GUM® SOFT-PICKS® PRO versus GUM® SOFT-PICKS® ADVANCED – a comparison of two interdental picks *in vitro*

Ann-Kristin Haerdter[1] and Christian Graetz[1]

[1]Clinic of Conservative Dentistry and Periodontology, University of Kiel, Arnold-Heller-Str. 3, Haus B, 24105 Kiel, Germany

Introduction:

There are numerous aids, such as dental floss, interdental brushes or dental sticks, which are available for mechanical interdental hygiene. In terms of cleaning effectiveness and adaptation to the interdental area, conventional interdental brushes in different sizes (ISO code) show the best cleaning results and are still considered the gold standard until today [1]. They consist of nylon bristles arranged in a circular pattern around a metal core. However, many patients find interdental brushes difficult to use due to their cumbersome handling, discomfort, frequent bending, or increased potential for trauma, and therefore prefer to floss, which, however, has been shown to provide only marginal plaque reduction. Dental floss cannot ideally adapt to the concavity of a tooth's interdental area and additionally, like interdental brushes, it is complicated to use for many patients. A new aid, the interdental rubber pick, is intended to solve these problems of interdental hygiene. Unlike conventional interdental brushes, rubber picks do not require a metal core and are easier to use and were preferred [2]. However, based on the current literature, the reduction of gingivitis and plaque is lower compared to the conventional brushes [2].

Therefore, the company SUNSTAR developed a new generation of rubber picks (SOFT-PICKS® PRO, SUNSTAR Suisse S.A., Etoy, Switzerland) that clearly showed increased cleaning efficacy when directly compared to their current rubber pick standard (SOFT-PICKS® ADVANCED, SUNSTAR Suisse S.A., Etoy, Switzerland) in an internal test setting (internal *in vitro* efficacy testing, SUNSTAR/Interbros).

Although the testing equipment used was developed for this sort of interdental aid testing, the company aimed to challenge their internal measures to gain final proof of the potential superiority of the newly developed picks. To do so, the cleaning efficacy of the two rubber picks was evaluated once more by using a well described testing equipment [3] for interdental cleaning aids. The equipment as well as an optimized testing method were developed at the university of Kiel and present an appreciated tool for testing all sorts of interdental aids - from rubber picks to interdental brushes [3,4,5].

Hypothesis:

The higher number and increased length of flexible bristles of the new rubber pick variant SOFT-PICKS® PRO account for an improved cleaning efficacy due to an overall better adaptability in the interdental space.

Aim:

Comparing the cleaning efficacy of two rubber picks (SOFT-PICKS® ADVANCED vs. SOFT-PICKS® PRO, Fig. 1) should

a) indicate the reliability of the internal measurements done by SUNSTAR/Interbros
b) allow to gain final proof on the potential superiority of the new development.

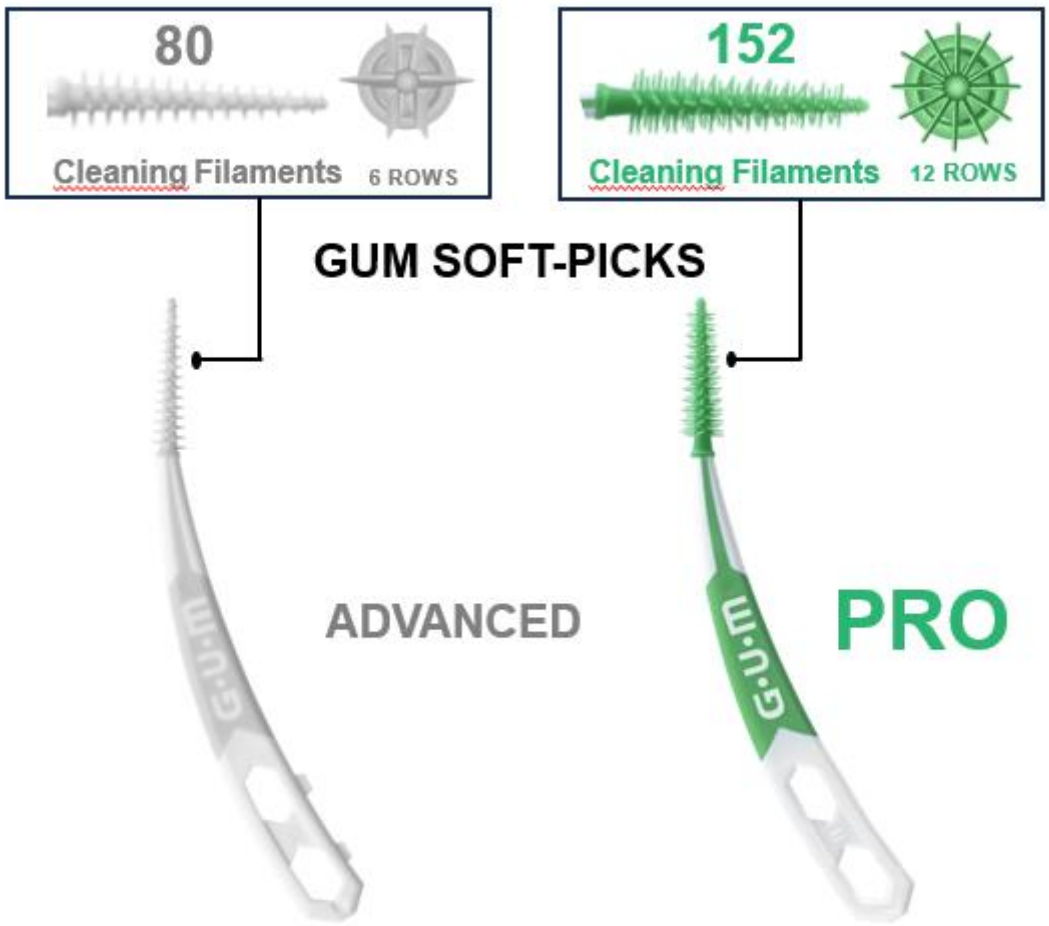

Figure 1: Illustration of the two versions of the tested cleaning devices in large size. ©SUNSTAR

Methods:

In this in *vitro study*, all sizes (small, medium, and large) of the currently available rubber picks SOFT-PICKS® ADVANCED as well as the improved design of the Soft Picks (= SOFT-PICKS® PRO) were tested (Fig. 1). All picks were used size-fitted for isosceles triangles, meaning the S-types were used for interdental area (IDR) sizes corresponding to ISO 2 and ISO 3, the M-types were used for IDR sizes corresponding to ISO 3 and ISO 4 and the L-types were used for ISO 4, ISO 5, and ISO 6.

The method was performed as described previously in detail [3,4,5] and an overview of the experimental setting is shown in Figure 2. In brief, 3D printed replicas of human teeth were created by a computer software (Autodesk Fusion 360, Autodesk Direct Limited, Hampshire, United Kingdom) which were printed by a 3D printer (Form 2, Formlabs Sommerville, MA, USA) in a stereolithography way by using liquid photopolymer resin (White Resin V04 (RS-F2-GPWH-04), Formlabs, Sommerville, MA, USA).

To simulate the interdental cleaning process, the replicas were fixed pairwise in a socket with an embedded load cell (KD34s, ME-Meßsysteme GmbH Hennigsdorf, Germany; measuring range: ±500 mN with precision class of 0.1%). This allowed a continuous measuring of the applied forces during ten cleaning cycles and an automatic documentation in a table (Microsoft Excel 2016, Microsoft Corporation, Redmond, WA, USA), as well as the removal and replacement of the adjacent teeth surfaces in a reproducible manner. Due to the background noise of the load cell between two cleaning cycles, only data>0.09N were included. Subsequently, the interdental area replicas were stained by one investigator with Occlu Spray Plus (Hager & Werke, Duisburg, Germany). A standardized powder thickness (mean±SD: 20±5 µm) was ensured by a standardized procedure and appropriate time protocol. The baseline surface was digitally photographed (Canon EOS 400D Digital, Uxbridge, United Kingdom) and documented. Afterwards, a mechanical device, which converts rotation into a horizontal motion, moved the interdental cleaning aids with a controlled speed ten times (10×for- and back-ward) into the artificial interdental area. After the test, all artificial interdental area replicas were again photographed in order to subsequently perform an evaluation of ECE (= experimental cleaning efficacy) by digital image subtraction (Image J, NIH, Bethesda, USA). ECE was determined as the difference of simulated biofilm before and after cleaning the interdental area in percent.

Statistical analysis:

For the sample size, we adopted the sample size of n=25 per group determined by a power calculation in our previously published in *vitro* study [4]. The statistical analysis was done with SPSS Statistics (SPSS Statistics 24, IBM, Chicago, IL, USA). We tested all data for normal distribution with the Kolmogorov–Smirnov/Lilliefors test and found that there was no normal distribution for all data ($p < 0.001$).

We compared the mean values of ECE of all different test products, product sizes as well as the interdental gap sizes and morphologies. Subsequently, statistical significance was inquired using the non-parametric Mann-Whitney-U-Test and Kruskal-Wallis-Test. All tests were two-sided, and the statistical significance was assumed when $p \leq 0.05$ and adjusted with the Bonferroni correction ($p = 0.05 / 3 = 0.0167$).

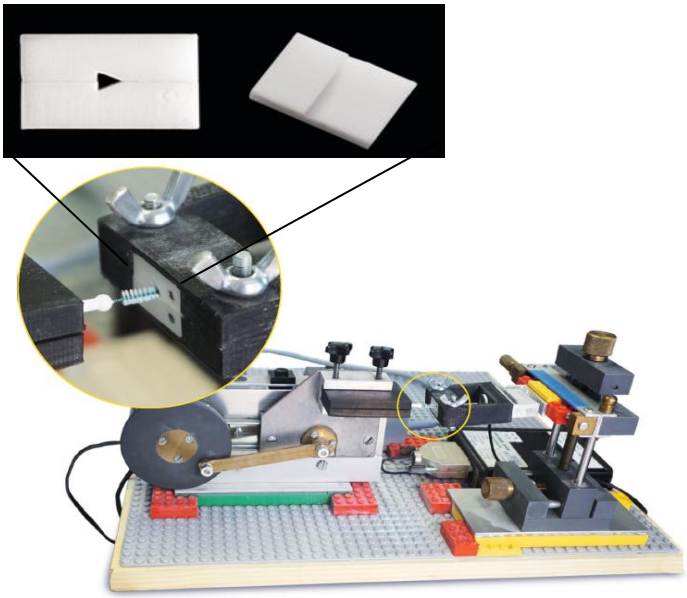

Figure 2: Overview of the mechanical device used in the experiment. Rotation is converted into linear motion, moving the test products into the isosceles interdental areas (depicted in the left upper corner). Picture used is modified from [4].

Results:

Overall, the experimental cleaning efficacy (ECE) was higher for the new product SOFT-PICKS® PRO in direct comparison to the current product SOFT-PICKS® ADVANCED. This applies to all pick sizes used (small: 33% vs. 19%, medium: 40% vs. 25% and large 38% vs. 24%; for all $p<0.001$, see Table 1). The highest mean difference was achieved between the smallest SOFT-PICKS as indicated by 74% improvement of ECE, followed by the regular SOFT-PICKS (60% improvement) and the large SOFT-PICKS (58% improvement).

Size	SOFT-PICKS product	ECE in %	% improvement compared to ADVANCED
Small	**Pro**	32.53±8.01	74% p<0.001
	Advanced	19.36±6.66	
Medium	**Pro**	39.82±6.23	60% p<0.001
	Advanced	25.23±6.45	
Large	**Pro**	38.09 ±13.96	58% p<0.001
	Advanced	24.40±12.28	

Table 1: ECE comparison of SOFT-PICKS® PRO and SOFT-PICKS® ADVANCED. The detailed data tables can be found in the attachments.

Discussion:

By using the established *in vitro* procedure, it could be clearly demonstrated that the new generation of rubber picks SOFT-PICKS® PRO provides a significantly better overall cleaning efficacy compared to the previous standard SOFT-PICKS® ADVANCED. Thus, the superiority of the new head design, that was inspired by an interdental brush, and consists of more (almost doubled) and longer flexible bristles, was confirmed in this study. Overall, the improved design allows for better access and adaptability and thus improved coverage of the interdental areas.

The data are further in line with a previous in-house testing performed by SUNSTAR/Interbros that measured the same interdental picks with a comparable equipment, also using size-fitted isosceles interdental spaces *in vitro*. They could show an overall cleaning efficacy improvement of more than 50%, with the largest differences between the smallest picks (small: +114%: medium: 59%, large: 72%, internal data SUNSTAR/Interbros) over the whole range of sizes, which is in line with the results obtained in the current subgroup investigation, showing an overall improvement of more than 50 %.

This strongly indicates the reliability of the internal method. Nevertheless, it cannot be expected that two individually performed studies result in the exact same numbers since there are many variables influencing the outcome (i.e., different evaluators, slightly different interdental spaces, different analysis tools etc.).

Conclusions:

The data of the current *in vitro* study could clearly prove that the internal measures done at SUNSTAR/Interbros are reliable when using the same setting (comparable ISO sizes for interdental spaces, same morphologies i.e. isosceles triangles). This is relevant for the company, since this enables

them to do reliable initial testings in order to assess their new developments internally, before it is given out to evaluation by external partners.

The new generation SOFT-PICKS PRO performed better and showed at least 50 % increased experimental cleaning efficacy when compared to SOFT-PICKS ADVANCED for all sizes used (S, M, L).

Study limitations:

Although the experimental model is constantly improved to mimic the *in vivo* situation of the oral cavity in the best possible way [6], the experiments remain an *in vitro* study, and can be compared with clinical data only to a limited extent. One example is the straight brushing movements needed for the comparability of the results, which do not occur in this way in a real-life oral hygiene setting.

While in this *in vitro* subgroup analysis only isosceles morphologies have been used, the oral cavity situation is much more complex. Therefore, other shapes should be included as well to exhibit a more representative picture of the oral cavity by including concave and convex shapes as well. These measures were partially done but are not shown in this report because the original data from the internal testing was done with isosceles triangles only.

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