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Abstract: Purpose. To investigate pH and osmolality changes in the solutions stored in contact lens cases, when different case rinsing and drying methods are used on a daily basis.
Methods. Four multipurpose solutions (Opti-Free Express®, Solo-Care AquaTM, Re-Nu Multiplus® and Complete®) and two hydrogen peroxide systems (AOsept® and Oxysept®) were studied. Cases were filled with the solutions and kept sealed. After 8 hours, the cases underwent different rinsing (rinsing; non-rinsing) and drying (air drying -AD-; lint-free tissue drying -LFTD-; non-drying -ND-) procedures on a daily basis. Five cases of each rinsing/drying combination for each solution were evaluated. The pH and osmolality of the case contained solution were evaluated on the first, 7th, 15th, and then, 30th day.
Results. pH and osmolality increased significantly from day 1 to day 30, except for Complete in which a significant decrease in pH was found. Rinsing vs non-rinsing contact lens cases did not have any influence on the pH or osmolality, except for Oxysept, which showed a significantly higher osmolality value when cases were not rinsed. However, the drying procedure did influence both measurements; pH was significantly higher in the AD compared to the ND group ($p<0.05$) and there was a significant difference in osmolality between the three drying conditions ($p<0.05$), with the AD group showing the highest values, and the LFTD group showing the lowest.
Conclusions. Osmolality and pH values are time and drying process-dependent in a contact lens case cleaning schedule. Regarding drying conditions, LFTD causes less increase in osmolality. Future studies should determine whether these changes might affect bacterial growth, lens parameters or subject comfort during contact lens wear.

Synopsis of manuscript

The aim of this study is to determine whether different CL case cleaning procedures can lead to variations in osmolality and pH values of the solution in the storage case in a short-term soft CL care routine (one month). Our results show that both osmolality and pH values of the storaged solution are time and drying process-dependent.

Contact lens cleaning procedures affect storage solution pH and osmolality

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Abstract

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Methods. Four multipurpose solutions (Opti-Free Express®, Solo-Care Aqua™, Re-Nu Multiplus® and Complete®) and two hydrogen peroxide systems (AOsept® and Oxysept®) were studied. Cases were filled with the solutions and kept sealed. After 8 hours, the cases underwent different rinsing (rinsing; non-rinsing) and drying (air drying -AD-; lint-free tissue drying -LFTD-; non-drying -ND-) procedures on a daily basis. Five cases of each rinsing/drying combination for each solution were evaluated. The pH and osmolality of the case contained solution were evaluated on the first, 7th, 15th, and then, 30th day.

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Conclusions. Osmolality and pH values are time and drying process-dependent in a contact lens case cleaning schedule. Regarding drying conditions, LFTD causes less increase in osmolality. Future studies should determine whether

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To avoid contact lens (CL) microbial contamination, it is not only necessary to have an effective disinfectant solution but also an adequate CL and case hygiene procedure.[1,2] Storage cases are the most frequently contaminated CL care accessories,[3-5] even in asymptomatic CL wearers.[6-9] Scientific literature shows that there are inconsistent CL case cleaning recommendations among practitioners, without protocols or guidelines to show patients an effective method to clean cases.[10]

CL care solutions must not only avoid microbial growth but should also be biocompatible with the ocular surface, and this biocompatibility depends on their physical and chemical properties.[11] Multi-purpose solutions (MPS) and hydrogen peroxide systems (HPS) are the most common soft CL cleaning and maintenance regimens used at present.[12-14] Both systems are made up of different components that determine their physical and chemical properties.[11,15] One of the main components in a lens care solution is the buffering system, which modulates and maintains pH constant in a solution. Phosphate, borate and citrate are the most common buffers in use due to their physiological compatibility.[16,17] These buffering agents must maintain the pH of CL care solutions close to the tear film pH mean value.[18]

Another chemical property of CL care solutions is the total concentration of dissolved particles, expressed either per kilogram of solvent (units Osm/kg) (osmolality) or per liter of solution (units Osm/L) (osmolarity). However, both terms are often considered equivalent for clinical purposes.[19]

According to previous research, the average pH of tears is 7.45 and the zone of ocular comfort is between 6.6 to 7.8.[18] In addition, mean osmolality of the tear film is 302.2 ± 9.7 mOsm/kg H_2O,[20] ranging from 300 mOsm/Kg H_2O to

310 mOsm/Kg H_2O in healthy eyes.[21,22] pH and osmolality values out of the physiologic range have been linked with CL-related patient discomfort.[23,24] Moreover, changes in these physical properties may alter soft CL physical properties.[25-27]

Although previous studies have addressed the changes in pH over time,[28,29] there is little information regarding the relation between cleaning instructions and physical properties of current CL care solutions. The aim of this study is to determine whether different CL case cleaning procedures in a short-term soft CL care routine with four MPSs and two HPSs can lead to variations in osmolality and pH values of the solution in the storage case.

Materials and methods

CL care solutions and lens cases

Four brands of commercial MPS and two of HPS were selected for pH and osmolality measurements and comparison. The MPS were Opti-Free Express® (Alcon Inc., Switzerland), Solo-Care Aqua™ (Ciba Vision Corporation, Duluth, GA, USA), Re-Nu Multiplus® (Bausch & Lomb Inc, Rochester, NY, USA), and Complete® (AMO, Santa Ana, CA, USA). The HPS solutions were AOSept® (Ciba Vision Corporation, Duluth, GA, USA) and Oxysept® (AMO, Santa Ana, CA, USA). Because CL cases could not be rinsed with HPS after neutralization, a saline solution (Saline, Avizor, Madrid, Spain) was used in these cases.

Standard CL cases used for MPSs were purchased from Eurolents Servicios Ópticos (Madrid, Spain) and were made of acrylonitrile butadiene styrene (ABS). For the HPSs, the CL cases provided by the manufacturers were used, and both types were made of polycarbonate.

The names, manufacturers and compositions of each CL care solution tested in this study are detailed in table 1.

CL cleaning procedures

In order to evaluate case cleaning procedures, 180 CL cases were initially divided into 6 groups of 30 CL cases each. Of these, 4 groups were filled with each one of the four MPS and 2 groups with each of the two HPS solutions. These 6 groups were further subdivided into 2 groups of 15 cases each: rinsed (RI) and non-rinsed (NR). And finally, RI and NR groups were subdivided into 3 groups of 5 cases each, depending upon the drying procedure after removal of the cleaning solution: air drying (AD), lint-free tissue drying (LFTD) and non-drying (ND). This scheme yielded groups of 5 cases for each rinsing/drying combination and for each solution studied, as is clarified in figure 1.

Standard soft CL cases from the MPS groups were filled with 2 mL of each of them. Each HPS case was filled with 7.5 mL of AOSept or 10 mL of Oxysept. Neutralization process for HPS was achieved according to the manufacturer´s guidelines.

All the cases were closed and left at controlled room temperature (24ºC) for 16 hours. Then, the cases were opened, samples of the solutions were removed and pH and osmolality were measured. The solution remaining in each case was discarded, and cases from the RI group were rinsed with a saline solution (Saline, Avizor, Madrid, Spain) if they were filled with HPS, or with the same care regimen if filled with MPS. The NR group was not rinsed. Finally, the CL cases from each AD group were left open (cases and caps were left facing up), the CL cases from each LFTD group were dried with a lint-free tissue and closed, and CL cases from each ND group were left closed without any drying procedure. After 8 hours, cases were filled again to restart the 24 hour process, which was repeated for 30 consecutive days.

In order to determine pH and osmolality variations of the solutions after the 16 hour period in each case, two samples of 1 µL and 20 µL were collected from each CL case to measure pH and osmolality, respectively. Samples were measured at 1, 7, 15 and 30 days (T1, T2, T3 and T4, respectively).

pH was measured using HI 2210 pH Bench Meter (Hanna Instruments Inc. Woonsocket, RI, USA), and osmolality was measured with Fiske® 210 Micro-Sample Osmometer (Advanced Instruments Inc., Norwood, MA, USA). Both instruments were calibrated before every measurement session using the manufacturer's control solution.

Osmolality gradient

Prior to removing lenses from the case, Oxysept cases should be turned upside down to ensure full neutralization of all residual disinfecting solution, in accordance with the manufacturer's recommendation. In addition, although hydrogen peroxide neutralization process with catalase tablets releases non-toxic products for the eye, they may alter osmolality and pH of the solution.[11]

In order to determine whether or not the upside down procedure with the Oxysept neutralized solution in the CL case could modify osmolality, a different experiment was performed. In this case, 5 HPS cases were filled with 10 mL of Oxysept solution, a catalase tablet was added and the cases were kept closed for 24 hours. Cases were then opened carefully. Then, 20 μL were collected from the top of the solution. After that, the pipette was introduced carefully into the case from the top to avoid mixing up the solution, and 20 μL were collected from the bottom. The cases were closed again and turned upside down twice and, following the procedure explained above, osmolality was determined in the same two locations. The osmolality gradient was calculated by the difference between osmolality obtained at the bottom of the case and that measured at the top.

Finally, all the cases were drained, rinsed with saline solution, dried with lint-free tissue and refilled with Oxysept. Then, the whole process was repeated over 4 consecutive days.

Statistical analysis

All data were expressed as mean ± standard error of the mean (SEM). Analyses were performed with SPSS 17.0 (SPSS for Windows, Rel. 17.0.0. 2008. Chicago: SPSS Inc). Linear mixed models (LMM)[30] were fitted to the osmolality data set and to the pH data set. To cope with dependences among errors corresponding to the CL cases at different time intervals, the covariance structure was initially specified as an unstructured covariance matrix for both models. Statistical analyses of the osmolality gradient data set were performed by Student's t-test and P-values below 0.05 were considered to indicate statistical significance.

Results

pH

We fitted a LMM to analyze pH variability due to four sources of variation: care solutions, time and rinsing or drying conditions of the CL cases. Significance of all main effects and second order interactions yielded by the analysis is briefly summarized. Rinsing produced no significant change in the pH values, neither its main effect nor any of its interactions with the other factors. In contrast, the rest of the factors and interactions produced significant changes in pH values.

The type of CL care solution caused major quantitative changes, followed by time and their corresponding interaction. The absolute values of the remaining significant effects are below 0.02 pH units.

pH data for the six CL care solutions over time with all the rinsing and drying situations evaluated are shown in table 2. At T1 (day 1), there were significant differences ($p<0.05$) among the mean pH values of each care solution. Solo-Care, Complete and Oxysept showed similar pH values, Re-Nu pH value was slightly above, and Opti-Free Express and AOSept had the most extreme values (Opti-Free Express had the highest and AOSept had the lowest extreme values), although within the ocular comfort zone.

pH values increased at T2 (day 7) and decreased progressively at T3 (day 15) and at T4 (day 30). However, T4 pH value was significantly above T1 in all solutions ($p<0.05$), except for Complete, in which T4 was significantly below T1 (table 2). Differences between measurement sessions for all the solutions were significant ($p<0.05$) except for Complete and AOSept which showed a non significant decrease between T2 - T3 and T3 - T4, respectively.

Regarding the influence of the different rinsing and drying methods used, rinsing the case did not influence the pH values, but there was a significant difference ($p<0.05$) among drying processes between the AD and ND groups (7.186 ± 0.021 and 7.190 ± 0.021, respectively) (figure 2).

Osmolality

Repeating the previous analysis for osmolality, we found that all main effects and second order interactions were statistically significant ($p<0.05$), except the main effect of rinsing ($p>0.05$). The absolute values of the significant effects were all below 10 mOsm/kg H_2O except for care solutions, time, drying procedure and the second order interaction between care solutions and time.

Table 3 shows the osmolality values for all care solution tested over time. Initial osmolality values (T1) indicate that Opti-Free Express was hypotonic, and Re-Nu, Solo-Care and Complete were isotonic, compared with normal human tears. Neutralized AOSept and Oxysept solutions had similar and slightly hypotonic osmolality values.

Osmolality increased significantly ($p<0.05$) from T1 (day 1) to T4 (day 30) for all the solutions studied. Between T1 and T2 (day 7), a significant increase was observed in all the solutions ($p<0.05$), except for Oxysept. At T3 (day 15) lower values were found with respect to T2 (significant differences for Solo-Care, $p<0.05$) except for Oxysept in which values increased significantly ($p<0.05$). At T4 (day 30), all the values were significantly ($p<0.05$) higher with respect to T3, except for Oxysept and Re-Nu which showed a non-significant increase.

Regarding the influence of different rinsing and drying procedures on the osmolality, rinsing did not have any influence on the results, except for Oxysept in which a significantly ($p<0.05$) higher osmolality value was found when the cases were not rinsed (figure 3). However, the drying method did influence osmolality results (figure 4). The AD group showing the higher osmolality values and the LFTD group the lower ones (301.23 ± 2.06 and 291.26 ± 1.94 mOsm/kg H_2O, respectively), with significant differences ($p<0.05$) among the three drying methods studied, except for AOSept, in which the difference between ND and LFTD was not significant ($p>0.05$), and Complete and Oxysept with non-significant differences between AD and ND.

Osmolality gradient

When cases with neutralized Oxysept solution were not turned upside down, a gradient in osmolality was found (top sample: 216.19 ± 2.35 mOsm/kg H_2O, bottom sample: 439.71 ± 10.91 mOsm/kg H_2O; $p<0.05$). Also a pink colour gradient due to the colour indicator (cyanocobalamin) was observed in the solution. However, this difference among both samples disappeared when cases were inverted (top sample: 296.89 ± 1.85 mOsm/kg H_2O, bottom sample: 296.84 ± 1.45 mOsm/kg H_2O; $p>0.05$), as well as the colour of the solution turned into a homogeneous pink colour.

Discussion

Previously, it has been shown that microbial growth depends on CL cases cleaning procedures, the place where they are stored, as well as disinfecting effectiveness of care solutions.[7,31,32] This study has shown that the osmolality and pH of cleaning solutions stored on CL cases are affected by the cleaning procedure of the cases.

pH values of some of the tested solutions differed significantly from the tear film physiologic pH (7.45 pH units),[18] however these changes can be neutralized by the buffering capacity of tears.[33] On the other hand, pH of CL care solutions must be inside the range of ocular comfort (from 6.6 to 7.8 pH units)[18] to avoid discomfort and stinging upon CL insertion.[23,34] Although there were remarkable differences among the solutions studied, all of them were inside this ocular comfort range at T1, as it has been shown previously for some of the tested solutions used in our study.[35]

Slight variations over time (but significant in 5 out of the 6 solutions) were found in pH values, the higher variability being for Solo-Care and Opti-Free Express (T1-T2: 0.136 pH units; T1-T2: 0.115 pH units, respectively), although they still remained within the ocular comfort range, except for Opti-Free Express at T2 and T3 (see table 2). In addition, the pH of all care solutions increased after 30 days except for Complete in which a significant decrease was found. These differences might be due to the concentration and the type of buffering system which can provoke normal pH fluctuations over time. The kind of buffer used in the solution formulation[36] and fluctuations over time found in this and other studies,[28,29,34] could affect ocular comfort in CL wearers over time. However the clinical significance of pH changes found in this study on subject comfort requires more investigation.

Regarding the influence of the cleaning methods, rinsing of the CL cases did not have any influence on the pH values; however a slight but significant difference among the drying methods studied was shown (AD and ND conditions). Further investigations are needed to determine whether case drying procedures may improve CL wearers' comfort due to pH variations.

Osmolality is a measurement of solute concentration in a solution, expressed in units of mOsm/kg of solvent. It is an important chemical parameter in CL care solutions as well as in tear film. Initial osmolality values showed that Opti-Free Express and Neutralized AOSept and Oxysept were hypotonic; and Re-Nu, Solo-Care and Complete were isotonic compared with normal human tears. The hypotonic solutions could potentially cause patient discomfort as they are quite different than human tears, as other authors have pointed out,[11] although all care solutions are commercially successful and their effects on ocular surface health need further investigation.

We have found a significant increase in the osmolality values of the storage solutions in the CL cases over time; however it is possible that this increase is only affected by the drying process not the rinsing. The higher increase in osmolality was found when cases were submitted to air drying (T1:

287.13 ± 3.75mOsm/Kg H_2O; T4: 308.10 ± 3.67 mOsm/Kg H_2O, all solutions and rinsing and drying conditions data shown). This could be due to the salt deposits that are formed in the surface of the case when the solution evaporates, increasing the level of electrolytes when it is refilled with fresh solution from day to day.[37] On the other hand, the lowest increase in osmolality was found when cases were dried with a lint-free tissue (T1: 287.53 ± 3.86 mOsm/Kg H_2O; T4: 299.67 ± 3.63 mOsm/Kg H_2O, all solutions and rinsing conditions data shown), thus removing all the solution and avoiding formation of salt deposits.

This increase in the osmolality of the solution that soaks the CL could induce changes in hydrogel CL parameters such as radius of curvature, diameter, or even power,[26,27] and according to Karkkainen, high values of CL osmolality may modify tear film osmolality by producing an osmotic gradient.[38] It is known that CL osmolality is inversely correlated with comfort in CL wearers,[24] and high values of tear film osmolality have been associated with dry eye symptoms in daily and extended CL wear.[39-41] In addition, it has been postulated that this increase in osmolality values could adversely affect the disinfecting performance of the cleaning solutions.[37] In conclusion, hyperosmolality of CL solutions should be avoided in order to improve ocular comfort in CL wearers as well as not to alter CL parameters. The clinical significance of our data deserves further investigation.

Hydrogen peroxide must be neutralized before CL wear to avoid hyperemia and corneal injury.[42] Thus, one and two-step HPS are available to clean CL. One-step systems do not need a separate neutralization step and are therefore easy to use for CL wearers. In this study, we used two different one-step HPS, which use a platinum coated disk (AOSept) or a soluble catalase tablet (Oxysept) as neutralizing method.

According to the manufacturer, Oxysept CL cases must be turned upside down to ensure full neutralization of the solution. Our data also support this maneuver to avoid osmolality gradient in neutralized Oxysept solution. This osmolality gradient may be due to a lack of homogeneity solubilization of tableting agents as well as cyanocobalamin (vitamin B12 used as a colour indicator), because colour gradient was visually observed in the non-upside down CL cases; in addition, only Oxysept solution showed a statistical osmolality increase when cases were not rinsed. This osmolality increase might also be due to the presence of complementary tableting agents. When cases are rinsed, tableting agents might be dissolved by saline solution. However, when cases are not rinsed, tableting agents might accumulate on case surface over time leading to an increase of osmolality in the solution.

This study also shows that there is an increase in osmolality and pH over a period of time in the solutions stored on the CL cases, and that it is affected by the CL case cleaning method, mainly on the drying process not the rinsing. However, although the rinsing process does not seem to have much influence on the studied physical properties, this procedure, along with the LFTD method, may decrease microbial contamination of CL cases.[43,44]

This study has some limitations. First, as there were no CL in the cases, and the presence of a CL could affect the osmolality and pH of the solutions, this possibility would need to be addressed. Second, this is a short-term study, in which changes in pH and osmolality have been tracked for one month, assuming that CL wearers change their cases on a monthly basis. A longer replacement period or soiled cases could affect the results. Third, we have to bear in mind that different types of CL cases (which is the case of the cases used for HPSs) have different surface areas. Thus, this might affect the load of solutes similarly to the differences in microbial contamination with different CL cases.[7] All these issues need to be addressed in future work.

In conclusion, and based on the results of our investigations, CL cases should be dried with a lint-free tissue in order to avoid the increase of solution osmolality with current CL care solutions. Further studies are necessary to know whether these findings might affect CL parameters, CL cases contamination, and patient comfort.

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Figure 1 Scheme of the groups for each contact lens (CL) care solution (CS). RI: rinsed; NR: non-rinsed; AD: air-drying; LFTD: lint-free tissue drying; ND: non-drying.

Figure 2 Mean pH values (± SEM) for the six contact lens care solutions over time for each drying procedure (all rinsing and non-rinsing data at all time points included). AD: air-drying; LFTD: lint-free tissue drying; ND: non-drying. *p<0.05.

Figure 3 Mean osmolality values (± SEM) for the six contact lens care solutions for the rinsing conditions (all drying methods data at all time points included). RI: rinsed; NR: non-rinsed. *p<0.05.

Figure 4 Mean osmolality values (± SEM) for the different drying conditions (all rinsing and non-rinsing data at all time points included). AD: air-drying; LFTD: lint-free tissue drying; ND: non-drying. *p<0.05.

Table

Table 1 Components of contact lens care solutions evaluated

Brand	Manufacturer	Components			Neutralizing agent
		Buffers	*Preservatives*	*Surfactant*	
Optifree Express	Alcon, Inc.	Boric acid, citrate (citric acid)	myristamidopropyl dimethylamine 0.0005% (Aldox®), polyquaternium-1 0.001% (Polyquad®), EDTA	Poloxamine (Tetronic 1304)	—
Complete	AMO	Phosphates	Polyhexamethylene biguanide 0.0001%, EDTA	Poloxamer 237	—
Re-Nu Multiplus	Bausch & Lomb Inc	Boric acid, sodium borate	Polyaminopropyl biguanide 0.0001% (DYMED®), EDTA	Poloxamine (Tetronic 1107)	—
Solo-Care Aqua	CIBA Vision	Sodium phosphate dihydrogen	Polyhexamethylene biguanide 0.0001%, EDTA	Pluronic F127 (poloxamer 407)	—
Oxysept	AMO	Phosphates	Hydrogen peroxide 3%	—	Catalase
AOSept	CIBA Vision	Phosphates	Hydrogen peroxide 3%	—	Platinum disc

Table 2 Mean pH values (± SEM) for the six contact lens care solutions over time (all rinsing and drying methods are included).

* significant difference ($p<0.05$) between consecutive measuring times (T1, T2, T3 and T4 are measurements performed at 1, 7, 15 and 30 days, respectively).

† significant difference ($p<0.05$) between T1-T4.

pH values (pH units)						
Sample	Opti-Free	Solo-Care	Re-Nu	Complete	AOsept	Oxysept
T1	7.728±0.003	7.092±0.003	7.243±0.003	7.076±0.002	6.676±0.004	7.025±0.004
	*	*	*	*	*	*
T2	7.843±0.003	7.228±0.001	7.323±0.003	7.141±0.005	6.760±0.002	7.099±0.005
	*	*	*		*	*
T3	7.815±0.002	7.177±0.001	7.279±0.004	7.137±0.003	6.728±0.002	7.085±0.004
	*	*	*	*		*
T4	7.759±0.003†	7.159±0.002†	7.256±0.001†	7.056±0.002†	6.728±0.007†	7.047±0.004†

Table 3 Mean osmolality values (± SEM) for the six contact lens care solutions over time (all rinsing and drying methods data included).

* significant differences ($p<0.05$) between consecutive measuring times (T1, T2, T3 and T4 are measurements performed at 1, 7, 15 and 30 days, respectively).

† significant difference ($p<0.05$) between T1-T4.

Osmolality values (mOsm/kg H_2O)						
Sample	Opti-Free	Solo-Care	Re-Nu	Complete	AOsept	Oxysept
T1	223.70±0.31	310.90±0.43	299.57±0.27	304.30±0.28	293.27±0.25	292.20±1.05
	*	*	*	*	*	
T2	234.77±1.03	332.00±2.41	309.80±1.43	317.30±1.57	301.03±0.96	294.70±3.27
		*				*
T3	232.03±1.18	321.03±1.44	306.30±1.14	316.67±1.28	300.10±1.57	312.97±2.59
	*	*		*	*	
T4	245.07±1.63†	327.43±1.65†	310.80±1.24†	324.17±1.77†	308.50±0.59†	314.83±1.70†

Figure 1
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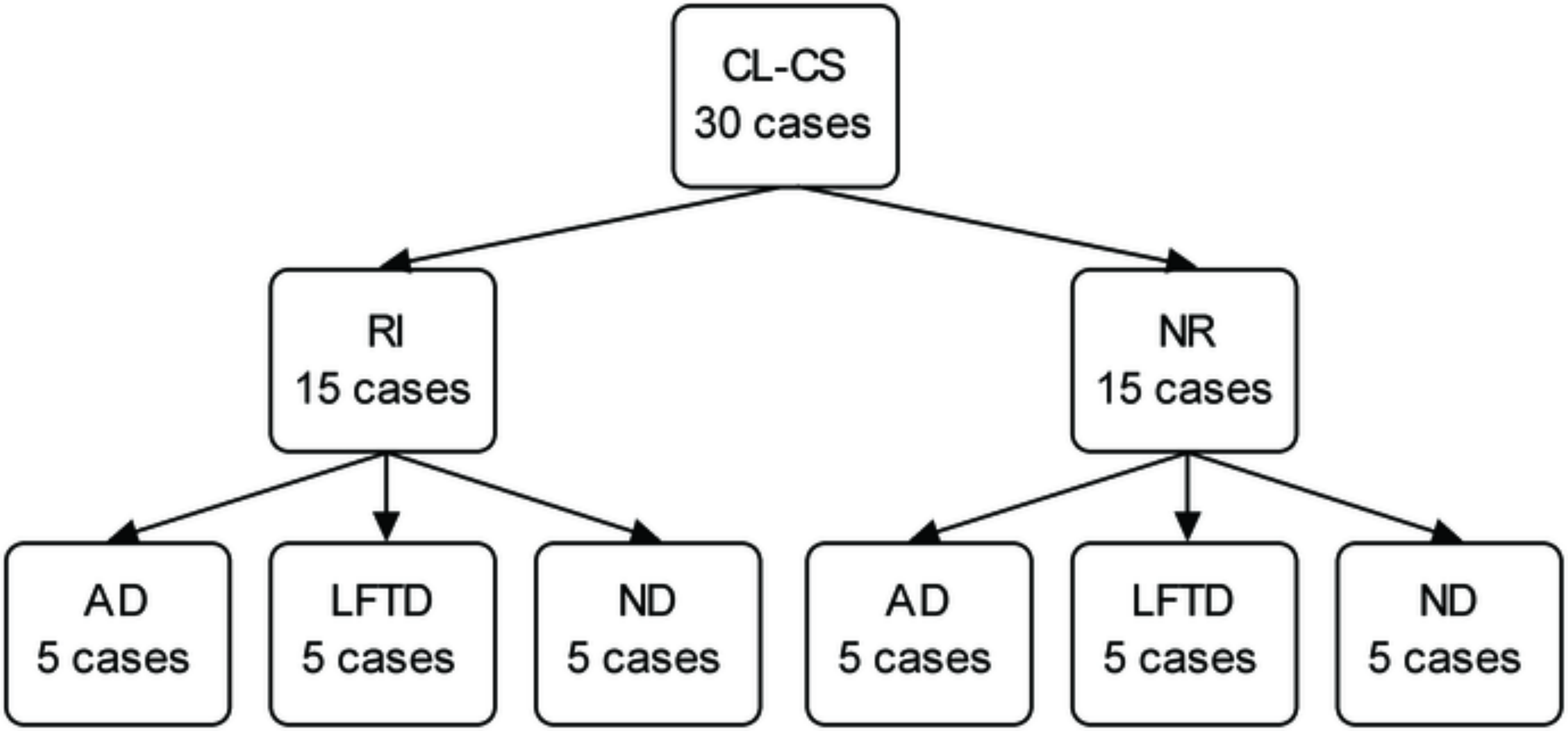

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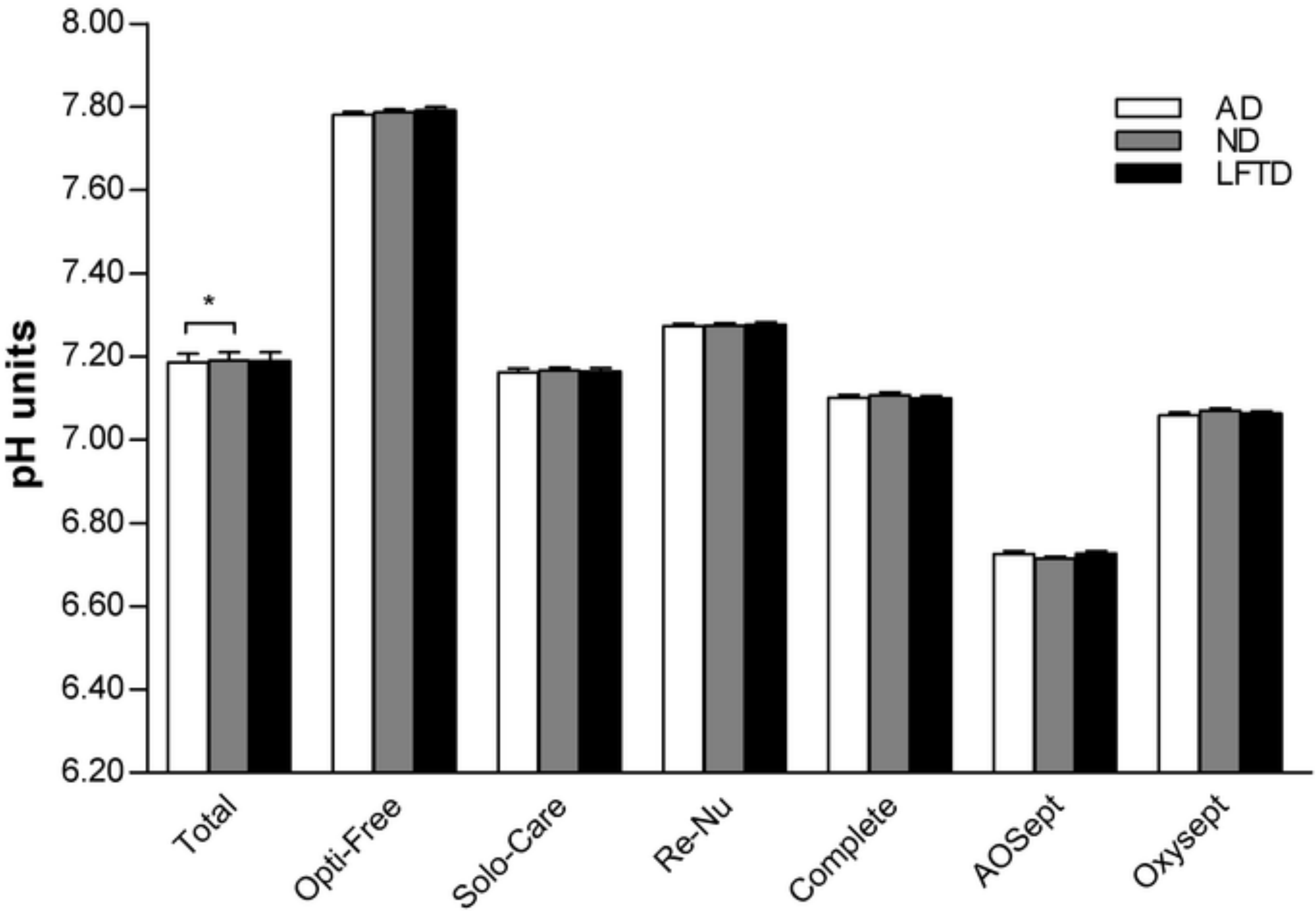

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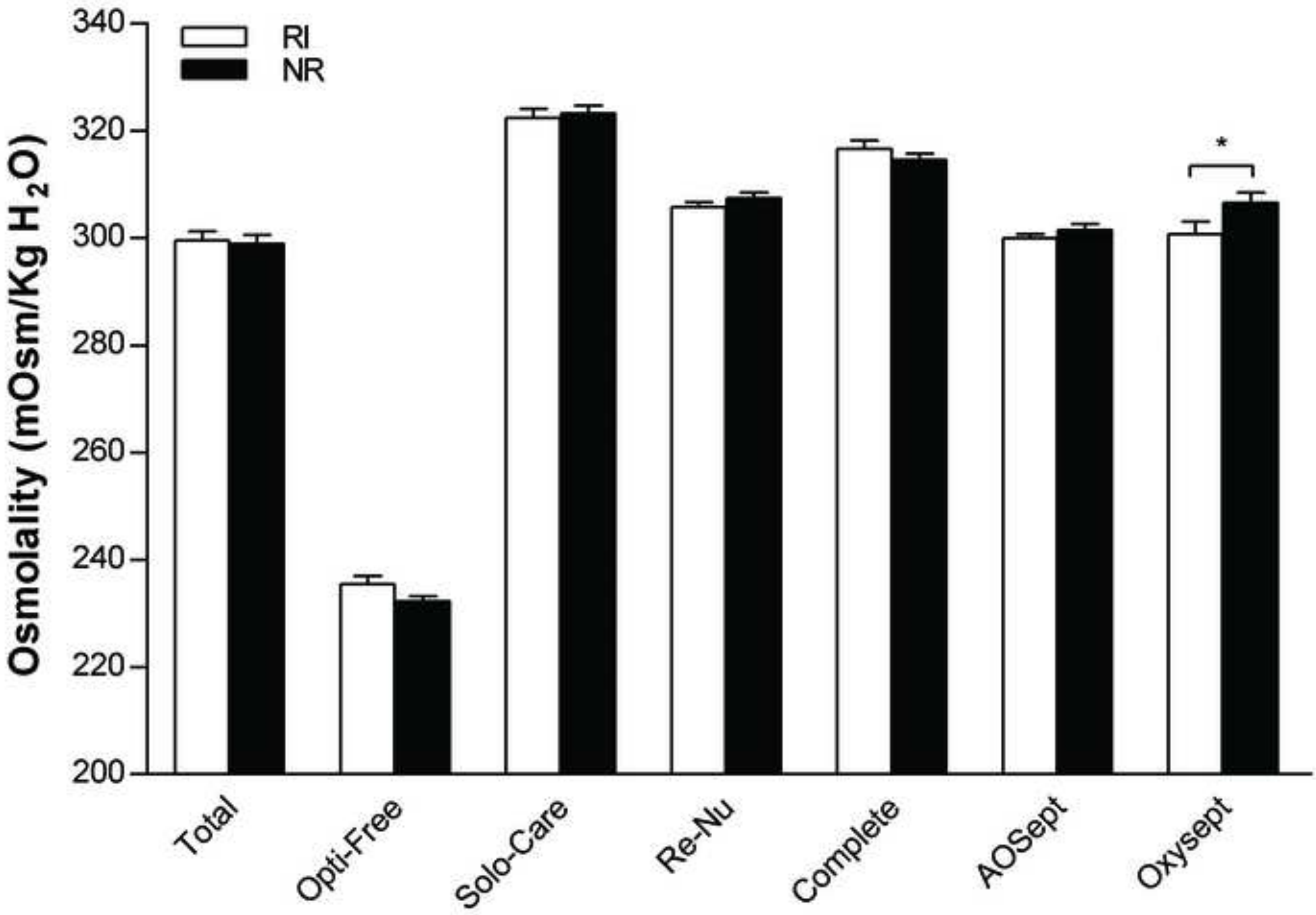

Figure 4

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