

ORIGINAL RESEARCH

Patient Experience with the SensoReady[®] Autoinjector Pen versus a Comparator Device: Results from a Canadian Patient Survey in Rheumatoid Arthritis and Crohn's Disease

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Purpose: Medication delivery device design impacts treatment satisfaction, adherence, and compliance in patients receiving biologics. This survey assessed autoinjector attributes that are important to patients, and assessed patient perceptions and preferences between an adalimumab biosimilar autoinjector (Hyrimoz[®] SensoReady[®] Pen [SDZ-ADL pen]) and the reference adalimumab autoinjector (Humira[®] Pen [ref-ADL pen]) in patients with rheumatoid arthritis (RA) or Crohn's disease (CD) in Canada.

Patients and Methods: In this survey, adult patients were recruited for web-assisted telephone interviews. Patients had ≥ 3 months' experience with the ref-ADL pen and 1–12 months' experience with the SDZ-ADL pen.

Results: The survey included 120 patients with RA (n = 32) or CD (n = 88). Mean experience with the ref-ADL pen was 7 years for RA or 5 years for CD vs 9 months with the SDZ-ADL pen. The most important autoinjector attributes were the ability to use the pen independently and the ease and simplicity of self-injection. When comparing the two autoinjectors, patients significantly preferred the SDZ-ADL pen over the ref-ADL pen for nearly every attribute evaluated, with the greatest differences reported for visual and audible feedback mechanisms, ease of self-injection, and ability to use the device independently. Overall, 82% of patients preferred the SDZ-ADL pen over the ref-ADL pen, with buttonless activation and less injection pain being the main drivers for this preference.

Conclusion: Patients with RA or CD indicated a preference for the SDZ-ADL pen over the ref-ADL pen, independent of the duration of use of the pen. The preference for a biosimilar device within 1 year of switching provides reassurance of rapid patient acceptance of biosimilars and may simplify the switching process. These results confirm the importance of ensuring autoinjector design supports independent self-administration of medication and align with previous data showing high patient satisfaction with the SDZ-ADL pen. **Keywords:** adalimumab, adherence, autoinjector, biosimilar, patient preference

Introduction

Immune-mediated inflammatory diseases (IMIDs) are a diverse set of diseases, including rheumatoid arthritis (RA) and Crohn's disease (CD), with some common molecular targets for treatment. Among these molecular targets is tumor necrosis factor-alpha (TNF- α), which has been the focus for the development of several successful disease-modifying biologics. TNF- α biologics, such as adalimumab, have been a key part of the treatment algorithms for RA and CD for several decades.

Most biologic therapies for IMIDs, including adalimumab, are delivered subcutaneously via devices such as prefilled syringes or autoinjectors, both of which allow for convenient self-administration by patients.^{4,5} Previous studies have

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reported patient preference for autoinjectors over prefilled syringes, in terms of reduced discomfort, ease of use, and improved adherence.^{6–8}

Appropriate and convenient autoinjector design is essential for optimizing patient satisfaction and adherence to treatment. This can be achieved by the inclusion of autoinjector features that are optimized for self-administration while minimizing injection-site pain, as has been assessed in patient and clinician surveys and clinical studies.^{5,9–13} Autoinjectors that have been developed for anti-TNF- α biologics can include features such as audible clicks to confirm the start and completion of injection, medication viewing windows, ergonomically shaped pens, and other features to improve the patient experience.⁵ Some patients with IMIDs, such as those with RA or multiple sclerosis (MS), may have compromised dexterity; ease of grip and ease of operation for self-injection have been noted as important autoinjector features for patient satisfaction in several surveys, 9,11,12 Articular involvement has also been associated with inflammatory bowel disease, including CD, which can impact dexterity in these patients. 14-16

The adalimumab biosimilar, SDZ-ADL (Hyrimoz, manufactured by Sandoz, Kundl, Austria), was granted initial approval in Canada in November 2020 and is currently approved for use in Canada in the same indications as the reference product, ref-ADL (Humira; AbbVie Inc., Chicago, IL, USA): moderate-to-severe RA, psoriatic arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, CD, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis. ^{17,18} Policies facilitating the switch to adalimumab biosimilars in Canada have been determined at the provincial level, with provinces implementing various approaches between 2019 and 2022, ranging from mandatory non-medical switching in existing patients and preferential access to biosimilars for treatment-naïve patients, to giving biosimilars the same listing status and reimbursement criteria as the reference product. 19

SDZ-ADL and ref-ADL are both administered via subcutaneous injection using a prefilled autoinjector device, the SDZ-ADL pen (Hyrimoz SensoReady Pen) and the ref-ADL pen (Humira Pen), respectively. The ref-ADL pen has a circular cross-section, with a window for observing dose delivery on its side, and a button to release a spring to deliver the dose. The SDZ-ADL pen has a triangular cross-section, with a 360° window for observing dose delivery, and a two-step buttonless delivery system. ^{17,18} In Phase III trials in patients with psoriasis, self-administration of another biologic, secukinumab, with the SDZ-ADL pen was associated with sustained efficacy, an acceptable safety profile, and high acceptance among patients. 20-22 In two multicenter surveys, the SDZ-ADL pen was preferred over its comparator autoinjectors by patients with MS or RA receiving biologics, as well as by their nurses, mainly due to the device's ease of use and ease of grip. 11,13

Data from patients with RA or CD who are currently using the SDZ-ADL pen and have experience using comparator autoinjectors can help to assess the perception of these devices and inform further developments and improvements in autoinjectors.

The objectives of this survey in patients with RA or CD treated in Canada were to assess autoinjector device attributes of the most importance to patients, and to assess patient perceptions of the SDZ-ADL pen and the ref-ADL pen. Patient preference between the SDZ-ADL pen and the ref-ADL pen was also assessed.

Materials and Methods

Patient Population

All participants were recruited from the SDZ-ADL patient support program (the Hyrimoz® Patients Support Program, supported by Sandoz) in the Canadian provinces of British Columbia, Ontario, and Quebec. Participants eligible to complete the survey were aged ≥ 18 years and diagnosed with either RA or CD indicated for treatment with anti-TNF- α therapy in Canada, had previously used the ref-ADL pen for ≥ 3 months for the treatment of RA or CD, had 1–12 months' experience using the SDZ-ADL pen for the treatment of RA or CD, and had visited a physician at least once for the treatment of RA or CD within the past 12 months. All participants also required access to an internet service that allowed for web-assisted telephone interviews. Exclusion criteria were that participants could not be currently employed and/or paid by a pharmaceutical or biopharmaceutical company or healthcare manufacturer, serving as a clinical investigator conducting clinical trials or providing consulting services relating to RA or CD, or employed and/or paid by a market research firm or advertising agency at the time of the survey. All participants who met the inclusion/exclusion criteria were included on

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a continuous basis until the desired sample size was reached. All participants provided informed consent, which covered the use of de-identified data for publication of the study results.

Patients with either RA or CD were chosen for this survey as these are indications where adalimumab is used as first-line biologic treatment. The survey was limited to patients with either of these two indications to allow two homogeneous patient populations to be assessed. Given that the average differences observed in preferences between the two devices in an earlier survey of patients with RA and nurses in Europe, ¹³ 120 patients were recruited for this survey.

Patient Survey Design

This patient survey incorporated a mixed-methods approach to include quantitative (ratings and rankings) and qualitative (descriptive and open-ended) questions (<u>Supplement 1</u>). Quantitative questions were designed to gauge patient perceptions regarding the importance of specified attributes of the autoinjector devices. The attributes assessed were based on published literature, ^{5,9,11,13} and the survey questions and overall methodology were approved by the independent review board (IRB). Qualitative questions centered on patient history and patient perceptions regarding the autoinjector devices.

Patient Survey Procedure

All eligible patients were invited to participate in the survey by email and/or phone. Invitations outlined the survey objectives, design, and honoraria amount (CAD 180, based on Canadian Fair Market Value). Participants were provided with no other compensation for participating in the survey. Interested participants were contacted via email and/or phone to schedule the informed consent process and then complete the telephone screening interview on a first-come, first-served basis. Participants meeting all inclusion criteria at conclusion of the screening interview were then scheduled to complete the web-assisted telephone interview.

To gauge clarity and patient understanding of the interview questions, test interviews were carried out in a manner consistent with the planned data collection process. The interview questions and structure were then modified in line with findings from the test interviews, to improve clarity and question flow.

Data were captured using a one-on-one web-assisted interview technique. In-depth web-assisted telephone interviews lasted 45–60 minutes. Moderators conducting the interview shared visual aids based on the survey questionnaire that were designed to facilitate patient understanding of the questions being asked and ensure the accuracy of the data captured. Two experienced moderators completed the interviews. A separate data collection team then transcribed any recordings and notes into a spreadsheet. The first 10–15 interviews by each moderator were compared to ensure consistency between moderators and accuracy in data collection.

The telephone interview consisted of collecting both qualitative and quantitative data. Qualitative data were collected using descriptive and open-ended questions centered around aspects such as patient's history of their disease, how patients learned to use their autoinjector device, factors driving the switch from ref-ADL to SDZ-ADL, overall perceptions of autoinjectors (in general, and specifically the SDZ-ADL pen and ref-ADL pen), and why specific attributes may drive a preference for a particular autoinjector. Quantitative data were collected using several types of questions, including asking participants to rank attributes of autoinjector devices in order of importance and/or performance, and closed-ended questions.

Research conduct, including patient recruitment and screening, field interviews, data analysis, and reporting, was carried out by an independent agency (OLG Research, Fairfield, NJ, USA) without any interference from the sponsor. Patients did not know which company was sponsoring the survey until after the survey was completed.

Compliance with Ethics Guidelines

The informed consent form, survey protocol, survey questionnaires, and patient invitation materials were all approved by Advarra, Inc. (Aurora, ON, Canada), the local Canadian IRB.

This survey was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. All participants provided informed consent to participate in the survey.

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Data Analyses

Data collection was completed between January 23 and March 6, 2023. The analysis included all patients who met the inclusion criteria and completed the survey. Descriptive statistics were used to summarize responses to individual questions. In addition, analysis of quantitative data was implemented in a manner that compared the top-two box scores (a score of nine or 10 out of 10) for device attribute ratings and rankings to assess the variability between the ref-ADL and SDZ-ADL devices. R version 4.2.2 (R Project, R Foundation for Statistical Computing, Vienna, Austria) was used for all statistical analyses. Statistical significance ($p \le 0.05$) of differences between the SDZ-ADL pen and the ref-ADL pen was assessed using the Wald chi-squared test or the chi-squared test.

Qualitative analysis was completed using a combination of content, thematic, and narrative analysis. These data were organized by frequency of mention of themes and factors driving participant preference and behavior. Narratives and themes regarding patient experiences and device preferences were compared.

Results

Patient Characteristics

In total, 120 adult patients with RA (n = 32) or CD (n = 88) previously treated with ref-ADL and currently being treated with SDZ-ADL responded to the survey. The flow of patients from the beginning of the consent process to survey participation is shown in Figure 1. Baseline characteristics for the patients included in the survey are presented in Table 1.

Important Attributes of Autoinjector Pens

When asked to rate the importance of each feature of an autoinjector pen in general, participants rated administration attributes, such as ability to use a pen independently, ease of performing self-injection, simplicity, ease of preparation, and ease of learning to use a pen, as the most important (Figure 2A). Although physical attributes of a pen (eg, size, reusability, shape, weight) were rated lower in overall importance than administration attributes, these were still rated as important on

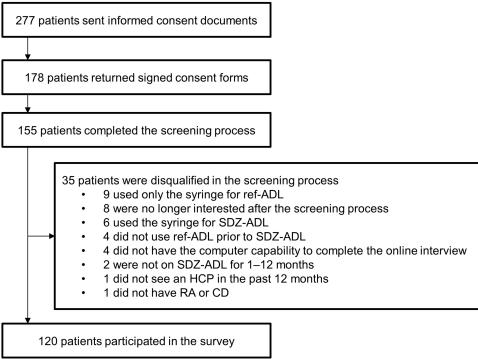


Figure I Flowchart of participants through the recruitment process. Abbreviations: CD, Crohn's disease; HCP, healthcare professional; RA, rheumatoid arthritis; ref-ADL, Humira; SDZ-ADL, Hyrimoz.

Table I Baseline Characteristics of Patients Who Responded to the Survey (N = 120)

Characteristic	Patients with CD (n = 88)	Patients with RA (n = 32)
Female sex, n (%)	39 (44)	22 (69)
Patient age, n (%)		
18–34 years old	23 (26)	I (3)
35–44 years old	24 (27)	4 (13)
45–54 years old	15 (17)	4 (13)
> 55 years old	26 (30)	23 (71)
Mean age, years	45	59
Mean time since diagnosis, years (range)	15 (1.5–47)	16 (3.5–50)
Previous time on ref-ADL pen, n (%)		
7–9 months	2 (2)	0 (0)
I0–I2 months	4 (5)	2 (6)
13–24 months	17 (19)	5 (16)
> 24 months	65 (74)	25 (78)
Average duration of use of ref-ADL pen, months	64.3	86.5
Time ^a on SDZ-ADL pen, n (%)		
I=3 months	3 (3)	2 (6)
4–6 months	18 (21)	6 (19)
7–9 months	32 (36)	6 (19)
10-12 months	35 (40)	18 (56)
Average duration of use of SDZ-ADL pen, months	8.5	9.0

Note: ^aAt time of interview.

Abbreviations: CD, Crohn's disease; RA, rheumatoid arthritis; ref-ADL pen, Humira Pen; SDZ-ADL pen, Hyrimoz SensoReady Pen.

the same scale ranking. On a scale of one to 10, with 10 indicating extremely important, patient ratings ranged from one to 10 for all but three attributes: no patient rated ease of performing self-injection or simple/self-explanatory below five, or ease of learning to use below three. The proportion of patients expressing an importance score of nine or 10 out of 10 for each attribute is shown in Figure 2B.

Patient Perceptions of the SDZ-ADL Pen and the Ref-ADL Pen Rating Each Pen Individually

Participants were asked to rate the SDZ-ADL pen and the ref-ADL pen individually on how well they performed over a list of attributes. The SDZ-ADL pen was rated more highly than the ref-ADL pen for all attributes across the three areas evaluated: administration attributes, ease of learning to use, and pen characteristics. The greatest differences between the two autoinjectors related to the feedback mechanisms (visual and audible), for which the SDZ-ADL pen significantly outperformed the ref-ADL pen by more than 40% in the top-two box score (Figure 3). Other statistically significant ($p \le 0.05$) distinctions between the autoinjectors included the ease of performing self-injection, ease of preparation/setup, time to complete injection, process required to initiate the injection, simple/self-explanatory nature of the pen, convenient shape, ease of gripping the pen, and right size of the pen, all favoring the SDZ-ADL pen vs the ref-ADL pen (Figures 3 and 4).

Directly Comparing the Two Pens

When asked to directly compare the performance of each autoinjector for each attribute, most patients reported a preference for the SDZ-ADL pen vs the ref-ADL pen for nearly all assessed attributes, except storage requirements, for which the majority were neutral (Figure 5). The difference was statistically significant ($p \le 0.05$) for all attributes except needle concealment.

Patients were asked to select which autoinjector they would prefer to use overall for their injections. A total of 98 patients (82%) preferred the SDZ-ADL pen over the ref-ADL pen (patients with RA, n = 25 [78%]; patients with CD, n = 73

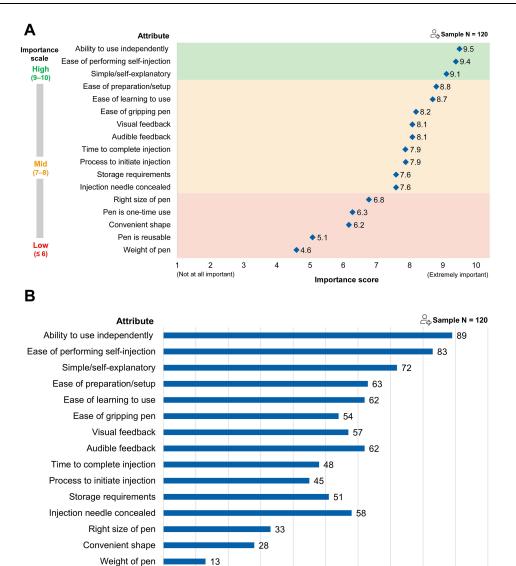


Figure 2 Importance of attributes for an autoinjector pen in general, expressed as (A) mean scores (0-10) and (B) top-two box score. Note: For part A, importance ratings are on a scale of one to 10, whereby one is not at all important and 10 is extremely important to the participant.

20

0

10

[83%]) (Figure 6). Among patients who preferred the SDZ-ADL pen over the ref-ADL pen, the main driving factors were less injection-site pain or lack of a burning sensation (n = 38; 32%) and buttonless activation (n = 38; 32%). Preference for the ref-ADL pen over the SDZ-ADL pen was mainly driven by its activation with a button (n = 12; 10%).

30

40

50

Percentage of patients reporting a top-two box score

60

70

80

90

100

Rating Device Features

When asked about the unique device features of the SDZ-ADL pen, respondents consistently perceived these features as "helpful", with the proportion of respondents describing specific attributes as "helpful" as follows: color indicator, 90%; viewing window size, 88%; viewing window, 80%; buttonless activation, 75%. The proportion of patients describing these attributes as "helpful" was consistent between indications and between age groups.

Regarding the device viewing windows, 88.3% of patients (78 patients with CD and 28 patients with RA) preferred the SDZ-ADL pen over the ref-ADL pen. Perceptions were that the large window of the SDZ-ADL pen was easier to see and confirm injection progress compared with that of the ref-ADL pen, and that the 360° visibility simplified viewing. Eight patients (all with CD) preferred the ref-ADL pen over SDZ-ADL pen in terms of the viewing window, noting that

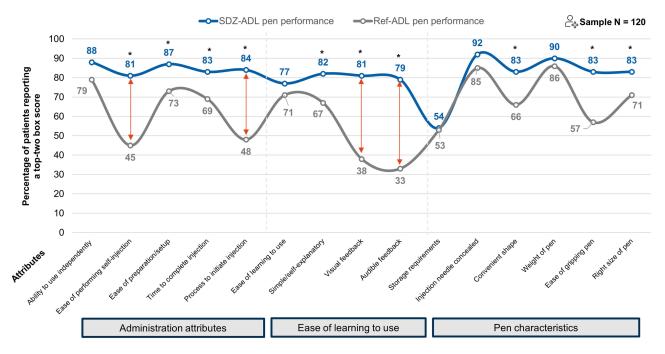


Figure 3 Individual performance rating scale for SDZ-ADL pen or ref-ADL pen, rated separately. **Note**: *Statistically significant difference (*p* ≤ 0.05) between SDZ-ADL and ref-ADL scores. *p* values were calculated using the Wald chi-squared test. **Abbreviations**: ref-ADL pen, Humira Pen; SDZ-ADL pen, Hyrimoz SensoReady Pen.

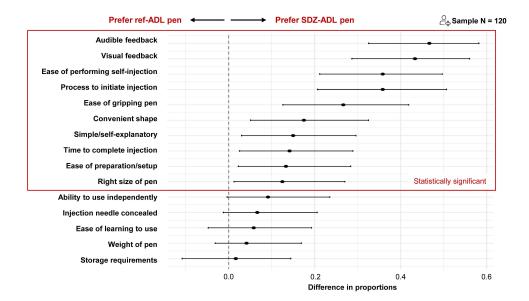


Figure 4 Preference for SDZ-ADL pen or ref-ADL pen, based on individual performance ratings. **Note:** The 95% confidence intervals are shown for the proportion of patients reporting a top-two box performance score for each attribute. Statistical significance (*p* ≤ 0.05) of differences between SDZ-ADL pen and ref-ADL pen preferences was assessed using the Wald chi-squared test. **Abbreviations:** ref-ADL pen, Humira Pen; SDZ-ADL pen, Hyrimoz SensoReady Pen.

the viewing window is smaller, more discreet, and adequate to confirm the injection has been completed. Six of these eight patients were under 40 years of age.

Likelihood to Continue Using the SDZ-ADL Pen

Patients were asked to rate their likelihood to continue using the SDZ-ADL pen for the next 6–12 months on a scale of one to 10; 99% (119 out of 120 patients) gave a score of nine or 10 out of 10, indicating that they were highly likely to

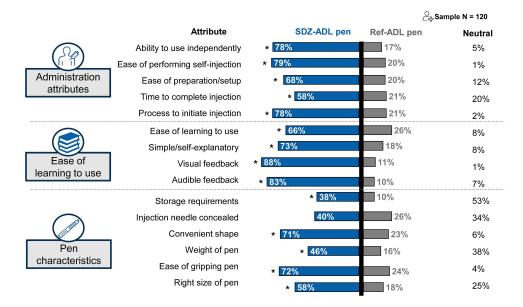


Figure 5 Preference for SDZ-ADL pen vs ref-ADL pen, by direct comparison.

Note: *Statistically significant difference ($p \le 0.05$) between SDZ-ADL pen and ref-ADL preferences. p values were calculated using the chi-squared test.

Abbreviations: ref-ADL pen, Humira Pen; SDZ-ADL pen, Hyrimoz SensoReady Pen.

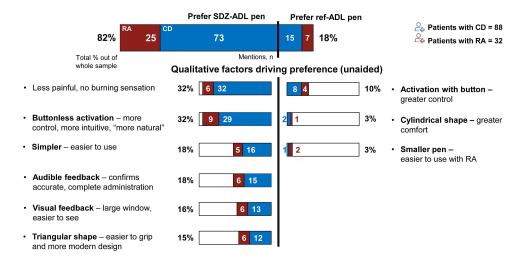


Figure 6 Preference for SDZ-ADL pen vs ref-ADL pen.

Abbreviations: CD, Crohn's disease; RA, rheumatoid arthritis; ref-ADL pen, Humira Pen; SDZ-ADL pen, Hyrimoz SensoReady Pen.

continue with the SDZ-ADL pen. As part of their response, patients also provided statements on why they would be continuing treatment, shown in Table 2.

Discussion

In this survey, patients with RA and CD indicated a clear preference for the SDZ-ADL pen over the ref-ADL pen for nearly every attribute evaluated. Such a positive patient response to an autoinjector within 1 year of initiation should reassure patients and physicians that patients adapt rapidly after switching to a biosimilar, and this preference may help to simplify the switching process when applicable.

Medication using self-injection has been shown to improve treatment compliance and persistence, ²³ and self-injection has been associated with a range of benefits, such as increased flexibility in the timing and location of injection, reduced costs for patients and healthcare systems, reduced travel time, and reduced caregiver burden. ^{5,24} Therefore, encouraging

Table 2 Examples of Patient Statements Regarding Their Likelihood of Continuing Treatment with the SDZ-ADL Pen

Patients with RA

- "It [Hyrimoz] is more practical, it requires fewer steps, it's smaller and lighter and overall offers better visual feedback"
- "If both Hyrimoz and Humira were available, I would continue with Hyrimoz. It is easier for me to use and the visual feedback is way better"
- "I prefer the buttonless activation and large window"
- "I feel the needle a lot less, Humira was more painful. The buttonless activation is also much easier for me"

Patients with CD

- "It [Hyrimoz] is simpler to use, there is one cap and the buttonless activation. The visual and audible feedback is also better"
- "I prefer Hyrimoz because it is perfectly pain-free and provides better feedback, both visually and audibly"
- "It is easier and a more natural process, the injection is also a bit faster and less painful"
- "I will continue because I have no choice. But I would continue regardless, I am very pleased with this product"

Abbreviations: CD, Crohn's disease; RA, rheumatoid arthritis; SDZ-ADL pen, Hyrimoz SensoReady Pen.

self-injection by optimizing delivery devices is a key consideration for patients receiving biologic therapies for chronic IMIDs. Patients receiving biologics have been found to prefer an autoinjector over a prefilled syringe when both are available.^{6–8} Therefore, by increasing patient satisfaction with autoinjectors, careful consideration of autoinjector design can have a substantial impact on patient well-being.

Efforts to assess the wide range of autoinjector attributes important to patients have been made across various biologics.⁵ In a study of patients with RA receiving an etanercept biosimilar, patients ranked ease of self-injection, ease of grip, and intuitive or self-explanatory usage as the most important attributes of an autoinjector.¹² In the current survey of patients with CD or RA, the ability to use the device independently and the ease and simplicity of the self-injection process were identified as the most important attributes of an autoinjector in general. Physical attributes of the pen, such as size, shape, and weight, were consistently rated by patients as lower in importance than other attributes, but were still rated as important, emphasizing the multifaceted nature of optimal autoinjector design.

In an interim analysis of the COMPACT study, a real-word study of biosimilar etanercept (GP2015) administered using the SDZ-ADL pen in patients with rheumatic diseases (n = 92), 85% of patients chose to continue self-injection after the study.²⁵ In the final analysis of COMPACT, responses from 459 patients with RA for the Self-Injection Assessment Questionnaire (SIAQ) showed high mean scores in all domains (self-image, feelings about injection, patient satisfaction, ease of use, and self-confidence). Patients who switched to GP2015 from reference etanercept or another biosimilar etanercept (n = 206) also reported high SIAQ scores in all domains, demonstrating no major concerns after switching.²⁶ These data are consistent with the willingness of 99% of patients in the current survey to continue with the SDZ-ADL pen. Non-medical switching to biosimilars in patients with IMIDs has been associated with the nocebo effect, where patients experience adverse medical outcomes in response to a non-medically necessary change in their therapy due to negative patient perceptions of the new therapy.^{27,28} While assessment of the nocebo effect was beyond the scope of the current survey, it appears to have had limited influence on outcomes, although it may explain the preference for the ref-ADL pen in a small number of patients in this survey.

In this survey, most participants preferred the SDZ-ADL pen over the ref-ADL pen; less injection pain and buttonless activation were expressed as the main drivers for this preference. In a study of an autoinjector for another adalimumab biosimilar in patients with inflammatory joint or bowel diseases, ease of use, ease of grip, and button-free initiation were also cited as the most important factors for preferring that autoinjector over other available autoinjectors.⁹

The findings of this survey are also consistent with those from a European survey, which reported that patients with RA and nurses perceived the SensoReady Pen for Erelzi® (etanercept biosimilar; Sandoz) to be easier to use than other available autoinjector devices, including the ref-ADL pen, the MyClic® autoinjector for the etanercept reference product (Pfizer, New York, NY, USA) and the Molly® autoinjector for an etanercept biosimilar (manufactured by Samsung Bioepis, Incheon, Republic of Korea, marketed in Europe by Biogen, Zug, Switzerland). As reported for the current survey, ease of use and audible and visual feedback were rated highly among the priorities for both patients and nurses. The findings in the current survey also agree with those from a survey carried out in Europe and the USA, which reported

that patients with MS and nurses preferred the SensoReady Pen (ofatumumab) over six comparator autoinjectors for their treatment, mostly driven by ease of self-administration. ¹¹ In that study, visual feedback was also very important to patients and nurses, whereas audible feedback carried less importance than it did in the current survey. ¹¹ It is unclear if this difference is due to how ofatumumab is used relative to adalimumab, a difference in survey methodology, or patient characteristics and disease symptoms. Among US patients with MS who started using the SensoReady Pen (ofatumumab) within the previous 12 months (n = 105), 54 (51.4%) were extremely satisfied and 37 (35.3%) were satisfied, based on a 5-point Likert scale. ²⁹

In the Phase III JUNCTURE^{20,21} and FUTURE 3^{22} trials, the efficacy and safety of secukinumab administration with the SensoReady Pen was assessed in patients with plaque psoriasis or psoriatic arthritis, respectively. In addition to these assessments, patients completed the SIAQ. Based on SIAQ scores for feelings about injections, self-confidence, and satisfaction with self-injections, high acceptability of the SensoReady Pen was observed in both trials. In JUNCTURE, SIAQ scores were high and consistent at Weeks 12 and $48.^{20,21}$ In FUTURE 3, SIAQ scores were assessed before the first self-injection and post self-injection, at baseline, Week 1, and Week 2. Feelings about injections, self-confidence, and satisfaction with self-injection were evaluated at all time points, and pain and skin reactions were additionally included in the post-injection SIAQ evaluations. Scores for feelings about injections, self-confidence, and satisfaction with self-injection were high before the first self-injection and remained high at Week 2 in all indications. Based on SIAQ scores, over 90% of patients reported no pain or reaction at baseline, Week 1, and Week 2. At Week 2, \geq 88% of patients were satisfied or very satisfied with the SensoReady Pen and found its use easy or very easy, with no external help required. The findings of the current survey align with and fortify results from previous studies showing high patient satisfaction with the SensoReady Pen across different indications.

A limitation of this survey is the possibility of recency bias (ie, patient bias for their current autoinjector), as all patients have switched from the reference product to the biosimilar. Such a bias may be caused by recent positive experience with the biosimilar, the time that has passed since use of the reference product, any positive statements regarding biosimilars communicated to patients at the time of the switch, or favorable media coverage of biosimilars in general. The patients included in the survey were experienced in using both devices, requiring a minimum of 3 months of experience with the ref-ADL pen and 1 month of experience with the SDZ-ADL pen, and patients visited a physician at least once in the past 12 months. This ensured that patients were sufficiently trained in using both devices and sufficiently experienced to provide feedback about both devices. Another potential limitation is that the patient experience of less injection pain might be related to the product instead of the device. This would rather amplify the positive experience of the device. Finally, although this survey was run by an independent company and Sandoz had no influence on patient screening or survey conduct, patients were selected from the SDZ-ADL patient support program; therefore, patients who are not currently using SDZ-ADL would not be included. This may exclude patients who switched from SDZ-ADL back to ref-ADL. However, in general, rates of switching back from adalimumab biosimilars are low in other real-world settings.^{30–33}

Conclusion

In this survey, patients with RA or CD indicated a clear preference for their current SDZ-ADL pen over their previous ref-ADL pen for nearly every attribute evaluated, independent of the duration of use of either pen. Regardless of indication, patients expressed a clear preference for autoinjector attributes that facilitate independent and easy use. The survey results are in alignment with previously reported data on SDZ-ADL pen usability and patient preference. Patient preference regarding autoinjector device characteristics should be considered when seeking ways to support patient adherence and satisfaction.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Informed Consent

The informed consent form, survey protocol, survey questionnaires, and patient invitation materials were all approved by Advarra, Inc. (Aurora, ON, Canada), the local Canadian Institutional Review Board.

This survey was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. All participants provided informed consent to participate in the survey and for the publication of anonymized responses.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Shrihari Jathanakodi and Charlotte Both were employees of Sandoz Group AG. Ines Brueckmann is an employee of Sandoz Group AG. Laura Rose is an employee of Sandoz Inc. Nahal Nasseri is an employee of Sandoz Canada Inc. Jean-Pierre Raynauld has been a speaker or advisor for AbbVie, Amgen, BIOJAMP, Janssen, Novartis, Organon, Orimed, Pfizer, Sandoz, Sanofi, and UCB. Neeraj Narula has been a speaker or advisor for AbbVie, Bristol Myers Squibb, Eli Lilly, Ferring, Fresenius Kabi, Innomar Strategies, Iterative Health, Janssen, Merck, Pfizer, Sandoz, Takeda, and Viatris. The authors report no other conflicts of interest in this work.

References

- 1. Kuek A, Hazleman BL, Ostor AJK. Immune-mediated inflammatory diseases (IMIDs) and biologic therapy: a medical revolution. *Postgrad Med J.* 2007;83(978):251–260. doi:10.1136/pgmj.2006.052688
- 2. McInnes IB, Gravallese EM. Immune-mediated inflammatory disease therapeutics: past, present and future. *Nat Rev Immunol*. 2021;21 (10):680–686. doi:10.1038/s41577-021-00603-1
- 3. Humphry N. The efficacy of anti-TNFs in immune-mediated disease. EMJ Gastro. 2022;115:2-9. doi:10.33590/emjgastroenterol/10102824
- Anselmo AC, Gokarn Y, Mitragotri S. Non-invasive delivery strategies for biologics. Nat Rev Drug Discov. 2019;18(1):19–40. doi:10.1038/nrd.2018.183
- van den Bemt BJF, Gettings L, Domańska B, et al. A portfolio of biologic self-injection devices in rheumatology: how patient involvement in device design can improve treatment experience. *Drug Deliv*. 2019;26(1):384–392. doi:10.1080/10717544.2019.1587043
- 6. Kivitz A, Cohen S, Dowd JE, et al. Clinical assessment of pain, tolerability, and preference of an autoinjection pen versus a prefilled syringe for patient self-administration of the fully human, monoclonal antibody adalimumab: the TOUCH trial. Clin Ther. 2006;28(10):1619–1629. doi:10.1016/j.clinthera.2006.10.006
- 7. Liu Y, Söderberg J, Chao J. Adherence to and persistence with adalimumab therapy among Swedish patients with Crohn's disease. *Pharmacy* (Basel). 2022;10(4):87. doi:10.3390/pharmacy10040087
- 8. Vermeire S, D'Heygere F, Nakad A, et al. Preference for a prefilled syringe or an auto-injection device for delivering golimumab in patients with moderate-to-severe ulcerative colitis: a randomized crossover study. *Patient Prefer Adherence*. 2018;12:1193–1202. doi:10.2147/PPA.S154181
- 9. Fenwick S, Thakur K, Munro D. Nurse and patient perceptions and preferences for subcutaneous autoinjectors for inflammatory joint or bowel disease: findings from a European survey. *Rheumatol Ther.* 2019;6(2):195–206. doi:10.1007/s40744-019-0144-8
- Ridyard CH, Dawoud DMM, Tuersley LV, Hughes DA. A systematic review of patients' perspectives on the subcutaneous route of medication administration. *Patient*. 2016;9(4):281–292. doi:10.1007/s40271-015-0160-x
- 11. Ross AP, Besser C, Naval S, et al. Patient and nurse preference for Sensoready autoinjector pen versus other autoinjectors in multiple sclerosis: results from a pilot multicenter survey. *BMC Neurol.* 2023;23(1):85. doi:10.1186/s12883-023-03100-1
- 12. Thakur K, Biberger A, Handrich A, Rezk MF. Patient perceptions and preferences of two etanercept autoinjectors for rheumatoid arthritis: findings from a patient survey in Europe. *Rheumatol Ther.* 2016;3(2):245–256. doi:10.1007/s40744-016-0048-9

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13. Tischer B, Mehl A. Patients' and nurses' preferences for autoinjectors for rheumatoid arthritis: results of a European survey. Patient Prefer Adherence. 2018;12:1413-1424. doi:10.2147/PPA.S169339

- 14. Orchard TR, Wordsworth BP, Jewell DP. Peripheral arthropathies in inflammatory bowel disease: their articular distribution and natural history. Gut. 1998;42(3):387-391. doi:10.1136/gut.42.3.387
- 15. Peluso R, Manguso F, Vitiello M, Iervolino S, Di Minno MND. Management of arthropathy in inflammatory bowel diseases. Ther Adv Chronic Dis. 2015;6(2):65-77. doi:10.1177/2040622314563929
- 16. Palm Ø, Moum B, Jahnsen J, Gran JT. The prevalence and incidence of peripheral arthritis in patients with inflammatory bowel disease, a prospective population-based study (the IBSEN study). Rheumatology (Oxford). 2001;40(11):1256-1261. doi:10.1093/rheumatology/40.11.1256
- 17. Health Canada. HYRIMOZ Product monograph; 2022. Available from: https://pdf.hres.ca/dpd_pm/00067757.PDF. Accessed April 5, 2024.
- 18. Health Canada. HUMIRA Product monograph; 2022. Available from: https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/pro ducts/HUMIRA PM EN.pdf. Accessed April 5, 2024.
- 19. GI Society. Provincial and Territorial Biologics Policies; 2022. Available from: https://badgut.org/information-centre/a-z-digestive-topics/provin cial-biologics-policies/#:~:text=Phase%204%3A%20On%202021%2D04,Brenzys%C2%AE%20and%20Erelzi%C2%AE. Accessed April 5, 2024.
- 20. Lacour J-P, Paul C, Jazayeri S, et al. Secukinumab administration by autoinjector maintains reduction of plaque psoriasis severity over 52 weeks: results of the randomized controlled JUNCTURE trial. J Eur Acad Dermatol Venereol. 2017;31(5):847-856. doi:10.1111/jdv.14073
- 21. Paul C, Lacour J-P, Tedremets L, et al. Efficacy, safety and usability of secukinumab administration by autoinjector/pen in psoriasis: a randomized, controlled trial (JUNCTURE). J Eur Acad Dermatol Venereol. 2015;29(6):1082-1090. doi:10.1111/jdv.12751
- 22. Nash P, Mease PJ, McInnes IB, et al. Efficacy and safety of secukinumab administration by autoinjector in patients with psoriatic arthritis: results from a randomized, placebo-controlled trial (FUTURE 3). Arthritis Res Ther. 2018;20(1):47. doi:10.1186/s13075-018-1551-x
- 23. Maniadakis N, Toth E, Schiff M, et al. A targeted literature review examining biologic therapy compliance and persistence in chronic inflammatory diseases to identify the associated unmet needs, driving factors, and consequences. Adv Ther. 2018;35(9):1333-1355. doi:10.1007/s12325-018-
- 24. Cross MJ, March LM, Lapsley HM, Byrne E, Brooks PM. Patient self-efficacy and health locus of control: relationships with health status and arthritis-related expenditure. Rheumatology (Oxford). 2006;45(1):92-96. doi:10.1093/rheumatology/kei114
- 25. Schmalzing M, Zinke S, Schnorfeil M, et al. Use of a self-injection assessment questionnaire to assess patient satisfaction with a self-injection device in rheumatoid arthritis patients receiving SDZ-ETN (GP2015) in Germany: an interim analysis of the real-world COMPACT study. Abstract presented at 48. Kongress der Deutschen Gesellschaft für Rheumatologie (DGRh), 34. Jahrestagung der Deutschen Gesellschaft für Orthopädische Rheumatologie (DGORh). September 9–12; 2020; virtual.
- 26. Schmalzing M, Askari A, Sheeran T, et al. Outcomes of the Self-Injection Assessment Questionnaire in rheumatoid arthritis, axial spondyloarthritis and psoriatic arthritis patients receiving GP2015 (etanercept biosimilar) in a real-world study: final results from COMPACT study. Abstract AB0419, presented at European Alliance of Associations for Rheumatology (EULAR) 2023 Congress. May 31-June 3; 2023; Milan, Italy.
- 27. Fleischmann R, Jairath V, Mysler E, Nicholls D, Declerck P. Nonmedical switching from originators to biosimilars: does the nocebo effect explain treatment failures and adverse events in rheumatology and gastroenterology? Rheumatol Ther. 2020;7(1):35-64. doi:10.1007/s40744-019-00190-7
- 28. Taylor PC, Gonzalez YS, Clark R, Faccin F, Howell O. Outcomes following adalimumab bio-originator to biosimilar switch-A comparison using real-world patient- and physician-reported data in European countries. Rheumatol Ther. 2023;10(2):433-445. doi:10.1007/s40744-022-00526-w
- 29. Ross AP, Nicholas J, Tai MH, et al. Real-world satisfaction and experience with injection and autoinjector device for ofatumumab indicated for multiple sclerosis. Poster LB09, presented at the Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting 2023. May 31-June 3; 2023; Aurora, CO, USA.
- 30. Brouwer R, Ten Klooster PM, Masselink JB, Vonkeman HE. Continuous effectiveness and safety after a hospital-wide switch to adalimumab biosimilar: an observational study in rheumatoid arthritis patients. Pharmacol Res Perspect. 2022;10(6):e01025. doi:10.1002/prp2.1025
- 31. Bruni C, Gentileschi S, Pacini G, et al. Switching from originator adalimumab to biosimilar SB5 in a rheumatology cohort: persistence on treatment, predictors of drug interruption and safety analysis. Ther Adv Musculoskelet Dis. 2021;13:1759720X211033679. doi:10.1177/
- 32. Nabi H, Georgiadis S, Loft AG, et al. Comparative effectiveness of two adalimumab biosimilars in 1318 real-world patients with inflammatory rheumatic disease mandated to switch from originator adalimumab: nationwide observational study emulating a randomised clinical trial. Ann Rheum Dis. 2021;80(11):1400-1409. doi:10.1136/annrheumdis-2021-219951
- 33. van Adrichem RCS, Voorneveld HJE, Waverijn GJ, Kok MR, Bisoendial RJ. The non-medical switch from reference adalimumab to biosimilar adalimumab is highly successful in a large cohort of patients with stable inflammatory rheumatic joint diseases: a real-life observational study. Rheumatol Ther. 2022;9(4):1109-1118. doi:10.1007/s40744-022-00465-6

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