Structured Assessment of Competency in Polypectomy

Dr Sachin Gupta
MBBS MRCP

Thesis Submitted for the degree of Doctor of Medicine (M.D.)

Imperial College London
Division of Surgery, Obstetrics, Reproductive Biology and Anaesthetics

2012
Abstract

Currently, there is no national endoscopic database in England. Information regarding the volume of therapeutic endoscopic procedures such as polypectomy is obtained mainly from small prospective studies. We examined the Hospital Episode Statistics (HES) national database to assess the number of patients who underwent a therapeutic polypectomy for a primary diagnosis of a benign colorectal polyp over a 10 year period, as well as analysing outcomes from the first three years of bowel cancer screening at a single tertiary endoscopy centre.

Despite the ubiquitous use of endoscopic snare polypectomy over the last four decades, there has been a void in formal training and assessment of polypectomy skills in the UK. We aimed to develop and validate an objective, structured assessment tool for assessing polypectomy competency in skilled accredited Bowel Cancer Screening endoscopists. This study led to the development of the DOPyS (Direct Observation of Polypectomy Skills) assessment tool. Validation and reliability of the DOPyS was demonstrated through assessment of polypectomy videos, performed by accredited Bowel Cancer Screening endoscopists, using Generalisability Theory (G theory). Construct validity of the DOPyS, and its ability to assess piecemeal Endoscopic Mucosal Resection, were determined through separate studies. The DOPyS validation studies highlighted variability in assessor scoring and DOPyS training days were held for Bowel Cancer Screening assessors in England, in order to align opinions prior to the implementation of the DOPyS into the Bowel Cancer Screening Accreditation Process in England.

Finally, in an effort to provide a structure for improved polypectomy outcomes and referral systems, a study was performed to determine the difficulty ‘level’ of a polypectomy, based on polyp characteristics.
Dedication

To all those who have motivated me and provided encouragement and support throughout, most especially my parents, my wonderful wife Jwala, and my adorable sons Arnav and Aaryan.
**Acknowledgements**

I am greatly indebted to a number of people for their help and support in this work. I have benefited from their enthusiasm, experience and imagination. I am extremely fortunate that during my time at the Wolfson Unit I have also made many good friends and colleagues. In particular I wish to acknowledge my supervisors Dr Siwan Thomas-Gibson and Mr Omar D Faiz. I am deeply appreciative of all their support, encouragement and assistance during the difficult periods of my research. I would especially like to thank Siwan, without whose support, this research would never have been carried out. I would also like to thank Dr Brian Saunders for his guidance and words of encouragement. I would also like to thank Dr Chris Fraser for making time to support this research. A special thanks to Mr Alex Almoudaris for his contribution in collecting and interpreting the HES data and co-authoring Chapter 2 of this thesis. I would not have been able to complete this work without the support from all the individuals in the Wolfson unit. I extend my personal thanks to Adam Haycock, Steve Preston, Eric Tripoli, Maggie Vance, Jean Mannings, Nicola Palmer, Aine Fitzpatrick, Lisa, Mariann Baulf, Ripple Man, Zacharias and Noriko Suzuki for their relentless support. A special thanks to Ed Despott, my colleague and dear friend, for his encouragement and moral support. I am also greatly appreciative of the continuous support given by the nursing and clerical staff within the unit. I am deeply grateful to those consultants who were willing to have their bowel cancer screening lists recorded for one of the studies. I am grateful to Paul Basset for his statistical advice and analysis in a number of the projects. They greatly contributed to the interpretation and evaluation of results. I would like to thank Professor Cees Van der Vleuten for his contributions in calculating raw data (given in Appendix) using the Generalisability Theory. I would like to thank Mr Steve Preston for his help with video editing for
Chapter 4. All other video editing was performed by me. I was also responsible for data collection, calculation, interpretation and authoring Chapter 3. I would finally like to thank all the patients who consented to having their procedures recorded anonymously.
# Table of Contents

**ABSTRACT** .................................................................................................................. 2

**DEDICATION** ............................................................................................................... 3

**ACKNOWLEDGEMENTS** ............................................................................................ 4

**TABLE OF CONTENTS** ............................................................................................... 6

**FIGURES** .................................................................................................................... 14

**TABLES** ...................................................................................................................... 16

**APPENDICES** ............................................................................................................ 18

**CHAPTER 1: INTRODUCTION** .................................................................................. 19

1.1 Overview .................................................................................................................... 20

1.2 History and importance of polypectomy .................................................................. 20

1.3 Types of polyps ........................................................................................................ 22

1.4 Polypectomy techniques .......................................................................................... 24

   1.4.1 Cold forceps .................................................................................................... 24

   1.4.2 Hot (biopsy) forceps ..................................................................................... 25

   1.4.3 Snare polypectomy ....................................................................................... 26

       1.4.3.1 Cold snare ......................................................................................... 27

       1.4.3.2 Hot snare ........................................................................................... 28

   1.4.4 Endoscopic Mucosal Resection .................................................................... 29

   1.4.5 Variability in polypectomy technique ............................................................. 30

1.5 Electrosurgery (Diathermy) in polypectomy ............................................................. 31

1.6 Complications of polypectomy ............................................................................... 32

   1.6.1 Bleeding ...................................................................................................... 33

       1.6.1.1 Immediate bleeding ........................................................................... 34
1.6.1.2 Delayed bleeding.........................................................34
1.6.2 Perforation........................................................................35
1.6.3 Incomplete polypectomy..................................................35

1.7 Polypectomy outcomes from large-scale data......................36
1.7.1 Bowel Cancer Screening................................................37
1.7.2 Hospital Episode Statistics (HES) database.......................39

1.8 Improving outcomes from polypectomy.............................40
1.8.1 Understand what defines a competently performed polypectomy ....41
1.8.2 Teaching competency in polypectomy skills.......................42
1.8.3 Define and provide a safe and effective polypectomy service.....43
1.8.3.1 Endoscopy Global Rating Scale (GRS)..........................44
1.8.4 What needs to be done....................................................45
1.8.4.1 Self awareness.........................................................45
1.8.4.2 Training...............................................................46

1.9 Assessment in endoscopy.................................................47
1.9.1 Need for assessment.....................................................47
1.9.2 Competency assessment...............................................49
1.9.3 Framework for assessment..........................................50
1.9.4 Attributes of an assessment process..............................52
1.9.4.1 Reliability..........................................................52
1.9.4.2 Validity.............................................................52
1.9.4.3 Acceptability........................................................53
1.9.4.4 Feasibility............................................................53
1.9.4.5 Educational impact...............................................53
1.9.5 Methods of assessment..............................................54
CHAPTER 1: CURRENT ASSESSMENTS IN ENDOSCOPY

1.9.6 Current assessments in endoscopy

1.9.6.1 Changes in endoscopy training and assessments in the UK

1.9.6.2 Endoscopy training and assessments internationally

1.10 Summary

1.11 Hypothesis

CHAPTER 2: POLYPECTOMY TRENDS IN ENGLAND

2.1 Background

2.1.1 Background to Hospital Episode Statistics

2.2 Methodology

2.2.1 Polyp selection

2.2.2 Procedure selection

2.2.3 Surgical polypectomies

2.2.4 ‘Top and Tail’ endoscopy patients

2.2.5 Procedure volume

2.2.6 Re-admission and 30-day mortality rates

2.3 Results

2.3.1 Procedures

2.3.2 Repeat attendances

2.3.3 Polyps

2.3.4 Institutional variation

2.3.5 28-day re-admission and 30-day mortality

2.4 Discussion

2.5 Conclusion
CHAPTER 3: POLYPECTOMY IN BOWEL CANCER

SCREENING........................................................................................................80

3.1 Background........................................................................................................81

3.2 Methodology........................................................................................................81

3.3 Results................................................................................................................84

3.3.1 Overall outcomes..........................................................................................84

3.3.2 Colorectal cancer characteristics..................................................................85

3.3.3 Individual colonoscopist performance.........................................................87

3.3.4 Surveillance procedures.................................................................................88

3.3.5 Additional procedures...................................................................................89

3.3.6 Complications.................................................................................................90

3.3.7 Patient satisfaction.........................................................................................91

3.4 Discussion..........................................................................................................94

3.5 Conclusions.......................................................................................................97

CHAPTER 4: ASSESSMENT OF POLYPECTOMY SKILLS……99

4.1 Background.......................................................................................................100

4.2 Methodology.....................................................................................................100

4.2.1 DOPyS development..................................................................................100

4.2.2 DOPyS validation........................................................................................101

4.3 Statistical Analysis..........................................................................................103

4.3.1 Reliability and G Theory.............................................................................104

4.4 Results.............................................................................................................108

4.4.1 Polyps and polypectomy techniques.........................................................108

4.4.2 Initial analysis of DOPyS scores...............................................................110
CHAPTER 5: ASSESSMENT OF PIECEMEAL ENDOSCOPIC MUCOSAL RESECTION (p-EMR)

5.1 Background

5.2 Methodology

5.3 Statistical analysis

5.4 Results

5.4.1 Polyps and patients

5.4.2 G Theory analysis

5.4.2.1 Variance components

5.4.2.2 Generalisability Coefficient (G coefficient)

5.4 Discussion

5.5 Conclusion

CHAPTER 6: CONSTRUCT VALIDITY OF DOPyS

6.1 Background

6.2 Methodology

6.2.1 Participants

6.2.2 Direct Observation of Polypectomy Skills (DOPyS)
CHAPTER 7: DOPyS TRAINING FOR BOWEL CANCER SCREENING ASSESSORS

7.1 Background

7.2 Training the Bowel Cancer Screening assessors

7.3 Workshop outcomes

7.4 Summary

CHAPTER 8: DEFINING ‘LEVELS OF DIFFICULTY’ OF POLYPECTOMY
APPENDIX 1: DIRECT OBSERVATION OF POLYPECTOMY SKILLS VERSION 1

APPENDIX 2: DIRECT OBSERVATION OF POLYPECTOMY SKILLS VERSION 2

APPENDIX 3 (PART 1): DOPYS DESCRIPTORS- GENERIC

APPENDIX 3 (PART 2): DOPYS DESCRIPTORS-STALKED POLYPS

APPENDIX 3 (PART 3): DOPYS DESCRIPTORS-SMALL SESSILE LESIONS/EMR

APPENDIX 3 (PART 4): DOPYS DESCRIPTORS-POST-POLYPECTOMY

APPENDIX 4: RAW DATA FOR ANALYSIS OF DOPyS SCORES FOR p-EMR
**Figures**

Figure 1  An example of a snare used for endoscopic polypectomy……………..…..21

Figure 2  Paris Classification of superficial polyps based on their morphology……23

Figure 3  Paris Classification of polyps based on their endoscopic morphological appearance………………………………………………………………….24

Figure 4  Cold forceps for polypectomy……………………………………………..25

Figure 5  Hot biopsy of a polyp………………………………………………………….26

Figure 6  A snare around a polyp………………………………………………………..27

Figure 7  Submucosal injection technique and EMR……………………………….30

Figure 8  An example of a electrosurgical unit used for polypectomy……………..32

Figure 9  Endoscopy Global Rating Scale……………………………………………..44

Figure 10  Ideal process of achieving competence (adapted from Peyton)………….49

Figure 11  Bloom’s taxonomy of learning domains…………………………………50

Figure 12  Miller’s framework for clinical assessment……………………………..51

Figure 13  Inclusion and exclusion criteria for data collection from HES database...68

Figure 14  Bar chart demonstrating the distribution of procedures by study year…..71

Figure 15  Bar chart demonstrating the change in distribution of the location of polyps………………………………………………………………………..73

Figure 16  Stacked bar chart representing the breakdown of procedures per tertile…76

Figure 17  Flow of patients through the Bowel Cancer Screening process…………85

Figure 18  Flow of participants through the study……………………………………103

Figure 19  Assessor variation in DOPyS scores……………………………………..110

Figure 20  Proposed Bowel Cancer Screening Accreditation process………………119

Figure 21  One of the 5 p-EMR cases scored by the two assessors for establishing reliability of the DOPyS.………………………………………………..123
Figure 22  Scatter plot of raw scores assigned to polyp videos by two experts……160
Tables

Table 1  ASGE Severity grading system for adverse events…………………………33
Table 2  Reliability and Validity of current methods of assessing technical skills….54
Table 3  ICD codes used for collection of HES polypectomy data…………………..64
Table 4  OPCS codes used in selection of procedures from the HES database……..66
Table 5  OPCS codes used for selecting surgical polypectomies from HES database.67
Table 6  Details of endoscopic procedures performed each year…………………..70
Table 7  Endoscopic procedures per tertile………………………………………75
Table 8  Re-admission rates per tertile………………………………………………76
Table 9  30-day mortality rates per tertile…………………………………………77.
Table 10 Cancer characteristics of the screening and symptomatic populations at
     St.Mark’s Bowel Cancer Screening Centre between October 2006 and
     September 2009………………………………………………………………87
Table 11 Performance of screeners at St.Mark’s Bowel Cancer Screening Centre….88
Table 12 Proportion of cases referred for additional procedures by each screening
     endoscopist……………………………………………………………………90
Table 13 Patient satisfaction questionnaire at St.Mark’s screening centre………..93
Table 14 Sources of Variance influencing reliability in G-Theory analysis………..108
Table 15 Polyp characteristics and polypectomy method……………………………109
Table 16 Number of cases and assessors required for reliable scoring by SEM……112
Table 17 Sources of Variance influencing reliability in G-Theory analysis………..121
Table 18 Patient and polyp characteristics…………………………………………122
Table 19 Number of assessors required to score five p-EMR videos to achieve a
     Generalisability coefficient >0.80………………………………………125
Table 20 Characteristics of polyps removed by expert and non-expert endoscopists

Table 21 Comparison of DOPyS overall polypectomy scores for the expert and intermediate endoscopists given by the two trained assessors

Table 22 Comparisons of individual DOPyS parameter scores for polypectomy across the Pass/Fail divide given by the two trained assessors

Table 23 Comparison of overall DOPyS scores for polypectomies performed by the expert and intermediate endoscopists scored by the two untrained assessors

Table 24 Feedback from Bowel Cancer Screening assessors from the DOPyS training workshops

Table 25 Working group response using Delphi technique

Table 26 Scoring system for determining the difficulty level of a polyp

Table 27 Range of scores for each polyp level

Table 28 Comparison of polyp levels assigned by the two experts for the 24 videos viewed to establish reliability of the scoring system
Appendices

Appendix 1  Direct Observation of Polypectomy Skills Version 1…………..199
Appendix 2  Direct Observation of Polypectomy Skills Version 2……………200
Appendix 3 (part 1) DOPyS Descriptors-Generic…………………………..201
Appendix 3 (part 2) DOPyS Descriptors-Stalked Polyps……………………..202
Appendix 3 (part 3) DOPyS Descriptors-Small Sessile Polyps/EMR…………..203
Appendix 3 (part 4) DOPyS Descriptors-Post-Polypectomy…………………204
Appendix 4: Raw data for analysis of DOPyS scores for p-EMR………………205
Chapter 1: Introduction
Chapter 1: Introduction

1.1 Overview and Aim

Endoscopic polypectomy involves the accurate identification, removal and retrieval of an intra-luminal polyp. For the purpose of this thesis, the term ‘polypectomy’ refers to colonic polypectomy. Polypectomy may be performed employing a variety of techniques, depending on the size of the polyp, its morphology and site in the colon. Large-scale data on polypectomy trends and outcomes may provide insight, or guidance for developments in the endoscopic service. Factors influencing outcomes from polypectomy and variability in polypectomy technique have not been clearly defined. Similarly, structured assessment of polypectomy technique has not been described in the literature. This chapter attempts to address some of these issues and forms the basis for this thesis.

1.2 History and importance of polypectomy

The modern day technique of snare polypectomy (technique described in detail in section 1.4.3) was first described by a Japanese endoscopist, Dr Hiromi Shinya in 1969, who effectively removed a 1.5cm polyp in the sigmoid colon. Over the last four decades, there has been little change in the basic design of snares being used in current practice (Figure 1).
Evidence indicates that over 95% of colorectal cancers in Western countries arise in slow growing adenomatous polyps (benign tumours of glandular origin) which may eventually turn malignant [1]. Several case-control studies have shown that endoscopic polypectomy prevents progression of the adenoma-carcinoma sequence and reduces incidence and mortality from colorectal cancer [2-4]. The National Polyp Study [5] compared the incidence of colorectal cancer in over 1400 patients who had a complete colonoscopy (and at least one polypectomy), with the incidence of cancer in three reference groups in which polypectomy was not performed. Colonoscopic polypectomy resulted in a 76-90% reduction in the incidence of colorectal cancer. In another study involving a population of over 32000 veterans, Muller and Sonnenberg
[6] showed that despite a relatively small difference in the number of endoscopic procedures performed between the control group (1166 out of 16531 persons had endoscopic procedures before colorectal cancer was diagnosed) and the case group (1051 out of 16531 persons had endoscopy and polypectomy), the risk of developing colorectal cancer was reduced by 50% in those who had polypectomy. Several other studies have shown a similar benefit of polypectomy in reducing the risk of future colorectal cancers and advanced adenomas [7-9]. The practice of polypectomy is therefore extremely clinically relevant in the field of endoscopy.

1.3 Types of polyps

The Borrman classification [10], initially proposed in 1926, was used for classifying advanced gastric tumours and included types 1-4. The Japanese Gastric Cancer Association [11, 12] added two further types: “type 0” for superficial lesions and “type 5” for unclassified advanced tumours. The combined Japanese-Borrman classification is as follows:

Type 0- Superficial polypoid, flat/depressed, or excavated tumours.

Type 1- Polypoid carcinomas, usually attached on a wide base

Type 2- Ulcerated carcinomas with sharply demarcated and raised margins

Type 3- Ulcerated, infiltrating carcinomas without definite limits
Type 4- Nonulcerated, diffusely infiltrating carcinomas

Type 5- Unclassifiable advanced carcinomas.

This classification of gastric tumours was later applied to large bowel (colonic) polyps as well. The Paris endoscopic classification [13] of superficial polyps (Type 0) in the colon is now used widely by endoscopists worldwide. The superficial neoplastic colonic lesions were sub-classified based on their endoscopic morphological appearances (Figures 2, 3).

**Figure 2.** Paris classification of superficial polyps based on their morphology [13]
**Figure 3.** Paris Classification of polyps based on their endoscopic morphological appearance

1.4 Polypectomy techniques

Polypectomy is a fundamental skill utilised by all endoscopists who perform colonoscopy. Colonoscopic polypectomy is one of the most powerful cancer prevention techniques in clinical medicine and has been shown to prevent 80% of incident colorectal cancers. However, it is not without its attendant risks.

1.4.1 Cold forceps polypectomy

This is the simplest method of polypectomy suitable for polyps less than 4mm in size, with the forceps (Figure 4) grasping the polyp tissue, without the use of diathermy or
electrocautery. After closing the forceps on the polyp, a gentle pull on the forceps removes the polyp from the colonic mucosa. A survey of colonoscopic polypectomy practices among clinical gastroenterologists found that cold forceps polypectomy was the technique of choice for small polyps up to 4mm in size [14]. The obvious advantages of this method of polypectomy are avoidance of the risk associated with electrocautery, definite tissue for diagnosis and negligible risk of colonic perforation [15], albeit with a slightly increased risk of leaving residual polyp tissue behind [16].

**Figure 4.** Cold forceps for polypectomy

1.4.2 **Hot (biopsy) forceps polypectomy**

This technique is similar to cold forceps with the additional use of electrocautery to destroy residual polyp tissue. In hot forceps polypectomy (Fig. 5), only the tip of the polyp is grasped in the forceps. The small polyp is pulled into the colonic lumen to create a tent-like effect and electrocautery is applied to destroy the polyp base while preserving some polyp tissue inside the forceps for histological analysis [17]. Over the years, the use of hot forceps has fallen out of favour. The main criticisms of this
technique are incomplete polypectomy and risk of perforation. A randomised study by Ellis looked at 72 polyps (≤6mm in size) and found that hot forceps left residual polyp tissue behind in 22% cases compared to 5%-14% with cold or hot snare polypectomy [18]. A retrospective analysis by Peluso studied 62 hot forceps polypectomies (3-6mm in size) and found residual polyp tissue in 17% cases on follow up endoscopic examination 1-2 weeks later [19]. Wadas evaluated the practice of 517 endoscopists. In that study, 71% of the endoscopists used hot biopsy forceps and reported 117 complications, including 85 episodes of bleeding, 19 perforations and one death. 87% of the colon perforations with hot forceps, occurred on the right side [20]. Hot forceps may have a place for small polyps with difficult access where adequate snare position may not be achievable.

**Figure 5.** Hot biopsy of a polyp

**1.4.3 Snare polypectomy**

In a survey of polypectomy practices, snare polypectomy was found to be the preferred method for removal of pedunculated polyps ≥1 cm in size [14]. A snare is a self contained metal ring that is opened over the polyp and then closed, entrapping
polyp tissue for resection by closing the snare ring (Figure 6). Resection may be supplemented with electrocautery (hot snare) or not (cold snare). Available data suggest that snaring is more effective than hot or cold forceps in eradicating diminutive colon polyps [18, 19]. However, this technique does require co-ordination between the endoscopist (who steers the snare accurately over the lesion) and an assistant who marks, opens and closes the snare. The endoscopist must ensure that no additional tissue is trapped within the snare prior to cutting.

Figure 6. A snare around a polyp

1.4.3.1 Cold snare

Cold snaring of small polyps (≤7mm) is associated with low complication rates [21, 22] but potential drawback associated with cold snaring is difficulty in specimen retrieval for pathologic examination. Deenadayalu analysed two retrieval methods for 400 polyps (mean size of 3.5mm) removed by cold snare and found no complications.
The rate of successful retrieval with the two methods ranged from 98%-100% [23]. In another study, McAfee studied the efficacy of small snares for removal of polyps ≤7 mm in size. 183 polypectomies were analysed. 94% of the polyps could be removed with a tiny snare and 88% of these were retrieved. The only complication was bleeding in one patient, in whom snare polypectomy without electrocautery (cold snare) was used [24]. Cold snaring may be associated with an increased rate of immediate haemorrhage but this is not usually clinically significant. Cold snaring is accepted a safe and effective technique for the removal of diminutive colorectal polyps.

1.4.3.2 Hot snare

A hot snare is one that is supplemented with electrocautery. Some endoscopists prefer to complete the snare closure during application of electrocautery, whilst others rely on their assistant to fully close the snare. If the snare is too tight prior to electrocautery application, it could result in inadvertently cold cutting the polyp, resulting in bleeding from the stalk or in the snare becoming entrapped into coagulated tissue in the stalk [25]. Once the snare is in position, a few seconds of electrocautery can be applied if opted for, and then the snare is fully closed to cut through the polyp. Hot snaring is the preferred method of polypectomy for polyps greater than 8mm in size.

Two recent randomised controlled trials have compared the safety of hot and cold snaring techniques for small (3-8mm) polyps. Ichise Y et al [26] randomized 101 polyps to the cold snare technique and 104 for hot snaring. The results suggested that both techniques were identical in terms of bleeding risks and rate of polyp retrieval.
However, the hot snare technique caused more post-polypectomy abdominal symptoms. In a similar study, Paspatis GA et al [27] randomized 414 consecutive patients with small polyps to hot and cold snare groups. The results suggested that there was no difference between the two groups in terms of early or late post-polypectomy bleeding. However, there was significantly more intra-procedural bleeding with the cold snare technique. Both studies concluded that for small polyps (3-8mm), cold snaring was the preferred method.

1.4.4 **Endoscopic Mucosal Resection**

Sessile polyps, small or large, may be removed by Endoscopic Mucosal Resection (EMR), using the ‘inject and cut’ technique, which involves injection of fluids into the submucosa beneath the polyp (Fig. 7), increasing the distance between the base of the polyp and the serosa, reducing the risk of bleeding, thermal injury and perforation [28,29]. This technique may offer an alternative to surgery for the safe and effective removal of large non-pedunculated colorectal polyps, thereby obviating the need for surgical intervention with its attendant morbidity, mortality and cost of prolonged hospital admission. The raised polyp can be hot snared either *en bloc* (in one piece), or removed piecemeal (multiple snarings) if the lesion is large. However, the cut-off for defining ‘large’ lesions varies in the literature, with some authors defining a large lesion as one that is too large to resect in one piece (i.e. too large for *en bloc* resection)-usually larger than 1.5cm [30, 31]. Other studies have used a cut-off of 2cm for large lesions [32, 33]. EMR is a relatively safe technique with perforation rates of 0.7-3.7% and post EMR bleeding rates of 0.4-3.8% [30, 34, 35]. To minimise complications and improve outcomes, the endoscopist undertaking the removal of
large lesions using EMR technique should undergo training. However, no consistent training or assessment of this technique is described to date.

**Figure 7.** Submucosal injection technique and EMR.

1.4.5 Variability in polypectomy technique

In the absence of established, universally accepted guidelines, paucity of randomised controlled trials with evidence for the superiority of individual techniques and wide variations in training, endoscopists exhibit wide variability in their method of polypectomy. This variation in technique has been considered a factor in the effectiveness of polyp resection [18, 36, 37] and in complication rates of polypectomy [22, 24]. Singh carried out a survey of colonoscopic polypectomy practices among clinical gastroenterologists in the United States [14] and concluded that polypectomy technique was highly variable. This variability was higher for removal of polyps less than 1 cm in size, particularly for polyps 4-6mm in size. In England, the first large
scale prospective study of endoscopy practice looked at over 9000 procedures performed across three National Health Service regions [38]. In this analysis, polyps were the most common diagnosis (occurring in 22.5% of the colonoscopies), with endoscopists employing a wide range of polypectomy techniques including snare polypectomy with or without diathermy, cold biopsy with snare, hot biopsy and hot biopsy with snare. Factors influencing the choice of polypectomy technique and comparison of techniques utilised by experienced and non-experienced endoscopists have not been previously studied in any detail.

1.5 Electrosurgery (Diathermy) in polypectomy

The therapeutic basis of electrosurgery is the production of heat at the cellular level. Heat is produced due to the resistance provided by the tissue to the flow of current. With high current concentrations, cells membranes burst. When these bursting cells are aligned along a snare or wire (as in snare polypectomy), the result is described as electrosurgical cutting. For areas farther from the wire or snare, the current concentration is lower, resulting in slower cell heating and coagulation (such as that required to control haemorrhage). Modern electrosurgical units (Figure 8) provide both ‘cutting’ and ‘coagulation’ currents (known as ‘blend’ currents) at the same time and are therefore ideal for polypectomy. Electrosurgical unit settings for snare polypectomy are not standardised, and data from large controlled trials on which to base the optimal electrosurgical method for polypectomy are lacking. In a survey of 189 US endoscopists, the current used for polypectomy varied, with 46% of endoscopists using ‘pure coagulation’ current, 46% using ‘blend’ and 3% ‘pure cut’. The other 4% varied the current during polypectomy [14]. Evidence suggests that
polypectomy related complications may partly be due to the type of current used. A pure cutting current may lead to increased immediate bleeding, while coagulation may increase the risk of delayed post-polypectomy bleeding or perforation [39]. It is therefore vital for the endoscopist to be familiar with the electrosurgical unit being used and to understand the merits of each type of diathermy setting for any individual polypectomy.

**Figure 8.** An example of an electrosurgical unit used for polypectomy

1.6 *Complications of polypectomy*

The two critical requirements for polypectomy in terms of reducing the risk of colorectal cancer are: safe removal and complete resection. Endoscopic polypectomy has a small but well defined complication rate that may be partially related to the endoscopists’s skill. The most serious complications after polypectomy are bleeding and colonic perforation. Endoscopic complications (adverse events) may be classified
based on the American Society of Gastrointestinal Endoscopists (ASGE) recommendations [40]. The ASGE defines a complication as an event that prevents the completion of a procedure, or requires hospital admission, or necessitates another intervention. The complication (adverse event) may occur pre-procedurally, during the procedure, post-procedurally (up to 14 days) or at a later stage (any time after 14 days). The adverse event may also be classified based on severity (see Table 1).

Table 1. ASGE Severity grading system for adverse events [40]

<table>
<thead>
<tr>
<th>Consequence</th>
<th>Severity grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td>Procedure aborted (or not started) because of an adverse event</td>
<td>x</td>
</tr>
<tr>
<td>Postprocedure medical consultation</td>
<td>x</td>
</tr>
<tr>
<td>Unplanned anesthesia/ventilation support, ie endotracheal intubation during conscious sedation</td>
<td>x</td>
</tr>
<tr>
<td>Temporary ventilation support by bagging or nasal airway during conscious sedation, and endotracheal intubation during a modified anesthesia care procedure are not adverse events</td>
<td>x</td>
</tr>
<tr>
<td>Unplanned hospital admission or prolongation of hospital stay for ≤3 nights</td>
<td>x</td>
</tr>
<tr>
<td>Unplanned admission or prolongation for 4-10 nights</td>
<td>x</td>
</tr>
<tr>
<td>Unplanned admission or prolongation for &gt;10 nights</td>
<td>x</td>
</tr>
<tr>
<td>ICU admission for 1 night</td>
<td>x</td>
</tr>
<tr>
<td>ICU admission &gt;1 night</td>
<td>x</td>
</tr>
<tr>
<td>Transfusion</td>
<td>x</td>
</tr>
<tr>
<td>Repeat endoscopy for an adverse event</td>
<td>x</td>
</tr>
<tr>
<td>Interventional radiology for an adverse event</td>
<td>x</td>
</tr>
<tr>
<td>Interventional treatment for integument injuries</td>
<td>x</td>
</tr>
<tr>
<td>Surgery for an adverse event</td>
<td>x</td>
</tr>
<tr>
<td>Permanent disability (specify)</td>
<td>x</td>
</tr>
<tr>
<td>Death</td>
<td>x</td>
</tr>
</tbody>
</table>

1.6.1 Bleeding

This is the most common post-polypectomy complication. The risk of post-polypectomy bleeding ranges from 0.3 to 6.1% [41]. Dobrowolski [42] noted that the risk of post-polypectomy haemorrhage was more likely in polyps larger than 17mm in
size, pedunculated polyps with stalks greater than 5mm, and in sessile and malignant polyps. Bleeding is usually divided into immediate (less than 12 hours post-procedure) and delayed (after 12 hours post-procedure but within 30 days).

1.6.1.1. Immediate bleeding

Most bleeding that occurs intra-procedurally can be controlled by the endoscopist. Haemostasis can be achieved using a variety of techniques: grasping the stalk of a pedunculated polyp with the snare and holding pressure for 5 minutes [43], prophylactic injection of dilute adrenaline (1:10000), placement of endoclips to tamponade any supplying blood vessels [44] or placement of an Endoloop (a detachable nylon loop that can be placed over a lesion to prevent it from bleeding).

1.6.1.2. Delayed bleeding

This may occur from 5-7 days on average post-polypectomy in up to 2% of patients [45] and usually settles spontaneously. If a therapeutic intervention is required, it is usually treated by adrenaline injection combined with a thermal modality [46] or clips. In an analysis of delayed post polypectomy bleeding, Do Hyoung Kim et al [47] concluded that endoscopic therapy of delayed post polypectomy bleeding was dependant on polyp characteristics, method of resection and patient factors. In that study, delayed haemorrhage was found to be commoner in sessile polyps, polyps found in the right colon, adenomas and male patients and re-scoping is advisable in patients with these ‘risk factors’.
1.6.2. Perforation

Colonic perforation is arguably the most serious post-polypectomy complication. Factors contributing to perforation include mechanical stress from the scope, barotrauma, electrocautery, and the depth of the polyp resection itself. The risk of perforation with all colonoscopies ranges from one perforation per 1000 to 2000 colonoscopies [48-50], with the risk being greater for therapeutic colonoscopy as compared to a diagnostic procedure [51, 52]. Risk of perforation also increases with electrocautery time, increasing polyp size, sessile polyps requiring piecemeal removal and location in the caecum. Although colonoscopic perforation is a rare complication, it is associated with a high rate of morbidity and mortality [53-56]. The mortality rate might be up to 14% depending on patients’ characteristics and co-morbidities [57]. Most patients with colonic perforation require open surgery; however, there is recent evidence that colonic perforation can be successfully managed by endoluminal repair [52] and laparoscopic surgery [58, 59].

Similar to perforation but less serious is post-polypectomy syndrome, which refers to the development of pain, fever, leucocytosis and peritoneal inflammation in the absence of frank perforation [41]. Treatment is usually conservative involving antibiotics, fluids and bowel rest [60], but does require an inpatient stay.

1.6.3. Incomplete polypectomy

Colonoscopy is associated with a varying risk of missing colorectal cancer. Evidence suggests that colorectal cancer is diagnosed within 3 years in 2-6% of people with colorectal cancer who undergo colonoscopy in whom the cancer was not detected at initial colonoscopy [61, 62]. There may be a number of reasons for these ‘missed’ or
‘interval’ cancers [63], including incomplete polypectomy at initial colonoscopy, genuinely ‘missed’ cancer, incomplete initial colonoscopy (either due to inadequate bowel preparation or poor technique), or a rapidly growing new cancer. The central role of polypectomy in reducing colorectal cancer incidence has been established. In a 14 year follow-up study from St.Mark’s Hospital, London, 1618 patients underwent rigid sigmoidoscopy and polypectomy. The incidence of subsequent rectal cancer was strongly associated with a history of incompletely polypectomy [8]. In another study, 27% of colorectal cancers diagnosed within 5 years of a complete colonoscopy, developed at the site of a previous polypectomy [64]. A retrospective study reported results from over 2000 patients with polyps who had a baseline clearing colonoscopy followed by another clearing colonoscopy at 1 year, and then surveillance colonoscopy at 4 years [65]. In that study, 31% patients in whom post-colonoscopy colorectal cancer was diagnosed, the cancer was attributed to an incompletely removed polyp at previous colonoscopy. These studies emphasise the importance of complete polypectomy.

1.7. Polypectomy outcomes from large-scale data

Currently, outside of the National Bowel Cancer Screening Programme, there is no national data on the number and outcomes of polypectomies performed each year in England. Bowles et al [38] performed a survey looking at colonoscopic practice across three National Health Service regions. The survey showed that polyps were found in 22.5% of the colonoscopies and polypectomy was undertaken in 90.7% of these colonoscopies. In 18.1% of colonoscopies where polypectomy was undertaken, the polyp was reported as being incompletely removed by the endoscopists, mainly
due to technical difficulties. Incomplete polypectomy results in diagnostic uncertainty, the need for repeat procedures and an increased risk of subsequent recurrence/interval cancer [64,66].

In the analysis performed by Bowles, out of the 34 patients who had bleeding either during or after the procedure, 25 (73.5%) had undergone snare polypectomy. The other bleeds were attributable to techniques such as hot biopsy. The perforation rate in those colonoscopies where therapy was performed was 1:460. In this group there were 4 perforations, all related to polypectomy. However, much of current knowledge on case volumes and complications is based on relatively small prospective [67] and retrospective [68, 69] studies. One such study was a prospective multicentre study carried out in 13 centres in Munich, Germany [67], in which a total of 3976 snare polypectomies were analysed. There was a 10% complication rate but the majority of these were of minor clinical significance. Polyp size and right-sided polyp location were the main risk factors associated with complications. These studies give an idea of the incidence of complications related to polypectomy. In England, there are two potential sources of national polypectomy related data: bowel cancer screening and hospital episode statistics (HES).

1.7.1. **Bowel Cancer Screening**

There is evidence that population screening for colorectal cancer using faecal occult blood testing (FOBT) reduces the disease-specific mortality [70-74]. Two large population based studies carried out in Nottingham, England [71] and in Funen, Denmark [72] have shown a reduction in deaths from colorectal cancer after screening, of 15% and 18% respectively. In 2000 the UK National Screening
Committee commissioned a pilot across two sites to assess the feasibility of introducing a national bowel cancer screening programme (BCSP). Results from the pilots [75] led to the implementation of a national BCSP throughout the United Kingdom using biennial FOBT. The BCSP was rolled out in a phased manner starting in 2006 with screening data being meticulously recorded and stored in a national database. In the programme, all people aged 50-69 years are invited to take part, and sent a HemaScreen Faecal Occult Blood kit, comprising a card with six points. All those who have a weakly or strongly positive result, are then offered an appointment with a Specialist Screening Practitioner (SSP) who provides information regarding further tests. The FOBT positive participants are then offered a colonoscopy. In a small minority of medical circumstances, a CT colonography (CTC) is offered as an alternative to colonoscopy. In the first three years of the national bowel cancer screening programme (BCSP), greater than 36000 screening colonoscopies have been performed [76], with high completion rates (95.2%), low adverse events and a mean adenoma detection rate per colonoscopist of 46.5%. Evidence also suggests that good clinical outcomes can be achieved, even with large and flat lesions [77, 78]. The introduction of the national bowel cancer screening programme has led to a significant stage shift between the non-screen and screen detected colorectal cancer populations (30.9% of screened colorectal cancers are Dukes’ A i.e. early stage, as compared to 13.6% of non-screen detected colorectal cancers) [79]. Complications are rare, but have been described, even in experienced hands [80]. Based on the results of the screening pilot [75], it was envisaged that approximately 40% of faecal occult blood test (FOBT) positive patients would have resectable polyps. Similarly, the first three rounds of the English arm of the Bowel Cancer Screening pilot showed that FOBT positive screenees had positive predictive values of adenoma detection at
42.6%, 47.7% and 36.9% [81]. However, data collected as part of this thesis have shown a higher adenoma detection rate (of approximately 62%) in this cohort of patients who are FOBT positive [82]. This has implications with regards to a higher therapeutic workload than previously anticipated. Chapter 3 describes this data.

Flexible sigmoidoscopy offers an alternative to the FOBT/colonoscopy based bowel cancer screening. This was demonstrated by Atkin WS et al [83] in a large, randomised trial undertaken in 14 UK centres. Eligible men and women, who had indicated willingness to accept an invitation for screening, were randomly allocated to the intervention group (offered flexible sigmoidoscopy screening) or the control group (not contacted). During screening and median follow up of 11.2 years, colorectal cancer incidence in the intervention group was reduced by 23% and mortality by 43% as a result of finding and removing cancers and adenomas (polyps) from the left side of the colon. In this study, people performing the flexible sigmoidoscopies underwent no specific training and were relatively inexperienced. Better training and improved techniques may possibly have shown improvement on the excellent reduction in incidence and mortality from colorectal cancer.

1.7.2. Hospital Episode Statistics (HES) database

In keeping with the contemporary drive towards quality improvement and social demands for safer services within healthcare, clinicians should be aware of their outcomes both within their institutions but also nationally. With greater emphasis on self-auditing and governance it is important to have an appreciation of what happens in one’s own field for comparison. Recently, several clinical registries have been instituted in different specialities in part for this reason; however these take
considerable time and effort to institute, implement and maintain [84,85]. Furthermore, not all are mandatory and thus may under-report cases or morbidity.

In the United Kingdom, the NHS Information Centre receives reports of more than 11 million patient episodes each year, including diagnostic and procedural information on every patient admitted to an NHS institution in England. These are collated into the Hospital Episode Statistics (HES) datasets [86] which are being increasingly used to illustrate variations in health status and the delivery of care, as well as for medical research performance evaluation and policy development [87,88]. The HES data may be interrogated for information related to polypectomy numbers and outcomes on a national level, which may serve as a guide for national endoscopy resource allocation.

1.8. Improving outcomes from polypectomy

Colonoscopy is widely accepted as the most accurate method of screening the colon for neoplasia in patients over the age of 50 years [89], and has the benefit of being able to offer therapeutic intervention thereby reducing the incidence of colorectal cancer by up to 90% in both average and high-risk patient groups [5,90]. However, it is not without its attendant risks. The complications of polypectomy (described in section 1.6) include post-polypectomy bleeding, perforation and incomplete polypectomy. It is vital to ensure that all endoscopic therapy is performed competently and with minimal adverse outcomes to ensure that benefit is not outweighed by harm. This section outlines the principles of improving quality [91] and performance in polypectomy by defining the process, suggesting a competency framework to add structure to training, and endoscopist assessment in order to demonstrate competency and thereby reduce complications. It applies to anyone
involved in endoscopy practice, training, and quality assurance (QA) and developers of endoscopic policy. Performance may be improved by applying a number of principles.

1.8.1. Understand what defines a competently performed polypectomy

Although it is accepted that individual endoscopists may vary in their techniques, adherence to the basic principles of polypectomy is likely to improve outcomes [92]. Performance of any clinical skill can be assessed in the domains of knowledge, skills, attitudes and judgement. A sound understanding of the principles underlying safe and competent polypectomy is an essential pre-requisite to improving performance. Whilst an assessment of knowledge is a recognised part of the Bowel Cancer Screening accreditation process in England [93], knowledge is not formally assessed at any other stage of endoscopic training within the UK. To date, assessment in the technical skills of polypectomy is ad hoc and lacks structure.

The technical skill of polypectomy may be broken down into ‘pre-procedural’ or ‘generic’ skills (e.g. checking availability of equipment, optimising polyp position, maintaining clear views, scope stabilisation, relaying clear instructions to endoscopy staff), ‘specific skills’ depending on the size, site and morphology of the lesion (e.g. use of appropriate method of polypectomy, use of appropriately sized snare and accurate snare positioning, correct use of diathermy) and ‘post-polypectomy’ skills (e.g. examination of polypectomy base for remnant tissue, management of complications, polyp retrieval) . These factors are useful as a framework for training and forming the basis for competency assessment in polypectomy and structured feedback to trainees.
1.8.2. **Teaching competency in polypectomy skills**

Endoscopic trainees typically acquire the necessary technical skills by performing actual endoscopic procedures under the supervision of a trainer. However, increasing demands on endoscopic services and changes to junior doctors’ working patterns have significantly limited the time available for training [94]. Structured training, including dedicated endoscopic training courses, has been demonstrated to improve outcomes for diagnostic endoscopy [95]. However, training is potentially more challenging for therapeutic endoscopy due to unpredictability and non-standardisation of cases, concerns regarding patient safety, as well as increasing awareness of training costs, outcomes and difficulties in competency assessment. As a result, in the last decade there has been increasing development and utilisation of non-human training models and inanimate simulators in endoscopy training [96]. There is some evidence for the effectiveness of training in haemostatic endoscopic skills using ex-vivo animal models [97-100] which allow the trainer to use structured skills-based teaching methodologies [101] in a controlled environment without putting patients at risk. The same systematic approach to training, aimed specifically at teaching polypectomy skills, may allow development of uniform practice and reduce complications [102]. A purpose-designed polypectomy assessment tool (with explicit statements on what constitutes good and bad polypectomy technique), would provide a framework for training and allow structured feedback [103] in both simulated and real-life polypectomy; initial validation of such an assessment tool has been achieved [104].
1.8.3. Define and provide a safe and effective polypectomy service

Outcomes from polypectomy are dependent on patient, endoscopist, team and environmental/unit factors. Appropriate patient selection with careful consideration of the risk-benefit equation for each individual patient, adequate pre-procedural assessment, consent, and bowel preparation are probably at least as important to the eventual outcome as the procedure itself. Endoscopist factors may include accurate lesion characterisation and safe and complete removal of the lesion. A high quality polypectomy service undoubtedly requires a close working relationship between administrative staff and clinicians, including competent endoscopists, a dedicated team of nursing and allied staff, and a supportive environment and department within which they work. Endoscopy unit factors which may influence polypectomy outcomes include quality of polypectomy kit and diathermy unit, use of standardised nomenclature [105], a cohesive approach to endoscopy reporting and automated collection of intra-procedural quality data, as well as adherence to peer-reviewed follow up guidelines [106]. A system by which all adverse events are reported and evaluated is necessary so that repetitive or systematic errors can be identified and rectified. In addition, anaesthetic support and resources available in the event of an unexpected emergency are also needed to provide a safe and effective service.

Advanced, complex, or large sessile lesions generally require subspecialty endoscopic management to achieve the optimal clinical outcome. They may require advanced endoscopic skills, specialised equipment, extra procedural time and an experienced wider team, and thus should be managed by specialists with the relevant expertise. The choice between a surgical or endoscopic approach may depend on local expertise but the development of a network of specialist endoscopic teams may realise a wider choice for patients. A large Australian study [107] has shown that when difficult or
advanced lesions are managed by a tertiary referral team, substantial cost savings can be realised with limited morbidity and no mortality as compared with surgery.

1.8.3.1. Endoscopy Global Rating Scale (GRS)

The GRS (Figure 9) is a web-based tool that enables endoscopy units in England to assess how well they provide a patient-centred service. It makes a series of statements requiring a yes or no answer, from which it automatically calculates the GRS scores, providing a summary view of the endoscopy service and allowing comparison between units across the country. The scale has different layers:

- Dimensions
- Items
- Descriptors or levels
- Measures

Figure 9. Endoscopy Global Rating Scale
Dimension

There are two broad dimensions: quality and safety (Clinical Quality); and customer care (Quality of Patient Experience).

Items

The items beneath each dimension give a more detailed picture of what each consists of. The items are qualitatively different and therefore no item is more or less important than another. However, a patient may regard one item to be more important than another.

Descriptors

Descriptors describe in words different levels of achievement for an item. These levels vary from minimum (D) to excellent (A). While scoring an item with descriptors gives an accurate picture of what is going on, the scoring process can be subject to bias. To minimise bias, the descriptors have been underpinned with measures.

Measures

These are statements that are intended to be unambiguous. In other words a unit has either achieved them or it hasn't. In the GRS a measure requires either a yes or no answer.

1.8.4 What needs to be done?

1.8.4.1 Self awareness

Currently, the Bowel Cancer Screening accreditation process is the only validated endoscopic certification process in the UK [93]. All screening colonoscopists in England and Wales have to pass this prior to performing screening colonoscopies.
within the Bowel Cancer Screening programme, but polypectomy is not necessarily or comprehensively assessed. Therefore both screening and non-screening endoscopists are left to make a judgement about their own abilities in dealing with a particular lesion. A better understanding of one’s own limitations may be helped by a structured/tiered competency framework

1.8.4.2 Training

All endoscopy departments should have a training lead, responsible for all trainees, and to support other trainers within the department. Endoscopy training leads and trainers need to evaluate their polypectomy training paradigms to ensure they are based on the core principles of adult learning [108]. In England, the endoscopy Global Rating Scale (GRS) is a tool that enables endoscopy units to assess how well they provide a patient-centred service. It was originally created as a quality improvement and assessment tool for the gastrointestinal endoscopy service. On an individual level, the Joint Advisory Group (JAG) for gastrointestinal endoscopy in the UK requires an endoscopic sign off for all those training in endoscopy prior to allowing independent endoscopy. In acknowledgement of the pressing need for training and assessment in polypectomy, the JAG certification process for trainees [109] has been modified to incorporate mandatory assessment of polypectomy skills as part of the process of gaining certification in colonoscopy. Trainees now have to demonstrate competency in basic polyps (<1cm, called ‘level 1’ polyps) and more advanced polypectomy skills (polyps >1cm, called ‘level 2’ polyps) prior to colonoscopy certification.
1.9. Assessment in endoscopy

For the purpose of this thesis, the term ‘assessment’ describes tests that measure the technical skills of an endoscopist. Assessments can be formative i.e. during the training process or summative i.e. at the end of training to ascertain whether standards have been met. Historically, training and assessment in endoscopy has largely been through apprenticeship and experiential learning. In the last decade there has been a shift in emphasis from a numbers based competency to an outcomes based competency assessment [110]. Despite this, a lack of formal training and assessment and deficiencies in performance were highlighted in a national audit of colonoscopy practice in England [38]. This is mirrored elsewhere in the world [111,112]. Until now, the focus of endoscopy competency assessment has been primarily on intubation skills rather than polypectomy competencies or polypectomy quality outcomes.

1.9.1 Need for assessment

A reduction in hours spent in training positions in the UK and increasing demands for therapeutic colonoscopy has highlighted a pressing need for formal training and assessment in basic and advanced polypectomy. Due to the recognised variability in colonoscopy technique, strict criteria were developed for the accreditation of screening colonoscopists within the BCSP in the UK. Eligibility criteria for potential screeners include a lifetime minimum of 1000 colonoscopies and submission of key performance indicators (accepted minimum standards in brackets) such as procedure completion rate (90% unadjusted caecal intubation rate), adenoma detection rate (15 per 100 colonoscopies) and complication rate (perforation <1:1000 colonoscopies; post-polypectomy bleeding requiring transfusion <1:100 colonoscopies). Along with submitting their key performance indicators, potential screeners have to pass the
bowel cancer screening accreditation (BCSA) process, which tests their knowledge (using multiple choice questions –MCQs), as well as colonoscopy skills. In its current form, the candidates have to demonstrate competency at colonoscopy skills, assessed by two trained assessors. However, it does not necessarily include assessment of polypectomy skills in any detail. The endoscopy quality assurance (QA) group of the NHS Bowel Cancer Screening Programme (BCSP) has issued guidance on the quality and safety key performance indicators and auditable outcomes of colonoscopy in the BCSP [113]. As part of this process, BCS England prospectively collects all data on BCS colonoscopy (including complications), which are fed back to all BCS centres and individual endoscopists. The data suggest that polypectomy related complications do occur within the BCS programme in spite of skilled operators [80,114], although rates are still below those predicted. This has been one of the drivers in the development of an assessment tool for polypectomy skills.

Trainee endoscopists in the UK undergo similar formative and summative assessments as recommended by the Joint Advisory Group for endoscopy (JAG) [115], and this has recently been modified to include assessment of polypectomy skills (as outlined in section 1.8.4.2). A ‘high-stakes’ assessment of the technical skills required for basic and advanced polypectomy requires the development of a standardised, validated tool. This should assess the various ‘levels’ of polypectomy; including small, diminutive polyps, pedunculated polyps as well as sessile lesions requiring piecemeal removal by endoscopic mucosal resection (EMR). A high stakes assessment process is in place within the national training programme in colorectal surgery (lapco; www.lapco.nhs.uk) but at the time of writing, a similar structure for polypectomy assessment is lacking.
1.9.2 Competency assessment

‘Competency’ may be defined as the ‘minimum level of skill required to safely and proficiently perform a task’. Learners go through a process in achieving competence (Figure 10) from unconscious incompetence to unconscious competence [116]. The first step is being aware of deficiencies in skill i.e. moving from the stage of unconscious incompetence to conscious incompetence (box A to box B in figure 10). When the requisite skills are learnt, historically most learners move directly to the stage of unconscious competence, bypassing the stage of conscious competence i.e. they are able to perform the task ‘competently’ without necessarily being able to deconstruct the task into its individual components (box B to box D in figure 10, bypassing box C). However, as a trainer, expert performance requires awareness of weaknesses and active engagement in deliberate practice focused on improving particular tasks [117] i.e. conscious competence.

Figure 10. Ideal process of achieving competence (adapted from Peyton) [116]
1.9.3 Framework for assessment

Bloom’s taxonomy of Learning Domains [118] (Figure 11) provides us with a framework for assessments. It identifies three main domains of educational activity, and therefore areas in which assessment may take place; cognitive, affective and psychomotor.

Figure 11. Bloom’s taxonomy of learning domains

![Bloom's Taxonomy Diagram](image)

For the purpose of this thesis, ‘assessment’ refers to assessment in the psychomotor domain. The psychomotor domain refers to the acquisition of skills, from imitation (copying actions) to naturalisation (mastery of activity and related skills at strategic level). Bloom’s taxonomy can provide a structure for assessment and forms the basis for the ‘knowledge, skills and attitudes’ assessment methodology. The domains can be incorporated into frameworks for clinical assessment such as described by Miller [119] (Figure 12).
At the base of the pyramid, the learner must first demonstrate that they ‘know’ what is required to carry out the skill (level 1). The learner then needs to ‘know how’ to apply that knowledge i.e. be functionally adequate (level 2). Following this, they must then ‘show how’ they perform when faced with a patient (level 3) and finally, at the top of the pyramid, the learner is assessed on how they function independently i.e. what the individual ‘does’ (level 4). If we apply this framework to polypectomy assessment in the current BCSA process, potential screeners demonstrate core knowledge through a multiple choice question exam (level 1). The ability to apply that knowledge i.e. competence, is implied from diagnostic colonoscopy skills (level 2). Demonstration of competency in polypectomy skills (level 3) is entirely dependent on the chance occurrence of a polyp during the assessment process. Independent practice is judged through the key performance indicators (level 4) collected during a clinical procedure, and not the assessment. However, performance at any one particular time may be influenced by many factors other than just the technical skills of the individual and assessment tools should take this into account.
1.9.4. Attributes of an assessment process

In devising a new clinical assessment tool, a number of criteria have to be met. There are five required attributes of an assessment process [120]:

1.9.4.1. Reliability

Reliability is a measure of the variation in scores due to differences in performance between subjects and also the correlation of assessors rating the same performance. It is generally accepted that the reliability of a regulatory assessment must be at least 0.8

1.9.4.2. Validity

Measures to determine validity include:

**Face validity** of a test is a measure of how well the test *appears* to measure a criterion. It can be judged by both experts and laymen.

**Content validity** is a measure of the degree to which a test contains a representative sample of desired competencies, usually determined by expert opinion.

**Construct validity** determines how well the test measures the attributes that the examination is testing. It involves the empirical and theoretical support for the interpretation of the test, including how well it correlates with other tests it is predicted to correlate with (*convergent validity*) or how well it does not correlate with other tests it is predicted it should not correlate with (*divergent validity*).
Criterion validity reflects the success of a test used for prediction or estimation of performance. Concurrent validity refers to how well the test results correlate with the markers of performance done at the same time. Predictive validity refers to how well the test results predict performance at some time in the future.

1.9.4.3. Acceptability

Acceptability is the degree to which the assessment process is acceptable to all stakeholders. In tests of competence of a doctor, the stakeholders are the individuals being assessed, the assessors, the patients, the profession, future patients of that individual, and society.

1.9.4.4. Feasibility

Feasibility is the degree to which the assessment can be delivered to all those who require it within real costs of staff and time constraints.

1.9.4.5. Educational impact

Educational impact is the degree to which the assessment can assist the doctor to improve his or her performance, usually through the provision of feedback on specific strengths and weaknesses together with prioritised and specific strategies for improvement.
1.9.5 Methods of assessment

There are currently five methods available for assessing technical skills that are valid and reliable to varying degrees (Table 2) [121]. It is evident that some of the methods of assessing technical skills currently in use have poor validity and reliability.

**Table 2.** Perception of Reliability and Validity of current methods of assessing technical skills

<table>
<thead>
<tr>
<th>Method of Assessment</th>
<th>Reliability</th>
<th>Validity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure lists with logs</td>
<td>Not applicable</td>
<td>Poor</td>
</tr>
<tr>
<td>Direct Observation</td>
<td>Poor</td>
<td>Modest</td>
</tr>
<tr>
<td>Direct Observation with criteria</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Animal models with criteria</td>
<td>High</td>
<td>Proportional to realism</td>
</tr>
<tr>
<td>Videotapes</td>
<td>High</td>
<td>Proportional to realism</td>
</tr>
</tbody>
</table>

The availability of set criteria against which technical skills can be assessed, minimises subjectivity of the evaluation process. Several studies have shown that video-based technical skills evaluation using checklist-based and global competency scales is feasible, valid and reliable [122-132]. Evidence also suggests that global
scores have higher validity and reliability than procedure-specific checklists [122], though it is accepted that global scores do not assess all aspects of a technical skill [133]. In a study performed at the Department of Biosurgery and Surgical Technology, Imperial College, London [122], nineteen surgeons (6 novice and 13 experienced) performed a median of 2 laparoscopic cholecystectomies each on 53 patients. Surgical technical skills were rated in a blinded manner by 2 experienced observers on 4 video-based rating scales, incorporating a global score and a procedure-specific checklist. 14 of the procedures were performed by 6 novice surgeons and 33 by the 13 experienced surgeons. The results showed that there were significant differences between performance of the 2 groups on the generic global rating scale, though not on procedural or checklist-based scales. The authors concluded that video-based technical skills assessments were feasible, valid and reliable. Chapter 4 describes the development of a checklist and global score based tool for the assessment of competency specifically for polypectomy. Reliability of the tool was established using the generalisability theory (Chapter 4).

1.9.6 Current assessments in endoscopy

Technical performance may be assessed through direct observation by someone of greater experience, who makes a subjective judgement of proficiency based on his or her own experience. Unfortunately, without a structured framework on which to base such observations, this method generally lacks reliability and reproducibility. A number of assessment tools in endoscopy exist [134,135], but these focus more on diagnostic rather than therapeutic skills such as polypectomy. In therapeutic endoscopy, studies investigating training in hemostasis have used checklists for
various skills such as use of injection therapy, haemoclips and band ligation. Checklists and expert rating scales have been developed and used for assessment of dilation of oesophageal strictures and percutaneous endoscopic gastrostomy insertion. However, these have limited data to support reliability and accuracy.

1.9.6.1. Changes in endoscopy training and assessment in the UK

In the UK, historically, all endoscopists (including nurses, surgeons and physicians) underwent training through the ‘apprenticeship’ model, in which trainees initially learnt endoscopy through repeated observations of senior mentors, followed by ‘hands-on’ experience under direct supervision, until requisite numbers were reached, to achieve competency (the ‘see one, do one’ approach). This led to discrepancies in training with wide variation. Before the formation of the Joint Advisory Group for gastrointestinal endoscopy (JAG) in 1999, there was no formalised programme for endoscopic training or competency assessment in the UK. An audit was conducted in 2002 [136], looking at the experience of trainees in a large training region of London, with regards to the standard of colonoscopy training. The results showed that colonoscopy training was poor and competency assessment was extremely variable. Since then, formal guidelines for training and assessment have been published [115]. Competency-based criteria (‘directly observed procedural skills’) have also been developed for skills assessment. A prospective study was performed within the same training region to evaluate changes in assessment and training between 2002 and 2007 [137]. This showed significant improvement in formal training of colonoscopy and polypectomy skills in 2007, with 59% of trainees being certified as competent at polypectomy (however, in 2007, specific assessment for polypectomy skills had not
been developed). This is likely to have been as a result of formal and a more structured endoscopy training programme as recommended by JAG, along with an increased awareness of competency assessment in the UK between the two study periods.

1.9.6.2. Endoscopy training and assessment internationally

Throughout the world, the majority of endoscopy training is under the supervision of senior clinicians. This is done via the ‘apprenticeship model’ in New Zealand, Australia and the United Kingdom. The United States and Canada have a parallel system called the ‘postgraduate training model’.

In the apprenticeship model, senior clinician mentors, work side-by-side with trainees to impart knowledge and skill. During training, trainees usually have one or two primary mentors. In the postgraduate training model, trainees undertake rotations that involve a combination of lectures, courses and clinical training, with clinical training being the largest component. Rotations through different sub-specialities ensure that trainees work with multiple mentors and, thereby, are exposed to a variety of techniques and perspectives. Both of these models deliver training through a combination of didactic learning and hands-on procedural practice. Both training models share numerous attributes which include:

• Support by senior clinicians

• Course offerings – for example, basic courses and Train-the-Trainers courses

• Feedback processes
• Use of a procedure log

• Requirements for completion of training and/or accreditation

In the USA, endoscopy is performed by doctors, surgeons and proceduralists with advanced training. The USA postgraduate training model is institution-based but each institution’s programme includes a clinical training component mentored by senior clinicians. Fellowship or residency training involves course requirements, lectures and rotations through multiple units. Endoscopy is one component of the training and is usually affiliated with at least two rotations for surgery and multiple rotations for gastroenterology. The American Society of Gastrointestinal Endoscopists (ASGE) core curriculum identifies threshold numbers to be reached prior to assessment of competency. They further state that competency is to be assessed on the basis of achievement of endoscopic and quality markers of competence including caecal intubation, ileal intubation, retroflexion in the rectum and polypectomy ability. However, to date, validated assessment methods to assess diagnostic and therapeutic endoscopy skills are not in place.

1.10 Summary

Despite wide variability in choice of polypectomy method, the basic principles of safety and competency underpin all polypectomy techniques. There is a need (and increasing interest within the endoscopic community) for structured assessment of polypectomy skills, which, arguably, are the most dangerous aspect of colonoscopy.
This is especially important as recent data suggest polypectomy complications are occurring even in experienced hands within the national bowel cancer screening programme in England. This requires the development of a reliable and comprehensive polypectomy assessment tool. An advantage of a checklist based assessment is the deconstruction of a task into its individual components, which provides a basis for structured feedback and enhanced training.

At present, there is no national endoscopic database in England and information on outcomes of polypectomy services is largely based on relatively small studies. Chapter 2 attempts to address this issue by looking at polypectomy trends across all NHS regions in England. A framework for improving outcomes from polypectomy is also suggested. Arbitrarily, in the UK, there are four levels of polypectomy service. An attempt is made to define the difficulty level of a polypectomy based on polyp characteristics, to reflect these levels of service. This is described in greater detail in Chapter 8 through the development of a validated scoring system. This thesis attempts to address some of the gaps in certain aspects of polypectomy such as unavailability of large-scale data and lack of valid and structured assessment, in an effort to provide an improved and safer polypectomy service.

### 1.11 Hypothesis

Formal, structured, and objective assessment of polypectomy skills is feasible, and can reliably determine the competency of an endoscopist.

**The aims of this research were:**

1. To examine polypectomy trends in England using the national HES database
2. To analyse volume of polypectomy and related complications within the national Bowel Cancer Screening Programme at a single centre

3. To develop and establish reliability of a novel method of assessing competency in polypectomy-Direct Observation of Polypectomy Skills (DOPyS)

4. To establish reliability of the Direct Observation of Polypectomy Skills (DOPyS) tool in assessing piecemeal endoscopic mucosal resection.

5. To determine the construct validity of the DOPyS

6. To define difficulty levels of polypectomy
Chapter 2:

Polypectomy trends in England
Chapter 2: Polypectomy trends in England

2.1 Background and Aim

Currently there is no national database for endoscopy in the UK and knowledge on case volumes and complications is based on relatively small prospective and retrospective studies. These studies allow an estimation of the incidence of complications related to polypectomy. Endoscopists need to be aware of their institution’s outcomes, and how these compare nationally, in order to provide a high quality endoscopy service. Any variation in performance across different units and endoscopists may possibly be reduced through improvements in training and assessments in polypectomy.

This chapter aims to investigate the case volume of polypectomy and institutional variation in English NHS hospitals over a ten year period using the HES database. 28-day readmission and 30-day mortality rates were the main polypectomy outcomes examined. This chapter also reports polypectomy trends over time and variation in volume across English NHS trusts.

2.1.1 Background to Hospital Episodes Statistics (HES)

The HES database is a record based system that since 1986 has collected patient-level data from all public sector English NHS Trusts. The data are taken from each hospital’s Patient Administration (PAS) system. Each HES record contains geographic, demographic, diagnostic as well as procedural data pertaining to an individual patient attendance to an NHS hospital using a unique patient identification
number. The patient identifier allows identification of previous or subsequent attendances or procedures that pertain to that individual patient.

Each record contains primary and up to 19 secondary diagnoses, categorised according to the International Classification of Disease convention (ICD). Procedures (which include operations) are coded into a primary procedure field using the Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures convention (OPCS) and up to a further 23 secondary procedures. The patients’ main presenting reason for attendance is given in Diagnosis 1 and their main operation or procedure undertaken is similarly given as Procedural code 1. Further diagnoses and operations/procedures are given in subsequent fields known as secondary diagnoses/procedures.

2.2 Methodology

2.2.1 Polyp selection

Using the HES database we identified all elective patients in English NHS trusts that had a lower gastrointestinal tract therapeutic endoscopy for a diagnosis of a benign polyp between 1st Jan 1997 and 31st December 2007. Where units have merged over the study period, patients were allocated to the most contemporary trust.

We selected patients using the relevant ICD benign polyp related codes which included- D12.0 to D12.8 (inclusive), notably benign neoplasms of the anus and the anal canal were excluded- see Table 3. Polyps can be assigned ICD codes depending upon histology- benign, malignant or carcinoma in-situ. HES also incorporate an
‘indeterminate’ code whereby the patients’ notes are coded before the histology is ready. We only included polyps that were assigned the benign code and excluded those coded as indeterminate. This will under-estimate the true benign polypectomy rate to a degree as some of the indeterminate polyps would subsequently be given a benign code however this is minimised by taking a wide year range giving ample opportunity for coding to occur.

Table 3. ICD codes used for collection of HES polypectomy data

<table>
<thead>
<tr>
<th>ICD code</th>
<th>Description of polyp</th>
</tr>
</thead>
<tbody>
<tr>
<td>D12.0</td>
<td>Benign neoplasm of caecum</td>
</tr>
<tr>
<td>D12.2</td>
<td>Benign neoplasm of ascending colon</td>
</tr>
<tr>
<td>D12.3</td>
<td>Benign neoplasm of transverse colon</td>
</tr>
<tr>
<td>D12.4</td>
<td>Benign neoplasm of descending colon</td>
</tr>
<tr>
<td>D12.5</td>
<td>Benign neoplasm of sigmoid colon</td>
</tr>
<tr>
<td>D12.6</td>
<td>Benign neoplasm of colon, unspecified</td>
</tr>
<tr>
<td>D12.7</td>
<td>Benign neoplasm of rectosigmoid junction</td>
</tr>
<tr>
<td>D12.8</td>
<td>Benign neoplasm of rectum</td>
</tr>
</tbody>
</table>
2.2.2 Procedure selection

Office of Population, Census and Surveys codes, version 4 (OPCS-4) were used to identify what type of endoscopic management patients underwent. The included OPCS codes are given in Table 4. Specifically codes were included that related to endoscopic removal of lesions using snare resections, laser destruction or destruction not elsewhere classified. Endoscopic cauterisation (hot biopsy) was not included in the analysis. Furthermore, submucosal resection of polyps was also excluded, as being a relatively novel procedure numbers on HES were very small making meaningful comparisons difficult. Management was divided into endoscopic intervention or surgical interventions. Examinations and therapy using rigid sigmoidoscopes alone were excluded from this analysis.

2.2.3 Surgical polypectomies

Patients were allocated to the surgical management group if they had a benign polyp diagnosed as above and a surgical operative OPCS-4 primary code pertaining to a colectomy (both open and laparoscopic)-without a concurrent or previous diagnosis of a colorectal cancer, diverticular disease, Crohns or Ulcerative colitis (see table 5). This was to ensure, in so far as possible, the operative intervention was for the primary diagnosis of benign polyp and no other diagnosis. Patients were also included in the surgical polypectomy group if they had a primary procedural code pertaining to an open removal of a colorectal lesion as there are HES codes specifically for this too (see table 5).
**Table 4.** OPCS codes used in selection of procedures from the HES database

<table>
<thead>
<tr>
<th>OPCS code</th>
<th>Description of endoscopic procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colonoscopic resection codes</strong></td>
<td></td>
</tr>
<tr>
<td>H20.1</td>
<td>Endoscopic extirpation of lesion of colon, Fibreoptic endoscopic snare resection of lesion of colon</td>
</tr>
<tr>
<td>H20.3</td>
<td>Endoscopic extirpation of lesion of colon, Fibreoptic endoscopic laser destruction of lesion of colon</td>
</tr>
<tr>
<td>H20.4</td>
<td>Endoscopic extirpation of lesion of colon, Fibreoptic endoscopic destruction of lesion of colon nec</td>
</tr>
<tr>
<td>H20.8</td>
<td>Endoscopic extirpation of lesion of colon, Other specified</td>
</tr>
<tr>
<td>H20.9</td>
<td>Endoscopic extirpation of lesion of colon, Unspecified</td>
</tr>
<tr>
<td>H22.1</td>
<td>Diagnostic endoscopic examination of colon, Diagnostic fibreoptic endoscopic examination of colon and biopsy of lesion of colon</td>
</tr>
<tr>
<td><strong>Sigmoidoscopy resection codes</strong></td>
<td></td>
</tr>
<tr>
<td>H23.1</td>
<td>Endoscopic extirpation of lesion of lower bowel using fibreoptic sigmoidoscope, Endoscopic snare resection of lesion of lower bowel using fibreoptic sigmoidoscope</td>
</tr>
<tr>
<td>H23.3</td>
<td>Endoscopic extirpation of lesion of lower bowel using fibreoptic sigmoidoscope, Endoscopic laser destruction of lesion of lower bowel using fibreoptic sigmoidoscope</td>
</tr>
<tr>
<td>H23.4</td>
<td>Endoscopic extirpation of lesion of lower bowel using fibreoptic sigmoidoscope, Endoscopic destruction of lesion of lower bowel using fibreoptic sigmoidoscope nec</td>
</tr>
<tr>
<td>H23.8</td>
<td>Endoscopic extirpation of lesion of using fibreoptic sigmoidoscope, Other specified</td>
</tr>
<tr>
<td>H23.9</td>
<td>Endoscopic extirpation of lesion using fibreoptic sigmoidoscope, Unspecified</td>
</tr>
</tbody>
</table>
Table 5. OPCS codes used for selecting surgical polypectomies from HES database

<table>
<thead>
<tr>
<th>OPCS code</th>
<th>Description of Surgical procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>H12.2</td>
<td>Extirpation of lesion of colon, Excision of lesion of colon</td>
</tr>
<tr>
<td>H12.3</td>
<td>Extirpation of lesion of colon, Destruction of lesion of colon</td>
</tr>
<tr>
<td>H19.1</td>
<td>Other open operations on colon, Open biopsy of lesion of colon</td>
</tr>
<tr>
<td>H04.0 to H04.3, H04.8, H04.9</td>
<td>Panproctocolectomies</td>
</tr>
<tr>
<td>H07.1 to H07.4, H07.8, H07.9</td>
<td>Right sided colonic excision</td>
</tr>
<tr>
<td>H06.1 to H06.4, H06.8, H06.9</td>
<td>Extended right sided colonic excision</td>
</tr>
<tr>
<td>H08.1 to H08.5, H08.8, H08.9</td>
<td>Excision of transverse colon</td>
</tr>
<tr>
<td>H33.1 to H33.9</td>
<td>Excision of rectum</td>
</tr>
<tr>
<td>H02.1, H02.9, H02.2</td>
<td>Interval appendicectomies</td>
</tr>
<tr>
<td>H05.1, H05.2, H05.3, H05.8, H05.9, H11.1 to H11.5, H11.8, H29.9, H29.8</td>
<td>Total and subtotal colectomies</td>
</tr>
<tr>
<td>H10.1 to H10.5 and H10.8, H10.9</td>
<td>Sigmoid colectomy</td>
</tr>
<tr>
<td>H09.1 to H09.5 and H09.8, H09.9</td>
<td>Left sided colon excision</td>
</tr>
<tr>
<td>H34.1, H34.2, H34.4, H34.5, H34.8 and H34.9</td>
<td>Open excision of rectal lesions</td>
</tr>
</tbody>
</table>
2.2.4 ‘Top and tail’ endoscopy patients

We included patients if they had undergone an upper gastrointestinal endoscopy with a concurrent lower gastrointestinal endoscopy (as in for investigation of anaemia) where a secondary diagnosis of a colorectal polyp was made plus a polypectomy at the same sitting- this takes into account patients where the primary diagnosis maybe related to the UGI endoscopy. Also polyps were included if patients with a primary diagnosis of anaemia and/or non-infective enteritis/diarrhoea and colitis were found to have a secondary diagnosis benign polyp found during the same endoscopy if it was removed at the time of diagnosis (see figure 13).

Figure 13. Inclusion and exclusion criteria for data collection from HES database
2.2.5 Procedural volume

Case volume was categorised into tertiles according to the aggregated volume of total number of therapeutic endoscopic procedures performed over the study period per unit. Tertiles were calculated to give roughly equal number of units in each cohort. Low, medium, and high volume provider status correspond to the number of patients undergoing endoscopic polypectomy over the study period (low < 1050, medium 1050-2100 and high > 2100). Units that performed less than two therapeutic procedures (either colonoscopy or flexible sigmoidoscopy) per year over the study years were excluded from volume analysis. Units were considered according to their trust code. In addition, 28-day readmission and 30-day mortality in patients undergoing endoscopic polypectomy were analysed by tertile.

2.2.6 Re-admission rates and 30-day mortality rates

Units were also compared for their within 28 day of discharge re-admission rates and in-hospital 30 day mortality rates.

2.3 Results

2.3.1. Procedures

Between 1st January 1997 and 31st December 2007, 334,753 therapeutic lower GI endoscopies were performed for the removal of benign colorectal polyps in English NHS trusts. 233,119 patients underwent colonoscopy and 101,634 patients, flexible sigmoidoscopies for the removal of polyps. Over the 10-year period, polyps were removed endoscopically in 94.7% (334,753/353,469) patient episodes and surgically in
5.3% (18716/353469) cases. Details of procedures performed each year are outlined in Table 6.

**Table 6.** Details of endoscopic procedures performed each year.

<table>
<thead>
<tr>
<th>Year</th>
<th>Colonoscopy</th>
<th>Flexible Sigmoidoscopy</th>
<th>Surgery</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>14609</td>
<td>5680</td>
<td>1560</td>
<td>21849</td>
</tr>
<tr>
<td>1998</td>
<td>19128</td>
<td>8134</td>
<td>1750</td>
<td>29012</td>
</tr>
<tr>
<td>1999</td>
<td>21636</td>
<td>10064</td>
<td>1885</td>
<td>33585</td>
</tr>
<tr>
<td>2000</td>
<td>22855</td>
<td>10650</td>
<td>1817</td>
<td>35322</td>
</tr>
<tr>
<td>2001</td>
<td>22737</td>
<td>10498</td>
<td>1753</td>
<td>34988</td>
</tr>
<tr>
<td>2002</td>
<td>24902</td>
<td>11130</td>
<td>1798</td>
<td>37830</td>
</tr>
<tr>
<td>2003</td>
<td>26676</td>
<td>11345</td>
<td>1806</td>
<td>39827</td>
</tr>
<tr>
<td>2004</td>
<td>19775</td>
<td>8623</td>
<td>1619</td>
<td>30017</td>
</tr>
<tr>
<td>2005</td>
<td>17919</td>
<td>7962</td>
<td>1560</td>
<td>27441</td>
</tr>
<tr>
<td>2006</td>
<td>20146</td>
<td>8781</td>
<td>1567</td>
<td>30494</td>
</tr>
<tr>
<td>2007</td>
<td>22736</td>
<td>8767</td>
<td>1601</td>
<td>33104</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>233119</strong></td>
<td><strong>101634</strong></td>
<td><strong>18716</strong></td>
<td><strong>353469</strong></td>
</tr>
</tbody>
</table>

The number of therapeutic colonoscopies and flexible sigmoidoscopies for the removal of polyps coded rose by 29.1% between two periods studied (1997-2001 and 2002-2007). Details of time trends over the 10 year study period are given in Figure 14. In contrast, the number of patients undergoing surgical procedures for polypectomy did not change significantly over the two time periods analysed (8765 in 1997-2001 and 9951 in 2002-2007).
2.3.2 Repeat attendances

With longitudinal analysis we were able to determine the number of times the same patient underwent a therapeutic endoscopy for a benign colorectal polyp. Over the 10 year period, 192,980 patients (67.4%) appeared only once on the dataset. 39,295 (13.73%) of patients underwent a further endoscopic polypectomy for a benign polyp over the 10 year period. Over the ten year period 98.1% of patients had three or fewer procedures for removal of a benign polyp endoscopically. Possible reasons for several procedures could be additional procedures required for further polyps, polyp recurrence and surveillance procedures.


2.3.3. Polyps

Given the nature of how the data is recorded, it is not possible to quantify the number of polyps removed per endoscopic session. We can however assume from the coding that at least one polyp was removed (as there are separate diagnostic codes for endoscopies without therapy i.e diagnostic procedures alone). A total of 286,204 patient episodes had a primary diagnosis of a benign polyp made between January 1997 and December 2007. Polyps were found in the sigmoid colon in 29.2% (83492/286204) of patient episodes. 25328 (8.8%) of the patient episodes had right-sided colonic (caecal, appendiceal and ascending colon) polyps. Left sided colonic polyps were significantly more prevalent (in 153982 patient episodes- p<0.0001). Between 1997 and 2003 there was a steady increase in the number of patient episodes with caecal (394 in 1997 to 1674 in 2003), ascending colon (279 in 1997 to 1458 in 2003), transverse colon (761 in 1997 to 2524 in 2003), descending colon (698 in 1997 to 1846 in 2003), sigmoid colon (4103 in 1997 to 10566 in 2003), recto-sigmoid (438 in 1997 to 771 in 2003) and rectal (2484 in 1997 to 4702 in 2003) polyps found. This is illustrated in figure 15.
Figure 15. Bar chart demonstrating the change in distribution of the location of polyps

Overall, between two study periods analysed (1997-2001 and 2002-2007), the number of patient episodes with a primary diagnosis of polyp rose by 26.4%. However, between 2003 and 2004 there was a 25.2% reduction (32033 in 2003 compared to 23956 in 2004) in the number of patient episodes with a primary diagnosis of a benign polyp. In particular, the number of patient episodes with a diagnosis of a sigmoid polyp fell from 10566 in 2003 to 7531 in 2004. After 2005, the number of patient episodes with a primary diagnosis of polyp rose each year (21883 in 2005 to 26945 in 2007). There were 59 patients with appendiceal polyps diagnosed within the time-frame examined with no significant variation over the 10-year period. In instances
where the coders were unable to elicit the site of polyp extraction (e.g due to insufficient / illegible records) polyps were classified to the ‘Other’ category. There was a steady decline in the number of patients with polyps diagnosed as ‘Other’ between 1999 (11728) and 2006 (3815) p<0.001 indicating likely improvement in the coding, better documentation, increased awareness and more accurate diagnostic modalities.

2.3.4. Institutional variation

The numbers of procedures for endoscopic benign polypectomy (flexible sigmoidoscopy and colonoscopy combined) were assessed for each unit in England over the 10-year period. The analysis showed wide variation in the number of polypectomy procedures per year between individual units (range- 21 to 724). Based on case volumes, the units were divided into roughly equal tertiles on the number of procedures performed over the study period representing- low (<1050 procedures), medium (1050 to 2100 procedures) and high volume (>2100 procedures) for total number of procedures over the ten year study period per unit (see table 7). There were significantly more procedures performed in the high volume units (153,419 vs 33,827 p<0.001) as compared to the low volume units over the 10-year period. Only 9 units performed greater than 400 polypectomy procedures per year, with the busiest two units performing 724.4 procedures and 654.5 procedures per year as averaged over the study period. Figure 16 demonstrates the relative breakdown of the proportion of procedures undertaken per tertile over the study.
Table 7. Endoscopic procedures per tertile

<table>
<thead>
<tr>
<th>Tertile</th>
<th>No. of units</th>
<th>Total no. procedures for tertile</th>
<th>Mean number polypectomy procedures per unit per year (endoscopic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low volume</td>
<td>61</td>
<td>33,827</td>
<td>55.5</td>
</tr>
<tr>
<td>Medium volume</td>
<td>65</td>
<td>98,958</td>
<td>152.2</td>
</tr>
<tr>
<td>High volume</td>
<td>47</td>
<td>153,419</td>
<td>326.4</td>
</tr>
</tbody>
</table>

2.3.5 28-day readmission and 30-day mortality

Unplanned re-admission rates within 28 days of endoscopic polypectomy was analysed according to tertiles. There was no statistical difference when the average re-admission rates were compared across tertiles- 2.06% vs 2.14% vs 2.3% for low, medium and high volume units respectively (p=0.261). However, when we examined the range of re-admission rates, we found significant (p=0.03) variability in units appearing in the lower volume tertile. These represent unadjusted crude figures (see table 8).
Table 8. Re-admission rates per tertile

<table>
<thead>
<tr>
<th></th>
<th>Average re-admission rate (%)</th>
<th>Range for re-admission rates (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low volume (n=33,827)</td>
<td>2.06</td>
<td>0 - 6.12</td>
</tr>
<tr>
<td>Medium volume (n=98,958)</td>
<td>2.14</td>
<td>1.29 - 3.17</td>
</tr>
<tr>
<td>High volume (n=153,419)</td>
<td>2.3</td>
<td>1.56 - 3.13</td>
</tr>
</tbody>
</table>

Figure 16. Stacked bar chart representing the breakdown of procedures per tertile

When comparing mortality rates there were no differences between the average percentage death rate between percentiles, however non-statistically significant
variation was apparent in the lowest tertile once again (table 9). Possible explanations for variation in re-admission and mortality rates in the low tertile centres could be a lack of experience amongst endoscopists in those centres as a result of relatively low volumes of cases.

**Table 9.** 30-day mortality rates per tertile

<table>
<thead>
<tr>
<th></th>
<th>Mean death rate as a percentage of cases</th>
<th>Range of death rates within tertiles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low volume (n=33,827)</td>
<td>0.015</td>
<td>0.00 - 0.40</td>
</tr>
<tr>
<td>Medium volume (n=98,958)</td>
<td>0.012</td>
<td>0.00 - 0.09</td>
</tr>
<tr>
<td>High volume (n=153,419)</td>
<td>0.016</td>
<td>0.00 - 0.09</td>
</tr>
</tbody>
</table>

### 2.4 Discussion

The results of this study suggest that across 174 English NHS trusts, approximately 335,000 therapeutic lower GI endoscopies were performed in the 10-year time-frame examined. This is likely to be an under-representation of the actual number of procedures performed, due to coding limitations as described in the methodology section (inclusion of specific colonoscopy and sigmoidoscopy related OPSC-4 codes), coding inaccuracies and exclusion of submucosal resections (which constitute a significant proportion of endoscopic polypectomy). The analysis suggests that over a 10-year period, there was a trend towards more endoscopic polypectomies being
performed across English NHS trusts (a 55% rise over the study period, with 95% of
patients undergoing endoscopic, as compared to surgical polypectomy). The rise in
number of endoscopic polypectomies performed over the study period is likely to be
multifactorial. Changes in coding, improvement in colonoscopy technique and
colonoscopes (i.e. the ability to reach a lesion), better diagnostic tools (such as
chromoendoscopy and narrow band imaging (NBI) to help identify and characterise
the lesion), structured training, detailed assessments, and a change in attitude of
endoscopists towards the management of colonic polyps, are some of the possible
factors.

Over the same time-period, the proportion of surgical colonic resections (for benign
polyps) did not change significantly. This, however, is likely to represent a fall in the
actual number of surgical procedures being carried out for polypectomy, as the
number of patients with polyps coded rose steadily over the study period. A
longitudinal analysis showed that 13.7% of patients who had a therapeutic endoscopy
had to undergo an ‘additional’ procedure for endoscopic polypectomy. It is possible
that a proportion of these ‘additional’ procedures were performed for the removal of a
polyp first seen at the initial lower GI endoscopy, and not as part of follow-up (this
figure stood at 10.4% in a single bowel cancer screening centre [82]). This has
resource implications for the endoscopic service. Better training in polypectomy and
adherence to peer-reviewed follow-up guidelines may reduce the number of
‘additional’ procedures that a patient undergoes. The results suggest that there was
wide variation in the number of procedures performed between individual English
NHS trusts. It is, however, acknowledged that one of the limitations of this study is
analysis through tertiles, which is only one of the many ways in which data of this
nature can be interpreted. The analysis highlighted that only 9/174 units (5%)
performed more than 400 polypectomy procedures per year with two of the busiest units performing approximately 5% of UK’s polypectomy procedures. On the other hand, the low tertile units, on average, performed 6 times fewer procedures per year, than the units in the high tertile. This could possibly reflect wide variation in resource allocation in these units, but may also be due to variation in technical skills.

2.5 Conclusion

Polypectomy is now an integral part of colonoscopy. It has been shown to reduce the incidence of colorectal cancer and is potentially, the most likely endoscopic therapy to cause harm. This study is likely to have under-reported the volume of polypectomy performed in England due to coding and non-inclusion of incidental diagnosis of colorectal polyps. Explicit polypectomy data on this large a scale requires the development of a prospective, national endoscopy and polypectomy database (similar to the one used in the national BCSP) to monitor adherence to endoscopic quality assurance guidelines.
Chapter 3:
Polypectomy in
Bowel Cancer Screening
Chapter 3: Polypectomy in Bowel Cancer Screening

3.1 Background and Aim

Currently the most meticulously recorded endoscopic patient data in England is in the context of the national bowel cancer screening programme. In the United Kingdom, there are approximately 30,000 new cases of colorectal cancer each year, with 20,000 deaths annually [138]. It is the third most common cancer in the United Kingdom, after breast and lung cancer and is the second most common cause of death from malignant disease. There is evidence that population screening for colorectal cancer using faecal occult blood testing (FOBT) reduces the disease-specific mortality. The UK national bowel cancer screening programme was rolled out in a phased manner in 2006. The St. Mark’s BCS centre was the second centre in England to be rolled out between October 2006 and November 2007 and is now in its third year and therefore second year of surveillance for its high risk patients. It receives FOBT positive patients from four large Primary Care Trusts in North-West London test population and caters to a population of approximately 1 million. It was a pilot site for age extension (70-75 years) from October 2008. The results from this single centre are reported here with the aim of highlighting that high volume endoscopic therapy can be performed safely, but complications do occur, even in experienced hands. At the time of writing, this is the first comprehensive single centre review of the national bowel cancer screening programme.

3.2 Methodology

FOBT kits were sent to adults aged 60-69 years (60-75 years after October 2008) in a phased manner in screening catchment areas. Screening participants were referred to
St. Mark’s bowel cancer screening centre following positive FOBT and offered a 45 minute appointment to discuss the potential implications of their FOBT finding with a bowel cancer specialist screening practitioner (SSP). They were then offered a screening colonoscopy or an alternative such as CT virtual colonoscopy (CTC), flexible sigmoidoscopy or CT abdomen in accordance with the centre’s policy for the management of patients unfit for colonoscopy.

Data regarding gender, age, colonoscopy findings and screening outcomes were collected prospectively and entered into a national screening database. Patients with diagnoses other than polyp or colorectal cancer (such as colitis, diverticulosis, ischaemic colitis) were grouped under ‘normal’ findings for the purposes of this study. Screening colonoscopies were performed by five accredited colonoscopists of varying backgrounds- 3 UK trained consultant gastroenterologists, one UK trained consultant nurse endoscopist and a Japanese trained honorary consultant endoscopist. Seven key performance indicators (KPIs) were prospectively collected for each endoscopist. All colonoscopies performed for polyp surveillance were included in this analysis. Data regarding the timing, number, size and histology of polyps were collected prospectively. Patients were divided into high, low and intermediate risk based on the number and size of polyps according to the British Society of Gastroenterology guidelines [139].

Information regarding the number of additional procedures performed by each colonoscopist as well as the indication for which they were done, was recorded and analysed. An additional procedure in the context of the BCSP was defined as a procedure required- either flexible sigmoidoscopy or colonoscopy, following an index investigation-colonoscopy, flexible sigmoidoscopy or virtual colonoscopy.
The stage of colorectal cancers found in the screening population was compared with that in the symptomatic population in this catchment area. The symptomatic population was comprised of a prospectively collected group of patients with gastrointestinal symptoms such as weight loss, abdominal pain and rectal bleeding, who presented to the hospital in a conventional manner and were diagnosed and treated during the same period. Data for the screening group were obtained from the BCS centre’s database and for the symptomatic population, from prospectively collected data of one surgeon performing the majority of colorectal cancer resections at this institution. Only elective cases were reviewed. Information regarding age, sex, Dukes’ staging, site of cancer and T- staging was analysed. All colonoscopic complication information was prospectively collected in the adverse events registry. Additional information was obtained by specifically questioning all members of the bowel cancer screening team. Data regarding the type of complication, number and size of polyps, polypectomy method and any prophylactic measures used, along with outcomes were analysed.

Differences in patient satisfaction between the screening and symptomatic patients were assessed. 100 consecutive patients (50 routine diagnostic and 50 BCSP colonoscopies), were given a questionnaire to complete at home following their procedure. The questionnaire addressed three domains – pre, during and post procedure experiences. Colonoscopy in the routine diagnostic group was performed by other independent endoscopists in the same department. In addition, the BCS database was interrogated to assess presenting symptomatology of those patients found to have colorectal cancer.

Variation in performance between different screening endoscopists was statistically analysed using the Chi-square test. Fisher’s exact test was used for comparing polyp
data from screening colonoscopies as well as for comparing satisfaction responses between the BCS patients and the symptomatic group.

3.3 Results

3.3.1 Overall outcomes

98815 FOBT kits were sent out and 42523 returned (43 % uptake (men 20.79%)). Uptake increased with each year of screening (41.9% in 2007, 42.2% in 2008 and 46.6% in 2009). The proportion of those completing the test with a positive result requiring further investigation was 1.5% (1488 participants). These were referred to the SSP clinic. 1339 (90%) of the 1488 attended. 57% were men. 1138 (85%) patients were considered suitable for a colonoscopy, 122 (9%) for a virtual colonoscopy, and 17 (1%) for flexible sigmoidoscopy. 62 (5%) were not referred further on medical grounds. Of the 1339 FOBT positive screenees who attended the specialist nurse clinic, 1057 (79%) went on to have a first procedure colonoscopy (of the 1138 considered suitable for colonoscopy 81 did not attend), 115 had a virtual colonoscopy and 8 had a flexible sigmoidoscopy (figure 17).
Overall, 583 (50%) patients had polyps, 517 (44%) procedures were grouped under 'normal' i.e. all diagnoses other than polyps or colorectal cancer, and 80 patients (6%) had colorectal cancer. Of the patients with polyps (n=583), 155 (26%) were high risk, 170 (29%) intermediate risk, and 258 (45%) low risk, based on the number and size of polyps in accordance with the British Society of Gastroenterology guidelines [139]. In 583 patients with polyps, 1625 polyps were found (2.8 polyps per patient). Median polyp size was 5mm (1-80). Overall, 1200 colonoscopies were performed by five accredited colonoscopists till September 2009 with an unadjusted caecal intubation rate of 96% (93.2%-98.11%).

3.3.2 Colorectal cancer characteristics

68/80 (85%) patients who were diagnosed with colorectal cancer in the screening programme had abdominal symptoms such as pain, change in bowel frequency, occasional rectal bleeding, urgency, rectal irritation or weight loss in the six months prior to their diagnosis. Details of the cancer characteristics for the screening and
symptomatic group are shown in table 10. For the purposes of this analysis, polyp cancers (cancer that was removed by endoscopic snaring at the time of colonoscopy) were included in Dukes’ stage A. There were 10 polyp cancers found, nine in the sigmoid and one in the ascending colon. Six of the 10 polyp cancers were completely excised endoscopically with clear resection margins on histology. Four required laparoscopic surgery for removal. Nine of the 10 polyp cancer patients were transferred to the symptomatic service and one entered surveillance under the bowel cancer screening programme. Of the non-polyp cancers (n=70), one was treated in another hospital, four were treated palliatively and 65 underwent curative surgery. 46/65 (70.7%) were performed laparoscopically. Overall 50/69 (72.7%) patients with colorectal cancer underwent laparoscopic resection. There was one 30-day post surgical mortality.
Table 10. Cancer characteristics of the screening and symptomatic populations at St.Mark’s Bowel Cancer Screening centre between October 2006 and September 2009

<table>
<thead>
<tr>
<th></th>
<th>Screening patients</th>
<th>Symptomatic patients</th>
<th>p value (Fisher’s exact test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cancers</td>
<td>80</td>
<td>251</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>46 (57.5%)</td>
<td>146 (58%)</td>
<td></td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td>66.7 (5.9)</td>
<td>66.3 (14.3)</td>
<td></td>
</tr>
<tr>
<td>Dukes’ A</td>
<td>21 (26%)</td>
<td>52 (20%)</td>
<td>0.35</td>
</tr>
<tr>
<td>Dukes’ B</td>
<td>24 (30%)</td>
<td>78 (31%)</td>
<td>0.89</td>
</tr>
<tr>
<td>Dukes’ C</td>
<td>22 (27%)</td>
<td>98 (39%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Dukes’ unknown</td>
<td>13 (16%)</td>
<td>23 (9%)</td>
<td></td>
</tr>
<tr>
<td>T ½</td>
<td>25 (35%)</td>
<td>67 (27%)</td>
<td></td>
</tr>
<tr>
<td>T ¾</td>
<td>36 (50%)</td>
<td>162 (64%)</td>
<td></td>
</tr>
</tbody>
</table>

3.3.3 Individual colonoscopist performance

The difference in performance between screening colonoscopists of varying backgrounds is shown in table 11. Screeners 1, 2 and 4 were accredited at the start of the programme in October 2006. Screener 3 was accredited in 2007 and screener 5 had been performing screening lists regularly for only 13 months at the time of analysis. All the five endoscopists had passed an accreditation process which allows endoscopists to perform screening colonoscopies in the UK under the national BCSP [140]. The BCS accreditation process evaluates the key performance indicators (KPI) of potential screeners [141] and tests competencies of knowledge and skill. It is the
only formal endoscopic assessment process in the UK. Despite differences in training received by the screeners, there was little variation in completion rates (93.2%–98.11%). On an intention to treat basis, there were 51 incomplete procedures, with poor bowel preparation and looping/fixed sigmoid accounting for 21.5% (11/51), and 37.2% (19/51) respectively. Similarities were also noted in polyp retrieval and cancer detection rates.

**Table 11.** Performance of screeners at St.Mark’s Bowel Cancer screening centre

<table>
<thead>
<tr>
<th>Colonoscopist</th>
<th>Number done since 2006</th>
<th>Mean duration of colonoscopy (min:sec)</th>
<th>Completion percentage (national target 90%)</th>
<th>Adenoma detection rate (national target 35%)</th>
<th>Polyp retrieval percentage (national target 90%)</th>
<th>Cancer detection rate (%) (national target 11%)</th>
<th>Number of adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>287</td>
<td>25:4</td>
<td>94.0</td>
<td>63.8</td>
<td>90.5</td>
<td>4.7</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>280</td>
<td>24:1</td>
<td>95.3</td>
<td>67.9</td>
<td>88.5</td>
<td>5.2</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>229</td>
<td>38:0</td>
<td>97.4</td>
<td>72.9</td>
<td>94.6</td>
<td>2.2</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>298</td>
<td>22:3</td>
<td>93.2</td>
<td>38.5</td>
<td>94.4</td>
<td>4.1</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>106</td>
<td>25.2</td>
<td>98.1</td>
<td>70.4</td>
<td>88.5</td>
<td>3.8</td>
<td>1</td>
</tr>
<tr>
<td>p-value</td>
<td></td>
<td></td>
<td>0.1</td>
<td>&lt;0.001</td>
<td>0.01</td>
<td>0.4</td>
<td></td>
</tr>
</tbody>
</table>

**3.3.4 Surveillance procedures**

67 1-year polyp surveillance procedures were performed (64 for high risk polyps, two for intermediate risk, one for polyp cancer). Overall, there were 6.0(3.76) (mean(SD)) polyps found per index procedure and 3.0(2.4) per surveillance procedure (p<0.0001).
In three procedures however, there were more polyps found at surveillance compared to index procedure. Mean polyp size in the index procedure was 18.1(11.8) mm (SD) compared to 5.26(2.9)mm in the surveillance group (p<0.0001). Three of the 67 surveillance procedures revealed polyps >1cm (11mm, 14mm and 16mm). In 26 cases, the findings at surveillance colonoscopy downgraded the risk of subsequent polyps from high to intermediate and in 30 cases, to low risk following the surveillance procedure. In 11 cases, the risk remained high based on the number and size of polyps found at surveillance. Histologically, all the polyps found in these 11 high risk cases were tubular adenomas with low grade dysplasia.

3.3.5 Additional procedures

Of the 1200 procedures performed by the five accredited colonoscopists within the given time frame, 125 were additional procedures (42 following a virtual colonoscopy, 81 following an index colonoscopy, one following a flexible sigmoidoscopy and one following an abdominal CT scan). Of the 125 additional procedures, 47 were flexible sigmoidoscopies and 78 colonoscopies. Of the 82 who had an index lower gastrointestinal endoscopy, 36 required an additional procedure. 30 of these were needed to remove a polyp first seen at the index procedure and six for further biopsy and tattooing of a suspected carcinoma seen at the first procedure. Details of the number of additional procedures referred by each screener are shown in table 12.
Table 12. Proportion of cases referred for additional procedures by each screening endoscopist

<table>
<thead>
<tr>
<th>Colonoscopist</th>
<th>Number of index procedures</th>
<th>Number referred for 'additional' procedures</th>
<th>Number performed by another endoscopist</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>276</td>
<td>2 (0.7%)</td>
<td>0 (0.0%)</td>
<td>Cancer tattoo, Polyp removal</td>
</tr>
<tr>
<td>2</td>
<td>263</td>
<td>3 (1.1%)</td>
<td>0 (0.0%)</td>
<td>Polyp removal</td>
</tr>
<tr>
<td>3</td>
<td>223</td>
<td>8 (3.5%)</td>
<td>4 (50%)</td>
<td>Cancer tattoo 2, Polyp removal 5, Site recheck 1</td>
</tr>
<tr>
<td>4</td>
<td>295</td>
<td>21 (7.1%)</td>
<td>21 (100%)</td>
<td>Cancer biopsy 2, Polyp removal 19</td>
</tr>
<tr>
<td>5</td>
<td>106</td>
<td>2 (1.8%)</td>
<td>1 (50%)</td>
<td>Polyp removal, Site recheck</td>
</tr>
</tbody>
</table>

3.3.6 Complications

There were eight (0.6%) reported adverse events and an additional five (0.4%) recalled by screening team. Ten of these were related to colonoscopy (eight post-polypectomy bleeds, one post-polypectomy syndrome and one colonic perforation). Only one out of the eight patients with post-polypectomy bleeding required a blood transfusion. This patient had a myocardial infarction post polypectomy and required two units of blood transfusion, but made an uneventful recovery. Another had post polypectomy syndrome (comprising of localised abdominal pain, fever, leucocytosis and absence of frank perforation on CT) following the removal of 16 (2-25mm)
polyps but the patient was managed conservatively. The most significant complication was a perforation following the removal of a 60mm flat sigmoid lesion by piecemeal endoscopic mucosal resection. The perforation was recognised and treated during the colonoscopy through the placement of three Boston resolution clips. The patient did not have to undergo surgery and made a complete recovery.

There were three non colonoscopic complications. The first patient had severe sustained hypertension recognised pre-procedure and the procedure was abandoned. The second had hyponatremia (sodium of 114 mEq/L) secondary to bowel preparation and went on to have an uneventful colonoscopy which found a circumferential sigmoid cancer. The patient underwent surgery following emergency admission and electrolyte correction, but died postoperatively. The third had hypokalemia induced atrial fibrillation (AF), underwent an uneventful colonoscopy and was admitted electively for 24 hours to reverse the hypokalemia and manage the AF.

3.3.7 Patient satisfaction

The patient satisfaction questionnaire is shown in table 13. Colonoscopies in the elective group were performed by the five accredited screening colonoscopists as well as other independent colonoscopists within the same unit. The overall response rate was 76% (42 in BCSP and 34 diagnostic group). The overall level of satisfaction between the two groups was similar however, 4/30 (13%) of patients having diagnostic colonoscopy reported not having been given adequate explanation of the risk, compared to no patients within BCSP (p=0.03). 6/24 (25%) of patients in the routine colonoscopy group felt they needed more sedation compared to 0/30 (0%) of patients in the BCSP group (p=0.005). Similarly, the level of discomfort reported was
higher in diagnostic group compared to BCSP, with 14/33 (42%) diagnostic patients reporting a ‘quite or extremely uncomfortable procedure’ compared to only 4/41 (10%) in the BCSP, p=0.004. 39/40 (97%) of patients in the BCSP felt they were given adequate explanation of findings compared to 21/32 (64%) of those having routine colonoscopy, p<0.001.
<table>
<thead>
<tr>
<th>Question</th>
<th>Patient Response</th>
<th>Elective Number (%)</th>
<th>BCSP Number (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the pre-procedure information clear</td>
<td>No</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>34 (100%)</td>
<td>41 (98%)</td>
<td></td>
</tr>
<tr>
<td>Given opportunity to ask questions</td>
<td>No</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>24 (100%)</td>
<td>41 (100%)</td>
<td></td>
</tr>
<tr>
<td>Was sufficient information given for consent</td>
<td>No</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>33 (100%)</td>
<td>42 (100%)</td>
<td></td>
</tr>
<tr>
<td>Where was consent signed</td>
<td>Procedure room</td>
<td>11 (33%)</td>
<td>11 (28%)</td>
<td>0.62</td>
</tr>
<tr>
<td></td>
<td>Elsewhere</td>
<td>22 (67%)</td>
<td>29 (72%)</td>
<td></td>
</tr>
<tr>
<td>Were procedure risks made clear</td>
<td>No</td>
<td>4 (13%)</td>
<td>0 (0%)</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>26 (87%)</td>
<td>41 (100%)</td>
<td></td>
</tr>
<tr>
<td>Was there pre-procedure anxiety</td>
<td>Relaxed</td>
<td>11 (33%)</td>
<td>13 (32%)</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>Slight Concern</td>
<td>16 (48%)</td>
<td>18 (44%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Worried-Fearful</td>
<td>6 (18%)</td>
<td>10 (24%)</td>
<td></td>
</tr>
<tr>
<td>Was the room unexpected and overwhelming</td>
<td>No</td>
<td>28 (85%)</td>
<td>31 (76%)</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>5 (15%)</td>
<td>10 (24%)</td>
<td></td>
</tr>
<tr>
<td>Was the level of sedation adequate</td>
<td>Right amount</td>
<td>18 (75%)</td>
<td>30 (100%)</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>Needed more</td>
<td>6 (25%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Was privacy maintained during the procedure</td>
<td>Always</td>
<td>32 (97%)</td>
<td>41 (100%)</td>
<td>0.45</td>
</tr>
<tr>
<td></td>
<td>Most of time</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Level of discomfort experienced during procedure</td>
<td>Minimal</td>
<td>10 (30%)</td>
<td>24 (59%)</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>Slight discomfort</td>
<td>9 (27%)</td>
<td>13 (32%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quite uncomfort.</td>
<td>9 (27%)</td>
<td>4 (10%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ex. Uncomf/ pain</td>
<td>5 (15%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Did you ask for procedure to be stopped</td>
<td>No</td>
<td>32 (97%)</td>
<td>40 (100%)</td>
<td>0.45</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Was enough time given to recover</td>
<td>No</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>0.45</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>31 (97%)</td>
<td>39 (100%)</td>
<td></td>
</tr>
<tr>
<td>Were the findings adequately explained</td>
<td>Yes</td>
<td>21 (64%)</td>
<td>39 (97%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Told to see GP / OPD</td>
<td>9 (27%)</td>
<td>1 (3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>2 (6%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Were you given instructions on what to do next</td>
<td>No</td>
<td>1 (3%)</td>
<td>2 (5%)</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>29 (97%)</td>
<td>40 (95%)</td>
<td></td>
</tr>
<tr>
<td>Was an appointment given before you left</td>
<td>No</td>
<td>13 (57%)</td>
<td>22 (69%)</td>
<td>0.40</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>10 (43%)</td>
<td>10 (31%)</td>
<td></td>
</tr>
<tr>
<td>Was follow up offered to discuss blood results</td>
<td>No</td>
<td>12 (57%)</td>
<td>20 (71%)</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>9 (43%)</td>
<td>8 (29%)</td>
<td></td>
</tr>
<tr>
<td>Were you treated with dignity</td>
<td>Yes</td>
<td>34 (100%)</td>
<td>41 (100%)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Less than all time</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>
3.4 Discussion

For a national screening process to be effective, uptake is of key importance. An uptake of 43% as seen in this population was lower than in other studies [71,72,142-144], but comparable with the reported London Strategic Health Authority (LSHA) BCS uptake data of 40.28%. A study by Wagner et al revealed wide variation in uptake of FOBT in London [145]. Test kit return in his study was lower for postcode sectors with higher ethnic diversity, area mobility or poor health, characteristics that were all associated with area deprivation. Other studies also suggest that compliance is lower for ethnic populations [146]. The local census report suggests that nearly 55% of the population served by St. Mark's BCS centre is of ethnic background. An uptake of only 43% as seen in our study could possibly be due to the combination of a proportionately higher ethnic and mobile population base. The results of this analysis showed improved uptake with each year of screening. One of the possible reasons for this could be due to the services of a ‘health improvement specialist’, employed by the St. Mark’s bowel cancer screening centre to increase awareness and improve patient education regarding the BCSP in the community.

The FOBT positivity rate of 1.5% in this population was lower than in other UK pilots [142,143], but higher than the incidence round in Funen (1%) [72]. The colonoscopy uptake in this study was 71% (1057/1488). A non-attendance rate of 7% as seen in this analysis was due to various reasons for including refusal by the patient to have the procedure done, actual failure to attend and further time required by the patient to arrive at a decision. This was comparable to non-attendance figures published by the LSHA with regards to BCS (6%) and with this institute’s maximum non-attendance rate in the symptomatic service.
The results from this analysis suggest that despite their varied training backgrounds, there were no significant differences in performance between the screening endoscopists except for a lower adenoma detection rate for colonoscopist 4 (which was still above the national target). In screening, the individual's ADR is calculated by the number of polyps seen and removed, but not necessarily retrieved for histology. Table 12 shows the number of cases referred by each endoscopist. Endoscopist 4 detected lesions in 21 cases which were referred for a second colonoscopy to remove the lesion due to the complexity of the lesion. Although endoscopist 4 detected these lesions, they were not recorded as part of the endoscopist’s ADR, because, although detected, they were not removed at the time. If endoscopist 4 had removed the additional 21 lesions, then the ADR for that endoscopist would have been 45.8% which is a true reflection of the amount of adenomas endoscopist 4 detected at initial colonoscopy.

In 62 of the 67 (92%) polyp surveillance procedures, there was a reduction in both the size and number of polyps seen at 1 year surveillance with 56 patients being downgraded in terms of risk. This highlights the importance of colonoscopic surveillance within the BCS programme. However, in a small number of cases there were significant polyp findings at surveillance. A robust mechanism is needed for providing feedback to screening endoscopists as some of these polyps are likely to have been missed at the index procedure. This reinforces that even in very experienced hands where KPIs are excellent, there is a recognised miss rate for significant pathology [147].

One aim of the Bowel Cancer Screening Programme is for screenees to be able to have a definitive index procedure and cases are therefore given at least 45 minutes to be completed. It is expected that all accredited bowel cancer screening endoscopists
should be able to manage the majority of pathology encountered and only a minimum number of cases should be referred for advanced techniques. There is however no national target for recommended maximum number of additional procedures. Additional procedures have resource implications for the screening programme and usually entail the patient having further bowel preparation. 24% of the additional procedures in this study were performed for removal of polyps first seen at the index procedure. Patients should be consented for this and national data should provide recommendations for how frequently an additional procedure can be expected.

Significant pathology (cancers and polyps) was found in 56% of patients undergoing a procedure. The positive predictive value of a FOBT positive result was 5.5% (80/1488) for invasive cancer. This was lower than the Scottish (12.0%) [143] and English (10.9%) [142] pilots. 85% of cancer patients had preceding symptoms in the 6 months prior to diagnosis. Their diagnosis might possibly have been expedited through earlier presentation to the health services. This data suggests that there are trends to earlier presentation of colorectal cancer in the screening population as compared to the symptomatic group. There was however no significant difference between the two groups. This result is different to that seen in other centres where a significant proportion of early cancers were found [144,148]. Differences in positive predictive value of FOBT and stage of presentation of colorectal cancer between St. Mark’s and other centres could possibly be due to the centre’s participation in previous flexible sigmoidoscopy trials [83,149] during which a number of polyps in the catchment population were diagnosed and removed. Results from the trial [149] in which men and women aged 55-64 years were randomly assigned to undergo sigmoidoscopy screening, reported 2617 colorectal cancers diagnosed in 2524 participants. A proportion of these patients are likely to have been from this centre’s
current screening population and the trial findings of a significant number of cancers is likely to have impacted on the results of this current analysis. While this discrepancy in results (as compared to other published screening data) cannot be fully explained by the centre’s participation in the national flexible sigmoidoscopy trial, this centre also participated in a similar flexible sigmoidoscopy trial for a nurse flexible sigmoidoscopy screening study between 2004-2007 which involved 1500 patients being screened from our local region. This may have had an additive impact on the reduction in cases of cancer in our local population.

Results from the patient satisfaction survey indicated that there was a statistically significant difference between the elective and BCSP group of patients in terms of sedation requirements, discomfort experienced and clarity of explanation regarding the procedure risks and findings. However, there was no difference in terms of overall satisfaction between the two groups. The explanation for the differences reported between these two groups is likely to be multifactorial. The involvement of specifically trained SSPs, the knowledge that all colonoscopists within the BCSP have undergone a rigorous accreditation process and the fact that the screening patients are usually asymptomatic, may be some of the relevant factors. Improvements in pre and post procedural care are being addressed to ensure an equal quality of service is offered to all patients.

3.5 Conclusions

This study reports the first complete dataset of 3 years of screening at St. Mark’s bowel cancer screening centre representing the results of over 42000 individuals screened. FOBT and colonoscopy uptake, cancer detection and the positive predictive value of a positive FOBT remained lower than other UK centres. Possible
explanations could be the different population mix, typical of a metropolitan environment, and the effectiveness of previous flexible sigmoidoscopy adenoma clearance in the local population. The analysis shows that despite a high therapeutic workload, screening colonoscopy can be performed safely with low complication rates and a high degree of patient satisfaction. The number of procedures performed, colonoscopy completion rates, adenoma detection, polyp retrieval and complication rates compare very favourably to national standards, demonstrating an excellent service can be provided by a multidisciplinary team. Screening relies on doing no harm and ensuring benefit to all those who take up the service. Long-term outcomes such as interval cancer rate and mortality reduction are additional parameters required to ensure there is continued improvement in both screening and diagnostic colonoscopy.
Chapter 4:

Assessment of Polypectomy Skills
Chapter 4: Assessment of Polypectomy Skills

4.1 Background and Aim

Evidence suggests that the majority of endoscopic complications are polypectomy related. More recent literature from the national Bowel Cancer Screening programme shows that complications do occur, in spite of skilled operators. A ‘high-stakes’ assessment of the technical skills required for basic and advanced polypectomy requires the development of a standardised, validated tool. This should assess the various ‘levels’ of polypectomy; including small, diminutive polyps, pedunculated polyps as well as sessile lesions requiring piecemeal removal by endoscopic mucosal resection (EMR). Currently, the only patient based polypectomy assessment tool described in the literature for assessing polypectomy is a video scoring system for basic polypectomy.

This study describes the development, content validation and reliability of a polypectomy skills assessment tool (DOPyS) for polypectomy technique. It is envisaged that in its final form, the validated tool may be used to assist structured training, as well as in both formative and summative assessments in polypectomy techniques.

4.2 Methodology

4.2.1 DOPyS development

A study working group was formed, comprising members of UK based endoscopic training and accreditation body-JAG, British Society of Gastroenterology (BSG) and representation from all the professional bodies that perform BCS colonoscopy
(physicians, surgeons and nurse endoscopists). Through interviews of the working group and two group discussions, a tabulated form for assessing polypectomy skills was developed. Polypectomy as a skill was broken down into ‘pre-procedural’ or ‘generic’ skills (applicable to all polyps), ‘specific skills’ required depending on size and morphology of the lesion, and ‘post-polypectomy’ skills. It was designed for use both in live and video polypectomy assessment (acknowledging the fact that some aspects of polypectomy cannot be assessed using videos). The task of polypectomy was deconstructed into its individual components and a 33-point structured checklist and global assessment scale for assessing polypectomy skills was developed (DOPyS-Appendix 1). Each individual component or parameter, as well as the global assessment was scored from 1 to 4, with scores ≥3 denoting competency. A detailed description of what constituted expert (score of ‘4’) or poor (score of ‘1’) technique for each parameter, was drawn and reviewed by the working group. Initial validation of the DOPyS was performed using polypectomy videos as a feasible method both for the study as well as eventual use of the tool in practice. Videos of polypectomy performed on Bowel Cancer Screening (BCS) lists were used for this study as they were performed by accredited screening colonoscopists and it was envisaged that BCS lists would invariably have a wide range of pathology. The study was not designed to assess competency of the individual screening endoscopists, but to test the reliability and content validity of the DOPyS.

4.2.2 DOPyS reliability

Bowel Cancer Screening endoscopists in England were invited to take part in this development of the BCS QA process. Thirty BCS colonoscopists were randomly
selected from a cohort of 189 screeners in England and invited to submit a video recording of one BCS list each. It was envisaged that each list would have four patients, giving a total of 120 patients. Based on the results of the BCS pilots [75], at least 50% of these faecal occult blood test (FOBT) positive patients would have pathology in the form of polyps, providing a minimum of 60 polyps. It was thought that this number of polyps obtained from screening lists would be adequately representative of the range of pathology and endoscopist skills encountered in day to day screening practice. The videos incorporated only the endoscopic view and were edited to include only the entire polypectomy procedure. The videos were coded to ensure anonymity of patients and the screening endoscopists. Twenty three of the 30 screeners submitted 82 polypectomy videos of which 60 were randomly selected for initial independent scoring by the seven members of the working group. The scores obtained were analysed using G-theory to determine the sample of polypectomy cases and assessors needed to make reliable inferences about an endoscopist's competency. Of the 60 polypectomies, 47 were included in the final G-theory analysis (see Figure 18).
4.3 Statistical analysis

Raw data analysis for all 59 assessable videos was performed to determine the number of assessors who agreed across the competency (pass/fail) divide. For the purpose of G-theory, only 47 of the 60 polypectomy videos could be included as these were performed by endoscopists who had submitted more than one polypectomy (allowing measurement of variation across different cases).
4.3.1 Reliability and G-theory

Reliability refers to the reproducibility of assessment data or scores over time and occasions. A fundamental principle of scientific method is that experiments must be reproducible in order to be interpreted properly i.e. if the results of an experiment cannot be reproduced, then any conclusions drawn from that experiment are dubious, and generalisations are limited [150].

The basic formula for calculating the reliability of an assessment is as follows:

**Observed Score = True Score + Errors of Measurement**

Hence, a perfectly reliable test produces a score which is only influenced by the construct of interest and is completely unaffected by the circumstances of the test (e.g. when, where, and by whom it is administered). A test score like this might be called the true score. The reliability diminishes as circumstantial or error factors affect the test score in the real world.

The most elegant estimates of inter-rater agreement (and estimates of other sources of error) use generalisability theory (GT) analysis. GT is particularly useful in medical education because of the variety and complexity of assessments used and the large number of factors that impact on scores (i.e. sources of error: examinees, assessors, type of assessment, cases, case mix, setting etc). GT falls within the family of regression techniques – techniques which model and quantify relationships between variables to make predictions. It builds on the mathematical approach ‘variance component analysis’. In essence, GT quantifies the impact that the relevant factors exert on the assessment score. The relative size of each factor’s contribution to the test score variance reveals valuable information. If a trainee’s scores are consistent across different assessors, then they are likely to be reliable; if the assessors give very
different scores to the same candidate on the same challenge then a single score is unreliable.

The reliability coefficient (R) can be expressed as a fraction involving the two sources of variation, with the ‘true variance’ being the variance of the trainee, and hence what one wishes to measure [151]:

$$R = \frac{\text{Assessee (true) Variance, } V_a}{\text{Total Variance, } V_{tot}}$$

Where $$V_{tot} = V_a + \text{Error Variance, } V_e$$ (or ‘noise’)

$$V_e = V_o + V_c + V_{axo} + V_{axc} + V_{oxc} + V_{axoxc}$$

The different sources of variance are listed below:

- **Va** the assesseee (‘true’ variance; the effect one wants to measure between assessees)
- **Vo** the observer (stringency of assessor; tendency to be a hawk or dove)
- **Vc** the case (the sample of the performance taken for the assessment, e.g. particular polyp; the case specificity)
- **Vaxo** the interaction between assesseee and observer (the tendency for an assessor to mark a particular trainee differently, perhaps due to prior bias and so is separate from the overall stringency of an assessor)
- **Vaxc** the interaction between trainee and case (tendency for a trainee to perform differently with a different case, perhaps because they are innately suited to a particular case due to prior experience)
- **Voxc** the interaction between observer and case (tendency for an observer to mark differently on a particular case, perhaps due to idiosyncratic view of the complexity of the case. For example, a cardiologist may generally be a dove, but on OSCE stations involving examination of the heart they might be much more hawkish)
- **Vaxoxc** the interaction between assesseee, observer and case (the tendency for observer to mark a particular assesseee-case interaction differently. For example, an
observer with prior knowledge of a trainee’s experience of cardiology might mark a cardiology OSCE station differently for that particular trainee). Often called ‘residual error’

The sources of error can be quantified using a single variance component analysis by using the results of a number of assessments, with a range of assessesees, observers and cases (e.g. ANOVA, available on Statistics Package for the Social Sciences, SPSS 10 or more recent). From the formula above, it can be seen that the sources of variance can be combined to reflect all possible measurements of the construct of interest. This results in a fraction between 0 and 1, and is called the generalisability coefficient (‘G’). The greater the factor, the smaller contribution to the observed score is made by the error variance (or ‘noise’), and so the more reliable the assessment. For high stakes assessments, a value of 0.8 or higher is considered acceptable.

Another way of presenting the meaning of variance estimations is to calculate the Standard Error of Measurement (SEM). The SEM for the entire distribution of scores on an assessment is given by the formula:

\[ \text{SEM} = \sqrt{\text{error variance (Ve)}} \]

A 95% confidence interval of the true score can be calculated from the SEM with the formula:

\[ \text{True Score} = \text{Observed Score} \pm (\text{SEM} \times 1.96) \]

Quoting the confidence interval of an observed score can provide a very tangible notion of how reliable that score is.

To estimate reliability of the DOPyS, we used generalisability theory (G-theory). The G-theory analysis [150] uses variance component analysis to measure the contributions that all relevant factors make to the final result (assessor variation,
polypectomy case variation, endoscopists skill variation and their interactions). G-theory allows estimation of the size of the relevant variables that influence the reliability of a given score. This resulted in a design in which five sources of variance could be distinguished (see table 14). In this study two key factors were identified potentially influencing the reliability: variation between assessors and variation of performance across polypectomy cases. From the variance components a variety of reliability indices can be estimated. Reliability was expressed as the standard deviation of all influences that have a negative effect on the measurement, given a particular sample of cases and assessors. This is the Standard Error of Measurement (SEM). Multiplied by 1.96 (area under the curve at 95%), a 95% confidence interval is obtained. This interval may be plotted around any score of an individual e.g. an endoscopist scores 3 and the SEM x 1.96 = 0.5, one can then confidently decide that the endoscopist exceeded the pass mark of 2.5 and should pass. Half a point (0.5) divided by 1.96 is 0.26 as a potential critical SEM. By varying the number of cases and assessors in the above formula an estimate of how large the SEM would be by different sample sizes can be made. Samples of cases and assessors leading to an SEM below 0.26 were considered to be acceptable.
Table 14. Sources of variance influencing reliability in G-Theory analysis

<table>
<thead>
<tr>
<th>Source of Variance</th>
<th>Description</th>
<th>Estimated Variance Component</th>
<th>Percentage of Total Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>V_p</td>
<td>Systematic variation between endoscopists</td>
<td>0.05836</td>
<td>14.35%</td>
</tr>
<tr>
<td>V_c:p</td>
<td>Variation in difficulty of cases and variability of endoscopists across cases</td>
<td>0.06820</td>
<td>14.67%</td>
</tr>
<tr>
<td>V_a</td>
<td>Systematic variability between assessors (leniency/stringency)</td>
<td>0.05134</td>
<td>11.04%</td>
</tr>
<tr>
<td>V_ca:p</td>
<td>All remaining variability (unexplained error)</td>
<td>0.28487</td>
<td>61.27%</td>
</tr>
</tbody>
</table>

4.4 Results

4.4.1 Polyps and polypectomy techniques

All of the assessable videos (n=59) were analysed to characterise polyps and identify polypectomy techniques used. The median size of the polyps as judged by the seven assessors was 6mm (1-18mm). Twenty seven polyps were less than 6mm in size and 32 were between 6mm and 18mm. The morphological characteristics and polypectomy methods used are outlined in Table 15. In contrast to the larger polyps, there was more variation in polypectomy technique used for polyps <6mm in size.
The segment of colon from which the polyp was removed could not be assessed from the endoscopic-view only videos.

**Table 15.** Polyp characteristics and polypectomy method

<table>
<thead>
<tr>
<th>Polyp size</th>
<th>Morphology</th>
<th>Polypectomy technique</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6mm</td>
<td>Flat (n=2)</td>
<td>Lift and cold snare</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Snare diathermy alone</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Sessile (n=23)</td>
<td>Lift and cold snare</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Snare diathermy alone</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cold snare alone</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lift and snare diathermy</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Pedunculated (n=2)</td>
<td>Cold snare alone</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Snare diathermy alone</td>
<td>1</td>
</tr>
<tr>
<td>&gt;6mm</td>
<td>Flat (n=5)</td>
<td>Lift and cold snare</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lift and snare diathermy</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Sessile (n=7)</td>
<td>Lift and snare diathermy</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Snare diathermy alone</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Pedunculated (n=20)</td>
<td>Snare diathermy alone</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lift and snare diathermy</td>
<td>3</td>
</tr>
</tbody>
</table>
4.4.2 Initial analysis of DOPyS scores

The data was initially assessed using all 59 assessable videos scored by the seven assessors. Raw data analysis for the seven assessor scores for the global rating scale (Overall Competency) across all 59 polyps showed that across the pass/fail divide, the majority (i.e. at least four out of seven) of the assessors agreed across the pass/fail divide in 58/59 (98%) polyps. In 10/59 (17%) polyps, the majority of the assessors felt the polypectomy was suboptimally performed (global score less than or equal to 2). There was total agreement amongst the seven assessors in 14/59 (24%) polyps (13 optimally performed, one suboptimal performance). Six of the seven assessors (86%) had agreement on a further 23 (39%) polyps (22 optimal, one suboptimal). The preliminary data also suggested wide variability amongst the assessors with the seven assessors scoring \( \geq 3 \) for overall competency in 57%, 70%, 74%, 75%, 77%, 79% and 92% cases respectively, suggesting that some assessors were more stringent or lenient than others - the ‘hawk-dove effect [152] (see figure 19).

**Figure 19.** Assessor Variation in DOPyS Scores

![Assessor Variation in DOPyS Scores](image)
4.4.3 G-Theory analysis

4.4.3.1 Variance components

In Table 14 the estimated variance components are given for all sources of variance and also expressed as a percentage of the total variance. $V_p$ was the variance of persons (endoscopists). As the eventual purpose of this assessment tool will be to reliably distinguish between the competency of different endoscopists, $V_p$ was the most significant variance and all other components represented error in the measurement. $V_p$ of approximately 15% is more or less normal in any form of assessment, therefore the variance seen was in keeping with this. $V_{c:p}$ was the variance associated with cases. It represents the combined variation in performance across different tasks and the difficulty of the case (both sources cannot be disentangled due to the nesting in the data-gathering design). $V_{c:p}$ variance is usually a large component, and higher than 14.6% as seen in this study. $V_A$ represents the systematic (across persons and cases) leniency or stringency of assessors. Compared to the general error term, it was relatively small. $V_{pa}$ was the interaction between assessor and person or the leniency/stringency of the assessors for some endoscopists. In this study, it was negligible (0.4%). $V_{ca:p}$ included all other variance and is therefore called the general error term. It is usually large (61.2%).

4.4.3.2 Standard Error of Measurement (SEM)

Table 16 provides information on the number of polypectomy cases an endoscopist should perform, and the number of assessors required, to obtain a critical SEM of 0.26. As the number of cases and assessors increases, the SEM (i.e. the spread of
scores around the observed score) decreases, making the DOPyS more reliable. The data suggests that for the DOPyS to be reliable, a minimum of two assessors would have to assess a minimum of five polypectomies performed by the same endoscopist to give the critical SEM of 0.26.

**Table 16.** Number of cases and assessors required for reliable scoring by SEM

<table>
<thead>
<tr>
<th>Number of Assessors</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>0.64</td>
</tr>
<tr>
<td>2</td>
<td>0.49</td>
</tr>
<tr>
<td>3</td>
<td>0.43</td>
</tr>
<tr>
<td>4</td>
<td>0.39</td>
</tr>
<tr>
<td>5</td>
<td>0.37</td>
</tr>
<tr>
<td>6</td>
<td>0.35</td>
</tr>
<tr>
<td>7</td>
<td>0.34</td>
</tr>
<tr>
<td>8</td>
<td>0.33</td>
</tr>
</tbody>
</table>

**4.5 Discussion**

This study is the first to describe the development and prospective validation of competency assessment for endoscopic polypectomy (Direct Observation of Polypectomy Skills-DOPyS) using video of patient procedures. Training and structured assessment of polypectomy techniques is vital to ensure that polypectomy related complications are minimised. Currently, polypectomy is not a mandatory part of the accreditation/certification process for bowel cancer screeners, but polypectomy assessment has been introduced recently for trainees who wish to gain endoscopic certification in the UK.
In any clinical assessment, there are several variables that influence reliability of the method of assessment. The classical methods of assessment quantify each of the variables individually (e.g. inter-observer agreement). Generalisability theory is an extension of the classical reliability theory and analyses all the components of variance, making use of all the data to quantify all the sources of error without multiple experiments. In this study, $V_c:p$ (variance associated with different cases) was much lower than normally expected (14.6%), suggesting that assessor variation ($V_a$) was impacting the measurement more than endoscopist variation (notably inconsistent performance across cases). One possible explanation could be the fact that all the endoscopists in the study had passed the BCSA process and were practicing independently at the time of recruitment. It is likely that the endoscopist variation may have been greater had our study included endoscopists with a wider range of experience.

G-theory analysis of the scores indicated that the domain referenced critical SEM of 0.26 (i.e. reliability) could be achieved if a minimum of two assessors independently used this assessment tool to assess a minimum of five polypectomies performed by the same endoscopist, taking into account the variability of the endoscopist’s technique and the assessors across different cases. The scores obtained in such a format would be reliable and representative of the endoscopist’s true competence. Fewer cases may be used, but then more assessors are required. As the endoscopist performs a number of cases (in this case, five) the assessors are likely to have an opportunity to assess skills over a variety of polypectomy techniques. In this study however, it is recognised that the polyps were, on the whole, small and further studies are required for the assessment of larger and more complex polypectomy. Furthermore, the reliability inferences drawn from this study (which utilised bowel
cancer screening accredited endoscopists) may not necessarily be applicable to all endoscopists.

In an assessment process, subjective judgments can be made more reliable by regulating the freedom of the assessor. Using a structured tool (which specifies criteria for good and bad performance) to guide their assessment, assessors can be trained to align their behaviour. Detailed DOPyS descriptors defining good (scores of 3 or 4) and bad (scores of 1 and 2) technique were available to the assessors during scoring. An explicit statement about what constitutes good and bad technique enhances the potential educational impact of an assessment as it provides a framework for explicit feedback [103]. However, we acknowledge that the Overall Competency scores could have been influenced by subjectivity despite the descriptors outlining the marking scheme for the individual parameters, as there was no way of calculating the overall competency score from the objective parameters.

The use of polypectomy videos from bowel cancer screening lists may not be representative of wider endoscopic practice, however for the purpose of validation, all scorers assessed the same videos. Thirteen of the 60 videos were excluded from the final G-theory analysis which limited the range of polyps assessed. All 47 polyps seen were <2cm in size. This is a development study which looked at the feasibility of video-scoring polypectomy using a purpose designed assessment tool. It was designed to assess content validity and reliability of the DOPyS and analysed assessor variability and variation in endoscopists’ techniques. Further validation studies including live assessments, assessing a wider range of endoscopist skills and polyps and assessment of symptomatic rather than screening lists are required to improve the applicability of the DOPyS.
4.6 Conclusion

This study reports the G-theory analysis of polypectomy video assessment using the DOPyS and establishes its reliability, provided a minimum of two assessors use the DOPyS to assess a minimum of five polypectomy cases performed by the same individual. The DOPyS is a step towards competency assessment in polypectomy and assesses polypectomy in much greater detail than the present DOPS. One aim of this QA development is to improve training and formative assessment for all endoscopists. In its present form, the DOPyS has wide applicability as a training tool for all endoscopists.
Chapter 5: Assessment of piecemeal

Endoscopic Mucosal Resection
Chapter 5: Assessment of piecemeal Endoscopic Mucosal Resection (p-EMR)

5.1 Background and Aim

With increasing volume of colonoscopy being performed worldwide and an emphasis on earlier detection through increased screening programmes, together with improved methods of detection, there is a significant increase in the presentation of advanced benign lesions suitable for piecemeal EMR (p-EMR) [78]. To mirror the increased requirement for therapy, there is a greater need for training and assessment in polypectomy skills.

p-EMR is an established endoscopic therapy for the resection of large sessile/flat colonic polyps (>2 cm in size) [153, 154]. It is described as the ‘lift and cut’ technique, where piecemeal snare resection is preceded by a submucosal injection of a solution [155, 156]. Large prospective, and various retrospective studies show that p-EMR, as a minimally invasive procedure, is a safe and effective method for the excision of complex colonic polyps [157, 158] in tertiary endoscopic referral centres.

However, even in experienced hands, p-EMR of large colonic adenomas can be associated with complications and have a recurrence rate up to 55 % in some series [159]. In case of incomplete p-EMR, larger areas of polyp recurrence often have significant submucosal fibrosis, making resection more complex, potentially hazardous and often incomplete [160].
The development of a polypectomy skills assessment tool (direct observation of polypectomy skills-DOPyS), and its reliability in assessing polypectomy performed on small polyps has been described in the previous chapter. As a result, the BCS accreditation (BCSA) process in England has been modified, to include specific assessment of the endoscopists’ polypectomy skills, in addition to testing their theoretical knowledge and diagnostic colonoscopy skills (Figure 20) [140]. Trainee endoscopists in the UK also undergo formative and summative assessments, as recommended by the Joint Advisory Group (JAG) for gastrointestinal endoscopy, to test colonoscopic skills and more recently to include basic polypectomy competency, using the validated DOPyS tool. To date, however, more advanced skills required for piecemeal removal of large sessile polyps are not assessed and nor has the DOPyS been validated in assessing competency in this context.

This chapter aims to describe the feasibility and reliability of DOPyS assessment of competency at piecemeal resection of large complex colonic polyps. It is envisaged that DOPyS may be used as a validated tool to assist structured training as well as a part of formative and summative assessments in p-EMR.
**Figure 20.** Proposed Bowel Cancer Screening Accreditation process

* MCQ-Multiple Choice Questions
** KPI-Key Performance Indicators
*** DOPS-Directly Observed Procedural Skills
**** DOPyS- Direct Observation of Polypectomy Skills

5.2 **Methodology**

5.2.1. **DOPyS reliability**

The development of the DOPyS has been described in detail in the previous chapter. Through interviews of the working group and two group discussions, a tabulated form
for assessing polypectomy skills was developed. To summarise, polypectomy was deconstructed into its individual components and a 34-point structured checklist of parameters and a global assessment scale (Overall Competency) was developed (Appendix 2). DOPyS development and validation is a process in evolution and the DOPyS marking scheme used by the assessors in this chapter was an updated version of the DOPyS shown in Appendix 1. Each individual component or parameter (as defined by a set of descriptors-Appendix 3), as well as the global assessment was scored from 1 to 4, with scores ≥3 denoting competency. Two endoscopists with expertise in p-EMR were invited to assess five randomly selected p-EMR videos performed by a single independent endoscopist (>3000 colonoscopies) undergoing advanced training in p-EMR. The assessors were blinded to the identity and experience of the endoscopist performing the procedures. The videos incorporated only the endoscopic view and were edited to include only the entire polypectomy procedure. The videos were coded to ensure anonymity of patients and the performing endoscopist. The DOPyS scores obtained were analysed using Generalisability theory (G theory) [151] to determine the number of polypectomy cases needed to make reliable inferences about an endoscopist’s competency.

Patients gave informed consent and the study was approved by the local research and ethics committee.

5.3 Statistical analysis

To estimate reliability G theory was used which has been described in detail in the previous chapter. G-theory allows estimation of the size of the relevant variables that influence the reliability of a given score. This resulted in a design in which three
sources of variance could be distinguished (see table 17). In this study two key factors were identified potentially influencing the reliability: variation amongst cases (Vc) and variation amongst assessors (Va). From the variance components a variety of reliability indices can be estimated. Reliability was expressed as the G coefficient, with values equal to, or greater than 0.8 regarded as being acceptable (reliable).

Table 17. Sources of variance influencing reliability in G-Theory analysis

<table>
<thead>
<tr>
<th>Source of Variance</th>
<th>Description</th>
<th>Estimated Variance Component</th>
<th>Percentage of Total Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vc</td>
<td>Systematic variation between cases</td>
<td>0.40000</td>
<td>50.00%</td>
</tr>
<tr>
<td>Va</td>
<td>Systematic variability between assessors (leniency/stringency)</td>
<td>0.30000</td>
<td>37.50%</td>
</tr>
<tr>
<td>Vca</td>
<td>Systematic variability between assessors across all cases</td>
<td>0.10000</td>
<td>12.50%</td>
</tr>
</tbody>
</table>

5.4 Results

5.4.1 Polyps and patients

Polyp and patient details are described in Table 18. Figure 21 shows still images of one of the p-EMR cases scored by the two assessors.
Table 18. Patient and polyp characteristics

<table>
<thead>
<tr>
<th>Pt N°</th>
<th>Age</th>
<th>Gender</th>
<th>Polyp location</th>
<th>Polyp size (mm)</th>
<th>Laterally Spreading Tumour (LST)* classification</th>
<th>Paris classification*</th>
<th>Adenoma Histology</th>
<th>Adenoma Dysplasia</th>
<th>p-EMR Duration (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>67</td>
<td>Male</td>
<td>Caecum</td>
<td>30</td>
<td>Granular</td>
<td>0-Ia</td>
<td>Tubular</td>
<td>LGD**</td>
<td>28</td>
</tr>
<tr>
<td>2</td>
<td>57</td>
<td>Female</td>
<td>Sigmoid</td>
<td>25</td>
<td>Non-Granular</td>
<td>0-IIa</td>
<td>Tubular</td>
<td>LGD</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>68</td>
<td>Male</td>
<td>Transverse Colon</td>
<td>20</td>
<td>Granular</td>
<td>0-Ia</td>
<td>Tubular</td>
<td>LGD</td>
<td>15</td>
</tr>
<tr>
<td>4</td>
<td>81</td>
<td>Male</td>
<td>Caecum</td>
<td>35</td>
<td>Granular</td>
<td>0-Ia</td>
<td>Tubulo-Villous</td>
<td>LGD</td>
<td>24</td>
</tr>
<tr>
<td>5</td>
<td>66</td>
<td>Female</td>
<td>Rectum</td>
<td>30</td>
<td>Non-Granular</td>
<td>0-IIa</td>
<td>Tubular</td>
<td>LGD</td>
<td>20</td>
</tr>
</tbody>
</table>

*Paris Classification [13]; **LGD-Low Grade Dysplasia
Figure 21. One of the 5 p-EMR cases scored by the two assessors for establishing reliability of the DOPyS

5.4.2 G-Theory analysis

Raw data for G theory analysis of DOPyS scores for p-EMR are shown in Appendix 4
5.4.2.1 Variance components

In Table 17 the estimated variance components are given for all sources of variance and also expressed as a percentage of the total variance. \( V_c \) was the variance associated with cases. It represents the combined variation in performance across different tasks and the difficulty of the case. This variance is usually forms a large component, as seen in this study (50.0%). \( V_a \) represents the systematic (across persons and cases) leniency or stringency of assessors (the ‘hawk-dove index’) [152] and was fairly high in this analysis (37.5%). \( V_{ca} \) represented variation amongst the assessors across the different cases assessed, and was relatively small (12.5%).

5.4.2.2. Generalisability coefficient (G-coefficient)

Table 19 shows the number of assessors required to score five p-EMR cases to obtain a critical G coefficient of 0.8. As the number of assessors increases, the G coefficient also increases, making the DOPyS more reliable. In this study, the data suggest that for the DOPyS to be reliable, a minimum of two assessors would have to assess five p-EMR cases performed by a single endoscopist to give the critical G coefficient of 0.80 and make the assessment reliable.
Table 19. Number of assessors required to score five p-EMR videos to achieve a Generalisability coefficient >0.80

<table>
<thead>
<tr>
<th>Number of Assessors</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generalisability</td>
<td>0.69</td>
<td>0.82</td>
<td>0.87</td>
<td>0.90</td>
<td>0.92</td>
</tr>
<tr>
<td>Coefficient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.5 Discussion

Polypectomy is now assessed as part of the colonoscopy certification process for all endoscopy trainees in the UK and as a part of the high stakes assessment within the national bowel cancer screening programme in England (www.saas.nhs.uk).

This study is the first to assess competency in p-EMR using a structured and validated assessment tool. The previous chapter demonstrated that the DOPyS was a reliable tool for assessing competency in polypectomy performed on diminutive polyps, when two assessors scored five cases performed by a single endoscopist (the ‘2 by 5’ format). The resultant DOPyS scores would then reflect the endoscopist’s competence. The current study was designed to test the 2 by 5 format and applying it to p-EMR. It is assumed training and structured assessment of polypectomy techniques should improve outcomes. This assumes a greater importance for larger and more complex lesions requiring p-EMR as these are at higher risk of developing complications and recurrence.

In this study, Vc was the variation in performance across the 5 p-EMRs. The results suggested that the endoscopist varied in performance across the different cases (Vc of 50%). As the five videos were randomly selected from all the p-EMR cases
performed by the endoscopist, this variation in performance across cases may possibly have been due to different stages of training of the endoscopist. The study also highlighted variability amongst assessor scores (Va of 37.5%). To address this issue, the assessors for this study were selected on the basis of their expertise in the field of p-EMR and were regular endoscopy trainers. In addition, both assessors were familiar with the DOPyS assessment tool. It is therefore possible that examiner variability in this study was largely due to difference in opinion regarding the competent completion of a procedure, and is likely to be due to lack of universally accepted p-EMR technique. Although there was broad agreement amongst the assessors, they disagreed on issues such as adequate sub-mucosal injection and obtaining optimal views of the lesion.

G-theory analysis of the scores indicated that a G-coefficient of 0.80 (i.e. reliability) could be achieved if a minimum of two assessors independently used this assessment tool to assess five p-EMR cases performed by the same endoscopist, taking into account the variability of the endoscopist’s technique and assessor scoring across different cases (mirroring the results obtained from the original DOPyS study). The scores obtained in such a format would be reliable and representative of the endoscopist’s true competence. As the endoscopist performs a number of cases (in this case, five) the assessors are likely to have an opportunity to assess skills over a range of lesions.

The technical skill required for p-EMR is challenging and incorporates a steep learning curve. The technique involves multiple repetitive steps, which require detailed, objective assessments. In an assessment process, subjective judgments can be made more reliable by regulating the freedom of the assessor. Using a structured tool (which specifies criteria across a range of performance) to guide their assessment,
assessors can be trained to align their opinions. Detailed DOPyS descriptors defining
good (scores of 3 or 4) and poor (scores of 1 and 2) technique were available to the
assessors during scoring.

5.6 Conclusion

This chapter reports the G-theory analysis of p-EMR video assessment using the
DOPyS in an attempt to establish its feasibility and reliability in assessing this
technique. It is acknowledged that the number of p-EMR cases and assessors in this
study was small. Further large-scale studies incorporating a wider range of p-EMR
techniques, endoscopists, and assessors are necessary to further validate this
assessment tool. The results did reflect, however, that DOPyS assessment of p-EMR
is feasible and reliable for the cohort of cases and assessors used in this study.
Chapter 6: Construct Validity of DOPyS
Chapter 6: Construct Validity of DOPyS

6.1 Background and Aim

Over the last two decades there has been increasing interest in the field of assessment in endoscopy [161]. There is some evidence for improved training and informal assessment of polypectomy skills in the UK over the last 10 years since the introduction of national training courses [137]. However, the focus of endoscopy competency assessment has been primarily on intubation skills and key performance indicators (KPIs), rather than polypectomy competencies. The American Society for Gastrointestinal Endoscopy (ASGE) [162] recommends objective measures of competency assessment and direct observation of trainees for certification in advanced endoscopic techniques such as polypectomy. However, current methods of polypectomy technique assessment are inadequate for this purpose.

A tool designed specifically for the assessment of technical skills in polypectomy (Direct Observation of Polypectomy Skills (DOPyS)) has been developed, and its feasibility and validity determined [104]. There is general agreement that there are five required attributes of an assessment process [120]: Reliability, Validity, Acceptability, Feasibility and Educational impact. This study aims to determining the construct validity of the DOPyS, which is a measure of its ability to differentiate between operators of varying experience. It is envisaged that in its final form, the validated tool may be used to assist structured training, and in both formative and summative assessments in polypectomy techniques.
6.2 Methodology

6.2.1 Participants

Eight independently practicing endoscopists, working in a single tertiary endoscopic referral centre, were invited to participate in the study. Two of the endoscopists had expertise in advanced therapeutic endoscopy and had each performed more than 1000 colonoscopies. The other six endoscopists were trainees but had fulfilled the Joint Advisory Group (JAG) for Gastrointestinal Endoscopy, UK criteria [109] for provisional colonoscopy certification, and had performed 200-500 procedures. The rationale for selecting these groups was to determine whether the DOPyS could reliably distinguish between polypectomy skills of highly competent endoscopists i.e. the experts, from those of non-expert independently practicing endoscopists i.e. not novices.

6.2.2 Direct Observation of Polypectomy Skills (DOPyS)

The development of the DOPyS assessment tool is described in Chapter 4. Polypectomy as a skill was broken down into ‘pre-procedural’ or ‘generic’ skills (applicable to all polyps), ‘specific skills’ required depending on size and morphology of the lesion, and ‘post-polypectomy’ skills. The task of polypectomy was deconstructed into its individual components and a 34-point structured checklist and global assessment scale for assessing polypectomy skills was developed (DOPyS). Each individual component or parameter, as well as the global assessment was scored from 1 to 4, with scores ≥3 denoting competency.
6.2.3 Polypectomy videos and DOPyS assessment training

Videos of 32 polypectomies were obtained from the eight participants; 17 from the expert group and 15 from the intermediate group. The mean polyp size was 7.2mm (1-45mm). The videos were edited to include only endoscopic view of the entire polypectomy procedure (from initial detection, to attempt at polyp retrieval). These were then arranged in random order. Four blinded, experienced endoscopists scored the videos independently, using the DOPyS. Two of the assessors were very familiar with the DOPyS and had been instrumental in its design (“trained assessors”). Both trained assessors had an hour long training session in which they practiced scoring five polypectomy videos (not included in the study), and received feedback on their scoring in an effort to align opinions. Scores of ‘1’, ‘2’, ‘3’ and ‘4’ were clearly defined for each parameter, using detailed descriptors, and the assessors undergoing training were asked to refer to these regularly. It is acknowledged that training for all BCS assessors will have to be uniformly structured before the implementation of the DOPyS into the BCSA process, but for the purpose of this study, it was felt that the amount of time spent on training the assessors who were already familiar with the DOPyS, was sufficient. The other two assessors were not familiar with the DOPyS (“untrained assessors”). Each of the 34 parameters on the DOPyS, as well as the overall competency, was marked 1 (standards not met), 2 (some uncorrected errors), 3 (competent and safe performance), or 4 (highly skilled performance), with scores <3 implying that part of the procedure was sub-optimally performed.

The results were analysed in two ways. Firstly, the scores given by each of the four assessors (for individual parameters and the overall score) were grouped into 1s and 2s (i.e. sub-optimal performance) and 3s and 4s (i.e. competent performance). This represented the ‘pass’/’fail’ divide. Secondly, agreement between the assessor scores
was sought using the scores as individual figures of 1, 2, 3 or 4 (i.e. not grouping them into the pass/fail divide). Fisher’s exact test was used to compare scores given by the ‘trained’ and ‘un-trained’ assessors for both groups (expert and intermediate) of endoscopists. In addition, the inter-rater reliability for the overall competency scores given by the two trained and untrained assessors was calculated using the standard kappa statistic.

6.3 Results

6.3.1 Polyp characteristics

There were no significant differences in the polyps removed by the expert and nonexpert group of endoscopists (see Table 20). The non-expert endoscopists did, however, use cold snare more often than the expert endoscopists, and this difference approached marginal statistical significance.

Table 20. Characteristics of polyps removed by expert and non-expert endoscopists

<table>
<thead>
<tr>
<th>Polyp Characteristics</th>
<th>Polypectomies performed by non-expert group (n=15)</th>
<th>Polypectomies performed by expert group (n=17)</th>
<th>P value (Fisher’s test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site (left sided)</td>
<td>13</td>
<td>12</td>
<td>0.4</td>
</tr>
<tr>
<td>Morphology (sessile)</td>
<td>15</td>
<td>16</td>
<td>1.0</td>
</tr>
<tr>
<td>Size (&lt;10mm)</td>
<td>15</td>
<td>14</td>
<td>0.22</td>
</tr>
<tr>
<td>Cold snare</td>
<td>7</td>
<td>2</td>
<td>0.05</td>
</tr>
<tr>
<td>EMR*</td>
<td>8</td>
<td>13</td>
<td>0.26</td>
</tr>
</tbody>
</table>

*EMR: Endoscopic Mucosal Resection
6.3.2 Overall DOPyS scores for Polypectomies scored by the two trained assessors

This analysis compared the overall scores for polypectomy performed by expert and intermediate group of endoscopists, as scored by the two trained assessors. The results are summarised in Table 21. The figures presented are the number and percentage of polypectomies with each score (either 1, 2, 3, 4 or across the pass/fail divide) for each of the two groups (experts and intermediates). The results of the analysis show that for both the trained assessors, there was a difference in the results between the expert and intermediate endoscopists, both when scores were analysed as individual scores (i.e. 1, 2, 3 or 4), and also across the pass/fail divide. For both assessors, the experts had higher scores than the intermediate endoscopists group. For example, assessor 2 ‘passed’ 94% of experts passed compared to only 20% of the intermediate group (p<0.001). The kappa value for inter-assessor agreement was 0.32.
Table 21. Comparison of DOPyS overall polypectomy scores for the expert and intermediate endoscopists given by the two trained assessors.

<table>
<thead>
<tr>
<th>Trained Assessor</th>
<th>Overall DOPyS Score</th>
<th>Polypectomies performed by Expert Endoscopists Number (%)</th>
<th>Polypectomies performed by Intermediate Endoscopists Number (%)</th>
<th>P-value Fisher’s Exact Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Score 1</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 2</td>
<td>2 (12%)</td>
<td>7 (47%)</td>
<td><strong>0.001</strong></td>
</tr>
<tr>
<td></td>
<td>Score 3</td>
<td>5 (29%)</td>
<td>8 (53%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 4</td>
<td>10 (59%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fail (Score 1 or 2)</td>
<td>2 (12%)</td>
<td>7 (47%)</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Pass (Score 3 or 4)</td>
<td>15 (88%)</td>
<td>8 (53%)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Score 1</td>
<td>0 (0%)</td>
<td>2 (13%)</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td></td>
<td>Score 2</td>
<td>1 (6%)</td>
<td>10 (67%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 3</td>
<td>16 (94%)</td>
<td>3 (20%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 4</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fail (Score 1 or 2)</td>
<td>1 (6%)</td>
<td>12 (80%)</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td></td>
<td>Pass (Score 3 or 4)</td>
<td>16 (94%)</td>
<td>3 (20%)</td>
<td></td>
</tr>
</tbody>
</table>
6.3.3 Individual DOPyS parameter scores across the Pass/Fail divide as marked by the two trained assessors

This analysis compared the scores given for each parameter (across the pass/fail divide) between the expert and non-expert endoscopists, as scored by the two trained assessors. The vast majority of the polyps removed in this study were less than 10mm in size and the assessors only scored the section of the DOPyS marksheet that was relevant to ‘small sized polyps’. As previously mentioned, the parameters that could only be assessed during live polypectomy were also not scored. Therefore, the assessors could only score 19 of the 34 parameters for any polypectomy. Due to insufficient data for 5 parameters, only 14 of the 19 DOPyS parameters scored, were used for statistical analysis. The results are summarised in Table 22. The figures presented are the number and percentage of polypectomies that were deemed to have passed (scored ≥3) for each of the two groups (experts and non-experts).

The results of the analysis for assessor 1 show that they found a significant difference between experts and intermediate endoscopists for parameters 2 (ensures adequate polyp view by aspiration, insufflation, lens wash), 22 (steers snare accurately over lesion head), 24 (positions snare appropriately over lesion head as the snare is closed), 25 (ensures no additional tissue is trapped within snare) and 32 (retrieves, or attempts retrieval of polyp). For all instances where differences were observed, polypectomies performed by expert endoscopists had a significantly higher pass rate than those performed by the intermediate group. For example, for parameter 22, 88% of the polypectomies performed by the experts passed, compared to only 33% of those performed by the intermediate group (p=0.003). For assessor 2, there were differences between the two groups for eight of the 34 parameters. As with assessor 1, where
differences were found, polypectomies performed by experts had a higher pass rate than those performed by intermediate experience endoscopists for all the eight parameters.

Table 22. Comparisons of individual DOPyS parameter scores for polypectomy across the Pass/Fail divide given by the two trained assessors

<table>
<thead>
<tr>
<th>Trained Assessor</th>
<th>DOPyS Parameter</th>
<th>DOPyS Score ‘Pass’ Expert Endoscopist Number (%)</th>
<th>DOPyS Score ‘Pass’ Intermediate Endoscopist Number (%)</th>
<th>P-value Fisher’s Exact Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>17/17 (100%)</td>
<td>12/15 (80%)</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>16/17 (94%)</td>
<td>9/15 (60%)</td>
<td><strong>0.03</strong></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>13/17 (76%)</td>
<td>12/15 (80%)</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>11/17 (65%)</td>
<td>13/15 (87%)</td>
<td>0.23</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>12/16 (75%)</td>
<td>7/13 (54%)</td>
<td>0.27</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>14/16 (88%)</td>
<td>10/13 (77%)</td>
<td>0.63</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>15/17 (88%)</td>
<td>5/15 (33%)</td>
<td><strong>0.003</strong></td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>14/17 (82%)</td>
<td>14/15 (93%)</td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>15/17 (88%)</td>
<td>6/15 (40%)</td>
<td><strong>0.008</strong></td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>16/17 (94%)</td>
<td>9/15 (60%)</td>
<td><strong>0.03</strong></td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>17/17 (100%)</td>
<td>12/15 (80%)</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>17/17 (100%)</td>
<td>9/12 (75%)</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>15/17 (88%)</td>
<td>8/15 (53%)</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>14/15 (93%)</td>
<td>6/13 (46%)</td>
<td><strong>0.01</strong></td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>16/17 (94%)</td>
<td>4/27 (27%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>17/17 (100%)</td>
<td>9/15 (60%)</td>
<td><strong>0.006</strong></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>17/17 (100%)</td>
<td>8/15 (53%)</td>
<td><strong>0.002</strong></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>17/17 (100%)</td>
<td>12/15 (80%)</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>11/11 (100%)</td>
<td>7/9 (78%)</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>11/11 (100%)</td>
<td>8/9 (89%)</td>
<td>0.45</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>13/13 (100%)</td>
<td>5/15 (33%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>13/13 (100%)</td>
<td>13.15 (87%)</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>10/14 (71%)</td>
<td>1/15 (7%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>13/13 (100%)</td>
<td>7/15 (47%)</td>
<td><strong>0.002</strong></td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>13/13 (100%)</td>
<td>9/15 (60%)</td>
<td><strong>0.02</strong></td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>12/12 (100%)</td>
<td>6/11 (55%)</td>
<td><strong>0.01</strong></td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>14/14 (100%)</td>
<td>8/10 (80%)</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>7/9 (78%)</td>
<td>2/5 (40%)</td>
<td>0.27</td>
</tr>
</tbody>
</table>
6.3.4 Overall DOPyS scores for polypectomies scored by two untrained assessors

This analysis compared the overall scores for polypectomy performed by expert and intermediate group of endoscopists, as scored by the two untrained assessors. The results are summarised in Table 23. The figures presented are the number and percentage of polypectomies with each score (either 1-4 or across the pass/fail divide) for each of the two groups (experts and intermediates). The results of the analysis show that the untrained assessors were unable to differentiate between polypectomies performed by expert and intermediate endoscopists as there was no significant difference in overall scores for polypectomies performed by the two groups of endoscopists. However, there was a difference between the two groups for assessor 4 when only the individual scores (1,2,3 or 4) was considered. This assessor gave higher scores to the expert group, with 42% of the expert group scoring 4, compared to nobody in the intermediate group (p=0.007). However, when the scores (as marked by assessor 4) were analysed across the pass/fail divide, the results were not found to significantly vary between the two group of endoscopists. The kappa value for inter-assessor agreement was 0.07.
Table 23. Comparison of overall DOPyS scores for polypectomies performed by the expert and intermediate endoscopists scored by the two untrained assessors.

<table>
<thead>
<tr>
<th>Untrained Assessor</th>
<th>Overall DOPyS Score</th>
<th>Polypectomies performed by Expert Endoscopists Number (%)</th>
<th>Polypectomies performed by Intermediate Endoscopists Number (%)</th>
<th>P-value Fisher’s Exact Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Score 1</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 2</td>
<td>6 (35%)</td>
<td>4 (27%)</td>
<td>0.84</td>
</tr>
<tr>
<td></td>
<td>Score 3</td>
<td>10 (59%)</td>
<td>11 (73%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 4</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fail (Score 1 or 2)</td>
<td>6 (35%)</td>
<td>4 (27%)</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td>Pass (Score 3 or 4)</td>
<td>11 (65%)</td>
<td>11 (73%)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Score 1</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 2</td>
<td>1 (6%)</td>
<td>4 (29%)</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>Score 3</td>
<td>9 (53%)</td>
<td>10 (71%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Score 4</td>
<td>7 (42%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fail (Score 1 or 2)</td>
<td>1 (6%)</td>
<td>4 (29%)</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>Pass (Score 3 or 4)</td>
<td>16 (94%)</td>
<td>10 (71%)</td>
<td></td>
</tr>
</tbody>
</table>
6.4 Discussion

Numerous technical skills assessment tools have been utilised across a broad range of surgical specialities [163-170]. However, there is paucity of literature on specific training in the use of these tools or training in assessment. It is well known that examiner variability can reduce the validity of an assessment process [152]. It is therefore necessary to provide training in assessment, and feedback to assessors in order to ‘align’ scoring. Structured assessments require training and the General Medical Council (GMC) in the UK recommends specific training for all Objective Structured Clinical Examination (OSCE) examiners prior to assessing students. There is no such guidance or evidence for training in assessment in endoscopy. For the purpose of this study, the two assessors already familiar with the DOPyS underwent a detailed ‘training’ session. In this session, scores of ‘1’, ‘2’, ‘3’ and ‘4’ for each parameter were clearly explained with the help of descriptive statements (descriptors). Utilising polypectomy videos, the two assessors were trained to assess the individual steps (using the parameters) of the polypectomy procedure and differentiate between a polypectomy performed ‘competently’ (i.e. scores ≥3 for overall competency) and sub-optimally (i.e. scores ≤2 for overall competency). The clearly defined marking scheme of the DOPyS attempted to minimise subjectivity in the assessments made. For the DOPyS to be used as a summative assessment tool, it should be able to differentiate between safe, competent technique and polypectomy performed sub-optimally (i.e. the pass/fail divide). The training session aimed to provide the two assessors with a clearer understanding of how to arrive at this conclusion in their assessment, through detailed feedback during and after the training session. On comparison of the overall scores in this study, the two trained assessors could reliably distinguish between polypectomies performed by the expert and intermediate
endoscopists, both when the scores were given on the 1,2,3,4 scale, and also across the pass/fail divide, although the results for assessor 1 across the pass/fail divide were of marginal significance. However, the kappa values for the trained assessors remained low at 0.32, although they did demonstrate better agreement than the non-trained assessors (kappa value 0.07). One of the untrained assessors (assessor 3) scored the polypectomies performed by the intermediate endoscopists higher than the experts, with 73% of the intermediate group scoring 3 in overall competency, compared to 59% for the experts (p=0.84). Similarly, this assessor scored a 2 (sub-optimal performance) for 35% of the polypectomies performed by experts, compared with 27% of those performed by the intermediate endoscopists. The second untrained assessor (assessor 4) could, however, reliably differentiate between the polypectomies performed by the two groups of endoscopists on the 1,2,3,4, scale, but not across the pass/fail divide. The results suggest that specific training in polypectomy assessment using the DOPyS may be required before any reliable inferences can be drawn from the assessment. However, once trained, an assessor can distinguish between a polypectomy performed competently or sub-optimally. The results in this study however, are based on assessor scoring of single polyps performed by the expert and intermediate endoscopists. They need to be interpreted with caution as data from stalked polyps could not be assessed due to inadequacy of numbers. The results of this study, therefore apply only to sessile lesions. To determine an individual endoscopist’s competence level, a wider range of cases from the same endoscopist are likely to be needed to provide a spread of polyps and technique. Studies are currently on-going to assess this in more detail.
6.5 Conclusion

This study forms part of the validation process for the DOPyS and is limited by the small number of participants and polyps. However, it does suggest that trained assessors using the DOPyS can reliably distinguish between polypectomies performed by independently practicing endoscopists of varying experience. Further, large-scale validation studies are required to strengthen the evidence-base for this novel assessment tool. The DOPyS will be incorporated into the current National Bowel Cancer Screening Accreditation (BCSA) process in England. Prior to its incorporation into this high-stakes assessment process, training in the use of DOPyS has been carried out for all the Bowel Cancer Screening assessors in England. DOPyS has also been incorporated into the National Joint Advisory Group for Gastrointestinal Endoscopy Training System (JETS) in the UK, and demonstration of competence in polypectomy is now mandatory for achieving full certification in colonoscopy.
Chapter 7:

DOPyS Training for Bowel Cancer

Screening Assessors
Chapter 7: DOPyS Training for Bowel Cancer Screening Assessors

7.1 Background and Aim

The direct observation of polypectomy skills (DOPyS) assessment tool comprises a polypectomy specific check-list along with a global rating scale, and was originally developed to test competency in polypectomy skills in the bowel cancer screening accreditation (BCSA) process [104]. The bowel cancer screening (BCS) lists are performed by accredited endoscopists and comprise of screenees who are faecal occult blood test (FOBT) positive. Based on the results of the initial bowel cancer screening pilots [75], it is expected that approximately 50% of these patients would have pathology (40% polyps, 10% cancers). In order to reduce incidence of colorectal cancer, it is essential that polyps are removed safely, competently and completely, with minimal risk to the patient. The current BCSA process, however, does not include assessment of polypectomy skills in any detail. To incorporate the DOPyS as an assessment of polypectomy competency into this high stakes assessment process, adequate measures to train the assessors must be in place in order to reduce assessor variability and make assessments more robust. Evidence suggests that examiner training improves the reliability of an assessment process [171].

Chapters 4-6 have described the development and validation of the DOPyS for assessing both small and large polyps, as well as its ability to distinguish between endoscopists of varying ability. Chapter 6 has highlighted the need for training assessors prior to meaningful scoring.
7.2 Training the Bowel Cancer Screening assessors

7.2.1. DOPyS training days

All bowel cancer screening assessors across England were invited to attend one of two one-day DOPyS training workshops. The objectives of the DOPyS training were:

1. To familiarise assessors with the development of and background to the DOPyS framework
2. To be able to use the DOPyS to assess polypectomy skills in the context of Bowel Cancer Screening accreditation
3. To align opinions of experienced endoscopists in acceptable polypectomy technique
4. To understand the descriptors behind the marking scheme.

Of the 31 screening assessors in England, 30 attended either of the workshops. In both workshops, the assessors were first asked to provide a brief introduction along with previous examining experience. This was followed by a plenary overview of the DOPyS and its grade descriptors (explicit statements describing each of its parameters, outlining what standards are expected for each of the scores ranging from 1 to 4). The assessors were then shown polypectomy videos submitted by bowel cancer screening accredited endoscopists, which were used in the initial DOPyS validation study. The assessors were divided into 3 or 4 groups of four. Discussion in the groups was facilitated by a member of the working group that had scored the videos for the original validation study. In this session, the assessors were asked to score a number of polypectomy videos showing a range of polyp sizes and morphology performed by different endoscopists. The aim of this session was to
provide an opportunity for the assessors to score polypectomies independently using the DOPyS, as well as to try and align opinions through explicit feedback and discussion. Options on how best to incorporate the DOPyS into the BCSA process were also discussed and any practical difficulties in its implementation were highlighted.

### 7.2.2. Polypectomy videos

The assessors were shown, and asked to score three sets of videos using the DOPyS: Sets 1, 2 and 3. The first set (Set 1) included five polypectomy videos performed by different endoscopists. These videos showed examples of good and sub-optimal technique (based on the original scoring by the working group). Videos with a wide ‘spread’ of scores were also identified and included in the first set, so as to generate discussion and align opinions. The assessors were encouraged to identify ‘safe and competent’, as well as ‘sub-optimal’ techniques as this differentiation was thought to be of greatest value in a summative assessment process such as the BCSA.

The second set (Set 2) included five videos performed by one individual endoscopist. There was a dual purpose to showing a number of polypectomies done by the same endoscopist: Firstly, a summative judgment on competency level cannot be made based on one polypectomy alone, as there are a number of factors (variables) that might have influenced the endoscopist’s technique at that particular time, for that particular polyp (e.g. lack of appropriate equipment, patient factors etc.). These variables must be taken into account. A larger number of polypectomies performed by an individual may also provide a range of polypectomy techniques employed
(depending on the morphology, size, site and accessibility of the polyp). Secondly, this provided an opportunity to ‘test’ the ‘2 by 5’ format obtained from the initial validation study. The five polypectomy videos in Set 2 were viewed and scored by 30 assessors over the two training days. However, the primary purpose of the training days was to familiarise the assessors with the DOPyS. They were not designed to enable data collection for validation purposes. The most obvious bias being the inability of the assessors to score strictly independently and impartially, without being influenced by comments or remarks from adjacent scorers.

The third set (Set 3) included four videos performed by a single endoscopist. In addition to the ‘2 by 5’ format, reliability results from the original DOPyS validation study also provided the ‘3 by 4’ format (i.e. if 3 assessors independently scored 4 videos performed by one endoscopist, then the DOPyS scores given would reliably reflect the endoscopist’s competency level).

The assessors were asked to score all the ‘parameters’ in the DOPyS check-list as well as giving Overall Competency Scores (the parameters and overall competency were scored on a 4-point scale with scores greater than or equal to 3 denoting competency).

### 7.3 Workshop outcomes

#### 7.3.1 Acceptability of DOPyS training

Feedback questionnaires were distributed in both the workshops and collected at the end of the day. On a scale of 1 to 10 (where 1 was very poor and 10 was excellent),
the assessors gave a median score of 9 for the quality and relevance of the following sessions: ‘Background to DOPyS’, ‘Introduction of DOPyS into BCSA’, ‘Case Discussion & Scoring’ and ‘Future of DOPyS’ (Table 24).

Table 24. Feedback from Bowel Cancer Screening assessors from the DOPyS training workshops

<table>
<thead>
<tr>
<th>Workshop Sessions</th>
<th>Quality of Sessions (Scale 1--10)</th>
<th>Mean (SD)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background to DOPyS</td>
<td>8.90 (0.94)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>DOPyS Results</td>
<td>8.81 (1.03)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Introduction of DOPyS into BCSA</td>
<td>8.95 (0.92)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>DOPyS and Descriptors</td>
<td>8.71 (1.06)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Case Discussion &amp; Scoring</td>
<td>9.10 (0.89)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Polypectomy Levels &amp; Technique</td>
<td>8.57 (1.40)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Case 5 Scoring &amp; Discussion</td>
<td>9.14 (0.91)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Future of DOPyS</td>
<td>8.81 (1.03)</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Experience (Scale 1--10)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>How did you rate the course overall?</td>
<td>9.18 (0.81)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>How far did it meet your expectations?</td>
<td>9.24 (0.75)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>How much did you enjoy the course?</td>
<td>9.06 (0.90)</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

81% of the assessors in both the workshops thought that the process of scoring polypectomy videos, followed by discussion and feedback, would be useful for all bowel cancer screening endoscopists.

All the assessors felt that the ‘DOPyS training’ days equipped them to assess polypectomy more effectively in the bowel cancer screening assessment process and that the objectives of the workshops were met. Some of the comments received from the attending bowel cancer screening assessors are shown in Box 1.
Box 1. Comments given by the bowel cancer screening assessors at the two DOPyS training workshops held in London and York.

- Enabled reflection on technique
- Gave clarity to assessment process
- Standardisation of process and descriptors
- Highlighted lack of polypectomy training courses
- Encouraged objective thinking
- Interactive discussion challenged current position

7.3.2 Outcomes of collective DOPyS scoring of polypectomy videos

Outcomes from the workshops must be interpreted with caution as they were not designed to be studies, but rather an educational process for DOPyS training. The results are likely to be ‘coincidental’ rather than the product of careful methodology. The crude results did however highlight the following important points, which may inform the process of incorporating the DOPyS into the BCSA.

1. There was generally good agreement amongst the assessors on the pass (overall DOPyS score ≥ 3) fail (overall DOPyS scores ≤ 2) divide with at least 22 of the 30 assessors agreeing in 11 of the 15 polypectomy videos scored.
However, there was also some variability in assessor scoring amongst the three sets of videos seen e.g. in three of the 15 videos scored, 66% of the assessors thought the polypectomy was performed adequately (i.e. gave a score of 3 or more in the Overall Competency), whereas the other third gave a score of 2 or less for the same polypectomy videos indicating suboptimal performance. Possible explanations for this might include variability in levels of difficulty of the polyps and less experience amongst this group of assessors compared with the original working group who developed the DOPyS over a period of time.

2. Crude data analysis of the DOPyS individual parameter scores suggested that some of the parameters influenced the overall competency score obtained by the endoscopist, more than others (these parameters may be called ‘major’). For example, for some pedunculated polyps which were given a score of 3 or 4 in Overall Competency, the majority of assessors scored either a 3 or 4 for the parameter “accurate positioning of the snare on the stalk”. This may imply that this particular parameter was considered by the assessors to be an important discriminatory factor affecting the overall competency score given.

3. All assessors felt it was more representative to score a series of 4/5 videos from the same endoscopist (sets 2 & 3), rather than assessing individual polypectomies performed by different endoscopists (set 1), as recurring themes or patterns could be identified e.g. in a series of videos performed by the same endoscopist (set 3), the assessors identified several cases where the endoscopist failed to position the polyp along the 5 o’clock-11 o’clock axis,
thereby hampering optimal access. This demonstrates a technical point where constructive feedback may be helpful to the endoscopist and shows assessing more than one case may identify persistent or repetitive technical errors.

This exercise highlighted inter-rater variability. Large-scale prospective data collection is required to ‘test’ the inter-rater reliability of the DOPyS. The proposed use of paired assessments using the DOPyS for paired ‘live’ and video assessment in the bowel cancer screening accreditation process offers such an opportunity.

7.4 Summary

The reliability of the DOPyS assessment methodology was established in the initial validation studies. These studies, however, also highlighted variability in assessor scoring and the need for assessor training prior to reliable scoring using the DOPyS. Despite extensive research into the development of assessment tools, there is a deficiency of studies addressing the formal training of assessors. There are no documented selection criteria for endoscopy assessors, but it is assumed that the likely attributes of an assessor would be similar to those of a trainer. In the field of endoscopy, the characteristics of a trainer have been described by C Wells [172], and include interpersonal attributes i.e. the ability to create a learning atmosphere, endoscopy attributes i.e. having the knowledge and skills required, and teaching attributes i.e. the ability to transfer that knowledge and skills to the trainee. However, a good trainer may not necessarily be a good assessor as different sets of skills are required for each discipline (training and assessing), albeit with some overlap. An assessor should have an additional understanding of the assessment process (in this
case, the DOPyS) and the ability to be consistent and impartial in their assessment. Feedback to assessors is important in order to align opinions. The Bowel Cancer Screening Accreditation process in England provides such a feedback to its assessors. Assessor training is feasible, as demonstrated by the assessor feedback obtained from the two training days. Further DOPyS workshops, involving endoscopy trainers from within and outside the Bowel Cancer Screening Programme, are needed to raise awareness of competency requirements for polypectomy, and may help in reducing assessor variability.
Chapter 8: Defining ‘Levels of difficulty’ of Polypectomy
Chapter 8: Defining ‘levels of difficulty’ of Polypectomy

8.1 Background and Aim

Colonoscopy has transgressed from a diagnostic [173] to a therapeutic tool. Endoscopists are now expected to perform polypectomy on a routine basis [109]. However, supportive training and assessment, specific to polypectomy, is yet to be incorporated formally as part of the bowel cancer screening assessment process in the UK.

There are clear, albeit poorly defined differences in the difficulty ‘levels’ of various diagnostic endoscopic procedures, ranging, from oesophagoduodenoscopy to colonoscopy. Similarly, colonic polypectomy can vary in difficulty, depending on polyp morphology and size. The measurement of the degree of difficulty of polypectomy, based on polyp characteristics, has not been previously studied. However, evidence does suggest that large, right colonic polyps are associated with more adverse outcomes [67]. Polypectomy performed on a 2cm flat lesion behind a fold in the ascending colon requires a different set of skills as compared to a 1cm pedunculated polyp in the left colon with easy access. These polyps offer distinctly different challenges to the endoscopist as they are of different ‘levels’ of difficulty. The complications of polypectomy are well documented, even in experienced hands. Colonoscopists inevitably have different levels of competency according to the stage of their training and experience of larger polyps. Relatively few will gain enough experience of larger lesions to remove them safely and completely. In view of this it
is potentially dangerous if a less competent colonoscopist attempts to remove ‘difficult’ lesions. To make the best judgments about whether to remove a polyp, an operator must be aware of the complexity of the lesion they are about to remove and their own level of competency.

Defining a lesion in terms of complexity of excision should help a colonoscopist make the right decision of whether or not to proceed. Furthermore, it has been proposed there be minimum levels of polypectomy competency for different contexts and case mix. For example the high frequency of large and difficult to remove lesions in patients identified by faecal occult blood test (FOBT) screening suggests that colonoscopists scoping these patients should have a higher level of competency than those dealing with symptomatic patients. The converse is true for those offering screening flexible sigmoidoscopy where a lesser level of competency may be all that is required.

To measure the level of difficulty of a polyp, its characteristics have to be quantified. The aims of this study were to identify and classify colorectal polyp characteristics based on expert consensus and to validate a scoring system to predict the difficulty level of colonoscopic polyp excision, thereby creating ‘levels of polypectomy’ competency.

8.2 Methodology

8.2.1 Expert group

A study working group of experienced endoscopists was formed, comprising nine members of UK based endoscopic training and accreditation body-Joint Advisory
Group (JAG) for gastrointestinal endoscopy, British Society of Gastroenterology (BSG) and representation from all the professional bodies that perform Bowel Cancer Screening (BCS) colonoscopy (physicians, surgeons and nurse endoscopists).

**8.2.2 Group discussion and Delphi method**

Consensus by the nine experienced endoscopists regarding the characteristics of a polyp which determine its difficulty level, was sought using two focus group meetings and the Delphi method. The focus group discussions were led by one author (SG) and group members were asked to identify parameters that are likely to increase the complexity of a polypectomy. Answers were categorised and listed on an electronic data base. Using the Delphi method, these lists with characteristics were individually sent by email to the group members and each expert was asked to assign a score ranging from 1 (strongly disagree) to 5 (strongly agree) for each item regarding how likely it increased the complexity of a polypectomy. This process was repeated in a second round but this time the average results and standard deviations from the previous round were displayed to the experts. This process intended to encourage experts to reflect on their previous decision and the opinion of their peers [174]. A simple scoring system was devised using the defining characteristics (parameters) as determined by the group. The scores for each parameter were weighted based on the relative importance the group assigned to each parameter. The same group of experts was then used to individually rate each possible combination of parameters with regards to a complexity level. This resulted in four levels of difficulty, each with a range of scores as determined by the working group rating.
8.2.3 Reliability of the scoring system

The scoring system (with four difficulty levels and a range of scores defining each level) was validated by two very experienced endoscopists with a special interest in advanced endoscopy. Both expert endoscopists independently viewed 24 polypectomy videos. The videos incorporated only the endoscopic view and were edited to show only the size and morphology of the polyp but not the polypectomy itself. The expert endoscopists were informed about the site of the polyp in the colon as this could not be determined from the endoscopic view. The 24 videos included six examples of each of the four levels, arranged in random order. Both endoscopists had to assign a score to each polyp using the new scoring system as well as assigning a difficulty ‘level’ to each polyp. The polyp scores and difficulty levels as assigned by the two experts were compared using interclass correlation and Cohen’s kappa, respectively.

8.3 Results

8.3.1 Focus group discussion and Delphi method

Three parameters were identified by the group as being most relevant for determining the difficulty level of a polyp (Table 25). These were site (S), morphology (M) and size (S). In two Delphi rounds, the range for each of these polyp parameters was determined. The polyp could either be left or right sided (two variables). It could be pedunculated, sessile or flat (three variables) and of varying size. The group agreed on the following cut-offs for size: <1cm, 1-1.9cm, 2-2.9cm, 3-3.9cm or >4cm (five variables). Each variable was assigned a score (Table 26). The group was then asked
to look at all possible combination of the variables (two for site, three for morphology and five for size, giving a total of 30 ‘scenarios’) and assign a level to each scenario. Using the scoring system, each level (as determined by the group response to the scenarios) was assigned a range of scores (Table 27). As polyp size is one of the key factors in determining the difficulty of a polypectomy, it was weighted higher than the other factors.

Table 25. Working group response using Delphi technique

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>AVERAGE SCORE</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you feel site, size and morphology of a polyp is useful to help define the level of difficulty?</td>
<td>4.75</td>
<td>0.46</td>
</tr>
<tr>
<td><strong>Level 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should Level 1 polyps be &lt;1cm in size?</td>
<td>4.50</td>
<td>0.53</td>
</tr>
<tr>
<td>Can Level 1 polyps be right or left sided?</td>
<td>3.38</td>
<td>1.60</td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Left sided lesions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should Level 2 polyps include pedunculated lesions&lt;3cm in size?</td>
<td>3.44</td>
<td>1.51</td>
</tr>
<tr>
<td>Should Level 2 polyps include sessile lesions&lt;2cm in size?</td>
<td>3.44</td>
<td>1.42</td>
</tr>
<tr>
<td><strong>Right sided lesions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should Level 2 polyps include pedunculated and sessile lesions&lt;2cm</td>
<td>2.67</td>
<td>1.58</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Left sided lesions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should Level 3 polyps include pedunculated lesions&gt;3cm in size?</td>
<td>3.63</td>
<td>1.69</td>
</tr>
<tr>
<td>Should Level 3 polyps include sessile lesions&gt;2cm in size?</td>
<td>3.75</td>
<td>1.28</td>
</tr>
<tr>
<td><strong>Right sided lesions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should Level 3 polyps include pedunculated and sessile lesions&gt;2cm</td>
<td>3.63</td>
<td>1.41</td>
</tr>
<tr>
<td><strong>Level 4</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Should Level 4 polyps include any lesion &gt;5cm?</td>
<td>4.44</td>
<td>1.01</td>
</tr>
<tr>
<td>Any polyp with difficult access (clamshell distribution, peri-appendicular, peri-dicerticular, extending into I-C valve) ?</td>
<td>4.56</td>
<td>0.53</td>
</tr>
<tr>
<td>Should Level 4 polyps include all LST &gt;3cm?</td>
<td>3.89</td>
<td>1.54</td>
</tr>
<tr>
<td>Should Level 4 include residual polyps on scars?</td>
<td>3.78</td>
<td>1.48</td>
</tr>
</tbody>
</table>
**Table 26.** Scoring system for determining the difficulty level of a polyp

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;1 cm</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>1-1.9 cm</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2-2.9 cm</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>3-3.9 cm</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>&gt;4 cm</td>
<td>9</td>
</tr>
<tr>
<td><strong>Morphology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pedunculated</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Sessile</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Flat</td>
<td>3</td>
</tr>
<tr>
<td><strong>Site</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Left</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td>2</td>
</tr>
<tr>
<td><strong>Access</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Easy</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Difficult</td>
<td>3</td>
</tr>
</tbody>
</table>

**Table 27.** Range of scores for each polyp level

<table>
<thead>
<tr>
<th>Polyp Level</th>
<th>Range of Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>4-5</td>
</tr>
<tr>
<td>Level 2</td>
<td>6-8</td>
</tr>
<tr>
<td>Level 3</td>
<td>9-12</td>
</tr>
<tr>
<td>Level 4</td>
<td>&gt;12</td>
</tr>
</tbody>
</table>
8.3.2 Reliability of the scoring system and difficulty levels

Two experts independently saw 24 polyp videos of varying difficulty ‘levels’ and assigned a score along with a ‘level’ to each video. Figure 22 is a scatter plot comparing the raw scores given by the two experts (1 and 2) for each video. The inter-class correlation coefficient (ICC) was 0.938, suggesting a high level of inter-rater reliability. Table 28 compares the levels assigned by experts 1 and 2. The results for levels 1 and 2 demonstrated 100% agreement. There were only two cases rated as level 3 by expert 1 and level 4 by expert 2. This results in an inter-rater reliability (Cohen’s kappa) of $\kappa=0.888$.

Table 28. Comparison of polyp levels assigned by the two experts for the 24 videos viewed to establish reliability of the scoring system

<table>
<thead>
<tr>
<th>Levels (Expert 1)</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levels (Expert 2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
</tbody>
</table>
Figure 22. Scatter plot of raw scores assigned to polyp videos by two experts.

Inter-class correlation coefficient (ICC) of 0.938
8.4 Discussion

The Munich Polypectomy Study [67] analysed 4000 snare polypectomies across 13 institutions and performed multivariate regression analysis to determine risk factors for polyp related complications. The study results demonstrated that polyp size and right sided location were associated with a higher complication rate. The authors concluded that polyps larger than 1cm in the right colon or 2 cm in the left colon carried an increased risk of complications. Applying those cut-offs to the present study results, using our scoring system, right sided lesions greater than 1cm in size or left sided lesions greater than 2cm in size would score a minimum of 8 points. According to the Munich study, anything above this cut-off would qualify as high risk. Similarly, any polyp which scores above 8 points in this study would be deemed a relatively difficult (difficulty level 3) polyp. It is expected that the majority of bowel cancer screening colonoscopists should be able to manage level 3 polyps competently.

The scoring system and polyp levels were validated by two specialist endoscopists. This could possibly have skewed the scoring towards an expert level of ability. As an example, both experts assigned a 3cm sessile, left sided polyp with easy access (giving a score of 11), to level 3. However, it is acknowledged that not all colonoscopists would be able to manage a lesion of this size and morphology competently. Whether or not a particular endoscopist opts to perform polypectomy on this type of lesion, may depend on other individual or situation specific factors such as experience, technical ability and availability of equipment. The scoring system may then serve as a guide alongside the above mentioned factors. It is acknowledged that it is not applicable under all circumstances for all endoscopists, but may help define standards for each level. Further, large-scale, prospective validation by less experienced is required to strengthen the reliability of this new scoring system.
Intuitively, both experts agreed on level 1 and 2 polyps. However, for the more difficult lesions, there was disagreement in two cases, which were rated as level 3 by expert 1 (i.e. could be performed by most screening endoscopists), and level 4 by expert 2 (i.e. only to be performed by specialist endoscopists). This variation in assigning levels may be explained by differences in individual experience or approach to polypectomy. However, it highlights the fact that individual judgement should be used in conjunction with the polyp score on a case to case basis.

8.5 Conclusion

This study is the first attempt in world literature to devise a simple scoring system to determine the difficulty level of a polyp. It defines and quantifies easily measurable characteristics which determine the difficulty of a particular polypectomy. This, in turn, may help to stratify polypectomy ‘service levels’ and allocate resources to reflect the four levels of difficulty.
Chapter 9: Discussion
Chapter 9: Discussion

9.1 Summary

This thesis aims to highlight the volume of colonic polypectomy performed both in and out of the bowel cancer screening programme in England. It highlights the lack of agreed standards and describes a novel structured method of assessment. It outlines the history of polypectomy, polyp classification, the variability in polypectomy techniques amongst endoscopists, and associated complications. The importance of large volume polypectomy is discussed in Chapters two and three. The thesis emphasises the importance of training and competency assessment in polypectomy and provides a structure which may improve polypectomy outcomes. Some of these aspects are discussed in further detail below.

9.2 Large-scale polypectomy data

9.2.1 Hospital Episode Statistics (HES) polypectomy data

Chapter two details polypectomy data on a national level from the HES database to assess trends in endoscopic polypectomy. It assesses the number of patients undergoing polypectomy across all English NHS trusts between 1997 and 2007. It also examines the variation in volume between different NHS trusts and analyses polypectomy related 28-day re-admission and 30-day mortality rates.

Over the study period, approximately 286,000 patients were given a primary diagnosis of a benign polyp. The HES database does not allow quantification of the number of polyps removed (or found) per endoscopic session. The actual number of polyps diagnosed over the study period is therefore likely to be greater than the above figure indicates. Technological advances in the field of optical endoscopic diagnosis, more
accurate coding, and improvements in training, may have contributed to the 50% rise in the number of patients diagnosed with benign polyps, and a significant reduction in the number of polyps diagnosed as ‘other’ over the study period.

28-day re-admission rates for those patients who had undergone endoscopic polypectomy were not significantly associated with unit case volume, indicating that despite performing significantly more procedures, the high volume tertile centres did not experience more endoscopy related re-admissions. This may possibly reflect concentration of endoscopic expertise in these centres, along with careful patient selection. On the other hand, the wider range of re-admission rates seen in the lower volume tertile units may have been related to operator inexperience.

9.2.2. Bowel Cancer Screening data

The national screening programme for bowel cancer began in England in October 2006. Over the period reviewed, more than 36000 BCS procedures have been performed nationally but no comprehensive data set has yet been published. Chapter three reports the St. Mark’s bowel cancer screening experience over the first 35 months of screening. It details aspects of the screening programme, patient outcomes, the performance of individual screening colonoscopists, complications encountered during the screening process, the cancer characteristics as well as describing surveillance procedure outcomes.

Over the period reviewed, more than 1200 colonoscopies were performed by the five accredited endoscopists with excellent completion rates, which were higher than the BSG Endoscopy Committee quality and safety recommendation of 90% completion rates. The ADR (as calculated by the BCSS), and polyp detection rate (PDR) are calculated using different denominators and require cautious interpretation. For
screening, an individual endoscopist’s adenoma detection rate (ADR) was calculated using the number of polyps removed, but not necessarily retrieved for histology. The screening service assumes that each polyp removed is an adenoma if histology is not available. This figure is derived from all colonoscopy cases done by the endoscopist, including additional and surveillance procedures. The polyp detection rate of 50%, is based on all index procedures in the screening programme and includes CT colonography (approximately 80% of which showed no pathology) and flexible sigmoidoscopies. This figure does not include additional or surveillance procedures, and is therefore lower than the ADR.

Colonoscopy remains the gold standard for diagnosis and therapy within the lower gastrointestinal tract. It is however, an invasive test with recognised complications particularly in therapeutic procedures. The incidence of polyps, and hence the need for therapy is higher in bowel cancer screening as compared to the symptomatic population. The current national bowel cancer screening patient information leaflets quote a ‘heavy’ bleeding risk of 1 in 150 and that of perforation as 1 in 1500. Overall, out of the 1200 procedures performed in this centre, there were 13 (1%) adverse events. This compares favourably to BCS colonoscopy related complication rates across London (1.8%). Less than 1:500 patients undergoing polypectomy required a blood transfusion. Overall bleeding risk (including small bleeds without transfusion) was approximately 1:80 for patients requiring polypectomy. Perforation risk was approximately 1:1200 in patients undergoing colonoscopy and about 1:600 in patients requiring polypectomy. The reported perforation rate for patients undergoing therapeutic colonoscopy in the London hub is 1.95:500 patients. No patients undergoing colonoscopy in our analysis required emergency surgery or prolonged
admission, with no colonoscopy related mortality. These figures were comparable to other studies.

9.3 Development and validation of competency assessment in polypectomy

9.3.1 Development and initial validation of DOPyS
The Directly Observed Procedural Skills (DOPS) form devised by the Joint Advisory Group (JAG) for Gastrointestinal Endoscopy in the UK is currently the only endoscopic assessment tool available for both diagnostic and therapeutic procedures [93]. However, it does not assess polypectomy skills in any detail. The technical skill required for a therapeutic procedure such as polypectomy is clearly different to that for a diagnostic colonoscopy. Therefore the assessment of technical skills for diagnostic and therapeutic procedures should also be distinct and clearly defined. Chapter 4 describes the development of an assessment tool for polypectomy skills. The Direct Observation of Polypectomy Skills (DOPyS) assessment tool was designed to assess a wide range of polypectomy techniques used in day to day practice, from cold snaring a diminutive lesion to EMR, across a range of difficulties. The tool was developed through a series of interviews with highly experienced endoscopists and its reliability had to be determined prior to any training in its use. Ideally, an assessment should be matched against level of difficulty of the procedure being assessed. However, quantification of the level of difficulty of a polypectomy had never been attempted prior to the study in Chapter 8. The DOPyS was not
designed for this purpose. The next stage in its development will involve conjunctive use with polypectomies of varying levels of difficulty.

The DOPyS analysis showed that the majority of the assessors agreed across the pass/fail divide in 98% of the polypectomies. Whereas this study was not designed or powered to judge the competency of the individual, polypectomies submitted by fully accredited bowel cancer screening endoscopists were deemed to have been suboptimally performed in 17% cases. The study also highlighted variability amongst assessor scores. It is recognised that examiner variability can reduce the validity of an assessment process. With other variables being comparable in this study, two assessors stood out as either being lenient (8% polypectomies deemed suboptimal) or more stringent in their marking (43% cases deemed to have been suboptimally performed). Possible reasons for examiner variability could be lack of standardised formal training in polypectomy assessment amongst assessors, lack of experience of video assessment or a genuine difference in opinion as to what is competent technique (i.e. subjectivity). To address these issues, the assessors for this study were selected on the basis of their expertise in the field of polypectomy and were all regular endoscopy trainers. Not all, however, were bowel cancer screening accreditors. In addition, the working group had opportunities to practice video scoring using the DOPyS prior to study assessment. It is therefore possible that examiner variability in this study was largely due to difference in opinion regarding the competent completion of a procedure. This may partly be due to the non-standardisation of polypectomy criteria, and although there was broad agreement amongst the assessors, they disagreed on issues such as suitability of the polypectomy technique used by endoscopists. BCS accreditors in the English BCS accreditation process are given feedback on their relative stringency or leniency- the ‘hawk-dove index’. Introduction
of polypectomy assessment should involve training and feedback to assessors to minimise variation in scoring due to assessor subjectivity.

An assessment process should be feasible and have educational impact. If the objective of a national BCSP is to reduce incidence and mortality of colorectal cancer (given the fact that it is well established that polypectomy reduces the incidence of colorectal cancer), emphasis should be placed on the objective assessment of polypectomy skills of a screening endoscopist to ensure they perform safely and competently. The current $2 \times 5$ model proposed by the G-theory (2 assessors to independently score 5 polypectomy videos performed by a single endoscopist) reliably reflects the endoscopist’s competence and lends itself readily to the current BCSA process. The polypectomy competency of a potential screening endoscopist may be determined by assessing un-selected polypectomy videos performed by the endoscopist. To reduce assessor variance, the BCS assessors will need training in video-assessment using the DOPyS prior to any implementation and potential screeners will need to be familiarised with the assessment method before being tested. The roll-out of the DOPyS and incorporation into the current BCSA process is planned as a phased process.

9.3.2. Construct validity of DOPyS

The DOPyS is a novel tool designed specifically for the assessment of technical skills in polypectomy. Any such assessment must be able to distinguish reliably between practitioners of different skill levels (construct validity). Chapter four describes the feasibility, content validity and reliability of the DOPyS in very experienced endoscopists performing bowel cancer screening. Chapter six determines the construct validity of the DOPyS which was performed using polypectomy videos as a feasible
method both for the study as well as eventual use in practice. The results suggested that only assessors familiar with (and trained in) the DOPyS could reliably distinguish between the expert and non-expert endoscopists.

Procedure-specific checklists (the individual DOPyS parameters), though less reliable than the global score (overall competency), have a place in formative assessment and for providing structured feedback. The ‘trained’ assessors could reliably distinguish between polypectomies performed by endoscopists of different experience on the basis of a number of different parameters. These factors were deemed important by the assessors for safe and competent polypectomy and are likely to be the discriminant factors in polypectomy performed competently or sub-optimally. This may be used as a template for training and in providing structured feedback to trainees.

One of the limitations of this study is the non-standardisation of polypectomy skills of the expert and intermediate level endoscopists. The intermediate level endoscopists, though practicing independently, did not attempt removal of large or complex polyps unsupervised, in the interest of patient safety. The experts, however, performed polypectomy on a wider range of polyp sizes. All of the 15 polyps removed by the intermediate endoscopists were less than 10mm in size, whereas 3 of the 17 polyps removed by the experts were greater than 10mm (with the largest polyp measuring 45mm). This may have influenced scoring by the assessors, who, though blinded, may have been able to infer the endoscopist’s experience, based on the difficulty of polypectomy attempted. All four assessors, however, reviewed the same polypectomy videos and only the trained assessors could reliably distinguish between polypectomies performed by the two groups of endoscopists. The DOPyS is designed to be able to assess polyps of varying sizes and further work to validate the DOPyS in advanced lesions is underway.
9.4. Defining levels of polypectomy difficulty

There is recognised variability in polypectomy techniques [14] depending on the site, size and morphology of the polyp. These polyp dependent variables influence the difficulty of a polypectomy procedure. However, polypectomy is also dependent on factors other than polyp characteristics, such as the endoscopist’s technical ability, or patient co-morbidities. The purpose of this study was to define and devise an easily reproducible scoring system which quantifies polyp characteristics and links them to service provision. The assigning of scores to polyps, and creation of levels, may help endoscopists decide when not to attempt to remove a particularly challenging polyp. It is not meant to discourage endoscopists operating at a particular level to attempt more complex polypectomy, but to make them aware of the increased risks of such lesions. This may help to streamline endoscopic referral services and reduce complications.

There was a high degree of inter-rater agreement amongst the two expert endoscopists with regards to polyp scores as well as polyp levels. This demonstrates that the experts generally agreed on the expected level of competency required for each polypectomy difficulty ‘level’. This may help target training and assessment of polypectomy skills at a particular level. The high inter-rater agreement for the scores assigned to each polyp also illustrates the fact that the scoring system was feasible and reliable.
9.5. *Training in polypectomy*

As previously mentioned, endoscopy trainees in England now have to demonstrate competency in polypectomy skills prior to achieving accreditation in colonoscopy. The polypectomy skills are assessed using the DOPyS as described in chapter four. Currently, however, formal polypectomy training is not mandatory for UK endoscopy trainees. Trainers responsible for trainees may themselves need support in new polypectomy assessment methodology to ensure reliability. Training programmes and courses such as the Train the Colonoscopy Trainer (TCT) course may need revision to specifically include training in polypectomy competencies. Endoscopy courses providing training in polypectomy techniques which utilise animal models, require further development to ensure the models have lesions which are realistic and can represent the variety of pathology encountered in day to day practice, but this will not replace supportive, well structured, supervised training in patients. Units should have regular audit meetings to review any adverse events and the circumstances surrounding them, to ensure learning.

9.6. *Future Directions*

This thesis emphasises the relevance and importance of structured training and assessment of polypectomy skills. One of the factors determining competent polypectomy is the technical skill of the endoscopist. These skills may be assessed using the DOPyS, which has been shown to be a reliable assessment tool. However, the initial validation study utilised videos from independently practicing bowel cancer screening endoscopists. Further work, involving a wider range of endoscopists (from
both within and outside the bowel cancer screening programme), assessors and techniques will be required to strengthen the evidence base for this novel assessment method. Variation in polypectomy techniques, and the factors determining the choice of a particular technique over another, have not been previously studied. A decision making analysis, using experienced endoscopists and trainees may help highlight the factors which influence an endoscopist’s choice of polypectomy technique.

The DOPyS is in the process of being incorporated into the bowel cancer screening accreditation process. This will provide an opportunity for ‘live’ polypectomy assessment by two bowel cancer screening assessors and will provide data for validation purposes. Ultimately the benefits of training and assessment in polypectomy need to be measured against outcome data. Prospective DOPyS data collection within the bowel cancer screening programme (in which the key performance indicators of screeners are regularly monitored) may provide such an opportunity. Safe and competent polypectomy, however, requires skills other than technical skills of the endoscopist. Evidence from the aviation industry shows that the majority of adverse events occur not due to deficiencies in technical skills, but due to human errors in communication. The 2004 NCEPOD report ‘Scoping our Practice’ suggests, this is likely to apply equally to gastrointestinal endoscopy. Domain specific non-technical skills (NTS) need to be included within endoscopy training which may allow endoscopists to recognise deficiencies in practice, and improve performance. At regional and national levels, policy leaders need to be clear about processes for endoscopic certification in colonoscopy including polypectomy, the Key Performance Indicators (KPIs), revalidation criteria and QA of training within the wider endoscopy service.
Bibliography


54. Iqbal CW, Cullinane DC, Schiller HJ, Sawyer MD, Zietlow SP, Farley DR. Surgical management and outcomes of 165 colonoscopic perforations from a single institution. *Arch Surg* 2008; 143: 701-706; discussion 706-707


75. Steele RJC. UK Colorectal Cancer Screening Pilot Group. Results of the first round of a demonstration pilot of screening for colorectal cancer in the United Kingdom *BMJ* 2004; 329(7458):133.

76. Lee TJ, Blanks RG, Rutter MD, on behalf of Northern Region Endoscopy Group (NREG), Moss SM, Goddard AF, Chilton A, Nickerson C, McNally RJQ, Patnick J, Rees C on behalf of Northern Region Endoscopy Group (NREG). Efficacy and safety of colonoscopy in the UK NHS Bowel Cancer Screening Programme. *Gut* 2011;60(Suppl 1):A22


116. Peyton JWR. Teaching and Learning in Medical Practice: Manticore; 1998


122. Aggarwal R, Grantcharov T, Moorthy K, Milland T, Darzi A. Toward


130. Moorthy K, Munz Y, Orchard TR, Gould S, Rockall T, Darzi A. An


155. Soetikno R, Kaltenbach T. Dynamic submucosal injection technique. 

156. Mahadeva S, Rembacken BJ. Standard "inject and cut" endoscopic mucosal 
   resection technique is practical and effective in the management of superficial 

   Endoscopic indications for endoscopic mucosal resection of laterally 

   Zanati S, Chen RY, Byth K. Endoscopic mucosal resection outcomes and 
   prediction of submucosal cancer from advanced colonic mucosal neoplasia. 

159. Khashab M, Eid E, Rusche M, Rex DK. Incidence and predictors of “late” 
   recurrence after endoscopic piecemeal resection of large sessile adenomas. 
   Gastrointestinal Endoscopy 2009; 70: 344-9

160. Tsiamoulos ZP, Bourikas LA, Saunders BP. Endoscopic Mucosal Ablation 
   (EMA): a new APC/injection technique to assist complete resection of 
   recurrent, fibrotic colonic polyps (with video). Gastrointest. Endosc. 2011 In 
   press accepted manuscript.

161. Spier BJ, Durkin ET, Walker AJ et al. Surgical resident’s training in 
   colonoscopy: numbers, competency and perceptions. Surg Endosc 

   Prepared by the ASGE Taskforce on Ensuring Competence in Endoscopy. 
   http://www.asge.org/WorkArea34 Site Accessed 15th April 2011


171. Bank AL, Macneill SE, Hall EM, Nadjarian RK, Zaccagnini AV, Lichtenberg PA. More than meets the eye: how examiner training affects the reliability of
the MacNeill-Lichtenberg decision tree in geriatric rehabilitation patients.  


172 Wells C. The characteristics of an excellent endoscopy trainer. *Frontline Gastroenterology* 2010;1:13-18


Publications arising from this research


6. Consistency Between Bowel Cancer Screening Colonoscopists of Varying

7. Surveillance Procedures in the St Mark’S Bowel Cancer Screening Programme.


9. UK National Bowel Cancer Screening Programme: A Tertiary Centre Experience.


11. *Colonoscopic Adverse Events in a UK Based Bowel Cancer Screening Centre.


## Appendix 1  Direct Observation of Polypectomy Skills (v.1)

### Direct Observation of Polypectomy Skills (DOPyS)

<table>
<thead>
<tr>
<th>Colonoscopist: ………………</th>
<th>Case ID:……….</th>
<th>Date ……/….. /……</th>
<th>Assessor………………</th>
</tr>
</thead>
</table>

| Scale: | 4 - Highly skilled performance | 3 - Competent & safe throughout procedure, no uncorrected errors | 2 - Some standards not yet met, aspects to be improved, some errors uncorrected | 1 - Accepted standards not yet met, frequent errors uncorrected | N/A - Not applicable/Not assessable |

The underlined parameters can only be assessed during ‘live’ polypectomy

### Overall Competency at polypectomy:

<table>
<thead>
<tr>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
</table>

### Polyp Level

<table>
<thead>
<tr>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
</table>

### Was it appropriate to remove this polyp at index colonoscopy (i.e. on standard BCS consent)

| YES | NO |

### Polyp size

| ……………..mm |

---

### Generic

- Optimising view of / access to the polyp:
  1. Optimises polyp position
  2. Optimises view by aspiration/insufflation/wash
  3. Determines full extent of lesion (+/- use of adjunctive techniques e.g. bubble breaker, NBI, dye spray etc) if appropriate
  4. Adjusts/stabilizes scope position
  5. Uses appropriate polypectomy technique (e.g. taking into account site in colon)
  6. Checks all polypectomy equipment (forceps, snare, clips, loops) available
  7. Checks (or asks assistant to) snare closure prior to introduction into the scope
  8. Clear instructions to, and utilisation of, endoscopy staff
  9. Checks diathermy settings are appropriate
  10. Photo-documents pre and post polypectomy

### Stalked polyps: Generic, then

- 11. Pre-injects stalk/applies endo-loop/clips prophylactically if appropriate
- 12. Selects appropriate snare size
- 13. Directs snare accurately over polyp head
- 14. Correctly selects en-bloc or piecemeal removal depending on size
- 15. Advances snare sheath towards stalk as snare closed
- 16. Places snare at appropriate position on the stalk
- 17. Mobilises polyp to ensure appropriate amount of tissue is trapped within snare
- 18. Applies appropriate degree of diathermy

### Small sessile lesions / Endoscopic mucosal resection: Generic, then

- 19. Adequate submucosal injection using appropriate injection technique, maintaining views
- 20. Only proceeds if the lesion lifts adequately
- 21. Directs snare accurately over the lesion head
- 22. Correctly selects en-bloc or piecemeal removal depending on size
- 23. Appropriate positioning of snare over lesion as snare closed
- 24. Ensures appropriate amount of tissue is trapped within snare
- 25. Tents lesion gently away from the mucosa
- 26. Uses cold snare technique or applies appropriate diathermy, as applicable
- 27. Ensures adequate haemostasis prior to further resection

### Post polypectomy

- 28. Examines remnant stalk/polyp base
- 29. Identifies and appropriately treats residual polyp
- 30. Identifies bleeding and performs adequate endoscopic hemostasis if appropriate
- 31. Retrieves, or attempts retrieval of polyp
- 32. Checks for retrieval of polyp
- 33. Places tattoo if appropriate
Appendix 2  Direct Observation of Polypectomy Skills (v.2)

Direct Observation of Polypectomy Skills (DOPyS)

Date ……/…../……   Assessor………………   Colonoscopist: …… ………… Case ID:………    Polyp Number………………

| Polyp site: C / AC / HF / TC / SF / DC / SC / R |

Scale: 4  - Highly skilled performance
3  - Competent & safe throughout procedure, no uncorrected errors
2  - Some standards not yet met, aspects to be improved, some errors uncorrected
1  - Accepted standards not yet met, frequent errors uncorrected
N/A - Not applicable/Not assessable

The underlined parameters can only be assessed during 'live' polypectomy

<table>
<thead>
<tr>
<th>Generic</th>
<th>Score</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimising view of / access to the polyp:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Attempts to achieve optimal polyp position</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Optimises view by aspiration/insufflation/wash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Determines full extent of lesion (+/- use of adjunctive techniques e.g. bubble breaker, NBI, dye spray etc) if appropriate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Uses appropriate polypectomy technique (e.g. taking into account site in colon)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Adjusts/stabilises scope position</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Checks all polypectomy equipment (forceps, snare, clips, loops) available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Checks (or asks assistant to) snare closure prior to introduction into the scope</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Clear instructions to and utilisation of endoscopy staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Checks diathermy settings are appropriate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Photo-documents pre and post polypectomy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Stalked polyps: Generic, then | | |
| 11. Applies prophylactic haemostatic measures if deemed appropriate | | |
| 12. Selects appropriate snare size | | |
| 13. Directs snare accurately over polyp head | | |
| 14. Correctly selects en-bloc or piecemeal removal depending on size | | |
| 15. Advances snare sheath towards stalk as snare closed | | |
| 16. Places snare at appropriate position on the stalk | | |
| 17. Mobilises polyp to ensure appropriate amount of tissue is trapped within snare | | |
| 18. Applies appropriate degree of diathermy | | |

| Small sessile lesions / Endoscopic mucosal resection: Generic, then | | |
| 19. Adequate sub mucosal injection using appropriate injection technique, maintaining views | | |
| 20. Only proceeds if the lesion lifts adequately | | |
| 21. Selects appropriate snare size | | |
| 22. Directs snare accurately over the lesion | | |
| 23. Correctly selects en-bloc or piecemeal removal depending on size | | |
| 24. Appropriate positioning of snare over lesion as snare closed | | |
| 25. Ensures appropriate amount of tissue is trapped within snare | | |
| 26. Tents lesion gently away from the mucosa | | |
| 27. Uses cold snare technique or applies appropriate diathermy, as applicable | | |
| 28. Ensures adequate haemostasis prior to further resection | | |

| Post polypectomy | | |
| 29. Examines remnant stalk/polyp base | | |
| 30. Identifies and appropriately treats residual polyp | | |
| 31. Identifies bleeding and performs adequate endoscopic hemostasis if appropriate | | |
| 32. Retrieves, or attempts retrieval of polyp | | |
| 33. Checks for retrieval of polyp | | |
| 34. Places tattoo competently, where appropriate | | |

<table>
<thead>
<tr>
<th>Polyp Size</th>
<th>.........................mm</th>
</tr>
</thead>
</table>

| Overall Competency at Polypectomy: | 4 | 3 | 2 | 1 |


### Appendix 3 (part 1): DOPyS Descriptors-Generic

#### Scale 4: Highly Skilled Performance

1. Ensures good (5-11 o'clock axis) polyp position with no errors. Attempts made at position correction throughout the procedure.
2. Maintains clear polyp views throughout the procedure.
3. Determines the full extent of the lesion, using adjunctive measures where appropriate.
4. Uses most appropriate polypectomy technique safely with no errors.
5. Maintains stable scope position throughout polypectomy. This may involve asking an assistant to hold the scope in position to provide a stable platform for polypectomy.
6. Checks all polypectomy equipment is available and functioning with correct settings prior to the procedure.
7. Checks snare prior to introduction into the scope and ensures that snare is marked appropriately on the snare handle.
8. Maintains effective communication with the staff and addresses patient’s concerns.
9. Checks diathermy settings are appropriate and ensures diathermy equipment is available and working. Ensures pad is attached to patient, foot pedal is accessible, no contraindication to diathermy.
10. Accurately photo documents pre and post polypectomy accurately

#### Scale 3: Competent and safe throughout procedure, no uncorrected errors

1. Maintains 5-11 o'clock axis during procedure with attempts at position correction.
2. Attempts to obtain clear polyp views through aspiration, insufflation and lens wash.
3. Determines the full extent of the lesion, may not use adjunctive measures.
4. Uses appropriate polypectomy technique safely based on size, site and morphology.
5. Adjusts and stabilises scope position prior to polypectomy.
6. Checks polypectomy equipment is available and functioning.
7. Checks snare prior to introduction into the scope and ensures handle is marked.
8. Maintains effective communication either with the staff or patient.
9. Checks diathermy settings are appropriate. Ensures diathermy equipment is available and working. Epad is attached to patient, foot pedal is accessible, no contraindication to diathermy.
10. Photo documents pre and post polypectomy

#### Scale 2: Some standards not yet met, aspects to be improved, some errors uncorrected

1. Does not maintain 5-11 o'clock axis. Few attempts made at position correction.
2. Clear polyp views not maintained.
3. Does not determine or visualise full extent of the polyp or fails to recognise features suggestive of malignancy.
4. Chooses inappropriate polypectomy technique.
5. Scope not stabilised adequately. Little or no attempts made at use of adjunctive techniques.
6. Does not check essential polypectomy equipment is available and functioning prior to the procedure.
7. Does not check snare functioning and marking prior to introduction into the scope.
8. Fails to give clear instructions to endoscopy staff during the procedure or ignores patient concerns.
10. Does not photo document pre and post polypectomy

#### Scale 1: Accepted standards not yet met, frequent errors uncorrected

1. Does not maintain polyp in the optimal position at any time during the procedure.
2. Poor polyp views throughout the procedure with no attempts at correction.
3. No attempts made at determining or visualising full extent of the polyp. Attempts polypectomy on lesions which are unlikely to be endoscopically resectable.
4. Inappropriate polypectomy technique. Uses inappropriate diathermy settings. Uses diathermy or hot biopsy technique unsafely or inappropriately.
5. Unstable scope position throughout procedure with no attempts made at correction.
6. Does not check for any polypectomy equipment.
7. Does not check snare functioning and marking prior to introduction into the scope.
8. Does not communicate with the endoscopy staff or patient throughout the procedure.
9. Makes no attempt to check, or uses inappropriate diathermy settings.
10. Does not photo document
Appendix 3 (part 2): DOPyS Descriptors-Stalked Polyps

**Scale 4: Highly Skilled Performance**

11. Applies prophylactic haemostatic measures (e.g. endo-loop, clips) where appropriate with excellent technique.

12. Always selects snare size appropriate to the polyp.

13. Always steers the snare over the polyp head accurately.

14. Correctly selects en-bloc or piecemeal removal.

15. Advances snare sheath slowly towards stalk as snare is closed gradually

16. Excellent position on stalk with snare, midway between polyp head and stalk base

17. Always mobilises the polyp to tent stalk away from mucosa and contra-lateral wall.

18. Applies appropriate degree of diathermy with no evidence of contra-lateral burns or cutting through too quickly causing bleeding.

**Scale 3: Competent and safe throughout procedure, no uncorrected errors**

11. Applies prophylactic haemostatic measures (e.g. endo-loop, clips, if deemed appropriate) with good technique.

12. Selects appropriate snare size.

13. Steers the snare over the polyp head with reasonable accuracy.

14. Correctly selects en-bloc or piecemeal removal.

15. Advances snare sheath in a controlled fashion towards stalk as snare is closed.

16. Appropriate position on stalk with snare

17. Mobilises the polyp e.g. to tent stalk away from mucosa and contra-lateral wall if necessary.

18. Applies appropriate degree of diathermy. Does not cause contra-lateral burns or cut through too quickly causing bleeding.

**Scale 2: Some standards not yet met, aspects to be improved, some errors uncorrected**

11. Attempts to use prophylactic measures where appropriate but with poor technique and uncorrected errors.

12. Snare size may be inappropriate for polyp size.

13. Multiple attempts at snare positioning over polyp head.


15. Closes snare too rapidly or in an uncontrolled fashion.

16. Poor snare position on polyp stalk

17. Does not attempt to mobilise the polyp prior to diathermy where deemed necessary. Does not check for additional trapped tissue

18. Inappropriate diathermy technique risking either bleeding or burns.

**Scale 1: Accepted standards not yet met, frequent errors uncorrected**

11. Makes no attempt to use prophylactic measures where required.

12. Inappropriately small or large snare size used.

13. Multiple unsuccessful attempts at snare positioning over polyp head.


15. Closes snare too rapidly, cutting/shearing through the polyp stalk.

16. Poor snare position on polyp stalk, either too close to the polyp head, or too close to the base.

17. Makes no attempt to mobilise the polyp prior to diathermy where necessary. Does not check for additional trapped tissue.

18. Uses inappropriate diathermy technique causing either bleeding or burns.
Appendix 3 (part 3): DOPyS Descriptors-Small Sessile Lesions/Endoscopic Mucosal Resection

**Scale 4: Highly Skilled Performance**

19. Accurately injects the submucosa, maintaining excellent views of the lesion
20. Always checks for lifting and only proceeds if the lesion lifts adequately.
21. Always selects snare size appropriate to the polyp.
22. Steers appropriately sized snare accurately over the lesion head with no errors.
23. Correctly selects en-bloc or piecemeal removal depending on size of lesion. Removes piecemeal in as few pieces as possible.
24. Accurately positions snare over lesion as snare closed gradually.
25/26. Always ensures no additional tissue is trapped within snare by gently tenting the lesion away from the mucosa and mobilising the snare.
27. Applies appropriate diathermy with no complications.
28. Always ensures adequate hemostasis prior to further resection.

**Scale 3: Competent and safe throughout procedure, no uncorrected errors**

19. Injects the submucosa, maintaining adequate views of the lesion
20. Only proceeds if the lesion lifts adequately.
21. Selects appropriate snare size.
22. Steers appropriately sized snare accurately over the lesion head with minimal difficulty.
23. Correctly selects en-bloc or piecemeal removal depending on size of lesion.
24. Advances snare sheath in a controlled fashion towards stalk as snare is closed.
25/26. Ensures no additional tissue is trapped within snare by gently tenting the lesion away from the mucosa.
27. Applies appropriate diathermy with no complications.
28. Ensures adequate hemostasis prior to further resection.

**Scale 2: Some standards not yet met, aspects to be improved, some errors uncorrected**

19. Attempts submucosal injection but inadequate views of the lesion obtained.
20. May proceed despite parts of the lesion not lifting and inadequate attempts at further lifting.
21. Snare size may be inappropriate for polyp size.
22. Clumsy steering of snare over the lesion head.
23. Incorrectly selects en-bloc or piecemeal removal, or piecemeal removal in excessive pieces.
24. Closes snare too rapidly or in an uncontrolled fashion.
25/26. Does not ensure that additional tissue is not trapped within snare. Inadequate attempt to tent the lesion away from the mucosa.
27. Inappropriate diathermy technique risking either bleeding or burns.
28. Does not necessarily ensure adequate hemostasis prior to further resection.

**Scale 1: Accepted standards not yet met, frequent errors uncorrected**

19. Does not attempt submucosal injection. Optimal views of the lesion not obtained.
20. Does not check for lifting prior to attempting polypectomy.
21. Inappropriately small or large snare size used.
22. Clumsy steering of snare causing mucosal injury.
23. Incorrectly selects en-bloc or piecemeal removal.
24. Closes snare too rapidly, cutting/shearing through the polyp tissue.
25/26. Does not check for additional tissue trapped within snare prior to applying diathermy. No attempt to tent the lesion away from the mucosa.
27. Applies inappropriate diathermy with bleeding or burns.
28. Does not ensure adequate hemostasis prior to further resection.
## Appendix 3 (part 4): DOPyS Descriptors-Post-Polypectomy

### Scale 4: Highly Skilled Performance

29. Always examines remnant stalk/polyp base thoroughly to check for bleeding and any residual polyp tissue.

30. Identifies and resects any residual tissue accurately.

31. Identifies bleeding and performs adequate endoscopic hemostasis promptly.

32. Retrieves polyp using method appropriate to polyp/s size.

33. Checks for retrieval of entire polyp tissue and confirms retrieval with endoscopy staff.

34. Uses tattooing in the appropriate setting. Raises a bleb at appropriate site prior to switching to appropriate ink. Places appropriate number of tattoos.

### Scale 3: Competent and safe throughout procedure, no uncorrected errors

29. Examines remnant stalk/polyp base to check for bleeding and any residual polyp tissue.

30. Identifies and resects any residual tissue.

31. Identifies bleeding and performs adequate endoscopic hemostasis with satisfactory immediate results.

32. Retrieves, or attempts retrieval of polyp. May not use method appropriate to polyp/s size.

33. Attempts to check for retrieval of polyp.

34. Uses tattooing in the appropriate setting (e.g. high risk polyp size/morphology/method of resection) but may not raise a bleb prior to switching to appropriate ink. May not place appropriate number of tattoos.

### Scale 2: Some standards not yet met, aspects to be improved, some errors uncorrected

29. Makes inadequate attempt to examine remnant stalk/polyp base

30. Does not adequately identify or treat visible residual polyp tissue

31. Inadequately identifies or treats bleeding.

32. Inadequate attempt at retrieval of polyp.

33. Does not check for retrieval of polyp.

34. May not use tattooing in the appropriate setting. Does not raise a bleb prior to switching to appropriate dye. May not place tattoos at appropriate site. Inappropriate depth of ink, risking peritoneal staining.

### Scale 1: Accepted standards not yet met, frequent errors uncorrected

29. Makes no attempt to examine remnant stalk/polyp base

30. Leaves residual polyp tissue behind

31. Does not identify or treat bleeding.

32. No attempts made at polyp retrieval.

33. Does not check for retrieval of polyp with endoscopy staff

34. Does not use tattooing in the appropriate setting. Place tattoos at inappropriate site. Inappropriate depth of ink, risking peritoneal staining.
## Appendix 4: Raw data for analysis of DOPyS scores for p-EMR

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Polyp 1</th>
<th>Polyp 2</th>
<th>Polyp 3</th>
<th>Polyp 4</th>
<th>Polyp 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assessor 1</td>
<td>Assessor 2</td>
<td>Assessor 1</td>
<td>Assessor 2</td>
<td>Assessor 1</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>NA</td>
<td>na</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>NA</td>
<td>na</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>7</td>
<td>NA</td>
<td>na</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>8</td>
<td>NA</td>
<td>na</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>9</td>
<td>NA</td>
<td>na</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>10</td>
<td>4</td>
<td>unclear</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>19</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>20</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>21</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>22</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>23</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>24</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>25</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>26</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>27</td>
<td>NA</td>
<td>NA</td>
<td>4</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>28</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>29</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>30</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>31</td>
<td>NA</td>
<td>4</td>
<td>NA</td>
<td>na</td>
<td>2</td>
</tr>
<tr>
<td>32</td>
<td>NA</td>
<td>not clear</td>
<td>3</td>
<td>not clear</td>
<td>2</td>
</tr>
<tr>
<td>33</td>
<td>na</td>
<td>na</td>
<td>NA</td>
<td>na</td>
<td>NA</td>
</tr>
<tr>
<td>34</td>
<td>NA</td>
<td>not seen</td>
<td>3</td>
<td>NA</td>
<td>not seen</td>
</tr>
<tr>
<td>Overall Competency</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>