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Clinical Paper

Orthognathic surgery

Surgical site infections in orthognathic surgery: prolonged versus single-dose antibiotic prophylaxis

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Abstract. The oral cavity is densely populated with microorganisms. As a result, intraoral surgical sites are prone to contamination by pathogens, potentially triggering surgical site infections (SSIs). Prophylactic antibiotics have proven beneficial in reducing the rate of SSIs. However, no consensus has been reached regarding the most effective regimen. The purpose of this study was to investigate two different antibiotic regimens – single-dose and prolonged antibiotic prophylaxis – regarding the rate and severity of postoperative SSIs in patients undergoing orthognathic surgery. Data were analysed retrospectively. Patients who underwent bilateral sagittal split ramus osteotomy or bimaxillary surgery in the study department in 2017 were screened for eligibility. Ninety-nine patients were included in the study and were divided into two groups. The prolonged-antibiotic prophylaxis group (PAP; $n = 49$) received a 5-day antibiotic prophylaxis regimen, while the single-dose antibiotic prophylaxis group (SDAP; $n = 50$) received single-dose antibiotic prophylaxis. The groups were assessed for the rate and severity of SSIs following orthognathic surgery. Five patients (10.2%) in the PAP group and seven (14%) in the SDAP group developed infections; no statistically significant difference in the occurrence of SSIs was found ($P = 0.380$). Single-dose antibiotic prophylaxis is as effective as a 5-day antibiotic prophylaxis regimen in preventing SSIs in orthognathic surgery and is a suitable antibiotic prophylaxis option when considering the risk of antibiotic resistance.

Keywords: Orthognathic surgical procedures; Antibiosis; Antibiotic prophylaxis; Surgical wound infection; Antimicrobial drug resistance.

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Orthognathic surgical procedures are common surgical interventions in the field of maxillofacial surgery that allow the correction of skeletal malocclusion to improve occlusal function, facial harmony, and aesthetics.[1] Orthognathic surgery is generally considered safe, however it continues to be associated with numerous

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complications. What is more, postoperative wound infections are amongst the most common and most severe sequelae that may potentially impair a patient's wellbeing and jeopardize the surgical outcome. These wound infections particularly occur with intraoral surgical approaches used in orthognathic surgery.[2] The advantages of intraoral approaches include the avoidance of extraoral scarring while maintaining adequate visibility and surgical access to the operating area. Additionally, the risk of injury to the facial nerve and regional blood vessels is minimized. However, the oral cavity is densely populated with bacteria, which may favour the occurrence of surgical site infections (SSIs). This issue has been highlighted by the American Society of Health System Pharmacists (ASHP), and as a result, orthognathic surgery has been categorized as clean-contaminated surgery.[3]

By definition, SSIs are infections that occur within the first 30 days postoperatively or within 1 year after the implantation of foreign material.[3] Possible consequences of SSIs include negative effects on the surgical outcome, a prolonged inpatient stay, re-hospitalization, and increased costs. Considering the highly elective nature of orthognathic surgical procedures, avoiding SSIs is of enormous importance.[4]

The SSI rate reported in orthognathic surgery ranges from 1.4% to 33.4%.[5] Peterson[6] estimated the rate of SSIs to amount to 10–15% without antibiotic prophylaxis. This rate was reduced to 1% when perioperative antibiotic prophylaxis was administered. These results correspond to those of Flynn and Lawrence,[7] who reported that a lower incidence of SSIs may be achieved when using standard aseptic techniques and antibiotic prophylaxis. According to Cousin et al.,[5] SSIs following orthognathic surgery occurred in 8% of cases. Antibiotic prophylaxis was administered in both studies. The importance of antibiotics was further demonstrated by Zijderveld et al.,[8] who described a significantly increased risk of SSIs after orthognathic surgery without antibiotic prophylaxis. This is consistent with other research on this topic, which has shown a reduction in the infection rate when antibiotic prophylaxis was used, regardless of the regimen applied.[4,9,10]

Hence, the clinical guidelines published by the American and British associations of oral and maxillofacial surgeons (AAOMS, BAOMS) recommend the judicious use of antibiotic prophylaxis to reduce the risk of postoperative complications.[1] However, no consensus has yet been reached regarding the type, dose, interval, and duration of prophylactic antibiotics.[1,4,11] Numerous different prophylactic antibiotic regimens are currently in use, but none have proven to be superior in reducing SSIs.[4] Moreover, the use of antibiotics should be minimized to prevent antimicrobial resistance and side effects (e.g. anaphylaxis and serum sickness), while ensuring the optimal efficacy for the prevention of SSIs.[4,5,12,13] Antibiotic resistance, a major global health threat, needs highlighting in this context.[14]

The purpose of this study was to compare two common antibiotic regimens for the prevention of postoperative SSIs in orthognathic surgery. The aim is to reduce the antibiotic medication to a necessary minimum while still guaranteeing optimal SSI prophylaxis.

Materials and methods

Study design

This retrospective study was conducted in the Division of Oral and Maxillofacial Surgery at the Medical University of Graz in 2017 as part of a quality improvement project that aims to reduce the amount of prophylactic antibiotics administered in orthognathic surgery (ethical approval, 30–356 ek17/18). In this regard, the standard perioperative antibiotic regimen deployed in the study department was changed from a prolonged 5-day antibiotic prophylaxis regimen to a single-dose regimen.

To identify possible differences in the efficacy of prophylactic antibiotics in preventing SSIs, these antibiotic regimens were compared by means of well-defined primary and secondary outcome measures. Patients who met defined inclusion criteria and who had received single-dose antibiotic prophylaxis (SDAP group) were matched to a control group of patients who had received prolonged antibiotic prophylaxis (PAP group); the groups were similar in sample size and surgical techniques applied.

Patients

Male and female patients who underwent bilateral sagittal split ramus osteotomy (BSSO) or bimaxillary surgery (BIMAX) during the 5 months before or after the change in antibiotic protocol were screened for eligibility. Only patients who were classified as either ASA I or ASA II according to the physical status classification of the American Society of Anesthesiologists (ASA), were included in the study. Reasons for patient exclusion included the following: incomplete follow-up (less than 6 months), additional surgical procedures performed in the same operative session (e.g. genioplasty, rhinoplasty), systemic diseases associated with reduced immunity (e.g. lupus erythematosus or HIV), and diabetes mellitus.

Perioperative management and surgical procedure

In both the PAP and SDAP groups, intravenous (IV) antibiotic prophylaxis was started within 60 min before mucosal incision. Further information on the regimens applied is given in Table 1.

Preparation of the intraoral surgical site was performed using chlorhexidine gluconate 0.1%; for extraoral prepping, octenidine dihydrochloride was used.

All operations were performed by experienced maxillofacial surgeons in accordance with the standard operating procedures established in the department. The Le Fort I osteotomy was performed as described by Bell and Schendel.[15] Four miniplates (MODUS_orthognathics 1.5; Medartis AG, Basel, Switzerland) were used to stabilize the maxillary osteotomy. The BSSO was performed according to Hunsuck.[16] Mandibular fixation involved the placement of three bicortical screws on each side via an extraoral (transmasseteric) approach using a trocar. Wound closure was achieved with resorbable sutures; no tissue glue or surgical drains were used.

Specific instructions on how to maintain adequate postoperative oral hygiene were given to each patient (e.g. the use of antiseptic mouthwash (chlorhexidine gluconate 0.1%), a soft toothbrush etc.). Pain management included ibuprofen IV and oral metamizole as basic analgesia and piritramide IV as an add-on for 3 days.

The patients were examined on a daily basis during their inpatient stay. Once discharged, weekly follow-up appointments were arranged over a period of 6 weeks to check healing, signs of infection, oral hygiene, and occlusion.

Table 1. The antibiotic regimens used in the two study groups. The first dose was given within 60 min before mucosal incision in both groups.

Group	Antibiotic regimen (including dosage)
PAP	Amoxicillin–clavulanate or ampicillin–sulbactam: IV twice daily on days 1–2 (AMC 2.2 g; SAM 3 g), orally three times daily on days 3–5 (AMC 625 mg; SAM 625 mg) Clindamycin (in the case of penicillin allergy): IV three times daily on days 1–2 (600 mg), orally three times daily on days 3–5 (300 mg)
SDAP	Amoxicillin–clavulanate or ampicillin–sulbactam: IV single dose (AMC 2.2 g; SAM 3 g) Clindamycin (in the case of penicillin allergy): IV single dose (600 mg)

AMC, amoxicillin–clavulanate; IV, intravenous; PAP, prolonged-antibiotic prophylaxis; SAM, ampicillin–sulbactam; SDAP, single-dose antibiotic prophylaxis.

Outcome measures

The primary outcome measure was the overall SSI rate over a period of 6 months. Furthermore, the severity of the SSIs was quantified using the Clavien–Dindo classification.[17] This well-validated tool defines complications as any deviation from the normal postoperative course. Depending on the need for a therapeutic intervention and the level of that intervention, the classification differentiates five grades, of which grades III and IV are each divided into subgrades a and b (Table 2).

Secondary outcomes included the localization of the SSI, duration of surgery, length of in-hospital stay (LOS), and time to onset of infection.

Statistical analysis

The statistical analysis was conducted using IBM SPSS Statistics software version 26 (IBM Corp., Armonk, NY, USA). Fisher's exact test and the Mann–Whitney *U*-test were applied to compare the demographic data between the PAP and SDAP groups and to investigate potential differences in the rate and severity of SSIs. Parameters such as the operation time needed and the localization of the SSIs were also analysed using these tests. The χ^2 test was used to analyse the SSI rate in relation to the various antibiotic agents used.

Results

Patients

A total of 99 patients (68 female, 31 male; mean age 30.1 ± 8.6 years) were included in the final analysis, 50 of whom received single-dose antibiotic prophylaxis (SDAP group) and 49 of whom received a prolonged 5-day antibiotic prophylaxis regimen (PAP group). There was no significant difference between the two groups in terms of age, sex, the duration of surgery, or the length of inpatient stay (Tables 3 and 4). In terms of the surgical techniques applied, 55 of the 99 study patients underwent BIMAX and 44 received a BSSO. BIMAX was performed in 27 patients in the PAP group and 28 patients in the SDAP group, while 22 patients in each group underwent BSSO.

Primary outcome—the SSI rate

Overall, 12 infections were observed when analysing the data without subgrouping patients according to the antibiotic regimen applied. This equates to an SSI rate of 12.1%. When comparing the SSI rate between the PAP group and SDAP group, no statistically significant difference was observed between the two antibiotic regimens ($P = 0.380$): five infections (10.2%) occurred in the PAP group, while seven infections (14%) occurred in the SDAP group.

Table 2. The Clavien–Dindo classification,[17] which was used to categorize surgical site infections that occurred in the study cohort.

Grade	Description
I	Complications that require drugs such as antiemetics, antipyretics, analgesics, diuretics, and electrolytes, as well as physiotherapy
II	Complications that require drugs other than those permitted for grade I cases (antibiotics), as well as blood transfusions and total parenteral nutrition
III	Complications that require a surgical, endoscopic, or radiological intervention IIIa: Intervention under local anaesthesia IIIb: Intervention under general anaesthesia
IV	Complications that require intermediate or intensive care IVa: Single organ dysfunction IVb: Multi-organ dysfunction
V	Death of the patient

SSI rate according to the antibiotic agent

Amoxicillin–clavulanate was the most common antibiotic administered (80/99: 35/49 in the PAP group, 45/50 in the SDAP group). Ampicillin–sulbactam was given to 11 patients (10/49 in the PAP group, 1/50 in the SDAP group) and eight patients were given clindamycin (four patients in each group). Ten of the 12 SSIs occurred in patients on amoxicillin–clavulanate (10/80, 12.5%). Two infections were found in patients on clindamycin (2/8, 25%). There was no statistically significant difference in the occurrence of SSIs between the antibiotics used ($P = 0.215$).

Within the PAP group, four SSIs occurred in patients on amoxicillin–clavulanate (4/35, 11.4%) and one SSI in a patient on clindamycin (1/4, 25%). Regarding the SDAP group, six SSIs were seen in patients who had received amoxicillin–clavulanate (6/45, 13.3%) and one SSI in a patient on clindamycin (1/4, 25%).

Severity of the SSIs

The 12 SSIs included three cases of persistent swelling (25%), one sinusitis (8.3%), four cases of wound dehiscence (33.3%), and four abscesses (33.3%) (Fig. 1).

Regarding the Clavien–Dindo classification, three complications (3/12) were rated as mild and were categorized as grade I; a further three complications (3/12) were classified as grade II. No surgical intervention was required with regard to any of these SSIs.

Table 3. Relevant patient data for the study cohort. There was no statistically significant difference between the PAP and SDAP groups for any of the parameters assessed.

	PAP group	SDAP group	Total	*P*-value
Sex				0.473
Female	33 (67.3%)	35 (70%)	68 (68.7%)	
Male	16 (32.7%)	15 (30%)	31 (31.3%)	
Total	49	50		
Age (years)				0.743
Min.	18.1	17.7	17.7	
Max.	55.3	52.2	55.3	
Mean ± SD	30.4 ± 8.9	29.9 ± 8.4	30.1 ± 8.6	
Operation				0.545
BIMAX	27	28	55	
BSSO	22	22	44	
Smoker				0.363
No	24	32	56	
Active	20	16	36	
Former	4	3	7	
LOS (days)				0.769
Min.	3	3	3	
Max.	8	9	9	
Mean ± SD	5.4 ± 1.1	5.3 ± 1.2	5.4 ± 1.3	

BIMAX, bimaxillary surgery; BSSO, bilateral sagittal split osteotomy; LOS, length of stay; PAP, prolonged-antibiotic prophylaxis; SD, standard deviation; SDAP, single-dose antibiotic prophylaxis.

However, systemic antibiotics had to be re-introduced as a therapeutic measure in the grade II cases. Six SSIs (6/12, 50%) met the criteria for grade IIIa of the Clavien–Dindo classification, as surgical treatment under local anaesthesia was deemed necessary: an intraoral mucosal incision was required to ensure adequate drainage of the surgical site.

The prevalence of grade I and grade II complications within the entire study population was 3.0% and 3.0%, respectively, while the prevalence of grade IIIa complications was 6.1%.

The severity of the SSIs did not differ significantly between the PAP and SDAP groups ($P = 0.842$).

Secondary outcomes—the SSI rate according to the localization of the SSI, surgical procedure, and duration of surgery

Regarding the localization of the 12 SSIs, nine (75%) were located in the lower jaw and three were situated in the upper jaw (25%). This disparity in the SSI rate between mandibular and maxillary surgical sites was not statistically significant ($P = 0.583$). In the PAP group, four of the five SSIs (80%) were located in the mandible and one (20%) was located in the maxilla. In the SDAP group, five of the seven SSIs (71.4%) affected the mandible and two (28.6%) were located in the maxilla.

Table 4. Duration of the surgery according to the study group, type of surgery performed, and occurrence of surgical site infection.

	Duration of surgery (min)		*P*-value
	Mean	SD	
Study group			0.353
PAP group	125.2	79.3	
SDAP group	111.7	59.0	
Patients undergoing BIMAX			0.333
With SSI	171.4	66.2	
Without SSI	144.8	75.4	
Patients undergoing BSSO			0.812
With SSI	86.0	51.1	
Without SSI	80.3	38.8	
All patients			0.088
With SSI	150.1	71.8	
Without SSI	113.4	68.2	

BIMAX, bimaxillary surgery; BSSO, bilateral sagittal split osteotomy; PAP, prolonged-antibiotic prophylaxis; SD, standard deviation; SDAP, single-dose antibiotic prophylaxis; SSI, surgical site infection.

Nine of the 12 SSIs (75%) occurred in patients who underwent BIMAX and three (25%) occurred in individuals who received a BSSO. Within the PAP group, all five SSIs (100%) were associated with BIMAX. Regarding the SDAP group, four of seven infections (57.1%) occurred following BIMAX and three (42.9%) following BSSO.

The average duration of surgery amounted to 117.4 ± 69.8 min. No statistically significant difference in operating time was seen when comparing the PAP group with the SDAP group: 125.2 ± 79.3 min vs 111.7 ± 59.0 min, respectively ($P = 0.353$). Unsurprisingly, BIMAX was associated with a significantly longer operating time in comparison to BSSO: 149.6 ± 73.9 min vs 80.7 ± 39.0 min, respectively ($P < 0.001$). The occurrence of SSIs was not associated with a significantly longer operating time: 150.1 ± 71.8 min in those with SSIs vs 113.4 ± 68.2 min in those without SSIs ($P = 0.088$) (Table 4). However, within the PAP group, a significantly longer operating time was detected in cases where SSIs were observed in comparison to those where no infection was reported: 200.2 ± 79.2 min vs 115.6 ± 75.0 min ($P = 0.023$).

Onset of the SSIs

The SSIs occurred on average 37.4 ± 42.6 days after surgery. In the PAP group, SSIs were found to occur 23.1 ± 30.5 days postoperatively, whereas in the SDAP group the SSIs

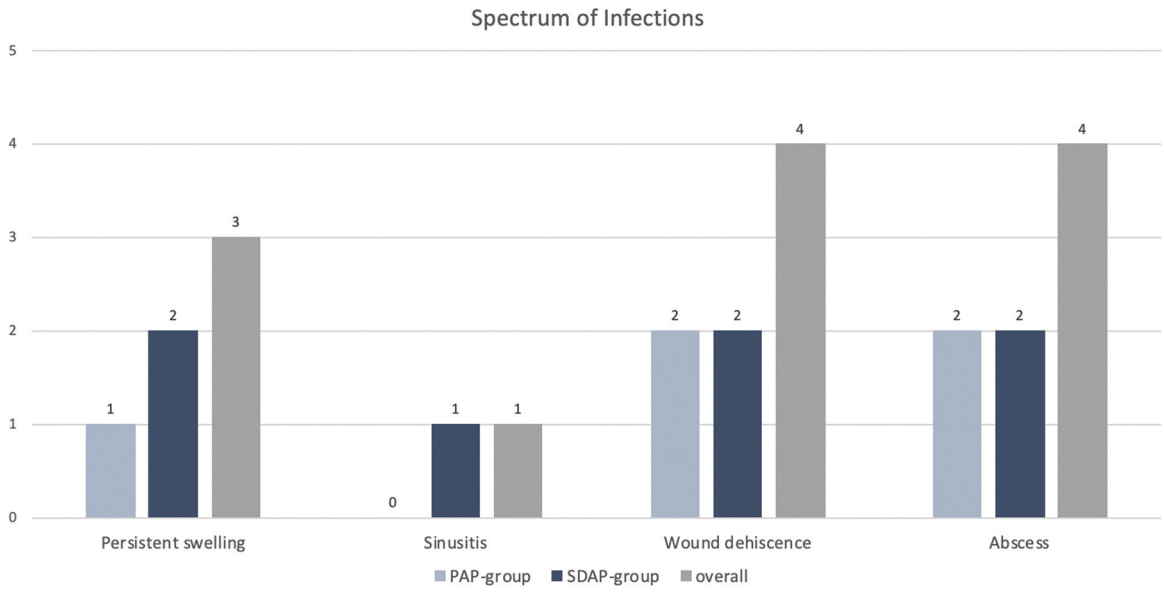

Fig. 1. The numbers and types of surgical site infections that occurred.

were noted to occur 57.4 ± 52.3 days after surgery. No statistically significant difference was observed when comparing the two groups ($P = 0.181$) (Fig. 2).

Duration of hospitalization (LOS)

LOS amounted to an average of 5.4 ± 1.1 days in the PAP group and 5.3 ± 1.2 days in the SDAP group (Fig. 3). No statistically significant difference was found with respect to this parameter ($P = 0.863$). Patients with SSIs had a mean LOS of 5.9 days, whereas patients without SSIs were hospitalized for a mean 5.3 days ($P = 0.251$).

Discussion

Due to the highly elective nature of orthognathic surgery, reducing the rate of complications to a minimum is paramount. Besides haemorrhage, nerve transection, and nasal septum deviations, SSIs are amongst the most frequent complications.[1,18] Among other reasons, this can be attributed to the use of intraoral surgical approaches in orthognathic surgery, which may result in contamination with endogenous bacteria. The prevalence of SSIs ranges between 1% and 33.4%.[5,6] The SSI rate of 12.1% found in this study is within this range.

In a clinical trial performed in 1999, Bentley[19] found that a 5-day antibiotic regimen was significantly more effective in preventing postoperative infection when compared to a 1-day regimen. Davis et al.[20] described a significant reduction in SSIs with a 3-day regimen when compared to a 1-day regimen. Moreover, prolonged antibiotic prophylaxis has been described as advantageous in reducing the infection rate compared to preoperative single-dose antibiotic prophylaxis.[1,18] Furthermore, numerous others have successfully shown the benefit of long-term antibiotic prophylaxis over short-term use in the prevention of SSI.[1,18] Danda et al.[11] even described the clinical advantage of a 1-day regimen compared to a single-dose antibiotic prophylaxis; however, no statistical difference was found.

In contrast, Ghantous et al.[21] compared a prolonged 5-day regimen to single-dose antibiotic prophylaxis, which yielded no statistically significant differences between the two groups. As a result, their study group cautiously proposed a reduction in antibiotic administration in healthy patients. Lindeboom et al.[22] found no significant difference either, when comparing a single-dose and four-time administration of clindamycin. In addition, several other authors have noted no benefit for extended postoperative antibiotic prophylaxis.[8,11] With regard to the incidence of SSIs in clean-contaminated wounds in maxillofacial surgery, Villanueva et al.[23] reported no significant difference between single-dose antibiotic prophylaxis and prolonged application of prophylactic antibiotics. Similarly, no statistically significant difference in the occurrence of SSIs was found in the present study when comparing a prolonged 5-day regimen to single-dose antibiotic prophylaxis.

Van Camp et al.[12] argue against the need for prolonged antibiotic prophylaxis as it is associated with numerous drawbacks, such as disruption of the patient microbial flora, pharmacological adverse events, economic consequences, and, particularly, antibiotic resistance. In fact, multiple trials have shown that even single-dose or short-term application (3 days) of amoxicillin increases the load of resource-resistant viridans streptococci in saliva.[24,25] Against growing global concerns about antibiotic resistance, Van Camp et al.[12] specifically advocate the use of single-dose regimens for antibiotic prophylaxis in maxillofacial surgery.

In the current study, antibiotics were administered prior to mucosal incision to ensure an adequate tissue concentration at the time of surgery. According to Classen et al.,[26] the lowest postoperative infection rate is possible when antibiotics are given within 2 h prior to the skin incision. The World Health Organization guidelines from 2016 recommend performing antimicrobial shielding 120 min before mucosal incision. For antibiotics with a short half-life (cephalosporins, penicillins), which are often used in maxillofacial surgery, administration less than 60 min before the start of the procedure is recommended.[27]

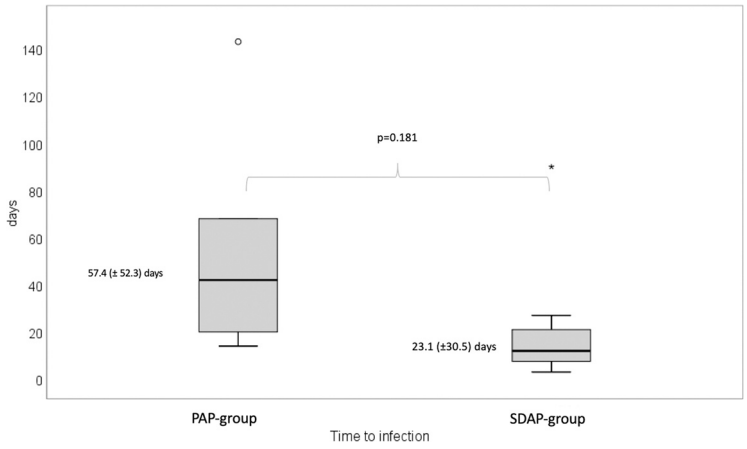

Fig. 2. The mean time period between orthognathic surgery and the onset of infection: 57.4 ± 52.3 days in the prolonged-antibiotic prophylaxis (PAP) group vs 23.1 ± 30.5 days in the single-dose antibiotic prophylaxis (SDAP) group. No statistically significant difference was detected ($P = 0.181$).

Previous trials have been criticized for including medically compromised patients and for using unclear criteria to define SSIs.[4] In addressing the first point of criticism, this study strictly adhered to the stated inclusion and exclusion criteria to ensure that only healthy patients (i.e., ASA I or ASA II) were included in the study. Regarding the second point of criticism, the severity of the SSIs was defined by means of the Clavien–Dindo classification.[17] Thus, any deviation from the normal postoperative course (longer-lasting swelling) was rated as an SSI. It is probable, however, that this led to the higher incidence rate of SSIs reported in this study in comparison to other studies in the field (12.1%).

Furthermore, it is acknowledged that the selection of antibiotics used might have affected the SSI rate in this study. Barrier et al.[28] noticed a higher rate of SSIs when using agents other than amoxicillin–clavulanate. Davis et al.[2] inferred that first-generation cephalosporins were more effective than penicillin and clindamycin for the prevention of SSIs. As well as amoxicillin–clavulanate, ampicillin–sulbactam and clindamycin were also used in the current study. However, it was not possible to demonstrate an association between the occurrence of SSIs and any of the antibiotics used.

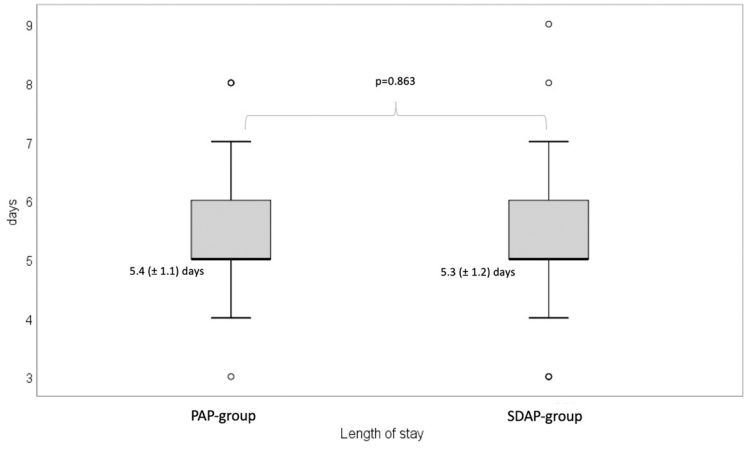

Fig. 3. The mean length of inpatient stay. No statistically significant difference was found when comparing the prolonged-antibiotic prophylaxis (PAP) group with the single-dose antibiotic prophylaxis (SDAP) group ($P = 0.863$).

Previous publications have reported an increased occurrence of SSIs in the mandible. It was hypothesized that this is due to the mandible's poorer blood supply together with the issue of gravity, which favours an accumulation of saliva and food residues in the lower jaw.[4,11–13,18,19,29] In contrast, the current study did not find that SSIs affected the mandible more often than the maxilla ($P = 0.583$).

SSIs have also been associated with increased LOS, which consequently places a burden on the financial budget of a healthcare system. In fact, Broex et al.[30] demonstrated that the longer hospitalization as well as additional diagnostic and therapeutic measures following SSIs result in an approximate doubling of the costs on average when compared to patients without SSIs. Data on the extent of the increased LOS associated with SSIs in maxillofacial surgery, let alone orthognathic surgery, are unfortunately lacking. Across multiple surgical disciplines, the duration of hospitalization is expected to increase by 176% with SSIs.[30] In the present study, SSIs had no statistically significant impact on LOS (5.9 vs 5.3 days; $P = 0.251$). Regarding the study population, complications took more time until they developed. Thus, they usually emerged after patient discharge and, subsequently, had little effect on the LOS.

Possible limitations of this study include the fact that more than one senior surgeon performed the surgeries. However, all surgeons followed the departmental standard operating procedures. Furthermore, differences in patient oral hygiene may have had an impact on the outcomes. Additionally, studies investigating SSIs in orthognathic surgery should follow up on patients for at least 1 year, since SSIs are defined as infections that occur either within 30 days after surgery or within 1 year after the implantation of foreign material.[3] Thus, the chosen follow-up period of 6 months in this study leaves further room for improvement. In contrast to extending the follow-up period, however, it is proposed that the rate of SSIs would have been underreported if the study had solely focused on the first 30 days after surgery. Reasons for a later onset of infection (after 30 days) are multifactorial and may also be related to

other contributing factors such as screw loosening and non-union.[31] This, however, was not found to be the case in the study cohort. Furthermore, no statistically significant difference between the groups compared in terms of the onset of infection was found when assessing the cohort over the defined follow-up period. Lastly, it is acknowledged that this work, being retrospective in nature, may show susceptibility to intrinsic bias. Therefore, further prospective studies are needed.

Based on the study results, single-dose antibiotic prophylaxis was statistically as effective as a perioperative 5-day antibiotic prophylaxis regimen in preventing SSIs. Taking into account the issue of increasing antimicrobial drug resistance, a timewise reduction of antibiotic prophylaxis for young, healthy adults undergoing standardized orthognathic surgical procedures is proposed.

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Competing interests

None.

Ethical approval

Ethical approval was obtained from the Ethics Committee of the Medical University of Graz (30–356 ek17/18).

Patient consent

Not required.

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