5aBAa3. Ultrasonic assessment of the in vitro biomechanical stability of a dental implant

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Dental implants are widely used for oral rehabilitation. However, there remain risks of failure which are difficult to anticipate. The objective is to investigate the potentiality of a quantitative ultrasound method to assess the biomechanical stability of a dental implant in vitro. Two experimental configurations were considered using a 10 MHz contact transducer located at the implant extremity. For each ultrasound measurement, a quantitative indicator I is derived based on the time variation of the amplitude of the rf signal. Firstly, seven implants were embedded in tricalcium silicate-based cement. One implant was left without any mechanical solicitation and six implants were subjected to mechanical stresses during 24 hours. The ultrasonic response of each implant was measured during 24 hours. The results show no variation of I without mechanical solicitation, while I significantly increases as a function of fatigue time. Secondly, ten implants were unscrewed from bone tissue and their ultrasonic response was measured after each turn. Analysis of variance tests revealed a significant effect of the amount of bone in contact with the implant on the distribution of I. The results show the feasibility of our QUS device to assess the biomechanical quality of the interface surrounding the implant.

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INTRODUCTION

Dental implants [1] are widely used clinically and have allowed considerable progress in oral and maxillofacial surgery, to restore one or more missing teeth caused by old age or accidents and for aesthetic purposes. However, implant failures, which may have dramatic consequences, still occur and remain difficult to anticipate.

Accurate measurements of implants biomechanical stability are of interest since they could be used to improve the surgical strategy by adapting the choice of the healing period to each patient. Empirical methods based on palpation and patient sensation are still used by dental surgeons to determine when the implant should be loaded with the prosthesis because it remains difficult to monitor bone healing in vivo [2]. Accurate noninvasive quantitative methods capable of assessing implant stability could be used to guide the surgeons and hence to reduce the risk of failure. The implant stability is determined by the quantity and biomechanical quality of bone tissue around the implant. Assessing the implant stability is a difficult multiscale problem due to the complex heterogeneous nature of bone and to remodeling phenomena [3, 4].

Different approaches have been suggested in the past to assess the implant stability in vivo: X-ray radiography, µCT, or magnetic resonance imaging (MRI), but these techniques are not entire satisfaction. As a consequence, biomechanical methods have been developed, their main advantage consisting in the absence of ionizing radiation, inexpensiveness, portability and noninvasiveness. Periotest (Bensheim, Germany) and Osstell (Gothenburg, Sweden) for example. The most commonly used biomechanical technique is the resonance frequency analysis (RFA) [5], which consists in measuring [6] the first bending resonance frequency. The RFA technique allows to assess the implant anchorage depth into bone [7], marginal bone level [8] and the stiffness of the bone-implant structure [9, 10]. However, the RFA cannot be used to identify directly the bone-implant interface characteristics [11]. No correlation between the ISQ and BIC nor between ISQ and cortical thickness has been evidenced [12].

The use of quantitative ultrasound (QUS) as an alternative method to assess the implant biomechanical stability has first been suggested using an aluminum screw inserted in a metallic medium [13]. The principle of the measurement relies on the dependence of ultrasonic propagation within the implant on its boundary conditions, which are related to the bone-implant interface biomechanical properties [14]. An in vitro preliminary study was carried out by our group with a prototype titanium cylinder shaped implants inserted in bone tissue, showing the feasibility of the approach [14]. Numerical simulation [15] were also carried out to understand the experimental results, thus quantifying the sensitivity of the technique. However, the dependence of the ultrasonic response on the stability of an implant inserted in bone tissue has not yet been established.

The first aim of this study is to investigate the evolution of the ultrasonic response of an implant embedded in TSBC and subjected to fatigue stresses and more details on this study can be found in [16]. Secondly, this study aim at assessing the potentiality of QUS to assess the amount of bone in contact with a dental implant inserted in bone tissue. More details on this study can be found in [17].

MATERIAL AND METHODS

Tricalcium Silicate-Based Cement Experiments

Sample preparation

Figure 1A describes the experimental set up. Biodentine (Septodont, Saint Maur des Fossés, France) is introduced in a 8 mm diameter, 14 mm deep cylindrical hole machined in PMMA after its preparation under clinical conditions. The cement paste was obtained by mixing the commercial Biodentine powder with an increased volume of the liquid part in order to reach a very fluid material which can be easily inserted inside the mold cavity. Then, the implant was carefully inserted in liquid Biodentine so that the hole axis coincides with the implant axis. The implant is a 12 mm long and 4 mm diameter titanium dental implant IDOH 1240 manufactured by Implant Diffusion International (Montreuil, France).

Mechanical fatigue

Cyclic stresses are applied to the implant via a custom made mechanical device shown in Fig. 1B and composed of a translation stage driven by an electrical motor (Leroy-Somer 36-35612, Angoulême, France). The amplitude and frequency of the force are equal to 1 N and 1 Hz respectively. These values were chosen because they correspond to physiological lateral stresses applied to the teeth during normal chewing motions or through bruxism [18, 19]. Cyclic loading is applied to the implant during 24 hours to each sample.

Ultrasonic device

The ultrasonic device is composed of a 5 mm diameter planar ultrasonic contact monoelement transducer (V129SM, Panametrics, Waltham, MA, USA) generating a broadband ultrasonic pulse propagating perpendicularly to its active surface. The ultrasonic probe is used in echographic mode and its center frequency
is equal to 10 MHz. Based on the method developed in [14], an indicator \( I \) was devised to quantitatively estimate the average amplitude of the signal before 80 \( \mu \text{s} \). All ultrasonic measurements were realized 20 times in order to assess the reproducibility of the estimation of the indicator \( I \).

**Experimental Protocol**

First, the ultrasonic response of an implant embedded in Biodentine with no mechanical solicitation was measured at different times (respectively \( T_0 \), \( T_0+1 \), \( T_0+2 \), \( T_0+4 \), \( T_0+7 \) and \( T_0+24 \) hours after the implant insertion in Biodentine, where \( T_0 \) corresponds to 48 hours) in order to determine the evolution of the indicator \( I \) as a function of time without any stress applied to the implant interface. \( T_0=48 \) hours corresponds approximately to the time necessary for a stabilization of Biodentine material properties [20].

![Figure 1](image_url)

**FIGURE 1.** (A) Schematic description of the experimental set up including the implant inserted in Biodentine \( \text{TM} \); (B) Schematic description of the mechanical fatigue device. Numbers 1 and 2 correspond to motions and forces in both lateral directions relatively to the implant axis.

Second, six other implants of the same reference were used to assess the effect of fatigue stresses on the ultrasonic response of the implant following the experimental protocol illustrated in Fig. 5. \( T_0=48 \) hours after the implant insertion in Biodentine, the ultrasonic response of each implant was measured. Then, a fatigue cycle was applied to each implant during one hour and the ultrasonic response of the implant was again determined. Different and consecutive fatigue cycles with durations equal to 1, 1, 1, 3, 6, 9 and 15 hours respectively were realized and the ultrasonic measurements were carried out after each fatigue solicitation in order to measure the variation of the indicator \( I \) as a function of the fatigue duration. Here, six different samples were considered in order to account for possible variability in implant positioning and in the preparation of Biodentine.

**Statistical analysis**

One-way analysis of variance (ANOVA) and Tukey-Kramer tests were performed to investigate the dependence of the indicator \( I \) as a function of time in the different experiments.

**Implant inserted in bone tissue**

**Implant and bone samples**

Ten bone samples were cut from the proximal part of the humerus of bovine cadavers obtained at the local butcher shop. One cylindrical cavity (3.5 mm diameter and 13 mm deep) was created in each sample prior to implant insertion, similarly as what is done in the clinic. Cavities were thoroughly rinsed with isotonic saline to remove bone fragments prior to the insertion of the titanium implants. The cavity axis coincides with the axis of the resin block, which was fixed to a handy torque gauge to measure the insertion torque between the implant and ultrasonic transducer. The ten dental implants used herein are similar and manufactured by Implant Diffusion International (IDOH 1240, 12 mm of length and 4 mm of diameter).

**Experimental measurements**

The ultrasonic device is composed of a 5 mm diameter planar ultrasonic contact transducer (Sonaxis, Besançon, France) generating a broadband ultrasonic pulse propagating perpendicularly to its active surface (monoelement transducer). The probe is used in echographic mode and its center frequency is equal to 10 MHz, with a frequency bandwidth approximately equal to 6–14 MHz. The probe is attached rigidly to a healing...
abutment which can be screwed into the implant so that the measurements are not influenced by positioning problems of the probe relatively to the healing abutment.

The ultrasonic response of an implant embedded in air was first measured by inserting the healing abutment (with the transducer on top of it) with a torque of 0.05 N.m. The healing abutment was then removed and inserted again following the same procedure in order to assess the reproducibility of the measurements.

Each implant was then initially entirely inserted in the dedicated cavity. The ultrasonic transducer was screwed into the implant with a torque of 0.05 N.m and the 10 MHz ultrasonic response of the implant was measured. The healing abutment was then removed and inserted again 10 times to assess the reproducibility of the measurements. The implant was then unscrewed by 2π rad in order to reduce the surface area of the implant in contact with bone tissue. The ultrasonic response was then recorded by inserting the healing abutment with the same torque of 0.05 N.m. The procedure was repeated until the implant was spontaneously detached from the bone cavity. The number of measurements corresponding to the number of rotations before implant detachment depends on bone quality around the implant. The same experimental procedure described above was carried out for ten dental implants.

![Diagram of ultrasonic experimental setup](image)

**FIGURE 2.** Schematic description of the ultrasonic experimental set-up with the use of handy torque gauge. The dental implant is completely inserted in the bone sample.

**Statistical analysis**

Analysis of variance (ANOVA) tests was performed to evaluate the significance of $I$ variations as a function of the drilling method.

**RESULTS**

**Tricalcium silicate-based cement experiment**

Table 1 shows the variation of the minimum, maximum, mean and standard deviation of the values of the indicator $I$ at different times after being embedded in Biodentine without any mechanical solicitation of the implant. The results show no significant effect of time on the value of the indicator $I$ ($p=0.78$, $F=0.56$).

Table 2 shows the results obtained with the six implants for the ANOVA analysis as well as for the average standard deviation of $I$ ($Em$) and for the slope $d$ of the linear regression of the mean value of $I$ as a function of time. As shown in Table 2, comparable results were obtained for all six implants.

**TABLE 1.** Variations of the mean, standard deviation, minimum and maximum values of the indicator $I$ for the implant without mechanical stresses applied during 24 hours. $T_0=48$ hours. No significant influence of time on $I$ is obtained.

<table>
<thead>
<tr>
<th>Time (hours)</th>
<th>$T_0$</th>
<th>$T_0+1$</th>
<th>$T_0+2$</th>
<th>$T_0+4$</th>
<th>$T_0+7$</th>
<th>$T_0+24$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean value of $I$</td>
<td>112.3</td>
<td>115.3</td>
<td>111.6</td>
<td>113.6</td>
<td>112.8</td>
<td>115.0</td>
</tr>
<tr>
<td>Standard deviation of $I$</td>
<td>4.4</td>
<td>6.4</td>
<td>7.0</td>
<td>6.1</td>
<td>4.6</td>
<td>5.4</td>
</tr>
<tr>
<td>Minimum value of $I$</td>
<td>107.8</td>
<td>104.3</td>
<td>101.0</td>
<td>106.5</td>
<td>104.9</td>
<td>108.3</td>
</tr>
<tr>
<td>Maximum value of $I$</td>
<td>116.3</td>
<td>123.9</td>
<td>123.2</td>
<td>124.9</td>
<td>119.7</td>
<td>122.4</td>
</tr>
</tbody>
</table>
TABLE 2. Results obtained with the six implants under fatigue loading for the variation of the indicator \( I \) as a function of fatigue time. \( p \) value and \( F \) statistic correspond to results obtained with the ANOVA analysis for the dependence of \( I \) as a function of fatigue time. \( Em \) corresponds to the mean value of the standard deviation of \( I \) and \( d \) to the slope of the linear regression of \( I \) as a function of time.

<table>
<thead>
<tr>
<th>Implant #1</th>
<th>Implant #2</th>
<th>Implant #3</th>
<th>Implant #4</th>
<th>Implant #5</th>
<th>Implant #6</th>
</tr>
</thead>
<tbody>
<tr>
<td>(&lt; 10^{-5})</td>
<td>(&lt; 10^{-5})</td>
<td>(&lt; 10^{-5})</td>
<td>(&lt; 10^{-5})</td>
<td>(&lt; 10^{-5})</td>
<td>(&lt; 10^{-5})</td>
</tr>
<tr>
<td>160.6</td>
<td>200.2</td>
<td>84.31</td>
<td>209.1</td>
<td>327.1</td>
<td>213</td>
</tr>
<tr>
<td>5.5</td>
<td>5.8</td>
<td>5.7</td>
<td>5.7</td>
<td>5.9</td>
<td>5.8</td>
</tr>
<tr>
<td>1.7</td>
<td>2.1</td>
<td>1.5</td>
<td>2.5</td>
<td>2.8</td>
<td>2.2</td>
</tr>
</tbody>
</table>

Average \(< 10^{-5}\) 199.1 5.8 2.2

Ultrasonic response of bone tissue

The value of the indicator \( I \) obtained when the implant was embedded in air is equal to 434.1± 1.7. The value of \( I \) significantly increases as a function of the number of rotation applied to the implant. Each rotation corresponds to \( 2\pi \) rad. The average of the standard deviation of the indicator (when the implant is fully inserted in bone tissue) is equal to 1.42. The average of the correlation coefficient corresponding to the linear regression analysis of the variation of \( I \) as a function of the number of rotations is equal to 0.91. The average of slope \( a \) of the same linear regression is equal to 4.47. The results show that bone quantity in contact with the implant has a significant influence on its ultrasonic response. For example, the implant of the sample #1 was detached from the surrounding bone after a total number of 5 rotations, so that six measurement points were obtained.

Table 3 summarizes the results obtained for the 10 implants (number of rotations, reproducibility \( \Delta y \) corresponding to the standard deviation of the indicator \( I \) obtained for ten measurements, slope \( a \) of the linear regression of the indicator \( I \) as a function of the number of rotations and the associated correlation coefficient \( R^2 \)). Table 3 shows that comparable results in terms of order of magnitude are obtained for all implants. In particular, an increase of the indicator \( I \) as a function of the bone quantity in contact with the implant is obtained for all implants. ANOVA shows a significant effect of rotation on the value of \( I \) (\( p<10^{-5}, F=29.42 \)).

TABLE 3. Results obtained for 10 implants. \( a \) is the slope of the linear regression of the curve, \( R^2 \) is the correlation coefficient and \( \Delta x \) is the incertitude of the measure.

<table>
<thead>
<tr>
<th>Number of rotations</th>
<th>Standard Deviation</th>
<th>( a )</th>
<th>( R^2 )</th>
<th>( \Delta x ) (in mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant #1</td>
<td>5</td>
<td>0.89</td>
<td>3.32</td>
<td>0.92</td>
</tr>
<tr>
<td>Implant #2</td>
<td>6</td>
<td>2.08</td>
<td>4.89</td>
<td>0.86</td>
</tr>
<tr>
<td>Implant #3</td>
<td>6</td>
<td>2.19</td>
<td>8.49</td>
<td>0.96</td>
</tr>
<tr>
<td>Implant #4</td>
<td>6</td>
<td>0.84</td>
<td>1.95</td>
<td>0.95</td>
</tr>
<tr>
<td>Implant #5</td>
<td>6</td>
<td>2.02</td>
<td>5.83</td>
<td>0.98</td>
</tr>
<tr>
<td>Implant #6</td>
<td>7</td>
<td>1.40</td>
<td>4.41</td>
<td>0.97</td>
</tr>
<tr>
<td>Implant #7</td>
<td>7</td>
<td>1.39</td>
<td>6.82</td>
<td>0.83</td>
</tr>
<tr>
<td>Implant #8</td>
<td>6</td>
<td>1.65</td>
<td>2.48</td>
<td>0.90</td>
</tr>
<tr>
<td>Implant #9</td>
<td>6</td>
<td>1.09</td>
<td>2.47</td>
<td>0.79</td>
</tr>
<tr>
<td>Implant #10</td>
<td>6</td>
<td>1.93</td>
<td>4.01</td>
<td>0.90</td>
</tr>
<tr>
<td>Mean</td>
<td>6.1</td>
<td>1.42</td>
<td>4.47</td>
<td>0.91</td>
</tr>
<tr>
<td>± Standard Deviation</td>
<td>±0.57</td>
<td>±0.48</td>
<td>±2.10</td>
<td>±0.06</td>
</tr>
</tbody>
</table>

DISCUSSION

To the best of our knowledge, this is the first study investigating the variation of the ultrasonic response of a dental implant as a function of fatigue time when the implant is subjected to physiological cyclic mechanical solicitations and as a function of bone quantity in contact with its external interface. The findings obtained herein
open new paths in the domain of dental implantology because i) they constitute a first prove of concept towards the development of an ultrasonic method to investigate the implant osseointegration and ii) the approach could also be used in the development of bone substitute biomaterials in the context of dental implantology. The second originality of the present study lies in that variations of the ultrasonic response of a real implant are evidenced as a function of the insertion depth, which is related to its primary stability. The two aforementioned breakthroughs are possible due to the multimodal nature of the present study, which couples mechanical engineering together with material science and ultrasound characterization in the context of dental implantology.

Without mechanical solicitation, the indicator $I$ remains constant between 48 and 72 hours after implant insertion in Biodentine, which is consistent with previous results [20] showing that the mechanical properties of Biodentine (obtained with Vickers microhardness tests) weakly vary as a function of time. However, for all implants subjected to cyclic stresses, a significant increase of $I$ was obtained as a function of fatigue time, which may be explained by the debonding of the interface between Biodentine and the implant. As shown in Fig. 3B, fatigue testing induces interface debonding around the implant. In the regions where interface debonding occurs, the implant surface is surrounded by liquid water, which has different material properties than (solid) Biodentine. When the biodentine-implant interface is debonded [21], a stronger gap of mechanical properties is obtained at the implant interface, thus explaining that the transmission coefficient at the implant external interface is lower, which explains the slower decrease of the ultrasonic energy recorded by the sensor. Note that similar behavior has been obtained with a planar bone implant interface in previous studies by our group [22], which shows the potentiality of our approach. In summary, the acoustic energy recorded at the upper surface of the implant decreases faster when the interface is fully bonded than when it is debonded.

FIGURE 3. Pictures taken after cutting the sample in a plane containing the implant axis for a sample without mechanical solicitation (A) and after 24 hours of fatigue testing (B). Ellipses show the debonded area between titanium implant and Biodentine.

When the implant is unscrewed from the bone cavity, the amount of bone in contact with the implant decreases, due to its approximately cylindrical shape. When the bone-implant interface is debonded [21, 23], a stronger gap of mechanical properties is obtained at the implant interface, thus explaining that the transmission coefficient at the implant external interface is lower. Therefore, energy leakage of the ultrasonic wave out of the implant (which acts as a wave guide) is lower when the bone-implant is debonded, which explains the slower decrease of the ultrasonic energy recorded by the sensor. In summary, the acoustic energy recorded at the upper surface of the implant decreases faster when the implant external interface is fully bonded than when it is debonded.

The insertion torque of the transducer is likely to affect its ultrasonic response due to variations of contact conditions between the implant and the healing abutment. In the present study, the ultrasonic probe is screwed with a torque of 0.05 N.m before all measurements, which is around 5 times lower than torque values recommended by implant manufacturers [24]. We verified (data not shown) that changing the torque value between 0.03 and 0.08N.m does not affect the reproducibility of the measurements.

Several works need to be realized to comfort our approach. First, the understanding of propagation phenomena in the bone-implant system should be achieved using numerical simulations. Second, other implants should be considered. Third, in vivo studies should aim at assessing the effect of healing time of the implant ultrasonic response, leading to possible estimation of the implant secondary stability. Note that the 10 MHz ultrasound response of a planar bone-implant interface has been shown to be sensitive to healing time in a previous study by our group [22], which shows the potentiality of our approach. This study paves the way for the development of a new ultrasonic tool to be used in oral implantology for the monitoring of osseointegration. The main advantage of ultrasonic based technology compared with RFA
technique lies in its sensitivity to the bone-implant interface properties in terms of biomechanical quantity and quality [25]. More details on the present study can be found in [16, 17].

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REFERENCES


