INTRODUCTION

The introduction of nickel-titanium (Ni-Ti) alloys has brought a new era in the specialty of endodontics. Contemporary root canal therapy is almost unimaginable without Ni-Ti instruments. These instruments exhibit superior elastic flexibility and higher resistance to fracture than the stainless steel files.1 Despite numerous innovations in instrument design, manufacture, the sequence of use, etc., instrument separation is still a considerable problem with Ni-Ti instruments.2,3 These files can fracture without any visible warning signs of permanent deformation making their use highly unpredictable.6

Rotary Ni-Ti instruments typically fracture due to cyclic flexural fatigue or torsional failure or both.3 Fracture incidence ranging from 0.39% to 1.83% has been reported for rotary NiTi instruments.7,8 Several factors are implicated for the same, vis-à-vis, manufacture, instrument design, instrument use dynamics, the technique of instrumentation, number of uses, cleaning and sterilization processes, etc.9 However, the current literature presents inconsistent findings regarding the effect of NaOCl and sterilization on the flexural strength of NiTi instruments.10-12

In the year 2013, ProTaper Gold (PTG) rotary NiTi files were introduced with a proprietary gold heat treatment, which could affect their corrosion resistance. These instruments are reported to have higher cyclic fatigue resistance than the traditional alloy of ProTaper Universal (PTU) NiTi instruments.13 The present study was aimed to assess the impact of sodium hypochlorite immersion and autoclave sterilization on the fracture resistance of PTG rotary instruments.

METHODS

An observational study, was conducted in the Department of Conservative Dentistry and Endodontics, in collaboration with the Department of Prosthodontics, KIST Medical College and Teaching Hospital (KIST MCTH), Lalitpur, Nepal. Ethical clearance was obtained from the institutional review committee (IRC76-77-08-no07) of KIST MCTH. The study was performed from 1st January 2020 to 30th March 2020.

The sample size (N) was calculated using the formula

\[ N = \frac{2(Z_a + Z_b)^2 \sigma^2}{d^2} \]

Test groups were created by immersion and autoclave sterilization. The files were divided into four groups (N=10) with Control (no immersion/ sterilization), one cycle each of NaOCl immersion and sterilization, five cycles each of NaOCl immersion and sterilization, and ten cycles each of NaOCl immersion and sterilization. The instruments were immersed in NaOCl for five minutes in all test groups, and were subjected to cyclic fatigue testing in artificial canals with 25 mm length, 60° curvature, and radius of curvature 4 mm. The number of cycles to fracture (NCF) was calculated for each instrument. The obtained data were subjected to statistical analysis (p-value < 0.05). The Kolmogorov Smirnov test was performed to examine the normality distribution of the NCF values. One-way ANOVA test was used to compare the mean NCF values for the different groups.

RESULTS

Sodium hypochlorite immersion and autoclave sterilization exhibited no significant difference in NCF values between the control and test groups (p-value > 0.05). All the experimental groups demonstrated comparable NCF values and significant difference was not found between the groups (p-value > 0.05).

CONCLUSIONS

Repeated cycles of sodium hypochlorite immersion and autoclave sterilization do not seem to influence ProTaper Gold instruments’ fracture resistance.
The value of ‘σ’ was derived using the largest standard deviation among different groups, while the value of ‘d’ was computed using the mean difference of NCF values. Using the above equation, the value of 10.035 was obtained and rounded off to the nearest whole number, i.e., 10.

Forty new ProTaper Gold (Dentsply Maillefer, Switzerland) F2 instruments with tip size 25, length 25 mm were randomly divided into one control and three test groups (N=10) as follows:

Group I (Control): No NaOCl immersion or sterilization.

Group II: One cycle of five minutes dynamic immersion in 3% NaOCl and one sterilization cycle.

Group III: Five cycles of five minutes dynamic immersion in 3% NaOCl and five sterilization cycles.

Group IV: Ten cycles of five minutes dynamic immersion in 3% NaOCl and ten sterilization cycles.

The PTG instruments were freely rotated in a 3% NaOCl solution (PRIME Dental Products Pvt. Ltd., MH, India) at a speed of 300 rpm and torque 3.0 N.cm, to accomplish dynamic immersion. The study used an endodontic rotary hand-piece, Endomate DT (NSK, Nakanishi Inc., Japan) for this purpose. Each cycle of NaOCl treatment was followed by a sterilization cycle of 15 minutes duration at 121°C temperature and 15 psi pressure using a steam autoclave (Narula Udyog India Pvt. Ltd.).

The cyclic fatigue testing device (figure 1) was designed according to recommendations from previous researchers. Artificial canals with 25 mm length, 60° curvature, and radius of curvature 4 mm were milled in a stainless-steel block using a computer numerical cutting machine. The canals’ width and depth corresponded to the dimensions of PTG F2 instruments and were covered with toughened glass to limit instrument movement during testing. The steel block was screwed onto a steel table. The canals were filled with WD-40 lubricant (WD-40 Company, San Diego, CA 92110, USA) to minimize the friction and heat during testing. All of the instruments were insert-

The obtained data were subjected to statistical analysis using the IBM SPSS software (IBM, Chicago, IL) for Windows, version 21.0. The level of significance was fixed at p < .05. The Kolmogorov Smirnov test was performed to examine the normality distribution of the NCF values. One way ANOVA test was used to compare the mean NCF values between and within different groups.

**RESULTS**

The mean and standard deviation of NCF values of all the experimental groups is represented in the table (Table 1). Group III (5 cycles of NaOCl immersion and sterilization each) and group IV (10 cycles of NaOCl immersion and sterilization each) demonstrated the maximum and minimum values of NCF, respectively. The one way ANOVA test showed no significant difference amongst the experimental groups. The **p-value** was found to be 0.931 (> .05) for the comparison between control and test groups. When the NCF values were compared between the groups (Table 2), the **p-value** came out to be 0.894 (> .05)

**DISCUSSION**

Rotary NiTi instruments are quite popular amongst endodontists nowadays as they save time, are easier to use, and are
likely to improve the success rate of root canal therapy than hand instruments.\textsuperscript{14} However, their propensity to fracture without any visible deformation makes their use somewhat precarious. Strindberg reported a 19% lower healing rate when a fractured instrument was retained in the canal.\textsuperscript{15} Current literature suggests that retained-fractured instruments do not affect the prognosis of cases without periapical lesion, but the healing rate is significantly lower for preoperative periapical lesion.\textsuperscript{9,18}

Innovations in endodontic instruments are shaping the future of endodontic practice. ProTaper Gold rotary NiTi instruments are a popular set of contemporary endodontic files which undergo a proprietary gold heat treatment. According to the manufacturer, this treatment makes these instruments more fatigue resistant than ProTaper Universal files. The results of our study suggest that multiple NaOCl immersion and autoclave sterilization cycles do not have a significant effect on the fracture resistance of ProTaper Gold NiTi files. Our study results concur with the previous findings concerning the impact of NaOCl immersion and autoclave sterilization on NiTi instruments.\textsuperscript{19,20}

The fatigue/fracture resistance of the PTG instruments was not altered by sodium hypochlorite immersion in our study, enunciating the findings by earlier papers supporting the formation of a stable oxide surface layer mainly composed of TiO\textsubscript{2}.\textsuperscript{11,12,22} The presence of this layer could protect the PTG instruments from corrosion due to NaOCl. The thermomechanical treatment of NiTi alloys significantly affects their transformation behaviour which in turn has an impact on the mechanical properties of NiTi instruments.\textsuperscript{23} The martensitic transformation of the Ni-Ti alloy can either be a 1-stage austenite (A) to martensite (M) transformation or a 2-stage (A-R phase-M) transformation owing to the thermomechanical processing.\textsuperscript{24} The PTG files are reported to have a unique two-phase transformation due to the enhanced thermomechanical treatment. DSC (differential scanning calorimetry) analysis of ProTaper Gold revealed approximately 50 °C for austenite finish temperature, which suggests these instruments mainly possess R-phase or martensitic phase under clinical conditions.\textsuperscript{25} Figueiredo et al.\textsuperscript{26} demonstrated NCF values of approximately 100 times greater in martensitic NiTi wires than austenitic NiTi wire. So, the improved flexibility and fatigue resistance of PTG files compared to PTU files is attributable to the martensitic state, which in turn, makes them more suitable for preparing abruptly curved canals.\textsuperscript{25,26}

Additionally, Plotino G et al.\textsuperscript{14} revealed that repeated cycles of sterilization did not affect the mechanical properties of NiTi instruments except for K3 XF files, which demonstrated improved cyclic fatigue resistance. Ozyurek T et al.\textsuperscript{28} observed a significantly higher fatigue resistance after sterilization in ProTaper Next and ProTaper Gold instruments. The difference in the findings of these studies and our study may be explained by variations in operator ability, experience, varying experimental conditions and equipment used. The angle and radius of curvature, the major determinants affecting cyclic fatigue also differ from our research. Hence, within the limitations of the current study, it can be assumed that the fracture of ProTaper Gold instruments in the clinical scenario is attributable to factors other than sterilization and NaOCl irrigation, presumably, the cyclic fatigue pertaining to the curvature, length, and width of the canal. To attain more conclusive results, more researchers need to conduct studies assessing the fatigue behaviour of various NiTi instruments.

CONCLUSION

This study concludes that sodium hypochlorite immersion and sterilization did not affect the fracture resistance of the PTG NiTi rotary instruments. The ProTaper Gold rotary NiTi instruments can be safely sterilized and used with sodium hypochlorite irrigant for root canal preparation. However, the manufacturer’s instructions must be followed religiously.

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