Inferior load generated by pre-loaded vs manually-loaded haemorrhoid banding devices: the effect of 'creep relaxation'

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Abstract

Purpose

The efficacy of rubber band ligation of haemorrhoids relies on the load generated on haemorrhoidal tissue by bands as they return to their preformed shape after being deployed. ‘Preloaded’ haemorrhoid banding devices are widely available, but the effect of the resultant prolonged stretch on bands while stored in this manner has never been examined by comparing these to manually-loaded devices, which are stretch immediately prior to being deployed. A difference could have clinical relevance, potentially resulting in a higher rate of clinical failure. The present study aimed to investigate any difference in load generated by preloaded vs manually loaded devices.

Methodology

A preloaded and a manually-loaded device were selected for comparison. Each type was measured on a testing rig. The device type, load generated by each band and the time to expiry were recorded.

Results

137 haemorrhoid bands were tested: 66 preloaded and 71 manually-loaded. There was a statistically significant overall reduction in load generated by preloaded versus manually-loaded devices (284.0 vs 272.1g, mean difference -11.9g, 95%CI -17.5 to -6.3g, p = 0.0001).

Adjusted for time, the load generated by preloaded bands fell 3.7g (95%CI 2.7 to 4.8, $p < 0.001$) grams for each month closer to the expiry date.

Conclusions

The load generated by haemorrhoid bands from preloaded devices is lower and deteriorates significantly towards their expiry date compared with bands from manually-loaded devices. This is mostly likely due to their storage in a stretched state. This should be considered by clinicians when using haemorrhoid banding devices.

Main Text

Background

Rubber band ligation is a well-established and effective treatment for symptomatic haemorrhoids, which is usually performed by direct rigid anoscopy in an office-based or endoscopy unit setting. Devices to perform haemorrhoidal banding vary in their design (1). Original devices, described by Blaisdell (2) and later refined by others including Barron (3), manually grasped haemorrhoidal tissue during ligation. However, more recently developed devices utilize suction to stabilize haemorrhoidal tissue during ligation, which allows one-handed application of ligature bands, which are usually composed of silicone rubber. There are many suction-assisted devices currently in use to perform this procedure, which can be broadly categorized into ‘preloaded’ or ‘manually-loaded’ based upon the way the ligature band is loaded onto the banding device. Preloaded devices are manufactured with up to six ligature bands loaded onto the device during manufacture (and as such, bands are stored in a state of stretch), whereas manual devices require unstretched ligature bands to be loaded at the time of the procedure (thus stored in an unstretched state).

The authors have anecdotal experience of visible deformation of ligature bands when using preloaded devices: where ligature bands deployed ex vivo from devices which were beyond their recommended expiry date were observed to remain stretched and deformed. It was hypothesized that there may be a significant difference between preloaded devices and manually loaded devices (even prior to the expiry date of the device), and that this difference may become more significant as devices approached their expiry date. This could have clinical relevance, potentially resulting in a higher rate of clinical failure.

Methods

A testing rig was devised to measure uniaxial load generated by bands once deployed from each device (figures 1 and 2), measured using a scale (Model PCB 2500-2, KERN + SOHN, Balingen, Germany). For comparison, two suction-assisted band ligation devices commonly used to perform haemorrhoidal banding by direct rigid anoscopy were selected (figure 3): one preloaded (Haemoband^{TM}, Haemoband Surgical, Belfast, Ireland) and one manual (Killroid^{TM}, Wellspect, Mölndal, Sweden). A materials engineer was consulted to ensure validity of the testing rig in accordance with testing standards of elastomers (4).

A pilot study, five devices from each type, found mean load measurements of 269 (SD 14.4) grams and 252 (SD 14.0) grams for manual and pre-loaded devices respectively. A minimum sample size of 46 per group was calculated, based upon an unpaired t-test using a SD of 14.5 grams with power set at 0.9, two-sided alpha at 0.05 and a load difference greater than 10 grams.

For each band, load generated and time to expiry was recorded. When each band was deployed, a degree of ‘drift’ in load measurement was observed; measurements were thus recorded once equilibrium had been reached for 5 seconds, or at 20 seconds after deployment if no equilibrium was reached. Bands were lubricated with water to minimize this drift, and to more closely simulate in vivo deployment. Calibration of the testing rig using a standard weight (2kg) was performed after intervals of 20 bands. All devices were within the expiry date range recommended by the manufacturer.

Data were summarized as mean (SD), minimum and maximum according to distribution. Ordinary least squares regression was used to test associations between load generated and both main effects (device type and time to expiry) and an interaction between them. Regression diagnostics were performed. Model predictions at four times to expiry, within the range of the data, were also generated. All hypothesis testing was two-sided with the significance level set at 0.05. Analysis was performed using Stata v15 statistical software (StataCorp. 2017.Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC).

Results

A total of 137 ligature bands were tested: 66 were preloaded, 71 were manually-loaded. Load developed both overall and by time to expiry are presented in table 1. The mean time to expiry was not different between devices 0.6 (95%CI -1.3 to 2.5, p = 0.55) grams. There was an overall difference in load generated comparing manual and preloaded devices (284.0 vs 272.1g, mean difference -11.9g, 95%CI -17.5 to -6.3g, $p = 0.0001$).

The results of the regression model are presented in table 2. Regression diagnostics were satisfactory. There is evidence of a strong interaction between device type and months to expiry. Adjusted for time, the load generated by preloaded bands fell 3.7g (95%CI 2.7 to 4.8, $p < 0.001$) grams for each month closer to the expiry date (table 2). Figure 4 presents raw data, mean values for each device for months to expiry and model predictions. Table 3 presents predicted loads for both devices at four separate expiry times.

Discussion

Haemorrhoidal banding relies on the mechanical property of a band to return to its unstretched state after deployment, which constricts haemorrhoidal tissue to induce necrosis of prolapsing tissue, with subsequent fibrous fixation of the mucosa to the rectal wall (5). Silicone rubber used in the production of haemorrhoid bands is an example of an elastomer. Its inert nature makes it safe for many medical applications. All elastomers undergo alterations when placed under constant stress, such as prolonged stretch (6). In materials literature, 'elastic recovery' relates to the tendency of a material to return to its preformed shape once a strain (such as stretch) is removed. When placed under constant stretch for a prolonged period, the tendency of an elastomer to return to its preformed shape is reduced (an effect termed 'creep relaxation'). It is well established in materials literature that creep relaxation is time-dependent (6), but the duration at which creep relaxation may become significant has, to our knowledge, never been examined in the published literature as it relates to haemorrhoid ligature bands.

The results of the present study show a statistically significant reduction in load generated by ligature bands which have been stored in a stretched state (i.e. preloaded devices), and that effect is exaggerated as time elapses from the date of manufacturing. At 16 months to expiry, the observed and predicted load generated by bands is equivalent (281 vs 284g) but prediction curves diverge from this point as the date of expiry approaches. A 12.3% reduction is observed in load generated by preloaded devices from 16 months to 4 months to expiry. At 4 months to expiry, predicted load generated is 14.4% lower in preloaded devices than manually loaded devices.

The observed difference between preloaded and manually-loaded devices in the present study could have clinical implications. Reported failure and recurrence rates in the literature are broad, reflecting the inconsistent definition of recurrence, and differences in the length of follow up and number of banding episodes performed(7). Rates of 12-29.5% have been reported in large case series (8-11), but up to 49% in a contemporary RCT evaluating novel treatment of haemorrhoids, where 32% of patients required repeat procedures (12). While clinical success is achieved in the majority of patients, many patients require multiple banding episodes to achieve this. While this may be attributed to the inability to band all haemorrhoidal tissue at the index procedure, this does not explain all clinical failures or early recurrences. Many patients have clinical failure or recurrence despite seemingly adequate haemorrhoidal banding, even when banding is staged, which could conceivably be due to banding device issues.

Other technical considerations do little to influence the decision to use either a preloaded or manually-loaded banding device. All suction-assisting devices are easy to use with one-handed technique, and cause less haemorrhoidal tissue trauma and peri-procedural bleeding compared with manually-grasping devices. Manually loaded devices are readily available in most hospitals, require no alteration of technique, and are equally easy to use in either an office-based on endoscopy unit setting. While manually loading haemorrhoid bands does take additional time, overall disruption is minimal and can be further minimized with the use of an assistant if desired. It is additionally worth noting the difference in shelf life of preloaded vs manually-loaded devices, with implications for cost-effectiveness. The preloaded device used in the present study have a shelf life of 18 months from manufacture, compared with 48 months for manually-loaded devices.

It must be acknowledged that no direct clinical inferences can be made from this mechanical study, but this requires further investigation. The load required to avoid band dislodgment from the internal haemorrhoidal plexus after deployment has not been studied. Clinical studies comparing outcomes in manually-loaded and preloaded devices have yet to be performed.

Conclusion

The load generated by haemorrhoid bands from preloaded devices is lower and deteriorates significantly towards their expiry date compared with bands from manually-loaded devices. This is most likely due to their storage in a stretched state. This should be considered by clinicians when using haemorrhoid banding devices.

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<u>Figure 1: Testing rig design for measurement of load generated by haemorrhoid bands</u>

<u>Figure 2: Testing rig schematic diagram</u>

*Footnote: The 9mm stretch length of bands during testing was chosen to be in accordance with manufacturers specifications for use.

<u>Figure 3: Devices selected for testing: preloaded (Haemoband^{TM}, above) and manually-loaded (Killroid^{TM}, below)</u>

Figure 4. Scatter plot of raw and mean load (grams) by time to expiry (months) along with predicted regression curve for both preloaded and manual banding devices

Table 1. Raw load measurements (overall and by months to expiry)

	Preloaded (n = 66)		Manual (n = 71)	
Time to expiry (months) Range	12.0 (3.99) (3.9-16.0)		12.6 (6.76) (1.0, 23.0)	
Months to expiry	Number	Mean load (grams)	Number	Mean load (grams)
1	-	-	10	291.9 (14.3)
4	8	250.2 (17.4)	-	-
6	-	-	8	290.7 (10.5)
9	14	259.1 (16.4)	-	-
11	8	278.9 (12.2)	24	286.3 (17.1)
13	12	275.2 (12.4)	-	-
16	24	283.1 (13.5)	17	278.6 (10.7)
23	-	-	12	276.1 (13.0)
Overall	66	272.1 (18.5)	77	284.0 (14.8)

Data presented as mean (SD) and (minimum, maximum)

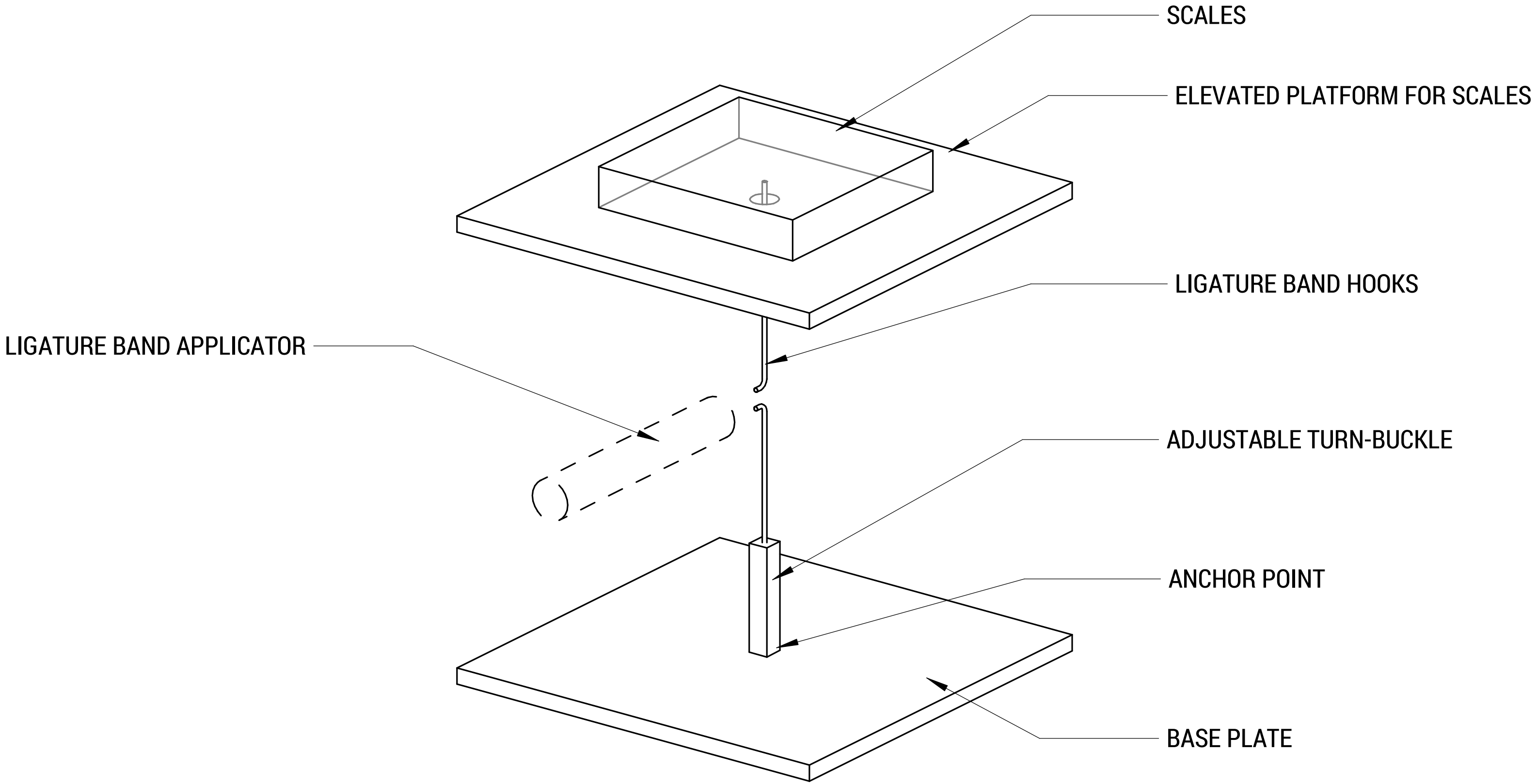
Table 2. Regression model for load generated

Variable	Coefficient	SE	p-value	95%CI
Preloaded	- 57.3	7.17	< 0.001	- 71.6 to - 43.2
Months to expiry	-0.80	0.23	< 0.001	-1.3 to -0.4
Model*months to expiry	3.7	0.53	< 0.001	2.7 to 4.8
constant	294.2	3.38	< 0.001	287.5 to 300.9

F-statistic (3,133 df) = 22.14, $p < 0.001$. $R^2 = 0.38$. Reference category is manually-loaded device.

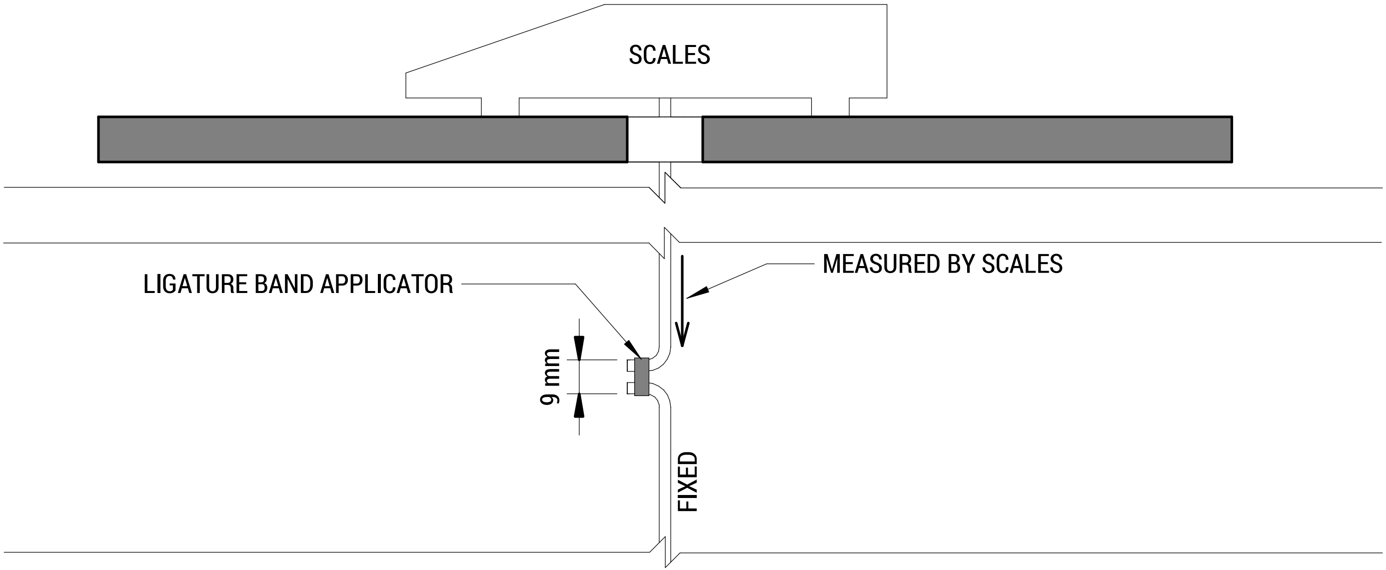
Table 3. Predicted load (grams) for preloaded and automatic devices by time to expiry.

Time to expiry (months)	Load generated and 95% confidence interval (grams)	
	Manual	Automatic
16	281 (278 – 285)	284 (279 – 288)
12	284 (281 – 288)	272 (269 – 276)
8	288 (284 – 292)	260 (255 – 266)
4	291 (286 – 296)	249 (240 – 258)



STRUCTURAL SUPPORTS FOR ELEVATED PLATFORM NOT SHOWN FOR CLARITY

1:5 SCALE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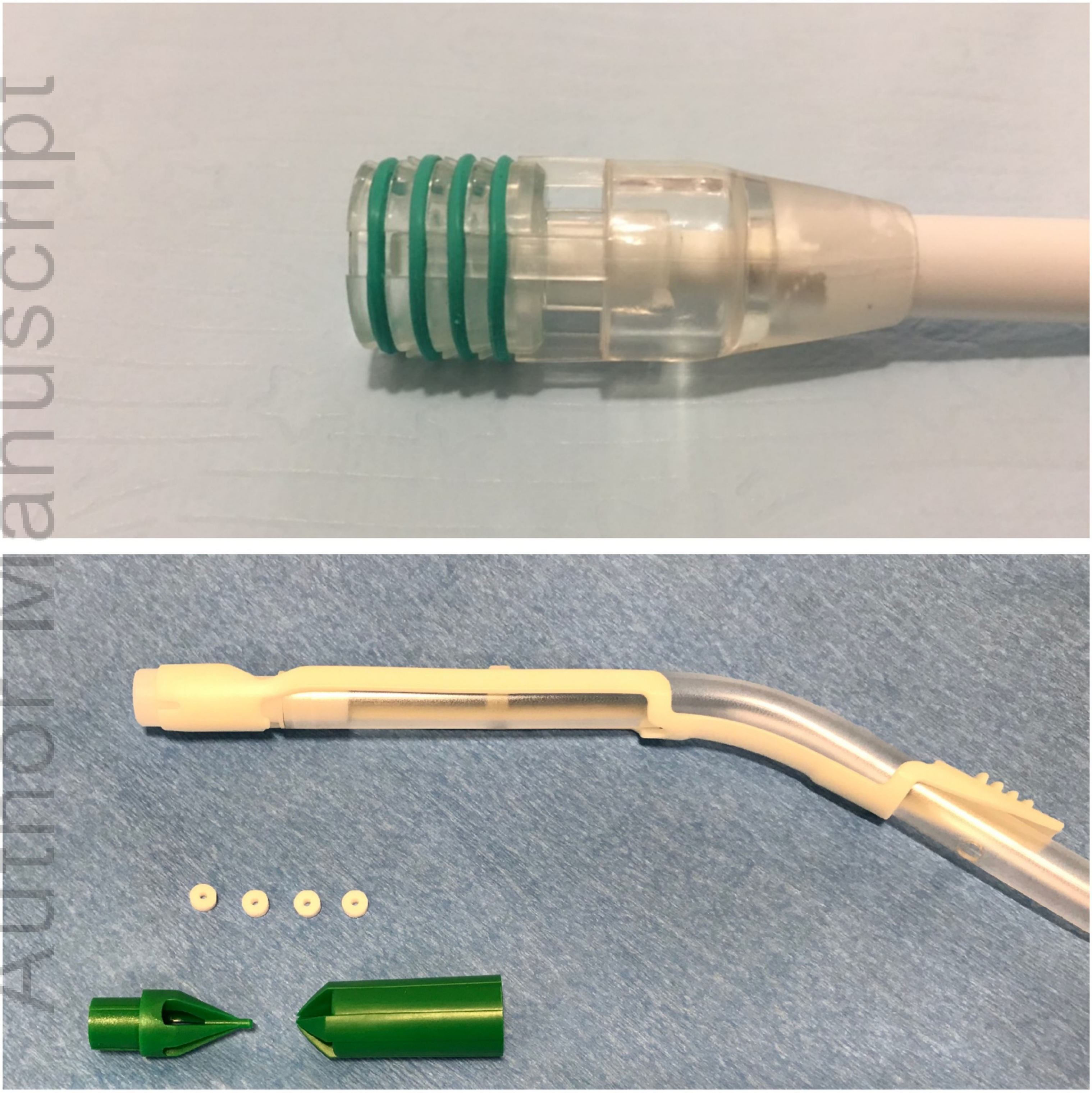

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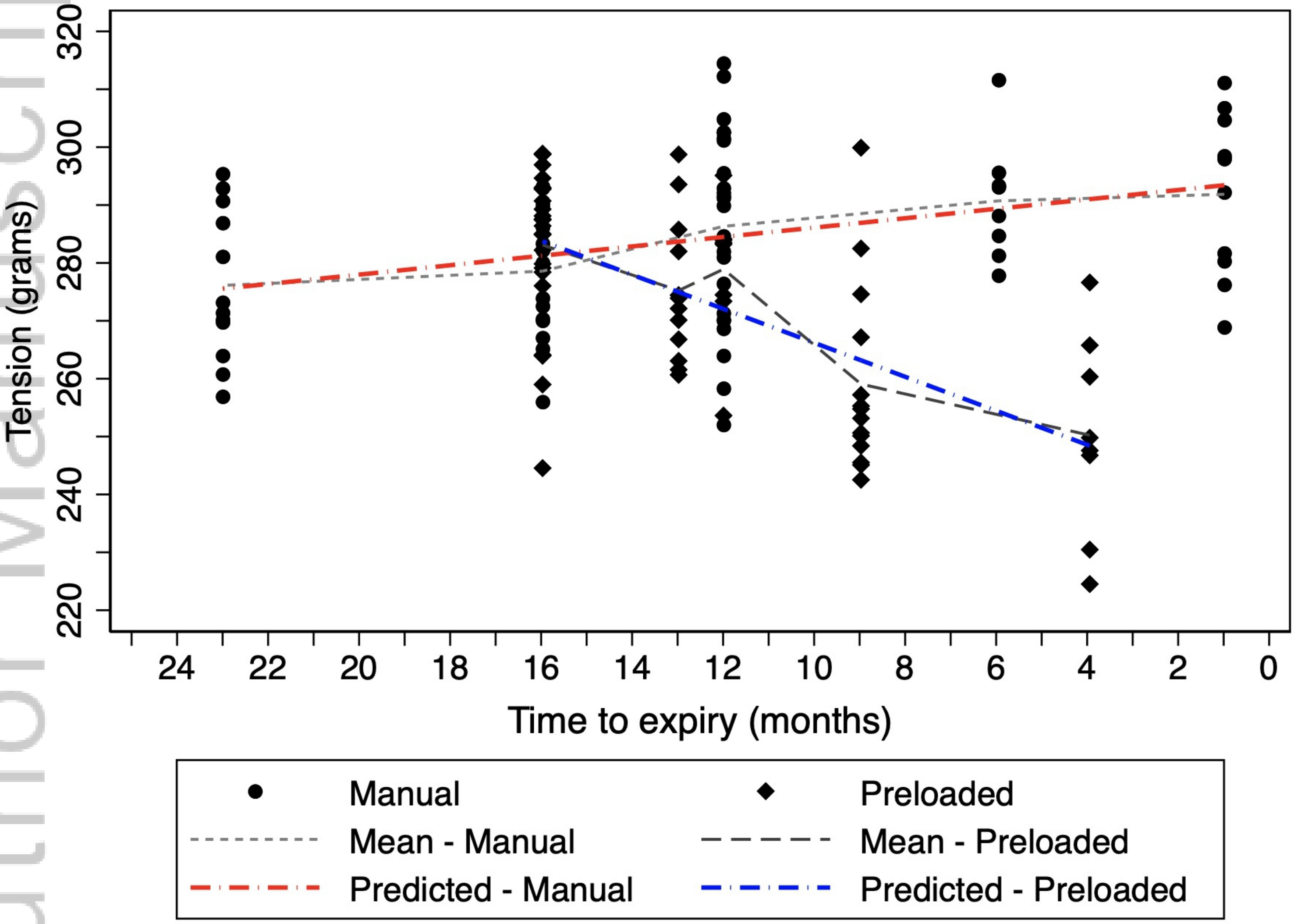

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