



Barber, J., Puryer, J., McNally, L., & O'Sullivan, D. (2015). The contents of dental implant patient information leaflets available within the UK. *British Dental Journal*, 218(4), E7. 10.1038/sj.bdj.2015.99

Peer reviewed version

Link to published version (if available):
[10.1038/sj.bdj.2015.99](https://doi.org/10.1038/sj.bdj.2015.99)

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The Contents of Dental Implant Patient Information Leaflets available within the UK

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Keywords: Consent, information, dental, implants

Abstract

Purpose: Patient information leaflets are designed to provide easy to follow information summaries and first point of contact information about treatment options. This survey reviewed the content of dental implant patient information leaflets, produced by implant companies and available within the UK in 2011.

Methods: Dental implant companies in the UK were asked to provide samples of their patient information leaflets. The information within the leaflets was then summarised as well as the quantity, the types of images used to illustrate the leaflets and whether the source of the information was given. Quantitative data was obtained on the amount of information provided, size of images and number of references.

Results: A response rate of 71% was obtained, and 23 leaflets were studied. Great variation was found between the leaflets, with the word counts ranging from 88 to 5434, and 44 different topics were identified. The majority of the images used were decorative, and none of the leaflets gave any reference to the sources of their information. Implant treatment was generally described in a positive way, concentrating on describing the treatment and giving the advantages. Much less information was given about the potential disadvantages and risks of complications or failure, including the relevance of periodontal disease or smoking.

Conclusion: Implant patient information leaflets provided by dental implant companies should not be solely relied upon to provide patients with all the information they need to give informed consent to treatment.

Introduction

The use of dental implants to provide support and retention for fixed and removable dental prostheses has increased rapidly over recent years¹. By 2003 there were approximately 80 worldwide manufacturers, with approximately 220 different implant brands between them². The dental implant market is highly competitive, and implant companies work hard to promote their products to both clinicians and patients using promotional material to highlight the particular advantages of their systems. Information leaflets are produced by the majority of implant companies to advertise to potential patients.

It has been shown that the level of knowledge about dental implants amongst the general public is poor³. For those patients considering implant treatment, their baseline level of knowledge may be low, such that their clinician needs to ensure they have sufficient knowledge and understanding of any proposed treatment. Other sources of information about dental implant for patients, for example the internet, may give information that is inaccurate, incomplete or difficult to read. The news media can also give a negative perspective on implants⁴.

Dental implant companies provide promotional material to professionals to distribute to their patients, an important means of advertising which can help increase sales. While implant companies are free to advertise to dentists, there is little advertising directly to patients, and importantly, direct-to-consumer advertising is banned in Europe⁵.

Clinicians already effectively use leaflets to assist when informing patients about implant treatment⁶. Studies have shown that patients often forget or misunderstand the information

they have been given by a clinician^{7,8}, and the provision of written material can increase the amount of information retained⁹. However, care must be taken not to overload a patient with information, nor provide inadequate information¹⁰.

If the information contained within the leaflet is of good quality and comprehensive, the clinician would be able to rely on it to back-up their discussions with the patient. The clinician would be able to document in a patient's notes that they have been given a particular leaflet. This could be used as evidence if there is a complaint about the lack of information provided to a patient prior to commencing treatment⁷. The use of detailed information leaflets which could be used as a defence in potential malpractice lawsuits have been advocated¹¹. Often written patient information is not referenced and does not give an indication of the strength of evidence to support the information that is being provided which makes verifying the scientific quality of the information more difficult¹². There is also a potential for bias within the patient information leaflets produced by commercial manufacturers, and information leaflets available in general dental practices have been found to have limitations¹³.

For a patient information leaflet to be effective it must be well designed,^{14,15,16,17,18} and the layout of a patient information leaflet is important in determining how usable the leaflet is¹⁹. Many leaflets have illustrations to accompany the text. Previous authors have shown that text with illustrations can be more effective than using text or illustrations alone, especially for patients with low literacy skills²⁰. The age of the person reading the information is a relevant factor and illustrations may not be beneficial for older patients²¹. Others have found illustrations in hand-outs not to be effective in improving patients' recall of information, and that their level of education was a more important factor²².

It is clear that patient leaflets should be well designed, containing sufficient, good quality information, and it is evident that there is a potential challenge in designing leaflets that incorporate the differing interests of all parties involved. The dental implant companies who produce them wish to have attractive and appealing written material that promotes their product in the best possible light. The dental professionals wish to give their patients clear, balanced, and detailed information. Patients would like information which answers the questions important to them, in a way which is easy to read and understand.

Aim of study

The aim of this study was to compare the material contained within dental implant information leaflets produced by implant companies within the UK. The objectives included:

- Which topics are discussed?
- How much information is there in each leaflet and on each topic?
- What images are used?
- What are the primary claims made by implant companies about the treatment and why a patient should choose to have that treatment?
- Are the sources of information referenced?

Methods

Collection of Data

The inclusion criteria for the study were written patient information literature produced by dental implant companies in the period of March - May 2011. A list of dental implant

companies and distributors operating in the UK and their contact details was compiled using three methods:

1) Internet search for websites for dental implant manufacturers and distributors worldwide.

If the website had contact information for a UK sales or UK customer services operation, the details were recorded. The websites of Dental Implant Associations were also searched for lists of implant companies.

2) The UK dental free press was searched for advertisements from dental implant companies.

3) Dental implant company representatives were approached and samples of their company's patient information literature requested.

Each company was sent an e-mail requesting an example of their current written patient information literature. If after two weeks there was no response, the e-mail was followed up with a letter addressed to the company. If there was no reply to this letter within a four week period, a result of no response was recorded.

When the information material was received it was checked to see if it met the above inclusion criteria. If numerous leaflets from one company met the criteria, they were all included, and treated as separate leaflets. Each leaflet that was eligible for the study was then analysed. A combination of qualitative and quantitative analysis of the contents of the written patient information material was chosen in order to demonstrate what the leaflets contained and the quantity of each item. As the emphasis of this study was upon the information itself, and not how it was consumed by patients, readability tests were not used. All of the data was extracted from the leaflets by one of the authors to help with reliability.

Topics

Each paragraph or block of text was read and the topic recorded. The number of words contained in each paragraph or block of text was also recorded. All the topics on a similar subject were then grouped together. If the topic did not fit within a group, further topic groups were made. In this way each topic group was representative of the content of the paragraph or block of text.

Claims

The primary claims made by each company about the benefits of dental implant treatment or advantages of their dental implant system were recorded. These claims could then be compared to current scientific literature on the subject to test their validity.

Number of References

All of the leaflets were assessed to see if any sources for the information they contain was given. This would include references to scientific journal articles, books, or company research. This would show where the information came from, so that the validity could be verified.

Photographs and Diagrams

The total area of each leaflet was calculated by measuring the dimensions in square centimetres (cm²).

The number and area of each image in each leaflet was recorded in square centimetres (cm²). The images were divided into six categories.

1) Photographs of smiling people or people eating happily.

- 2) Decorative photographs: other pleasant images not directly relevant to dental implants.
- 3) Photographs of models representing different types of possible patients.
- 4) Photographs of treatment cases, such as "before and after" photographs.
- 5) Other informative photographs, such as prostheses or clinical situations.
- 6) Descriptive diagrams to help explain the treatment, such as dental implants, or implant retained over dentures.

Results

Collection of leaflets

The search for dental implant companies, which have a UK sales and/ or customer services department identified 17 companies to contact. Most of the implant companies which were contacted as part of the study responded rapidly and sent examples of their patient information leaflets. 4 companies did not have any patient leaflets available, and one company only had a draft leaflet that was not available in the UK.

Patient information leaflets which met the inclusion criteria were received from 12 of the 17 companies contacted, giving a response rate of 71%. Some of these companies produced a single leaflet, whilst others produced a range of leaflets. 23 leaflets were included in the study, and the distribution of these leaflets from the various companies is shown below.

- 1 leaflet: Bicon, Biomet 3i, Dentsply, Euro teknika, Implantium, Neoss
- 2 leaflets: BioHorizons, OsteoCare, Osteo-Ti, Straumann
- 4 leaflets: Nobel Biocare

- 5 leaflets: Astra Tech

Topics discussed in the information leaflets: overall

The leaflets were all analysed and a very wide range of 44 different topics were identified. However, information about periodontal disease and its relevance to implant treatment was not present in any leaflet. 25 of the 44 topics were mentioned in only one or two leaflets. Some topics would not be relevant to all potential implant patients (e.g. "Description of a sinus lift"). The presence of each topic was recorded for each leaflet as well as the number of words devoted to each topic. These topics, along with the total number of words devoted to each topic, are listed in Table 1. From the 44 topics, 15 were identified for further analysis. These were deemed to be of greater importance and have been highlighted. The importance of each topic was estimated by calculating the total number of words devoted to each topic by all the leaflets. Topics which had more than 300 words were selected, as well as "Importance of a smile" as it is a strong motivational factor for patients to seek dental implant treatment and "Smoking" due to its importance as a risk factor for dental implant failure. The popularity of each of the 15 selected topics was analysed. The most popular topics which were written about in the leaflets were:

- Why might you want dental implants
- Description of dental implants and what they do
- Advantages of implant treatment
- Description of how implants support different types of prostheses
- Advice to consult a dentist for an individual treatment plan
- Description of the treatment procedure and timeframe

The least frequently mentioned topic was "Smoking", which should have been present in the majority of the leaflets.

Topics discussed in the information leaflets: by individual leaflet

At least one of the 15 selected topics was included in all the leaflets, though some contained many more than others.

Information contained in each leaflet: overall

The number of words contained in each leaflet and per topic was calculated. The larger the amount of text in the leaflets, the more information they are likely to contain. From the individual 23 leaflets studied, the word count ranged from 88 to 5434 words (mean = 1119).

Information contained in each leaflet and on each topic: by each leaflet

The total of number of words per leaflet and per topic give an overall indication of the amount of information present, but does not clearly demonstrate the variation between the leaflets on the amount of information given about each of the selected topics that are highlighted in Table 1. None of the leaflets contained information on all of the 15 selected topics, and for these 15 selected topics, the maximum number of words ranged from 45 to 1145 (mean = 447).

Images used in the leaflets

Six distinctive types of images were used in the leaflets. These can be broadly grouped into *decorative* and *informative* images.

Images were an important element on the composition of the leaflet designs, accounting for over 20% of the total surface area of the majority of the leaflets. *Decorative* images took up a larger area of each leaflet than *informative* images, in most of the leaflets. The leaflet

Osteo-Ti 1 contained no *informative* images and over 50% of the total area of the leaflet was given over to *decorative* images. All the other leaflets contained some *informative* images. The proportion of the total surface area of each leaflet devoted to *decorative* and *informative* images is demonstrated in Table 2.

The most commonly used type of image across all the leaflets were those in the happy people/smiles category, depicting people with a lifestyle, self-confidence and masticatory ability to which potential implant patients are likely to aspire. Descriptive diagrams were the second most used images. Table 3 shows the proportion of the total area of images in each leaflet which were devoted to the different types of images.

Claims made in information leaflets

The main claims which were made by each company about implant treatment and the reasons for choosing implants and their system were recorded for each leaflet. Many of the claims were common to numerous companies' leaflets and a few were isolated to particular implant systems. The common claims fell into 6 general categories:

- Claims about implants
- Problems caused by missing teeth
- Advantages of implant treatment
- Advantages of implant retained overdentures
- Disadvantages of dentures
- Implant aftercare

As there is a degree of consensus about these claims across the sample group of information leaflets they were collated and summarised in Table 4.

Some claims were only made by individual implant companies in their implant information leaflets. These were claims specifically about their implant system or claims about the benefits and advantages of implant treatment, which other implant companies had not made. Some claims were potentially more contentious.

Sources of the information contained in each leaflet

None of the leaflets contained any references as to where their information originated.

Discussion

The results clearly show that there is a wide range of variation in the substance and quantity of information contained in dental implant patient information leaflets available in the UK. Some give relevant information about a wide range of topics which would be of interest to a patient considering implant treatment, whilst others only provide a very brief introduction to dental implants. These topics could be considered the main selling points for implant treatment and it is therefore understandable that the implant companies would concentrate on these topics. Much less is written about other important topics such as "Description of alternative treatment options", "Smoking" and "Cost", which may act as a disincentive for a patient considering implant treatment.

The general claims made by implant companies about dental implant treatment are mostly supported by the literature, although often from a positive perspective regarding implant treatment. There are some company specific claims which would not appear to be supported by the literature. None of the leaflets contained any references to the sources of their information. It was therefore not possible to verify the validity of the information or

compare it with that which was found by searching published papers in peer reviewed journals.

There was a wide variation in the number of leaflets in which each topic was selected to be included. The most popular topic was "Description of dental implants and what they do", and as this is the most fundamental information about implant treatment and it is understandable that it is commonly included. "Risks at placement", "Smoking", "How long implants last", and "Risk of implant infection" are important topics for informed consent and avoiding later patient dissatisfaction with treatment. These may not have been included in the leaflets, so that patients are not discouraged from seeking implant treatment.

Images form an important part of the leaflets, taking up approximately a quarter of the total area of the majority of the leaflets. The majority of the leaflets have a larger proportion of their total area devoted to *decorative* images than to *informative* images, and understandably tried to link implant treatment with a lifestyle patients are likely to aspire to. This gives an indication of the relative importance of the leaflets as a means of marketing dental implants as opposed to informative tools to the implant companies which produce them. Of the different types of images the most commonly used were: photographs of happy people / smiles and descriptive diagrams. The photographs of happy people/ smiles are the most popular because they underlie the primary motivations for seeking implant treatment. Commonly, photographs of people biting into apples are used, to demonstrate that foods which can be difficult to eat with dentures or missing teeth can be enjoyed following implant treatment. The descriptive diagrams are useful to help patients understand what is involved with implant treatment. Cut away diagrams of an implant in an alveolar ridge or an exploded diagram of an implant, abutment and crown fitting together are good examples of helpful images which are commonly used.

The claims made about dental implants in the written patient information material included in this study are generally correct. There are many articles in peer reviewed scientific journals that show a good success rate for dental implants over a 10 year period. This backs, by independent research, the statement in many of the leaflets that dental implants have scientifically proven long term success. Some of the information leaflets give a success rate of over 96% for dental implants. Of more relevance to the individual patient is the success rate of implants placed by their own dental surgeon, and their own personal risk factors for implant failure. This is the information that their dentist should be giving them, and the figures given in the leaflets give a more general indication of international reported success rates. The claim that an implant can 'last a lifetime' with proper care and good oral hygiene is difficult to prove, and this would appear to be an optimistic claim, which cannot be fully backed by current scientific findings.

Another bold claim made by a number of implant companies is that implants cannot be distinguished from your real teeth in function or appearance. However, there is a significant difference in the threshold of tactile sensitivity between teeth replaced by dental implants and natural teeth²³. It is possible to replace missing teeth with implant retained restorations which have an appearance very similar to natural teeth, but this can be difficult. A meta-analysis of published data on implant-supported single crowns revealed the cumulative rate of crowns having unacceptable or semi-optimal aesthetic appearance was 8.7%²⁴. In cases where such aesthetic failures have occurred, the teeth would be clearly distinguishable from real teeth.

Many of the leaflets highlight the possible problems which can be experienced by patients when teeth are lost. This is to encourage patients to undergo dental implant treatment, and

also forms part of the informed consent process for implant treatment. They are the reasons why implant treatment should be considered, and some of the consequences of not having the treatment. There are psychological, functional (physical) and social problems which patients experience when teeth are lost. It is important for prospective patients to realise that there are potential physical, functional and psychological benefits to dental implant treatment, as well as the aesthetic improvements which are often only emphasised.

The other problem which was commonly stated was the changes to the face that can follow the loss of teeth, which can give the appearance of premature aging. Tooth loss does contribute to skeletal changes in the mid-face region. However, therefore the ability of implant treatment to prevent premature aging should not be overstated, and a recent review paper found that dental implants do not have an active role in the preservation and maintenance of alveolar bone height²⁵.

The after care of implants was addressed by some, but not all of the implant companies. It is vitally important for the long term success of the treatment, and prospective patients should be aware of their obligations in this regard from the early stages of treatment planning.

Conclusions

There is great variation in the quantity and quality of the information provided in UK dental implant patient information leaflets. If a leaflet provides a good range and depth of information to patients, it will support the information that is given verbally or by other means. Clinicians need to know how reliable the information leaflet is that they give to their patients. If the information leaflet is weak, the shortcomings must be made up for in other ways. Some leaflets contain statements which are not fully supported by studies published in

scientific journals. A patient will assume that a dentist concurs with all that is written in an information leaflet that is given to them by that person, unless stated otherwise. The descriptive diagrams and photographs of example cases are a useful aid in explaining dental implant treatment, which can prove difficult for patients to fully understand.

Dentists have a moral and legal obligation to obtain informed consent prior to implant treatment. None of the leaflets provide sufficient information to fully inform a patient. Informed consent requires information about the proposed procedure, the potential risks and benefits, alternative procedures, the effect of not having treatment, the diagnosis, a prognosis and progress of treatment. Some leaflets in this study provided very little information and would not be useful in gaining informed consent. The more comprehensive leaflets would be a good additional source of information about the procedure, and the benefits, with some limited information on alternative treatments and prognosis of treatment. The available leaflets generally do not provide information about the risks of treatment. Due to this wide range in the quantity and quality of the information provided, dental implant patient information leaflets should not be solely relied upon to provide patients with sufficient information to give informed consent to treatment.

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Table 1 Information leaflet topic and the combined total number of words devoted to each topic. Those highlighted indicate those which were selected for further analysis

Topic	Total Number of Words	Topic	Topic Number
Importance of a smile	150	Temporisation	63
Why might you want dental implants	1409	Treatment procedure and timeframe	3346
Description of dental implants and what they do	1960	Costs	421
Advantages of implant treatment	2064	Aftercare of implants and prostheses	1330
Description of how implants support different types of prostheses	2914	Description of a sinus lift	81
Disadvantages of alternative treatment options	1103	Description of a ridge split	91
Comparison of treatment options	274	Description of a bone graft	233
Description of alternative treatment options	625	For further information: go to company website	283
Advise to consult a dentist for an individual treatment plan	736	Introduction to brochure	202
Description of example cases	217	Where can I go to have Dental Implants placed?	96
Case Testimonies	2466	Aesthetic improvements to remaining natural teeth	85
Information about implant system and manufacturer	2096	Materials for crowns	85
Risks at placement	129	Preparation for implant consultation	82
Loading protocols	194	Day-surgery procedure; Surgery under LA in practice; Is a GA required?	166
Description of trans-mucosal healing	66	How long implants last?	82
Description of submerged healing	66	Foreign body feeling	43
Airport security	60	Immediate implant placement	251
Suitability for implant treatment	977	Implant material	163
Implant as an alternative to RCT	87	Risk of implant infection	46
Biocompatibility	247	Replacement and modification of denture	168
Smoking	77	Sport- rest after placement Work- after placement	94
Discomfort	163	Technician makes custom prosthesis	17

Table 2 The percentage of total surface area of each leaflet devoted to decorative and informative images

	Percentage of total area of leaflets devoted to other content <i>decorative</i> images	Percentage of total area of leaflets devoted to other content <i>informative</i> images	Percentage of total area of leaflets devoted to other content (eg text & background)
Astra Tech 1	21	3	76
Astra Tech 2	21	6	73
Astra Tech 3	21	4	75
Astra Tech 4	24	4	72
Astra Tech 5	24	4	72
Bicon	8	11	81
BioHorizons 1	7	16	77
BioHorizons 2	7	10	83
Biomet 3i	8	7	85
Dentsply Frident	5	7	88
Euro teknika	9	13	78
Implantium	9	11	80
Neoss	18	6	76
Nobel Biocare 1	25	4	71
Nobel Biocare 2	25	6	69
Nobel Biocare 3	21	10	69
Nobel Biocare 4	25	7	68
OsteoCare 1	15	2	83
OsteoCare 2	22	7	71
Osteo-Ti 1	55	0	45
Osteo-Ti 2	26	2	72
Straumann 1	3	5	65
Straumann 2	19	3	78

Table 3 Proportion of the total area of images in each leaflet devoted to the different types of images

	Proportion of images which were descriptive diagrams	Proportion of images which were informative photographs	Proportion of images which were photograph of example cases	Proportion of images which were of characters	Proportion of images which were decorative photographs	Proportion of images which were of happy people or smiles
Astra Tech 1	0.14	0	0	0	0	0.86
Astra Tech 2	0.21	0	0	0	0	0.79
Astra Tech 3	0.16	0	0	0	0	0.84
Astra Tech 4	0.13	0	0	0	0	0.87
Astra Tech 5	0.10	0.04	0	0	0	0.86
Bicon	0.08	0	0.51	0	0	0.41
BioHorizons 1	0.59	0	0.10	0	0	0.31
BioHorizons 2	0.59	0	0	0	0	0.41
Biomet 3i	0.24	0.23	0	0	0	0.53
Dentsply Frident	0.45	0.16	0	0.25	0.08	0.07
Euro teknika	0.58	0	0	0	0	0.42
Implantium	0.52	0	0.04	0	0	0.45
Neoss	0.24	0	0	0	0.09	0.67
Nobel Biocare 1	0.13	0	0	0	0	0.88
Nobel Biocare 2	0.20	0	0	0	0	0.80
Nobel Biocare 3	0.18	0.14	0	0	0	0.69
Nobel Biocare 4	0.22	0	0	0	0	0.78
OsteoCare 1	0.12	0	0	0	0	0.88
OsteoCare 2	0.23	0	0	0	0	0.77
Osteo-Ti 1	0	0	0	0	0.44	0.56
Osteo-Ti 2	0	0.07	0	0	0	0.93
Straumann 1	0.14	0	0	0	0.03	0.83
Straumann 2	0.13	0	0	0	0.01	0.86

Table 4 Summary of claims made by implant companies in their information leaflets - General

General Claims	
Claims about Implants	<p>Implant can replace missing teeth</p> <p>Implants have been used for more than 40 years</p> <p>Scientifically proven long term success by independent research.</p> <p>Implants have a success rate of over 96%</p> <p>Implants are made of biocompatible materials.</p> <p>An implant can last a lifetime, with proper care and good oral hygiene.</p> <p>Implants cannot be distinguished from your real teeth in function or appearance</p>
Problems caused by missing teeth	<p>Missing teeth make you self-conscious about your appearance; you may even stop laughing and smiling spontaneously.</p> <p>Losing your teeth causes the shape of your face to change, causing you to look prematurely aged. Implants help you to maintain a youthful appearance</p> <p>Missing teeth stops you eating many of the foods you enjoy. Implant treatment restores chewing allowing improved diet and digestion.</p>
Advantages of implant treatment	<p>Implant treatment restores your natural smile.</p> <p>Implants give improved quality of life, by giving back confidence, dignity, self-esteem.</p> <p>Adjacent teeth do not need to be prepared for bridge abutments.</p> <p>When kept in good oral hygiene implants can last longer than bridges or prostheses, therefore implants provide a more economical long-term solution.</p> <p>Anchoring dental implants in the jawbone stimulates bone tissue and gums, ensuring an attractive, aesthetic result, while helping to maintain facial structures.</p>
Advantages of implant retained overdentures	<p>Implants can stabilize dentures, making them more comfortable.</p> <p>Implant treatment can often use the existing denture.</p> <p>Implant treatment removes the need for denture adhesives.</p>
Disadvantages of dentures	<p>Conventional dentures can be painful, inconvenient, awkward, may affect how you pronounce words, and stop you eating some foods.</p> <p>Due to ill-fitting dentures patients withdraw from social engagement, leaving them with reduced confidence and low self-esteem.</p> <p>Majority of people suffer a great deal of discomfort from wearing loose or ill-fitting dentures.</p>
Implant aftercare	<p>Implants are taken care of just like natural teeth.</p> <p>Sonic and electric toothbrushes can be more effective than ordinary toothbrushes for cleaning teeth and implants.</p>