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Prevalência de nódulos pulpares em molares: Análise em Tomografia Computadorizada de Feixe Cônico

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Dissertação apresentada à Faculdade de Odontologia de Araçatuba, Universidade Estadual Paulista "Júlio de Mesquita Filho" - UNESP, como parte dos requisitos para a obtenção do título de Mestre em Ciência Odontológica, área de concentração Endodontia.

Orientador: Prof. Ass. Eloi Dezan Junior

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Resumo

Vasques, AMV. Prevalência de nódulos pulpares em molares: Análise em Tomografia Computadorizada de Feixe Cônico, 2019. 53p. Dissertação (Mestrado em Endodontia) – Universidade Estadual Paulista (Unesp), Faculdade de Odontologia, Araçatuba.

RESUMO

Nódulos pulpares são calcificações presentes na câmara pulpar, aderidos nas paredes dentinárias ou como nódulos soltos e podem bloquear parcialmente ou totalmente o acesso aos orifícios dos canais radiculares. Devido à limitação de estudos realizados anteriormente com radiografias, o objetivo desse trabalho foi determinar a prevalência de nódulos pulpares por meio da tomografia computadorizada de feixe cônico (TCFC) e explorar qualquer correlação potencial entre a ocorrência de nódulos pulpares com gênero, idade, dente, arcada e estado da coroa dentária. Para isso foram utilizadas TCFC de 300 pacientes, totalizando 631 molares. Todos os molares foram analisados nos planos sagital, axial e coronal e, quando presentes, os nódulos pulpares foram identificados como uma massa redonda ou oval hiperdensa. Após tabulação dos dados, a análise estatística foi realizada através da aplicação de testes de qui-quadrado. De um total de 300 pacientes, os nódulos pulpares foram identificados em 35% e em 25.5% dos 631 molares analisados. A presença dos nódulos pulpares foi mais frequente no sexo feminino (41.1%) do que no masculino (27.7%) e nos indivíduos com idade acima de 80 anos. Os primeiros molares superiores exibiram a maior incidência de nódulos pulpares. Nenhuma diferença significativa foi observada quando os arcos maxilar e mandibular e os lados foram comparados. A presença de nódulos pulpares foi elevada em molares restaurados quando comparados aos dentes íntegros ($P < 0,05$). A Tomografia Computadorizada de Feixe Cônico é um recurso eficiente para o diagnóstico e localização dos nódulos pulpares.

Palavras-chave: Calcificações da polpa dentária; Endodontia; Tomografia computadoriza de feixe cônico.

Abstract

Vasques, AMV. Prevalence of pulp stones in molars: a cone-bean computed tomographic evaluation, 2019. 53p. Dissertation (Master's Degree in Endodontics) – São Paulo State University (Unesp), School of Dentistry, Araçatuba.

ABSTRACT

Pulp stones are calcifications present in the pulp chamber adhered to dentin walls or as loose nodules and can partially or totally block access to root canals entrance. Due to radiographic limitation of previous reports, the objective of this study was to determine the prevalence of pulp stones by cone beam computerized tomography (CBCT) and to explore any potential correlation between the occurrence of pulp stones with gender, age, tooth, arches and condition of the dental crown. CBCT of 300 patients were assessed, totaling 631 molars. All molars were analyzed in the sagittal, axial and coronal planes and, when present, pulp stones were identified as a round or oval hyperdense mass. After data tabulation, statistical analysis was performed using chi-square tests. Of a total of 300 patients, pulp stones were identified in 35% and in 25.5% of the 631 analyzed molars. The presence of pulp stones was most frequently found in females (41.1%) than in males (27.7%) and in individuals aged over 80 years. The first upper molars showed the highest incidence of pulp stones. No significant difference was observed when maxillary and mandibular arches were compared neither sides. The presence of pulp stones was higher in restored molars when compared to intact teeth ($P < 0.05$). Cone Beam Computerized Tomography is an efficient resource for the diagnosis and location of pulp stones.

Keywords: Dental pulp calcifications; Endodontics; Tomography, Emission-Computed.

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INTRODUCTION

Computerized tomography (CT) is a diagnostic imaging method that uses X-ray and allows the reproduction of a section of the human body in any of the three planes (axial, coronal and sagittal) (Da Silva & Sant 'anna 2013). Cone Beam Computerized Tomography (CBCT), was developed specifically for dentistry (Ferreira et al. 2008) and allows the visualization of anatomical structures in 3 dimensions with higher resolution. This improvement in the quality of imaging tests facilitates the diagnosis, planning and follow-up of oral diseases (Nair & Nair 2007, Patel et al. 2015).

Unlike conventional radiographs that project in a single plane all structures crossed by X - rays, the CT shows the structural relationships in depth (Da Silva & Sant 'anna 2013). The unit that compose the tomographic image, named voxel, is classified as isotropic presenting height, width and depth of equal dimensions (Cavalcanti 2014), allowing objects within this volume (voxel) to be accurately measured in different planes (Farman & Scarfe 2006).

Another feature of Cone Beam Tomography is the different sizes of the field of view (FOV). The advantage of different FOV sizes is to enable the evaluation of the region of interest with high resolution and greater accuracy, without exposing the patient to unnecessary radiation (Scarfe et al. 2006).

The CBCT can be used in all dental specialties such as Implantology, Endodontics, Orthodontics, Periodontics, Bucco-Maxillofacial Surgery and Traumatology (Tsiklakis et al. 2004). In endodontics, CBCT assists the root canal treatment in several clinical situations, such as locating calcified canals, position and size of periapical lesions, furcal perforations and interpretation of root canal anatomy (Ball et al. 2013, Dutra et al. 2016), aiding the treatment planning. In addition, a clinical situation that may hinder endodontic treatment is the presence of a calcification in the pulp chamber, known as pulp stone (Goga et al. 2008), suspended, adhered or embedded in dentinal walls (Neville 2009). It's important to emphasize that a single tooth may present more than one calcified nodule, varying its size from small particles to large masses that occupy the entire pulp chamber (Johnson & Beveander, 1956). The main clinical significance is their interference in the endodontic treatment, since pulp stones may partially or totally block access to root canals (Goga et al. 2008, Verma et al. 2015) leading to accidents such as furcal perforation or even treatment failure.

The etiological factors for pulp stone formation are inconsistent in the literature, but some authors state that age, gender, systemic diseases, long-term irritation (deep cavities and restorations) may be involved in its emergence (Ranjitkar et al. 2002, Bauss et al. 2008, Edds et al. 2005, Jung et al. 2013, Kannan et al. 2015). Although pulp stones can be found in all groups of teeth, the greatest occurrence is observed in molars (Baghdady et al. 1988, Ranjitkar et al. 2002, Goga et al. 2008).

Previous studies using radiographic analysis indicated that the occurrence of pulp stones ranges from 4 to 90%. However, only nodules larger than 200 μm in diameter are radiographically visible (Sayegh & Reed 1968, Moss-Salentijn & Klvvertm 1988, Chandler et al. 2003). According to Da-Silva et al (2016), the real prevalence of pulp stones is probably greater than most of those studies have suggested.

Due to variation in current results and limitation of previous studies performed with radiographs, the objective of this study was to evaluate the prevalence of pulp stones in molars using Cone Beam Computerized Tomography.

MATERIALS AND METHODS

Study sample

The present study was approved by the Human Research Ethics Committee of Araçatuba School of Dentistry (Process 2.352.750). From August 2017 to July 2018, CBCT scans were selected from a private radiology clinic (Brazil Imagem, Araçatuba, SP, Brazil). All CT scans were performed with previous clinical indication, without exposing the patient to unnecessary radiation. Free and informed consent was signed by the patient before CBCT examination.

The inclusion criteria were: CBCT exams with FOV of 5cm x 5cm, 6cm x 8cm and 8cm x 8cm from upper and lower molars region, presenting first and second molars with complete apex. Exclusion criteria encompassed: patients younger than 18 years of age and images showing orthodontic retention device, endodontic treatment and metallic crowns. Due to anatomical variations and limited endodontic indication, third molars were not analyzed. At the end, 300 tomographic exams were selected for analysis, of which 137 were male and 163 female.

All images were acquired according to the protocol recommended by the manufacturer and ALARA (As Low As Reasonably Achievable) principle was strictly followed by the clinic.

Acquisition and analysis of CBCT

All CBCT images were acquired by a licensed and experient radiologist using the EAGLE V-BEAM Cone Beam (Dabi Atlante, SP, Brazil) with the fields of view (FOV) of 5cm x 5cm, 6cm x 8cm and 8cm x 8cm. The image volume was reconstructed with isometric isotropes 5x5 (0,10 x 0,10 x 0,10); 6x8 e 8x8 (0,16 x 0,16 x 0,16) voxels.

The tube voltage was 85 KVp and 4 mA, using an exposure time of 25.5 s. The workstation used the operating system Windows® 7 Professional 64 bits (Microsoft Corporation, Redmond, WA, EUA) processor Intel CORE i7 2.8 GHZ 6ª GER (Intel Corporation, EUA), graphic card GEFORCE GTX 1060 6GB XLR8 GAMING OC EDITION DDR5 256 BITS (Parsippany, New Jersey, EUA) and monitor Dell E2211H 21,5 inches - Resolution widescreen de 1920 x 1080 pixels (Dell Corporation, Round Rock, EUA).

The images in DICOM format were processed, interpreted and measured by Ondemand 3D Dental software (Cybermed Inc, Seoul, South Korea), brightness adjustments and contractions were performed to facilitate visualization. The

tomographic images were analyzed by maxillary and mandibular hemi-arches, following the long axis of the tooth, in the coronal, sagital and axial planes, with definition of a transverse range of 0.1 mm and a panoramic interval of 0.2 mm. The analyzed parameters are shown in table 1.

Table 1. Analyzed parameters

1. Molar Location	• Maxilla or mandible • Right or left

2. Pulp Stones	• Present
	  ○ Round or oval shape;
	  ○ Loose or adhered to dentinal wall;
	• Absent

3. Restoration	• Present
	  ○ Shallow (1/3 restored dentin)
	  ○ Medium (over 1/3 restored dentin)
	  ○ Deep (3/3 restored dentin)
	• Absent

5. Gender	• Female • Male
6. Age	• Over 18 years old

Statistical Analysis

Tabulated data were submitted to statistical analysis using Sigma Plot software (version 12.0). Shapiro-Wilk normality test indicated chi-square analysis, performed with a significance level of 5%.

RESULTS

Prevalence of pulp stones and distribution between genders

Of the 300 analyzed individuals, pulp stones were detected in 35% of the patients and in 25.5% of the molars. Pulp stones were observed in 27.7% of 137 male patients, while 163 female, showed calcifications in 41.1%. The association between gender and pulp stone is statistically significant (P <0.05), as observed inTable 2.

Distribution of pulp stones between age groups

The age of the selected patients ranged from 18 to 89 years, with the highest occurrence of pulp stones in the age group of 80-89 years old (50%), and lower occurrence in individuals aged 18-29 years old (21.1%). There was a significant association between age groups and distribution of pulp stones (P <0.05) (Table 3).

Occurrence of pulp stones by dental arches

The comparison between presence and absence of pulp stones according to the dental arch and the side is shown in table 4. There was no significant difference when comparing maxillary and mandibular arches, neither right and left sides (p = 0.875).

Prevalence of pulp stones between molars

Among molars that presented pulp stones, the first upper right molar showed the highest prevalence (40.4%), and a low occurrence was observed in the second lower (16.1%) and upper (16%) molars. Statistical analysis showed a significant difference in the occurrence of pulp stones within the analyzed molar groups (P<0.05) (Table 5).

Pulp stones and the condition of dental crown

Of 161 teeth with pulp stones, 125 (77.6%) showed restoration. Shallow depth restoration was observed in 78 teeth, a medium depth in 40 teeth and 7 teeth presented deep restoration.

Only 36 teeth (22.4%) with calcified nodules were considered healthy (Table 5). There was a statistical difference between the association of the pulp stones and the condition of the dental crown (p = 0.005).

Characteristics of Pulp Stones

Within the observed teeth with pulp stones, 70 molars had a round shape nodule, while 91 was oval, with a significant difference between shapes (P<0.05). In addition, pulp stones were mostly adhered to the floor of the pulp chamber (68.3%) when compared to loose nodules (31.7%) (P<0.05).

Table 2. Distribution of Pulp Stones by Gender

Gender	Number of patients examined	Number of patients with pulp stones (%)	Number of patients without pulp stones (%)
Male	137	38 (27.7)	99 (72.3)
Female	163	67(41.1)	96 (58.5)
Total	300	105 (35)	195 (65)

Table 3. Distribution of presence and absence of pulp stones by different age groups

Age group	Number of patients examined	Number of patients with pulp stones (%)	Number of patients without pulp stones (%)
18-29	157	33 (21.1)	124 (78.9)
30-39	124	29 (23.4)	95 (76.6)
40-49	137	43 (31.4)	94 (68.6)
50-59	145	33 (22.7)	112 (77.3)
60-69	57	19 (33.3)	38 (66.7)
70-79	9	3 (33.3)	6 (66.7)
80-89	2	1 (50)	1 (50)
Total	631	161	470

Table 4. Comparison of presence and absence of pulp stones according to arch and side

Teeth location	Total n (%)	Teeth with pulp stones n (%)	Teeth without pulp stone n (%)
Molar	631 (100)	161 (25.5)	470 (74.5)
Maxillary arch[a]	404 (100)	103 (25.5)	301 (74.5)
Maxilla/right	200 (100)	55 (27.5)	145 (72.5)
Maxilla/left	204 (100)	48 (23.5)	156 (76.5)
Mandibular arch[a]	227 (100)	58 (25.5)	169 (74.5)
Mandibular/right	108 (100)	36 (33.3)	72 (66.7)
Mandibular/left	119 (100)	22 (18.5)	97 (81.5)

Different superscript letters indicate statistical significance (p<0,05)

Table 5. Distribution of pulp stones according to each group and dental crown condition.

Location		Teeth with pulp stones						Teeth without pulp stone				
		Number of teeth examined (n)	Without restoration n (%)	Shallow n (%)	Medium n (%)	Deep n (%)	**Total n (%)**	Without restoration n (%)	Shallow n (%)	Medium n (%)	Deep n (%)	**Total n (%)**
Right/maxilla	First molar	94	13 (13.8)	14 (14.9)	8 (8.5)	3 (3.2)	**38 (40.4)**	15 (15.9)	26 (27.7)	6 (6.4)	9 (9.6)	**56 (59.6)**
	Second molar	106	2 (1.9)	8 (7.5)	6 (5.7)	1 (0.9)	**17 (16.0)**	21 (19.8)	43 (40.7)	16 (15.0)	9 (8.5)	**89 (84.0)**
Left/maxilla	First molar	87	7 (8.0)	12 (13.8)	3 (3.5)	2 (2.3)	**24 (27.6)**	19 (21.8)	24 (27.6)	11 (12.6)	9 (10.4)	**63 (72.4)**
	Second molar	117	5 (4.3)	10 (8.5)	9 (7.7)	-	**24 (20.5)**	27 (23.1)	43 (36.8)	15 (12.8)	8 (6.8)	**93 (79.5)**
Right/mandible	First molar	51	4 (7.8)	9 (17.7)	5 (9.8)	1 (2.0)	**19 (37.3)**	7 (13.7)	17 (33.3)	5 (9.8)	3 (5.9)	**32 (62.7)**
	Second molar	57	2 (3.5)	11 (19.3)	4 (7.0)	-	**17 (29.8)**	9 (15.8)	25 (43.9)	4 (7.0)	2 (3.5)	**40 (70.2)**
Left/mandible	First molar	57	1 (1.8)	9 (15.8)	2 (3.5)	-	**12 (21.1)**	12 (21.1)	29 (50.9)	2 (3.5)	2 (3.5)	**45 (78.9)**
	Second molar	62	2 (3.2)	5 (8.1)	3 (4.8)	-	**10 (16.1)**	14 (22.6)	27 (43.6)	8 (12.9)	3 (4.8)	**52 (83.9)**
	Total (n)	631	36	78	40	7	**161**	124	234	67	45	**470**

DISCUSSION

In order to facilitate visualization of pulp stones and correctly plan treatment, clinicians may use imaging exams such as CBCT. Pulp stones are routinely observed in conventional or digital intraoral and extra-oral radiographs, but it is only possible to detect pulp stones radiographically when larger than 200 μm (Goga et al., 2008).

In the present study, the use of CBCT allowed a detailed evaluation of tooth and pulp stones anatomy (Figure 1), since through the 3-dimensional reconstructions it is possible to eliminate the overlap of adjacent structures, facilitating analysis (Patel et al., 2015).

Pulp stones were observed in 35% of patients and in 25.5% of molars, which is not consistent with previous studies using CBCT. Da Silva al. (2016) detected calcified nodules in 31.9% of the patients and in 9.5% of the evaluated teeth, showing lower result values when compared to the results of the present study while Rodrigues et al. (2014) notice that 55% of the patients had pulp stones, with both studies performed with Brazilian population. Patil et al. (2018), conducted a study with the population of Saudi Arabia and verified the presence of pulp stones in 50.93% of the population and in 13.34% of the evaluated teeth.

Surveys performed with populations in other countries have used radiographs for the detection of pulp stones. Kannan et al. (2015) studied the prevalence of pulp stones in Malaysians, and found that 44.9% of the population and 15.7% of the teeth examined presented the calcified nodules. Ranjitkar et al. (2002) found that the prevalence of pulp stones in the Australian population is 46.1% and 10.1% per tooth. Compared to our findings, these populations had a higher incidence of pulp stones. However, the population of Turkey had 12% of nodules, with a prevalence of 5% of the teeth (Gulsahi et al., 2009), showing lower values when compared to this study.
The results obtained in this research differ from those reported in the literature, possibly related to factors as sample size, methodology employed, ethnicity and geographical differences.

The prevalence of pulp stones was higher in females (41.1%) than in males (27.7%). The elevated incidence in women was also seen in the Australian population (Ranjitkar et al., 2002), Malaysian (Kannan et al., 2015), and Turkish (Sener et al. 2009) but did not present differences between genders. In contrast to our findings,

authors reported a higher prevalence of calcified nodules in men when compared to women (Baghdady et al. 1988, Hamasha & Darwazeh 1998, Gulsahi et al. 2009, Patil et al. 2018).

The present study showed a higher prevalence of pulp stones in patients older than 80 years, corroborating previous studies (Tamse et al. 1982, Shafer et al. 1983, Seltzer & Bender et al. 1985, Gulsahi et al. 2009, Kannan et al. 2015), which evidenced a correlation between a more advanced age and the incidence of calcified nodules.

A similar prevalence of pulp stones was observed in both maxillary and mandibular arches without statistical difference. These findings are consistent with results reported by Patil et al. (2018), da Silva et al. (2016) Kannan et al. (2015), Gulsahi et al. (2009) and Hamasha & Darwazeh (1998).

Regarding the evaluated molars, the first upper molar was the group that had a higher occurrence of pulp stones, in accordance with Ranjitkar et al. (2002), Kannan et al. (2015), Baghdady et al. (1988). This may be explained by the fact that first molars are the first teeth to outbreak in the permanent dentition, therefore, earlier subjected to etiological factors related to the development of pulp stones (Sener et al. 2009). Hamasha & Darwazeh (1998) emphasized that molars normally shows an elevated pulp chamber volume, thus larger blood vessels and bloodstream, favoring precipitation of calcified structures.

According to Baghdady et al. (1988), Jung et al. (2013) and Ertas et al. (2017), any irritation to the pulp caused by surgical procedures, orthodontic treatment or even chronic irritants such as caries and restorations, may have deleterious influence on pulp tissue, resulting in the deposition of calcium salts inside the tissue, which possibly explain the correlation of higher prevalence of calcified nodules in restored teeth. The deposition of calcium salts can also occur in other parts of the body, as kidneys and gallbladder, as shown by Malhotra et al. (2012) and Virk et al. (2018), which studied the relation of renal and vesicle calculi with pulp stones, evidencing a positive correlation. In the present study, of the 161 molars that presented pulp stones, 125 were restored.

The size, shape, location and number of pulp stones may vary between individuals (Kannan et al. 2015). In this study 5 isolated pulp stones were observed in a single tooth and most of the nodules investigated were adhered to the canal walls, presenting an oval shape. When endodontic treatment is required, removal of the pulp

stones can be achieved with the use of ultrasonic (Lim & Le Clerc 2019), since not removing them may interfere with the outcome of endodontic treatment.

One of the main limitations of this study would be the limited sample size, which was obtained from only one center, requiring additional multicenter studies with a larger number of samples.

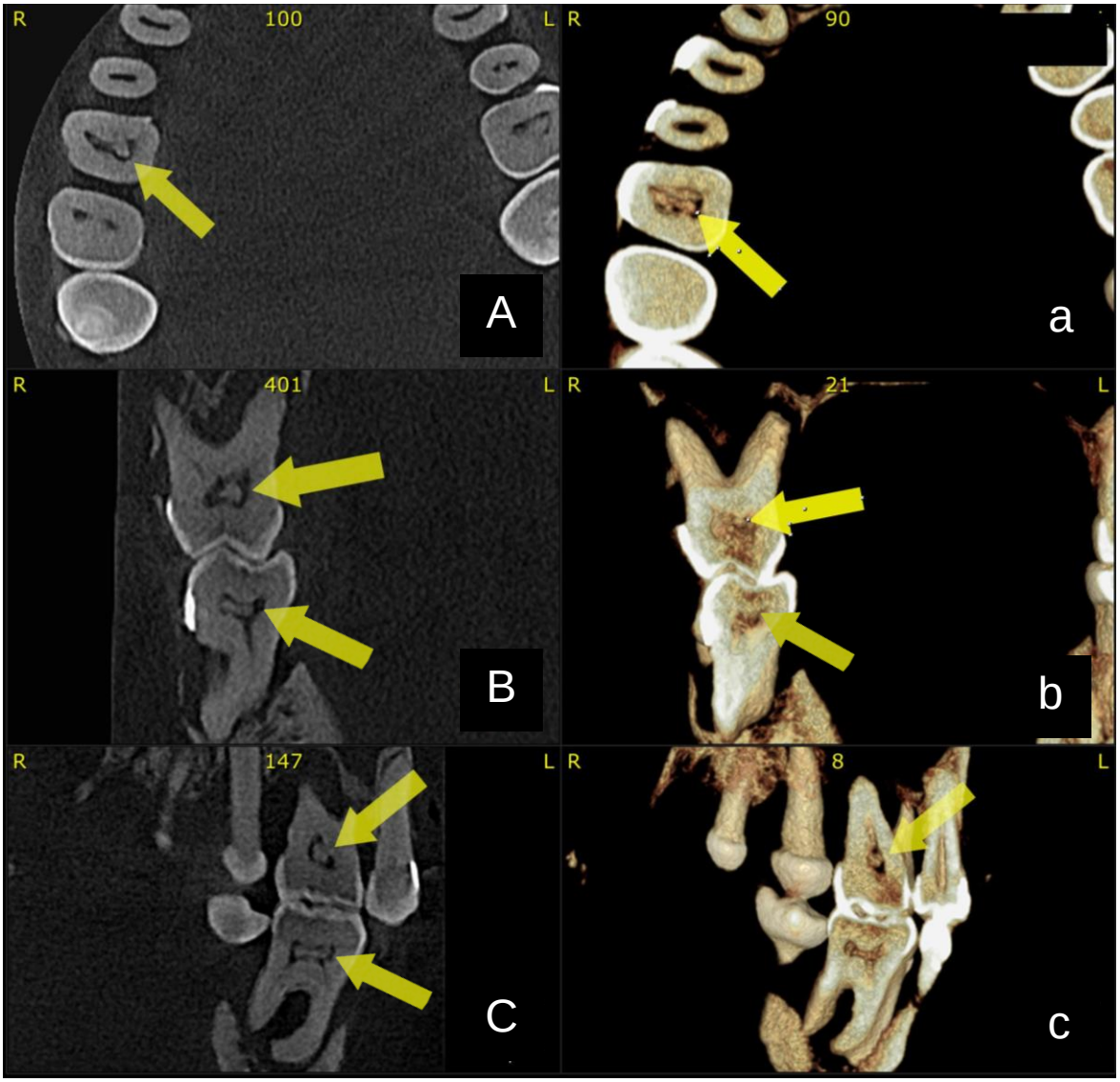

Figure 1. Presence of pulp stone in first superior right molar (yellow arrow) and in first lower right molar, on axial (A), sagittal (B) and coronal (C) planes, by 3D CBCT reconstruction.

CONCLUSION

The prevalence of pulp stones was observed in 35% of the patients and in 25.5% of the evaluated molars. Restored first upper molars showed the highest incidence of pulp stones, mostly found in female patients. Routine cone beam tomography is an efficient resource for diagnosis and location of pulp stones.

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Anexos

ANEXO A

International Endodontic Journal

Author Guidelines

Content of Author Guidelines: 1. General, 2. Ethical Guidelines, 3. Manuscript Submission Procedure, 4. Manuscript Types Accepted, 5. Manuscript Format and Structure, 6. After Acceptance

Useful Websites: **Submission Site**, **Articles published in *International Endodontic Journal***, **Author Services**, **Wiley's Ethical Guidelines**, **Guidelines for Figures**

The journal to which you are submitting your manuscript employs a plagiarism detection system. By submitting your manuscript to this journal you accept that your manuscript may be screened for plagiarism against previously published works.

1.GENERAL

International Endodontic Journal publishes original scientific articles, reviews, clinical articles and case reports in the field of Endodontology; the branch of dental sciences dealing with health, injuries to and diseases of the pulp and periradicular region, and their relationship with systemic well-being and health. Original scientific articles are published in the areas of biomedical science, applied materials science, bioengineering, epidemiology and social science relevant to endodontic disease and its management, and to the restoration of root-treated teeth. In addition, review articles, reports of clinical cases, book reviews, summaries and abstracts of scientific meetings and news items are accepted.

Please read the instructions below carefully for details on the submission of manuscripts, the journal's requirements and standards as well as information concerning the procedure after a manuscript has been accepted for publication in *International Endodontic Journal*. Authors are encouraged to visit **Wiley Author Services** for further information on the preparation and submission of articles and figures.

2. ETHICAL GUIDELINES

International Endodontic Journal adheres to the below ethical guidelines for publication and research.

2.1. Authorship and Acknowledgements

Authors submitting a paper do so on the understanding that the manuscript has been read and approved by all authors and that all authors agree to the submission of the manuscript to the Journal.

International Endodontic Journal adheres to the definition of authorship set up by The International Committee of Medical Journal Editors (ICMJE). According to the ICMJE, authorship criteria should be based on 1) substantial contributions to conception and

design of, or acquisiation of data or analysis and interpretation of data, 2) drafting the article or revising it critically for important intellectual content and 3) final approval of the version to be published. Authors should meet conditions 1, 2 and 3.

Acknowledgements: Under acknowledgements please specify contributors to the article other than the authors accredited. Please also include specifications of the source of funding for the study and any potential conflict of interests if appropriate. Please find more information on the conflict of interest form in section 2.6.

2.2. Ethical Approvals

Experimentation involving human subjects will only be published if such research has been conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki (version 2008) and the additional requirements, if any, of the country where the research has been carried out. Manuscripts must be accompanied by a statement that the experiments were undertaken with the understanding and written consent of each subject and according to the above mentioned principles. A statement regarding the fact that the study has been independently reviewed and approved by an ethical board should also be included. Editors reserve the right to reject papers if there are doubts as to whether appropriate procedures have been used.

When experimental animals are used the methods section must clearly indicate that adequate measures were taken to minimize pain or discomfort. Experiments should be carried out in accordance with the Guidelines laid down by the National Institute of Health (NIH) in the USA regarding the care and use of animals for experimental procedures or with the European Communities Council Directive of 24 November 1986 (86/609/EEC) and in accordance with local laws and regulations.

All studies using human or animal subjects should include an explicit statement in the Material and Methods section identifying the review and ethics committee approval for each study. The authors MUST upload a copy of the ethical approval letter when submitting their manuscript and a separate English translation. Editors reserve the right to reject papers if there is doubt as to whether appropriate procedures have been used.

2.3 Clinical Trials

The International Endodontic Journal asks that authors submitting manuscripts reporting from a clinical trial to register the trials in any of the following public clinical trialsregistries: www.clinicaltrials.gov, https://www.clinicaltrialsregister.eu/, http://isrctn .org/. Other primary registries if named in the WHO network will also be considered acceptable. The clinical trial registration number and name of the trial register should be included in the Acknowledgements at the submission stage.

2.3.1 Randomised control clinical trials

Randomised control clinical trials should be reported using the guidelines available at www.consort-statement.org. A CONSORT checklist and flow diagram (as a Figure) should also be included in the submission material.

2.3.2 Epidemiological observational trials

Submitting authors of epidemiological human observations studies are required to

review and submit a 'strengthening the reporting of observational studies in Epidemiology' (STROBE) checklist and statement. Compliance with this should be detailed in the materials and methods section. (www.strobe-statement.org)

2.4 Systematic Reviews

Systematic reviews should be reported using the PRISMA guidelines available at http://prisma-statement.org/. A PRISMA checklist and flow diagram (as a Figure) should also be included in the submission material.

Systematic reviews must be registered prospectively in the PROSPERO database. The review registration number should be included in the Acknowledgements at the submission stage.

2.5 DNA Sequences and Crystallographic Structure Determinations

Papers reporting protein or DNA sequences and crystallographic structure determinations will not be accepted without a Genbank or Brookhaven accession number, respectively. Other supporting data sets must be made available on the publication date from the authors directly.

2.6 Conflict of Interest and Source of Funding

International Endodontic Journal requires that all authors (both the corresponding author and co-authors) disclose any potential sources of conflict of interest. Any interest or relationship, financial or otherwise that might be perceived as influencing an author's objectivity is considered a potential source of conflict of interest. These must be disclosed when directly relevant or indirectly related to the work that the authors describe in their manuscript. Potential sources of conflict of interest include but are not limited to patent or stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company. If authors are unsure whether a past or present affiliation or relationship should be disclosed in the manuscript, please contact the editorial office at iejeditor@cardiff.ac.uk. The existence of a conflict of interest does not preclude publication in this journal.

The above policies are in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals produced by the International Committee of Medical Journal Editors (http://www.icmje.org/).

It is the responsibility of the corresponding author to have all authors of a manuscript fill out a conflict of interest disclosure form, and to upload all forms individually (do not combine the forms into one file) together with the manuscript on submission. The disclosure statement should be included under Acknowledgements. Please find the form below: Conflict of Interest Disclosure Form

2.7 Appeal of Decision

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2.9 OnlineOpen

OnlineOpen is available to authors of primary research articles who wish to make their article available to non-subscribers on publication, or whose funding agency requires grantees to archive the final version of their article. With OnlineOpen, the author, the author's funding agency, or the author's institution pays a fee to ensure that the article is made available to non-subscribers upon publication via Wiley Online Library, as well as deposited in the funding agency's preferred archive. For the full list of terms and conditions, see http://wileyonlinelibrary.com/onlineopen#OnlineOpen_Terms

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3. MANUSCRIPT SUBMISSION PROCEDURE

Manuscripts should be submitted electronically via the online submission site http://mc.manuscriptcentral.com/iej. The use of an online submission and peer review site enables immediate distribution of manuscripts and consequentially speeds up the review process. It also allows authors to track the status of their own manuscripts. Complete instructions for submitting a paper is available online and below. Further assistance can be obtained from iejeditor@cardiff.ac.uk.

3.1. Getting Started

• Launch your web browser (supported browsers include Internet Explorer 5.5 or higher, Safari 1.2.4, or Firefox 1.0.4 or higher) and go to the journal's online Submission Site: http://mc.manuscriptcentral.com/iej
• Log-in, or if you are a new user, click on 'register here'.
• If you are registering as a new user.
- After clicking on 'register here', enter your name and e-mail information and click 'Next'. Your e-mail information is very important.
- Enter your institution and address information as appropriate, and then click 'Next.'
- Enter a user ID and password of your choice (we recommend using your e-mail address as your user ID), and then select your areas of expertise. Click 'Finish'.
• If you are registered, but have forgotten your log in details, please enter your e-mail address under 'Password Help'. The system will send you an automatic user ID and a new temporary password.
• Log-in and select 'Author Centre '

3.2. Submitting Your Manuscript

• After you have logged into your 'Author Centre', submit your manuscript by clicking on the submission link under 'Author Resources'.
• Enter data and answer questions as appropriate. You may copy and paste directly from your manuscript and you may upload your pre-prepared covering letter.
• Click the 'Next' button on each screen to save your work and advance to the next screen.
• You are required to upload your files.
- Click on the 'Browse' button and locate the file on your computer.
- Select the designation of each file in the drop down next to the Browse button.
- When you have selected all files you wish to upload, click the 'Upload Files' button.
• Review your submission (in HTML and PDF format) before completing your submission by sending it to the Journal. Click the 'Submit' button when you are finished reviewing.

3.3. Manuscript Files Accepted

Manuscripts should be uploaded as Word (.doc) or Rich Text Format (.rft) files (not write-protected) plus separate figure files. GIF, JPEG, PICT or Bitmap files are acceptable for submission, but only high-resolution TIF or EPS files are suitable for printing. The files will be automatically converted to HTML and PDF on upload and will be used for the review process. The text file must contain the abstract, main text, references, tables, and figure legends, but no embedded figures or Title page. The Title page should be uploaded as a separate file. In the main text, please reference figures as for instance 'Figure 1', 'Figure 2' etc to match the tag name you choose for the individual figure files uploaded. Manuscripts should be formatted as described in the Author Guidelines below.

3.4. Blinded Review

Manuscript that do not conform to the general aims and scope of the journal will be returned immediately without review. All other manuscripts will be reviewed by experts in the field (generally two referees). International Endodontic Journal aims to forward referees´ comments and to inform the corresponding author of the result of the review process. Manuscripts will be considered for fast-track publication under special circumstances after consultation with the Editor.
International Endodontic Journal uses double blinded review. The names of the reviewers will thus not be disclosed to the author submitting a paper and the name(s) of the author(s) will not be disclosed to the reviewers.
To allow double blinded review, please submit (upload) your main manuscript and title page as separate files.
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All documents uploaded under the file designation 'title page' will not be viewable in the html and pdf format you are asked to review in the end of the submission process. The files viewable in the html and pdf format are the files available to the reviewer in the review process.

3.5. Suspension of Submission Mid-way in the Submission Process

You may suspend a submission at any phase before clicking the 'Submit' button and save it to submit later. The manuscript can then be located under 'Unsubmitted Manuscripts' and you can click on 'Continue Submission' to continue your submission when you choose to.

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After submission you will receive an e-mail to confirm receipt of your manuscript. If you do not receive the confirmation e-mail after 24 hours, please check your e-mail address carefully in the system. If the e-mail address is correct please contact your IT

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You can access ScholarOne Manuscripts any time to check your 'Author Centre' for the status of your manuscript. The Journal will inform you by e-mail once a decision has been made.

3.8. Submission of Revised Manuscripts

To submit a revised manuscript, locate your manuscript under 'Manuscripts with Decisions' and click on 'Submit a Revision'. Please remember to delete any old files uploaded when you upload your revised manuscript.

4. MANUSCRIPT TYPES ACCEPTED

Original Scientific Articles: must describe significant and original experimental observations and provide sufficient detail so that the observations can be critically evaluated and, if necessary, repeated. Original Scientific Articles must conform to the highest international standards in the field.

Review Articles: are accepted for their broad general interest; all are refereed by experts in the field who are asked to comment on issues such as timeliness, general interest and balanced treatment of controversies, as well as on scientific accuracy. Reviews should generally include a clearly defined search strategy and take a broad view of the field rather than merely summarizing the authors´ own previous work. Extensive or unbalanced citation of the authors´ own publications is discouraged.

Clinical Articles: are suited to describe significant improvements in clinical practice such as the report of a novel technique, a breakthrough in technology or practical approaches to recognised clinical challenges. They should conform to the highest scientific and clinical practice standards.

Case Reports: illustrating unusual and clinically relevant observations are acceptable but they must be of sufficiently high quality to be considered worthy of publication in the Journal. On rare occasions, completed cases displaying non-obvious solutions to significant clinical challenges will be considered. Illustrative material must be of the highest quality and healing outcomes, if appropriate, should be demonstrated.

Supporting Information: *International Endodontic Journal* encourages submission of adjuncts to printed papers via the supporting information website (see submission of supporting information below). It is encouraged that authors wishing to describe novel procedures or illustrate cases more fully with figures and/or video may wish to utilise this facility.

Letters to the Editor: are also acceptable.

Meeting Reports: are also acceptable.

5. MANUSCRIPT FORMAT AND STRUCTURE

5.1. Format

Language: The language of publication is English. It is preferred that manuscript is professionally edited. A list of independent suppliers of editing services can be found at http://authorservices.wiley.com/bauthor/english_language.asp. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication

Presentation: Authors should pay special attention to the presentation of their research findings or clinical reports so that they may be communicated clearly. Technical jargon should be avoided as much as possible and clearly explained where its use is unavoidable. Abbreviations should also be kept to a minimum, particularly those that are not standard. The background and hypotheses underlying the study, as well as its main conclusions, should be clearly explained. Titles and abstracts especially should be written in language that will be readily intelligible to any scientist.

Abbreviations: International Endodontic Journal adheres to the conventions outlined in Units, Symbols and Abbreviations: A Guide for Medical and Scientific Editors and Authors. When non-standard terms appearing 3 or more times in the manuscript are to be abbreviated, they should be written out completely in the text when first used with the abbreviation in parenthesis.

5.2. Structure

All manuscripts submitted to *International Endodontic Journal* should include Title Page, Abstract, Main Text, References and Acknowledgements, Tables, Figures and Figure Legends as appropriate

Title Page: The title page should bear: (i) Title, which should be concise as well as descriptive; (ii) Initial(s) and last (family) name of each author; (iii) Name and address of department, hospital or institution to which work should be attributed; (iv) Running title (no more than 30 letters and spaces); (v) No more than six keywords (in alphabetical order); (vi) Name, full postal address, telephone, fax number and e-mail address of author responsible for correspondence.

Abstract for Original Scientific Articles should be no more than 350 words giving details of what was done using the following structure:

• **Aim**: Give a clear statement of the main aim of the study and the main hypothesis tested, if any.

• **Methodology**: Describe the methods adopted including, as appropriate, the design of the study, the setting, entry requirements for subjects, use of materials, outcome measures and statistical tests.
• **Results**: Give the main results of the study, including the outcome of any statistical analysis.
• **Conclusions**: State the primary conclusions of the study and their implications. Suggest areas for further research, if appropriate.

Abstract for Systematic Review Articles should be no more than 350 words giving details of what was done using the following structure where applicable:

• **Background**: Provide a brief introduction of the subject and why it is important.
• **Aim**: Give a clear statement of the main aim of the study and the main hypothesis tested, if any.
• **Data sources**: Describe the databases searched.
• **Study eligibility criteria, participants, and interventions**: Briefly describe the methods adopted including exclusion/inclusion criteria.
• **Study appraisal and synthesis methods**: Describe bias, study type and quality
• **Results**: Give the main results of the review, including the outcome of any statistical meta-analysis.
• **Limitations**: Highlight problems with the current review end research area
• **Conclusions and implications of key findings**: State the primary conclusions of the study and their implications. Suggest areas for further research, if appropriate.

Abstract for Review Articles (narrative)

The Abstract should be unstructured and no more than 350 words.

Abstract for Case Reports should be no more than 350 words using the following structure:

• **Aim**: Give a clear statement of the main aim of the report and the clinical problem which is addressed.
• **Summary**: Describe the methods adopted including, as appropriate, the design of the study, the setting, entry requirements for subjects, use of materials, outcome measures and analysis if any.
• **Key learning points**: Provide up to 5 short, bullet-pointed statements to highlight the key messages of the report. All points must be fully justified by material presented in the report.

Abstract for Clinical Articles should be no more than 350 words using the following structure:

• **Aim:** Give a clear statement of the main aim of the report and the clinical problem which is addressed.
• **Methodology:** Describe the methods adopted.
• **Results:** Give the main results of the study.
• **Conclusions:** State the primary conclusions of the study.

Main Text of Original Scientific Article should include Introduction, Materials and Methods, Results, Discussion and Conclusion

Introduction: should be focused, outlining the historical or logical origins of the study and gaps in knowledge. Exhaustive literature reviews are not appropriate. It should close with the explicit statement of the specific aims of the investigation, or hypothesis to be tested.

Material and Methods: must contain sufficient detail such that, in combination with the references cited, all clinical trials and experiments reported can be fully reproduced.

(i) Clinical Trials should be reported using the CONSORT guidelines available at www.consort-statement.org. A CONSORT checklist and flow diagram (as a Figure) should also be included in the submission material.

(ii) Experimental Subjects: experimentation involving human subjects will only be published if such research has been conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki (version 2008) and the additional requirements, if any, of the country where the research has been carried out. Manuscripts must be accompanied by a statement that the experiments were undertaken with the understanding and written consent of each subject and according to the above mentioned principles. A statement regarding the fact that the study has been independently reviewed and approved by an ethical board should also be included. Editors reserve the right to reject papers if there are doubts as to whether appropriate procedures have been used.

When experimental animals are used the methods section must clearly indicate that adequate measures were taken to minimize pain or discomfort. Experiments should be carried out in accordance with the Guidelines laid down by the National Institute of Health (NIH) in the USA regarding the care and use of animals for experimental procedures or with the European Communities Council Directive of 24 November 1986 (86/609/EEC) and in accordance with local laws and regulations.

All studies using human or animal subjects should include an explicit statement in the Material and Methods section identifying the review and ethics committee approval for each study, if applicable. Editors reserve the right to reject papers if there is doubt as to whether appropriate procedures have been used.

(iii) Suppliers: Suppliers of materials should be named and their location (Company, town/city, state, country) included.

Results: should present the observations with minimal reference to earlier literature or to possible interpretations. Data should not be duplicated in Tables and Figures.

Discussion: may usefully start with a brief summary of the major findings, but repetition of parts of the abstract or of the results section should be avoided. The Discussion section should progress with a review of the methodology before discussing the results in light of previous work in the field. The Discussion should end with a brief conclusion and a comment on the potential clinical relevance of the

findings. Statements and interpretation of the data should be appropriately supported by original references.

Conclusion: should contain a summary of the findings.

Main Text of Review Articles should be divided into Introduction, Review and Conclusions. The Introduction section should be focused to place the subject matter in context and to justify the need for the review. The Review section should be divided into logical sub-sections in order to improve readability and enhance understanding. Search strategies must be described and the use of state-of-the-art evidence-based systematic approaches is expected. The use of tabulated and illustrative material is encouraged. The Conclusion section should reach clear conclusions and/or recommendations on the basis of the evidence presented.

Main Text of Clinical Reports and Clinical Articles should be divided into Introduction, Report, Discussion and Conclusion,. They should be well illustrated with clinical images, radiographs, diagrams and, where appropriate, supporting tables and graphs. However, all illustrations must be of the highest quality

Acknowledgements: *International Endodontic Journal* requires that all sources of institutional, private and corporate financial support for the work within the manuscript must be fully acknowledged, and any potential conflicts of interest noted. Grant or contribution numbers may be acknowledged, and principal grant holders should be listed. Acknowledgments should be brief and should not include thanks to anonymous referees and editors. See also above under Ethical Guidelines.

5.3. References

It is the policy of the Journal to encourage reference to the original papers rather than to literature reviews. Authors should therefore keep citations of reviews to the absolute minimum.

We recommend the use of a tool such as **EndNote** or **Reference Manager** for reference management and formatting. The EndNote reference style can be obtained upon request to the editorial office (**iejeditor@cardiff.ac.uk**). Reference Manager reference styles can be searched for here: **www.refman.com/support/rmstyles.asp**

In the text: single or double authors should be acknowledged together with the year of publication, e.g. (Pitt Ford & Roberts 1990). If more than two authors the first author followed by *et al.* is sufficient, e.g. (Tobias *et al.* 1991). If more than 1 paper is cited the references should be in year order and separated by "," e.g. (Pitt Ford & Roberts 1990, Tobias *et al*. 1991).

Reference list: All references should be brought together at the end of the paper in alphabetical order and should be in the following form.

(i) Names and initials of up to six authors. When there are seven or more, list the first three and add *et al.*
(ii)Year of publication in parentheses

(iii) Full title of paper followed by a full stop (.)
(iv) Title of journal in full (in italics)
(v) Volume number (bold) followed by a comma (,)
(vi) First and last pages

Examples of correct forms of reference follow:

Standard journal article

Bergenholtz G, Nagaoka S, Jontell M (1991) Class II antigen-expressing cells in experimentally induced pulpitis. *International Endodontic Journal* **24**, 8-14.

Corporate author

British Endodontic Society (1983) Guidelines for root canal treatment. *International Endodontic Journal***16**, 192-5.

Journal supplement

Frumin AM, Nussbaum J, Esposito M (1979) Functional asplenia: demonstration of splenic activity by bone marrow scan (Abstract). *Blood* **54** (Suppl. 1), 26a.

Books and other monographs

Personal author(s)

Gutmann J, Harrison JW (1991) *Surgical Endodontics*, 1st edn Boston, MA, USA: Blackwell Scientific Publications.

Chapter in a book

Wesselink P (1990) Conventional root-canal therapy III: root filling. In: Harty FJ, ed. *Endodontics in Clinical Practice*, 3rd edn; pp. 186-223. London, UK: Butterworth.

Published proceedings paper

DuPont B (1974) Bone marrow transplantation in severe combined immunodeficiency with an unrelated MLC compatible donor. In: White HJ, Smith R, eds. Proceedings of the Third Annual Meeting of the International Society for Experimental Rematology; pp. 44-46. Houston, TX, USA: International Society for Experimental Hematology.

Agency publication

Ranofsky AL (1978) Surgical Operations in Short-Stay Hospitals: United States-1975. DHEW publication no. (PHS) 78-1785 (Vital and Health Statistics; Series 13; no. 34.) Hyattsville, MD, USA: National Centre for Health Statistics.8

Dissertation or thesis

Saunders EM (1988) In vitro and in vivo investigations into root-canal obturation using thermally softened gutta-percha techniques (PhD Thesis). Dundee, UK: University of Dundee.

URLs

Full reference details must be given along with the URL, i.e. authorship, year, title of document/report and URL. If this information is not available, the reference should be removed and only the web address cited in the text.
Smith A (1999) Select committee report into social care in the community [WWW document]. URL http://www.dhss.gov.uk/reports/report015285.html [accessed on 7 November 2003]

5.4. Tables, Figures and Figure Legends

Tables: Tables should be double-spaced with no vertical rulings, with a single bold ruling beneath the column titles. Units of measurements must be included in the column title.

Figures: All figures should be planned to fit within either 1 column width (8.0 cm), 1.5 column widths (13.0 cm) or 2 column widths (17.0 cm), and must be suitable for photocopy reproduction from the printed version of the manuscript. Lettering on figures should be in a clear, sans serif typeface (e.g. Helvetica); if possible, the same typeface should be used for all figures in a paper. After reduction for publication, upper-case text and numbers should be at least 1.5-2.0 mm high (10 point Helvetica). After reduction, symbols should be at least 2.0-3.0 mm high (10 point). All half-tone photographs should be submitted at final reproduction size. In general, multi-part figures should be arranged as they would appear in the final version. Reduction to the scale that will be used on the page is not necessary, but any special requirements (such as the separation distance of stereo pairs) should be clearly specified.

Unnecessary figures and parts (panels) of figures should be avoided: data presented in small tables or histograms, for instance, can generally be stated briefly in the text instead. Figures should not contain more than one panel unless the parts are logically connected; each panel of a multipart figure should be sized so that the whole figure can be reduced by the same amount and reproduced on the printed page at the smallest size at which essential details are visible.

Figures should be on a white background, and should avoid excessive boxing, unnecessary colour, shading and/or decorative effects (e.g. 3-dimensional skyscraper histograms) and highly pixelated computer drawings. The vertical axis of histograms should not be truncated to exaggerate small differences. The line spacing should be wide enough to remain clear on reduction to the minimum acceptable printed size.

Figures divided into parts should be labelled with a lower-case, boldface, roman letter, a, b, and so on, in the same typesize as used elsewhere in the figure. Lettering in figures should be in lower-case type, with the first letter capitalized. Units should have a single space between the number and the unit, and follow SI nomenclature or the nomenclature common to a particular field. Thousands should be separated by a thin

space (1 000). Unusual units or abbreviations should be spelled out in full or defined in the legend. Scale bars should be used rather than magnification factors, with the length of the bar defined in the legend rather than on the bar itself. In general, visual cues (on the figures themselves) are preferred to verbal explanations in the legend (e.g. broken line, open red triangles etc.)

Figure legends: Figure legends should begin with a brief title for the whole figure and continue with a short description of each panel and the symbols used; they should not contain any details of methods.

Permissions: If all or part of previously published illustrations are to be used, permission must be obtained from the copyright holder concerned. This is the responsibilty of the authors before submission.

Preparation of Electronic Figures for Publication: Although low quality images are adequate for review purposes, print publication requires high quality images to prevent the final product being blurred or fuzzy. Submit EPS (lineart) or TIFF (halftone/photographs) files only. MS PowerPoint and Word Graphics are unsuitable for printed pictures. Do not use pixel-oriented programmes. Scans (TIFF only) should have a resolution of 300 dpi (halftone) or 600 to 1200 dpi (line drawings) in relation to the reproduction size (see below). EPS files should be saved with fonts embedded (and with a TIFF preview if possible). For scanned images, the scanning resolution (at final image size) should be as follows to ensure good reproduction: lineart: >600 dpi; half-tones (including gel photographs): >300 dpi; figures containing both halftone and line images: >600 dpi.

Further information can be obtained at Wiley Blackwell's guidelines for figures: **http:/authorservices.wiley.com/bauthor/illustration.asp.**

Check your electronic artwork before submitting it: **http://authorservices.wiley.com/bauthor/eachecklist.asp**.

5.5. Supporting Information

Publication in electronic formats has created opportunities for adding details or whole sections in the electronic version only. Authors need to work closely with the editors in developing or using such new publication formats.

Supporting information, such as data sets or additional figures or tables, that will not be published in the print edition of the journal, but which will be viewable via the online edition, can be submitted. It should be clearly stated at the time of submission that the supporting information is intended to be made available through the online edition. If the size or format of the supporting information is such that it cannot be accommodated on the journal's website, the author agrees to make the supporting information available free of charge on a permanent Web site, to which links will be set up from the journal's website. The author must advise Wiley Blackwell if the URL of the website where the supporting information is located changes. The content of the supporting information must not be altered after the paper has been accepted for

publication.

The availability of supporting information should be indicated in the main manuscript by a paragraph, to appear after the References, headed 'Supporting Information' and providing titles of figures, tables, etc. In order to protect reviewer anonymity, material posted on the authors Web site cannot be reviewed. The supporting information is an integral part of the article and will be reviewed accordingly.

Preparation of Supporting Information: Although provision of content through the web in any format is straightforward, supporting information is best provided either in web-ready form or in a form that can be conveniently converted into one of the standard web publishing formats:

• Simple word-processing files (.doc or .rtf) for text.
• PDF for more complex, layout-dependent text or page-based material. Acrobat files can be distilled from Postscript by the Publisher, if necessary.
• GIF or JPEG for still graphics. Graphics supplied as EPS or TIFF are also acceptable.
• MPEG or AVI for moving graphics.

Subsequent requests for changes are generally unacceptable, as for printed papers. A charge may be levied for this service.

Video Imaging: For the on-line version of the Journal the submission of illustrative video is encouraged. Authors proposing the use such media should consult with the Editor during manuscript preparation.

6. AFTER ACCEPTANCE

Upon acceptance of a paper for publication, the manuscript will be forwarded to the Production Editor who is responsible for the production of the journal.

6.1. Figures

Hard copies of all figures and tables are required when the manuscript is ready for publication. These will be requested by the Editor when required. Each Figure copy should be marked on the reverse with the figure number and the corresponding author's name.

6.2 Proof Corrections

The corresponding author will receive an email alert containing a link to a web site. A working email address must therefore be provided for the corresponding author. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from the following Web site: **www.adobe.com/products/acrobat/readstep2.html**. This will enable the file to be opened, read on screen, and printed out in order for any corrections to be added. Further instructions will be sent with the proof. Hard copy proofs will be posted if no e-mail address is available; in your absence, please arrange for a colleague to access your e-mail to retrieve the proofs. Proofs must be returned to the Production Editor within three days of receipt. As changes to proofs are costly, we ask that you only

correct typesetting errors. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately. Other than in exceptional circumstances, all illustrations are retained by the publisher. Please note that the author is responsible for all statements made in his work, including changes made by the copy editor.

6.3 Early Online Publication Prior to Print

International Endodontic Journal is covered by Wiley Blackwell's Early View service. Early View articles are complete full-text articles published online in advance of their publication in a printed issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so Early View articles cannot be cited in the traditional way. They are therefore given a Digital Object Identifier (DOI), which allows the article to be cited and tracked before it is allocated to an issue. After print publication, the DOI remains valid and can continue to be used to cite and access the article.

6.4 Online Production Tracking

Online production tracking is available for your article through Blackwell's Author Services. Author Services enables authors to track their article - once it has been accepted - through the production process to publication online and in print. Authors can check the status of their articles online and choose to receive automated e-mails at key stages of production. The author will receive an e-mail with a unique link that enables them to register and have their article automatically added to the system. Please ensure that a complete e-mail address is provided when submitting the manuscript. Visit **http://authorservices.wiley.com/bauthor/** for more details on online production tracking and for a wealth of resources including FAQs and tips on article preparation, submission and more.

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Please note that unless specifically requested, Wiley Blackwell will dispose of all hardcopy or electronic material submitted two months after publication. If you require the return of any material submitted, please inform the editorial office or production editor as soon as possible.

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Free access to the final PDF offprint of your article will be available via Author Services only. Please therefore sign up for Author Services if you would like to access your article PDF offprint and enjoy the many other benefits the service offers.

Additional paper offprints may be ordered online. Please click on the following link, fill in the necessary details and ensure that you type information in all of the required fields: **Sheridan Printer**. If you have queries about offprints please email **Customer Service**.

The corresponding author will be sent complimentary copies of the issue in which the paper is published (one copy per author).

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For more substantial information on the services provided for authors, please see **Wiley Blackwell Author Services**

6.8 Note to NIH Grantees: Pursuant to NIH mandate, Wiley Blackwell will post the accepted version of contributions authored by NIH grant-holders to PubMed Central upon acceptance. This accepted version will be made publicly available 12 months after publication. For further information, see **www.wiley.com/go/nihmandate**

7. Guidelines for reporting of DNA microarray data

The *International Endodontic Journal* gives authors notice that, with effect from 1st January 2011, submission to the *International Endodontic Journal* requires the reporting of microarray data to conform to the MIAME guidelines. After this date, submissions will be assessed according to MIAME standards. The complete current guidelines are available at **http://www.mged.org/Workgroups/MIAME/miame_2.0.html**. Also, manuscripts will be published only after the complete data has been submitted into the public repositories, such as GEO (**http://www.ncbi.nlm.nih.gov/geo/**) or ArrayExpress (**http://www.ebi.ac.uk/microarray/submissions_overview.html**), in MIAME compliant format, with the data accession number (the identification number of the data set in the database) quoted in the manuscript. Both databases are committed to keeping the data private until the associated manuscript is published, if requested.

Prospective authors are also encouraged to search for previously published microarray data with relevance to their own data, and to report whether such data exists. Furthermore, they are encouraged to use the previously published data for qualitative and/or quantitative comparison with their own data, whenever suitable. To fully acknowledge the original work, an appropriate reference should be given not only to the database in question, but also to the original article in which the data was first published. This open approach will increase the availability and use of these large-scale data sets and improve the reporting and interpretation of the findings, and in increasing the comprehensive understanding of the physiology and pathology of endodontically related tissues and diseases, result eventually in better patient care.

ANEXO B

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Prevalência de nódulos pulpares em molares em uma população da região noroeste do Estado de São Paulo por meio de análise de CBCT

Pesquisador: ANA MARIA VEIGA VASQUES

Área Temática:

Versão: 2

CAAE: 71402617.8.0000.5420

Instituição Proponente: Universidade Estadual Paulista Júlio de Mesquita Filho

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.352.750

Apresentação do Projeto:

A radiografia digital tem se popularizado por uma série de razões que incluem a possibilidade de aquisição quase instantânea da imagem, eliminação do processamento químico e possibilidade de edição da imagem. A tecnologia que reúne estas qualidades inclui as técnicas tomográficas. A Tomografia Computadorizada Cone Beam (CBCT) foi desenvolvida especificamente para a área da Odontologia, e permite a visualização das estruturas anatômicas em 3 dimensões. Os nódulos pulpares livres, aderidos ou embutidos na câmara pulpar são frequentemente encontrados, podendo influenciar o sucesso do tratamento endodôntico. Serão realizadas análises de imagens de CBCT, de uma clínica de radiologia privada, para verificar a prevalência de nódulos pulpares na população miores de 18 anos, da região noroeste do estado de São Paulo. Serão incluídos

exames de CBCT apresentando primeiro e segundo molares com ápices totalmente formados. Todas as imagens serão adquiridas usando o sistema EAGLE V-BEAM-Cone Beam (Dabi Atlante, SP, BRASIL) com FOV de 5cm x 5cm, 6cm x 8cm e 8cm x 8cm e analisadas por hemi-arcadas da maxila e mandíbula, utilizando o software Ondemand3D, nos planos coronal, sagital e axial, com definição de intervalo transversal de 0.1mm. Os dados tabulados serão submetidos a análise estatística, com um nível de significância de 5%.

Objetivo da Pesquisa:

avaliar a prevalência de nódulos pulpares em molares em uma população da região Noroeste do

Estado de São Paulo por meio da CBCT

Avaliação dos Riscos e Benefícios:

Riscos:

A participação nesta pesquisa não infringe as normas legais e éticas. Os procedimentos adotados nesta pesquisa obedecem aos critérios de Ética em Pesquisa com Seres Humanos conforme Resolução no. 466/12 do Conselho Nacional de Saúde. Existe o risco de desconforto durante a obtenção da imagem, e complicações podem ocorrer durante o procedimento, como o paciente se movimentar durante a realização do exame e ser exposto novamente a outra dose de radiação.

Benefícios:

Esperamos que esta pesquisa resulte em informações importantes sobre a prevalência de nódulos pulpares encontrados nas tomografias, de forma que o conhecimento construído a partir desta pesquisa possa contribuir para que o cirurgião-dentista tenha conhecimento a respeito do desempenho das tomografias no diagnóstico e prevalência de nódulos pulpares em molares. A equipe desta pesquisa se compromete a divulgar os resultados obtidos, respeitam-se o sigilo das informações coletadas, conforme previsto no item anterior.

Comentários e Considerações sobre a Pesquisa:

Pesquisa interessante bem fundamentada

Considerações sobre os Termos de apresentação obrigatória:

pesquisador fez adequações sugeridas.

Recomendações:

não há.

Conclusões ou Pendências e Lista de Inadequações:

não há.

Considerações Finais a critério do CEP:

Não havendo pendências, o CEP propõe a aprovação do projeto de pesquisa salientando que, de acordo com a Resolução 466 CNS de 12/12/2012 (título X, seção X.1., art. 3, item b, e, título XI, seção XI.2., item d), há necessidade de apresentação de relatórios semestrais, devendo o primeiro relatório ser enviado até 01/05/2018. O CEP reitera a necessidade de entrega de uma via (não cópia) do TCLE ao sujeito participante da pesquisa e solicita ao pesquisador responsável leitura da

carta circular 003/2011 CONEP/CNS antes do início do projeto.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_940274.pdf	26/09/2017 09:02:44		Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	25/09/2017 11:05:25	ANA MARIA VEIGA VASQUES	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.docx	25/09/2017 10:36:15	ANA MARIA VEIGA VASQUES	Aceito
Folha de Rosto	Folha.pdf	17/07/2017 10:34:47	ANA MARIA VEIGA VASQUES	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

ARACATUBA, 27 de Outubro de 2017

Assinado por:
Aldiéris Alves Pesqueira (Coordenador)

ANEXO C

DEPARTAMENTO DE ODONTOLOGIA RESTAURADORA
DISCIPLINA DE ENDODONTIA

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

‘’Prevalência de nódulos pulpares em molares em uma população da região noroeste do Estado de São Paulo por meio de análise de CBCT’’

Nome da pesquisadora: Aluna de mestrado Ana Maria Veiga Vasques
Nome do orientador: Prof. Dr. Eloi Dezan Junior

1. **NATUREZA DA PESQUISA:** O (a) sr. (a) está sendo convidado(a) a participar desta pesquisa, que tem como finalidade avaliar a prevalência de nódulos pulpares em molares de uma população da região noroeste do Estado de São Paulo por meio de análise de imagens de Tomografia Computadorizada Cone Beam. Os exames serão utilizados para verificar a presença ou ausência de estruturas endurecidas no interior do dente. Utilizando o aparelho de tomografia (chapa do dente) da clínica Brazil Imagem, em Araçatuba, SP. Os exames serão realizados por um radiologista (profissional treinado para realizar o exame de imagem).
2. **PARTICIPANTES DA PESQUISA:** Os pacientes que procurarem a clínica Brazil Imagem para realização de tomografia com indicação clínica de outro cirurgião-dentista.
3. **ENVOLVIMENTO NA PESQUISA:** Ao participar deste estudo o sr.(a) permitirá que a pesquisadora Ana Maria Veiga Vasques utilize as imagens de seu exame que se adequarem no estudo. O sr.(a) tem liberdade de se recusar a participar e ainda se recusar a continuar participando em qualquer fase da pesquisa, sem qualquer prejuízo para o sr.(a). Sempre que quiser, poderá pedir mais informações sobre a pesquisa por meio do telefone da pesquisadora do projeto, e se necessário, através do telefone do Comitê de Ética em Pesquisa.

4. **RISCOS E DESCONFORTO:** A participação nesta pesquisa não infringe as normas legais e éticas. Os procedimentos adotados nesta pesquisa obedecem aos critérios de Ética em Pesquisa com Seres Humanos conforme Resolução no. 466/12 do Conselho Nacional de Saúde. Existe o risco de desconforte durante a obtenção da imagem, e complicações podem ocorrer durante o procedimento, como o paciente se movimentar durante a realização do exame e ser exposto novamente a outra dose de radiação.
5. **CONFIDENCIALIDADE:** Todas as informações coletadas neste estudo são estritamente confidenciais. Somente o pesquisador e seu orientador (e/ou equipe de pesquisa) terão conhecimento de sua identidade e nos comprometemos a mantê-la em sigilo ao publicar os resultados dessa pesquisa.
6. **BENEFÍCIOS:** Esperamos que esta pesquisa resulte em informações importantes sobre a prevalência de nódulos pulpares encontrados nas tomografias, de forma que o conhecimento construído a partir desta pesquisa possa contribuir para que o cirurgião-dentista tenha conhecimento a respeito do desempenho das tomografias no diagnóstico e prevalência de nódulos pulpares em molares. A equipe desta pesquisa se compromete a divulgar os resultados obtidos, respeitam-se o sigilo das informações coletadas, conforme previsto no item anterior.
7. **PAGAMENTO:** O sr.(a) não terá nenhum tipo de despesa para participar desta pesquisa, bem como nada receberá por sua participação. Todas as despesas tidas com a pesquisa serão de responsabilidade do pesquisador responsável. Haverá garantia do direito a indenização diante de eventuais danos decorrentes da pesquisa.

Após estes esclarecimentos, solicitamos o seu consentimento de forma livre para participar desta pesquisa. Portanto, preencha, por favor, os itens que se seguem:

Confiro que recebi via deste termo de consentimento, e autorizo a execução do trabalho de pesquisa e a divulgação dos dados obtidos neste estudo.

Obs.: Não assine este termo se ainda tiver dúvida a respeito.

CONSENTIMENTO LIVRE E ESCLARECIDO

Tendo em vista os itens acima apresentados, eu, _____, de forma livre e esclarecida, manifesto meu consentimento em participar desta pesquisa.

Assinatura do Participante ou Responsável

Assinatura da pesquisadora
Ana Maria Veiga Vasques

Pesquisadora: Ana Maria Veiga Vasques – (17) 99731-1675

Orientador: Prof. Dr. Eloi Dezan Junior – (18) 3636-3254

Coordenador do Comitê de Ética em Pesquisa: Prof. Dr. André Pinheiros de M. Bertoz

Vice coordenador: Prof. Dr. Aldires Alves Pesqueira

Telefone do Comitê: (18) 3636-3234

E mail: cep@foa.unesp.br

ANEXO D

unesp UNIVERSIDADE ESTADUAL PAULISTA
"JÚLIO DE MESQUITA FILHO"
Campus de Araçatuba

INSTRUÇÃO NORMATIVA N.º 014-CPPGCO, de 14 de março de 2013.

Dispõe sobre as Normas para Redação de Dissertações e Teses do Programa de Pós-Graduação em CIÊNCIA ODONTOLÓGICA, de acordo com a Resolução UNESP-24, DE 24/02/2012.

O Coordenador do Programa de Pós-Graduação em Ciência Odontológica desta Faculdade, considerando a decisão do Conselho do Programa, por ocasião de sua reunião, levada a efeito em 08/03/2013, baixa a seguinte instrução normativa:

Artigo 1º - A redação do trabalho de Dissertação ou Tese do aluno do Programa de Pós-Graduação em Ciência Odontológica poderá ser realizada pela forma tradicional ou em formato de artigo.
Artigo 2º - O trabalho em formato de artigo deverá conter os seguintes elementos em sua estrutura:
I – Trabalho resultando em somente um artigo
1. Capa;
2. Folha de Rosto;
3. Ficha catalográfica (no verso da folha de rosto);
4. Dados Curriculares (facultativo);
5. Dedicatória (facultativo);
6. Agradecimentos (facultativo);
7. Epígrafe (facultativo);
8. Título e Resumo em Português;
9. Título e Resumo em Inglês (Abstract);
10. Lista de figuras (facultativo);
11. Lista de tabelas (facultativo);
12. Lista de abreviaturas (facultativo);
13. Sumário;
14. Artigo na íntegra (redigido nas normas do periódico escolhido)
15. Anexos

II – Trabalho resultando em dois artigos ou mais
1.Capa;
2. Folha de Rosto;
3. Ficha catalográfica (no verso da folha de rosto);
4. Dados Curriculares (facultativo);
5. Dedicatória (facultativo);
6. Agradecimentos (facultativo);
7. Epígrafe (facultativo);
8. Título e Resumo Geral em Português;
9. Título e Resumo Geral em Inglês (Abstract);
10. Lista de figuras (facultativo);
11. Lista de tabelas (facultativo);
12. Lista de abreviaturas (facultativo);
13. Sumário;
14. Introdução Geral (com referências inseridas como notas de rodapé);
15. Artigos na íntegra (redigido nas normas do periódico escolhido)
16. Anexos

Parágrafo único – Os anexos deverão obrigatoriamente conter as normas dos periódicos nos quais os artigos foram redigidos. Além disso, toda a informação que vier a complementar o trabalho e que não constar no texto do artigo deverá ser colocada sob a forma de anexos. Estes poderão incluir, mas não se limitam a, imagens, fluxogramas, protocolos laboratoriais, tabelas, etc.
Artigo 3º - Esta instrução normativa entra em vigor na data de sua publicação.

Conselho do Programa, 14 de março de 2013.

Prof. Adj. ALBERTO CARLOS BOTAZZO DELBEM
Coordenador do Programa