A REVIEW ON ORAL OSMOTICALLY DRIVEN SYSTEMS

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Abstract
In recent years, oral controlled release (CR) system is most acceptable dosage form by the patients. Drugs having short biological half-life and poor water solubility are the suitable candidate for development of CR system. Research revealed that conventional matrix or reservoir type formulations exhibits bioavailability issues due to gastric pH variations and is also affected by the hydrodynamic conditions of the body. Introduction of Osmotically controlled oral drug delivery systems (OCDDS) overcame these issues. OCDDS utilize osmotic pressure for controlled delivery of active agent(s). Drug delivery from these systems is independent of the physiological factors of the gastrointestinal tract and these systems can be utilized for systemic as well as targeted delivery of drugs. The release of drug(s) from osmotic systems follows zero order. It is mainly governed by various formulation factors such as solubility and osmotic pressure of the core component(s), size of the delivery orifice, and nature of the rate-controlling membrane. The present review highlights an overview of OCDDS. Further, the challenges of these technologies and its future perspective are also discussed at length.

Keywords: Osmotic pumps, Osmosis, Zero-order, Semipermeable membrane, Osmotic agent

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Available online: www.ijipsr.com May Issue 423
INTRODUCTION

Osmotically Controlled Drug Delivery System (Ocdds). For many decades treatment of an acute disease or a chronic illness has been mostly accomplished by delivery of drugs to patients using various pharmaceutical dosage forms. Traditionally, the oral drug delivery has been popular as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs. Conventional oral drug delivery systems are known to provide an immediate release of drug, in which one cannot control the release of the drug and effective concentration at the target site. The bioavailability of drug from these formulations may vary significantly, depending on factors such as physico-chemical properties of the drug, presence of excipient, various physiological factors such as the presence or absence of food, pH of the GI tract, GI motility, etc [1].

To overcome this limitation of oral route is replied by parenteral route. This route offers the advantage of reduced dose, targeting of site and avoiding GI stability, hepatic by-pass of drug molecule. In the recent years, pharmaceutical research has led to the development of several novel drug delivery systems. The role of drug development is to take a therapeutically effective molecule with sub-optimal physicochemical and/or physiological properties and develop an optimized product that will still be therapeutically effective but with additional benefits such as [2].

Sustained and consistent blood levels within the therapeutic window:

- Enhanced bioavailability
- Reduced interpatient variability
- Customized delivery profiles
- Decreased dosing frequency
- Improved patient compliance

The drug release can be modulated by different ways but the most of novel drug delivery systems are prepared using matrix, reservoir or osmotic principle. In matrix systems, the drug is embedded in a polymer matrix and the release takes place by partitioning of drug into the polymer matrix and the surrounding medium. In contrast, reservoir systems have a drug core surrounded by a rate controlling membrane.

The osmotic systems utilize the principles of osmotic pressure for the delivery of drugs in both the routes oral as well as parenteral [3].

Available online: www.ijipsr.com      May Issue 424
Principle of Osmosis

Osmosis can be defined as the net movement of water across a selectively permeable membrane driven by a difference in osmotic pressure across the membrane. It is driven by a difference in solute concentrations across the membrane that allows passage of water, but rejects most solute molecules or ions. Osmotic pressure is the pressure which, if applied to the more concentrated solution, would prevent transport of water across the semi permeable membrane. The first osmotic effect was reported by Abbe Nollet in 1748. Later in 1877, Pfeffer performed an experiment using semipermeable membrane to separate sugar solution from pure water. He showed that the osmotic pressure of the sugar solution is directly proportional to the solution concentration and the absolute temperature. In 1886, Vant Hoff identified an underlying proportionality between osmotic pressure, concentration and temperature. He revealed that osmotic pressure is proportional to concentration and temperature and the relationship can be described by following equation.

$$\Pi = \Phi c RT$$

Where, $p =$ Osmotic pressure

$\Pi =$ osmotic coefficient

c = molar concentration

R = gas constant

T = Absolute temperature

Osmotic pressure is a colligative property, which depends on concentration of solute that contributes to osmotic pressure. Solutions of different concentrations having the same solute and solvent system exhibit an osmotic pressure proportional to their concentrations. Thus a constant osmotic pressure, and thereby a constant influx of water can be achieved by an osmotic delivery system that results in a constant zero order release rate of drug [4].

Osmotically Controlled Drug Delivery Systems

Osmotic pressure is used as driving force for these systems to release drug in controlled manner. Osmotic drug delivery technique is the most interesting and widely acceptable among all other technologies used for the same. Intensive research has been carried out on osmotic systems and several patents are also published. Development of osmotic drug delivery systems was pioneered by Alza and it holds major number of the patents analyzed and also markets several products based on osmotic principle. These systems can be used for both route of administration i.e. oral
and parenterals. Oral osmotic systems are known as gastro-intestinal therapeutic systems (GITS). Parenteral osmotic drug delivery includes implantable pumps.

**Historical Aspects of Osmotic Pumps**

Controlled drug delivery has taken an important place in pharmaceutical development, improving the tolerability and patient compliance with prescribed dosing regimens [5-7]. Despite the predominant use of polymer-based systems, alternatives have been developed to decrease the influence of the various physiological factors that occur following food intake or that are dependent on patient age [8-10]. One of the most promising technologies is the oral osmotically driven system (OODS) [10-12]. Nevertheless, over the past 30 years, the development of OODS technologies has been accompanied by controversies around product safety and concerns regarding the benefit/cost-of-good ratio. It is, therefore, interesting to begin this paper by reviewing the key milestones in OODS development. Oral osmotically driven systems have primarily evolved from being device concepts for the delivery of veterinary medicines, namely Rose-Nelson [13], HiguchiLeeper [14] (fig.1) and Higuchi-Theeuwes pumps [15]. Using osmotic pressure as the energy source, the semi permeable membrane controls water inflow, generating hydrodynamic pressure inside the device and, thereby controlling drug delivery. All these technologies have in common the ‘semipermeable’ membrane controlling the drug delivery rate.

Relatively complex and scalable with technical difficulties, a major milestone was achieved in 1974 with the description by Theeuwes and Alza’s coworkers of a tablet design [16-17] composed of a compressed tablet-core surrounded by a semipermeable membrane with a single passageway (orifice), the so-called elementaryosmotic pump (EOP). This design adaptation for human use was conveniently processable using standard tabletting and coating procedures and equipment [18]. The first two products indomethacin, Osmosin [19] and phenylpropanolamine, Acutrim TM [20], were launched in the 1980s. In contrast to the originally anticipated business success [21-23], Osmosin had to be withdrawn from the market due to severe side effects such as GI irritation and perforation of the intestinal wall [24- 26]. This opened a crucial debate on (i) the safety of administering non-degradable systems such as OODS per-os, (ii) the prolonged delivery of irritating drug substances from delivery systems that are somewhat hindered in their transit through the GI tract and thereby delivering the drug to one small region of the gut wall (i.e. area of the GI mucosa directly facing the delivery system orifice) over extended periods of time and (iii) the importance of adapting the drug delivery system to the drug properties and risks. Due to these adverse events seen with the OODS formulations of indomethacin, a well-known anti-
inflammatory drug since the 50s [27-30], the use of OODS has for many years been associated with the amplified risk of stagnation of the dosage form in the GI tract. Despite these events negatively affecting the reputation of these drug delivery systems, OODS development continued with two new OODS designs, the controlled-porosity osmotic pumps (CPOP) and the push–pull osmotic pumps (PPOP). The first of these was the CPOP, which was designed to decrease the risk of extremely localised drug-induced irritation at the site close to the orifice, as seen in the case of Osmosin. The applicability of the OODS to poorly soluble drugs was targeted by using PPOP. Thus, nifedipine PPOP (Procardia XL) was one of the most successful drug delivery systems of the last century, marking the revival of the OODS. This system was the gold-standard treatment for the management of hypertension [31-33] from 1990 to 1995. Despite the relatively low incidence of safety events seen with Procardia XL, there were continuous clinical controversies surrounding the risk of GI occlusions of this dosage form in patients with a certain disposition. In the 2000s, a new drug product based on OODS technology was formulated to deliver methylphenidate to children (above the age of 6 years) with attention-deficit hyperactivity disorder (ADHD). These delivery systems were based on a new design, then push–stick osmotic pumps (PSOP), which combined immediate and sustained drug release phases. This system, Concerta TM, seemed to mark the end of the controversies concerning good treatment compliance with the technology and demonstrated tolerability in children. The history of the OODS reflects the difficulty in developing an innovative technology in the pharmaceutical field. Often times, the return on the initial investment made to develop the technology was delayed after several setbacks during development. Currently, OODSs are becoming attractive technologies because of their abilities to enhance the clinical profile of certain therapeutic agents and to positively differentiate a drug product from others on the market. However, a systematic approach is needed in order to apply a coherent development strategy to future OODS products. Such a strategy should address the three fundamental questions, which are as follows:

Is the OODS technology safe for administering a specific drug? – Does the drug release profile over time match the target? (Desired) pharmacokinetics in the patient? To what extent is it beneficial in terms of the patient’s compliance?

**Rose-Nelson Pump**

Rose and Nelson, the Australian scientists, were initiators of osmotic drug delivery. In 1955, they developed an implantable pump, which consisted of three chambers: a drug chamber, a salt chamber contains excess solid salt, and a water chamber. The drug and water chambers are

**Available online:** [www.ijipsr.com](http://www.ijipsr.com)  **May Issue**  427
separated by rigid semipermeable membrane. The design and mechanism of this pump is comparable to modern pushpull osmotic pump. The major disadvantage of this pump was the water chamber, which must be charged before use of the pump [6].

**Higuchi-Leeper Pump**

Several simplifications in Rose-Nelson pump were made by Alza Corporation in early 1970s. The Higuchi-Leeper pump is modified version of Rose-Nelson pump. It has no water chamber, and the device is activated by water imbibed from the surrounding environment. The pump is activated when it is swallowed or implanted in the body. This pump consists of a rigid housing, and the semipermeable membrane is supported on a perforated frame. It has a salt chamber containing a fluid solution with excess solid salt [7-8].

**Higuchi-Theeuwes Pump**

In the early 1970s, Higuchi and Theeuwes developed another, even simpler variant of the Rose-Nelson pump. As with the Higuchi-Leeper pump, water to activate the osmotic action of the pump is obtained from the surrounding environment. In the Higuchi-Theeuwes device, however, the rigid housing is dispensed with and the membrane acts as the outer casing of the pump. This membrane is quite sturdy and is strong enough to withstand the pumping pressure developed inside the device. The device is loaded with the desired drug prior to use. When the device is placed in an aqueous environment, release of the drug follows a time course set by the salt used in the salt chamber and the permeability of the outer membrane casing. Most of the Higuchi-Theeuwes pumps use a dispersion of solid salt in a suitable carrier for the salt chamber of the device.

**Advantages of Osmotic Drug Delivery System** [9]

Apart from the general advantages of controlled drug delivery systems, osmotic pumps have certain unique advantages, as follows:

- Delivery of drug from osmotic pumps can be designed to follow true zero-order kinetics.
- Delivery may be delayed or pulsed, if desired.
- Drug release from osmotic pumps is independent of the gastric pH and hydrodynamic conditions of the body.
- Higher release rates are possible from osmotic systems than with conventional diffusion based drug delivery systems.
- The delivery rate of drug(s) from these systems is highly predictable and programmable by modulating the release control parameters.
- A high degree of in vitro/in vivo correlation can be obtained from osmotic pumps.
- Drug release from the osmotic systems is minimally affected by the presence of food.

**Basic Concepts**

**Principle of Osmosis**

Osmosis can be defined as the spontaneous movement of a solvent from a solution of lower solute concentration to a solution of higher solute concentration through an ideal semipermeable membrane, which is permeable only to the solvent but impermeable to the solute. The pressure applied to the higher-concentration side to inhibit solvent flow is called the osmotic pressure [10].

**Delivery Rate**

The OCDDS consists of an osmotic core containing drug and an osmogen surrounded by a semipermeable membrane with an aperture. A system with constant internal volume delivers a volume of saturated solution equal to the volume of solvent uptake in any given time interval. Excess solids present inside a system ensure a constant delivery rate of solute. The rate of delivery generally follows zero-order kinetics and declines after the solute concentration falls below saturation[17]. The solute delivery rate from the system is controlled by solvent influx through the semipermeable membrane. The osmotic flow of the liquid depends on the osmotic and hydrostatic pressure differences across the semipermeable membrane of the system. This phenomenon is the basic feature of nonequilibrium thermodynamics, which describes the volume flux across the semipermeable membrane [11].

**Formulation Considerations of OCDDS**

Generally OCDDS consists of two parts: One of this is core and another is semipermeable membrane (coating). Core of OCDDS consists of drugs, osmotic agents, hydrophilic and hydrophobic polymers, flux regulating agents, wicking agents, while coating includes polymer, coating solvent, plasticizers and poreforming agents.

**Drugs**

Which have short biological half-life (2-6hr) and which are used for prolonged treatment are ideal candidate for osmotic systems. Various drug candidates such as Diltiazem hydrochloride[14], Carbamazepine, Metoprolol[15], Oxprenolol, Nifedipine[16,17], Glipizide[18], etc are formulated as osmotic delivery.
Osmotic Agents [22]

Osmotic agents maintain a concentration gradient across the membrane. They also generate a driving force for the uptake of water and assist in maintaining drug uniformity in the hydrated formulation. Osmotic components usually are ionic compounds consisting of either inorganic salts or hydrophilic polymers. Different type of osmogens can be used for such systems are categorized in table 1.

**Hydrophilic and Hydrophobic Polymers**

These polymers are used in the formulation development of osmotic systems for making drug containing matrix core. The selection is based on the solubility of the drug as well as the amount and rate of drug to be released from the pump.

The polymers are of either swellable or non-swellable nature. Mostly, swellable polymers are used for the pumps containing moderately water-soluble drugs, since they increase the hydrostatic pressure inside the pump due to their swelling nature. The nonswellable polymers are used in case of highly water-soluble drugs. Ionic hydrogels such as sodium carboxymethyl cellulose are preferably used because of their osmogenic nature [23].

**Flux regulating agents**

Delivery systems can be formulated to regulate the permeability of the fluid by incorporating flux-regulating agents in the layer. Hydrophilic substances improve the flux, whereas hydrophobic materials tend to decrease the flux. Insoluble salts or insoluble oxides, which are substantially water-impermeable materials, also can be used for this purpose [23].

**Wicking agent**

A wicking agent is defined as a material with the ability to draw water into the porous network of a delivery device. A wicking agent is of either swellable or non-swellable nature. The function of wicking agent is to carry water to surfaces inside the core of the tablet, thereby creating channels or a network of increased surface area [23].

**Semipermeable Membrane [22]**

An important part of the osmotic drug delivery system is the semipermeable membrane housing. Therefore, the polymeric membrane selection is important to the osmotic delivery formulation. The membrane should possess certain characteristics, such as sufficient wet strength and water permeability

- Should be biocompatible
Rigid and non-swelling

Should be sufficient thick to withstand the pressure within the device.

Any polymer that is permeable to water but impermeable to solute can be used as a coating material in osmotic devices. Some of the polymers that can be used for above purpose are included in table 1 [24, 25, 26].

**Coating solvent**

Solvents suitable for making polymeric solution that is used for manufacturing the wall of the osmotic device include inert inorganic and organic solvents that do not adversely harm the core, wall and other materials. The typical solvents used are listed in table 1. The mixtures of solvents such as acetone-methanol (80:20), acetone-ethanol (80:20), acetone-water (90:10), methylene chloride-methanol (79:21), methylene chloride-methanol-water (75:22:3) etc. can be used [27].

**Plasticizers [22]**

Plasticizers lower the temperature of the second order phase transition of the wall or the elastic modules of the wall and also increase the workability, flexibility and permeability of the fluids. Generally from 0.001 to 50 parts of a plasticizer or a mixture of plasticizers are incorporated in to 100 parts of wall forming materials. Suitable polymers should have a high degree of solvent power for the materials, compatible with the materials over both the processing and the temperature range, exhibit permanence as seen by their strong tendency to remain in the plasticized wall, impart flexibility to the materials and should be non-toxic. Examples of plasticizers are included in table 1.

**Pore forming agents**

These agents are particularly used in the pumps developed for poorly water-soluble drug and in the development of controlled porosity or multiparticulate osmotic pumps. These pore forming agents cause the formation of microporous membrane. The microporous may be formed in situ by a pore former by its leaching during the operation of the system. The pore-formers can be inorganic or organic and solid or liquid in nature (table 1).

Pores may also be formed in the wall by the volatilization of components in a polymer solution or by chemical reactions in a polymer solution which evolves gases prior to application or during application of solution to the core mass resulting in the creation of polymer foams serving as the
porous wall. The pore-formers should be non-toxic, and on their removal, channels should be formed. The channels become a transport path for fluid [27].

Table 1: Classification of Osmotic drug delivery systems

<table>
<thead>
<tr>
<th>Type of Osmotic Pump</th>
<th>Composition</th>
<th>Mechanism of Action</th>
<th>Advantages</th>
<th>Figures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Chamber Osmotic Pumps</td>
<td>osmotic core (containing drug with or without an osmagent) coated with a semipermeable membrane (SPM) and a small orifice is created in the membrane</td>
<td>Imbibes water through the SPM because of the osmotic pressure gradient and forms a saturated solution inside the device. This increases the hydrostatic pressure inside the tablet and forces the saturated drug solution through the orifice present in the membrane</td>
<td>Suitable for delivery of drugs having moderate water solubility</td>
<td></td>
</tr>
<tr>
<td>Elementary osmotic pump (EOP) [24, 25,26]</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Osmotic Pump with NonExpanding Second Chamber [27]</td>
<td>Multi-chamber devices comprise of systems containing a nonexpanding second chamber.</td>
<td>Purpose of second chamber is either dilution of drug solution leaving the device (particularly useful in handling drugs with high incidence of GI irritation) or simultaneous delivery of two drugs</td>
<td>Relatively insoluble drugs can also be delivered.</td>
<td></td>
</tr>
<tr>
<td>Multiple Chamber Osmotic Pumps Push-pull osmotic pump (PPOP) [28, 29]</td>
<td>Two compartments: Upper compartment (drug compartment) contains the drug along with osmotically active agents. Lower compartment (push compartment) contains the polymeric osmotic agents.</td>
<td>When the dosage form comes in contact with the aqueous environment, both compartments imbibe water simultaneously. Because the lower compartment is devoid of any orifice, it expands and pushes the diaphragm into the upper drug chamber, thereby delivering the drug via the delivery orifice.</td>
<td>Deliver both highly water-soluble (oxybutynin hydrochloride) and practically waterinsoluble (nifedipine, glipizide) drugs.</td>
<td></td>
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| Modified Osmotic Pumps Controlled porosity osmotic pumps (CPOP) [30, 31,32] | CPOPs are similar to EOP, the only difference being that the delivery orifice from which the drug release takes place is formed by incorporation of a water-soluble additive in the coating. After coming in contact with water, water soluble additives present in the coating dissolves and it results in an in situ formation of a microporous membrane as shown in figure. The release of drug takes place through this microporous channels as shown in figure. Eliminates the need for a separate manufacturing step (creating an orifice using a laser drilling machine). Suitable for delivery of drugs having intermediate water solubility and extremes of water solubility by some modifications. |
|---|---|---|
| Monolithic Osmotic tablet Systems (MOTS)[35] | A simple dispersion of a water-soluble agent is made in a polymer matrix. Water imbibitions by the active agent takes place that ruptures the polymer matrix capsule surrounding the agent, thus liberating it to the outside environment. MOTS for a water-insoluble drug was developed using gum arabic as the osmotic, suspending, and expanding agent. |
| OROS-CT [36] | System can be a single osmotic unit or it may contain as many as 5–6 push–pull units enclosed within a hard gelatin capsule. Immediately after ingestion, hard gelatin capsule shell dissolves. Enteric coating on the system prevents entry of fluid from stomach to the system and it dissolves after entering into intestine. The drug is delivered out of the orifice at a rate controlled by the rate of water transport across the membrane. Once- or twice-a-day formulation for targeted delivery of drugs to the colon. |
| Sandwiched osmotic tablet (SOTS) [37] | Tablet core consisting of a middle push layer and two attached drug layers is coated with a SPM. After coming in contact with the aqueous environment, the middle push layer containing swelling agent swells and the drug is released from the delivery orifices. System delivers drug from two opposite orifices, rather from the single orifice of the PPOP. |
| **Liquid OROS controlled release system (L-OROS)** [38,39] | Two types: L-OROS Soft cap and L-OROS hard cap. In Soft cap, Liquid drug formulation is present in a soft gelatin capsule, which is surrounded with the barrier layer, the osmotic layer, and the release rate-controlling membrane. In hard cap, it consists of a liquid drug layer and an osmotic engine, all encased in a hard gelatin capsule and coated with SPM. | The expansion of the osmotic layer results in the development of hydrostatic pressure, thereby forcing the liquid formulation to break through the hydrated gelatin capsule shell at the delivery orifice. Water is imbibed across the SPM, expanding the osmotic engine, which pushes against the barrier, releasing the drug through the delivery orifice. | To deliver APIs as liquid formulations and combine the benefits of extended release with high bioavailability. Suitable for controlled delivery of lipophilic APIs |
| **Osmotic bursting osmotic pump** [40] | Similar to an EOP expect delivery orifice is absent and size may be smaller | When it is placed in an aqueous environment, water is imbibed and hydraulic pressure is built up inside until the wall rupture and the content are released to the environment. | This system is useful to provide pulsedated release. |
| **OROS Push-Stick Technology** | It consists of a bilayer capsule shaped tablet | Similar as PPOP tablets | Provides the greatest benefit for compounds with low water solubility and dosage greater than 150 mg |
| **Asymmetric membrane capsule** [41,42] | Capsule wall made up of water insoluble semipermeable polymer | Imbibition of water through the capsule wall and dissolving soluble components within it and releasing from same wall | High water permeability and controlled porosity |
Evaluation of Oral Osmotic Drug Delivery Systems

Oral osmotic drug delivery systems can be evaluated for following:

**Visual inspection**: Visual inspection of the film for smoothness, uniformity of coating, edge coverage and luster.

**Coating uniformity**:

The uniformity of coating among the tablets can be estimated by determining the weight, thickness and diameter of the tablet before and after the coating.

**Coat weight and thickness**: The coat weight and thickness can be determined from depleted devices following careful washing and drying of the film, using standard analytical balance and screw gauge, respectively.

**Orifice diameter**: The mean orifice diameter of osmotic pump tablet can be determined microscopically using pre calibrated ocular micrometer.

**In vitro drug release**: The in vitro delivery rate of drugs from osmotic systems can be determined using diverse methodologies, including vertically reciprocating shaker, conventional USP dissolution apparatus I and II, flow-through apparatus, etc.

**Effect of pH**

An osmotically controlled release system delivers its contents independently of external variables. To check this, dissolution media with different pH is used.

**Effect of agitation intensity**

In order to study the effect of agitational intensity of the release media, release studies is carried out in dissolution apparatus at various rotational speeds.

**In Vivo Evaluation**

As the environment in the intestinal tract of the dog is quite similar to that of the human beings in terms of pH and motility, dogs have been widely used for in vivo delivery rate measurement of drug(s) from oral osmotic drug delivery systems and also to establish in vitro /in vivo correlation (IVIVC). In vivo evaluation can also be performed in healthy human volunteers. Various pharmacokinetic parameters (Cmax, Tmax, AUC and MRT) and relative bioavailability are calculated.

**CONCLUSION**

Osmotic pumps have come a long way in the field of drug delivery, starting from complex systems developed for research purposes to the osmotic pumps used for humans. Osmotic drug
delivery systems are based on utilization of osmosis as driving force for drug delivery. Since its origin 25 years ago, osmotic drug delivery systems have come a long way and are still used as research tool to study the delivery of drugs with different physicochemical and pharmacokinetic properties. The release of drug(s) from these types of systems is affected by various formulation factors such as solubility and osmotic pressure of the core component(s), membrane characteristics, and size of the delivery orifice. By modulating these formulation factors, it is possible to use these systems to deliver variety of drugs at a pre-programmed rate. The products available in the market, patents done till date and effectiveness obtained for osmotic products are indicative of success of this drug delivery in future too.

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