

Original article

Readability of Surgical Informed Consent in Spain[☆]

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Introduction: To assess the readability of informed consent (IC) documents of the different national surgical societies.

Methods: During January 2012 we collected 504 IC protocols of different specialties. To calculate readability parameters the following criteria were assessed: number of words, syllables and phrases; syllables/word and word/phrase; averages; Word correlation index; the Flesch-Szigriszt index; Fernández-Huerta index; the Inflesz scale degree and the Gunning Fog index.

Results: The mean Flesch-Szigriszt index was 50.65 ± 6.72 , so readability is considered normal. There are significant differences between specialties such as Urology (43.00 ± 4.17) and Angiology and Vascular Surgery (63.00 ± 3.26 , $P < .001$). No ICs would be appropriate for adult readability according to the Fernández-Huerta index (total mean 55.77 ± 6.57); the IC of Angiology and Vascular Surgery were the closest ones (67.85 ± 3.20). Considering the Inflesz scale degree (total mean of 2.84 ± 3.23), IC can be described as “somewhat difficult”. There are significant differences between the IC of Angiology and Vascular Surgery (3.23 ± 0.47) that could be qualified as normal, or Cardiovascular Surgery (2.79 ± 0.43) as “nearly normal readability”; and others such as Urology (1.70 ± 0.46 , $P < .001$) and Thoracic Surgery (1.90 ± 0.30 , $P < .001$), with a readability between “very” and “somewhat” difficult. The Gunning Fog indexes are far from the readability for a general audience (total mean of 26.29 ± 10.89).

Conclusions: The ICs developed by scientific societies of the different surgical specialties do not have an adequate readability for patients. We recommend the use of readability indexes during the writing of these consent forms.

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Legibilidad del consentimiento informado quirúrgico en España

R E S U M E N

Palabras clave:
Consentimiento informado
Legibilidad
Cirugía

Introducción: Evaluar la legibilidad de los documentos de consentimiento informado (CI) de las diferentes sociedades nacionales quirúrgicas.

Métodos: Durante enero de 2012 se recogieron los 504 protocolos de CI de las diferentes especialidades. Para el cálculo de legibilidad se valoraron los parámetros: número de palabras, sílabas y frases, promedio sílabas/palabra y palabras/frase, índice de correlación Word, índice de Flesch-Szigriszt, índice de Fernández-Huerta, grado en la escala Inflesz y el índice de Gunning-Fog.

Resultados: La media del índice de Flesch-Szigriszt fue de $50,65 \pm 6,72$, por lo que se consideran de legibilidad *normal*. Existen diferencias significativas entre especialidades como Urología ($43,00 \pm 4,17$) y Angiología y Cirugía Vascular ($63,00 \pm 3,26$; $p < 0,001$). Ningún CI sería apropiado para la legibilidad de adultos según el índice de Fernández-Huerta (media total de $55,77 \pm 6,57$), solo se acercan los CI de Angiología y Cirugía Vascular ($67,85 \pm 3,20$). Considerando el grado en la escala Inflesz (media total de $2,84 \pm 3,23$), pueden ser calificados como *algo difíciles*. Existen diferencias significativas entre los CI de Angiología y Cirugía Vascular ($3,23 \pm 0,47$) que podrían calificarse como *normales*, o Cirugía Cardiovascular ($2,79 \pm 0,43$) como una legibilidad casi *normal* y otras como Urología ($1,70 \pm 0,46$; $p < 0,001$) o Cirugía Torácica ($1,90 \pm 0,30$; $p < 0,001$), con una legibilidad entre *muy* y *algo difícil*. El índice de Gunning-Fog está muy alejado de la legibilidad para la audiencia general (media total de $26,29 \pm 10,89$).

Conclusiones: Los CI desarrollados por las sociedades científicas nacionales de las diferentes especialidades quirúrgicas no poseen una legibilidad adecuada para los pacientes. Es recomendable el empleo de índices de legibilidad durante la redacción de los mismos.

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Introduction

The process for informed consent (IC) consists of two stages. The first stage refers to information on the proposed procedure which must conform to empirical knowledge and should be provided by the practitioner in a manner which is appropriate to the needs of each individual patient. The second stage is the free and voluntary decision on the part of the patients, once they have understood the information, expressing their consent or refusal of the diagnostic or therapeutic procedure which has been suggested to them. This is also a written document and a copy must be given to the patients to keep. This ensures that the patients have a copy of the information provided so that they can continue to reflect on it and reassess their decision.

Patients' capacity to understand the written information they receive can be significantly improved if the readability of the text is adapted to their reading level.¹

According to Act 41/2002, of 14 November,² IC is understood as the "free, voluntary and aware consent of a patient manifested in the full use of his or her faculties after receiving appropriate information to allow an action that affects his or her health". Furthermore, the extension to the Act in Act 8/2003³ of 8 April specifies that informed consent for surgical interventions or invasive therapeutic procedures must be in writing.

In 2002, when the first IC validated by the Spanish Association of Surgeons appeared, Spanish general surgeons expressed their commitment to its use.⁴ The other national

societies for different surgical specialties have been developing their own IC over the past decade: all of them now have these documents.

The objective of this study was to assess the readability of IC published by the Spanish societies of different surgical specialties in order to establish their suitability and offer valid tools for assessing IC for any medical process.

Materials and Methods

The 504 IC protocols of the different surgical specialties developed by their respective national societies were collected during January 2012 (Table 1). The chosen surgical specialties are those which could constitute the surgical core subjects, set out in the Royal Decree on Core Subjects of the Ministry of Health, Social Policy and Equality of 15 July 2011.⁵

There are three parts to the IC of the different specialties studied: the first identifies the hospital with a space for naming the doctor who provides the information, the second part is for clinical information and the third is for declaration and signatures. The practical standards for the correct use of systems for measuring readability⁶ imply eliminating almost all of the first and third parts of the document and analysing the readability of the part which contains the information on the procedure to be performed and its possible risks and complications.

The computer programme Inflesz, accessible in *freeware*⁷ was used to calculate the readability of the chosen texts. The following parameters were obtained: words, syllables,

Table 1 – Surgical Specialities Studied With Their Respective National Societies.

Angiology and Vascular Surgery	Spanish Society of Angiology and Vascular Surgery (SEACV)
Cardiovascular surgery	Spanish Society of Thoracic – Cardiovascular Surgery (SECTCV)
General and Digestive Surgery	Spanish Association of Surgeons (AEC)
Oral and Maxillofacial Surgery	Spanish Society of Oral and Maxillofacial Surgery (SECOM)
Orthopaedic Surgery and Traumatology	Spanish Society of Orthopaedic Surgery and Traumatology (SECOT).
Plastic, Aesthetic and Reconstructive Surgery	Spanish Society of Plastic, Aesthetic and Reconstructive Surgery (SECPRE).
Thoracic Surgery	Spanish Society of Pneumology and Thoracic Surgery (SEPAR).
Neurosurgery	Spanish Society of Neurosurgery (SENEC)
Urology	Spanish Association of Urology (AEU).
Paediatric Surgery	Spanish Society of Paediatric Surgery (SECIPE)

sentences, mean syllables/word, mean words/sentence, Word Correlation Index, the Flesch-Szigriszt Index, the Fernández-Huerta Index and Inflesz Scale grade. The Gunning Fog Index was calculated using a free online utility.⁸

Readability

Readability is the set of typographical and linguistic characteristics of a written text that allow it to be read and understood with ease, whereas legibility describes the quality of visual comfort, and is connected with comprehension and measured by the amount of time that the reader can spend with a block of text before becoming tired. Objective techniques have been developed for analysing linguistic readability, particularly in the English language.^{9,10} There are different computer utilities, applications and programmes, some of them available on the Internet, such as the Inflesz programme, a free download, which calculate, among other things, the parameters listed above and Szigriszt's clarity score, termed the Inflesz scale.¹

Word Correlation or Flesch Index

In general, most readability formulae are based on the hypothesis that a text is easier to read the shorter its words and sentences. Flesch is the most influential person in the development of formulae for analysing readability. His reading ease score (RES) formula applies the equation shown in Table 2, where w_l is the mean length of words, measured as the number of syllables in 100 words, and s_l is the mean length of sentences in 100 words of a text. This is possibly the most influential and best known formula in the history of readability. It is interpreted according to a scale proposed by the author, Flesch's RES scale, which goes from 0 to 100 points, divided into 7 sections. A text is of mean or standard difficulty if the score is between 60 and 70, below these figures the text

would be difficult to read and the nearer it is to 100, the easier it is to read.

Flesch-Szigriszt Index

The first formulae for analysing readability appeared in Spanish in the 1950s. There have been successive attempts to validate or adapt Flesch's original formula: the Fernández-Huerta readability formula and the Szigriszt-Pazos' clarity formula. Szigriszt-Pazos' validation of Flesch's RES formula should undoubtedly be considered the current benchmark for the Spanish language. He terms it Flesch-Szigriszt clarity formula or readability index (IFSZ) (Table 2).

On this scale, a text is of normal readability when it has a score between 50 and 65 and it becomes more difficult the closer it gets to 0, where scientific literature is placed.

Fernández-Huerta Index

The Fernández-Huerta index or readability formula is an adaptation of Flesch's RES formula, where level 0 is the most difficult and 100, the easiest. A result lower than 30 is considered very difficult, whereas a score of 70 is considered appropriate for adults (Table 2), where p is the number of syllables per 100 words and f the number of sentences per 100 words.

Inflesz Scale Degree

According to Barrio-Cantalejo et al.'s study of 2008,¹¹ neither Szigriszt's clarity index, nor Flesch's RES scale is appropriate for the reading habits of the Spanish population. They suggest that the new Inflesz scale should be used, which has been obtained by modifying both (the same formula used by the Flesch-Szigriszt readability index, but where the scale for interpreting the results is adjusted), for a more suitable assessment. On this scale, the score which marks the limit between that which is and is not accessible to the average reader is 55. "Normal" is between 55 and 65, "very difficult" is a score between 0 and 40, and "somewhat difficult" is between 40 and 55. Among the higher scores "quite easy" is between 65 and 80 points, and scores above 80, "very easy". This is changed to grades for statistical study and graphic description: Grade 1 or "very difficult", Grade 2 or "difficult", Grade 3 or "normal", Grade 4 or "quite easy" and Grade 5 or "very easy".

Table 2 – Readability Formulae.

Word Correlation or Flesch Index (RES)	$RES = 206 - 835 - 0.846 w_l - 1.015 s_l$
Flesch-Szigriszt Index (IFSZ)	$IFSZ = 206 - 835 - (62.3 \times s/p) - p/f$
Fernández-Huerta Index (IFH)	$IFH = 206 - 84 - (0.60 \times p) - (102 \times f)$
s: sentences; w/s: words/sentence; w: words; s/w: syllables/words; sl: mean sentence length; wl: mean word length.	

Table 3 – Results of the Different Readability Indices for the CI Published by the National Scientific Societies of the Different Surgical Specialities.

	Syllables	Words	Sentences	s/w	w/s
Total	1704 (±1657)	733 (±719)	65 (±47)	2.32 (±0.09)	11.37 (±3.19)
Angiology and Vascular Surgery	1418 (±415)	650 (±189)	84 (±25)	2.18 (±0.05)	8.13 (±2.61)
Cardiovascular Surgery	1373 (±551)	619 (±257)	46 (±15)	2.20 (±0.07)	13.84 (±2.02)
General and Digestive Surgery	1551 (±274)	669 (±114)	59 (±8)	2.31 (±0.04)	11.40 (±0.86)
Oral and Maxillofacial Surgery	1023 (±268)	438 (±114)	45 (±15)	2.33 (±0.07)	10.09 (±1.92)
Orthopaedic Surgery and Traumatology	1864 (±420)	786 (±217)	92 (±24)	2.34 (±0.08)	8.85 (±1.72)
Plastic, Aesthetic and Reconstructive Surgery	5922 (±3950)	2555 (±1723)	170 (±101)	2.32 (±0.05)	13.87 (±2.46)
Thoracic Surgery	1047 (±315)	464 (±116)	26 (±6)	2.32 (±0.05)	1805 (±1.96)
Neurosurgery	799 (±406)	343 (±182)	34 (±18)	2.34 (±0.09)	10.05 (±1.83)
Urology	1691 (±364)	695 (±145)	58 (±15)	2.43 (±0.05)	12.37 (±1.98)
Paediatric Surgery	1297 (±276)	547 (±113)	49 (±13)	2.37 (±0.06)	11.31 (±1.54)
P	<.001	<.001	<.001	<.001	<.001

Expressed as mean ± standard deviation.

w/s: words/sentence; s/w: syllables/words.

Gunning Fog Index

The Gunning Fog index uses an algorithm based on the mean words per clause and the percentage of words with three or more syllables. The specific formula is: (mean words per clause + number of words with 3 or more syllables) × 0.4. The result is an index which indicates how many years of education a person requires to be able to understand the content of a text. The lower this index, the more readable the text will be. Results above 17 are considered above the level of competence of a secondary school pupil. Texts designed for a general readership require an index below 12. Achieving near-universal understanding requires an index lower than 8. This index is used for texts in English.

Statistical Analysis

Mean ± standard deviation was used for the description of quantitative variables. A nonparametric Kruskal-Wallis test was used in the analysis of the differences between the means of the surgical specialities of the terms analysed after assessing the normality of the samples (Kolmogorov-Smirnov

test, $P < .001$, and Shapiro-Wilk, $P < .05$) and the homogeneity of the variances test (Levene test, $P < .001$). A P value lower than .05 was defined as statistically significant. The data were analysed using the statistics programme SPSS 17.0 for Windows® (SPSS, Chicago, IL, USA.).

Results

The results are presented in [Tables 3 and 4](#). There is a great discrepancy between the different surgical specialities with regard to the length of the IC. Thus, Neurosurgery (799±406 syllables, 343±182 words and 34±18 sentences), Thoracic Surgery (1047±315 syllables, 464±116 words and 26±6 sentences) and Oral and Maxillofacial Surgery (1023±268 syllables, 438±114 words and 45±15 sentences) have the shortest IC, compared with the very much longer ones for Plastic, Aesthetic and Reconstructive Surgery (5922±3950 syllables, 2555±1723 words and 170±101 sentences; $P < .001$). By contrast, there is a great similarity with regard to means of syllables per word, at between 2.18 for Angiology and Vascular Surgery and 2.43 for Urology. There are also major differences with regard to means per sentence. The IC for Thoracic Surgery use longer

Table 4 – Results of the Different Readability Indices for the CI Published by the National Scientific Societies of the Different Surgical Specialities.

	Word Correlation	F-S Index	F-H Index	Inflesz Grade	G-F
Total	184 (±8.66)	50.65 (±6.72)	55.77 (±6.57)	2.84 (±0.95)	26.29 (±10.89)
Angiology and Vascular Surgery	17.76 (±4.21)	63.00 (±3.26)	67.85 (±3.20)	3.23 (±0.47)	19.56 (±2.07)
Cardiovascular Surgery	8.74 (±3.49)	56.28 (±2.33)	60.79 (±2.53)	2.79 (±0.43)	21.65 (±0.76)
General and Digestive Surgery	2.72 (±3.76)	51.33 (±2.91)	56.43 (±2.84)	2.07 (±0.31)	21.96 (±0.64)
Oral and Maxillofacial Surgery	2.74 (±4.99)	51.35 (±3.88)	56.51 (±3.73)	2.17 (±0.39)	21.91 (±1.38)
Orthopaedic Surgery and Traumatology	4.22 (±4.61)	52.49 (±3.58)	57.69 (±3.48)	2.29 (±0.46)	21.94 (±0.86)
Plastic, Aesthetic and Reconstructive Surgery	-0.84 (±5.23)	48.57 (±4.06)	53.62 (±3.99)	2.11 (±0.32)	22.13 (±1.82)
Thoracic Surgery	-6.18 (±5.01)	44.38 (±3.89)	49.35 (±3.80)	1.90 (±0.30)	23.43 (±1.07)
Neurosurgery	2.07 (±6.83)	50.83 (±5.30)	56.02 (±5.11)	2.24 (±0.47)	22.25 (±1.43)
Urology	-8.02 (±5.37)	43.00 (±4.17)	48.35 (±4.08)	1.70 (±0.46)	21.29 (±1.20)
Paediatric surgery	-1.69 (±4.22)	47.91 (±3.27)	53.14 (±3.16)	2.01 (±0.25)	21.93 (±0.95)
P	<.001	<.001	<.001	<.001	<.001

Expressed as mean ± standard deviation.

F-H: Fernández Huerta; F-S: Flesch-Szigriszt; G-F: Gunning Fog.

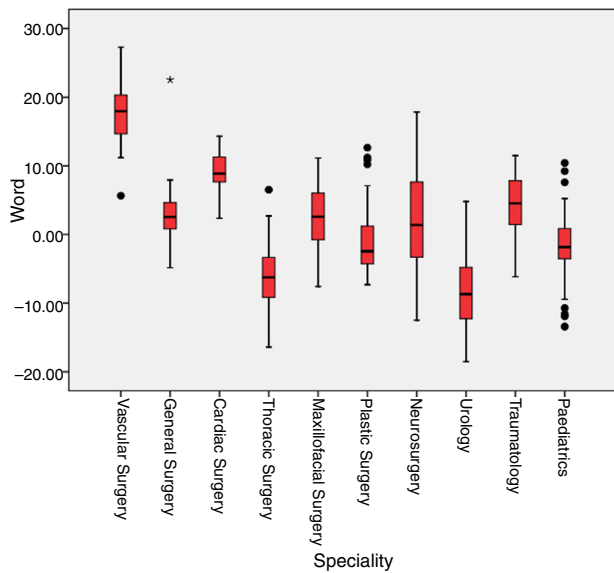


Fig. 1 – Graphic representation of the word readability index for the CI published by the national scientific societies of the different surgical specialities.

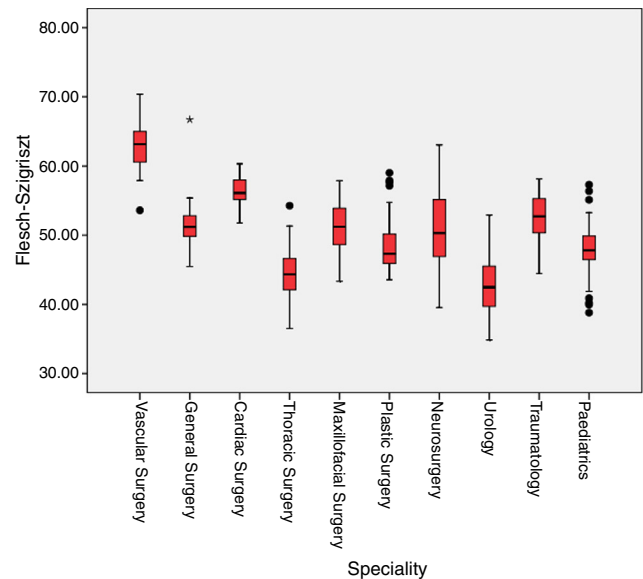


Fig. 2 – Graphic representation of the Flesch-Szigriszt index for the CI published by the national scientific societies of the different surgical specialities.

sentences (18.05 ± 1.96 ; $P < .001$) and the IC for Angiology and Vascular Surgery (8.13 ± 2.61 ; $P < .001$) and that for Orthopaedic Surgery and Traumatology are much shorter (8.85 ± 1.72 ; $P < .001$) (Table 3).

The Word Index and Flesch-Szigriszt mean was 50.65 ± 6.72 , and therefore they cannot be considered texts of normal readability (Figs. 1 and 2). Nonetheless, there are significant differences between the different specialities such as Urology (43.00 ± 4.17) and Angiology and Vascular Surgery (63.00 ± 3.26 ; $P < .001$). Using the Fernández-Huerta index, no Spanish surgical speciality IC would be appropriate for adult readability (total mean of 55.77 ± 6.57); considerably below the 70 points considered necessary, only the IC for Angiology and Vascular Surgery come close (67.85 ± 3.20) (Table 4).

In terms of the Inflesz Scale grade for the IC studied (total mean of 2.84 ± 3.23), they can be qualified as *somewhat difficult* (Fig. 3). However there are significant differences between the IC of the different surgical specialities, such as Angiology and Vascular Surgery (3.23 ± 0.47), which could be classified as normal, or Cardiovascular Surgery (2.79 ± 0.43), qualified as of almost normal readability, and others such as Urology (1.70 ± 0.46 ; $P < .001$) or Thoracic Surgery (1.90 ± 0.30 ; $P < .001$), with readability between *very and quite difficult*. Using the Gunning Fog Index (Fig. 4) all the ICs are very far from readable for a general readership (total mean of 26.29 ± 10.89) (Table 4).

Discussion

The readability of the IC of the Spanish surgical specialities is generally beyond the understanding of the population as a whole. The only national scientific society to have developed IC with appropriate readability is that of Angiology and Vascular Surgery. However, there are differences between the

IC proposed by the different scientific surgical societies; those of specialities such as Cardiovascular Surgery achieve more appropriate levels compared with the Urology and Thoracic Surgery IC which are well below the recommended readability.

This growing interest in readability (together with clarity and the appropriate organisation of linguistic material so that the reader can access content through smooth and clear reading) is linked to the gradually developing notion of the moral autonomy of patients in decision making.⁶ Research into improving patient-oriented texts is essential within the new model of clinical relationships based on putting the patient first.¹² The laws regulating human rights in the area of

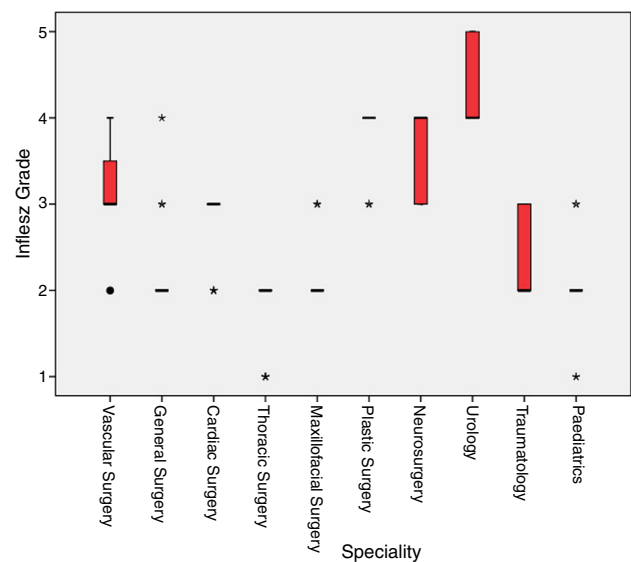


Fig. 3 – Graphic representation of the Inflesz grade scale for the CI published by the national scientific societies of the different surgical specialities.

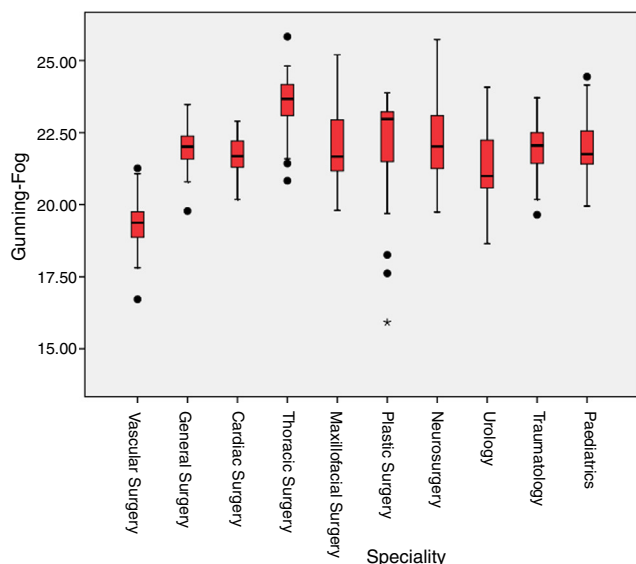


Fig. 4 – Graphic representation of the Gunning Fog index for the CI published by the national scientific societies of the different surgical specialities.

healthcare are allowing patients a greater role in making decisions which affect them so that healthcare professionals, in addition to their knowledge and technical competence, must be able to help patients understand their situation to enable them to make decisions. The information provided must, therefore, be true and adequate, as well as comprehensible, in order to assist the patients in reaching their decision.¹³

Of all the indices used, the grade on the Inflesz scale could be the most appropriate tool for assessing IC readability. Angiology and Vascular Surgery achieve the best results in terms of readability. All of their ICs were classified as *normal* or *quite easy*. Thus the most readable IC of all those studied belongs to this speciality: the IC for *Varicectomy* had a grade on the Inflesz Scale of *quite easy*, a Fernández-Huerta score of 70.45, a Flesch score of 21.17, a Flesch-Szigriszt score of 65.64, and a Gunning Fog score of 18.53. By contrast, the worst IC in terms of readability is for *Tubulo-deferential Anastomosis*, Urology, with *very difficult* scores of 42.79, 15.32, 37.33 and 18.53, respectively.

An essential element when preparing information is to take into account the characteristics of the reader for whom the text is intended, in this case the patient and users in general. Irrespective of grammatical correctness, our documents can be either complex or very complex in their structure and lexicon, compromising their comprehensibility. It is important to stress that these readability formulae only assess the text of the documents. None of the readability formulae will assess whether the documents include drawings to facilitate their understanding. This is clearly an aspect which could increase the readability and comprehensibility of patient information documents.

One of the recommendations for the process of IC for surgical patient is to give simple and intelligible information about the different aspects of the surgery.¹⁴ The wording of ICs

can occasionally constitute a barrier to interpreting, understanding and appreciating their content.¹⁵ The mechanisms proposed for improving readability are short sentences and words, avoiding unnecessary medical technicalities, using subsections and simple sentences, confining the consent form to one page, including graphs and explanatory drawings and using the readability indices.

Our study has various limitations. The most significant is that the analytical tools used relied on a computer programme, which limits their use to the availability of such a programme (both of those used are unrestricted and free of charge). Should IC documents need to be provided in versions other than Spanish, it would not be possible to use the indices described, as there are no validation studies for them. Furthermore, there is no assessment of the scientific and technical content of the IC. Finally, the information given to the patient is not confined to that provided in the document. Verbal information given by the medical practitioner and other sources researched by the patient have not been assessed in this study.

In conclusion, the readability of the IC developed by the national scientific societies of the different surgical specialities is not appropriate for the general population of patients in Spain. In order to convey information correctly, when ICs are being developed an assessment needs to be made of their content and comprehensibility for their intended readership. It is recommended that readability indices should be used in drafting ICs.

Conflict of Interests

The authors have no conflict of interests to declare.

REFERENCES

- Barrio I, Simón P. Medición de la legibilidad de textos escritos. Correlación entre método manual de Flesch y métodos informáticos. *Aten Prim*. 2003;31:104–8.
- Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Boletín Oficial del Estado, de 15 de noviembre de 2002. p. 40126–32.
- Ley 8/2003, de 8 de abril, sobre derechos y deberes de las personas en relación con la salud. Boletín Oficial del Estado, 30 de abril de 2003. p. 16650–9.
- Maíllo C, Ramos JL, Landa I, Gómez-Alonso A, Moreno-Azcoita M. Empleo de los documentos de consentimiento informado por los servicios de cirugía españoles. *Cir Esp*. 2002;71:269–75.
- Proyecto de Real Decreto por el que se regula la incorporación de criterios de troncalidad en la formación de determinadas especialidades en ciencias de la salud, la reespecialización troncal y las áreas de capacitación específica. Ministerio de Sanidad, Política Social e Igualdad. Available from: <http://www.fesemi.org/documentos/1335540348/grupos/formacion/publicaciones/troncalidad-2011.pdf> [accessed 01.10.12].
- Simón Lorda P, Barrio Cantalejo IM, Concheiro Carro L. Legibilidad de los formularios escritos de consentimiento informado. *Med Clin (Barc)*. 1997;107:524–9.

7. Programa INFLESZ. Available from: www.legibilidad.com [accessed 01.10.12].
8. Test document readability. Available from: www.online-utility.org [accessed 01.10.12].
9. Blanco A, Gutiérrez U. Legibilidad de las páginas web sobre salud dirigidas a pacientes y lectores de la población general. *Rev Esp Salud Publica*. 2002;76:321-31.
10. Paasche-Orlow MK, Taylor HA, Brancanti FL. Readability standards for informed-consent forms as compared with actual readability. *N Engl J Med*. 2003;348:721-6.
11. Barrio-Cantalejo IM, Simón-Lorda P, Melguizo M, Escalona I, Marijuán MI, Hernando P. Validación de la escala INFLESZ para evaluar la legibilidad de los textos dirigidos a pacientes. *An Sist Sanit Navar*. 2008;31:135-52.
12. Organización Mundial de la Salud Oficina Regional Europea. Health for all policy framework for the WHO European Region: 2005 update. Copenhagen: WHO; 2006.
13. Collazo E. Consentimiento informado en la práctica médica. Fundamentos bioéticos y aspectos prácticos. *Cir Esp*. 2002;71:319-24.
14. Acea B. El consentimiento informado en el paciente quirúrgico. Reflexiones sobre la ley básica reguladora de la autonomía de los pacientes. *Cir Esp*. 2005;77: 321-6.
15. Rubiera G, Arbizu A, Agúndez JJ, Riera JR. Legibilidad de los documentos de consentimiento informado en los hospitales de Asturias. *Gac Sanit*. 2004;18:153-8.