

Title:	Existing restrictions and barriers for manufacturing removable dentures using 3D printing technologies
Type of article:	Review / Research
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Abstract:

3D printing technologies have grown rapidly in production of removable dentures particularly in the past a few years.

Aim: The aim of this research was to investigate the restrictions in the use of 3D printing technologies for producing removable dentures especially in the UK.

Methods: An electronic search was the main method to select dental manufacturers or organizations able to print dentures' samples for research purposes. Connections were made via phone and by sending emails to the companies' representatives to discuss the possibility of using their products.

Results: Fourteen dental manufacturers were found offering the use of 3D printing to print dental restorations. But only 5 companies offered printing removable dentures and only one organization was able to offer 3D printed dentures here in the UK. The remainder were not able to sell and ship their resin materials used with 3D printing because of the strict regulations in Europe for receiving or using these materials within the EU even for testing purposes.

Conclusion: There are hidden challenges to finding available options for using 3D printing materials to print removable dentures, especially in the UK. This condition is different in USA and Canada.

Keywords:

3D printing, dentures, manufacturing, restrictions, barriers

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Introduction

The launch of digital technologies has led to significant advancements in the fabrication of partial and complete dentures, and it seems that digital manufacturing will change the face of dentistry in the near future especially in terms of treatment time and simplicity.^{1,2} The exponential popularity and spread of 3D printing encouraged many researchers and scientists to conduct further investigations on the materials used with these technologies.

The recent literature review regarding 3D printed dentures shows that many dental companies offer a variety of 3D printed dental prosthesis such as complete and partial removable dentures. Having said this, there are restrictions on using resin materials for manufacturing such dentures and these appear related to lack of some required information.³

Although the addressed literature review shows that digital manufacturing technology has made great changes in prosthodontics fields, essentially in producing large prosthesis, this search shows that the expressed science is not widely in use yet. Some professionals stated that the 3D printed biocompatible properties of materials used in (additive manufacturing systems) dentures are largely considered as one of the important reasons for the delay in its popularity.⁴ In addition, it is expected that this technology will take over the conventional complete dentures approaches and will simplify the fabrication process in the near future with

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its ability to produce models with precise details in relatively short time.⁵ Reasons for this are stated as maximizing time consumption, sustainability, and financial factors.

Less time spent to make a denture is another noted important advantage that may affect some criteria and promote this method as a sustainable and cost wise technique. Saving materials in production (denture resin) is an additional benefit for minimizing the charges and make it cost effective in comparison to CAD/CAM, with no need of any commercial specialized centre like some other existing systems.^{6,7,8} In contrast, one of the main disadvantages of 3D printing is the lower strength in comparison to the restorations produced by CAD/CAM.^{4,9} A further and possibly dangerous disadvantage is the cytotoxic effects on patients who using 3D printed prosthesis and the workers who are in touch with 3D printing machinery such as dentists, nurses and physicians all are subjected to this risk. Even, waste collection companies can be involved in this risk.¹⁰

Unavailable materials, despite provision in the literature review, was an unpredictable issue that was found in this study when we had to order the required samples. Very clearly and quickly the concerns about accessibility of the materials appeared. Following existing adverts, recommendations, and publications there was not any expectation of difficulty to order required samples due to availability of materials. This could be linked to lack of research and reliability of provided information and for this reason, although many dental companies offer all types of 3D printed technology for dental prosthesis it was not easy to find a source having the required printed samples for this study.

Methods

An electronic search has been carried out to select a dental manufacturers or organizations able to print dentures' samples for this task. These were contacted via telephones and by sending emails. Many companies across the world produce a wide range of 3D printing products. In this research only companies that were involved in using 3D printing to produce dental workpieces such as crowns and bridges were considered.

Many discussions took place with the companies' representatives and advisors about the availability of printing the required samples and their postage to the UK in case the production

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was outside the UK such as USA, Canada or China. All barriers and restrictions were discussed in detail with the companies' advisors, we also tried to understand the difference in rules and regulations between countries.

In order to provide scientific value to this work, we tried to contact most available dental suppliers and manufacture organizations both locally and internationally. Then we checked to make sure that those companies also produce 3D printed dentures as many of them mentioned on their websites. In most cases, direct contact was made with those companies to enquiry about two points, first, the ability to print removable dentures, second, the possibility to have this done in the UK or possibly shipped to the UK.

Results

Nine out of fourteen dental manufactures don't offer the fabrication of 3D printed dentures even though it seems they could fabricate other prosthetic appliances such as crowns and bridges by using 3D printing systems. This was explained as due to the complexity of denture manufacturing and the necessity of ensuring the biocompatibility of resin used in this manufacturing method.

Two manufacturers offer 3D printed dentures and resin materials, but not in the UK and just in USA and Canada. They did note that there is the possibility to sell or ship the resin anywhere outside of the U.S.A. and Canada according to Food and Drug Administration FDA agreement. It is clear that there is a strict EU regulation for these materials, even for testing purposes. The second company stated that they have many forms of dental printers and they manufacture 3D printed dentures, but again for the same reasons they cannot help us.

Only one organization was happy and able to provide the required samples. This company offered us by two options. The first option was to buy the 3D printer and resin materials for our research and complete the task, but its suggested prices did not justify it for this research. The second suggested option buy the material and they will import for us and print the samples in their organization which was found to be more convenient.

One company from Asia explained that they could print resin materials, but their products is limited to area such as preparing surgical guide and temporary crown and bridges.

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A number of producers stated they may provide the required resin materials, but clearly stated that these materials may not be suitable for intra oral purposes and its compatibility for this task has not been proven.

Discussion

From the assessed literature review, it can be noted that 3D printing technology appeared in industry more than three decades ago and it seems it will expand in dentistry in the coming few years.^{11,12} Designing dentures and producing them using this unconventional method is a branch of this new proposed technology that is currently engaging the minds of dental practitioners and manufacturers.^{3,13} This widespread prevalence in the recent previous years can be explained by the speedily increasing of the volume of the 3D printing market from less than \$300 million in 2012 to \$2.5 billion in 2013 and to almost \$16 billion in 2018 with an expectation of continuation of this growing trend but not in its all areas.^{8,10}

Based on our search in this paper and within its limitation, it is quite remarkable that most dental companies are capable of producing a variety of dental prosthesis including crowns or bridge, but have not developed in manufacturing removable prosthesis such partial and complete dentures. This fact can be explained differently, and this study proved that there is some lack of information regarding the materials that does not allow a manufacturer to use them in their industry comfortably. Whether these materials are biocompatible and safe for human use, is an important factor and question that even affected movement across borders and created limitations for their use. Solving this issue would help other researchers to work on other material properties such as mechanical properties.

Furthermore, there are noticeable dissimilarities between the existing restrictions and rules for the use of these technologies and materials between different countries. Therefore, what is allowed to be used in the USA, is not necessary the same in the UK depending on the restrictions of the local health authorities. One of the significant reasons for having those regulations is the safety of the materials used with this technology which is not totally established yet, in addition to the lack in information on some mechanical properties for these materials. Having said that, undertaking research the biocompatible and mechanical properties

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can help in removing some doubts about the safety and efficient usage of the mentioned materials and techniques.

Conclusion

There are hidden challenges and barriers to use 3D printing technologies to manufacture removable dentures, especially in the UK and Europe. Some of these restrictions are not present in other countries such as USA and Canada.

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