Focus article

The (in)adequacy of translational research in dentistry

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Translational research, as the name suggests, “translates” research findings into clinical practice to improve the health of human beings. The translational process builds on information from experiments conducted at a basic level (i.e., in vitro and/or animal studies) and progresses over experimental human studies for efficacy, efficiency, and safety to implementation. Therefore, all steps in the process should be based on studies conducted with the highest methodological quality possible in order to provide accurate and useful information. Furthermore, the systematic dissemination of new procedures/techniques should be done only when they have been proven to be effective and safe. This focus article describes examples of new techniques/procedures in dentistry that have not resulted from an adequate translational research process since the initial evidence was published. These procedures are generally characterised by lack of good evidence, particularly on their potential harms, and lack of adequate chronological order, regarding the translational research process (i.e., human research being conducted before animal research). Even so, they seem to be widely disseminated, and their promotion involves a wide range of sources, including social media. Some guidance is proposed to improve the quality of the translational research process in dentistry, as well as the level of awareness of all parties involved with the use of this research: clinicians, researchers, and patients. By improving the translational research process, optimization of the application and use of these resources, with less risk to the patients, is expected.

The translational research process passes several important steps on the way to support and justify the routine use of new drugs or techniques in the treatment of patients. The typical approach is first to test the efficacy and safety of the new drug or technique at a basic level, in other words, using in vitro and/or animal model studies (1). Hence, by virtue of these non-human models, a better understanding is obtained of the behaviour of these new therapies. These studies would enable us to predict, to a certain extent, the impact of these new therapies on human health. If promising results are found at this stage, the therapies may be further tested in trials involving humans. The translational research process involves different types of research designs integrated along a continuum from bench to chairside with a goal to save resources and minimize risks to patients (2). Some consider a broader definition for translational research that also involves concepts such as dissemination, knowledge transfer, health services research, and quality improvement (3, 4). Others may even see translational research as part of a larger concept called translational medicine (5). Figure 1 depicts a pathway for the translation of research for interventions in dentistry.

Translational research is nowadays attracting much attention in the dental community (6, 7). An adequate translation process may produce research of high quality and therefore play an important role in initiatives to reduce waste in biomedical research (8). Because clinical dentistry is focused on certain types of procedures and techniques, it is of interest to assess whether this sequence of events in the translational research process is systematically applied by dental researchers. Hence, the question addressed here is whether a new procedure/technique is routinely and comprehensively tested in basic research models (in vitro and/or animal model studies) before being tested on humans. Furthermore, the chronological order of publication of this research (animal and human trials) is assessed and reported. A check is also made on how these procedures have been disseminated to the dental community. This analysis corresponds to the steps (T1, T2) reported in Fig. 1. Finally, two cases are described where dental companies have failed to provide comprehensive evidence on the efficacy and potential harm of products at the time they were introduced to the market.

The first case singled out for examination is the “socket-shield technique” in implant dentistry (9). In
this technique, part of the buccal root is left in place after a tooth extraction to keep the form of the alveolar ridge. It is suggested that this procedure will prevent the ridge from collapsing (being reabsorbed) after the placement of the dental implant and will maintain the aesthetic results in the long-term.

PubMed was searched (on 24 September 2019) for evidence supporting the procedure. By using the keyword search “socket-shield” OR “socket shield” OR “partial extraction” OR “root membrane”, 214 documents were found. After the selection process and exclusion of non-relevant documents, 39 articles related to the topic were analysed (9–47). Generally, these publications reported promising results with this technique. The publications also revealed interesting information regarding the events in the research process. Figure 2 reports studies on the socket-shield technique published in chronological order. It is interesting to note that 19 of the case reports and case series (10–26, 34, 47) were published having only three animal experiments (9, 27, 30) as data to support the decision of performing these clinical studies. Furthermore, a case series (28) on this technique, conducted in three private practices between January 2006 and December 2016, reported 10-year follow-up data. It seems that in this study, patients were treated with the technique before an animal study was published. From 2018 to 2019, another three animal experiments were published, which reflects an inverted order in the translational research process, with human research being published before animal experiments. Finally, the 19 case reports and series were published before the first randomized clinical trial (RCT) on the technique was published in 2018 (29).

From this sample of studies, some information on potential side effects was found. For example, at the animal level, one experiment (9) reported that peri-implant tissues were free of inflammation after the technique was applied. Another animal experiment (30) reported mucositis and peri-implantitis in three inserted implants. At the clinical level, a case report described a periapical lesion on a dental implant after the socket-shield technique (31). In a case series (28), root fragment infection was reported over the follow-up of the study. Moreover, some animal experiment characteristics are noted. The six experiments were based on only 24 dogs [median = 4, interquartile range (IQR) = 3] and had their main objectives in understanding the efficacy of the new technique, while no objectives to evaluate potential side effects (harm) were described. Furthermore, no sample size calculation was reported for any of the animal experiments.

The second case is the procedure for the removal of the buccal fat pad (48) (also called bichectomy) for aesthetic purposes. A recent published systematic review (49) found only case reports and case series reporting on the effects of this procedure. In other words, no randomized study was identified in this systematic review, and the case reports and case series were rated as having a high risk of bias (49). Side effects, such as a haemorrhage and facial asymmetry, were reported in four of the eight studies included. Furthermore, not a single publication resulted when the search strategy of the systematic review was repeated (search performed on 24 September 2019) with the additional filter “other animals” to identify possible animal studies addressing the volumetric changes in the facial tissues and other potentially serious side effects of the removal of the buccal fat pad.

Gaps in the translation process

The findings described above may suggest the following: First, several clinical studies in the form of case reports and series were conducted with weak knowledge about the safety of the procedures. It seems that professionals applied the techniques to their patients based on evidence of only very few animal experiments (or even based on no evidence at all), as the chronology shown in Fig. 2 indicates. The question raised here is: were the patients informed about this weak evidence before they received treatment using these techniques? Second, the research conducted at basic and clinical levels seems to address inadequate research questions. Focus is mostly on the proof of principle/efficacy of therapies. However, it is insufficient to report only on some of the biological consequences of the therapies in animal experiments. It is important to adequately plan research questions for both animal experiments and clinical trials in order to aim at a comprehensive harm–benefit assessment (50). Third, researchers seem to disregard or be oblivious of the high methodological standards necessary when conducting and reporting animal experiments, at least in terms of an adequate sample of

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**Fig. 1.** Translational research process for interventions in dentistry (adapted from Westfall et al., 2007) (4). RCTs: randomized clinical trials.

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[Diagram showing the translational research process for interventions in dentistry with RCTs, case series, and systematic reviews.]
animals for precise and reliable results (51). Fourth, among the procedures evaluated here, there is currently only very weak evidence (if any) on the long-term clinical results for the procedure for the removal of the buccal fat pad. Fifth, conducting invasive procedures mainly for aesthetic reasons, may limit the possibilities for treatment of other conditions. For example, prior removal of the buccal fat pad for aesthetic purposes may result in limitations of treatments for other dental/facial conditions that could benefit from the use of the fat pad that is now unavailable (52).

**How are these procedures disseminated?**

Even if there is limited evidence supporting these techniques, courses about the techniques are nonetheless marketed to target dental practitioners (53–55). The author of this article has personally received invitations to attend a bichectomy course with practice on patients. Furthermore, social media groups of dentists have formed that focus on the dissemination of these techniques by reporting several clinical cases. By typing the words “socket shield” and “bichectomy” in the YouTube platform, several videos may also be found of clinical cases treated using these techniques, and some date as far back as 7 years. We may therefore conclude that these new techniques have been quickly applied to patients at a very preliminary stage of research, and most likely without a judicious analysis of their effects. This is one of the potential consequences of the dissemination of information through social media, where there is no appropriate filtering of scientific information and a higher risk of biased evidence. This “hurried” application of new techniques/procedures to patients may also be a consequence of the current status of post-graduation and short-courses offered to dental practitioners with the idea of “learn on the weekend to directly apply to your patients on Monday”.

**Are all research steps, in fact, necessary in the translational research process?**

Some think that basic research in the form of animal experiments should not be used in science, due to physiological and genetic differences between humans and other animals that make the replication of findings challenging (56). Going beyond the discussion of whether animals should be used in research at all, many will probably agree that when animal research is done, the studies should be conducted and reported with the highest quality possible. Hence, a robust methodology should be used when animal research is planned, and this includes the calculation of an adequate sample size (57).

However, the point of discussion here is not whether animal research is pivotal as a requirement for applying a new clinical procedure. The question is whether clinicians and patients should have solid information on potential efficacy and harm before a new technique is applied to a human being. Much of the evidence presented in the two cases outlined above is based on case reports and case series. Moreover, the researchers behind these case studies applied techniques to patients on the basis of poor data at the basic level (i.e., in the in vitro and animal studies). Furthermore, several case reports and case series were performed before the publication of a pilot RCT to understand the potential harms and benefits of the therapies (Fig. 1). One could consider that for a new therapeutic intervention, the analysis of potential harms and benefits should be tested in a controlled environment with robust methodology (for example, a pilot RCT), before it is freely conducted in patients (for example, in case reports and case series). Even with the assumption that an RCT is not necessary to demonstrate safety and efficacy, most will agree that patients should be comprehensively informed about the lack of good evidence on harms/benefits before entering any type of study, whether randomized or not.

The two examples described above may show only the “tip of the iceberg” of the problem. In an era where
information of dubious quality is flowing freely and quickly disseminated, dental practitioners can promptly apply this information in the treatment of their patients. However, because of the weak evidence supporting it, one can consider that the evidence should be improved before systematically applying the procedures to the clinical reality. A very recent published systematic review (58) recommended against the systematic application of the socket-shield technique; this recommendation was based on the current limitations of the evidence supporting the technique. The case of the buccal fat pad removal is even more dramatic, with patients being systematically treated without any published RCT on this topic.

The importance of reporting comprehensive information

A key concern is whether the patients involved in the clinical studies reported here were comprehensively informed about the (lack of) good evidence on efficacy and harm before they entered. For example, as a patient, one would ask whether the removal of the fat pad would bring any future long-term consequence. With aging, some loss of facial volume and decline of soft tissues may happen (59). Hence, as a 25-year-old patient, one would want to understand the impact of the removal of a fat pad that might have an effect on one’s health at the age of 60. In fact, one would be interested in knowing what proportion of the procedures have been conducted without any complications and what the risk of complications would be for both of these interventions. Furthermore, if randomized studies were available, one would be interested in obtaining other information, such as the number needed to treat (NNT) (60) regarding outcomes on harms. This background would give the patient more accurate information on which to base the decision to accept or deny the proposed therapies.

The arguments presented above should not be taken to mean that innovations in our profession should not become promptly available to clinicians. Rather, the arguments are meant to emphasize that important steps should be taken in research before new techniques are fully available to clinicians. For example, the U.S. Food and Drug Administration (FDA) requires several steps of research prior to giving permission for the use of new devices and drugs (61). One can argue that there are potential differences for the requirements of allowing new devices/drugs as opposed to new clinical procedures. However, any intervention in patients is susceptible to potential side effects. Furthermore, both the clinician and the patient should have comprehensive information on the balance between the benefits and harms (62) of these therapies before they are applied in any clinical study or dental practice. In a more advanced phase of the translational research process (T2, Fig. 1), ideally, the dissemination of research results should be done through unbiased and well-elaborated sources, under methodologically sound clinical guidelines that should be tailored to both clinicians and patients (63).

Ethics in medical research

In 2013, the World Medical Association (WMA) published the most recent version of the Declaration of Helsinki, a statement of ethical principles to be observed when doing research with humans (64). The entire document suggests broader guidance that is sensitive to interpretation. However, considering the evidence reported above, some of those ethical principles seem to have been overlooked or ignored in the examples. For example, the following sections (and statement numbers) of the Declaration of Helsinki specifically apply to the cases reported: General Principles (Statement 14); Risks, Burdens, and Benefits (Statements 16-18); Scientific Requirements and Research Protocols (Statement 21); Informed Consent (Statement 26); and Unproven Interventions in Clinical Practice (Statement 37) (Table S1). It is not clear whether the potential benefits outweighed the potential risks or whether there was conclusive proof of definitive outcomes (64).

The dental industry and the report of evidence supporting new products

Potential gaps in the research translational process might be overlooked by companies producing new products or techniques. For example, recently, a new product for periodontal regeneration was introduced to the market (65). The company reported the advantages of using the product on its website but with little evidence to support the claims (65). Although the material had been well researched over the last two decades, the particular form of application of the product and the periodontal condition (flapless) had not been thoroughly researched. Only one small RCT (66) had been published before the product was introduced to the market. Hence, long-term results were not presented before the material was made available to clinicians, and there is uncertainty as to whether there are improvements on important clinical outcomes, such as the clinical attachment level and tooth survival in a long-term perspective. This pattern of behaviour of dental companies seems to be consistent with other cases. Take, for instance, the relatively new dental composites described as “bulk-fill” that have been developed to allow polymerization with greater amounts of material. Companies claim that the level of shrinkage for these products is comparable to that of composites placed in an incremental way. Although some long-term evidence on the effectiveness of these composites already exists (67), only limited clinical evidence was available at the time the new material was released into the market. Furthermore, the evidence was recently considered inconsistent regarding the determination of the depth of cure (68).

Research on the socket-shield technique reported here also generated further development of a dental
device for carrying out the technique (69). Interestingly, authors of four (24–26, 28) of the publications reported in this sample seem to be directly involved with the development of this device, as reported in the advertising document (69). The present focus article did not investigate further the strength of the relationship between the authors of these four studies and the dental company producing the device.

Dental companies invest a considerable amount of resources to develop new products and techniques. It is easy to understand that these companies try to recoup their investments as soon as possible. However, some standards of reporting should be observed when advertising the product. For example, the companies should provide information on the type of studies supporting the product, results on the benefits and harms, results on the costs of maintenance, and specifically, long-term results (or just as important, the lack of long-term studies). Only with a comprehensive and accurate advertisement will clinicians have enough information to make an informed decision on the acceptance of these products into their clinical practice.

**What could we do to improve this situation?**

The information reported in this focus article may raise an important question about dentists’ behaviour: why are dentists so prone to jump so quickly onto new dental procedures/techniques without questioning their potential positive and negative effects?

The adequate application of new techniques and procedures as therapeutic interventions in clinical dentistry should be based on previously-published solid evidence on the potential positive and negative effects of the therapies. One key factor in the translational research process is dentists’ understanding of procedures that do, in fact, bring benefits to their patients. This understanding is possible when dentists develop sufficient skills to comprehensively evaluate the quality of information advertised by others (dental companies, lecturers, etc.). Furthermore, patients also need to acquire enough methodological knowledge to question dentists about the effect of proposed therapies. This knowledge may be of great help in making the patient an active agent in the process of deciding the best interventions for them. Table 1 details some of the measures that might be of some help when translating new ideas/concepts into dental clinical practice.

**Conclusions**

New dental techniques and procedures are always welcome if they improve the treatment of our patients. It is expected that an adequate translational research process has been conducted before widespread implementation. However, this process should be based on two main pillars: (i) an adequate methodological research translation, and (ii) comprehensive information reported to clinicians and patients on the current level of knowledge about the new technique.

Dentists should also be prepared to differentiate evidence-based treatments and keep high professional standards. In this way, treatment resources will be optimized, patients will not be put at unnecessary risk and higher ethical standards will be observed.

The present article did not intend to prove the efficacy and safety of specific clinical procedures. The

| Table 1 |
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| **Recommendations for translating new ideas/concepts into dental clinical practice** |

Editors of dental journals could contribute to more adequate translational research in our field by requiring comprehensive information on the potential harm of the new techniques/procedures reported in the submitted manuscripts that involve treatment in humans. When such evidence does not exist or is weak, the authors should present a strong rationale to justify the submission of the manuscripts.

Editors should also require, from researchers submitting case reports and case series based on weak evidence, a detailed informed consent signed by the patients (70). This consent should provide detailed information that: (i) the patient was aware that the evidence supporting the respective therapy was weak or even non-existent, and (ii) the patient accepted the proposed therapy and the potential risks of receiving the therapy.

Dental post-graduation and continuing professional development courses should provide balanced information about the new technique/procedure in terms of benefits and harm to the patient. If the evidence supporting the procedure is of low quality or even non-existent, it should be comprehensively reported and explained to those attending the course.

It is logical to think that clinicians who are also clinical researchers may have interesting ideas on how to improve treatments, because they are directly involved with the treatment of patients on a daily basis. However, before any systematic use of a new idea, they should observe the importance of first testing the technique with robust methodology to better understand the effects of these therapies on a patient’s health. Thus, case reports on new therapies/techniques should not be submitted when there are potential issues regarding the safety of the patients.

An adequate level of information among all parties involved in the decision-making is of paramount importance. Dental practitioners should develop a reasonable level of knowledge on the methodological aspects of research to better understand the impact of new therapies (i.e., to better understand the “bright” and “dark” sides of the therapies). This knowledge would be pivotal in adequately clarifying dental industry advertisements on these new products. Patients should be comprehensively informed on the effects of new therapies/techniques, mainly, when the evidence supporting them is incipient as the procedure is being developed. Ideally, these patients should also develop basic skills on methodological principles to better understand the pros and cons of the therapies proposed by their dentists. Only informed patients can make informed decisions about their own dental treatments. Dental companies should provide strong levels of scientific evidence to support the introduction of new materials into the market. This should involve long-term human data for the clinician to understand the potential benefits and harms of these materials. Furthermore, industry claims should be reported in a realistic way to avoid the risk of some sort of spin bias (71).
specific aim of the article was to focus on whether we, as research community, are observing the adequate steps in the translational research process. Therefore, the information reported might contribute to further debate for a more robust translational research process in our field.

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