
Peer reviewed version

Link to published version (if available): 10.1308/rcsfdj.2016.16

Link to publication record in Explore Bristol Research
PDF-document

This is the author accepted manuscript (AAM). The final published version (version of record) is available online via RCS at 10.1308/rcsfdj.2016.16.

University of Bristol - Explore Bristol Research
General rights

This document is made available in accordance with publisher policies. Please cite only the published version using the reference above. Full terms of use are available: http://www.bristol.ac.uk/red/research-policy/pure/user-guides/ebr-terms/
Patient Understanding and Recall of Risks and Complications of Dental Implant Treatment Following Written and Verbal Informed Consent

Dr T. Esau  
MSc Student  
timesau@hotmail.com

Dr J. Puryer  
Clinical Lecturer  
James.puryer@bristol.ac.uk

Dr. L McNally  
Senior Clinical Teaching Fellow  
L.M.McNally@bristol.ac.uk

Professor D O’Sullivan  
Professor of Restorative Dentistry  
d.j.osullivan@bristol.ac.uk

Department of Restorative Dentistry  
School of Oral and Dental Sciences  
Bristol Dental Hospital  
Lower Maudlin Street  
Bristol  
BS1 2LY  
United Kingdom
Abstract:

Introduction: A study undertaken to determine the risks and complications of dental implant treatment recalled by patients following a written and verbal informed consent process.

Method: A piloted questionnaire consisting of open and directed questions completed by 25 patients in a general practice setting.

Results: Complications recalled most readily with open questioning were nerve damage (80%) and bruising (80%), followed by implant fracture/loss (68%), infection (64%), bleeding (60%), and pain (56%). Directed questioning highlighted that 24% of patients believed that implants always integrate. 12% were unaware of possible additional charges. Patients failed to recall adjacent tooth complications or allergic reactions (16%), long-term sinus complications (20%), peri-implant gingival recession, peri-implantitis, implant fracture or permanent nerve damage (12%). 20% failed to recall periodontitis as an implant survival risk factor and 9% did not recall possible implant-crown fracture. Risks and complications recalled most readily were: complications experienced previously, risks with high perceived impact such as nerve damage, and ‘absolute’ risks, such as failed implant integration or implant fracture/loss. Males, older patients and those with a higher socio-economic status had greater understanding and recall.

Conclusions: Although patient recall of risks and complications was good, improvements in the consent process may create more realistic expectations, greater patient satisfaction, higher commitment to treatment and less likelihood of litigation.

Keywords: Dental Implants  Informed Consent
Introduction:

Dental implants are an accepted alternative to conventional tooth replacement. Nonetheless, despite their benefits, dental implants have possible risks and complications, some in common with conventional dentistry and others specific to dental implant treatment. These risks and complications can occur early, between implant surgery and implant restoration, or late, following implant restoration and during long-term maintenance. Complications relate to the surgery itself, the achievement and maintenance of osseointegration, the implant prostheses and influences of systemic factors and other patient attributes.

Early implant treatment risks and complications include: pain, bleeding and haemorrhage, nerve damage, infection and impaired healing, sinus complications, muscle complications, swallowing foreign bodies and mandibular fracture.

Early implant treatment failures relating to local factors include: failure to osseointegrate, poor operator technique, local infection, poor bone quality and lack of interdental space.

Systemic diseases and associated medications or treatments may also increase oral tissue susceptibility to diseases and infections or affect post-operative healing. Of particular relevance to implant complications, and which need careful consideration, are: smoking, head and neck cancers, osteoporosis and bisphosphonate treatment, diabetes, bleeding disorders, malnutrition and alcoholism.

Late complications occur following implant restoration and during the implant lifetime and maintenance. They relate to both implants and their restorations and can be divided broadly into biological, mechanical and aesthetic complications. Biological complications affect the peri-implant hard and soft tissues and include implant-loss, peri-implant mucositis, peri-implantitis.
fistulae\textsuperscript{19} and soft-tissue hyperplasia\textsuperscript{19} Systemic factors relating to late implant complications include: smoking\textsuperscript{20}, diabetes\textsuperscript{21} and increasing age.\textsuperscript{22}

Mechanical/technical and aesthetic complications can be related to the type of subsequent prosthetic restoration. When considering full implant fixed denture prostheses of a metal and acrylic construction, almost 70\% have complications over 15 years\textsuperscript{23} and these include: veneer fracture, material wear, prosthetic-screw loosening, abutment-screw loosening, prosthetic-screw fracture, aesthetic problems, framework fracture and abutment-screw fracture. Overdenture complications include retention-loss, need for relining/rebasing, clip or attachment fracture, prosthesis-screw loosening, abutment-screw loosening, abutment-screw fracture and implant fracture.\textsuperscript{2}

In addition to clinical or technical complications, aesthetics may be compromised when soft-tissues around implants deteriorate over time due to overzealous brushing or peri-implantitis. Visible metal of abutments and implants at gingival margins and deterioration of interproximal papillae may reduce patient satisfaction. Grey discolouration of gingivae by implants may also compromise aesthetics.\textsuperscript{24}

Despite these potential risks and complications, dental implant treatment, with its strong evidence-base, is now routinely offered. Clinicians should present treatment options clearly and without bias, to allow informed patient decisions\textsuperscript{25} and allow them to give informed consent. Whilst oral expressed consent may be sufficient for routine dentistry, dental implant treatment is more complex and written expressed consent before proceeding is advisable. Written information can also reduce anxiety prior to surgery and improve treatment satisfaction.\textsuperscript{26} However, a signed consent form following information about proposed treatment does not guarantee understanding
of this information. Impaired understanding of informed consent information can affect older people, and visual deficits may reduce understanding of written consent in older individuals. Poorer health literacy correlates with lower incomes and lower education levels and patients with lower socioeconomic status may have poorer health information recall.

The process of taking informed consent does not guarantee that a patient will be able to recall this information at a later stage. One previous study showed that 69% of hospital patients did not read a consent form before signing it, with two thirds of the remainder not reading the consent forms carefully. In addition, those who have read consent forms still have poor knowledge of risks and benefits. A thorough informed consent process can create more realistic expectations, greater patient satisfaction, higher commitment to treatment and less likelihood of litigation.

**Aims:**

The purpose of this study was to assess a dental implant consent process currently used in a general practice setting by one of the authors. The objectives were to determine:

- Which risks and complications of dental implant treatment are recalled most readily by patients immediately following the process of written and verbal informed consent?
- What is the degree of patient understanding and recall of specific risks and complications of dental implant treatment immediately following the process of written and verbal informed consent?
Method:

Patients due to have dental implant surgery were consented by standardised verbal and written information within one of the authors’ general dental practice. The implant consent process involved the following:

- An implant assessment appointment
- A treatment schedule, assessment findings, fees and treatment timings posted to the patient
- Discussion of treatment at a second appointment
- Asking the patient to read a standardised implant consent form
- Reading a standardised verbal consent prompt sheet
- Answering questions verbally
- Asking the patient to sign the implant consent form

Patients were then asked to complete a previously piloted questionnaire (Appendix A) immediately afterwards. This consisted an initial section of open questions which were retrieved on completion, followed by the patient being given a second section which consisted of directed questioning.

Bias was reduced during verbal consent by strict adherence to a rehearsed verbal checklist which was read verbatim to each patient by the author in the same setting. Whilst certain facts such as nerve damage risk or sinus complications were more relevant to certain implant sites, all facts were given during consent, regardless of the proposed implant site. However, risk relevance was clarified following questionnaire completion. Questionnaires were numbered in completion order, and answers were collated by a single author before being analysed. In-depth statistical analysis
was limited by the descriptive nature of the results, although potential differences between ages, gender and socioeconomic status were investigated.

**Results:**

The ages, genders, socioeconomic classifications, planned implant sites and prosthesis types for the 25 patients are shown in Table 1. 48% of patients were male and 52% female, with the mean age being 59.6 years. 20 treatments were proposed in the maxilla and 5 in the mandible, with 22 having fixed prostheses and 3 removable prostheses.

The results of combined long-term and short-term risks and complications showed that, following open questioning, nerve damage was equal to bruising as the most recalled risk (80%) (Figure 1). Implant fracture/loss (68%) was the next most recalled risk, followed by infection (64%) and bleeding (60%). Accidental inhalation/swallowing and allergic reactions were least recalled (12%). Further data analysis showed temporary and permanent nerve damage recalled by 64% and 48% of patients respectively.

Directed questions were answered well and recall was good. Least recalled answers were the possibility of failed implant integration (76%) and the possibility of additional charges (88%). Recall of specific short-term risks and complications following directed questioning was good, with the most recalled risks being bruising/swelling (100%) and accidental inhalation/swallowing (100%) (Figure 2). Least recalled were tooth sensitivity/looseness (84%) and allergic reactions (84%).
Recall of specific long-term risks and complications following directed questioning was also good, with the most recalled risks being adjacent tooth complications (96%) and speech impact (96%). Least recalled were sinus complications (80%).

Recall of specific factors affecting implant survival following directed questioning was good, with smoking, excessive alcohol intake, oral hygiene and excessive forces being recalled by 100% of patients. The least recalled risk was periodontal disease (80%).

Again, recall of specific restorative complications following directed questioning was good, with crown loosening, food trapping, denture rel ine/restorative component replacement and possible denture replacement being recalled by 100% of patients. Least recalled were crown fracture (91%) and denture repair (67%).

Males tended to recall better than females as the average numbers of risks and complications remembered per patient through open questioning were 9.7 and 8.9 for males and females respectively. Furthermore, the average numbers of directed questions, answered correctly were 7.8 and 6.9 for males and females respectively.

Older patients tended to have better recall. The average numbers of risks and complications remembered per patient through open questioning were 9.1, 8.6 and 10.5 for the younger, intermediate and older age ranges respectively. The average numbers of directed questions, answered correctly were 7.3, 7.1 and 7.7 and the average numbers of facts recalled were 21.3, 22.8 and 23.0 for the same respective age ranges.

The average numbers of risks and complications remembered per patient through open questioning were 11.4, 9.0 and 6.4 for National Statistics Socio-economic Classification (NS-SEC) classes 1, 2 and 3 respectively. The average numbers of directed questions answered correctly
were 7.8, 7.3 and 6.7 and the average numbers of facts recalled were 23.5, 21.8 and 21.3 for the same respective classes. Thus, the higher the NS-SEC class, the greater was the likelihood that patients would have better understanding and recall.

**Discussion:**

It in encouraging that overall patient recall of risks and complication was good. Open questioning highlighted the greatest recall for potential nerve damage and bruising, each of which were recalled by 80% of patients. The relatively high recall-rates for bruising (80%), infection (64%), bleeding (60%), pain (56%) and swelling (52%) suggest that clinical problems encountered previously may have been understood and recalled more readily. Whilst only one patient had undergone previous implant therapy, all had experienced the after-effects of tooth extractions. Similarly, conventional restoration and natural dentition experiences may have aided understanding of restored implant and adjacent tooth complications. Whilst implant fracture/loss (68%) was the third most recalled complication through open questioning, crown and denture loosening/fracture were recalled by 48% of patients. Peri-implantitis (56%), adjacent tooth complications (52%) and gingival recession around the implant (44%) were also recalled reasonably well. There was also good recall of restorative complications through directed questioning.

Directed questioning, compared with open questioning, showed smaller recall differences between individual risks and complications. However, whilst smoking, excessive alcohol intake, oral hygiene, general health changes and excessive forces were recalled well (96-100%), periodontal or ‘gum’ disease (80%) was less-readily recalled as a factor affecting implant survival. This may indicate that parallels between periodontal disease and peri-implant disease and associations with implant failure need more emphasis in future.
Implant fracture or loss (68%) and failed integration (56%), were recalled well through open questioning. However, this may reflect the perceived ‘absolute’, ‘all-or-nothing’ nature of these complications, rather than understanding of potential causes. Indeed, greater recall may relate to ‘shock’ value, with perceived severity of potential consequences, such as nerve damage, correlating with recall.\textsuperscript{31} In the current study, 80% of patients recalled either temporary or permanent nerve damage through open questioning.

Lesser recall, through open questioning, of speech impact (32%), reduced mouth opening (28%), accidental inhalation/swallowing (12%) and allergic reactions (12%) may indicate a lesser perceived impact of these risks by patients. Sinus complications were recalled more as short-term (48%) complications than long-term complications (24%) but, were recalled by 56% of patients overall and even by 60% of patients having mandibular implants. Sinus complication recall may have reflected familiarity with sinus problems experienced previously whether related or unrelated to dentistry.

Information recalled may not have been limited to first-hand experience of the consent process. Peers may have discussed implant experiences, and media information sources abound, with 77% of UK adults having broadband internet access. In addition, 47% of UK adults use social-networking sites regularly and 61% read news online.

Whilst there was 92% understanding and recall for directed questioning, the misunderstood or non-recalled facts could result in unexpected discomfort, disappointment, loss of confidence in the clinician or even permanent emotional and life-changing sequelae. 24% of patients believed that implants always integrate, 12% of patients were unaware of possible additional charges, and 16% of patients did not recall the possibility of adjacent tooth sensitivity and looseness or allergic
reactions. 20% of patients did not recall long-term sinus complications and 12% of patients did not recall the possibility of gingival recession around the implant, peri-implantitis, implant fracture or permanent nerve damage. 20% of patients were unaware that periodontal disease could affect implant survival. Open questioning indicated that the worst-recalled complications, such as allergic reactions and accidental inhalation or swallowing, were not recalled by 88% of patients and even permanent nerve damage was not recalled by 52% of patients. The medico-legal ramifications of just one unexpected complication are clear.

Interestingly, males showed better understanding and recall than females, which does not support previously reported higher female health literacy levels. Similarly, despite systematic review showing impaired understanding of informed consent information in older people, the current study showed that patients in the older age range had better understanding and recall. This may be attributable to the relatively small sample size.

Using the three-class version of the National Statistics Socioeconomic Classification (NS-SEC), the current audit showed that the higher the NS-SEC class, the greater was the likelihood that patients would have better understanding and recall. Therefore, NS-SEC classes may help to predict the degree of understanding and recall of informed consent information.

Previous studies have shown that much of the consent information will be forgotten. Only short-term or ‘working’ memory is sufficient at consent-signing. However, transfer of information to long-term memory, followed by accurate information retrieval is required for long-term complications and maintenance requirements, and testing of conveyed information improves long-term recall. Thus in the current study, affirmative questionnaire answers may have been due merely to recollection of words, rather than actual understanding of certain words or phrases.
Consequently, at each routine dental appointment, there should be constant reinforcement of implant maintenance requirements and advice to avoid potential risks and complications, and subsequent patient dissatisfaction with treatment.

**Conclusions:**

The aims of this study were to determine which risks and complications of dental implant treatment were recalled most readily by patients immediately following a process of written and verbal informed consent.

Overall, greater recall was associated with:

1) Risks with ‘shock value’, namely nerve damage and risks with high impact due to their ‘absolute’ nature such as failed implant integration or implant loss or fracture.

2) Complications such as bruising, swelling, pain, bleeding, infection and sinus problems, possibly encountered with previous dental treatment

3) Complications akin to those of natural teeth such as peri-implantitis, with its parallels to periodontal disease, or restoration loosening or fracture.

This study highlights potential limitations of the informed consent process with respect to dental implant placement and areas where patient recall of risks and complications were found to be deficient. Improvement in the informed consent process, with subsequent reinforcement of information may help to create more realistic expectations, greater patient satisfaction, higher commitment to treatment and less likelihood of litigation.
References:


Table 1: Patient demographics. Note: NS-SEC is The National Statistics Socio-economic Classification, three-class version (Office for National Statistics, 2010).

<table>
<thead>
<tr>
<th>Patient Reference</th>
<th>Age (years)</th>
<th>Gender</th>
<th>NS-SEC¹</th>
<th>Implant Site</th>
<th>Prosthesis Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>53.6</td>
<td>F</td>
<td>3</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>2</td>
<td>64.3</td>
<td>F</td>
<td>3</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>3</td>
<td>50.6</td>
<td>M</td>
<td>2</td>
<td>Mandible</td>
<td>Fixed</td>
</tr>
<tr>
<td>4</td>
<td>53.2</td>
<td>M</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>5</td>
<td>53.8</td>
<td>M</td>
<td>2</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>6</td>
<td>49.7</td>
<td>M</td>
<td>2</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>7</td>
<td>52.6</td>
<td>F</td>
<td>2</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>8</td>
<td>57.2</td>
<td>M</td>
<td>2</td>
<td>Mandible</td>
<td>Fixed</td>
</tr>
<tr>
<td>9</td>
<td>55.4</td>
<td>F</td>
<td>3</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>10</td>
<td>59.8</td>
<td>F</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>11</td>
<td>54.5</td>
<td>F</td>
<td>2</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>12</td>
<td>64.5</td>
<td>F</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>13</td>
<td>65.1</td>
<td>M</td>
<td>3</td>
<td>Mandible</td>
<td>Fixed</td>
</tr>
<tr>
<td>14</td>
<td>59.9</td>
<td>M</td>
<td>1</td>
<td>Mandible</td>
<td>Fixed</td>
</tr>
<tr>
<td>15</td>
<td>46.8</td>
<td>M</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>16</td>
<td>68.0</td>
<td>M</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>17</td>
<td>64.3</td>
<td>F</td>
<td>3</td>
<td>Maxilla</td>
<td>Removable</td>
</tr>
<tr>
<td>18</td>
<td>74.3</td>
<td>F</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>19</td>
<td>67.9</td>
<td>F</td>
<td>2</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>20</td>
<td>64.8</td>
<td>F</td>
<td>3</td>
<td>Maxilla</td>
<td>Removable</td>
</tr>
<tr>
<td>21</td>
<td>65.3</td>
<td>F</td>
<td>1</td>
<td>Maxilla</td>
<td>Removable</td>
</tr>
<tr>
<td>22</td>
<td>72.2</td>
<td>M</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>23</td>
<td>63.5</td>
<td>M</td>
<td>3</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>24</td>
<td>48.8</td>
<td>M</td>
<td>1</td>
<td>Maxilla</td>
<td>Fixed</td>
</tr>
<tr>
<td>25</td>
<td>58.7</td>
<td>F</td>
<td>2</td>
<td>Mandible</td>
<td>Fixed</td>
</tr>
</tbody>
</table>

Mean = 59.6  48% (M)  52% (F)  20 Maxilla  22 Fixed  5 Mandible  3 Removable
Figure 1: Combined short-term and long-term risks and complications recalled with open questioning.

- Nerve damage: 80%
- Bruising: 80%
- Implant fracture/loss: 68%
- Infection: 64%
- Bleeding: 60%
- Pain: 56%
- Sinus complications: 56%
- Peri-implantitis: 56%
- Failed integration: 56%
- Swelling: 52%
- Adjacent tooth complications: 52%
- Crown of denture loosening/fracture: 48%
- Gingival recession around implant: 44%
- Speech impact: 32%
- Reduced mouth opening: 28%
- Accidental inhalation/swallowing: 12%
- Allergic reactions: 12%
Figure 2: Combined short-term and long-term risks and complications recalled with direct questioning.

- Bruising/swelling: 100%
- Accidental inhalation/swallowing: 100%
- Infection: 96%
- Pain: 96%
- Adjacent tooth complications: 96%
- Speech impact: 96%
- Bleeding: 96%
- Temporary nerve damage: 92%
- Reduced mouth opening: 92%
- Sinus complications: 92%
- Permanent nerve damage: 88%
- Gingival recession around implant: 88%
- Implant fracture: 88%
- Peri-implantitis: 88%
- Tooth sensitivity/looseness: 84%
- Allergic reactions: 84%
- Sinus complications: 80%

% of patients to recall complications
Appendix A: The questionnaire

1. You have just been informed verbally and in writing about possible complications that can arise soon after implant surgery and during the following week or so.
Please list all of the complications that you recollect being informed about.

2. You have just been informed verbally and in writing about possible complications that can arise in the longer term after surgery, including complications involving adjacent structures.
Please list the complications that you recollect being informed about.

Please tick YES or NO to the following questions:

3. Will a dental implant always become attached to the bone after surgery?
4. Could your implant/s last your lifetime?

YES □
NO □

5. Could your implant/s fail and need removal?

YES □
NO □

6. Is there a chance that the false tooth or teeth (such as crown, bridge or denture) supported by the implant/s may need replacing or adjusting in the short and long-term?

YES □
NO □

7. Will regular maintenance and monitoring of the implant/s by a dentist be needed?

YES □
NO □

8. Will you need to pay particular care to your daily oral hygiene regime relating to your implant?

YES □
NO □

9. Can you get a type of gum disease and bone-loss around implants?

YES □
NO □
10. Will maintenance, repairs or replacement of your implant and overlying crown, bridge or denture incur additional charges?

YES □

NO □

11. Please tick those complications in the following list which you recall being informed as possible early after-effects and complications of implant surgery during the first week or so of healing:

a. Pain. □

b. Bruising, facial discolouration, facial swelling. □

c. Prolonged bleeding. □

d. Infection around the surgical site. □

e. Temporary nerve damage causing numbness, tingling or altered sensation. □

f. Sensitive or looseness of adjacent teeth. □

    g. Temporary reduced mouth-opening. □

    h. Infection or damage to the sinus or nasal cavity or dislodgement of the implant into these cavities. □

    i. Accidental inhalation or swallowing of foreign matter. □

    j. Allergic reactions to antibiotics, anaesthetics or other medication. □

12. Please tick those complications in the following list which you recall being informed about that can possibly arise in the longer term after surgery:
a. Permanent numbness, tingling or altered sensation of lip, tongue or cheek. □
b. Adjacent tooth gum recession, sensitivity, looseness or loss of vitality. □
c. Gum recession around the implant causing visible metal at the gum margin. □
d. Complications involving the sinus, including infection. □
e. Implant fracture, necessitating its removal or replacement. □
f. Gum disease and/or bone-loss around the implant possibly necessitating its removal. □
g. Possible impact on speech. □

13. Please tick those factors in the following list which you recall being informed as compromising implant survival or increasing problems with implant restorations:

a. Smoking. □
b. Excessive alcohol consumption. □
c. Gum disease. □
d. Poor oral hygiene. □
e. Changes to general health such as diabetes. □
f. Excessive forces on implants such as with tooth-grinding or biting too hard such as on ice-cubes. □

14. Please tick those complications in the following list which you recall being informed as possible complications or repairs of the false tooth or teeth (crown, bridge or denture) overlying the implant.
Only tick for the restoration relating to your implants.

If you are having an implant-retained crown or bridge, ONLY tick Option 1.

If you are having an implant-retained denture, ONLY tick Option 2.

Option 1 (Crown / Bridgework):

a. Loosening of the implant crowns. ☐

b. Fracture of the implant crowns. ☐

Option 2 (Dentures):

a. Fracture of the denture necessitating repair. ☐

b. Loosening of the denture, necessitating a reline or replacement of retentive components on the implants or in the denture. ☐

c. Wear and tear, necessitating the fabrication of a new denture. ☐

d. Possible food-trapping beneath the denture. ☐