DEVELOPMENT AND CONSTRUCTION OF DEVICES TO PERFECT THE PROCESS OF PRODUCTION OF BIODENTAL FILMS BY THE SOLVENT CASTING METHOD

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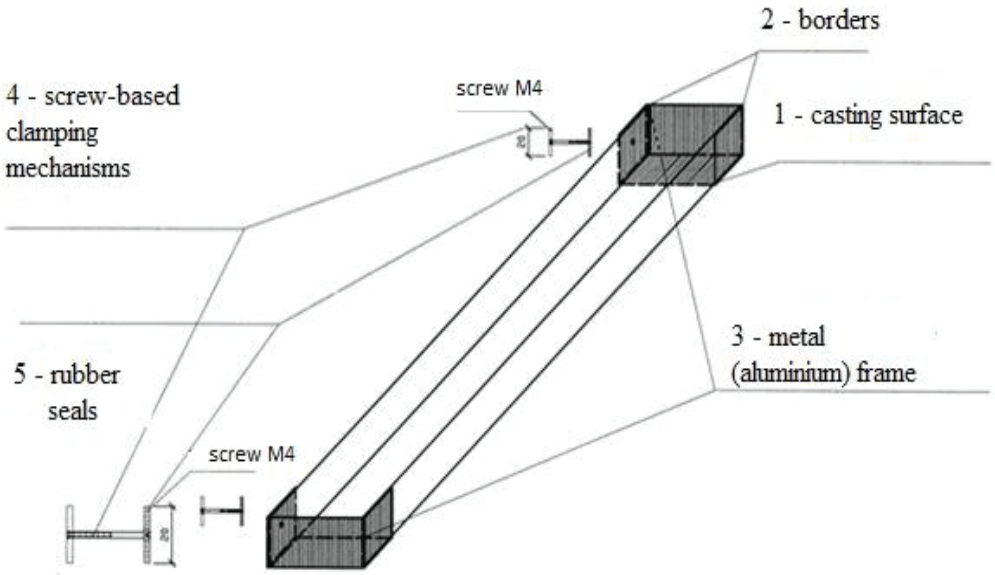
Abstract. One of the problems in standardizing Bioadhesive dental film (BDF) produced by the solvent casting method, is the use of a Casting Mould with clearly set geometrical parameters of 10.0 x 60.0 mm, when using a set volume of polymer gel. Many scientific studies dealing with the preparation of polymeric medical film fail to describe the technological equipment necessary for the manufacture of BDF (bio dental films) using the solvent casting method on a flat surface.

During the scientific development of this process, three types of devices were designed, tested and patented, these being a Casting Mould, and Perforating and Cutting Devices to be applied in the production of dental BDF using the solvent casting method.

The Casting Mould is made of a neutral glass and has the dimensions of 60 x 400 mm which allows the tie production of dental films of a standardized size using the solvent casting method. The Perforating Device results in improved perforated BDF in the process of its production. Meanwhile the Cutting Device allows the uniform distribution and cutting of the polymer film into dozaged strips with accurately specified geometrical dimensions of 10.0 x 60.0 mm.

Graphical abstract



Key words: Casting Mould, Perforating Device, Cutting Device, (BDF) Bioadhesive dental film.

Introduction

Taking into consideration the **gro**wing needs in the provision of quality therapeutic services and with an aim to simplify dental procedures, the research was carried out on the systematization and improvement of the process of obtaining polymer-based bio-adhesive dental film (BDF), using the solvent casting method [l]. BDF is applied to the mucosal surface inside the mouth and, depending on the active pharmaceutic ingredients used, can facilitate anti-inflammatory, wound-healing, antimicrobial and other curative effects [2]. This type of approach predominates over other medications, notably solutions, ointments, gels, pastes, aerosols and even injections, is in that the polymer based BDF gradually dissolves in the mouth and releases the active pharmaceutical ingredients in controlled doses, which penetrate locally through the intact protective epithelial barrier of the mucosal layer, without any excessive damage to tissue [3].

BDF can be used in various types of disorders in the mucosal layer of the oral cavity, as well as in post-surgical consequences, which are mostly accompanied by swelling of the epithelial tissue [4].

Illustration 1. *The Cutting Device used to obtain BDF using the solvent casting method.*

The use of this mould in the production of polymer films has a number of drawbacks: the bottom of the Petri dish and its edges are not geometrically flat in the horizontal and vertical dimensions of the casting surface. Therefore, when casting into such a mould, the BDF will have a variable thickness and thus an uneven concentration of active pharmaceutical ingredient. Moreover, the total area of a standard Petri dish is about 70 cm^2, while a single casting volume is limited to 25 ± 5 cm^3 and aren't recommended for the one-time use of large volumes of polymer solution, for instance 100 or 1000 ml [5].

Illustration 2. *Presently, to obtain BDF extemporally, using the solvent casting method, a Petri dish is used as the Casting Mould.*

Thus, the production of more than 10 BDF strips 10.0 x 60.0 mm in size, as well as the standardization of film obtained through the solvent casting method in a Petri dish is a technologically complex process.

Experimental Part

Materials and methods

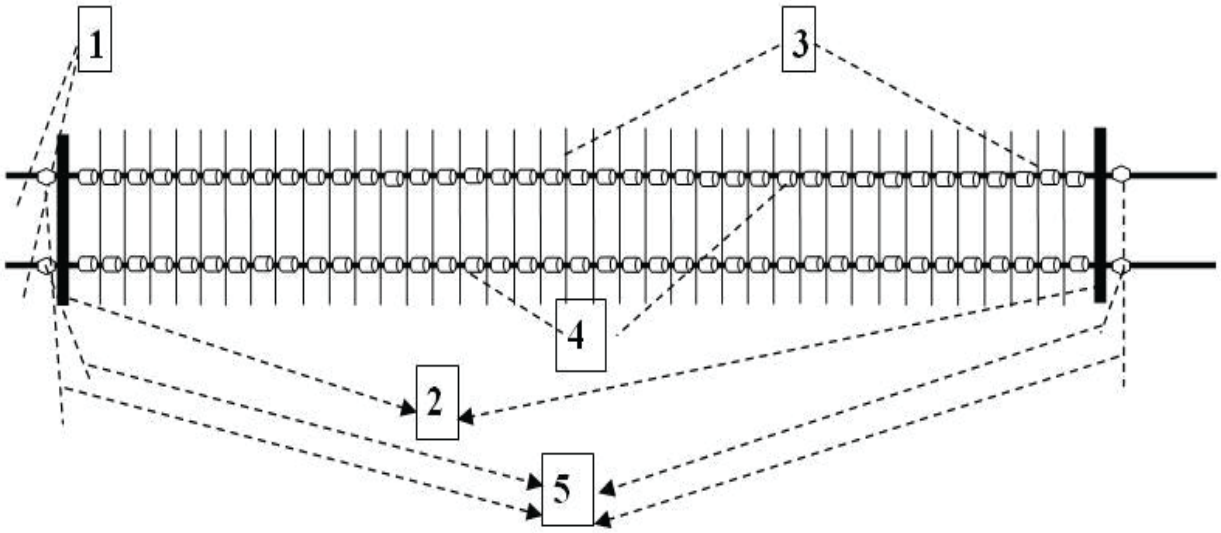
The main aim of the research was the development of a device in die form of a mould for the casting of polymer solution [7], which would allow for the production of polymer sheets geometrically even in area that can be cut into dosage strips of the necessary size [6]. This device will enhance the dosage precision of the finished product, will simplify the process of obtaining the die of BDF, will make easier the removal of the film from the casting surface, will simplify the cleaning and washing the casting surface both before and after the production process, as well as improving die production processes and standardization of the prepared for use medical product.

Results and discussion

The surface of the proposed mould for casting the polymer solution, which is accetable for a standardized BDF using the casting method extemporally, is made using a rectangular casting surface - 1, made from 6 mm-thick neutral glass; its polished edges have an exact perpendicular cut made at 90°angularly to the surface. To extemporally obtain BDF using the casting method, the dimensions of the casting surface - 1, were set at 60 x 400 mm, which corresponds to a casting volume of 100 ml. The perimeter of the casting surface is equipped with removable borders - 2 made of neutral glass. Also, the

borders of the casting surface -1 are fixed in place using a metal (aluminium) frame - 3. In order to hold the device together and prevent leakage, two screw-based clamping mechanisms with rubber seals are used [7].

Scheme 1. *Method of application of BDF to the mucous membrane of the oral cavity, where: 1 - longitudinal bearing pins, 2 - transverse fixing elements, 3 - cutting elements – blades, 4 - washers that set the distance between blades, 5 - nuts that fix and hold the cutting unit together.*



A special requirement in development of a Casting Mould is that the edges of the casting surface must have even perfectly polished perpendicular 90°cuts on all sides. This allows for an improved hermetic seal.

A Casting Mould that allows for standardized BDF is used in the following way. Before commencing the casting, all glass elements (the casting surface - 1 and the borders - 2) are treated with cleaning and disinfecting solutions, then thoroughly dried. The glass parts of the Casting Mould are placed into the aluminium frame - 3, and sealed in place by tightening the screw-based clamping mechanisms - 4. Before use, the assembled Casting Mould is disinfected with 96° ethanol and wiped with an oil solution.

The prepared polymer solution is poured into the mould, and the drying process is conducted until an elastic sheet is obtained. The mould is disassembled by unscrewing the clamping mechanisms and the the casting surface - 1 is removed; the polymer film is then removed from the casting surface and cut transversely into 10 x 60 mm strips.

The use of such a Casting Mould allows for the standardization polymer strips produced by the solvent casting method, and significantly simplifies the process of producing BDF in serial production medications contained in dental film [6].

To improve the technical process of obtaining BDF through the solvent casting method, in particular to make the cutting of the

produced polymer sheet easier, after the drying stage, for dosage application onto the 10.0 x 60.0 mm strips, a Cutting Device was designed. The basic dimensions of the Cutting Device correspond to four dimensions of four Casting Mould which allows for the production of 60.0 x 400.0 mm polymer sheets [8].

The designed Cutting Device consists of an assembled rectangular frame made of stainless steel, in which there are set of two bearing pins - 1 for mounting of the cutting elements - 3 (in the form of 38 blades), washers - 4, which accurately set the distance between each blade, and four nuts - 5, which fix the blades onto the longitudinal mounting parts, and two transverse fixing elements - 2, which when attached to the longitudinal bearing pins - 1 create a frame and generally reinforce the device. Thus, the two longitudinal pins -1, carry uniformly planted cutting elements in the form of rectangular blades with 0.1 mm thickness of the cutting edge. The ends of the two longitudinal bearing pins - 1 are equipped with clamping mechanisms consisting of nuts - 5. The distance between each blade of assembled Cutting Device is 10.0 mm. The number of cutting blades -38 is dependent on the size of the Casting Mould. Sequential use of both devices technically allows the production of dosated medicinal BDF as 40 dosed rectangular strips form 10.0 x 60.0 mm [8].

A special requirement in the design of the Cutting Device in tandem with the Casting Mould used to obtain BDF, is that the distance between the cutting blades must be set at 10.0 mm. This will make possible the production of BDF dosed stripes in sizes of 10.0 x 60.0 mm.

To obtain BDF through the casting method, the Cutting Device, which forms a part of the Casting Mould, is used in the following way. Before commencing the work the cutting elements - 3 are treated with cleaning and disinfecting solutions.

Then the 38 cutting blades - 3 are separated from each other by washers - 4, and are set onto the longitudinal bearing pins - 1, which fixes them in the necessary position on the Cutting Device. The longitudinal bearing pins - 1, which form part of the Cutting Device, are fixed by two transverse elements - 2, which are tightened by four nuts. - 5 (two on either side). The assembled device is used to cut the polymer sheet. After use, the Cutting Device is disassembled, and its component parts are cleaned.

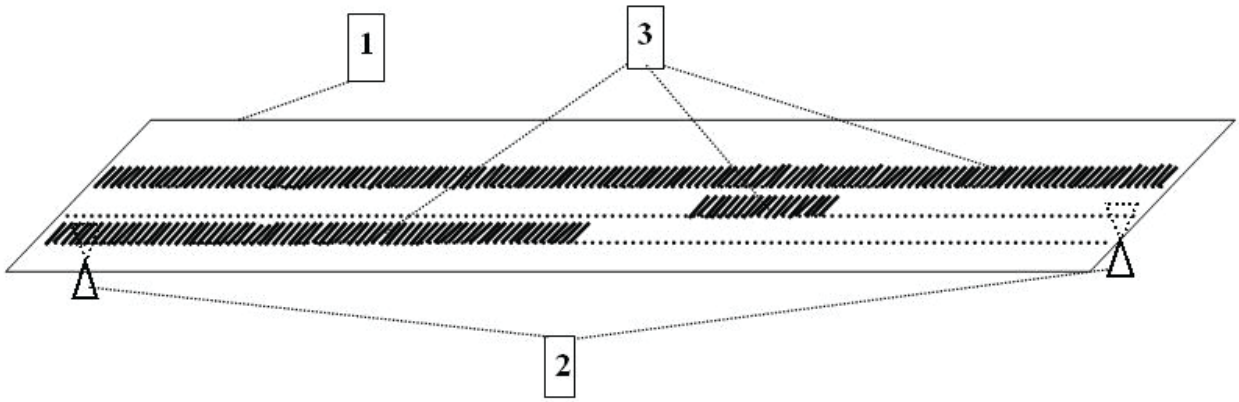
The developed Cutting Device simplifies the process of cutting the polymer sheet into dosed strips 10.0 x 60.0 mm, as a part of the BDF production process using a Casting Mould with precise dimensions of 60.0 x 400.0 mm. The device, as a part of the Casting Mould for obtaining BDF using the solvent casting method, improves the dosage precision of the ready-made product and simplifies the BDF production process.

Thus, the use of the Cutting Device in tandem with the Casting Mould provides the uniform division of the polymer sheet for do sagged strips to separate to and simplifies the process of standardized production of BDF using the solvent casting method.

With the view of further improvement the methodology for the medicinal dosing using polymer film in the form of BDF, another device was designed - a Perforating Device which allows to obtain the BDF by the solvent casting method to have perforated holes of a required diameter [9].

The Perforating Device is made detachable, from stainless steel, as a rectangular 2 mm thick, 60 x 400 mm plate - 1, with base geometrical dimensions that correspond to the dimensions of the Casting Mould described above. The top part of the plate, for convenience of use of the Perforating Device, has two handles fixed to it - 2. The bottom part of foe Perforating Device is equipped with three longitudinal horizontal rows of spiked teeth - 3, in the form of combs with thin wire rods: 160 teeth in each of three rows, that is a total of 240 spikes - 3. The longitudinal distance between each of foe spiked teeth is 3.7 mm (± 0.1), and they are set apart 10 mm (± 0.1). The parameters of the wire rod are: height of the spiked teeth is 10 mm, and the diameter is 0.5 mm.

Scheme 2. *The Perforating Device for obtaining standardized BDF by the solvent casting method, where: 1 - rectangular plate, 2 - handle, 3 - spiked teeth.*



A special requirement in the construction of the Perforating Device as a part of the Casting Mould used to make BDF is the distance between the spiked teeth, which are to be: lengthwise -3.7 mm (± 0.1), and widthwise - 10 mm (± 0.1). By maintaining this location of the teeth we are able to obtain dosed rectangular polymer strips in the form of BDF 10.0 x 60.0 mm, the central part of which contains perforated holes with a diameter of 0.5 mm, which are uniformly spread across the polymer sheet.

The Perforating Device is used in the general technical process before the drying stage, and in the process of production of polymer film by the solvent casting method, by locating the device in the Casting Mould, and thus allowing the production of perforated BDF.

Before using the Perforating Device, the bottom part equipped with spiked teeth is treated with cleaning and disinfecting solutions. To stop the polymer solution from sticking to the Perforating Device during the drying process, the working surface covering in spiked teeth is treated with an oil solution. The polymer solution is first poured into the Casting Mould, then the Perforating Device is placed in situ, and the unit is transferred into the drying locker for drying and obtaining a polymer sheet 40.0 x 60.0 mm covered across its entire surface with perforation holes. After the process of drying is completed, the Perforating Device is removed and cleaned once more.

The use of the Perforating Device simultaneously with the Casting Mould and the Cutting Device allows us to obtain an improved BDF by way of casting onto a flat surface, and simplifies the process of standardization BDF production.

Conclusions

1. As a result of the above-mentioned scientific research, three devices were designed, tested and patented. These are: the Casting Mould, the Perforating Device and the Cutting Device, which can be used for the purpose of producing Bioadhesive dental films through the casting of solvent onto a flat surface.

2. The designed devices, which are made to be used consequently in a single technological cycle, allow the formation of a uniform polymer sheet which can be cut into evenly dosed strips, and this enhances the polymer product under conditions of serial production, as well as improving its standardization.

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