatric surgery will result in a loss of around 50% of excess body weight and up to two thirds of excess body weight in malabsorptive procedures[2]. This massive weight loss can result in ptotic skin, causing significant functional and psychological problems[3]. As bariatric surgery increases so will the demand for plastic surgery[4]. Currently there is no evidence based indication for massive weight loss body contouring and therefore there is no standardized provision[5]. However, restriction on the availability of surgery to rectify excess skin is an impediment to weight loss[6]. Studies have shown that there is improvement in mental health and psychological functioning following bariatric surgery[7, 4]. This study was carried out to investigate if there is a correlation between type of bariatric surgery, ptosis and psychological morbidity in patients who have undergone bariatric surgery.

Methods

We performed a prospective cross sectional multicentre, observational study of outcomes in patients undergoing bariatric and plastic surgery procedures at 2 clinical sites in Scotland, UK. Regional Ethical Committee approval was obtained for the study protocol. Written informed consent was obtained from all subjects. Seventy five patients over the age of 18, who had undergone or were undergoing bariatric surgery, were recruited from the regional bariatric service, with staggered entry between 2010 and 2012. Patients with a previous history of gluteal implants, abdominoplasty and body contouring procedures were excluded.

Currently there are no validated tools for the massive weight loss body contouring group. This led to a selection of patient report outcome measures being used, each selected for their individual data captured. The following patient report outcome measures (PROMs) were posted to patients:

1. Eating Disorders Questionnaire (EDQ)[8,9]. This is a validated baseline questionnaire including self-reported information on demographics, weight history, weight control behaviour, exercise, history of abuse, psychiatric history, past medical history, chemical use history, social history, and other factors.
2. Derriford Appearance Scale (DAS-24)[10]. This is a 24 item factorial scale measuring appearance related distress, social anxiety and avoidance, standardised on both general and hospital populations

3. Hospital Anxiety and Depression Score[11, 12,13]. This is a 14 item screening tool for anxiety and depression, standardised to both general and hospital populations that generates ordinal data. Seven of the items relate to anxiety and seven relate to depression.
4. Short Form-36[14,15, 16, 17,18,19.] This is a 36 item measure of health status commonly used in health economics as a variable in the quality-adjusted life year calculation to determine the cost-effectiveness of a health treatment.
5. Bariatric Analysis and Reporting Outcome System (BAROS)[20,21,22,23,24.] This is a tool validated for the bariatric cohort and allocates points for percentage weight loss, change in medical conditions, and a Likert scale is included for QoL changes: self-esteem, physical well-being, social well-being, ability to work and sexual intimacy.

Patients were followed up in clinic and completed questionnaires with a trained Clinical Research Nurse (CRN) who followed a standard operating procedure. Height and weight was measured. The same clinical practitioner took surface linear anthropometric measurements including arm circumferences; apex of axilla to lateral folds; suprasternal notch to left and right nipples; nipple to inferior mammary folds, suprasternal notch to umbilicus, pannus to pubic symphysis; umbilicus to pannus and pubic symphysis and waist and hip circumferences. A standard operational protocol was followed in taking anthropometric measurements to ensure inter subject consistency. (Appendix A).

Results

Data was analyzed with IBM SPSS V.19 statistical package, at Dundee University. 75 patients were recruited. 7 were lost to follow up. 68 patients were reviewed in clinic and underwent the above protocol. 24 were male and 44 were female.

The patients were divided up into 2 groups: bariatric surgery alone or bariatric surgery and reconstructive surgery and were a mean of 19.64 and 38.71 months post bariatric surgery, respectively. Mean time post plastic surgery was 14.3 months (range 3-45) (Table 1). Two sample t-test demonstrated no statistically significant differences in patients' height, current weight, weight loss or percentage weight loss (Table 1). There was variation between the two groups in the patients' age, previous weight, ideal weight and smoking history. The plastic surgery procedures carried out included abdominoplasty (24%), interim abdominoplasty (9%) (an abdominoplasty for those patients who are still losing weight but unable to exercise because of excessive panus length), fleur de lys abdominoplasty (9%), lower body lift (5%), thigh lift (5%), mastopexy (19%), mammoplasty (5%), brachioplasty (19%) and neck reduction (5%) (figure 1). Demographic data was collected from the Eating Disorder questionnaires and further triangulated by face to face

interviews. Information on exercise frequency and data were collected and allocated scores. Age, height, weight, BMI, weight lost, percentage of excess weight lost, complications, pain and limitation in function due to their feature (as defined in by the Derriford 24 score), smoking, exercise and career history were documented. Nine patients experienced complications. Mean age=51 (range 38-68). Mean weight loss 100.1kg (range 51.2kg – 199.58kg). There was a statistically significant reduction in pain from the physical feature patients sought plastic surgery for; from 1.35 to 0.8 (p value 0.049). Following plastic surgery patients were also less likely to report a limitation in their physical ability to their feature (p value 0.038) (Table 1).

Post plastic surgery patients smoked less by 50.5%, were 1.82 times more active and 2.75 times more likely to have reported career progression from either a professional or financial vantage point when compared to the control group of those who had reached their target weight but had not had reconstructive surgery.

They were further divided into two groups on whether they had undergone restrictive or malabsorptive bariatric surgery (Table 2). Following bariatric surgery patients lost 60.7% (restrictive) and 66.5% (malabsorptive) of their excess weight. This increased to 88.22% (restrictive) and 75.89% (malabsorptive) following plastic surgery.

Psychological outcomes can be seen in figures 2 and 3. A high score in SF36 and BAROS represents a good outcome, whereas high scores in Derriford 24 and HADS suggest “caseness” of depression or anxiety. There was a statistically significant improvement in psychological outcomes as reported through Derriford 24, BAROS, and HADS. This was not reflected in the SF-36. The best results were seen in the patients who had undergone body contouring procedures following restrictive bariatric surgery. This was consistent across all psychometric scores.

This same group of patients (plastic surgery following restrictive bariatric surgery) demonstrated best outcomes in anthropometric measurements (Table 2). This occurred despite this particular group of patients having lost the greatest amount of weight.

A spearman’s rank correlation coefficient was calculated comparing the PROMs to anthropometric measurements (Table 3). Spearman’s rank is a nonparametric measure of statistical dependence between two variables, it assesses how well the relationship between two variables can be described using a monotonic function.

Of all of them, the xiphisternum to pubic symphysis, umbilicus to pubic symphysis and hip circumference measurements were most closely correlated to psychometric outcomes. An analysis of variance (ANOVA) between the groups was carried out with the Derriford 24 as the dependent

(Table 4). ANOVA is used to determine whether there are any significant differences between the means of three or more independent (unrelated) groups. Both the spearman's rank correlation coefficient and the ANOVA demonstrated a statistically significant relationship between PROM and anthropometric measurement.

Anthropometric measurements were divided into four percentile groups (quartiles) and plotted on a box and whisker plot against, BAROS and Derriford and 8 variables (figure 4). A box and whisker plot is a visual representation of data, where the range between the second and third quartiles is represented by the boundaries of the box, with a vertical line inside to indicate the median value. The lower and upper quartiles are shown as horizontal lines either side of the rectangle (whiskers). The horizontal red lines indicate the normal values, and it can be seen that in the fourth quartile these psychological outcomes cross thresholds, from successful to unsuccessful outcomes. This indicates that in the fourth quartile, those patients with the largest anthropometric measurements had statistically significantly pathological psychometric outcomes.

As the xiphisternum to pubic symphysis, umbilicus to pubic symphysis and hip circumference measurements were most closely correlated to psychometric outcomes, anthropometric were reviewed in closer details. The anthropometric measurements were grouped into quartiles and box and whisker plots were drawn against BAROS, SF-36, HADS and Derriford 24. This closer analysis revealed that the top 25% (xiphisternum to pubic symphysis (≥91cm), umbilicus to pubic symphysis (≥38cm) and hip circumference (≥143cm)), had worse outcome scores on the Derriford 24, BAROS and HADS. However, this change was not detected with the SF-36. Note, that this was the case for all three measurements however only a sample of the figures were included to minimise replication.

Discussion

Studies have shown that following massive weight loss body contouring procedures patient expectations are for three main outcomes: improvement of appearance, self-confidence and quality of life, in that order[5, 25]. Our previous study demonstrated that patients sought massive weight loss body contouring for concerns about the appearance of different parts of their body and the consequences this has on their psychosocial well-being and physical ability to carry out the activities of daily living[26].

This study shows that post massive weight loss body contouring patients were less distressed about appearance (Derrifod 24), had an improvement in mood, quality of life and function. In addition, patients had improved outcomes in career progression and health metrics such as smoking cessation and exercise.

All of these patients reported improvements in exercise, career progression and relationship status, as well as statistically significant improvements in their SF36, Derriford 24 and BAROS despite post operative complications.

The patients who underwent body contouring following malabsorptive bariatric surgery, were reviewed after the longest post-operative period (41.5months post their initial surgery), yet still had worse anthropometric and psychological outcomes. Furthermore, these patients had lost more weight initially, but subsequently, following plastic surgery; the restrictive patients had the best outcome both in terms of weight loss, contour and the psychometric scores: Derriford 24, BAROS and HADs. This is in keeping with previous papers[27] that found that 1 year after restrictive bariatric surgery weight loss correlated with decrease in depressive symptoms, and as weight loss plateaued so did the improvement in mood. The lack of improvement in SF-36 has also been previously documented[28,29].[30]. However, our previous paper and work by Dymek[31, 32] suggests that some improvements in some subscales of the SF-36 are valid for the massive weight loss cohort. (Physical functioning, general health, vitality and mental health).

The patients who had malabsorptive procedures reported worse psychometric outcomes, and this is in keeping with previous work by Zwaan et al[33] who reported worse scores for bodily pain and overall physical composite scores. This study demonstrates malabsorptive bariatric surgery led to greater disfigurement with diffuse lipodystrophy and generalized skin laxity. Typically patients who undergo malabsorptive bariatric surgery lose weight more rapidly than patients who have restrictive bariatric surgery[34]. We believe that the increased rate of weight loss contributes to the degree of skin ptosis. We also found that increased ptosis leads to increased psychological morbidity, even after reconstruction with plastic surgery. It may be possible that the variations in physical appearance as a result of the varying rates of weight loss may contribute to worse psychometric outcomes. Further studies are warranted.

The modern concept of the aesthetic abdomen as described by Lockwood[35] will not be achieved through simple abdominoplasty in massive weight loss patients. Since it was developed in the 1960s, the abdominoplasty has undergone innovative modifications to obtain ever superior aesthetic outcomes[36, 37, 38, 39]. For the bariatric patient, innovative excisional contouring pioneered by Pitangy and Lockwood[40] is necessary[41]. However, in this cohort of patients, the reconstruction surgery offered was dominated by simple abdominoplasty. It has been seen that although abdominoplasty results in a functional improvement, it does not address all the aesthetic needs of this complex group of patients. This could account for the lesser degree of satisfaction in the malabsorptive patients, who had lost more weight and suffered a greater degree of ptosis. Given the complex

nature of these patients, there is an increasing belief that massive weight loss body contouring should be undertaken in a unit with a multi disciplinary team and the appropriate expertise to offer appropriate contouring procedures safely.

Limitations

Seven patients were lost to follow up and this lost data could account for different results. Patients in the post plastic surgery cohort were younger than the post bariatric surgery alone cohort with a mean age difference of 1.33 years. The authors believe that this age difference is unlikely to cause change in dermal laxity to account for difference in ptosis. The age difference could be accounted for by the fact that the post plastic surgery patients were the very first patients to have bariatric surgery in the South East of Scotland and therefore, were selected for lower risk factors associated with lower ages. However, as the operative experience has increased, a more diverse group of patients have been operated on.

This study was an exploratory study and further larger studies would need to be carried out to validate the results. As the patients were only followed up at two time points, the rate of weight loss was difficult to track. Ideally the patients' weight would have been tracked during the entirety of their weight loss programme as this would have provided very useful information in identifying whether plateaus in weight loss correlated with plateaus in psychological morbidity, or, if it is the rate of weight loss and not the final weight lost that leads to psychological outcomes. Further studies are warranted.

Conclusion

Massive weight loss body contouring (MWLBC) is not purely aesthetic surgery but leads to functional and psychosocial benefits. This study has given preliminary data on which anthropometric measurements and their thresholds lead to the greatest benefit from MWBLC. From this study, the fourth quartiles of the following anthropometric measurements: xiphisternum to pubic symphysis (≥91cm), umbilicus to pubic symphysis (≥38cm) and hip circumference (≥143cm) were statistically significant in crossing the psychometric tolerances from within the normal range to pathological psychology. Currently there is no evidence based guidance for provision of post bariatric surgery body contouring[7]. Therefore, these measurements could provide guidance when allocating limited resources in socially funded health systems.

Following massive weight loss body contouring the somatic health of patients dramatically improves with a reduction in smoking and increase in exercise, whilst the psychological health can in some cases, deteriorate. This paper has demonstrated in a limited number of patients that the rate of

weight loss associated with malabsorbtive bariatric surgery, the subsequent degree of ptosis and extent of disfigurement has an impact on psychological morbidity. The plastic surgeon has long appreciated how good pre operative counselling is imperative to optimise patients and manage expectations. This early data may guide surgeons carrying out massive weight loss body contouring procedures and highlight the importance of carrying out the correct procedure in the correct setting with the support of a multi disciplinary team that can address the complex needs of these patients.

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Conflicts of interest: None declared

Ethical approval:

All studies conformed to the World Medical Association Declaration of Helsinki (June 1964) and subsequent amendments (http://www.wma.net/en/30publications/10policies/b3/index.html. The research protocol was approved by South East Scotland regional ethical committee. Reference number: 10/S1102/2.

R&D Approval: Approval from NHS Lothian. 2010/SJ/PS/01

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Figure Legends

Figure 1: Distribution of plastic surgery procedures carried out in massive weight loss patients

Figure 2: Bar charts of Derriford and SF36 scores in post bariatric and plastic surgery in restrictive and malabsorptive massive weight loss patients.

Figure 3: Bar charts of HADS and BAROS scores in post bariatric and plastic surgery in restrictive and malabsorptive massive weight loss patients.

Figure 4: Box and whisker plots of Derriford against anthropometric measures

Tables

Table 1: Demographics

	Post Bariatric Surgery	Post plastic Surgery	Two sample t-Test assuming unequal variances
N	48	20	-
Sex	M = 17 F = 31	M= 7, F=13	-
Mean time post bariatric surgery (months)	19.64 (range 1-54)	38.71 (range 12-93)	-
Mean Age	49.39 (range 28 – 67)	48.02 (24-68)	0.64
Mean height (cm)	167.77 (138-185)	169.17 (150.0-183.49)	0.04
Mean current weight (kg)	102.75 (59.9-159)	90.54 (56.67-142)	0.07
Mean BMI (kg/m2)	36.71 (22.55-54.57)	31.40 (20.44-49.7)	0.01
Mean previous weight (kg)	161.10 (87.1-233.2)	171.78 (114.3-261.86)	0.27
Mean weight lost (kg)	58.34 (7.4-155.2)	81.19 (37.85-160.36)	0.004
Mean percentage of excess weight lost	63.62 (8.6-100)	82.06(36-100)	0.0005
Mean pack year history	17.73 (0-60)	17.59 (0-80)	0.81
Mean Exercise Score	6.77	12.33	-
Career progression	0.32	0.88	-
Physical pain from feature	1.35	0.80	0.049
Feature limits physical ability	1.67	1.05	0.038

REMOVED from table 1 to simplify

Ethnicity	W= 45 I=3	W=20	-
Mean ideal weight (kg)	70.20 (47.619-85.56)	70.52 (56.25-83.72)	0.84
Mean cigarettes per day	7.50 (0-40)	3.79 (0-30)	0.25

Table 2: Demographics of subgroups

	Post Bariatric Surgery		Post plastic Surgery	
	Restrictive	Malabsorptive	Restrictive	Malabsorptive
N	26	22	12	8
Mean time post bariatric surgery (months)	21 (range 1-36)	18.27 (range 2-54)	35.92 (range 12-60)	41.5 (range 14-93)
Mean BMI (kg/m^2)	37.0 (22.55-54.57)	36.4 (23.43-54.36)	29.42 (20.44-49.7)	33.38 (26.8-47.5)
Mean weight lost (kg)	53.32 (7.4-126.8)	63.36 (28.7-155.2)	89.21 (46.77-160.36)	73.17 (37.85-102.3)
Mean % of excess weight lost	60.7 (8.6-100)	66.5 (42-100)	88.22 (57.35-100)	75.89 (36-95.3)
Mean pack year history	17.31(0-60)	18.15 (0-80)	25.83 (0-80)	9.38 (0-40)
Mean Exercise Score	6.72	6.82	13.41	11.25
Career progression	0.19	0.45	0.75	1.0
Xiphisternum (xiphi) – umbilicus (umbo) (cm)	45.35 (12-60)	50.95 (40-60)	34.75 (24-45)	38.125(17-48)
Xiphisternum – pannus (cm)	63.6 (33-84)	66.00 (51-84)	N/A	N/A
Xiphisternum – pubic symphysis (PS) (cm)	75.58 (27-102)	80.36 (57-105)	49.5 (40-65)	52.625(36-67)
Umbilicis to pubic symphysis (cm)	30.30769 (15-56)	29.5 (12-45)	14.75 (10-20)	14.5(7-19)
Umbilicis to pannus (cm)	16.69231 (9-28)	15.23 (7-24)	N/A	N/A
Pannus to Pubic Symphisis (cm)	14 (4-48)	14.36 (4-34)	N/A	N/A
Waist Circumference (Circ) (cm)	111.04 (29-143)	116.05 (84-140)	91.08 (60-142)	92.25(51-123)
Hip Circumference (Circ) (cm)	126.42 (95- 164)	119.73 (11-155)	101.41 (63-146)	104.75(50-130)

Table 3: Spearman's Rank Correlation of psychometric scores against anthropometric measurements

		Xiphi-Umbo	Xiphi-PS	Umbo-PS	Pannus-PS	Waist Circ	Hip Circ
Derriford	Sig. (2-tailed)	.042	.001	.000	.001	.005	.001
Baros	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000
SF 36	Sig. (2-tailed)	.047	.011	.004	.008	.023	.010
HADS A	Sig. (2-tailed)	.022	.001	.000	.004	.004	.001
HADS D	Sig. (2-tailed)	.019	.003	.003	.008	.001	.001

Removed from table 3 to simply

Derriford	Correlation Coefficient	.224**	.351**	.437**	.374**	.306*	.369**
Baros	Correlation Coefficient	-.490**	-.621**	-.608**	-.520**	-.618**	-.669**
SF 36	Correlation Coefficient	-.219**	-.279**	-.316**	-.291**	-.249*	-.280**
HADS A	Correlation Coefficient	.252**	.364**	.413**	.311**	.312*	.355**
HADS D	Correlation Coefficient	.256**	.322**	.326**	.290**	.370*	.367**

Table 4: Univariate Analysis of Variance of Derriford against anthropometric measurements

	F	Sig.
Hip Circumference	5.509	.002
Waist Circumference	2.650	.055
Umbo-Pannus	2.469	.071
Umbo-PS	7.013	.000
Xiphi-PS	5.208	.002
Xiphi-Pannus	2.720	.053
Xiphi-Umbo	1.427	.241

Figure 1
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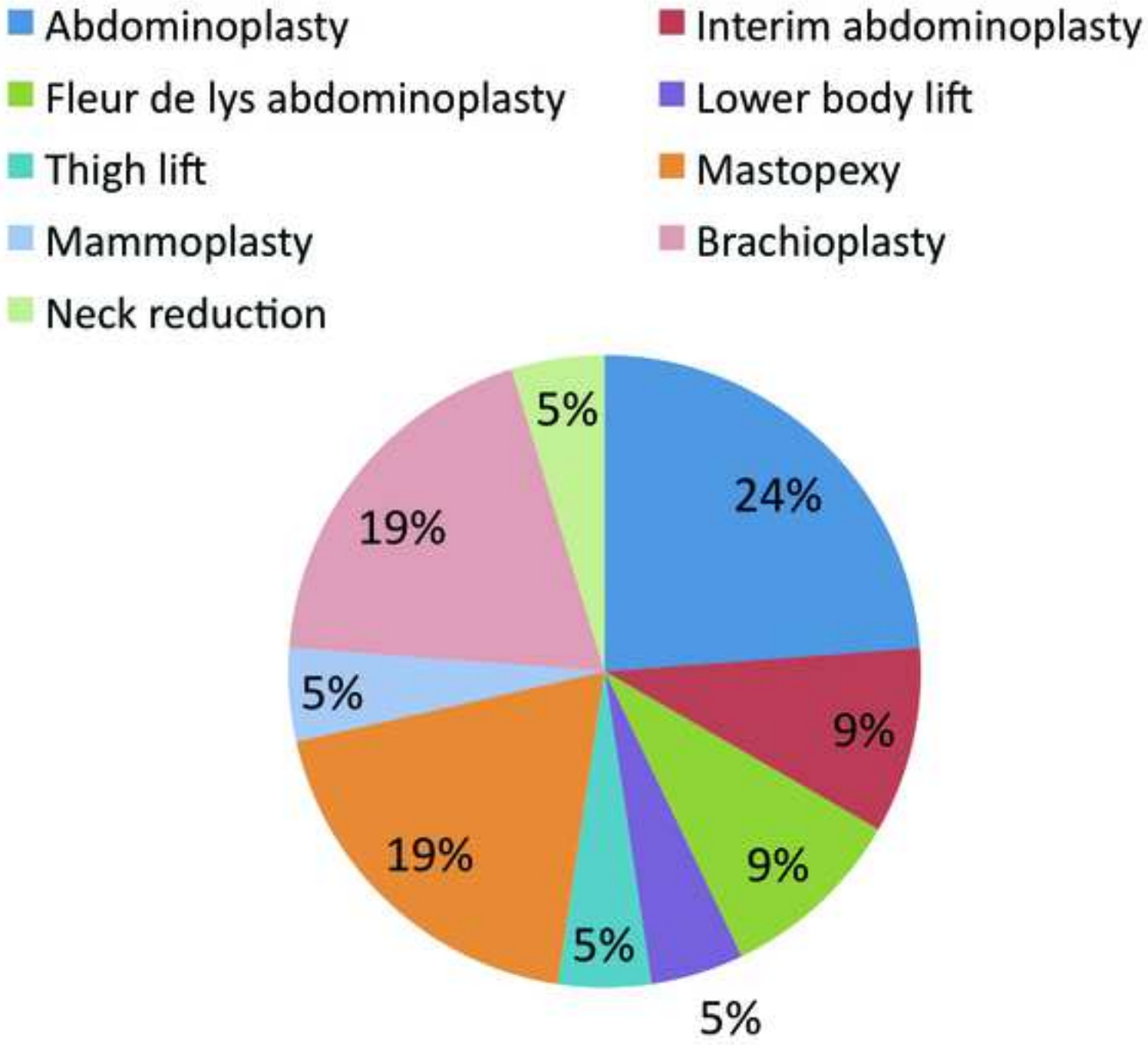

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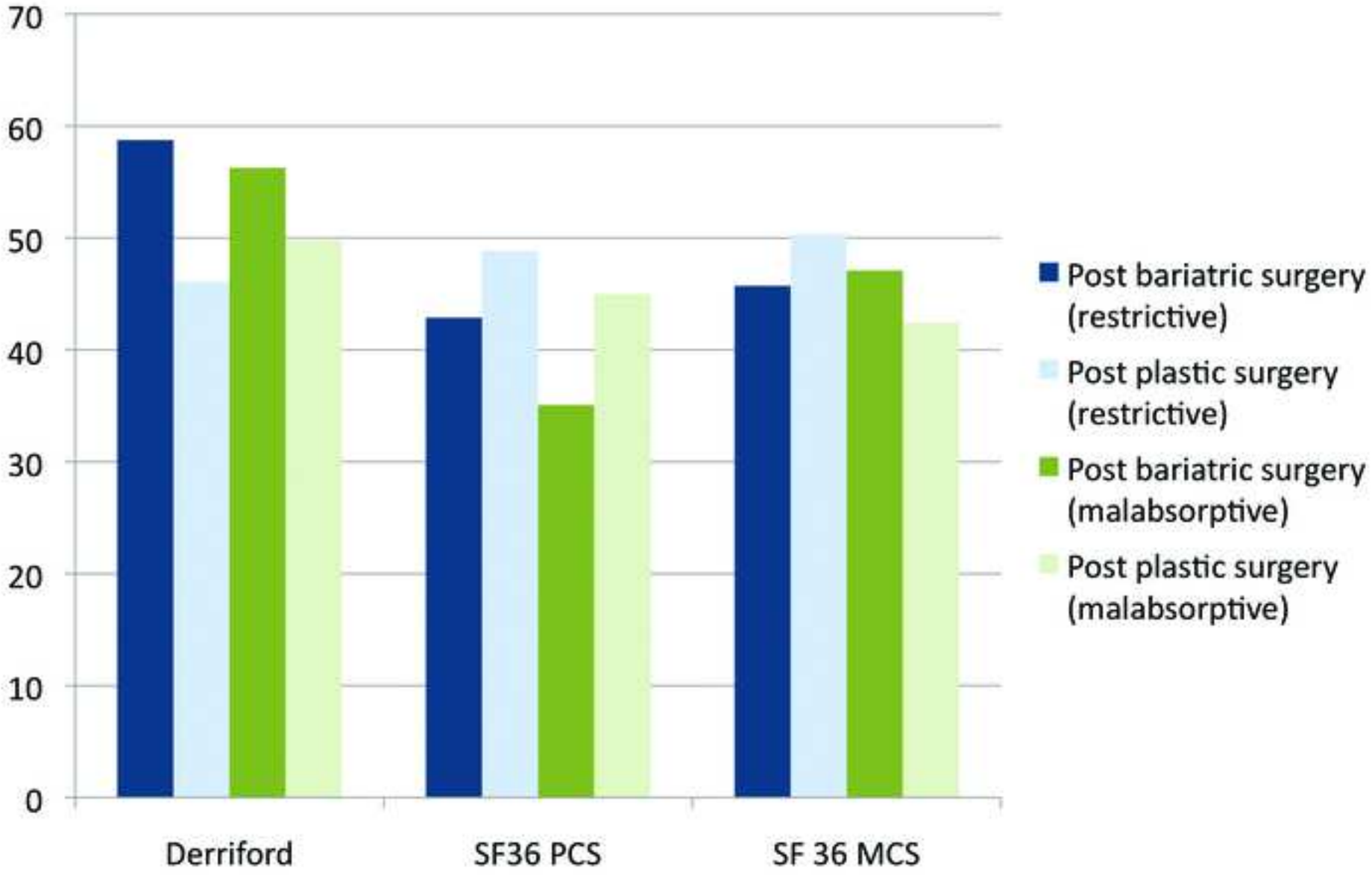

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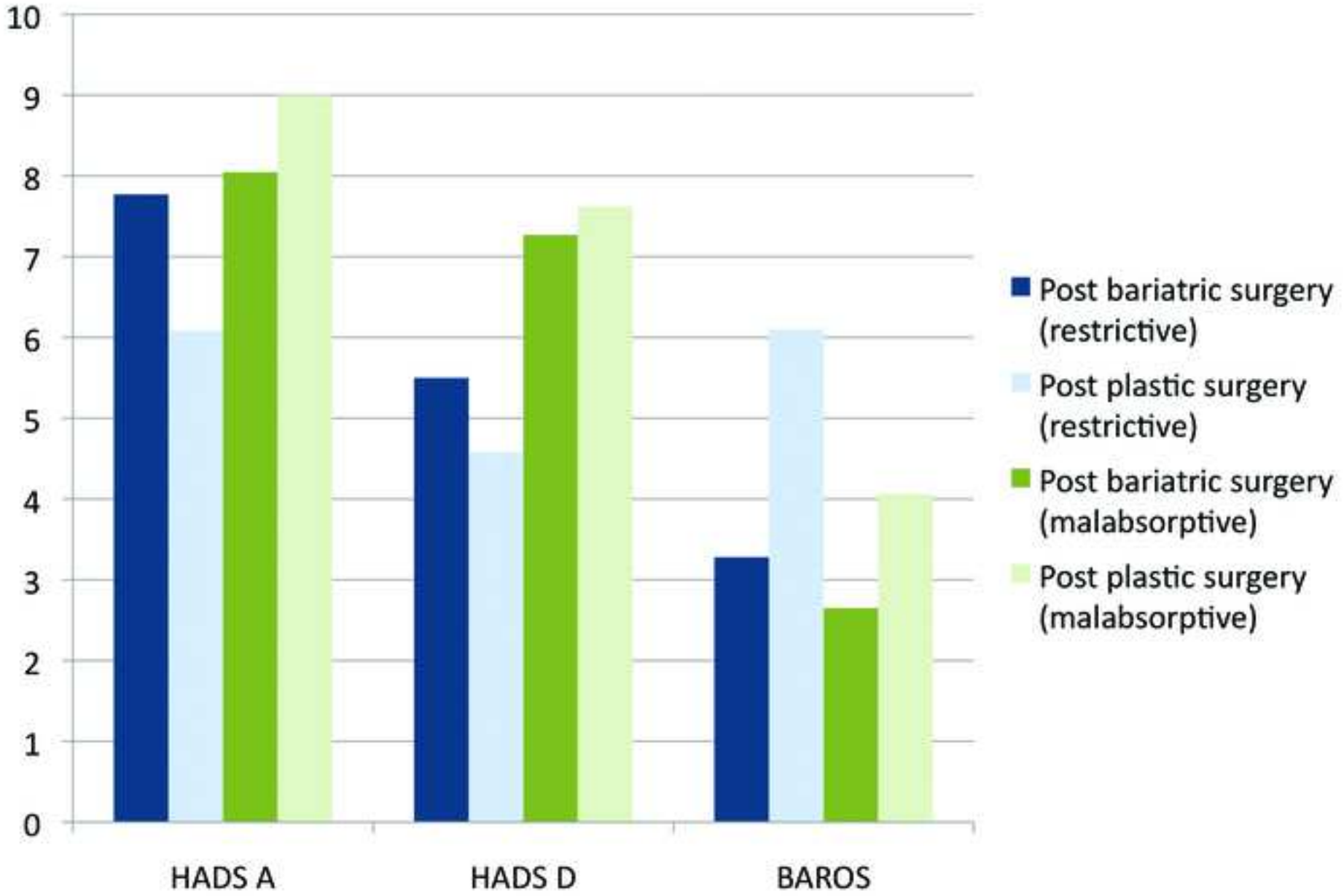

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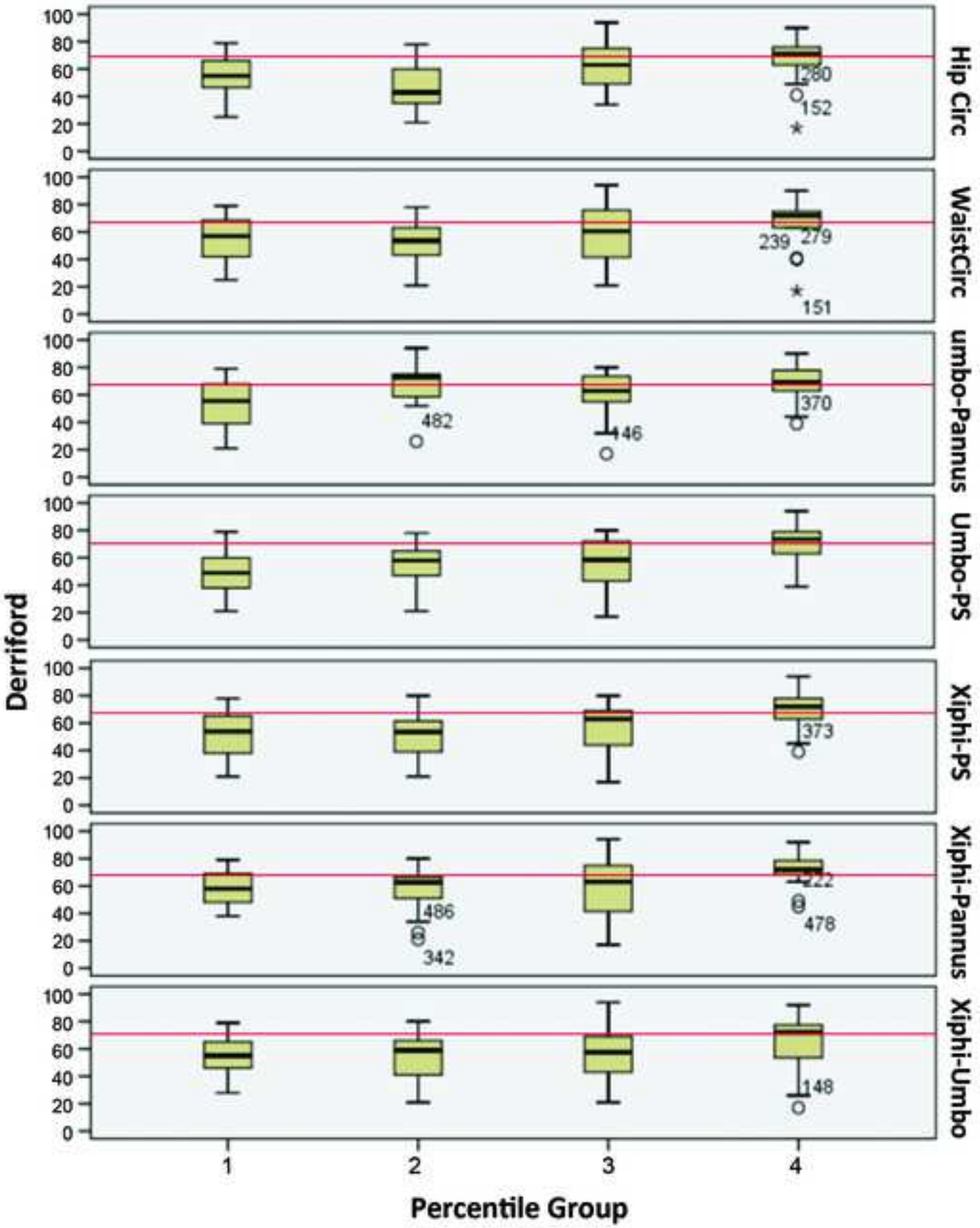

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19th November 2013

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If accepted, the paper will not be published elsewhere in the same or similar form, in English or in any other language, without written consent of the copyright holder.

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Yours faithfully

Nada Al-Hadithy

Aditya Hosakere

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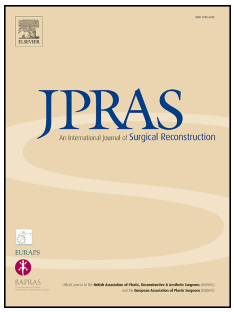

A preliminary report on the development of a validated tool for measuring psychosocial outcomes for massive weight loss patients

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A PRELIMINARY REPORT ON THE DEVELOPMENT OF A VALIDATED TOOL FOR MEASURING PSYCHOSOCIAL OUTCOMES FOR MASSIVE WEIGHT LOSS PATIENTS

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ABSTRACT

Aim: To validate the newly developed patient report outcome measure (PROM): the Post Bariatric Outcome Tool (PBOT). The tool is designed and developed for massive weight loss patients seeking body contouring procedures.

Method: The PBOT was piloted with three cohorts: massive weight loss patients seeking body contouring; massive weight loss patients who have had body contouring; and healthy, non-obese subjects as controls matched for age and gender. Each cohort completed two PROMS at week one, and then for a second time at week three. The PROMS used were the new Post Bariatric Outcome Tool (PBOT) and the Derriford Appearance Scale 24 (DAS24).

Conclusion

The PBOT was shown to be reliable both in terms of its internal consistency and test-retest reliability. Comparison to the DAS24 demonstrated the PBOT to be valid. However, the cohorts were small and responsiveness was not tested. This needs to be tested in further larger validation studies, ideally, with comparison to functional scales such as the SF-36 or other validated massive weight loss body contouring PROMs; such as the Body Q.

INTRODUCTION

Following bariatric surgery, morbidity and mortality decreases,[1] however ptotic redundant skin folds do not contract with the volume loss[2] resulting in intertriginous rash, hygiene issues and functional and psychological impairment.[3] Identifying outcomes in these patients requires an understanding of the complex adjustment they are making to their new body habitus, the redundant skin, removal of the coping mechanism of food, identity and the functional and psychosocial fall out. Evidence-based health policy emphasizes the importance of using scientifically rigorous patient-based outcome measures to evaluate the impact of disease and treatment.[4]

Ensuring valid, robust data is generated from patient reported outcome measures (PROMs) depends on an appropriate assessment tool,[5] reflecting the population, disease and specific domains relevant to the cohort. Although PROMs have been used widely in chronic illness and cancer, they are still a relatively new concept in the field of surgery.[6] The aim of PROMs is to assess the patient's perspective of health, illness, and the effects of health care interventions in a reliable, valid, acceptable, and feasible way.[7] Darzi's "NHS Next Stage Review"[8] indicates that PROMs will be increasingly used in the evaluation and policy making[9] of healthcare technologies and services. The drive to improve quality of care has led to the recognition of the importance of patient perspective and consequently the development of

robust PROMs.[10] Currently there is no measure for the massive weight loss body contouring (MWLBC) patient that is psychometrically sound; derived from patient and user experiences; has face validity; and is easy to administer and score.

We have developed a patient report outcome measure for massive weight loss (MWL) patients wishing to undergo body contouring called the Post Bariatric Outcome Tool (PBOT) (Appendix A). This PROM has been designed to fit in with the national guidelines of massive weight loss body contouring published by BAPRAS in 2014.[11]

Utilising this PROM as part of the referral pathway will help identify which patients meet the national criteria and will heighten awareness of psychological disturbance that may warrant early psychological intervention. We anticipate users of the PBOT will come from a range a professional backgrounds including GPs, bariatric surgeons, plastic and reconstructive surgeons, clinical health psychologists and specialist nurses, as well as academics. The PBOT is five pages long. The referrer completes pages 1-2. The patient completes pages 3-5.

The length of time taken to complete the PBOT varies, but is usually between 10 and 15 minutes for pages 3-5. The completed form (pages 1-5), along with a clinical photograph of the patient is then sent to the MWLBC MDT for analysis and scoring. Figure 1.

In order to measure psychological and functional adjustment to MWLBC it is recommended that the patient completes pages 3-5 of the PBOT for a second time at the final plastic surgery outpatient clinic.

To develop a conceptual model and generate items for the PBOT we followed an established method of: literature review; semi structured patient interviews and expert opinions. This has been described elsewhere[12] and is beyond the remit of this paper. This paper highlights

the outcomes of assessment of validity of the PBOT in a prospective study, as per the guidance developed by the Scientific Advisory Committee of the Medical Outcomes Trust.[13]

METHODS

FIELD TEST AND PSYCHOMETRIC ANALYSIS

The following 3 groups were posted and completed the PBOT and Derriford 24 (DAS24) at week one and week three.

- 10 non-obese, healthy population
- 10 patients following massive weight loss (MWL)
- 10 patients post massive weight loss and body contouring (MWLBC)

Psychometric analysis was then performed on results for conceptual and measurement model, acceptability, responsiveness, reliability and validity.

CONCEPTUAL AND MEASUREMENT MODEL

"A PROM should have documentation defining and describing the concept(s) included and the intended population(s) for use."[14, 15] The PROM is supported by appropriate documentation. Appendices B & C.

ADMINISTRATIVE BURDEN/ ACCEPTABILITY;

The burden of acceptability was assessed by completion percentage of the PBOT. We were willing to accept < 10% frequency of missing data from completed scores. Response distributions were examined, focusing on maximum endorsement frequencies, i.e. highest proportion of respondents who endorsed a single category for an item (should be <80%). Reading ease should be assessed. The Flesch/Flesch–Kincaid readability tests are designed to in-

dicate comprehension difficulty when reading a passage of contemporary academic English[16]. There are two tests, the Flesch Reading Ease, and the Flesch–Kincaid Grade Level.[17]

RESPONSIVENESS

This is the ability of a PROM to detect change over time or following intervention/surgery[18].

RELIABILITY

Reliability is a measure of the extent to which a PROM is free from random error.[6] For PROMs, the two most common types of reliability assessed are internal consistency and test-retest reliability. Internal consistency can be measured with Cronbach's Coefficient Alpha.[19] We judged r >0.70 acceptable[20]. Test-retest reliability is a measure of the reproducibility of the PROM to provide consistent scores over time in a stable population. Test-retest reliability was assessed by estimated Bland and Altman's method for agreement of repeated scores, where >95% of the mean of the re-test against the difference of the re-test within 2 standard deviations of the bias was considered acceptable.

VALIDITY

Construct validity is the extent to which scores on the PROM relate to other validated measures (for the PBOT we have compared it to the DAS24[21]) in a manner that is consistent with theoretically derived hypotheses concerning the constructs that are being measured.[7,22]It is calculated using Spearman rank correlation co-efficient for mean scores. Content validity was determined in our previous paper. Validity hypothesis testing is the ability to measure expected differences between groups within patient population[23].

RESULTS

DEMOGRAPHIC INFORMATION

30 subjects completed the DAS24 and the PBOT twice, 2 weeks apart. The groups were matched for sex. Table 1. Subjects were reviewed a mean of 27.85 months following bariatric surgery (range 12-60). There were equal numbers of laparoscopic gastric bypass procedures and laparoscopic gastric bands at 7 each. 6 patients had their bands converted to open procedures intra operatively. Table 2.

Completed forms for each group were assessed using the mark scheme and aid (Appendices B&C). The scores were reflected in two parts: one for the referral tool component (pages 1-2), and the other for the PROM component (pages 3-5). The DAS24 was scored for comparison. Table 3.

Analysis

Data was analyzed with IBM SPSS V.19 statistical package. The three groups were matched for sex. There was no statistical difference in age with a coefficient of variation of 28.94%, 22.62% and 26.67% respectively. ANOVA resulted in F value of 0.81, P value 0.45 and R square of 0.05.

Administrative burden/ Acceptability;

The burden of acceptability was assessed by percentage completeness of the PBOT. The mean completion percentage was 93.82%, which met our acceptance criteria of frequency of missing data. Table 4. The response distributions were examined in table 4. In the non-obese non-disease group 12-13 items had a >80% maximum endorsement frequency of the 27 items. This represents an 11.1% to 44.4% of the range of questions. In the post body contouring group alone, 3-4 items had a >80% maximum endorsement frequency, representing an 11.1%-14.8% range of questions.

The Flesch Reading Ease score for the PBOT was 62.3, indicating a reading age of approximately 13. A key can be seen in table 5.

Responsiveness

This was not measured as the same group of patients did not complete the PBOT before and after surgery or an intervention.

Reliability

Internal consistency can be measured with Cronbach's Coefficient Alpha.[19] The data was collated in groups and time (week 1 and 3). Table 6. Test-retest reliability was assessed by estimated Bland and Altman's method for agreement for repeated scores, where >95% of the mean of the re-test against the difference of the re-test within 2 standard deviations of the bias was considered acceptable. Table 7 and figure 2.

Validity

Construct validity was calculated using Spearman's Rank correlation coefficients for mean scores between DAS24 and the PROM component of the PBOT. Table 8. As n=10 for weeks 1 and 3, the p value was looked up on a table rather than determined by the statistical package. Spearman's ranks correlation was statistically significant with a p value of <0.0001 for the three groups.

Validity hypothesis testing

Kruskall Wallis test was used to identify if there was any similarity in the referral tool scores between the three groups. Kruskal – Wallis statistic 17.66. P value 0.0001. A score above 7 prompts the next step of the referral pathway to be activated, and this was found to be the case for the MWL group, who would be eligible for surgery if they meet the rest of the inclu-

sion criteria. The majority of the respondents in the non-obese and MWL were below the threshold and would not have screened positive for inclusion into the next step of the pathway (Appendix B).

DISCUSSION

The administrative burden was not too great, as the completion was 93.8%. Table 4. If patients do not complete a PROM or omit particular items frequently, this is a potential sign that the questions are difficult to understand, distressing or in some other way unacceptable. However, there are multiple factors which reduce acceptability beyond the nature of questions, including: length of form;[24] time taken to complete;[25] disease burden at time of completion;[26] method of administration;[27] and translation and cultural applicability.[28]

Another study12 has achieved an acceptability of 95%, however, in that study only 67% of the patients returned the PROM. In our study 100% of PBOTs posted were returned by patients. Furthermore, given this was a postal survey, a completion of 93.8% is good in comparison to the expected completion of 75–80% achievable according to some authors[29, 30, 31].

Rather than use completion percentages as a proxy for acceptability, other authors suggest direct assessment of patients' views about a new PROM.[32] This was carried out for the PBOT in the first stage of development. In clinical usage, depending on the dissemination strategy, it may be that forms are not completed satisfactorily and therefore assistance may be required. Further large scale studies are required for a more accurate measure of acceptability.

Maximum endorsement frequencies of >80% occurred in 12 items (at week 1) and 13 items (week 3) for the non-obese non-disease population. The questions with a >80% maximum endorsement in these two groups would not be applicable to the non-obese non-disease group. They included: weight fluctuation; satisfaction with medical care; satisfaction of most recent surgery; satisfaction with scar and contour. As the PBOT was not devised for this control group, this degree of maximum endorsement was expected.

In the MWL group there were no items with a maximum endorsement frequency of >80%. In the MWLBC group the following items had a >80% maximum endorsement frequency.

1. Have you had any weight fluctuation in the last 6 months?
2. I am satisfied with the medical care I received;
3. I find it difficult to move around;
4. I am unable to independently perform some activities of personal hygiene.

These questions were likely to have similar answers in the post MWLBC group as the inclusion criteria for surgery is stable weight. Furthermore, most patients were satisfied with their surgery and had an improvement in their quality of life. A maximum endorsement frequency of above 80% in a cohort of 10 represents only 2 patients answering differently. It would be worth reviewing the endorsement frequency with a greater number of patients and removing some questions to shorten the PBOT if possible. With a larger cohort, more detailed assessment of item distribution with Rasch analysis may be worthwhile. Some authors believe that if more than 20% of responders score at the maximum level of good or bad health, score distribution general suggests ceiling or floor effects, respectively.**Error! Bookmark not defined.**[33]

The Flesch Reading Ease score indicates a reading age of approximately 13, which should be fine for the referrer, and satisfactory for the patient. Administration of the PROM may be assisted if necessary. Table 5.

Responsiveness was not assessed, and further work is required here.

Interpretability testing has not been carried out and further work is required here. PROMS must provide scores that are easily interpretable to different stakeholders including patients, researchers, clinicians, and policy makers. In the supporting documentation information on scoring and inclusion and exclusion criteria has been included. Appendix B.

The reliability testing with Cronbach's Alpha reflected acceptable internal consistency in each group with scores of 0.788, 0.724 and 0.603 for non-obese, MWL and MWLBC groups respectively. When standardised, this became 0.837, 0.763 and 0.811 respectively. Table 6. Cronbach's alpha is grounded in the 'tau equivalent model' which assumes that each test item measures the same latent trait on the same measure. When each group was assessed independently the Cronbach's Alpha underestimated reliability[34] because the small size of the group violated the assumption of tau-equivalence. However, heterogeneous test items can also violate the assumptions of the true score equivalence or tau-equivalent model[35] which may be the cause of the difference between the standardised item alpha and Cronbach's alpha. Therefore a further Cronbach's alpha was carried out on all groups at all time periods (n=60), resulting in a Cronbach's alpha of 0.894. This is considered a good to excellent score.

Test-retest reliability was estimated by the Bland and Altman's method for agreement and all the scores for all groups were found to lie within 2 standard deviations of the bias except for one outlier. In a group of 10, 1 outlier accounts for 10% of the total. Therefore, further testing on larger numbers is warranted.

The validity of the PBOT was compared to outcomes on the DAS24 with Spearman's rank correlation co-efficients for mean scores. In all groups the p value was statistically significant for a correlation with r values of -0.60, -0.59 and -0.804 in the non-obese, MWL and MWLBC

groups respectively. In the DAS24, the higher the score, the greater distress from physical appearance, whereas in the PBOT, the higher scores reflect a greater ability to cope with MWL, which accounts for the minus score on the spearman's rank correlation. In massive weight loss patients, functional problems are also very relevant[36] and therefore it may be useful to do further validity testing with other PROMs such as the Short Form 36. At present there are no validated PROMs specifically designed for MWLBC cohort, however in the future use of the Body Q designed by Klassen[37] would be an interesting tool for comparison.

The PROM has good face validity, largely due to the items being emergent from patient accounts of the problems of living with massive weight loss. A study on the face validity of the PROM did not elicit any negative comments from users in a bariatric and MWLBC plastic surgery population.

The referral tool component was able to distinguish between the three groups. Therefore it had good validity for hypothesis testing between those who would meet the inclusion criteria and those who would not. To be eligible for MWLBC a score of 8 or more needs to be achieved. In the non-obese non-disease group no candidates met the inclusion criteria for MWLBC. The mean was 4.3 and the maximum sore achieved was 7.

In the MWL group a mean score of 7.9 was achieved. Four patients would have been excluded from the referral pathway with scores of 2, 6, 6 and 7. These patients had BMIs above the threshold. One had active psychiatric illness and another had a recent bereavement. Six patients would have met the threshold for progressing to the next step of the pathway. These patients had lost >50% of their excess body weight and were within the target BMI range and leading healthy lifestyles.

In the post body contouring group 1 patient reached the threshold for body contouring with a score of 9. This patient did not need any body contouring and was in excellent shape. However, the form has been devised for patients wishing to be referred for MWLBC when suffering functional and psychological problems with redundant skin. This patient would not have been referred.

Limitations

This preliminary validation study was carried out in 60 people. Further larger studies are required, ideally with multi centres. This would give a better understanding of the acceptability, maximum endorsement frequencies and reliability testing.

The authors can foresee some problems with the clinical photographs. Funding will be an issue, as will the photographs themselves. Medical photographs can make patients feel vulnerable and could prove to be a barrier to referral. However, recent studies show that patient comfort with full body photography improves quickly as they move through the surgical process[38] and the senior authors have found that these patients are very willing to have pictures taken if it improves their chances of getting funding.

The PBOT has been designed as part of the referral pathway and therefore, in the early stages patients who are keen to be approved for MWLBC may feel coerced to complete the PROM section of the form. Therefore, appropriate consent will need to be carried out before administration of the form. Other studies[12] have examined whether their PROMs can be used to compare new techniques, surgical teams and units. Given the novel stage of surgical approaches for MWLBC; the new BAPRAS guidance on service provision and best practice guidelines from NICE, it would be worth examining whether the PBOT can achieve this.

It is recommended that comprehensive assessment of outcome should include a combination of generic and specific measures[39]. One limitation of this study is that it has not been compared to other specific measures, as currently there are no other validated MWLBC PROMs published.

Further work required:

1. Development on a clinical population
2. Development on a non-clinical population
3. Maximum endorsement frequencies in a larger group of patients
4. Responsiveness, by asking the same patient cohort to complete the PBOT before and after surgery.
5. Interpretability testing
6. Inter rater reliability
7. Cultural and language translations required.

Conclusion

This new PROM was seen to be reliable both in terms of the internal consistency and test-retest reliability. Comparison to the DAS24 demonstrated it to be valid; however there need to be further larger validation studies, with comparison to functional PROMS such as the SF-36 or Kettering "Body Q".

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Funding: The William Rooney Plastic Surgery and Burns Research Trust.

Conflicts of interest: Nada Al-Hadithy, Ken Stewart and Mark Soldin devised the PBOT.

Ethical approval:

All studies conformed to the World Medical Association Declaration of Helsinki (June 1964) and subsequent amendments

(http://www.wma.net/en/30publications/10policies/b3/index.html. The research protocol was approved by South East Scotland regional ethical committee. Reference number: 10/S1102/2.

R&D Approval: Approval from NHS Lothian. 2010/SJ/PS/01

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Table 1: Demographic data

Group	N	Relationship Status	Sex	Mean Age (Range)	Mean BMI (Range)
Non obese	10	Single = 4 Married = 5 Widowed = 1	M=4 F=6	47.9 (31-68)	22.59 (17.75-26)
MWL	10	Single= 2 Married = 5 Widowed = 1 Separated = 2	M=4 F=6	45.00 (31-67)	30.19 (22.55-41)
MWLBC	10	Single = 5 Married =4 Widowed = 1	M=4 F=6	48 (24-67)	29.07 (20.44-49.7)

Table 2: Surgical history of MWL and BC groups

Group		Type of bariatric Surgery	Time post-surgery (months)	Type of plastic surgery	Time post plastic surgery (months)
Massive weight loss	1	Lap gastric bypass	18	N/A	N/A
	2	Lap gastric band	12	N/A	N/A
	3	Gastric band	12	N/A	N/A
	4	Lap gastric band	13	N/A	N/A
	5	Lap gastric bypass	14	N/A	N/A
	6	Lap gastric bypass	21	N/A	N/A
	7	Lap gastric bypass	20	N/A	N/A
	8	Lap gastric band	24	N/A	N/A
	9	Lap gastric bypass	44	N/A	N/A
	10	Gastric band	26	N/A	N/A
Massive weight loss & body contouring	1	Gastric band	60	Procedure 1: Abdominoplasty Procedure 2: breast augmentation & mastopexy	24 12
	2	Lap Gastric band	48	Procedure 1: Mastopexy & abdominoplasty Procedure 2: brachioplasty and thigh lift	12 3
	3	Lap Gastric band	19	Abdominoplasty	12
	4	Gastric band	33	Fleur de lys abdominoplasty, neck reduction, brachioplasty, breast reduction	5
	5	Lap gastric band	36	Procedure 1:Mastopexy Procedure 2: Lower body lift	13 4
	6	Gastric band	36	Abdominoplasty	21
	7	Gastric band	20	Interim Abdominoplasty	3
	8	Gastric band	19	Fleur de lys abdominoplasty & liposuction to flanks on	14
	9	Lap bypass	46	Fleur dy lys abdominoplasty	8
	10	lap Gastric bypass	36	Fleur de lys abdominoplasty	11

Table 3: PROM and Derriford 24 Scores for 3 Groups

Group	Ref Score		PROM Score		Total Score		DAS24	
	Week 1	Week 3	Week 1	Week 3	Week 1	Week 3	Week 1	Week 3
Non obese	4.30 (0-7)	4.3 (0-7)	92.28(74.5-102)	92.48 (75-102)	96.58 (74.5-109)	96.78(75-109)	29.3 (21-41)	29.5 (21-39)
MWL	7.9 (2-11)	7.9 (2-11)	57.68 (48.75-65.00)	57.9(49.00-64.00)	71.28(55.75-94.00)	71.28 (55.75-94.00)	72.7(60-84)	93.4(90.0-98.0)
MWLBC	4 (0-9)	4 (0-9)	85.1 (51-103)	85.1(51-102)	89.1(55-111)	89.1(55-110)	44.4 (25-75)	44.8(28-75)

Table 4: Administrative Burden: Completion rate of score in each group

	Non Obese Non Disease Group	Post MWL	Post MWLBC	Total Mean
Percentage Completions Week 1	94.4% (91-99%)	93.2%(90-98%)	93.5%(90-99%)	93.7%
Percentage Completion Week 3	94.3%(91-99%)	93.4%(90-98%)	94.1%(91-99%)	93.9%
Maximum Endorsement Week 1 >80%	13 items >80% Mean 83% (30-100%)	0 items >80% Mean 47.4% (30-80%)	4 items >80% Mean 58.7%(30-90%)	63.03%
Maximum Endorsement Week 3 >80%	12 items <80% Mean 82% (30-100%)	0 items >80% Mean 46.9% (30-80%)	3 items >80% Mean 58.26%(30-90%)	62.39%

Table 5: Flesch Reading Ease Scores

Score	Notes
90.0–100.0	easily understood by an average 11-year-old student
60.0–70.0	easily understood by 13- to 15-year-old students
0.0–30.0	best understood by university graduates

Table 6: Internal Consistency: Cronbach's Coefficient Alpha for 3 Groups' Score

Non Obese Group	n		Mean	Variance	Std. Deviation	Cronbach's Alpha	CA Standardised
	10	Week 1	67.28	61.895	7.87	0.788	0.837
	10	Week 3	67.27	61.895	7.87	0.788	0.837
	20	Average	67.27	58.64	7.66	0.788	0.837
MWL Group	N		Mean	Variance	Std. Deviation	Cronbach's Alpha	CA Standardised
	10	Week 1	63.38	119.74	10.94	0.724	0.763
	10	Week 3	63.38	119.74	10.94	0.724	0.763
	20	Average	63.38	113.44	10.65	0.724	0.763
MWLBC	N		Mean	Variance	Std. Deviation	Cronbach's Alpha	CA Standardised

Group	10	Week 1	67.35	45.59	6.75	0.603	0.811
	10	Week 3	67.35	45.55	6.75	0.603	0.811
	20	Average	67.35	43.16	6.57	0.603	0.811
All Groups	N		Mean	Variance	Std. Deviation	Cronbach's Alpha	CA Standardised
	30	Week 1	83.00	281.49	16.78	0.894	0.911
	30	Week 3	83.67	285.11	16.89	0.899	0.916
	60	Average	83.67	280.281	16.74	0.899	0.916

Table 7: Test-retest reliability: Bland Altman's Method for Agreement for 3 Groups

Group	Bias	SD of Bias	95% Limits of Agreement	Outliers
Non Obese	-0.20	0.42	-1.03-0.63	0
MWL	-0.23	1.03	-2.24-1.79	0
MWL BC	0.0	0.82	-1.60-1.60	0
Average of the 3 groups	-0.14	0.78	-1.66-1.38	1

Table 8: Construct validity: Spearman's Ranks Correlation Coefficients for mean questionnaire scores between DAS24 and the PROM.

Groups	Week 1		Week 3		Average of weeks 1 & 3	
	Spearman's Rank Correlation r	P Value (two tailed)	Spearman's Rank Correlation r	P Value (two tailed)	Spearman's Rank Correlation r	P Value (two tailed)
Non obese	-0.60	0.05	-0.61	0.05	-0.60 (-0.82 to -0.20)	0.0052
MWL	-0.561	0.05	-0.627	0.05	-0.59 (-0.83 to -0.19)	0.0057
MWLBC	-0.806	0.001	-0.802	0.001	-0.804 (-0.92 to -0.55)	<0.0001

Figure 1: Pathway for use of the PBOT

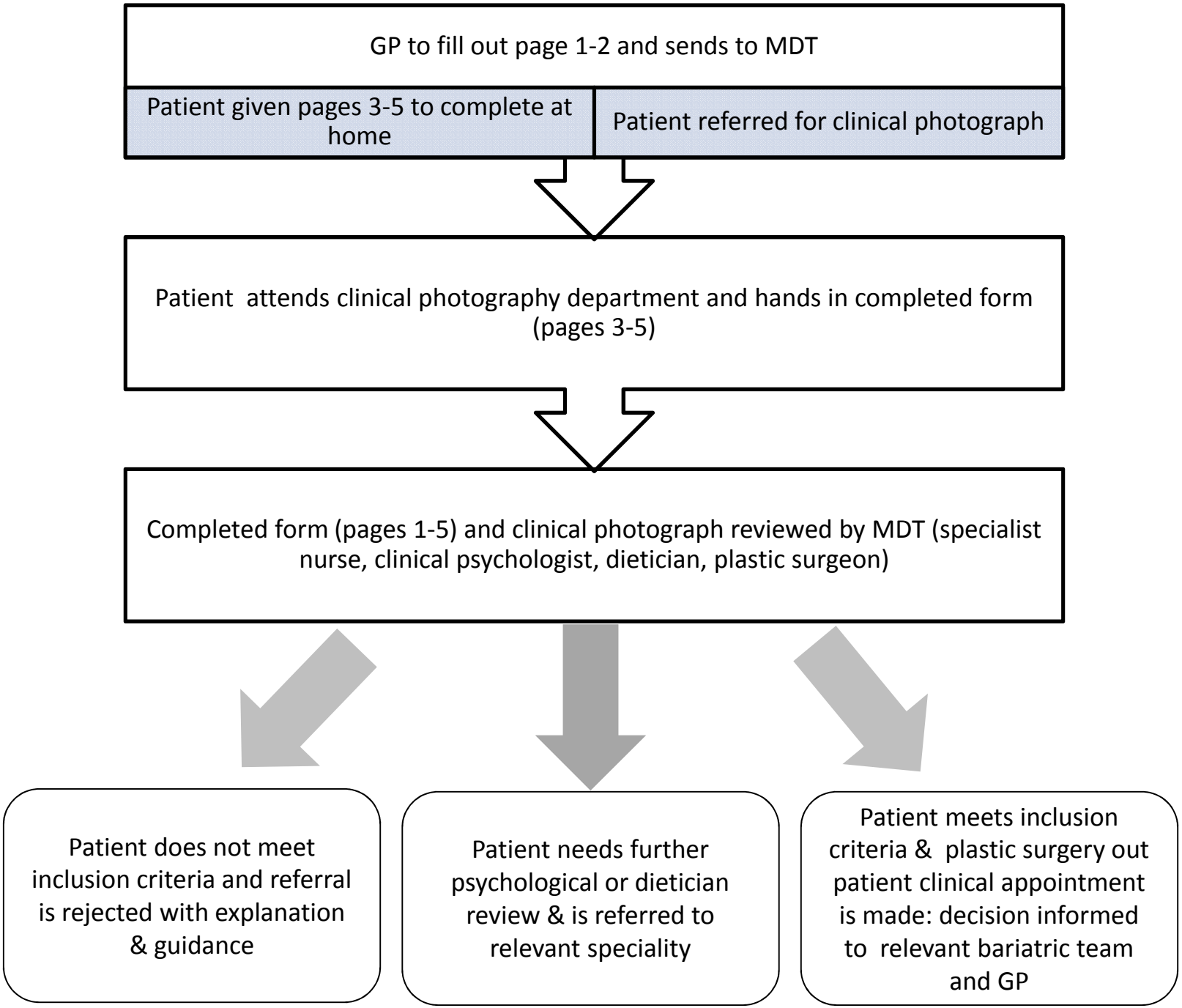
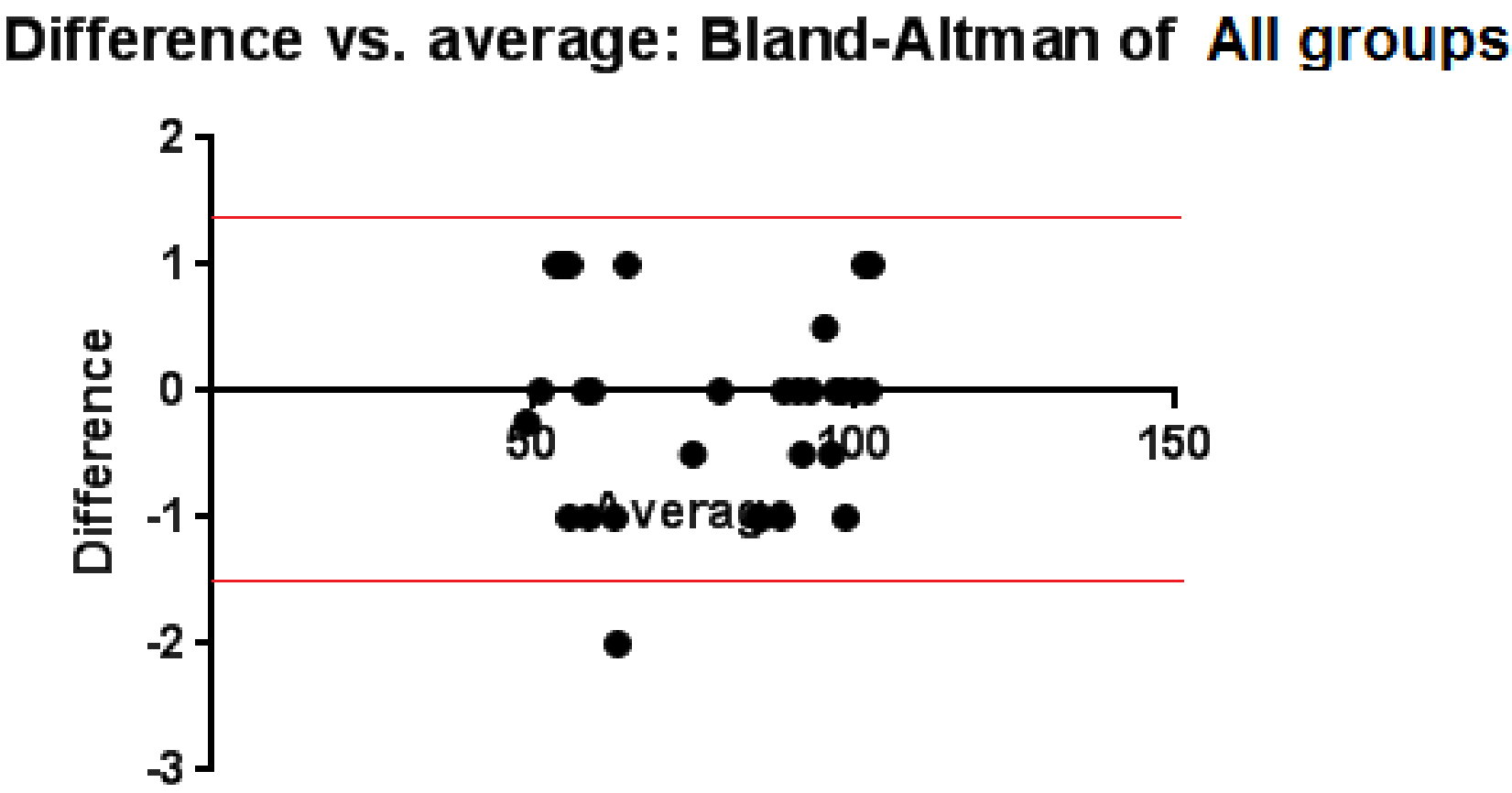


Figure 2: Test-retest: Bland Altman's Method



Pages 1-2: For the referrer to complete			
Patient name:			Date of referral:
Date of birth: NHS number:			Name of referrer:
Address:			Address:
Phone number:			Phone number:
Funding secured:	Yes ☐	No ☐	Email:

Maximum ever weight (kg):	Weight lost (kg):	Current weight (kg):	Current height (m):

Length of time maintained at current weight:	Weight fluctuation of ≥5kg in the last 6 months? Yes ☐ No ☐

Plastic surgery procedure desired:	1. 2.

Method of weight loss: please select any applicable from below:		
Diet ☐	Exercise ☐	Surgery ☐

Type of Bariatric Surgery			Not Applicable (please move on) ☐		
		Date & Details	Surgical Approach Please select one from below:		Date
Gastric Balloon	☐				
Gastric band	☐		Laparoscopic	☐	
Gastric sleeve	☐		Lap converted to open	☐	
Roux en Y	☐		Open	☐	
Duodenal Switch	☐				
Complications or additional information					

As a **result of the excess skin** the patient suffers with (please tick all that apply):						
Skin condition	Dermatitis ☐	Hidradenitis ☐	Intertrigo ☐	Infection ☐	Lymphoedema ☐	Ulceration ☐
Evidence of Functional impairment	Yes ☐ Give details:					No ☐
Evidence of Psychological impairment	Yes ☐ Give details:					No ☐

Patient Name/ Sticker:

Past Medical History: Please write:

Please tick if there is any history of the following:		Date of diagnosis & details
Active delusional or schizophrenic illness	☐	
Body dysmorphic disorder	☐	
Eating disorder	☐	
History of self-harm in last 2 years	☐	
Major depressive illness	☐	
Obsessive compulsive disorder	☐	
Substance abuse problem	☐	

Psychiatric History: (Please write)	
Drug History: Please write:	Any history of recreational drug use? Please give information
Allergies:	

Any additional information:

Patient Name/ Sticker:

Page 3-5: For the patient to complete		
Patient Name:	Date of Completion:	Date of Birth:

Describe and date the surgery you have had for weight loss and body contouring:
Describe any complications you may have experienced from the surgery above:

Have you had any weight fluctuation in the last 6 months? (Tick the box which applies to you)	None ☐	0-5kg ☐	>5-10kg ☐	>10-20kg ☐	>20kg ☐

For the above surgery please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
I am satisfied with the medical care I received					
I am satisfied with the outcome of my most recent surgery					
I am satisfied with my scar					
I am satisfied with my contour					

Have you **ever** smoked?	What was the most you **ever** smoked?		**If you are smoking now**, how much do you smoke?	
☐ Yes ☐ No (move onto the next question)	Very rarely	☐	Very rarely	☐
	Socially (≤2 cigarettes per week)	☐	Only socially (≤2 cigarettes per week)	☐
	< 5 cigarettes per day	☐	< 5 cigarettes per day	☐
	5-10 cigarettes per day	☐	5-10 cigarettes per day	☐
	11-20 cigarettes per day	☐	11-20 cigarettes per day	☐
	21-40 cigarettes per day	☐	21-40 cigarettes per day	☐
	>40 cigarettes per day	☐	>40 cigarettes per day	☐
If you have quit, when did you quit:				

Marital status (please check one):	Please tick	Current occupation (please write): _____		Please describe what you eat on a daily basis:
Single	☐	Full time employment	☐	
Married	☐	Self employed	☐	
Divorced	☐	Part time employment	☐	
Separated	☐	Student	☐	
Widowed	☐	Unemployed	☐	
Living with significant other	☐	Other:_____		

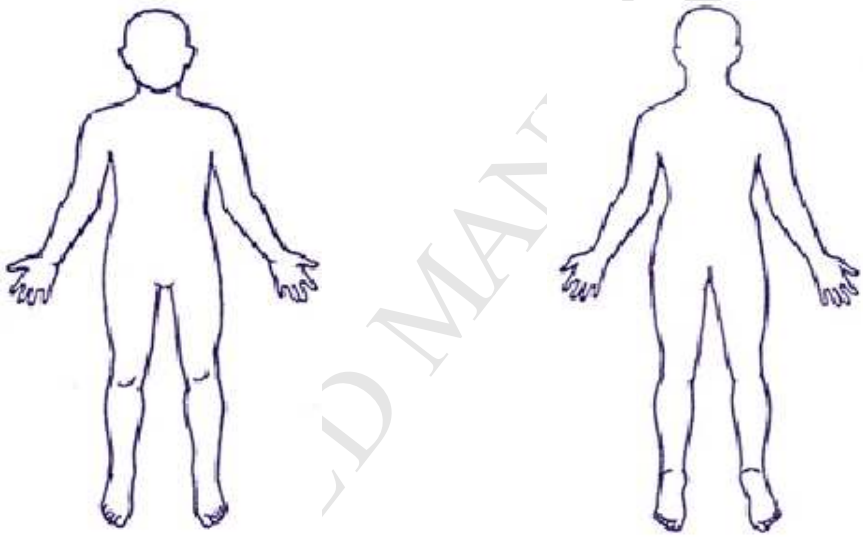
Have you had a pregnancy in the last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced the death of a close family member in last 12 months?	No ☐	Yes ☐	Please give details
Have you experienced a relationship breakdown in the last 12 months?	No ☐	Yes ☐	Please give details

Patient Name/ Sticker:

How frequently do you exercise?		If you exercise, how long do you exercise each time?		Where do you do most of your exercise?	
Not at all	☐	Less than 15 minutes	☐	Inside	☐
Once per month or less	☐	15 - 30 minutes	☐		
Several times per month	☐	31 - 60 minutes	☐	Outside	☐
Once per week	☐	61 - 120 minutes	☐		
Several times per week	☐	More than 120 minutes	☐		
Once per day	☐				
Several times a day	☐				

If you exercise, please indicate the types of exercise you do (fill in all that apply).									
Cycling	☐	Stationary bike	☐	Swimming	☐	Stairmaster	☐	Zumba	☐
Running	☐	Treadmill	☐	In-line skating	☐	Weight training	☐	Aerobics	☐
Walking	☐	Cross trainer	☐	Dancing	☐	Yoga	☐	Pilates	☐
Other (please write):									

Is there a part of your appearance that you are concerned with? Use the diagram to record where and write why you are concerned:



Front Back

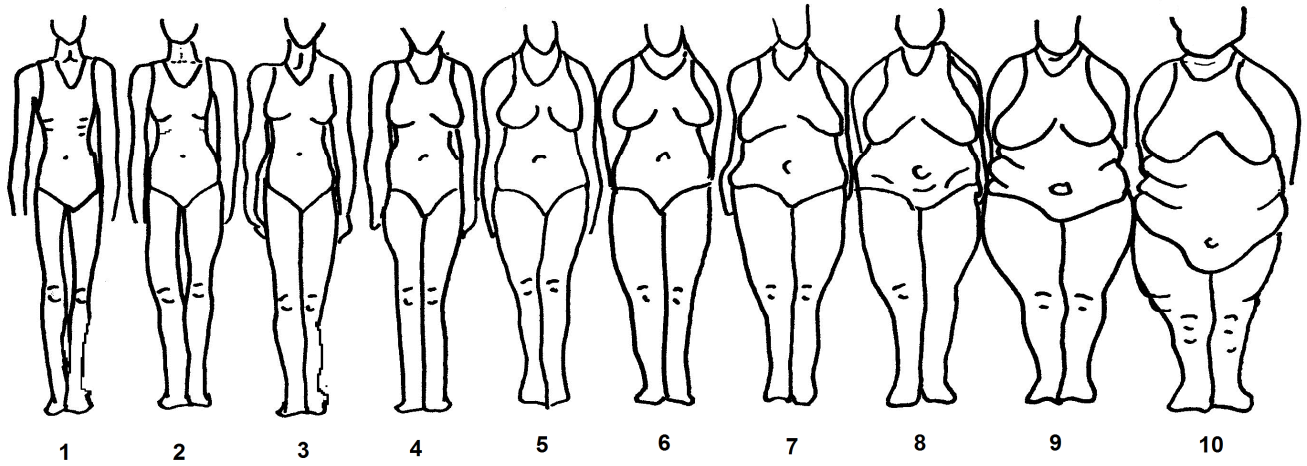
Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
I find it difficult to move around					
I avoid going out of the house					
I get distressed when I see myself in the mirror					
I have problems finding clothes that fit					
I am unable to exercise as much as I would like					
I feel uncomfortable getting undressed in front of my partner					
There is an adverse outcome on my sex life					
I have physical pain					
I am limited in what I can do during the course of a typical day					
I am unable to interact with my family as I would like					
I find it difficult to socialise					
There is an adverse outcome on my professional life					
I am unhappy with my physical appearance					
I do not undress in front of other people (changing rooms)					
I am unable to independently perform some activities of personal hygiene (eg bathing, brushing my hair or wiping myself after the toilet)					

Patient Name/ Sticker:

Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	☐
I can climb 1 flight of stairs without resting	☐
I can climb half a flight of stairs without resting	☐
I require a wheelchair	☐
I am housebound	☐

Activities of daily living	Please circle the choice that best suits you now			
In general my health is	Excellent	Good	Fair	Poor
I am able to work	Not at all	A little	Often	Very much
I am able to do the things I want to do	Not at all	A little	Often	Very much
I have satisfactory social contacts	Very many	Satisfactory	A few	None
I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all

Please select from the following scale, which image you think best represents your body size and shape.



Please write down any additional information you think is important:

Thank you for completing this form.
Please ensure it gets sent to the massive weight loss body contouring team at:

Patient Name/ Sticker:

The Post Bariatric Outcome Tool

What is the Post Bariatric Outcome Tool? (PBOT)

The underlying construct being measured is adjustment (psychological and functional) to massive weight loss and massive weight loss body contouring (MWLBC). From a psychological perspective, this will manifest differently for each individual respondent. However, we believe that the basic structure of adjustment is common across most people. Adjustment comprises negative emotions of fear, social anxiety, shame and negative affect along with behavioural response of avoidance and withdrawal that frequently disrupts lifestyle. We believe that we have captured this in the patient reported outcome measure (PROM) with contextually relevant questions specific to this unique cohort of patients.

Description of the PBOT

The PBOT is a 77 item scale designed to fulfil three purposes:

1. To streamline the referral process and ensure those patients being referred meet the national guidelines.
2. To measure distress and dysfunction due to problems of the side effects of massive weight loss.
3. To quantify patient reported outcomes following massive weight loss body contouring.

The first two pages are to be completed by the referring doctor with the patient. In the UK, this is usually the general practitioner (GP). Page 1 facilitates the collection of demographic and clinical information relevant to patients considering massive weight loss body contouring. Page 2 collates known problems with excess skin, functional and psychological morbidity, past medical history and drug history.

The third to fifth pages are to be completed by the patient. This consists of questions for further demographic data collection and post-operative complication history which will aid screening of appropriate patients for surgery; and identify: adjustment to massive weight loss; functional impairment and perception of disfigurement.

There are two diagrams. One is a visual prompt so that the patient can highlight areas of concern on his/her body. The other is a visual analogue scale of how he/she perceives his/her size and shape. The second visual analogue scale should be compared with the clinical photographs of the patient to identify how closely the patient's perception of his/her body image reflects objective assessment of the clinical photograph by the multi disciplinary team (MDT) panel. There are two versions of the PBOT, one with female figures and another with male figures. The appropriate scale should be given to the patient depending on his/her sex.

The final part of the questionnaire is a blank space for patients to include any additional information they feel is important.

Administering the Score

The scale deals with sensitive and personal information. It therefore should only be administered by professionals who are aware of the ethical implications of dealing with such data and are working within the ethical guidelines of appropriate governing bodies.

The PBOT should be completed before referral to the plastic surgery unit, and will be reviewed with clinical photographs by the massive weight loss body contouring multi disciplinary team (MDT). It can also be used at 3 months, 6 months and/or 1 year+ post massive weight loss body contouring in order to measure outcomes in this group of patients.

Scoring

Of the 77 items on the questionnaire, there are 41 items to score for the two components.

Score Component	Questions to Score	Minimum	Maximum
Referral Tool (Pages 1-2)	14 (of 30)	-26	16
PROM Component (Pages 3-5)	27 (of 47)	20	132

Rules

When marking the referral tool component, to qualify for next stage of screening process for massive weight loss body contouring they must score > 8: points in the referral tool. Of these 8 points, 3 must come from the first 3 questions, ie, the patients must score at least 1 for questions 1-3.

ANY psychiatric history should warrant referral to clinical psychologist for further enquiry.
ANY patients who have a discrepancy of more than 2 points between their self-assessment on the visual analogue scale of size and the objective assessment of the panel should warrant referral to the clinical psychologist.

Referral Tool Mark Scheme

Use the PBOT marking aid – which has all the questions for the referral tool component numbered in red.

1. Percentage excess weight lost = (weight Lost/ (maximum ever weight-ideal weight)) x 100 (Where ideal weight = 25 x height $(m)^2$)	Mark	Tick which applies
≤49%	0	
50-100%	1	
>100%	2	

2. Current BMI = current weight in kg/(height in m)2	Mark	Tick which applies
>30	-1	
>27-30	0	
26-27	1	
≤25	2	

3. Length of time maintained at current weight.	Mark	Tick which applies
<12 months	0	
>12 – 18 months	1	
>18 months	2	

4. Weight fluctuation ≥5kg in the last 6 months	Mark	Tick which applies
Yes	-2	
No	0	

5. Skin conditions	Points
Allocate one point for each condition (maximum 6)	

6. Evidence of functional impairment	Mark	Tick which applies
Yes	1	
No	0	

7. Evidence of psychological impairment	Mark	Tick which applies
Yes	1	
No	0	

8. Psychiatric History:	Mark	Tick which applies
Active delusional or schizophrenic illness	-1	
Body dysmorphic disorder	-1	
Eating disorder	-1	
History of self-harm in last 2 years	-1	
Major depressive illness	-1	
Obsessive compulsive disorder	-1	
Substance abuse problem	-1	

9. Any history of recreational drug use	Mark	Tick which applies

No	0	
Yes	-1	

10. Smoking History:	Mark	Tick which applies
Never smoked	1	
Quit smoking	0	
Smokes rarely	-1	
Smokes socially	-1	
Smokes <5 cigarettes per day	-2	
5-10 cigarettes per day	-3	
11-20 cigarettes per day	-4	
21-40 cigarettes per day	-5	
>40 cigarettes per day	-10	

Question	Mark	Tick which applies
11. Have you had a pregnancy in the last 12 months?		
No	0	
Yes	-1	
12. Have you experienced the death of a close family member in last 12 months?		
No	0	
Yes	-1	
13. Have you experienced a relationship breakdown in the last 12 months?		
No	0	
Yes	-1	

14 Patient's clinical photograph matches patient's self-selection of body image on scale	Mark	Tick which applies
Yes	1	
No	-2	
More than 2 points difference between patient assessment and objective assessment score by MDT panel should prompt a referral to psychologist		

Referral Tool total score _____

PROM Mark Scheme

Use the PBOT marking aid to help score. All the questions for the PROM component have been coded in letters in purple.

A. Have you had any weight fluctuation in the last 6 months?	None	0-5kg	>5-10kg	>10-20kg	>20kg
	1	-1	-2	-3	-4
Please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
B. I am satisfied with the medical care I received	5	4	3	2	1
C. I am satisfied with the outcome of my most recent surgery	5	4	3	2	1
D. I am satisfied with my scar	5	4	3	2	1
E. I am satisfied with my contour	5	4	3	2	1

How frequently do you exercise?		If you exercise, how long do you exercise each time?	
Not at all	0	Less than 15 minutes	0.25
Once per month or less	1	15 - 30 minutes	0.50
Several times per month	2	31 - 60 minutes	1
Once per week	3	61 - 120 minutes	1.5
Several times per week	4	More than 120 minutes	2
Once per day	5		
Several times a day	6		

F. Score = frequency x exercise time =

Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
G. I find it difficult to move around	5	4	3	2	1
H. I avoid going out of the house	5	4	3	2	1
I. I get distressed when I see myself in the mirror	5	4	3	2	1
J. I have problems finding clothes that fit	5	4	3	2	1
K. I am unable to exercise as much as I would like	5	4	3	2	1
L. I feel uncomfortable getting undressed in front of my partner	5	4	3	2	1
M. There is an adverse outcome on my sex life	5	4	3	2	1
N. I have physical pain	5	4	3	2	1
O. I am limited in what I can do during the course of a typical day	5	4	3	2	1
P. I am unable to interact with my family as I would like	5	4	3	2	1
Q. I find it difficult to socialise	5	4	3	2	1
R. There is an adverse outcome on my professional life	5	4	3	2	1
S. I am unhappy with my physical appearance	5	4	3	2	1
T. I do not undress in front of other people (changing rooms)	5	4	3	2	1
U. I am unable to independently perform some activities of personal hygiene (eg bathing, brushing my hair or wiping myself after the toilet)	5	4	3	2	1

V. Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	4
I can climb 1 flight of stairs without resting	3
I can climb half a flight of stairs without resting	2

I require a wheelchair	1
I am housebound	0

Activities of daily living	Please circle the choice that best suits you now			
W. In general my health is	Excellent	Good	Fair	Poor
	4	3	2	1
X. I am able to work	Not at all	A little	Often	Very much
	1	2	3	4
Y. I am able to do the things I want to do	Not at all	A little	Often	Very much
	1	2	3	4
Z. I have satisfactory social contacts	Very many	Satisfactory	A few	None
	4	3	2	1
Σ. I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all
	4	3	2	1

PROM total score_____

Pages 1-2: For the referrer to complete			
Patient name:			Date of referral:
Date of birth: NHS number:			Name of referrer:
Address:			Address:
Phone number:			Phone number:
Funding secured:	Yes ☐	No ☐	Email:

1. & 2.			
Maximum ever weight (kg):	Weight lost (kg):	Current weight (kg):	Current height (m):

3. Length of time maintained at current weight in months:	4. Weight fluctuation of ≥5kg in the last 6 months? Yes ☐ No ☐

Plastic surgery procedure desired:	1. 2.

Method of weight loss: please select any applicable from below:		
Diet ☐	Exercise ☐	Surgery ☐

Type of Bariatric Surgery			Not Applicable (please move on) ☐		
		Date & Details	Surgical Approach Please select one from below:		Date
Gastric Balloon	☐				
Gastric band	☐		Laparoscopic	☐	
Gastric sleeve	☐		Lap converted to open	☐	
Roux en Y	☐		Open	☐	
Duodenal Switch	☐				
Complications or additional information					

As a **result of the excess skin** the patient suffers with (please tick all that apply):						
5. Skin condition	Dermatitis ☐	Hidradenitis ☐	Intertrigo ☐	Infection ☐	Lymphoedema ☐	Ulceration ☐
6. Evidence of Functional impairment	Yes ☐ Give details:					No ☐
7. Evidence of Psychological impairment	Yes ☐ Give details:					No ☐

Patient Name/ Sticker:

Past Medical History: Please write:

8. Please tick if there is any history of the following:		Date of diagnosis & details
Active delusional or schizophrenic illness	☐	
Body dysmorphic disorder	☐	
Eating disorder	☐	
History of self-harm in last 2 years	☐	
Major depressive illness	☐	
Obsessive compulsive disorder	☐	
Substance abuse problem	☐	

Psychiatric History: (Please write)	
Drug History: Please write:	**9.** Any history of recreational drug use? Please give information
Allergies:	

Any additional information:

Patient Name/ Sticker:

Page 3-5: For the patient to complete		
Patient Name:	Date of Completion:	Date of Birth:

Describe and date the surgery you have had for weight loss and body contouring:
Describe any complications you may have experienced from the surgery above:

A. Have you had any weight fluctuation in the last 6 months? (Tick the box which applies to you)	None ☐	0-5kg ☐	>5-10kg ☐	>10-20kg ☐	>20kg ☐

For the above surgery please tick the box which applies to you	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
B. I am satisfied with the medical care I received					
C. I am satisfied with the outcome of my most recent surgery					
D. I am satisfied with my scar					
E. I am satisfied with my contour					

10. Have you **ever** smoked?	What was the most you **ever** smoked?		**If you are smoking now**, how much do you smoke?	
☐ Yes ☐ No (move onto the next question)	Very rarely	☐	Very rarely	☐
	Socially (≤2 cigarettes per week)	☐	Only socially (≤2 cigarettes per week)	☐
	< 5 cigarettes per day	☐	< 5 cigarettes per day	☐
	5-10 cigarettes per day	☐	5-10 cigarettes per day	☐
	11-20 cigarettes per day	☐	11-20 cigarettes per day	☐
	21-40 cigarettes per day	☐	21-40 cigarettes per day	☐
	>40 cigarettes per day	☐	>40 cigarettes per day	☐
If you have quit, when did you quit:				

Marital status (please check one):	Please tick	Current occupation (please write): _____		Please describe what you eat on a daily basis:
Single	☐	Full time employment	☐	
Married	☐	Self employed	☐	
Divorced	☐	Part time employment	☐	
Separated	☐	Student	☐	
Widowed	☐	Unemployed	☐	
Living with significant other	☐	Other:_____		

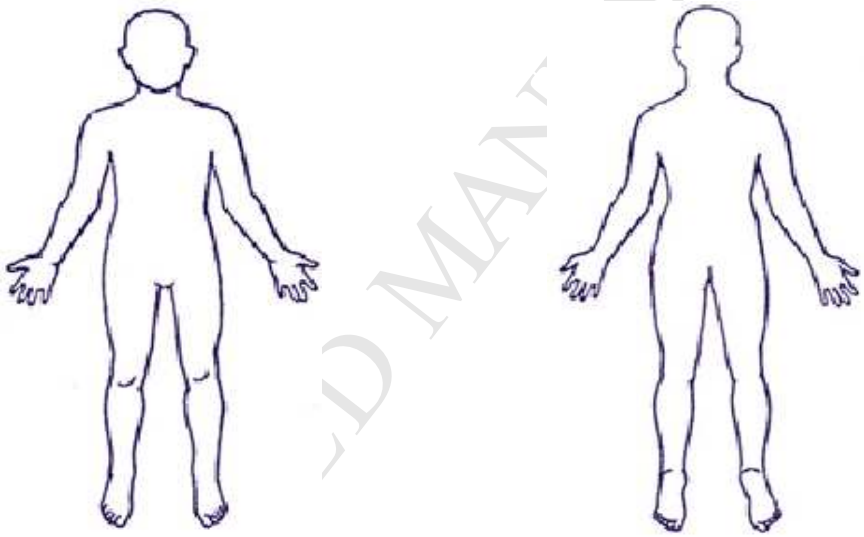
	No	Yes	Please give details
11. Have you had a pregnancy in the last 12 months?	☐	☐	
12. Have you experienced the death of a close family member in last 12 months?	☐	☐	
13. Have you experienced a relationship breakdown in the last 12 months?	☐	☐	

Patient Name/ Sticker:

F.					
How frequently do you exercise?		If you exercise, how long do you exercise each time?		Where do you do most of your exercise?	
Not at all	☐	Less than 15 minutes	☐	Inside	☐
Once per month or less	☐	15 - 30 minutes	☐		
Several times per month	☐	31 - 60 minutes	☐	Outside	☐
Once per week	☐	61 - 120 minutes	☐		
Several times per week	☐	More than 120 minutes	☐		
Once per day	☐				
Several times a day	☐				

If you exercise, please indicate the types of exercise you do (fill in all that apply).									
Cycling	☐	Stationary bike	☐	Swimming	☐	Stairmaster	☐	Zumba	☐
Running	☐	Treadmill	☐	In-line skating	☐	Weight training	☐	Aerobics	☐
Walking	☐	Cross trainer	☐	Dancing	☐	Yoga	☐	Pilates	☐
Other (please write):									

Is there a part of your appearance that you are concerned with? Use the diagram to record where and write why you are concerned:



Front Back

Because of this body area: Please tick the box which applies:	Not at all 1	2	Neutral 3	4	Extremely 5
G. I find it difficult to move around					
H. I avoid going out of the house					
I. I get distressed when I see myself in the mirror					
J. I have problems finding clothes that fit					
K. I am unable to exercise as much as I would like					
L. I feel uncomfortable getting undressed in front of my partner					
M. There is an adverse outcome on my sex life					
N. I have physical pain					
O. I am limited in what I can do during the course of a typical day					
P. I am unable to interact with my family as I would like					
Q. I find it difficult to socialise					
R. There is an adverse outcome on my professional life					
S. I am unhappy with my physical appearance					
T. I do not undress in front of other people (changing rooms)					
U. I am unable to independently perform some activities of personal hygiene (eg bathing, brushing my hair or wiping myself after the					

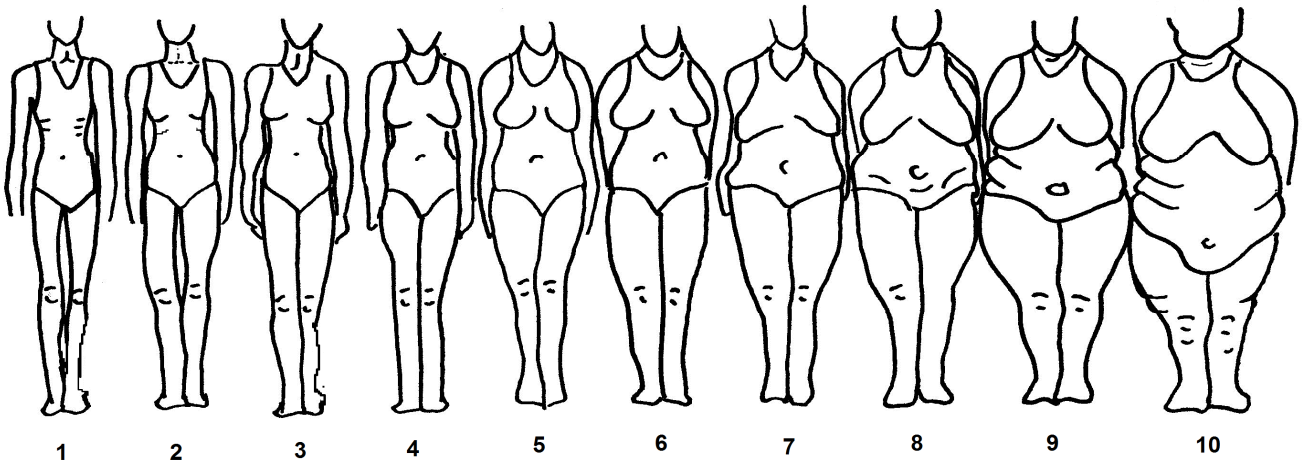
Patient Name/ Sticker:

toilet)					

V. Please select from the following, the item that applies best to you:	
I can climb 3 flights of stairs without resting	☐
I can climb 1 flight of stairs without resting	☐
I can climb half a flight of stairs without resting	☐
I require a wheelchair	☐
I am housebound	☐

Activities of daily living	Please circle the choice that best suits you now			
W. In general my health is	Excellent	Good	Fair	Poor
X. I am able to work	Not at all	A little	Often	Very much
Y. I am able to do the things I want to do	Not at all	A little	Often	Very much
Z. I have satisfactory social contacts	Very many	Satisfactory	A few	None
Σ. I get pleasure out of sexual intimacy	Very much	Often	A little	Not at all

14. Please select from the following scale, which image you think best represents your body size and shape.



Please write down any additional information you think is important:

Thank you for completing this form.
Please ensure it gets sent to the massive weight loss body contouring team at:

Patient Name/ Sticker:

National Commissioning Guidelines: Body Contouring Surgery after Massive Weight Loss.

Manuscript Word Count: 2189

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Summary:
The guidelines for body contouring reconstructive surgery present an evidence-based guide for management of redundant tissue after massive weight loss. A standardised referral pathway to ensure safe and equitable patient care on the National Health Service (NHS) throughout England is recommended. A database of all patients for research purposes is suggested.

Introduction:

The UK has the fifth most obese population in developed countries. Data published by the Health and Social care Information Centre in 2013 indicates that the prevalence of obesity has nearly doubled in the last decade [1]. This has caused an increase in the number of bariatric surgery procedures performed each year, with data showing a 30-fold increase in bariatric surgery procedures from just 261 in 2000/2001 to 6643 in 2010/2011 on the NHS [1].

Bariatric surgery is currently the only reliable treatment for morbid obesity and leads to massive weight loss (MWL) in patients[i]. There are multiple benefits to this surgical cure. However, resultant redundant skin folds can lead to difficulty in mobilizing, exercising, intertrigo, ulceration and infection [2-7]. The psychosocial impact of redundant skin may lead to an exacerbation of pre-existing psychological diseases [8-15]. A direct consequence of this is an increasing demand for body contouring surgery (BCS), to manage the complex problems associated with redundant skin and abnormal body contours [16,17,18]. Removing the skin folds involves variations of well-known cosmetic procedures and is often seen as aesthetic surgery. However the redundant skin can interfere dramatically with the patients' physical function, therefore the surgery should be deemed reconstructive.

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It is increasingly being recognized that the psychological burden of obesity carries on long after reduction in weight because of resultant redundant skin. Studies carried out by Wolf et al. and Taylor et al confirm the stigma associated with redundant skin and the need for body contouring surgery [19,20]. Al-Hadithy et al. suggests that 73.4% of the patients undergoing bariatric surgery wanted body-contouring procedures to combat the redundant skin [17]. This is similar to data published by Kitzinger et al. who reported 75% female and 68% male patients stating a desire for body contouring surgery [18]. BCS improves patients' body image, self-esteem and ability to function in society [21-23].

Variation in practice: the 'post code lottery'.

Mukherjee et al, state in their study that 23 trusts in England exclude all post MWL body contouring surgery [24]. This is a dramatic increase from 2009, where only 4.9% of units were not able to offer any surgery due to lack of funding [25]. Commissioning bodies in England are warning patients needing bariatric surgery that they will not fund the removal of redundant skin folds after weight loss. A recent study shows that 37.7% of patients who were approved for body contouring surgery in Scotland would not have fulfilled the Leeds criteria [17,26], thus further highlighting the existence of a 'postcode lottery' on commissioning for these plastic surgery procedures.

Butler et al.in their study mention that 56% of units offering body contouring do not offer psychological screening [25], even though it is well documented that there is a 25% increase in psychological disorders in obese patients, ranging from depression, mood and anxiety disorders to substance abuse and personality disorders [8-15].

In England, there is no standardised guidance for the provision of body contouring following MWL. The National Institute for Clinical Excellence (NICE) guidelines state that surgery for obesity should only

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be undertaken by a multidisciplinary team with access to plastic surgery and expertise including psychological support before and after the surgery [27]. The availability of surgery on the NHS has marked variations across the country [24,25,26]. Nonetheless, current research strongly suggests that there is a significant improvement in quality of life after MWL contouring procedures [22,28]. The inequality in the management of this complex group of patients has lead to the call for national guidelines.

Aims

The intention of these guidelines is to provide a safe, NICE accredited, equitable and streamlined reconstructive surgery referral pathway after massive weight loss (MWL) in England. An additional aim is to have the opportunity to collect national data for research and outcome studies.

Method

Development of Recommendations

The guidelines were developed in keeping with The Commissioning Guidance Process Manual, with reference to NHS Evidence Accreditation Process, the Scottish Intercollegiate Guidelines Network[ii] (SIGN) 50 Guideline Developer's Handbook, Appraisal of Guidelines for Research and Evaluation (AGREE) criteria[iii] and existing NHS Evidence accredited clinical guidance and commissioning guidance process manuals. A full register of those present in the commissioning meeting can be seen at the end of this document.

Evidence Base & Literature Search

A literature search was carried out following the PRISMA statement[iv] for systematic reviews to identify PROMs designed to measure patient

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Comment [N1]: This paragraph is straight out of the commissioning guidlines handbook. The SIGN guidlines are the same as the NICE guidlines but for Scotland. The Agree criteria. I have included references as endonotes to their websites.

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Comment [N2]: This is a well established approach for literature reviews for systematic reviews. I have added in a reference.

satisfaction, body image, and/or QOL concerns in patients who have undergone body contouring surgery. Articles from bibliographic database search conducted in NHS Evidence, National Guideline Clearing House, CRD – SARE and HTA, Cochrane database of systematic reviews, MEDLINE and EMBASE were included through March 2013. Published articles were included if they provided evidence of measurement and / or practical properties for multi-item instruments assessing aspects of health status or quality of life in patients undergoing cosmetic surgical procedures.

Further details of the literature search methodology and results can be seen in Appendix A.

BAPRAS Massive Weight Loss Body Contouring Recommendations:
Recommendations made by the commissioning development group are evidence based. These incorporate the use of a referral pathway initiated by the GP in primary care (Fig 1). . Further salient features of the guidance are:

- Use of the BAPRAS Post Bariatric Outcome Tool (PBOT): a referral tool and means of auditing outcomes.
- Surgery in centers with appropriate support for the massive weight loss patient. (Multidisciplinary panel)
- Improve access to patient information with equitable access to body contouring services throughout the country.
- Data collected from referral pathway to be used for further research.

Referral Pathway:
This pathway ensures patient selection by criterion set to ensure safe surgery (Fig 1).

Plastic surgery referral should be made once a patient fulfills the criteria outlined below and set in the PBOT.

General Criteria for Body Contouring Surgery:

- Age over 16 year
- Starting BMI over 40kg/m^2 or above 35kg/m^2 (with co morbidities) AND current BMI of less than or equal to 28
- Weight stability of 12 months and significant functional disturbances (both physical and psychological)

Exceptions to General Criteria:

- Starting BMI above 40kg/ m^2 or 35kg/m^2 (with co-morbidities) and loss of 75% excess body weight-should be eligible for an interim apronectomy, if they are unable to slim down to a BMI of 28kg/m**.**[2]

Exclusion Criteria:

- Current smoker
- Active psychosocial condition

Explanations

The incorporation of these criterions ensures patient safety by adequate patient selection, and appropriate use of resources by reduction in unnecessary referrals and intervention.

Starting BMI over 40kg/m^2 or above 35kg/m^2 (with co morbidities)

This reflects the current NICE guidelines for bariatric surgery

Current BMI of less than or equal to 28

Safety is a priority in this patient group, and this is why the BMI was set at 28 kg/m^2 or below. Many bariatric surgery patients will not be eligible

for BCS until they have lost enough weight – an added incentive to slim to a reasonable weight. BCS at higher BMIs is known to have a higher complication rate [29,30].

Weight stability of 12 months

This has been shown to be a critical factor in determining long term success following massive weight loss and body contouring. Many MWL patients have some weight regain – this period of weight stability encourages patients to maintain their weight loss.

Significant functional disturbances (both physical and psychological)

Surgery should only be undertaken if is going to improve the patient's functional and psychosocial outcomes.

Exceptions to general Criteria:

- Patients who have lost >75% of their excess body weight but are still above the 28kg/m^2 threshold are eligible for an interim apronectomy if required, to improve their function and allow for continued weight loss to meet their target BMI.

Exclusion Criteria:

- *Current smoker:* to minimize complications
- *Active psychosocial condition:* Elective surgery in the presence of psychological instability is likely to have postoperative difficulties.

The BAPRAS Post Bariatric outcome tool:

The BAPRAS PBOT is a 77-item scale designed to fulfill two purposes:

- Ensures standardized referral process where patients meet the inclusion criteria set in the national guidance.

- Measures the distress and dysfunction secondary to the side effects of massive weight loss. To systematically audit outcomes in this patient cohort.

The PBOT is filled out before referral to plastic surgery and is reviewed with clinical photographs by the MWL body contouring MDT. The referring doctor fills out the first two pages with the patient. Page 1 of the document facilitates collection of demographic data and relevant clinical information. Page 2 collates information on problems associated with excess skin, functional and psychological morbidity, past medical history and drug history. They directly relate to the national referral guidelines and therefore, indicate to the GP whether the patient meets the inclusion criteria, hence ensuring appropriate referrals.

The third to fifth pages are to be completed by the patient. This comprises further questions for collection of demographic data and provides a tool for further research patient adjustment to massive weight loss, functional impairment, and perception of disfigurement.

There are two diagrams: a visual prompt and a visual analogue scale. The MDT should compare the visual analogue scale with the clinical photographs of the patient to identify patient perception against objective assessment by the MDT.

The final part of the tool is left blank for the patient to include any additional information.

A scoring component added to the tool sets the rules for referral. To qualify the patient must score >8 points in the referral tool, out of these 3 must come from the first three questions. The PBOT can also be used at 3

and 6 months, and at 1 year or later in order to measure outcomes in this group of patients.

A review in the MDT completes the referral cycle with further management as per requirements of the score. (Fig 2) .

Conclusion:

National Guidelines for body contouring after massive weight loss will ensure better quality of care by standardization of treatments throughout the country, eradication of the postcode lottery and delivery of safe and improved patient care. The aim of addressing obesity should not simply be to reduce the financial burden on the state through the resolution of obesity related diseases. The goal should be to optimize the health of each patient, and for these people to rejoin society as active and productive individuals.

The following link provides access to the full guideline document.

http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/body-contouring-surgery

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The following were part of the guidance committee that met in April 2013. Subsequent communication was via email:

Mr Mark Soldin, Committee Chair, Consultant Plastic Surgeon

Mr Steve Lloyd, Chair, Hardwick CCG

Miss Fiona Hogg, Consultant Plastic surgeon

Miss Elaine Sassoon, Consultant Plastic surgeon

Mr Nick Wilson-Jones, Consultant Plastic surgeon

Dr Jo Gilmartin, Lecturer in health and psychology, Leeds University

Mr. Richard Welbourn, Consultant General Surgeon; President of British Obesity and Metabolic Surgery Society

Dr.Kiranmayi Penumaka, GP

Mr Ken Clare, Patient Representative, Chair Weight Loss Surgery Info

Mrs.Jane Deville-Almond, Patient Representative, Chair British Obesity Society

Miss Nada Al-Hadithy, Registrar Plastic Surgery

Miss Isabel Teo, Registrar Plastic Surgery

Miss Maleeha Mughal, Registrar Plastic Surgery

Disclaimer:

A multidisciplinary team has drawn up these guidelines with sponsorship from Department of Health (DOH), British association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) and the Royal College of Surgeons England (RCSEng).

Conflict of Interest:

The following members of the development group have completed a conflict of interest declaration.

Miss. Fiona Hogg: Received Fee from Ethicon to attend education events on massive weight loss body contouring surgery.

Dr.Jo Gilmartin: Received funding for undertaking quality of life research, which contributed to the commissioning guide.

Mr. Mark Soldin: Received funding for undertaking quality of life research, which contributed to the commissioning guide. He has a private practice in London.

Miss. Nada Al-Hadithy: Received funding from William Rainey Foundation to undertake Doctor of Medicine (MD) study.

Mr. Richard Welbourn: Occasional mentorship fee for surgeons visiting the unit paid to employer-none received in 2013,also obtained sponsorship for attending conferences from Ethicon Endo-surgery within the last year and writing fees for published articles in newsletters.

[i] Massive weight loss (MWL) is considered as reduction in 45.5 kg of weight or more, or 50% or greater loss of excess weight[i].

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[ii] http://www.sign.ac.uk/
[iii] http://www.agreetrust.org/resource-centre/practice-guidelines/
[iv] http://www.prisma-statement.org/statement.htm

MD thesis permission(2)

Permissions Helpdesk
To Me

Today at 8:54 PM

ELSEVIER

Dear Ms. Al-Hadithy:

Permission to include:

1. **Exploratory cohort study into psychological outcomes following massive weight loss body contouring procedures**

Al- Hadithy N, Hosakere A, Stewart K, J Plast Reconstr Aesthet Surg. – Accepted JPRAS

2. **A validated patient reported outcome measure for massive weight loss body contouring – introducing the British Association of plastic, reconstructive and aesthetic surgeons post bariatric outcome tool** . Al-Hadithy N, Welbourne R, Stewart KJ, Soldin M. JPRAS - J Plast Reconstr Aesthet Surg. 2014 Jul 18. pii: S1748-6815(14)00351-9. doi: 10.1016/j.bjps.2014.07.004. [Epub ahead of print]
3. **National Commissioning Guidelines: Body Contouring Surgery after Massive Weight Loss.**

Mughal M. Solidn M. Al-Hadithy N. Mughal M. Al-Hadithy N. Solidn M. J Plast Reconstr Aesthet Surg. 2014 Aug;67(8):1076-81. doi: 10.1016/j.bjps.2014.04.031. Epub 2014 May 10 JPRAS - accepted

4. **Desire for Post Bariatric Body Contouring in South East Scotland**

Al- Hadithy N, Mennie J, Magos T, Stewart K, J Plast Reconstr Aesthet Surg. 2012 Jan;66(1):87-94

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To Whom It May Concern,

Re: Papers published with Nada Al-Hadithy

As a co-author, I hereby grant permission for Nada Al-Hadithy to include copies of our paper(s) in her Medical Doctorate thesis submitted to the University of Edinburgh, pending any necessary approvals from the relevant publishing house.

With kind regards

Yours sincerely

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27th August 2014

To Whom It May Concern,

I can confirm that I give my full permission for Miss Nada Al-Hadithy to reprint the following paper, for which I am a co-author, in her thesis.

"Al-Hadithy N[1], Mennie J, Magos T, Stewart K. **Desire for post bariatric body contouring in South East Scotland.** *J Plast Reconstr Aesthet Surg.* 2013 Jan;66(1):87-94."

Should you require any further information, please do not hesitate to contact me.

Yours Sincerely

J. M

Miss Joanna Mennie

Research Fellow

Clinical Effectiveness Unit.

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Dear Miss. Al-Hadithy,

Re: Desire for post bariatric body contouring in South East Scotland

Nada Al-Hadithy, Joanna Mennie, Tiarnan Magos, Ken Stewart

Plastic and Reconstructive Surgery Department, St John's Hospital, Howden, Livingston EH546PP, United Kingdom

I am happy for the aforementioned paper to be reprinted at your discretion.

Kind regards,

Mr. Tiarnan Magos

BSc MB BS MRCS (ENT)

GMC: 7084579

Appendix Legends

Appendix 1: Cosmetic Framework Sept 2008 (updated April 2010) Appendix A: Surgery Following Significant Weight Loss (panniculectomy, arm and thigh reductions, mastopexy

Appendix 2: (Letter) Ethic approval

Appendix 3: (MA Letter) R&D approval

Appendix 4 Patient cover letter

Appendix 5: Patient Information sheets

Appendix 6: GP information sheets

Appendix 7: Consent form

Appendix 8: Recruitment PowerPoint presentation

Appendix 9: Eating disorder questionnaire

Appendix 10: Derriford Appearance Scale

Appendix 11: Hospital Anxiety and Depression Score

Appendix 12: Short Form 36

Appendix 13: BAROS

Appendix 14: Semi structured interview

Appendix 15: Standard operating protocol for surface linear anthropometric measurements

Appendix 16: Standard operating protocol for 3d stereophotograms

Appendix 17: BAPRAS Survey

Appendix 18: BAPRAS and RCS 2014 Commissioning guide: Massive Weight Loss Body Contouring

Appendix 19: Cover letter to BAPRAS commissioning group

Appendix 20: Cover letter to Darzi fellows

Appendix 21: PBOT V1

Appendix 22: PBOT V2

Appendix 23: PBOT V3

Appendix 24: PBOT supporting information

Appendix 25: PBOT scoring template

Appendix 26: Desire for Post Bariatric Body Contouring in South East Scotland. Al- Hadithy N, Mennie J, Magos T, Stewart K, J Plast Reconstr Aesthet Surg. 2012 Jan;66(1):87-94

Appendix 27: Does the degree of ptosis predict the degree of psychological morbidity in bariatric patients undergoing reconstruction? Al- Hadithy N, Hosakere A, Stewart K, J Plast Reconstr Aesthet Surg. – Accepted PRS

Appendix 28: A preliminary report on the development of a validated tool for measuring psychosocial outcomes for massive weight loss patients. Al-Hadithy N, Welbourne R, Stewart KJ, Soldin M. JPRAS - J Plast Reconstr Aesthet Surg. 2014 Jul 18. pii: S1748-6815(14)00351-9. doi: 10.1016/j.bjps.2014.07.004.

Appendix 29: National Commissioning Guidelines: Body Contouring Surgery after Massive Weight Loss. Mughal M. Solidn M. Al-Hadithy N. J Plast Reconstr Aesthet Surg. 2014 Aug;67(8):1076-81. doi: 10.1016/j.bjps.2014.04.031. Epub 2014 May 10

Appendix 30: National Commissioning Guidelines for Body Contouring Surgery after Massive Weight Loss. Anns Plastic Surgery – Mughal M. Solidn M. Al-Hadithy N. Accepted

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