COMPARATIVE ASSESSMENT OF INTRANASAL DRESSINGS MADE OF VARIOUS TYPES OF BIOMATERIALS, APPLIED AFTER FUNCTIONAL ENDOSCOPIC SINUS SURGERY

Azad Maou[1], Wirginia Likus[2], Anna Długosz-Karbowska[1], Jan Pilch[1], Jarosław Markowski[1]*

[1] Department of Laryngology,
Faculty of Medical Sciences in Katowice,
Medical University of Silesia in Katowice,
20-24 Francuska Str., 40-027 Katowice, Poland
[2] Department of Anatomy,
Faculty of Health Sciences in Katowice,
Medical University of Silesia in Katowice,
18 Medyków Str., 40-752 Katowice, Poland
*e-mail: jmarkow1@poczta.onet.pl

Abstract

The aim of the study was to make a comparative evaluation of four different types of intranasal dressings made from various types of biomaterials (three original dressings manufactured by various commercial suppliers, and the fourth one, in the form of nasal tamponage by means of a seton in a latex glove finger cot), concerning their efficacy as regards haemostatic action, assessment of postoperative pain, as well as proneness to the occurrence of postoperative adhesions.

All patients who were qualified for the study were operated on in the ENT Department, Medical University of Silesia in Katowice, Poland, due to chronic bilateral inflammation of the para-nasal sinuses, confirmed by computer tomography of the sinuses. A total of 180 patients were qualified for the study. After surgery, 4 different kinds of intranasal haemostatic dressings were applied. The results were analyzed in three categories: effectiveness in the field of haemostatic activity, postoperative pain assessment (Visual Analog Scale, VAS), and assessment of the tendency to develop postoperative adhesions.

Statistical analysis revealed no statistically significant differences between the 4 types of dressings in both haemostatic efficacy (p = 0.97) and the occurrence of postoperative adhesions (p = 0.84). Analysis of the intensity of pain according to the VAS scale indicated that it did not differ between the analyzed groups, both during the application of dressing (mild pain) and on the second day after the operation (medium intensity pain) – p = 0.30 and p = 0.39, respectively.

No advantage has been demonstrated for any of the 4 analysed types of intranasal haemostatic dressings over any other. Their properties turn out to be comparable.

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List of abbreviations:
EPOS – European Position Paper of Rhinosinustis and Nasal Polyps 2020
FESS – Functional endoscopic sinus surgery
NS – Nasal Sponge pack
MP – Merocelpope nasal dressing
RR – RapidRhino nasal dressing
RNP – Routine nasal pack

Introduction

Chronic rhinosinusitis affects between 5 and 15% of the total population in Europe [1]. Para-nasal sinusitis currently ranks as one of the 10 most common diseases. Therefore, chronic sinusitis is a medical and social problem. In today's medicine, functional endoscopic sinus surgery (FESS) is the gold standard for the treatment of chronic sinusitis; FESS is one of the most frequently performed operating procedures by otorhinolaryngologists [1]. In order to prevent the occurrence of complications in the form of postoperative bleeding, pain experienced during the removal of the internal dressing from the nasal cavities, and the development of adhesions in the nasal cavity, many techniques and dressing materials have been introduced; however, no ideal and widely accepted solution has been developed so far [2-13].

Although the use of endoscopes in operational techniques has introduced a new quality, both with regard to treatment results, as well as intraoperative safety, the most common complication of surgery performed in the area of para-nasal sinuses is postoperative bleeding, and pain associated both with the presence of a dressing in the nose itself, as well as pain developing during the procedure of dressing removal, and the development of adhesions [14-23]. For these reasons, more effective and patient-friendly techniques and nasal dressing materials are still being sought [17-24]. New soluble dressings, recently introduced into clinical practice, have been reported to be more comfortable for the patient [25-33].

The aim of the study was to perform a comparative assessment of four different types of intranasal dressings made of different biomaterials, three original dressings from different producers: NasalSponge® (MDD Medical Devices), MerocelPope® (Medtronic), RapidRhino® (Smith & Nephew), and the fourth type of dressing commonly used in the form of nasal tamponade seton soaked with antibiotic and steroid ointment in rubber glove finger made of latex. The comparative analysis of these 4 types of intranasal dressings was carried out from the perspective of their: (i) effectiveness of hemostatic effect, (ii) assessment of the level of postoperative pain during the application of the nasal dressing, (iii) the level of pain experienced during the removal of the intranasal dressing on the 2nd day after surgery, and (iv) assessment of the proneness to develop postoperative adhesions in the nasal cavities, assessed after 4 and 8 weeks after surgery.

Materials and Methods

In this prospective study, all patients qualified for the study were operated on in the Department and Clinic of Laryngology of the Medical University of Silesia in Katowice in the years 2021-2023, due to chronic bilateral sinusitis, confirmed by computer tomography of the sinuses (inclusion criteria). The diagnosis was made in accordance with the currently applicable EPOS 2020 guidelines.

A total of 180 patients were enrolled for the study (92 men and 88 women, average age 51.9 years). All patients who qualified for surgical treatment were operated on with the use of FESS for the first time on both sides, they did not suffer from hypertension or required surgical correction of the nasal septum (both were exclusion criteria). After the surgical procedure, one of the 3 types of above-mentioned commercially available dressings was applied in one side of the nasal cavity, while on the other side, a tamponade with a seton soaked with antibiotic and steroid ointment (due to its anti-inflammatory properties) in a rubber finger made of latex was used. A total of 180 patients after signing an informed consent were enrolled in the study, which means that a total of 360 intranasal dressings were applied (2 dressings in each patient, for both nasal cavities). After the surgical procedure, 4 different types of intranasal dressings were used in the randomized patients, as referred to above. Thus, a total of 60 NasalSponger® dressings, 60 MerocelPope® and 60 RapidRhino® dressings were used for the study, along with 180 tamponades in latex finger. In this way, 4 data groups were distinguished, depending on the type of dressing used after endoscopic surgery. All dressings were removed on the second day after surgery.

The approval of the Bioethical Commission of the Medical University of Silesia in Katowice, No. KNW/0022/KB289/18, was provided to conduct the research.

Characteristics of biomaterials used in dressings

NasalSponge® (MDD Medical Devices) is a haemostatic nasal sponge, sterile, absorbent, meant for single use, composed of PVA (polyvinyl alcohol) expanding sponge with a haemostatic gauze cover with a string attached, which simplifies the removal of the dressing (FIG. 1). Following the contact with fluid/water, the gauze cover can form a viscous gel and quickly stop capillary bleeding. In the meantime, the expanding sponge provides controlled pressure at the bleeding site. At the same time, the expanding sponge provides the possibility to control the pressure exerted on the bleeding site. The double function allows to achieve haemostasis easily. The dressing adapts to the anatomical shape of the nasal cavity. It does not stick to the tissue, thereby reducing possible complications such as clots or bleeding. NasalSponge has a double haemostatic function, which allows to: absorb body fluids and form gel through the outer layer of haemostatic gauze and allows blood coagulation, in order to accelerate physiological haemostasis (during contact of the gel with the wound surface). The outer part of the tampon, which is made of haemostatic gauze, turns into a gel after contact with blood; the mechanism of blood coagulation is activated to accelerate physiological haemostasis. The inner part of the tampon, made of a self-expanding sponge, can be expanded to exert adequate compression on the surface of the wound and elicit physical haemostasis by compression. The gel structure of the haemostatic gauze provides a moisture-containing environment to accelerate the epithelialization process of the nasal mucosa, it reduces damage and the possibility of re-occurrence of bleeding. The benefits of using this type of intranasal dressing comprise the safety of use, absence of side effects, rapid haemostasis, provision of a moist environment adjacent to the wound environment, and acceleration of the healing process, as well as no tampon sticking to the wound, lower risk of secondary trauma, ease of use, and painless application and removal of the tampon. The manufacturer recommends using the product for 24-48 hours and for a maximum of 72 hours if no active bleeding occurs. These tampons do not possess antibacterial properties. Before removing the sponge from the nose, one should instill saline solution into the nasal cavity and several minutes later gently remove the product. A total of 60 such dressings were applied.

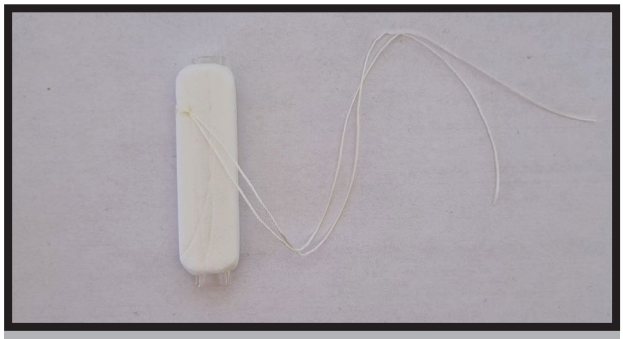

FIG. 1. NasalSponge type of dressing with string.

The second material examined was MerocelPope® (MP) dressing consisting of a microporous Merocel sponge made from high-density vinyl alcohol polymer (PVA) with oxidized cellulose (FIG. 2). This material maximizes the absorption and impermeability of tampons and minimizes pain and bleeding when tampons are removed. Fast-expanding tampons stop bleeding via gentle and even application of pressure upon the tissues, with platelets accumulating on the surface, which accelerates the formation of clots. 60 such dressings were applied.

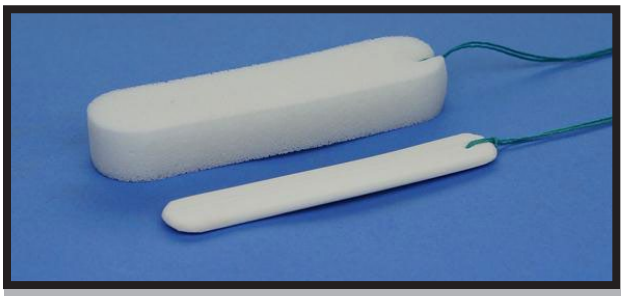

FIG. 2. MerocelPope type of dressing.

The third dressing that was examined was RapidRhino® made on the basis of carboxymethylcellulose (CMC – CarboxyMethyloCellulose) – a derivative of cellulose, whose innovative nature consists in double action: traditional wound tamponage, as well as accelerated haemostasis (FIG. 3). RapidRhino dressings accelerate platelet aggregation (which causes faster wound healing), perfectly protect the wound (which prevents infections), and do not cause secondary bleeding during their removal. These dressings, after preliminary preparation by a doctor (soaking in sterile water), are covered with hydrocolloid gel, which significantly facilitates their application and removal from the nasal cavity. They are designed for various types of treatments such as septorhinoplasty, turbinectomy, polypectomy, and FESS. A total of 60 such dressings were applied.

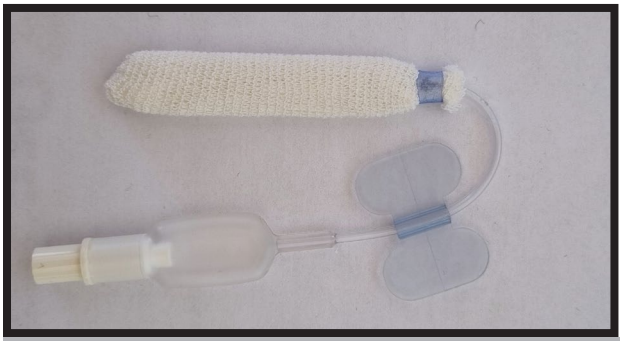

FIG. 3. RapidRhino type of dressing.

The fourth type of dressing applied was seton tamponade with antibiotic and steroid ointment in the latex glove finger (Routine nasal pack – RNP), commonly used in laryngology (FIG. 4). This type of dressing was applied in each surgically treated patient to one of the nasal passages, that is, a total of 180 of such dressings were applied (in each patient together with one of the three types of dressings mentioned above applied on the other side) (FIG. 5). It allowed us to compare modern commercial dressings with RNP in each patient.

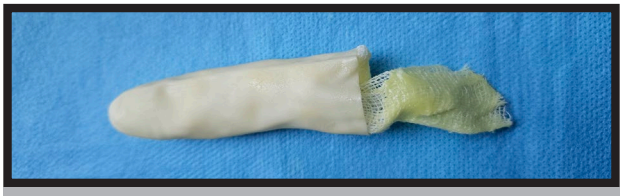

FIG. 4. Routine nasal pack – seton tamponade with antibiotic ointment (Oxycort) in latex surgical glove finger.

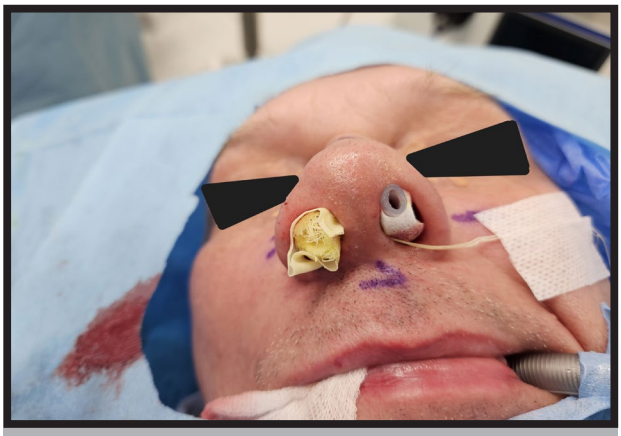

FIG. 5. Patient after surgery with bilateral intranasal dressings.

As mentioned above, four parameters were evaluated. The first parameter assessed was the haemostatic effectiveness of the dressing used. The assessment was carried out after the removal of the intranasal dressing on the second day after the surgery. The second evaluated parameter was the assessment of the level of pain in the nasal area during the application of the nasal dressing. In this case, the level of pain was subjectively assessed by the patient by means of visual analog scale (VAS) ranging from 0 and 10, the extremes being "absence of pain" – 0 points and "the most severe pain you can imagine" - 10 points. The third parameter evaluated was the assessment of pain experienced during dressing removal, also according to the VAS scale described above. The fourth parameter assessed was the development of postoperative adhesions within the nasal cavity. The presence of adhesions was always assessed by the surgeon performing the procedure during postoperative follow-up visits at weeks 4 and 8 after surgery. The study was conducted on both sides, using an endoscope with angles of 0° and 30°.

Statistical analysis

The results were subject to statistical analysis. At the beginning, descriptive statistics (percentage values) were calculated. The tests that were used to compare between the groups were: chi-squared test with Yates's correction ($\chi 2$) and Kruskal-Wallis test. The analysis was performed using STATISTICA 13.3 Tibco software. Statistical significance was assumed at the level of $p < 0.05$.

Results and Discussions

The results obtained are presented in the four above-mentioned ranges, i.e., the effectiveness of haemostatic action, assessment of the level of postoperative pain during dressing application, and assessment of pain experienced during dressing removal and assessment of the proneness for the formation of postoperative adhesions in the nasal cavity. The total number of subjects was 180 patients, which entails 360 intranasal dressings. Dressings of the following types: NasalSponge® (NS), MerocelPope® (MP), and RapidRhino® (RR) were applied in 60 patients each (60 nasal cavities), whereas seton with ointment in rubber glove finger (Routine nasal pack - RNP) was applied in 180 patients (180 nasal cavities).

Comparison of haemostatic properties of dressings

Bleeding after removal of the intranasal dressing of the NS type, which required re-establishment of tamponade, was found in 3 patients, after removal of the intranasal dressing of the MP type in 4 patients, in case of RR type of dressing, also in case of 3 patients, while in the case of 9 patients with RNP dressings the above was required (FIG. 6). Statistical analysis showed no differences between different types of dressings ($\chi 2 = 0{,}247$; $p = 0.967$).

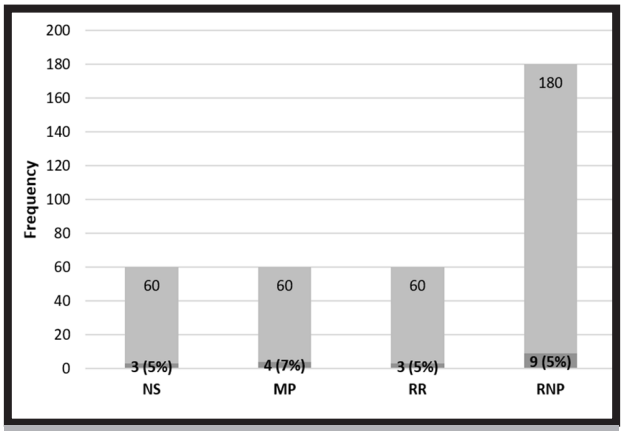

FIG. 6. Frequency of bleeding after removal of an intranasal dressing requiring tamponade. Explanation of abbreviations used: NasalSponge® (NS), MerocelPope® (MP), RapidRhino® (RR) (nasal cavities per each type of dressing, n = 60) and Routine nasal pack (RNP) (n = 180 nasal cavities).

Pain level after surgery

All patients qualified for the study assessed the level of postoperative pain on VAS scale. The pain assessment scores were between 0 and 6. In the NS-type dressing group, the average pain level was 3.2 (scores ranging from 2 to 5). For patients with MP dressings applied, the pain levels reported amounted to 3.1, on average (score range from 0 to 5). For patients with applied RR dressings, the pain levels reported amounted to 2.9, on average (score range from 0 to 5). For patients with applied RNP tamponage, the pain levels reported amounted to 3.1, on average (score range from 2 to 8). The difference in the level of postoperative pain associated with specific dressings between the different types of dressings was not statistically significant ($p = 0.399$) (FIG. 7).

The level of pain experienced when intranasal dressings were removed

All patients enrolled in the study indicated on the VAS scale the level of pain experienced when removing the intranasal dressing. The pain levels indicated ranged from 2 to 7.

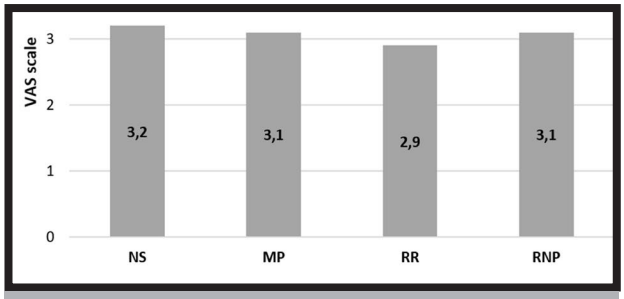

FIG. 7. Assessment of pain experienced during the removal of intranasal dressings 2 days after surgery) with the use of VAS scale. Explanation of abbreviations used: NasalSponge® (NS), MerocelPope® (MP), RapidRhino® (RR), Routine nasal pack (RNP).

In the case of dressings of NS type, the pain levels reported by patients amounted to 4.1, on average (range 3-7), in the case of dressings of MP type – 4.3 (range 2-7), in the case of dressings of RR type – 3.9 (range 3-7) while in the case of dressings of RNP type – 4.4 (range 3-7). No statistically significant differences were observed in the level of postoperative pain during the removal of internal dressing between the assessed types of dressings (p = 0.308) (FIG. 8).

Proneness to the formation of adhesions in middle nasal meatus

Endoscopic assessment of nasal cavities during follow-up visits 4 and 8 weeks after surgery revealed the development of unwanted nasal adhesions in 4 patients with dressings of NS type, 3 patients with dressings of MP type, 4 patients with dressings of RR type, and 9 patients with dressings of RNP type. No statistically significant differences were noted as regards the proneness to form adhesions, using the above-mentioned four types of dressings ($\chi 2 = 0{,}851$, p = 0.837) (FIG. 9).

Thanks to the use of intranasal dressings, we can control postoperative bleeding and the formation of adhesions in the middle nasal meatus, and can also minimize the level of pain associated with nasal tamponade. The results presented by us show that all types of dressings are effective in achieving postoperative haemostasis. Even in the case of significant intraoperative bleeding, these dressings are fully sufficient. Our study revealed that the use of the above 4 types of commercial dressings was associated with low levels of postoperative pain. The formation of adhesions within the middle nasal meatus after removal of ethmoidal cells, due to the tendency to lateralization of the central auricle, can significantly reduce the functional effect of surgery performed. In the world literature, the frequency of formation of unwanted adhesions is described in 1-35% of cases. An ideal postoperative dressing, in addition to good haemostatic properties, should also prevent the formation of adhesions. The results of our research showed that the percentage of adhesions after the use of all types of dressings applied by us was comparable (the differences were not statistically significant).

Haemostatic substances that are part of intranasal dressings have a double role to perform. Small sponge dressings covered with carboxymethylcellulose mesh can serve as a separator in the surgically treated region of the ethmoid sinuses, while larger ones are placed on the common nasal passages/meatuses and play mainly a haemostatic role. (RapidRhino® Nasal Dressing). On the other hand, removable tamponades made from oxidized cellulose in the form of sponges of different sizes perform haemostatic function mainly by compression (Merocel®).

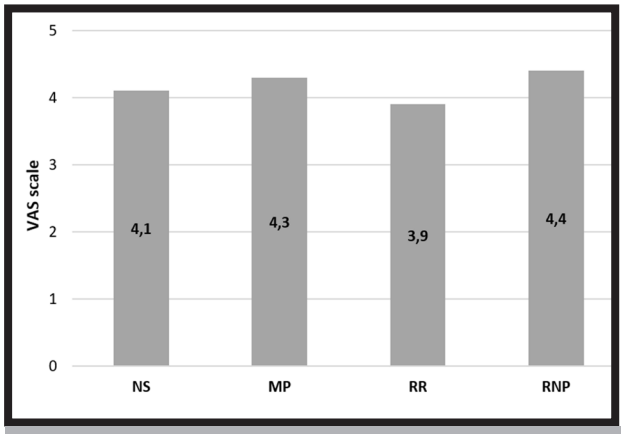

FIG. 8. Assessment of pain during the application of intranasal dressings (for 2 days after surgery) with the use of VAS scale. Explanation of abbreviations used: NasalSponge® (NS), MerocelPope® (MP), RapidRhino® (RR) (n = 60 nasal cavities per each type of dressing) and Routine nasal pack (RNP) (n = 180 nasal cavities).

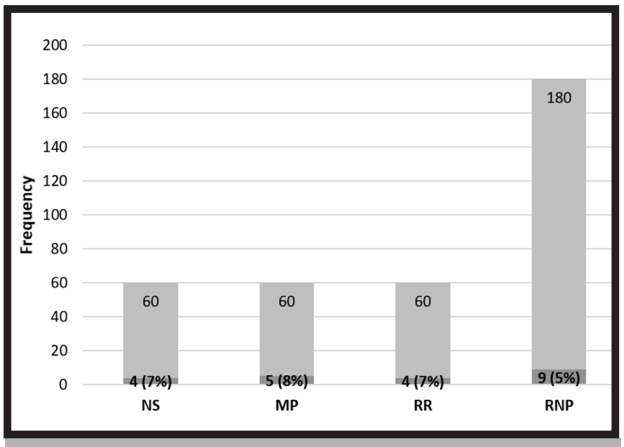

FIG. 9. Assessment of proneness to the formation of adhesions in nasal cavity, 4 and 8 weeks after the surgery. Explanation of abbreviations used: NasalSponge® (NS), MerocelPope® (MP), RapidRhino® (RR) (n = 60 nasal cavities per each type of dressing), and Routine nasal pack (RNP) n = 180 nasal cavities).

Conclusions

The application of intranasal dressings: NasalSponge®, MerocelPope®, RapidRhino® and Routine nasal pack is associated with a low level of pain both during the functioning of the dressing in the nasal cavity and in the course of removal of the dressing, a good haemostatic effect, and good effectiveness in preventing the formation of postoperative adhesions within the nasal cavity.

No statistically significant differences were demonstrated for the 4 intranasal types of dressings assessed as regards the haemostatic effect, the level of pain experienced when the dressing was in place in the nasal cavities, and during the removal of the dressing, assessed on the VAS scale, as well as concerning the formation of intra-nasal adhesions.

The level of pain assessed subjectively by the patient by means of Visual Analog Scale (VAS), after surgery and during the removal of the intranasal dressing did not differ statistically significantly.

No statistically significant differences were found in the frequency of formation of postoperative adhesions in the nasal cavity after the use of each of the 4 types of intranasal dressings assessed, provided that dressings were carefully applied/placed between the central auricle and the lateral nasal wall.

In conclusion, none of the analyzed 4 types of intranasal dressings proved to be distinctly advantageous. Their properties are comparable within the range of evaluated parameters. The obtained results do not indicate significant differences between the four types of dressings.

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ORCID iD

A. Maou: https://orcid.org/0009-0004-2865-9816
W. Likus: https://orcid.org/0000-0002-4738-6102
A. Długosz-Karbowska: https://orcid.org/0000-0002-3067-1935
J. Pilch: https://orcid.org/0000-0002-2682-4708
J. Markowski: https://orcid.org/0000-0003-3416-7354

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