

Importance of The Type of Oral Mucosa Model in The *In Vitro* Studies of Oral Drug Delivery

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Received: September 06, 2018; **Published:** September 17, 2018

Volume 3 Issue 5 September 2018

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Oral mucosa drug delivery has attracted the attention of researchers [1] because it offers several advantages respect to peroral route (the avoidance of liver detoxification and presystemic drug elimination within the gastrointestinal tract that inhibit oral administration peptides and proteins) [2-3]. Drug transport across oral mucosa can occur by paracellular or transcellular way. The first one is utilized from hydrophilic compounds and the latter from lipophilic molecules. However, considering that the oral epithelium is stratified, drug permeation involves a combination of these two ways [4].

Two layers, in fact, compose the oral mucosa: the surface epithelium (supported by connective tissue layer) and the lamina propria. The first one is a stratified squamous epithelium, which may be keratinized or non-keratinized depending from the area of the mouth [5].

The lamina propria contains fibroblasts and is composed by a network of type I and III collagen fibers and elastic fibers. Moreover, the lamina propria contains vascular and lymphatic components [5].

Nevertheless, this type of drug delivery is not yet widely used, for various reasons. One of these is the absence of standardized methodologies for the *in vitro* evaluation of buccal drug delivery systems. Hence the need to validate *in vitro* models of oral mucosa on which to perform (among others) cytotoxicity and mucoadhesion tests of the delivery system and release and permeability tests of the drug [2,6].

During the time, various *in vitro* models of the buccal mucosa were used in oral drug delivery studies. Since 1975, is known that human keratinocytes can growth, *in vitro*, on a 3T3 mouse fibroblasts monolayer [7]; however, because the oral epithelium is a complex multilayer structures, only a 3D multilayer culture system can represent a good model of oral mucosa [5].

Multilayer sheets of non-keratinizing oral epithelium, commercially available, is constituted by TR146 keratinocyte cell line [5,8] but, due to cancer origin of these cells, the permeability is not conform to normal keratinocytes. For this type of studies is available a keratinized stratified epithelium produced by air-liquid interface culture of normal gingival keratinocytes [5].

Citation: Giuseppina Nocca. "Importance of The Type of Oral Mucosa Model in The *In Vitro* Studies of Oral Drug Delivery". *Oral Health and Dentistry* 3.5 (2018): 730-731.

Obviously, to obtain an oral mucosa model similar to normal mucosa, lamina propria, basement membrane and stratified squamous epithelium are necessary and, to this purpose, researchers work to develop new type of scaffolds (also utilizing the new generation of 3D bio-printer) to reach this result [5,9]. Until this goal is achieved, it is important to keep in mind the limitations of the model used to interpret the experimental results obtained.

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