A l2-month longitudinal in vitro leakage study on a new silicon-based root canal filling material (Gutta-Flow)

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Objective. This study was performed to determine in vitro the short- and long-term sealing ability of a recently developed silicon-based root canal filling material (Gutta-Flow).
Study design. Sixty human upper central incisors were divided into 3 groups (n = 20). The root canals were instrumented and obturated with laterally compacted gutta-percha and AH26 sealer (group 1), continuous-wave thermal compaction (System B technique) and AH26 sealer (group 2), and Gutta-Flow technique (group 3). Leakage along entire root canal fillings was measured by the movement of an air bubble in a micropipette connected to the experimental root using a fluid-transport model. Short-term leakage measurements were carried out for 3 hours after 24 hours of equilibrium establishment. Leakage was measured again and at 3, 6, and 12 months after the initial measurement.
Results. At the 3-hour measurement, no significant differences were found among the 3 experimental groups. Long-term leakage measurements showed that at 3 and 6 months no significant differences were existed between Gutta-Flow and the other 2 techniques. However, at 12 months, root canal fillings with Gutta-Flow leaked significantly less than fillings of lateral compaction and System B technique.
Conclusions. Gutta-Flow technique showed a similar sealing ability to either lateral compaction or System B technique. This comparison improved significantly over time. These findings may be related to the possible expanding capacity of the material and the partial dissolution of the sealer over time in the other 2 groups. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;xx:xxx)**

The adequate and 3-dimensional obturation of the root canal system is of prime clinical importance for the long-term success of endodontic treatment.[1] This seal is developed mainly in order to minimize the leakage along root canal filling[2] and to protect the periapical tissues from bacteria and their byproducts.[3] Coronal leakage is a phenomenon implicated in all steps of endodontic treatment, and it may lead to failure of endodontic treatment.[4]

Microleakage along root canal fillings is expected to occur between dentin and sealer or between gutta-percha and sealer or through the sealer itself. A large number of studies[5-7] have examined in vitro the sealing ability of several root canal fillings and techniques[8-10] with the aim to evaluate coronal leakage. Although hard conclusions can not be drawn, these studies indicate that most root canal fillings do not completely fill the root canal system.

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Received for publication Jul 10, 2006; returned for revision Nov 13, 2006; accepted for publication Dec 15, 2006.
1079-2104/$ - see front matter

doi:10.1016/j.tripleo.2006.12.014

The sealing ability is a basic feature that needs to be tested for every new root canal filling material or filling technique.[11] A number of different methods have been used to assess the sealing ability of a root canal filling material by evaluation of microleakage. These methods include mainly dye penetration, spectometry of radioisotopes, fluorometric and electrochemical methods, bacterial penetration, and fluid-transport model.[12-15] Although in vitro leakage measurements cannot be extrapolated directly to in vivo condition,[16,17] very important data have been given for the quality of the root canal seals.

A new established silicon-based root canal filling material, Gutta-Flow (Coltene/Whaledent, Altstätten, Switzerland), was recently introduced in endodontic clinical practice. This new root canal filling is a modification of the RSA RoekoSeal Automix (Roeko Dental Products, Langenau, Germany), which has been shown to provide a consistent seal over a period of 18 months.[18,19] According to the manufacturer, Gutta-Flow contains very small gutta-percha particles in powder form, with a particle size of less than 30 μm, and sealer in its mass. Furthermore, the manufacturer claims a better seal and good adaptability because of the increased flowability and the fact that this material expands slightly on setting. Moreover, it has been shown that this material has an adequate adaptability to root canal walls.[20] However, the short- and long-term sealing ability of this material has not been evaluated by an in vitro study.

The aim of the present in vitro study was to evaluate the short- and long-term coronal microleakage along root canal fillings by comparing a new established (Gutta-Flow) obturation technique with 2 conventional techniques using a fluid-transport model.

MATERIALS AND METHODS

Specimen preparation

A total of 70 single-rooted human teeth (upper central incisors) were used in the present study. The teeth were kept in normal saline solution at 4°C until use. Initially, the teeth were immersed in 5% sodium hypochlorite (NaOCl) for 10 minutes to remove any organic components from the root surfaces. After that, the crowns were removed with a diamond disk (Komet; Brasseler, Lemgo, Germany) so that the length of the roots was standardized at 10 mm. An operating microscope (Protégé plus; Global Surgical, St. Louis, MO) was used to examine the roots for cracks under ×19.1 magnification. A #15 K-file (Dentsply Maillefer, Ballaigues, Switzerland) was inserted to the root canal to establish the working length 1 mm short of the apical foramen. The working length was established at 9 mm. The same K-file was passed through the apical foramen of the canals during and after instrumentation to ensure patency.

Mechanical instrumentation of the root canals was carried out serially to a size 40 K-file as master apical file (MAF). A step-back technique was used for the subsequent 4 file sizes larger (no. 60) than the MAF. The coronal 4 mm of root canals was instrumented by using Gates-Glidden drills (Dentsply Maillefer) no. 2 at 4 mm, no. 3 at 2 mm, and no. 4 at 1 mm. A total of 5 mL 2.5% NaOCl was used for irrigation of the canals between instruments with a syringe and a 27-gauge needle (Endo-Eze; Ultradent Products, Salt Lake City, UT). Five milliliters of 17% EDTA was used after instrumentation with K-files and Gates-Glidden drills to remove the smear layer. Final irrigation of all root canals was performed with 10 mL 2.5% NaOCl, and the canals were finally dried with sterile absorbent paper points. The prepared roots were randomly divided into 3 experimental groups of 20 roots each and 2 control groups of 5 roots each as follows.

Group 1. The root canals were obturated with gutta-percha and AH26 sealer (Dentsply Maillefer) using the cold lateral compaction technique. The AH26 sealer was prepared according to the manufacturer's instructions. Sealer was applied with a size 40 K-file used in a counterclockwise motion. An ISO size 40 master gutta-percha cone was inserted into the root canal to the working length until tug-back was obtained. The master gutta-percha cone was then coated with AH26 sealer and placed into the root canal to the working length. After placing the master cone, a size no. 30 NiTi spreader was inserted into the canal to a level approximately 2 mm short of the working length. Lateral compaction with accessory gutta-percha cones no. 25 was performed until the root canal was filled. Excess gutta-percha was removed with a System B condenser at the level of the coronal surface, and vertical force was applied with a vertical compactor to compact the remaining mass. In the present group no overfilling was observed.

Group 2. The root canals of group 2 were obturated with gutta-percha and AH26 sealer using the System B technique. A fine-medium master cone was fitted to the working length until tug-back was obtained. Then the master cone was coated with sealer and placed into the root canal to the working length. The temperature of the heat source was set at 210°C and the power at 10. A preheated fine-medium System B plugger was forced apically through the gutta-percha mass to within 6 mm of the working length. Maintaining constant apical pressure, the plugger continued to move apically for another 2 mm with the heat switch released. A little amount of sealer was observed to extrude through the apical foramen in only 1 specimen. The plugger was maintained at this position for 10 seconds, and then the heat switch was activated for 1 second for plugger withdrawal. A vertical plugger (Dentsply Maillefer) of 0.6 mm tip diameter was used to compact the remaining gutta-percha. The backfilling of the remaining coronal 5 mm was carried out with the same technique using a second fine-medium gutta-percha cone. The cone was cut off so that the tip diameter was 0.6 mm (600 μm), coated with sealer, and then placed in the backfill space of the canal. The heat source was set at 100°C.

Group 3. The root canals of group 3 were obturated with the Gutta-Flow technique. An ISO size 40 master gutta-percha cone was inserted into the root canal to the working length until tug-back was obtained. Gutta-Flow was provided in a double barrel automix system and prepared according to the manufacturer's instructions. The capsules were vibrated for 30 seconds on a vibration device (Silamat S5; Ivoclar Vivadent, Bendererstrasse, Liechtenstein). After that, the tip of the Gutta-Flow device was inserted into the root canal 3 mm short of the working length, and filling material was introduced until the flow of the material inside the canal could be observed. At the same time, the material was observed not to extrude through the apical foramen in all but 1 specimen. A fresh mix was obtained on a glass slab by pressing the mixing pistol. The master

Table I. Fluid transport results (F) at 3 hours and 3, 6, and 12 months

	NL ($F = 0$ μL/h)		SL ($0 < F < 20$ μL/h)		GL ($F > 20$ μL/h)		
	n	%	*n*	%	*n*	%	*P*
3 hours							
Lateral compaction	7	35%	7	35%	6	30%	.237
System B	9	45%	2	10%	9	45%	
Gutta-flow	5	25%	4	20%	11	55%	
3 months							
Lateral compaction	6	30%	8	40%	6	30%	.099
System B	9	45%	1	5%	10	50%	
Gutta-flow	5	25%	5	24%	10	50%	
6 months							
Lateral compaction	4	20%	4	20%	12	60%	.179
System B	5	25%	1	5%	14	70%	
Gutta-flow	5	25%	7	35%	8	40%	
12 months							
Lateral compaction	2	10%	3	15%	15	75%	.023
System B	2	10%	3	15%	15	75%	
Gutta-flow	5	25%	9	45%	6	30%	

gutta-percha cone was coated with Gutta-Flow and inserted to the working length. By pressing the master gutta-percha cone laterally, the tip of the device was inserted again into the canal to seal the backfill space. The excess material was removed with an excavator. After that, vertical force was applied with a hand plugger (Dentsply Maillefer) of 0.8 mm tip diameter to compact the root canal filling of the coronal portion of the canal. It should be noticed that this material (Gutta-Flow) has a working time of 15 minutes and a setting time of 25-30 minutes.

Group 4. The roots of this group were filled with laterally compacted gutta-percha without sealer and served as positive controls.

Group 5. The roots of this group were sealed with gutta-percha and AH26 sealer, covered entirely with 2 coats of nail varnish and served as negative controls.

After the preparation of all groups, roots were stored in gauze and placed in an incubator for 48 hours at 37°C and humidity 100% to allow the sealer to set.

Microleakage assessment using fluid-transport model

After 48 hours, teeth were transfered to the laboratory. Leakage along all root canal fillings was measured using a fluid-transport model. With a headspace pressure of 60 kPa (0.6 Atm), distilled water was forced through a plastic tube attached to the coronal end of the root specimen. The apical end of each root was tied to another plastic tube that was connected to a 20-μL glass capillary tube 170 mm long (Haak, Waller-Graf & Co., Werlheim, Germany). An air bubble about 3 mm long was introduced through the open end of the capillary. All connections were closed tightly by twisting pieces of stainless steel wire. Fluid conduction through the root filling was performed by applying pressure for 3 hours after an interval period of 24 hours necessary for air bubble stabilization. The fluid-transport results (F) were expressed in μL/h and divided into 3 categories: a) $F = 0$ (no leakage; NL); b) $0 < F < 20$ (slight leakage; SL); and c) $F > 20$ (gross leakage; GL).

After the initial assessment of leakage at 3 hours, the specimens of each group were detached from the measuring apparatus. Leakage was subsequently measured 3, 6, and 12 months after the initial measurement, for a total of 4 measurements for each root specimen. Between measurements, the roots were kept at 37°C in pieces of moist sponge.

Statistical analysis

Chi-squared statistical analysis was used to investigate differences in terms of leakage frequencies among the 3 study groups for each period. The magnitude of association is expressed as odds ratio (OR) and 95% confidence interval (CI). All tests were 2 sided, and the level of statistical significance was set at 5%.

RESULTS

Gross leakage was recorded in the positive control group (flow [F] > 20 μL/h), and no leakage was observed in the negative control group ($F = 0$ μL/h). The fluid-transport results at 3 hours for the 3 experimental groups are presented in Table I. No statistically significant differences were found at 3 hours among the 3 experimental groups ($P = .237$).

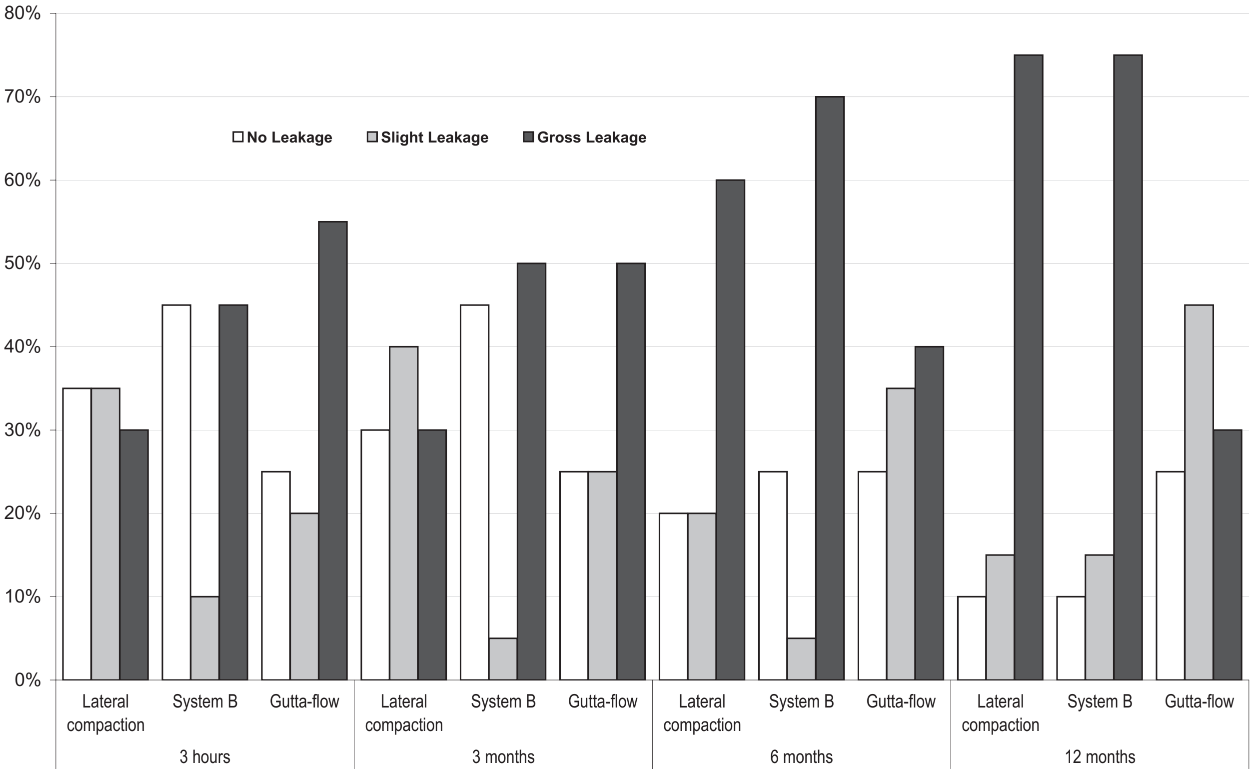

Fig. 1. Summated leakage data measured during 12 months.

The transport fluid results at 3 months for the 3 experimental groups also are shown in Table I. At 3 months, chi-squared test showed no statistically significant differences among the 3 experimental groups ($P = .099$). However, an odds ratio statistic revealed a statistically significant difference between System B and lateral compaction in NL and SL groups. More specifically, System B cases are less likely to develop SL than lateral compaction cases (OR = 0.08; 95% CI = 0.01-0.66).

At 6 months, chi-squared test showed no statistically significant differences among the 3 experimental groups ($P = .179$) (Table I).

The fluid-transport results at 12 months for the 3 experimental groups also are presented in Table I. The results showed that Gutta-Flow has statistically significantly fewer GL cases (30%) compared with System B group (75%) and lateral compaction group (75%) ($P = .023$). The OR statistic revealed a statistically significant difference between Gutta-Flow and lateral compaction and between Gutta-Flow and System B in the GL group. More specifically, Gutta-Flow cases at 12 months are less likely to develop GL than lateral compaction and System B cases (OR = 0.16; 95% CI = 0.03-0.95). Summated leakage data are illustrated in a diagram in Fig. 1.

DISCUSSION

Leakage in filled root canals has been widely studied the past 20 years. A variety of in vitro models have been used to evaluate leakage along root canal fillings. The basic problem is that the amount of leakage observed with various in vitro methods cannot be extrapolated to an in vivo situation. Despite this, leakage tests are an accepted method to evaluate and compare the seal of root canal filling materials. Laboratory assessment remains the only valuable preclinical test that can predict or indicate clinical performance of a new root canal filling material.[21] Among the existing in vitro methods the dynamic measurement methods are believed to be more reliable. In the present study, the leakage along root canal fillings was measured by the fluid-transport device, which has been shown to give reproducible quantitative results.[5,22]

The short- and long-term sealing ability represent 2 very important properties for all root canal filling materials. Leakage studies are performed to evaluate these properties and accordingly whether a basic criterion for the introduction of a new root canal filling material in clinical practice is fulfilled. It is very important to obtain leakage data measurements repeatedly after filling and over a long period of time, because the long-term sealing ability is the aim for each tested root canal filling material.

The results of the present study showed that Gutta-Flow provide a similar consistent seal over time with either lateral compaction or System B technique. Gutta-Flow group recorded an amount of leakage that remained relatively stable throughout the observation period of 12 months. Additionally, at the end of the same period, Gutta-Flow root canal fillings leaked significantly less than fillings of lateral compaction and System B technique. This finding may be attributed to the progressive dissolution of the sealer used in groups 1 and 2, resulting in an increase of the leakage along root canal fillings which have been stored in humid environment for a long time.[23,24] Moreover, in Gutta-Flow technique, this silicon-based sealer material is used alone to fill the root canal, with only 1 main gutta-percha cone in place, because it is supported by the manufacturer that it has an adequate flow rate. In combination with its synthesis (silicon plus gutta-percha), this probably makes the filling extensively stable over time without any solubility in the in vitro conditions.[25]

The significant reduction of GL at the end of the 12-month period could be attributed to the possible capacity of the material to expand over time. However, it is not clear why this reduction was not observed at the end of the 3- and 6-month periods.

To standardize the root canal instrumentation, upper central incisors were selected for the present study. All canals were instrumented to size 40 at the working length, step-back technique was performed to size 60, and the preparation was completed using Gates-Glidden drills in a standard sequence. This selection and preparation would be expected to control all the possible variables that could influence the results. In this way, leakage differences among the experimental groups could be attributed more reliably to the different materials and techniques used for root canal obturation.

The satisfactory short- and long-term sealing ability of Gutta-Flow is an important property of this new root canal filling material. Provided that the risk of overfilling is controlled, the use of this new material could be proposed in clinical endodontic practice, because of its good sealing ability, adaptability, and insolubility.

According to the present results, it could be concluded that:

1. All 3 obturation techniques investigated in the present study provided a similar consistent seal at the first measurement periods.
2. Root canals filled with lateral compaction and System B technique leaked significantly more than Gutta-Flow fillings at the 12-month leakage measurement. This result may be related to the possible partial dissolution of the sealer used in groups 1 and 2 at 12-month storage.
3. Gutta-Flow fillings maintained their good sealing ability at satisfactory levels over the measurement period.
4. The insolubility and homogeneity of the Gutta-Flow material seem to be the main factors that determine its behavior.
5. Under the appropriate circumstances (previous laboratory exercise, apical stop for the risk of overfilling), Gutta-Flow can be used in clinical endodontic practice.

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