SUMMARY
The purpose of this clinical trial was to evaluate the clinical outcomes of chlorhexidine when placed subgingivally with dental floss versus normal flossing alone. Thirty-seven dental students with gingivitis participated in this split mouth design study. Following the initial evaluation of all the indices, their quadrants were treated by chlorhexidine impregnated floss in one side and dental floss in another side randomly. Chlorhexidine impregnated floss showed a greater reduction in both gingival and plaque indices after 3 and 6 weeks, respectively.

RIASSUNTO
Lo scopo di questo studio clinico era la valutazione degli esiti clinici della clorexidina posizionata nella regione subgengivale con il filo interdentale rispetto all’uso del filo normale. Trentasette studenti di medicina dentale, affetti da gengivite, hanno partecipato a questo studio, condotto usando un design a “splint mouth”. In seguito alla valutazione iniziale di tutti gli indici, i quadranti dei partecipanti sono stati trattati, in modo randomizzato, da un alto con il filo impregnato di clorexidina, dall’altro con il filo normale. Il filo impregnato ha mostrato una maggiore riduzione sia negli indici gengivali che in quelli della placca da tre a sei settimane, rispettivamente.

INTRODUCTION
Plaque has been considered the main etiological factor to induce gingivitis for a long time (1) and the removal of supra and sub gingival plaque control is the major approaches in preventing and treatment of gingivitis. However, conventional therapy is not always
successful, so, various antimicrobial agents have been suggested as an adjunct to enhance the efficacy of mechanical plaque control\(^2\). Scaling and root planning of the teeth are also expensive, time consuming and exacting procedures. These shortcomings have convinced clinicians to use chemical agents as an adjunct to periodontal treatments. Chlorhexidine (CHX) is the most thoroughly investigated anti-plaque material that has high intra-oral substantivity and bactericidal activity\(^1, 2\). Clinical studies have demonstrated significant reductions in plaque and gingivitis rate in periodontal patients. However, reversible local side effects such as staining of teeth, impaired taste sensation, increased formation of supra gingival calculus and irritation of mucous membrane has been associated with prolonged use of CHX\(^3\). Therefore application of antimicrobial agents directly to the inter proximal site in high amount levels for sufficient period with minimal side effects seems to be a successful strategy of the treatment\(^4\). CHX has been shown to have antimicrobial efficacy up to 11 weeks when delivered through a sustained-release device for 9 days and its clinical efficacy was evident for up to 2 years\(^5\).

The purpose of this study was to evaluate the clinical outcomes of CHX impregnated floss versus normal flossing. Results could be useful to provide a more significant improvement of the clinical outcomes with CHX impregnated floss than dental flossing alone.

**MATERIAL AND METHODS**

A total of 50 female dental students (aged 18 to 24 years) from dental faculty, Qazvin University of Medical Sciences, examined for this blind, randomized, split mouth (intra, individual, cross arch) clinical trial.

Each person entered the study if she had gingivitis and in at least 2 sites with probing depth of 2mm in each quadrant which bled on probing. Individuals with systemic diseases, smoking habits, pregnancy, antibiotic therapy or periodontal therapy during the last 6 months were excluded. All patients signed consent form. Following the initial measurements of PI (O’Leary and Turesky & Gilmore), GI (Loe & Silness) and BI (Ainamo & Bay)\(^6\), they received SRP if needed, Prophylaxis and oral hygiene instruction. They were asked not to brush, floss or rinse for 2 days to allow for plaque development. Then their quadrants were treated by CHX impregnated floss in one side and normal floss in another side by selecting one card of 50 similar cards (25 labeled: 1, 25 labeled: 2) randomly. Each subject issued within two box labeled A (5cc CHX solution) or B (5cc normal saline) with a role of floss and a lid hole to minimize contamination. The persons had been selected “1” used “A” floss on right side (case) and “B” on left side and vice versa.

The spectrophotometry method was used as a technique to determine the best type of the floss with the most leakage of CHX in the pocket.

The absorbance of different types of current flosses\(^1\) in dry and humid form in 225 and

\(^1\) Marian dental floss: without wax and fluoride, 50 meters, Marjan factory, Made in Iran.
Mina dental floss: mint waxed floss with fluoride, 50 meter, Mina factory, Made in Iran.
Oral B: Tephlon floss, 25 meters, Oral B laboratory, Gillette group, Made in Ireland.
250 nanometer \(^{(7)}\) (CHX's absorbance pick) respectively in different randomized times (3, 6, 9 hours) were determined. Ultimately, humid form of Marjan floss that was impregnated more than 24 hours in CHX was shown the best one to release CHX over the time.

At last, all subjects were given the same type of dentifrice and tooth brush and received written flossing instructions (once daily use, each surface with a new section of the floss), moving 3 times in cervico-occlusal direction, from mesial of second molar to distal of canine with a new section of floss). They were asked not to eat or drink until one hour after flossing. The instructions were repeated at the end of the third week.

All measurements for each person were repeated at 3 and 6 weeks and by a trained dental student who was unaware of the treatment carried out for each subject.

**RESULTS**

Thirty seven subjects completed the study and 8 patients were excluded due to orthodontic therapy, medical treatments, loss of follow up (failure to return for recording on appointed days) and insufficient gingival inflammation. There were no adverse events in each case.

Both methods presented a reduction in percentage of Ainamo & Bay bleeding index (BI) \(^{(13)}\) but CHX impregnated floss had a greater improvement in BI after 3, 6 weeks (from 47.2 percent at baseline to 29 percent after 3 and 22.4 percent after 6 weeks) as compared to dental floss alone (from 45.4 percent at baseline to 44.8 percent after 3 and 43.8 percent after 6 weeks). The mean changes in plaque index (PI) and gingival index (GI) are shown in Table 1.

Both methods presented significant improvements after 3 & 6 weeks, but CHX impregnated floss showed a significantly greater reduction in PI after 3 weeks (from 1.99±0.00 to 1.2±0.4) versus dental floss alone (1.99±0.00 to 1.44±0.4, \(P<0.05\), Fig. 1) and GI after 6 weeks (from 2.3±0.3 to 1.7±0.7) versus dental floss alone (2.4±0.45 to 2.03±0.6, \(P<0.05\), Fig. 2).

**Table 1:** Mean scores and standard deviations for plaque indices at baseline, 3 & 6 weeks

<table>
<thead>
<tr>
<th>Index/Group</th>
<th>Baseline mean ± SD</th>
<th>3 weeks mean ± SD</th>
<th>6 weeks mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plaque Index</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHX + Floss</td>
<td>2.3±0.3</td>
<td>1.5±0.7∗</td>
<td>1.7±0.7∗</td>
</tr>
<tr>
<td>Floss</td>
<td>2.4±0.45</td>
<td>1.7±0.65∗</td>
<td>2.03±0.6∗</td>
</tr>
<tr>
<td><strong>Gingival Index</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHX + Floss</td>
<td>1.99±0.00</td>
<td>1.25±0.4∗</td>
<td>1.2±0.4∗</td>
</tr>
<tr>
<td>Floss</td>
<td>1.99±0.00</td>
<td>1.44±0.4∗</td>
<td>1.5±0.35∗</td>
</tr>
</tbody>
</table>

* Statistically significances \((P<0.05)\) from baseline to 3w and baseline to 6w
DISCUSSION
The results of this study showed that the CHX impregnated dental floss provide a significantly greater improvement in PI (after 6 weeks) and GI (after 3 weeks) as compared to dental floss alone. This indicates the additive effect of CHX as a chemotherapeutic agent beyond that obtained by mechanical therapy alone, especially these effects are more evident when it is delivered locally.

The results of this study concur with Mozeh study which the same CHX impregnated floss provides a significantly greater reduction in BI as comparison to dental floss alone \(^8\). However, in other studies with different methodology (27 subjects with probing depth of 3-4\(^\text{mm}\)) PHP-M was used as a plaque index and showed a significant reduction of PI, when CHX placed sublingually with dental floss versus CHX mouth rinse.

The length of the time that pocket is exposed to the drug is probably the most critical factor to determine the efficacy of the treatment. The sustained releasing of CHX has

* Statistically significant deference between 2 methods

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**Fig. 1.** PI score at baseline, 3 & 6 weeks in case & control sides

* Statistically significant deference between 2 methods

**Fig. 2.** GI score at baseline, 3 & 6 weeks in case & control sides

* Statistically significant deference between 2 methods
showed a short-time antibacterial effect, however, releasing of CHX for 6 to 9 days has
given long-lasting clinical results.
Since the antiplaque activity of CHX is dose dependent, and the pocket exposure time
to CHX may be short in this study, Spectrophotometry was used as a typical first
screening method to determine the best floss with the best leakage of CHX to increase
the CHX concentration(9). There was attempted by strict adherence to methodology, for
example intensive training, proper flossing instruction and supervision together with
critical components to improve duration of the study.
There were no significant differences in the reduction of GI after 3 weeks and PI after
6 weeks between two groups. In addition, a significant increasing in PI was found in
control group after 6 weeks.
These can be due to behavioral changes. It has been shown that the flossing effective-
ness decreases considerably in the absence of frequent reinforcement and instruction
and the motivation of flossing decreases since the last dental visit (10). So, reinforce-
ment of oral hygiene instruction was provided at the end of 3 weeks. Moreover, the split
mouth design of the study enabled us to compare the effect of mechanical debride-
ments with chemical treatment and also reduced the effect of confounding factors such
as the probable reinfection occurred from the no treated areas and tooth paste base for-
mulation.
The present study concluded that the CHX impregnated floss was more effective to
improve clinical parameters as compared to conventional dental floss, also had no side
effects, of CHX rinsing.
More researches are, however, needed to verify the results of this study to determine the
incremental effects of using CHX impregnated dental floss.

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