Introduction

A successful colonoscopy depends on completeness of the examination and the tolerability to the patient. In spite of sedation, there is great variation in reported cecal intubation rates in routine clinical work [1 - 4]. Refining the technology of colonoscopes is a continuous process to improve the endoscopist’s prospect of painless negotiation of the tortuous course of the large bowel. The biggest challenge is usually passage through the sigmoid colon, but the splenic and hepatic flexures may sometimes also present a problem.

Background and Study Aims: A new colonoscope (XCF-Q160AW prototype, Olympus, Tokyo, Japan) has been developed, designed with an additional passive bending function to ease intubation through the left colonic flexure. In this study we investigated whether this function could be included in a standard colonoscope without jeopardizing general performance, particularly passage through the sigmoid colon.

Patients and Methods: 280 outpatients referred for routine colonoscopy at Telemark Hospital were randomly allocated to colonoscopy with a standard colonoscope (Olympus 140 series) or the XCF-Q160AW prototype. Sedation was given on demand. End points were cecal intubation and the patients’ grading of pain in a questionnaire.

Results: Cecal intubation rates were 85% and 87% for standard and prototype endoscopes, respectively (P=0.57). On-demand sedation was given to nine (7%) and 15 (11%) of the patients, respectively (P=0.17). Of the patients, 256 (85%) returned their questionnaire, with 87 (63%) in the standard group and 109 (77%) in the prototype group reporting that they had experienced ‘no pain/slight pain’ (P<0.001). In a multiple logistic regression analysis, this difference in experienced pain remained statistically significant after adjustment for interendoscopist variation and the use of the endoscope-stiffening function. Two patients in the study, in whom there had previously been several unsuccessful attempts at negotiating the splenic flexure, were successfully examined with the prototype colonoscope.

Conclusion: Examination with the Olympus XCF-Q160AW prototype with a passive bending function caused less pain than use of a standard Olympus 140 series colonoscope, without compromising other endoscope functions for colonic intubation.
passively at an obtuse angle during endoscope insertion. The hypo-
thesis to be tested in the present study was that this endo-
scope would make it easier to negotiate sharp curves, particular-
ly in the flexures, and inflict less pain and discomfort on the pa-
tient.

Materials and Methods

One of the authors (G.H.) was approached by the manufacturer
to provide his opinion about their XCF−Q160AW prototype colo-
noscope. The request was accepted with an expressed wish to
evaluate its performance in a randomized study.

The Endoscope

The Olympus XCF−Q160AW prototype is, in effect, a standard,
variable−stiffness Olympus colonoscope with one exception: Ap-
proximatively 10 cm proximal to the distal, actively bendable tip,
there is a section which bends passively at an obtuse angle in
any direction during insertion (Fig. 1). The intention behind this
modification is to guide the force of insertion more in the desired
direction through sharp bends, particularly to prevent impaction
of the sharply bent distal tip in flexures.

Study Design

A consecutive series of outpatients referred to Telemark Hospital
for colonoscopy were candidates for randomization and exami-
nation with either the prototype colonoscope or one of the hos-
pital standard instruments (Olympus 140 series; Olympus). Pri-
mary end points were the patients’ evaluations of pain and rate
for reaching the cecum.

Examinations were performed by experienced endoscopists
(each having carried out more than 500 colonoscopies). CO2 in-
sufflation was used for all examinations. Endoscopists were dis-
couraged from using the stiffening function of the prototype
since this was not an integrated function of the standard endo-
scope. Each examination started without sedation, but on−de-
mand sedation was allowed as required.

Criteria for reaching the cecum were identification of the ileoce-
cal valve or intubation of the distal ileum. Reasons for not reach-
ing the cecum were categorized into ‘stricture’, ‘poor bowel
cleansing’ and ‘other reasons’. The latter comprised non−me-
chanical/non−obstructive reasons (mainly looping and pain) relat-
edlargely to the technique of insertion.

Pain experienced by the patients during the examination was
rated as ‘no pain’, ‘slight pain’, ‘moderate pain’, and ‘severe pain’, in a validated questionnaire to be filled in on the day after
the examination [5]. Free−text areas in the questionnaire allo-
wed description of any symptoms (e.g. suggestive of complications)
within 24 hours after the examination. At Telemark Hospital the
rate for use of sedation/analgesia is less than 10 % during colo-
noscopy in the outpatient department [5].

The systematic recording of the ‘endoscopist’s impression of loop
formation’, ‘the use of x−ray for visualization of positioning’, and
‘application of the endoscope stiffening function’ was not intro-
duced in the protocol until after first 58 patients had been includ-
ed. Thus, there was systematic recording of these variables in
222 persons (111 in each group).

Power Analysis

For analysis, the pain categories were dichotomized into ‘no or
slight pain’ versus ‘moderate or severe pain’, it being consider-
ed desirable to minimize the size of the latter group (critical factors
being design of endoscope, endoscopist performance, and seda-
tion/analgesia). To estimate the number of individuals needed in
the study, we performed a power analysis based on information
from the first 20 inclusions. We estimated that 130 patients
would have to be included in each arm to detect a 20 % difference
in pain with a statistical power of 90 % (alpha = 0.05). Inclusions
were stopped until after 280 patients, allowing for some non−
compliance in questionnaire replies.

Exclusion Criteria

Patients excluded were pregnant women, persons younger than
18 years, persons unable to comprehend the information given,
and persons requesting sedation before starting the examina-
tion, i.e. those who did not want sedation to be limited to ‘on−de-
mand’ during the course of the examination. Also, patients with
previous colorectal resections were excluded.

Blinding

It was impossible to make this study double−blinded since, to the
expert eye of an endoscopist, the appearance of the prototype
was obviously different from that of the standard type. Patients
were, however, blinded with regard to which type of endoscope
was used.

Statistical Analysis

The chi−squared test was used for statistical analysis of categori-
cal data and Student’s t test for continuous variables (age, time to
reach the cecum). A logistic regression model was applied using
‘no or slight pain’ versus ‘moderate or severe pain’ as the depen-
dent binary variable. Type of endoscope, endoscopist and the use
of endoscope stiffening function were included as categorical
variables. Statistical significance was defined as P < 0.05 using
two−sided tests. The statistical package SPSS 11.0 was used
(SPSS Inc., Chicago, Illinois, USA).

Figure 1 A conventional, endoscope, is shown on the left, and the
prototype XPCF−160AWY endoscope on the right. The direction of
force (A) tends to lodge the actively bent tip of conventional endo-
scopies in the flexure. With the XPCF−160AWY, external pressure tends
to bend the shaft of the endoscope passively at an obtuse angle at
point B, thus facilitating further insertion rather than impaction.
Ethical Considerations
The Regional Ethics Committee approved the study protocol. Written informed consent was obtained from all participants.

Results

There were no technical failures and no complications except for one case of vasovagal reaction that did not require intervention. The two groups were similar regarding age, gender, previous abdominal surgery, and the use of fluoroscopy during the examination (Tables 1 and 2). The cecal intubation rate was similar in the two groups, being 85% and 87% in the standard and prototype groups, respectively (Table 2).

A total of 256 patients (85%) returned the questionnaire. There was a difference between the groups in patients’ perception of pain, as none or only slight pain was reported by 63% in the standard group and 77% in the prototype group (P < 0.001), with no statistically significant difference between the groups regarding the use of on-demand sedation.

Also, the endoscopists’ judgements of loop formation were similar in both groups. There was, however, a slight difference between the groups in the distribution of loops (judged subjectively by the endoscopists), as nearly all loop formations in the standard group occurred in the sigmoid colon, being 48 out of 50 loop events (96%) compared with 37 out of 44 (84%) in the prototype group (P = 0.05).

There was no statistically significant difference between endoscopists in their cecum intubation rate, overall or for each type of colonoscope (data not shown). There was, however, a significant inter-endoscopist variation in the ability to perform examination with no or only slight pain, both for the standard colonoscope (range 47%–85%, P = 0.006) and the prototype (range 57%–89%, P = 0.05). The stiffening function of the prototype colonoscope was applied in 33 out of 111 documented examinations (30%).

In the multiple logistic regression analysis, the beneficial effect of the new prototype colonoscope remained after adjusting for endoscopist and the use of the stiffening function (Table 3).

Two patients deserve particular mention: One was a lady who had undergone three previous attempts at colonoscopy, all fail-

### Table 1 Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Standard (n = 139)</th>
<th>Prototype (n = 141)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women, n (%)</td>
<td>71 (51)</td>
<td>70 (50)</td>
<td>0.81</td>
</tr>
<tr>
<td>Mean age (95% CI)</td>
<td>57 (54–60)</td>
<td>56 (54–59)</td>
<td>0.50</td>
</tr>
<tr>
<td>Previous abdominal surgery, n (%)</td>
<td>36 (26)</td>
<td>38 (27)</td>
<td>0.93</td>
</tr>
</tbody>
</table>

### Table 2 Findings; n (%), unless stated otherwise

<table>
<thead>
<tr>
<th></th>
<th>Standard (n = 139)</th>
<th>Prototype (n = 141)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cecal intubation</td>
<td>118 (85)</td>
<td>123 (87)</td>
<td>0.57</td>
</tr>
<tr>
<td>Time to reach cecum, minutes (median, range)</td>
<td>14 (4–40)</td>
<td>13 (3–36)</td>
<td>0.55</td>
</tr>
<tr>
<td>Patients’ perception of pain during examination No pain/slight pain</td>
<td>87 (63)</td>
<td>109 (77)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Moderate/severe pain</td>
<td>43 (31)</td>
<td>17 (12)</td>
<td></td>
</tr>
<tr>
<td>Missing data on pain</td>
<td>9 (7)</td>
<td>15 (11)</td>
<td></td>
</tr>
<tr>
<td>Fluorescent screen used</td>
<td>41/111 (37)</td>
<td>38/111 (34)</td>
<td>0.76</td>
</tr>
<tr>
<td>Endoscopist impression of loop formation</td>
<td>50/111 (45)</td>
<td>44/111 (40)</td>
<td>0.45</td>
</tr>
<tr>
<td>Use of on-demand sedation</td>
<td>14 (11)</td>
<td>8 (6)</td>
<td>0.17</td>
</tr>
<tr>
<td>Cecal intubation failure</td>
<td>21</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Stricture</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Poor bowel cleansing</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>18</td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>

### Table 3 Crude and adjusted odds ratios (OR) with 95% confidence interval (CI) of inflicting moderate or severe pain during colonoscopy, adjusting for endoscope, endoscopist and the use of endoscope–stiffening function

<table>
<thead>
<tr>
<th></th>
<th>No. of examinations*</th>
<th>Crude OR</th>
<th>95% CI</th>
<th>Adjusted OR</th>
<th>Adjusted 95% CI</th>
<th>P value</th>
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<tr>
<td>Colonoscope</td>
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<td></td>
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<tr>
<td>Standard</td>
<td>130</td>
<td>0.32</td>
<td>0.17–0.59</td>
<td>0.42</td>
<td>0.17–0.81</td>
<td>0.05</td>
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<tr>
<td>Prototype</td>
<td>126</td>
<td>Reference</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoscopist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>99</td>
<td>Reference</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>56</td>
<td>7.18</td>
<td>3.10–16.62</td>
<td>7.55</td>
<td>2.86–19.97</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>C</td>
<td>23</td>
<td>3.89</td>
<td>1.25–11.73</td>
<td>4.16</td>
<td>1.23–14.18</td>
<td>0.02</td>
</tr>
<tr>
<td>D</td>
<td>30</td>
<td>4.45</td>
<td>1.63–12.72</td>
<td>3.70</td>
<td>1.17–11.75</td>
<td>0.03</td>
</tr>
<tr>
<td>E</td>
<td>4</td>
<td>8.90</td>
<td>1.13–37.02</td>
<td>2.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>23</td>
<td>0.85</td>
<td>0.17–3.94</td>
<td>1.10</td>
<td>0.21–8.72</td>
<td>0.91</td>
</tr>
<tr>
<td>G</td>
<td>21</td>
<td>2.09</td>
<td>0.59–67.46</td>
<td>1.66</td>
<td>0.17–16.04</td>
<td>0.66</td>
</tr>
<tr>
<td>Use of endoscope–stiffening function</td>
<td>No 174</td>
<td>0.79</td>
<td>0.26–2.21</td>
<td>0.88</td>
<td>0.24–2.24</td>
<td>0.84</td>
</tr>
<tr>
<td></td>
<td>Yes 27</td>
<td>Reference</td>
<td></td>
<td></td>
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<td></td>
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</tbody>
</table>

* 24 out of 280 patients did not return their questionnaire on pain.
Endoscopist E was dropped out in the statistical adjustment due to low numbers and missing data on endoscope–stiffening function.
ing to reach beyond the splenic flexure. At the most recent attempt she had been heavily sedated, but she still recalled this to have been a terrible experience. Four expert colonoscopists had tried in turn to negotiate the splenic flexure without succeeding. She was now randomly allocated to receive colonoscopy with a standard 140 series endoscope, and 40 minutes were spent trying to negotiate the splenic flexure, using every trick of the trade (apart from sedation), without succeeding. Fluoroscopy verified that the endoscope was impacted in the splenic flexure. The case was recorded as intubation failure. The XCF–Q160AW prototype was then used, and the cecum was reached easily without the use of the stiffening function and still without the use of sedation.

The second patient was a man who had undergone four previous colonoscopies, all with failure to reach the cecum. He was randomly allocated to the prototype group. Again, the cecum was reached without the use of sedation and without using the endoscope–stiffening function.

Discussion

In the present consecutive series of outpatients referred for colonoscopy it was demonstrated that the Olympus XCF–Q160AW prototype colonoscope has an advantage over standard colonoscopes regarding the patients’ comfort during the examination (low degree of pain/discomfort). The cecal intubation rates were similar for both types of endoscopes. Evaluation of the proposed advantage of the prototype in negotiating the splenic flexure was limited to two case reports within the study suggesting an advantage to that effect. It is worth noting that the presence of the additional bending section of the prototype did not increase the likelihood of sigmoid loop formation, but may even have reduced it.

The only difference reaching a statistically significant level was the patients’ perception of pain, showing less pain for patients in the new prototype group. Also, pain was the only variable recorded by a blinded party involved in the study (the patient).

There is, however, a possibility that the technical performance of the endoscopist may have been biased by the awareness of performing using ‘a new tool’ and thus taking more care. The greater interendoscopist variation in the standard group may support this view, where as the tendency towards a shorter time to reach the cecum with the prototype, without more sedation, does not. In the multiple regression analysis, adjustments were therefore made for endoscopist and for use of the design difference which was not blinded (i.e. the endoscope–stiffening function). The statistically significant advantage of the prototype in terms of less pain for the patient retained a borderline significance after these adjustments (Table 3). This may not be an issue in endoscopy centres where sedation is routinely given and a change in practice is not being considered. However, a decrease in the need for sedation may reduce costs and complications [6, 7].

A cecal intubation rate of less than 90 % may be considered low. A tradition of using none or only little sedation may explain some of this, although a survey from 68 centers in the UK (where practically all patients were sedated) showed cecal intubation rates of less than 80 % [2]. This should not, however, influence the comparative results between two endoscopes in a randomized trial. When pain is used as an end point, the routine use of medication may mask any relieving effect that might be contributed by progress in the development of endoscope functions and endoscopist performance, thus predisposing to a type II statistical error when possible progress in technique and technology is evaluated.

Patients were blinded to the type of endoscope used while the endoscopists were not. The feel of the endoscopes, including torque stability, was very similar for the endoscopists involved. Since the passive bending function does not require an additional control knob, it should be easy to perform a double–blinded study with this new functi on, but it would be necessary to make prototypes with and without the passive bending function. The adjustments made in the present multiple logistic analysis must be regarded as a compensation for the inability to apply a double blind design to the trial.

In conclusion, the Olympus XCF–Q160AW prototype colonoscope with a passive bending function caused less pain than a standard Olympus 140 series colonoscope, without compromising other functions of colonic intubation. This suggests that the present type of passive bending function may be safely incorporated in standard colonoscopes.

Acknowledgment

Two XCF–Q160AW prototype colonoscopes were provided by Olympus Europe, Hamburg, Germany, who also provided the drawings in Fig. 1. This study was carried out as part of routine work in Telemark Hospital, with no additional funding.

References